Addendum to Intrapartum care: care for healthy women and babies

Appendix G Evidence tables

G.1 Intermittent auscultation compared with cardiotocography on admission

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Mitchell,K., The effect of the labour electronic fetal monitoring admission test on operative delivery in low-risk women: a randomised controlled trial, Evidence Based Midwifery, 6, 18-26, 2008 **Ref Id** 66879 **Country/ies where the study was carried out** England **Study type** Randomised controlled trial **Aim of the study** To test the relationship between the labour electronic fetal monitoring (EFM) admission test and obstetric intervention **Study dates** 15th December 2002 to 30th June 2006 **Source of funding** Initial grant from the Buckinghamshire Hospitals NHS Trust's Research Department and establishment of a research midwife role in the unit	**Sample size** See entry in systematic review by Devane 2012 **Characteristics** **Parity (n (%))** - 0 Cardiotocograph (CTG): 203 (70) Auscultation: 199 (68) - 1 or more CTG: 95 (30) Auscultation: 85 (32) **Inclusion criteria** See entry in systematic review by Devane 2012 **Exclusion criteria** See entry in systematic review by Devane 2012	**Interventions** Admission CTG Intermittent auscultation	**Details** **Care during labour** Following the admission CTG, the decision to end tracing and start intermittent monitoring was left up to the midwives and clinicians caring for the woman. The CTG was stopped when it was considered normal (as defined by the 2001 NICE inherited guideline on the use of EFM). This meant that the length of CTG could vary between the 15 minute admission test and the whole labour period. Women allocated to auscultation were intermittently monitored during labour. However, regardless of allocation, if the woman was considered to have become higher risk, continuous EFM was offered and recommended as per unit policy. Analysis was by intention to treat	**Results** All priority outcomes of interest were reported by the authors of the systematic review	**Limitations** See entry in systematic review by Devane 2012 **Other information** MOST STUDY DETAILS ARE REPORTED IN DEVANE 2012. THIS ENTRY ONLY REPORTS EXTRA DETAILS THAT WERE NOT REPORTED IN THE COCHRANE REVIEW, WHICH THE TECHNICAL TEAM FELT WERE IMPORTANT CONSIDERATIONS WHEN INTERPRETING THE RESULTS
Full citation Cheyne,H., Dunlop,A., Shields,N., Mathers,A.M., A randomised controlled trial of admission electronic fetal monitoring in normal labour, Midwifery, 19, 221-229, 2003 **Ref Id** 158779	**Sample size** See entry in systematic review by Devane 2012 **Characteristics** **Women having artificial rupture of membranes (n (%))** Cardiotocgraph (CTG): 65 (44%) Auscultation: 60 (36%) **Primiparous women (n (%))**	**Interventions** Admission EFM Intermittent auscultation with a hand-held Doppler device	**Details** **Care during labour** Following randomisation, women received either a routine 20 minute period of EFM at the time of admission to the Midwives Birth Unit, or auscultation immediately following a contraction for a minimum of 60 seconds. With the exception of the randomised intervention, women received the same admission assessment, i.e. history taking, blood pressure measurement, temperature recording, abdominal palpation, and vaginal examination.	**Results** All priority outcomes of interest reported in trial are reported in the systematic review (Devane 2012)	**Limitations** See Devane 2012 for risk of bias assessment **Other information** MOST STUDY DETAILS ARE REPORTED IN DEVANE 2012. THIS ENTRY ONLY REPORTS EXTRA DETAILS THAT WERE NOT REPORTED IN THE COCHRANE REVIEW, WHICH THE TECHNICAL TEAM FELT WERE IMPORTANT CONSIDERATIONS WHEN INTERPRETING THE RESULTS

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Scotland **Study type** Randomised controlled trial **Aim of the study** To test the hypothesis that admission electronic fetal monitoring (EFM) for healthy pregnant women in spontaneous labour would lead to an increase in continuous EFM when compared to women who have no admission EFM **Study dates** Not reported **Source of funding** North Glasgow University Hospitals NHS Trust	CTG: 65 (44%) Auscultation: 76 (46%) **Inclusion criteria** See entry in systematic review by Devane 2012 **Exclusion criteria** See entry in systematic review by Devane 2012		Subsequently, all women were monitored using intermittent auscultation, at 15 minute intervals in the first stage of labour and at 5 minute intervals, or after a contraction, during the second stage of labour. EFM was used, where required, in accordance with the guidelines for the unit. However, it should be noted that in addition to the women who received continuous EFM during labour (as reported in the systematic review), a further 125 (84%) of women in the CTG arm and 61 (37%) of the auscultation arm received additional EFM during labour. The reasons were (n (%)): - Admission EFM not discontinued CTG: 80 (64) Auscultation: 1 (2) - FHR abnormalities noted CTG: 29 (23) Auscultation: 13 (21) - EFM commenced on transfer to labour ward CTG: 10 (8) Auscultation: 33 (54) - Meconium stained liquor CTG: 2 (2) Auscultation: 9 (15) - Other CTG: 4 (3) Auscultation: 5 (8)		
Full citation Devane,D., Lalor,J.G., Daly,S., McGuire,W., Smith,V., Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing, Cochrane Database of Systematic Reviews, 2, CD005122-, 2012 **Ref Id** 157062 **Country/ies where the study was carried out** Included trials were conducted in England, Scotland and Ireland **Study type** Systematic review of randomised controlled trials **Aim of the study**	**Sample size** Trials: N = 4 Women: N = 13296 **Characteristics** <u>Cheyne (2003)</u> - Inclusion criteria: Healthy women with a normal pregnancy, presenting in spontaneous labour and who were eligible for admission to the Midwives Birth Unit - Exclusion criteria: Women with risk factors - N = 344 women randomised on admission in labour - Admission CTG: Routine 20 minute period at time of admission - Intermittent Auscultation: Fetal heart was auscultated during and immediately following a contraction for a minimum of 60 seconds <u>Impey (2003)</u> - Inclusion criteria: Admitted in labour, singleton pregnancy, less than 42 completed weeks' gestation, no suspicion or evidence of antenatal fetal compromise, no adverse obstetric history, clear amniotic fluid, maternal	**Interventions** <u>Admission CTG:</u> Defined as a commonly used screening test, comprising a short, usually 20 minute long, recording of the FHR and uterine activity <u>Intermittent auscultation:</u> Intermittent surveillance of the FHR using a hand-held Doppler device or a Pinard stethoscope Both tests were performed upon the woman's admission to the labour ward.	**Details** <u>Searching for studies</u> The Trials Search Co-ordinator was contacted on 17 May 2011, and asked to search the Cochrane Pregnancy and Childbirth Group's Trials Register. In addition, CENTRAL, MEDLINE, CINAHL and Dissertation Abstracts were searched. The reference list of identified studies was also searched, and any studies assessed for eligibility. No language restrictions were applied. No studies were excluded. <u>Data collection and analysis</u> Two review authors independently assessed studies for inclusion. They then extracted data into a predesigned form and resolved discrepancies through discussion. Data were entered into RevMan and checked for accuracy. If there was any unclear information, the authors were contacted to provide details. <u>Quality assessment</u> Risk of bias was assessed independently by two authors using the The Cochrane Collaboration's tool for assessing risk of	**Results** **<u>Mode of birth (number/total)</u>** <u>a. Caesarean section</u> CTG: 248/5657 Auscultation: 207/5681 RR 1.20 (95% CI 1.00 to 1.44) Heterogeneity: I^2 = 0.0% Test for overall effect: Z = 2.00, p = 0.045 [Note: the interpretation of this result by the authors of the systematic review is as follows. "Given that (i) the 95% CI just reaches 1.00 and (ii) the absence of measurable heterogeneity in this outcome analysis (T^2 = 0.00, I^2 = 0%), the probability is that admission CTG increases the caesarean section rate by approximately 20%."] [4 trials: Cheyne 2003, Impey 2003, Mires 2001, Mitchell 2008] <u>b. Instrumental vaginal birth</u> CTG: 782/5657 Auscultation: 716/5681 RR 1.10 (95% CI 0.95 to 1.27) Heterogeneity: I^2 = 38%	**Limitations** The systematic review did not have any serious limitations. Impey (2003) included women with an early amniotomy, and only included women with clear amniotic fluid. The study also included some women (< 5%) who had a previous caesarean section (CS) and who went into labour prior to 37 completed weeks' gestation. However, the authors of the review contacted the study authors, who provided data for women who went into labour at 37-42 weeks and without a previous CS, and the data for these women were used in the main analysis in the systematic review. Mires (2001) randomised women in the third trimester, and between randomisation and admission in labour, 37% of women developed a complication, so that only 2367 were judged to be low risk in labour. The low risk subgroup data were provided by the authors, and these were used in the analysis in the systematic review. The following represents the review author's risk of bias for the included studies. Overall, all studies were assessed as being at low risk of bias: <u>Cheyne 2003</u> - Random sequence generation: low risk of bias - Allocation concealment: low risk of bias - Blinding of outcome assessors: high risk of bias; they were not blinded - Incomplete outcome data: low risk of bias; the trial publication reported that 22 women (7%) were excluded from the analysis (21 not in labour, 1 missing randomisation card); however, the review authors contacted the trial authors and received data for 21/22 of them - Selective reporting: low risk of bias <u>Impey 2003</u> - Random sequence generation: low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To compare the effects of admission cardiotocograph (CTG) with intermittent auscultation of the fetal heart rate (FHR) on maternal and infant outcomes for pregnant women without risk factors for intrapartum hypoxia **Study dates** Content was assessed as up-to-date on 14 November 2011 **Source of funding** Health Research Board, Ireland	temperature of 37.5 degrees or less at admission - N = 8628 women randomised on admission in labour - Admission CTG: 20 minute admission CTG immediately after early amniotomy performed on diagnosis of labour in women presenting to delivery ward - Intermittent auscultation: Performed for 1 minute after a contraction every 15 minutes in the first stage of labour and every 5 minutes in the second stage. It was performed after early amniotomy on diagnosis of labour in women presenting to the delivery ward. Mires (2001) - Inclusion criteria: Booked for hospital birth, attended a hospital or community based consultant led clinic in the third trimester, and had no obstetric complications at that visit that would warrant continuous monitoring of FHR (pre-eclampsia or hypertension in previous or current pregnancy, essential hypertension, diabetes, suspected intrauterine growth restriction (IUGR), placental abruption or praevia or bleeding of unknown origin, multiple pregnancy, fetal malformation, previous caesarean section, breech presentation, or rhesus isoimmunisation) - N = 3752 women randomised during third trimester. - Admission CTG: 20 minute CTG on admission in spontaneous uncomplicated labour - Intermittent auscultation: Auscultation of the fetal heart with hand-held Doppler device during and immediately after 1 contraction Mitchell (2008) - Inclusion criteria: Labouring women considered to be at 'low risk' of fetal or maternal complications on admission - Exclusion criteria: Any minor maternal medical complication (e.g. diabetes or essential hypertension), previous caesarean section, preterm labour (less than 37 completed weeks), multiple pregnancy, prolonged pregnancy (more than 42 weeks), prolonged membrane rupture (more than 24 hours), induction of labour, meconium-stained liquor, maternal pyrexia, rhesus sensitisation, polyhydramnios, oligohydramnios, pre-eclampsia or blood pressure over 140/90 mmHg, abnormal presentation or lie (e.g. breech, transverse), high head (5/5ths palpable per abdomen), antepartum or intrapartum haemorrhage, known or suspected IUGR, any known or suspected fetal medical complication, abnormal Doppler artery velocimetry, known fetal malformation, poor obstetric history (e.g. history of stillbirth), unbooked - N = 582 women randomised on admission in labour		bias. The following criteria were considered: - Sequence generation - Allocation concealment - Blinding: due to the intervention, it would not be possible to blind participants or those providing care; however, the authors reported that they did consider whether outcome assessors were blinded - Incomplete outcome data: low risk was defined as 20% or less missing data, and high risk as more than 20% missing data - Selective reporting bias: established by cross-checking the outcomes reported in the methods and results sections of the included publications - Other sources of bias Missing data Levels of attrition were noted for the studies. Sensitivity analysis was performed to explore the effect of including studies with high attrition. All analyses were carried out on an intention-to-treat basis. Denominators were the number randomised, minus any women whose outcomes were known to be missing. Analysis Statistical analysis was performed in RevMan. A random effects model was used. This was because the authors felt that there was sufficient clinical heterogeneity to expect that the underlying treatment effect would differ. In Impey 2003, only women whose liquor was known to be clear were included. In the other trials, membrane rupture and clear liquor were not inclusion criteria	Test for overall effect: Z = 1.28, p = 0.20 [4 trials: Cheyne 2003, Impey 2003, Mires 2001, Mitchell 2008] **Fetal and neonatal deaths (number/total)** CTG: 5/5658 Auscultation: 5/5681 RR 1.01 (95% CI 0.30 to 3.47) Heterogeneity: I^2 = 0.0% Test for overall effect: Z = 0.02, p = 0.98 [4 trials: Cheyne 2003, Impey 2003, Mires 2001, Mitchell 2008] **Major neonatal morbidity (number/total)** a. Hypoxic ischaemic encephalopathy CTG: 6/1186 Auscultation: 5/1181 RR 1.19 (95% CI 0.37 to 3.90) Heterogeneity: NA Test for overall effect: Z = 0.29, p = 0.77 [1 trial: Mires 2001] b. Neonatal seizures CTG: 10/4017 Auscultation: 14/4039 RR 0.72 (95% CI 0.32 to 1.61) Heterogeneity: I^2 = Test for overall effect: Z = , p = [1 trial: Impey 2003] **Admission to NICU (number/total)** CTG: 219/5656 Auscultation: 213/5675 RR 1.03 (95% CI 0.86 to 1.24) Heterogeneity: I^2 = 0.0% Test for overall effect: Z = 0.32, p = 0.75 [4 trials: Cheyne 2003, Impey 2003, Mires 2001, Mitchell 2008]	- Allocation concealment: low risk of bias - Blinding of outcome assessors: low risk of bias - data were entered and neonatal assessment was performed without knowledge of treatment allocation - Incomplete outcome data: low risk of bias; loss to follow-up was 0.5% in CTG arm and 0.6% in auscultation arm - Selective reporting: low risk of bias Mires 2001 - Random sequence generation: low risk of bias - Allocation concealment: low risk of bias - Blinding of outcome assessors: low risk of bias; data analysts were blind to randomisation code - Incomplete outcome data: low risk of bias - Selective reporting: low risk of bias - Other bias: between randomisation (third trimester) and admission in labour, 1384 women (37%) developed a complication that warranted continuous FHR monitoring in labour; the authors provided data for the low-risk women separately and these were used for the analysis in the systematic review Mitchell 2008 - Random sequence generation: low risk of bias - Allocation concealment: low risk of bias - Blinding of outcome assessors: unclear risk of bias - no details reported - Incomplete outcome data: low risk of bias - Selective reporting: low risk of bias **Other information** The systematic review is available online at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005122.pub4/full The authors identified one trial which was ongoing - the ADCAR trial; it was unclear when this trial would be published. **Monitoring during labour** 3 trials reported the number of women having continuous EFM in labour and in 2 of the trials, the difference was significant: **Cheyne 2003:** - CTG: 10/157 (6.4%) - Auscultation: 10/177 (5.6%) (NS) [Note: a further 125 women from the CTG arm and 61 women from the auscultation arm received additional EFM during labour] **Impey 2003:** - CTG: 2341/4017 (58.3%) - Auscultation: 1686/4039 (41.7%) (p < 0.00001) **Mires 2001:** - CTG: 672/1185 (56.7%) - Auscultation: 551/1178 (46.8%) (p < 0.00001) **Total:** - CTG: 3023/5359 - Auscultation: 2247/5394 (RR 1.30 [95% CI 1.14 to 1.48])

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	- Admission CTG: 15-minute CTG on admission in spontaneous uncomplicated labour - Intermittent auscultation: Auscultation of the fetal heart for 1 continuous minute using a Pinard stethoscope or Doppler ultrasound device, after a contraction, at least every 15 minutes in the first stage of labour and every 5 minutes in the second stage **Inclusion criteria** Randomised and quasi-randomised trials comparing admission CTG with intermittent auscultation of the FHR **Exclusion criteria** None reported				
Full citation Impey,L., Reynolds,M., MacQuillan,K., Gates,S., Murphy,J., Sheil,O., Admission cardiotocography: A randomised controlled trial, Lancet, 361, 465-470, 2003 **Ref Id** 60264 **Country/ies where the study was carried out** Ireland **Study type** Randomised controlled trial **Aim of the study** To compare the effect on neonatal outcomes of admission CTG versus intermittent auscultation of the fetal heart rate **Study dates** August 1997 to April 2001 **Source of funding** Research Committee of the National Maternity Hospital, Dublin	**Sample size** See entry in systematic review by Devane 2012 **Characteristics** The following relate to the whole study population, not the low risk subgroup from the systematic review. **Induction of labour (n/total (%))** Cardiotocograph (CTG): 765/4298 (18) Auscultation: 749/4282 (17) **Major congenital anomaly (n/total (%))** CTG: 27/4298 (1) Auscultation: 18/4282 (<1) **Parity (n/total (%))** - 0 CTG: 2093/4298 (49) Auscultation: 2077/4282 (49) - 1 to 3 CTG: 2121/4298 (49) Auscultation: 2115/4282 (49) - ≥ 4 CTG: 81/4298 (2) Auscultation: 90/4282 (2) **Inclusion criteria** See entry in systematic review by Devane 2012 **Exclusion criteria** See entry in systematic review by Devane 2012	**Interventions** Admission CTG Intermittent auscultation	**Details** **Care during labour** In the intermittent auscultation group, auscultation was performed for 1 minute after a contraction, every 15 minutes in the first stage of labour and every 5 minutes in the second stage. EFM was used only if any of the following occurred: a deceleration in fetal heart rate or persistent tachycardia on auscultation; meconium in liquor or heavily blood stained liquor; maternal temperature of 38 degrees or higher; labour lasting longer than 8 hours. In the CTG group, the CTG was reviewed by the admitting midwife after 20 minutes. If the baseline FHR was 110-160 bpm, variability was visually assessed as more than 5 per minutes, decelerations were absent, and if there was more than one acceleration, it was classified as normal. Subsequent care was then the same as the intermittent auscultation group. If the criteria for normal were not met, CTG was continued until birth; 58% of the CTG arm and 42% of the auscultation arm had continuous EFM during labour (this is reported as an outcome in the systematic review)	**Results** All priority outcomes were reported in the systematic review (see Devane 2012)	**Limitations** There is indirectness of population due to the proportion of women who had induction of labour **Other information** All women appear to have had an early amniotomy. MOST STUDY DETAILS ARE REPORTED IN DEVANE 2012. THIS ENTRY ONLY REPORTS EXTRA DETAILS THAT WERE NOT REPORTED IN THE COCHRANE REVIEW, WHICH THE TECHNICAL TEAM FELT WERE IMPORTANT CONSIDERATIONS WHEN INTERPRETING THE RESULTS
Full citation	**Sample size**	**Interventions**	**Details**	**Results**	**Limitations**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Mires,G., Williams,F., Howie,P., Randomised controlled trial of cardiotocography versus Doppler auscultation of fetal heart at admission in labour in low risk obstetric population, BMJ, 322, 1457-1460, 2001 **Ref Id** 97907 **Country/ies where the study was carried out** Scotland **Study type** Randomised controlled trial **Aim of the study** To compare the effect of admission CTG and Doppler auscultation of the fetal heart on neonatal outcome and level of obstetric intervention in a low-risk obstetric population **Study dates** Not reported **Source of funding** Chief Scientists Office of the Scottish Executive	See entry in systematic review by Devane 2012 **Characteristics** **Women having artificial rupture of membranes (n/total)** a. All women Cardiotocograph (CTG): 1065/1864 Auscultation: 1031/1879 b. Low-risk women CTG: 640/1185 Auscultation: 614/1175 Proportion of nulliparous and multiparous women in the trial was not reported **Inclusion criteria** See entry in systematic review by Devane 2012 **Exclusion criteria** See entry in systematic review by Devane 2012	Admission CTG Intermittent auscultation with Doppler	The reasons for which women were excluded from the 'low-risk' subgroup analysis are listed here. Some women could have had more than one reason (n (%)): - Antepartum haemorrhage: 159 (4.2) - Raised blood pressure: 271 (7.2) - Suspected small for gestational age: 56 (1.5) - Preterm labour: 48 (1.30) - Gestational diabetes: 2 (0.1) - Fetal anomaly: 2 (0.1) - Reduced fetal movements and suspected fetal compromise: 63 (1.7) - Meconium stained liquor: 99 (2.6) - Intrauterine death: 3 (0.1) - Persistent breech: 67 (1.8) - Membranes ruptured before labour: 164 (4.4) - Induction of labour: 833 (22.2) - Baby born before arrival at hospital: 19 (0.5) - Elective caesarean section: 61 (1.6) - Woman withdrew from trial: 31 (0.8) - Other: 44 (1.2) Total: 1384 (36.9) In the confirmed low-risk women, 21.5% of those randomised to CTG were considered to have an abnormal fetal heart trace at the onset of labour, compared with 3.6% in the Doppler group (p < 0.0001)	**Metabolic acidosis at birth (defined as umbilical cord pH < 7.20 with a base deficit of > 8.0 mmol/l)** a. All women CTG: 252/1370 Auscultation: 262/1378 b. Low-risk women CTG: 159/876 Auscultation: 154/860	For the outcome of metabolic acidosis, 1003/3751 (26.7%) of the whole study population, corresponding to 641/2367 (27.1%) of the low-risk women, had no outcome data available. Power calculation and sample size estimate were changed as the trial went along, once after the interim analysis and once following an audit of the data available. A significantly higher proportion of women randomised to CTG had an abnormal FHR pattern at the start of labour, when compared to women randomised to auscultation. Part of the reason that the original trial needed to be accessed was to establish the trial protocol for monitoring in labour. No details were reported beyond those reported in the Cochrane review, therefore it cannot be established whether the admission CTG compared with intermittent auscultation on admission was the only way in which monitoring during labour differed. The following data for the number of women receiving continuous monitoring in labour were reported: **Continuous fetal heart rate monitoring in labour (n/total (%))** a. All women CTG: 1246/1865 (66.8) Auscultation: 1128/1882 (59.9) b. Low-risk women CTG: 672/1186 (56.7) Auscultation: 551/1178 (46.8) **Other information** MOST STUDY DETAILS ARE REPORTED IN DEVANE 2012. THIS ENTRY ONLY REPORTS EXTRA DETAILS THAT WERE NOT REPORTED IN THE COCHRANE REVIEW, WHICH THE TECHNICAL TEAM FELT WERE IMPORTANT CONSIDERATIONS WHEN INTERPRETING THE RESULTS

G.2 Intermittent auscultation compared with cardiotocography during labour

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Grant,A., O'Brien,N., Joy,M.T., Hennessy,E., MacDonald,D., Cerebral palsy among children born during the Dublin randomised trial of intrapartum monitoring, Lancet, 2, 1233-1236, 1989 **Ref Id** 164086 **Country/ies where the study was carried out** Ireland **Study type** Randomised controlled trial **Aim of the study** To confirm that the absence of neonatal signs (such as seizures) suggestive of intrapartum asphyxia is strong evidence that asphyxia was not the cause of later cerebral palsy To estimate the proportion of all cases of cerebral palsy that might possibly be associated with intrapartum asphyxia **Study dates** Recruitment into the original trial began on March 31st 1981 and ended on April 10th 1983 Follow-up was at age 4 years **Source of funding** See entry on MacDonald 1985 for details of the trial	**Sample size** N = 13079 (number of live-born babies during the trial) **Characteristics** See entry of MacDonald 1985 for details **Inclusion criteria** See entry of MacDonald 1985 for details **Exclusion criteria** See entry of MacDonald 1985 for details	**Interventions** Intermittent auscultation (n = 6552 babies) Electronic fetal monitoring (EFM) (n = 6527 babies)	**Details** All 30 children from the original trial who survived following neonatal seizures and 125 (91%) of a further 138 children whose neurological status was judged to be abnormal, were considered. They underwent a general physical and detailed neurological examination by an experienced paediatrician who was blind to both the monitoring method and the nature of the neonatal neurological abnormality. In order to identify other cases, not originally identified as having abnormal neurological signs, data were sought from specialist remedial clinics in Ireland. Once a child was identified, information about the pregnancy, labour, delivery and neonatal period was extracted from the hospital case-record or trial data sheet. Then the children were divided based on allocation	**Results** **<u>Cerebral palsy (n/total)</u>** Auscultation: 10/6552 (0.15) EFM: 12/6527 (0.18) **<u>Details of the cases</u>** Note: - Auscultation group 3 were from the 21 babies with seizures that survived during the neonatal period 7 were identified via clinic notification - EFM group 4 were from the 9 babies with seizures that survived during the neonatal period 8 were identified via clinic notification <u>a. Children with abnormal neurological signs during neonatal period</u> 30 of the 39 babies with neonatal seizures survived to be discharged from hospital; 3 from each group were then judged to have cerebral palsy at 4 years old. 4 children (2 in each arm) had 'spastic quadriplegia with severe mental retardation'. There had been signs suggestive of asphyxia in 3 which were apparent both during labour and after the birth. The fourth child was born at 34 weeks' gestation with a 5-minute Apgar score of 8, then had severe respiratory distress syndrome following intraventricular haemorrhage and then post haemorrhage hydrocephalus. The other 2 children had mild spastic hemiplegias, and had a sequence of signs suggestive of asphyxia during labour and after birth. A seventh child with mild spastic hemiplegia was identified from among the 125 children who were formally reassessed because of neonatal neurologic abnormalities other than seizures. There had been transient abnormalities of tone, reflexes and behaviour, but they had resolved within 48 hours of birth. <u>b. Identified from clinics</u> In 12 of the 15 cases (of which one was a twin), labour delivery and the neonatal period seemed normal. Of the 3 others, 1 (allocated EFM) had respiratory distress syndrome and pneumonia following spontaneous rupture of the membranes and birth at 30 weeks. One (allocated auscultation) had an emergency caesarean section (CS) because of failed induction at 43 weeks and suspected intrauterine infection. The third (allocated auscultation) was discharged apparently well but later had severe gastroenteritis that had been complicated by cerebral oedema with seizures and later meningitis.	**Limitations** Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: Yes Missing data/loss to follow-up: Possible because apart from those babies with seizures/other symptoms after birth, other children were identified through specialist clinics in Ireland. This would not have covered any children who had moved away or possibly died Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: in the original trial 22.5% of women were considered 'high risk' **Other information** This is a follow-up to MacDonald 1985
Full citation Kelso,I.M., Parsons,R.J., Lawrence,G.F., Arora,S.S., Edmonds,D.K., Cooke,I.D., An assessment of continuous fetal heart rate monitoring in labor. A randomized trial,	**Sample size** N = 504 **Characteristics**	**Interventions** Auscultation (n = 251) EFM (n = 253)	**Details** All women under the care of the University Department at the Jessop Hospital for Women, Sheffield, admitted to the labour ward during the study period had their labours analysed. Women were admitted in spontaneous labour or to have labour induced. The	**Results** **<u>Mode of birth (n/total)</u>** <u>a. Spontaneous vaginal birth</u> Auscultation: 162/251 EFM: 158/253	**Limitations** Appropriate randomisation: Unclear - method of randomisation is not reported Allocation concealment: Yes Groups comparable at baseline: Yes; however, there was a significantly shorter first and second stage of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
American Journal of Obstetrics and Gynecology, 131, 526-532, 1978 **Ref Id** 164097 **Country/ies where the study was carried out** England **Study type** Randomised controlled trial **Aim of the study** To compare the usefulness of continuous fetal heart rate monitoring in labour using the dip area as a measure of fetal distress with or without intrauterine pressure recordings **Study dates** July 1976 to June 1977 **Source of funding** The first author received a British Commonwealth Medical Fellowship. Financial assistance was also gained from Pye Dynamics, Ltd and Devices, Ltd	**Maternal age/years (mean ± SD)** Auscultation: 25.6 ± 5.0 EFM: 26.0 ± 4.9 (NS) **Gestation/weeks (mean ± SD)** Auscultation: 39.75 ± 1.18 EFM: 39.67 ± 1.32 (NS) **Nulliparous (n/total)** Auscultation: 134/251 EFM: 116/253 **Cervical assessment using Bishop score (n/total)** 1 - 4 Auscultation: 43/251 EFM: 38/253 5 - 8 Auscultation: 154/251 EFM: 151/253 9 - 12 Auscultation: 54/251 EFM: 64/253 (NS) **Type of labour (n/total)** - Spontaneous Auscultation: 120/251 EFM: 132/253 - Accelerated Auscultation: 69/251 EFM: 51/253 - Induced Auscultation: 62/251 EFM: 70/253 (NS) **Intra or postpartum pyrexia (n/total)** Auscultation: 7/251 EFM: 8/253 (NS) **Birth weight / grams (mean ± SD)** Auscultation: 3349 ± 430 EFM: 3335 ± 459 **Inclusion criteria** Admitted to the labour ward during the study period **Exclusion criteria** Breech presentation Multiple pregnancy Maternal age of 40 years or greater Previously mentally disabled or spastic child resulting from birth		study authors wanted to evaluate a non high-risk population; therefore, the exclusion criteria aimed to exclude high-risk women. All other women were allotted a sealed envelope when they were admitted, containing treatment allocation. Women allocated to continuous monitoring had a fetal scalp electrode attached, with or without an intrauterine pressure catheter, at the earliest convenient time. Oxytocin was given to all women when indicated. In women allocated to intermittent auscultation, the fetal heart rate (FHR) was counted every 15 minutes (or more frequently if indicated) during or immediately after a contraction. A Pinard fetal stethoscope was used, and the rate was counted for 1 full minute. If there was any difficulty hearing the sounds, an ultrasonic Doppler was used intermittently. A double-clamped section of the cord was collected at birth before the baby's first breath. Arterial and venous blood gas measurements were taken. Augmentation, using amniotomy alone or amniotomy with oxytocin infusion, was performed if the progress of the labour fell to the right of the nomogram. Decisions to perform caesarean section or instrumental birth were the responsibility of duty staff. **Outcomes reported:** 1. Mode of birth: rate of spontaneous birth, forceps or ventouse, and caesarean section were reported 2. Perinatal death 3. Admission to special care baby unit (SCBU) 4. Abnormal neurological signs	b. Forceps or ventouse birth Auscultation: 78/251 EFM: 71/253 c. Caesarean section Auscultation: 11/251 (3 for fetal distress) EFM: 24/253 (4 for fetal distress) **Perinatal death (n/total)** Auscultation: 1/251 EFM: 0/253 (Note: the woman was multiparous and admitted at 41 weeks' gestation in spontaneous labour. The labour was slow despite an oxytocin infusion, and there were at least two separate episodes of fetal tachycardia [170 - 190 bpm]. After 12 hours and 45 minutes, meconium stained liquor was noted. The FHR was 190 bpm and the cervix was dilated. Forceps were applied to rotate the vertex. After birth, the baby was transferred to SCBU and intubated. The baby died of meconium aspiration at 4 hours) **Abnormal neurologic signs (n/total)** Auscultation: 3/251 EFM: 2/253 (Note: All 5 babies had depressed Apgar scores and were admitted to SCBU. In the EFM group: both babies were hypertonic at birth, but there were no symptoms at day 9 or week 6. in the auscultation group: the first baby was jittery and irritable for 3 days, but there were no abnormal neurological findings on day 6 or week 6. The second baby had a cyanotic attack and a left-sided convulsion at 6 hours after the birth. The baby was treated with phenobarbitone for 3 days, and there were no further convulsions, and no issues at day 12 or week 6. The third baby was 'stiff and irritable' at 11 hours and received phenobarbitone for 3 days, after which time there were no abnormal neurologic findings) **Admission to SCBU (n/total)** Auscultation: 43/251 EFM: 45/253 Note: the indications for admission were as follows (n): -- infant depressed at birth Auscultation: 12 EFM: 9 -- birthweight less than 2500 g or considered preterm by attending paediatrician Auscultation: 7 EFM: 6 -- jaundiced - admitted for phototherapy Auscultation: 10 EFM: 16 -- treated maternal thyrotoxicosis euthyroid at time of labour Auscultation: 4 EFM: 0 -- maternal thrombocytopenia Auscultation: 1 EFM: 0 -- maternal pyrexia > 38 degrees Auscultation: 1 EFM: 0 -- meconium aspiration Auscultation: 3	labour in the EFM arm Groups received same care (apart from intervention): Monitoring was internal; therefore, in order to fit the scalp electrode, women in the EFM arm were likely to have received an amniotomy to fit the electrode in cases where the membranes had not ruptured; this would not be necessary in the other arm of the trial. Blinding of participants: Not reported Blinding of staff providing care: Not reported Blinding of outcome assessors: Not reported Missing data/loss to follow-up: No Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: 26% of women had induction of labour **Other information** CTG: internal 2 other perinatal deaths were detailed in the article, but they were born to women excluded from the trial due to breech presentation. **Length of labour (mean ± SD)** a. First stage / hours Auscultation: 6.63 ± 3.88 EFM: 5.94 ± 3.36 ($p < 0.05$) b. Second stage / minutes Auscultation: 32.35 ± 25.23 EFM: 28.01 ± 21.00 ($p < 0.05$) c. Third stage / minutes Auscultation: 6.66 ± 10.32 EFM: 6.19 ± 8.13 (NS)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Previous perinatal death - cause unknown Previous severe fetal distress - Apgar score of 3 or less Hypertension with diastolic pressure 100 mmHg or 100 mmHg with proteinuria Two consecutive estrogen estimations outside 2 SD from the normal Anaemia of 8 g/dl or less Type 1 diabetes Admitted fully dilated and ready for birth Missed			EFM: 2 -- congenital anomalies Auscultation: 1 EFM: 2 -- hypothermia Auscultation: 1 EFM: 4 -- other Auscultation: 3 EFM: 6 **Cord blood gas values** The authors reported that cord arterial and venous blood gas analysis was performed for 37 babies in each arm. There were no statistically significant differences in the proportion of babies with pH of 7.25 or less, or base deficit of 10 mmol/l or more. No further details were reported; therefore, this is not reported in the GRADE table.	
Full citation Leveno,K.J., Cunningham,F.G., Nelson,S., Roark,M., Williams,M.L., Guzick,D., Dowling,S., Rosenfeld,C.R., Buckley,A., A prospective comparison of selective and universal electronic fetal monitoring in 34,995 pregnancies, New England Journal of Medicine,N Engl J Med, 315, 615-619, 1986 **Ref Id** 164091 **Country/ies where the study was carried out** USA **Study type** Quasi-randomised trial **Aim of the study** To compare the differences in perinatal outcome between universal and selective electronic fetal monitoring (EFM) in 34,995 births **Study dates** October 1st 1982 onwards, for a 36-month period **Source of funding** None reported	**Sample size** N = 34,995 (However, the population of interest for this review is 14,618) **Characteristics** The following represent characteristics of the entire study population. Details of the low-risk subgroup are not reported separately. **Parity (%)** - Nulliparous Selective: 39 Universal: 40 - Multiparous Selective: 61 Universal: 60 **Prenatal care (%)** Selective: 81 Universal: 82 **Birth weight / g (%)** - 500-999 Selective: 0.8 Universal: 0.8 - 1000-1500 Selective: 1.2 Universal: 1.1 - 1501-2000 Selective: 2.3 Universal: 2.5 - 2001-2500 Selective: 7.2 Universal: 7.2 - ≥ 2501 Selective: 88.5 Universal: 88.4	**Interventions** Selective monitoring: intermittent auscultation for low-risk women and EFM for high-risk women (n = 7330) Universal monitoring: all women monitored with EFM (n = 7288)	**Details** This was a trial comparing the policy of all women being monitored using EFM (universal monitoring) with a policy of only monitoring high-risk women with EFM (selective monitoring). The trial employed these different policies during alternating months, and compared the results. The standard policy in the unit (Parkland Memorial Hospital) was a policy of only using EFM in high risk pregnancies (see details listed in inclusion criteria above). Women who had complications were transferred into a labour intensive unit with 5 beds (this continued throughout both parts of the trial). Most electronic monitoring was done in this unit. A maximum of seven portable electronic monitors were available during selective monitoring months. During universal monitoring months, 12 additional monitors were made available and installed in labour rooms. Therefore, a total of 19 monitors were available for a 20-bed unit. The policy during these months was to use EFM for every pregnancy in which the baby was viable. Other than the policy of selective or universal monitoring, there were no differences in care during the alternate months. Nursing personnel were in a ratio of 2 women to one nurse. Oxytocin was administered according to a strict protocol. Women admitted to single-bed labour rooms were visited every 30 minutes, and had the fetal heart rate measured using intermittent auscultation with a Doppler device or visual inspection of the trace. Nurses attending each birth completed a perinatal data sheet, and research nurses assessed the data for consistency and completeness before it was stored electronically. Statistical analysis was done using chi-squared test or Fisher's exact test. Two sided p-values of 0.05 were considered significant	**Results** **Caesarean section for fetal distress (n/total (%))** Selective/auscultation: 28/7330 (0.4) Universal/EFM: 64/7288 (0.9) (p < 0.01) **Mortality (n/total (%))** a. Intrapartum fetal death Selective/auscultation: 0/7330 (0) Universal/EFM: 0/7288 (0) (NS) b. Neonatal death Selective/auscultation: 5/7330 (0.1) Universal/EFM: 4/7288 (0.1) (NS) **Admission to intensive care nursery (n/total (%))** Selective/auscultation: 17/7330 (0.2) Universal/EFM: 25/7228 (0.3) (NS) **Neonates with seizures (n/total (%))** Selective/auscultation: 3/7330 (0.4) Universal/EFM: 1/7288 (0.01) (NS) Note: non-significant p-values were not reported	**Limitations** Appropriate randomisation: No - low risk women received auscultation or EFM on alternating months Allocation concealment: No Groups comparable at baseline: Unclear - there were no significant differences in the selective versus universal groups, but this detail was not reported for low-risk women Groups received same care (apart from intervention): Yes Blinding of participants: Unclear, but unlikely considering the intervention Blinding of staff providing care: No Blinding of outcome assessors: Unclear - no details were reported Missing data/loss to follow-up: Unclear Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Unclear at what point seizures were assessed and the reasons for admission to NICU Intention-to-treat analysis performed: Unclear Overall, this study is not well reported for the guideline comparison and population of interest. The data for low-risk women were reported for the comparison of selective versus universal monitoring, and therefore, the technical team made the assumption that this represents auscultation versus EFM, because according to the trial protocol, in 'selective' months low-risk women should all have received auscultation and in 'universal' months they should have received EFM. This assumption is corroborated by the assumption of a Cochrane review (Alfirevic 2013) who reported this trial for the same comparison **Other information** Cardiotocograph (CTG): not reported whether monitoring was internal or external. Abnormal fetal heart rates were identified in 2.7% of selective/auscultation women and 7.6% of universal/EFM women (low risk). The difference was statistically significantly (p < 0.01)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	There were no significant differences identified between the two groups **Inclusion criteria** Not reported for the study; however, the following definitions are used to describe the different parts of the study population: High risk: - induction or augmentation of labour - dysfunctional labour (not defined) - abnormal fetal heart rate - presence of meconium in the amniotic fluid - other complications of pregnancy, including hypertension, vaginal bleeding, prolonged pregnancy, diabetes, twins, breech presentation and preterm labour Low risk: - single baby - cephalic presentation - spontaneous, uncomplicated labour - birth weight exceeding 2500 g **Exclusion criteria** Not reported				
Full citation MacDonald,D., Grant,A., Sheridan-Pereira,M., Boylan,P., Chalmers,I., The Dublin randomized controlled trial of intrapartum fetal heart rate monitoring, American Journal of Obstetrics and Gynecology, 152, 524-539, 1985 **Ref Id** 164093 **Country/ies where the study was carried out** Ireland **Study type** Randomised controlled trial **Aim of the study** To compare continuous electronic intrapartum fetal heart monitoring with a policy of intermittent auscultation **Study dates** March 31st 1981 to April 10th 1983 **Source of funding**	**Sample size** N = 12,964 **Characteristics** **Nulliparous n (%))** Auscultation: 1964 (39.3) Electronic fetal monitoring (EFM): 2015 (40.4) **Receiving induction of labour (n (%))** Auscultation: 475 (9.5) EFM: 434 (8.7) **Giving birth earlier than 37 weeks' gestation (n (%))** Auscultation: 133 (2.7) EFM: 156 (3.1) **Considered high risk at the start of labour (n (%))** Auscultation: 1137 (22.7) EFM: 1106 (22.2) (Note: this was defined as maternal age of 40 years or more, diabetes, pre-eclampsia, chronic hypertension, renal disease, cardiac disease, previous stillbirth or neonatal death, previous child with neurological abnormality, previous low birthweight baby, bleeding in pregnancy requiring admission to hospital after the first trimester, induction of labour for pregnancy of more than 42 completed weeks' gestation, multiple pregnancy, breech presentation in labour, and gestational age less than 34 completed weeks.)	**Interventions** Intermittent auscultation (n = 6490) EFM (n = 6474)	**Details** **Sample size calculation** A sample size calculation was based on adverse outcomes for babies, and the anticipated population of 10,000 had 80% power to detect a statistically significant difference if the rate was reduced by half through more intensive monitoring. An interim analysis, after 4,000 cases, determined that recruitment should be extended to 13,000 to assess the difference on the most unambiguous set of outcomes (deaths and seizures). This would have 75% power to to detect a 50% reduction. For practical reasons, data on umbilical venous acid-base status were limited to 1000 consecutive babies. The trial protocol pre-specified stratification by risk status and by time interval between entry to trial and birth (< 1 hour, > 1 hour). **Study population** During the study period, 17381 women gave birth. 4356 were ineligible due to having an elective caesarean section (CS), suffering a fetal death before labour, delivering so rapidly after arrival (< 1 hour from admission) that presence of meconium stained liquor and hence eligibility could not be assessed, less than 28 weeks, gross fetal abnormality, or meconium staining or no fluid. Out of the remaining 13,025 women eligible for inclusion, 12,964 were entered into the trial and gave birth to 13,084 babies. **Randomisation** Randomisation was performed after eligibility had been confirmed through assessment of liquor. Allocation was done by opening the next in a series of serially numbered, sealed opaque envelopes. **Monitoring in EFM arm** Following randomisation, an electrode was applied to	**Results** **Mode of birth and primary indication (n (%))** a. Caesarean section Auscultation: 144 (2.2) - Failure to progress in labour: 88 (1.3) - Fetal distress: 10 (0.2) - Other: 46 (0.7) EFM: 158 (2.4) - Failure to progress in labour: 84 (1.3) - Fetal distress: 25 (0.4) - Other: 49 (0.7) b. Forceps birth Auscultation: 407 (6.3) - Failure to advance: 313 (4.8) - Fetal distress: 75 (1.2) - Other: 19 (0.3) EFM: 528 (8.2) - Failure to advance: 323 (5.0) - Fetal distress: 190 (2.9) - Other: 15 (0.2) **Admission to SCN (n/total (%))** Auscultation: 543/6554 (8.3) EFM: 547/6530 (8.4) (Note: in an analysis based only on the first 10,000 women recruited, it was reported that 2.7% of babies were admitted for reasons that might have been affected by intrapartum care.) **Umbilical cord venous pH (n/total (%))** < 7.05 Auscultation: 2/535 (0.4) EFM: 2/540 (0.4)	**Limitations** Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes Groups received same care (apart from intervention): Yes (because clear liquor had to be demonstrated to enter the trial; therefore, extra amniotomy was not required for EFM arm) Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: Yes for neonatal outcomes Missing data/loss to follow-up: For cord blood gas values, there were limited data; for other outcomes, more detail was collected in the first part of the trial than in the second (i.e the last 3,000 women) i.e. for 'other neurological abnormality' data were only collected for 10,094/13,084 (77%) of study babies. Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: 22.5% of women were considered 'high risk' **Other information** CTG: monitoring was internal Rates of successful fetal blood sampling were 3.5% in the auscultation group and 4.4% in the EFM group. 97.7% of those allocated to auscultation received it throughout labour. In the EFM group, 80.7% received EFM throughout; birth was too rapid in 10.5%, 6.6%

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Medical Research Council of Ireland National Maternity Hospital Research Fund Wellcome Trust Department of Health and Social Security (supported the National Perinatal Epidemiology Unit [NPEU])	**Inclusion criteria** Live fetus of at least 28 weeks' gestation with no evidence of gross abnormality Diagnosis of labour made Amniotic fluid without significant meconium staining had been positively demonstrated, either at spontaneous rupture of membranes or early amniotomy **Exclusion criteria** Elective caesarean section Fetal death prior to the onset of labour		the fetal scalp and an external tocodynamometer was attached. If it was not possible to get a signal from the electrode, an external transducer was used. If the midwife was concerned about the trace, they first checked it using auscultation and then informed the nurse-midwife in charge of the labour ward. If the latter considered the trace to be abnormal, an obstetrician was called. The following fetal heart rate (FHR) patterns were considered to be suspicious: - marked tachycardia or bradycardia - moderate tachycardia or bradycardia with reduced variability - minimal variability (absent beat-to-beat variation, flat tracing) - late deceleration pattern - moderate and severe variable deceleration patterns - other confusing patterns with varying baselines which could not be clearly interpreted If any of these patterns had been present for at least 10 minutes and did not respond to measures such as changing position or adjusting transducers, then clinical action was taken. In the first stage of labour this was the taking of fetal scalp blood pH; in the second stage of labour the action was immediate birth. If the fetal scalp blood pH was less than 7.20 birth was actioned as soon as possible. If the pH was 7.20 - 7.25 and the FHR pattern remained suspicious, birth was also completed as soon as possible. If the FHR reverted to a normal pattern, the situation was managed expectantly. If the pH was over 7.25 and the trace stayed suspicious, scalp blood pH was measured 30 minutes to 1 hour later. Throughout the trial, tracings were reviewed by a single experienced observer, who was blinded to the outcome of the baby following birth. The trace was classified according to whether the observer felt that it should or should not have prompted clinical action. **Monitoring in auscultation arm** Women randomised to receive auscultation were managed according to the hospital's standard policy. The FHR was auscultated with a Pinard stethoscope for 60 seconds following a contraction. This was done at least every 15 minutes in the first stage and during every interval between contractions in the second stage. If there was an issue detecting the FHR with auscultation, intermittent Doppler ultrasound was used. If the FHR was < 100 or > 160 bpm during three contractions, and the abnormality did not respond to measures such as a change in posture or treatment of pyrexia, then clinical action was taken as above; i.e in the first stage of labour scalp pH was taken and a scalp clip attached, and in the second stage of labour, birth was expedited. **Outcomes reported** 1. Mode of birth 2. Mortality: intrapartum deaths and deaths within 28 days (neonatal deaths) were examined by a pathologist blinded to allocation. Each case was classified by primary cause of death, and in cases where the primary cause was not 'asphyxial conditions developing during	7.05-7.09 Auscultation: 9/535 (1.7) EFM: 3/540 (0.6) 7.10-7.20 Auscultation: 40/535 (7.5) EFM: 41/540 (7.6) > 7.20 Auscultation: 484/535 (90.4) EFM: 494/540 (91.4) **Neonatal morbidity (n/total (%))** a. Need for intubation Auscultation: 54/5058 (1.1) EFM: 58/5035 (1.2) b. Neonatal seizures (all women) Auscultation: 27/6554 (0.4) EFM: 12/6530 (0.2) (Note: in 10/12 cases in the EFM arm and 24/27 in the auscultation arm, seizures were first noted within 48 hours of birth. In 4 out of the 5 later cases, the cause was unlikely to be due to birth event [meningitis at 28 weeks, 2 cases of complications of hyaline membrane disease, and 1 case of hypoglycemia] and in the fifth, the seizures were first noted at 56 hours of age) c. Neonatal seizures (women without pregnancy risk factors)* Auscultation: 19/5015 (0.4) EFM: 7/5038 (0.1) d. Other neurological abnormality Auscultation: 25/5058 (0.5) EFM: 16/5035 (0.3) (Note: This is abnormalities other than seizures and was only reported in survivors. In the auscultation group, 5 babies had 'simultaneous abnormalities of tone and reflex' and 20 babies had 'other abnormal neurological signs persisting for at least a week'. In the EFM arm, the numbers were 4 and 12 respectively.) e. Neonatal trauma Auscultation: 66/5058 (1.3) EFM: 71/5035 (1.4) (Note: In decreasing order of prevalence: scalp laceration, abrasion or bruising; facial bruising, suffusion, forceps marks and conjunctival haemorrhage; cephalhematoma; other bruising; motor deficit in right arm; fractured clavicle; subdural haemorrhage and death; facial nerve injury) * Data from low risk women are reported in the GRADE table **Perinatal death (n/total (%))** a. Total Auscultation: 14/6554 EFM: 14/6530 b. Intrapartum stillbirth Auscultation: 2/6554	refused monitoring, and there were technical problems in 1.1% of cases.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			labour' they were reviewed to see if the conditions may have contributed 3. Neurological abnormalities: Neurological assessments were made by a blinded neonatologist. The babies were considered to have had seizures if the neonatologist felt there was evidence of seizures of the following types: generalised tonic, multifocal clonic, focal clonic, or myoclonic. This did not included babies with 'subtle seizure activity' or 'jitteriness'. - During recruitment of the first 10,000 women, serial standardised assessments were made on all babies admitted to the special care nursery (SCN) and any babies on the ward who staff were concerned about. Any babies identified in these ways were examined within 48 hours of birth, then at 72 hours, at 7 days, and at discharge. Assessment of tone, movement, reflexes and behaviour was performed to classify babies into one of the following categories: simultaneous abnormalities of both tone and reflexes, other neurological abnormalities persisting 1 week after birth, and other transient abnormalities resolved by 7 days - During recruitment of the last 3,000 women, the identification protocol was simplified and neonatologists only identified babies who had seizures in the neonatal period. 4. Admission to special care nursery 5. Umbilical cord blood gas values: Collection of blood samples only occurred during a 2-month period of the trial. A 15 cm section of cord was double clamped at birth and 3 ml of venous blood was aspirated anaerobically into a heparinised syringe. **Follow-up and statistical analyses** Babies who survived neonatal seizures or other abnormalities of tone and reflexes were followed up for at least 1 year, and seen by senior paediatricians who were not involved in the trial and were blinded to allocation. Chi-squared tests or t-tests of statistical significance were used to compare groups.	EFM: 3/6530 c. Neonatal deaths Auscultation: 12/6554 EFM: 11/6530 The following details are given about the primary causes of the deaths (n): -- Asphyxial conditions developing in labour Auscultation: 7 EFM: 7 -- Conditions associated with immaturity Auscultation: 4† EFM: 1 -- Birth trauma Auscultation: 1 EFM: 3* -- Other Auscultation: 2 EFM: 3 † in one of the babies in each of these groups, asphyxial conditions developing during labour may have been contributing factors but were not primary cause of death **Stratified analyses** a. By risk status 22.5% of women met the criteria for being high risk. Compared to the other participants of the trial, these women were 2.7 times more likely to have a caesarean section, and their babies were more than three times more likely to have an Apgar < 4 at one minute, to be admitted to SCN or to die. Within the risk groups, there was little evidence of a differential effect of the two policies on outcome. In the case of neonatal seizures, the effect of EFM in preventing neonatal seizures was stronger in women without risk factors when compared to women with risk factors. However, the effect of monitoring on neonatal seizures that resulted in survival was not different in the two risk groups. Neonatal seizures (rate per 1000) - Pregnancy risk factors present Auscultation: 5.2 EFM: 3.4 Risk difference (RD): -1.8 per 1000 - Pregnancy risk factors not present Auscultation: 3.8 EFM: 1.4 RD: - 2.4 per 1000 b. By duration of labour The longer labours demonstrated a protective effect of EFM, whereas in the shorter labours, the risk of seizures was similar in the two monitoring arms. Neonatal seizures (rate per 1000) - Labour < 5 hours Auscultation: 1.8 EFM: 1.6 RD: - 0.2 per 1000 - Labour > 5 hours Auscultation: 8.5	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				EFM: 2.4 RD: - 6.1 per 1000	
Full citation Vintzileos,A.M., Antsaklis,A., Varvarigos,I., Papas,C., Sofatzis,I., Montgomery,J.T., A randomized trial of intrapartum electronic fetal heart rate monitoring versus intermittent auscultation, Obstetrics and Gynecology, 81, 899-907, 1993 **Ref Id** 164083 **Country/ies where the study was carried out** Greece **Study type** Randomised controlled trial **Aim of the study** To determine whether the use of continuous electronic fetal monitoring (EFM) alone during labour is associated with decreased perinatal mortality and morbidity when compared to intermittent auscultation, in a population with a relatively high perinatal mortality rate **Study dates** October 1st 1990 to June 30th 1991 **Source of funding** Advanced Medical Systems provided financial support for the study	**Sample size** N = 1428 **Characteristics** **Maternal age/years (mean ± SD)** Auscultation: 26.6 ± 5.1 EFM: 26.2 ± 5.1 (NS) **Nulliparous (n (%))** Auscultation: 340 (50%) EFM: 408 (54.7%) (NS) **Gestational age distribution/weeks (n (%))** 26-37 Auscultation: 57 (8.3) EFM: 48 (6.4) (NS) 37-42 Auscultation: 608 (89.1) EFM: 686 (91.9) (NS) > 42 Auscultation: 17 (2.4) EFM: 12 (1.6) (NS) **Antepartum risk factors (n (%))** Auscultation: 94 (13.7) EFM: 89 (11.9) (NS) (Note: antepartum risk factors were: hypertension, diabetes, premature rupture of membranes, suspected fetal growth restriction, oligohydramnios and vaginal bleeding) **Meconium stained liquor (n (%))** Auscultation: 84 (12.3) EFM: 112 (15) (NS) **Presentation (n (%))** - Vertex Auscultation: 670 (98.3) EFM: 733 (98.2) (NS) - Breech Auscultation: 11 (1.6) EFM: 12 (1.6) (NS) - Other Auscultation: 1 (0.1) EFM: 1 (0.1) (NS) **Labour** - Spontaneous Auscultation: 374 (54.8)	**Interventions** Electronic fetal monitoring (n = 746) Intermittent auscultation (n = 682)	**Details** The study was performed in two university hospitals (total of 3000 births per year across the sites). Prior to the study, standard practice was intermittent auscultation, with only approximately 20% of women receiving continuous EFM. Intensive training sessions were given to all clinical personnel, although most were familiar with the use of EFM before the trial. The sample size calculation was based on showing a 2/3 decrease in perinatal mortality. This was based on background mortality rates and reported prevalence of perinatal asphyxia in the year prior to the study. It was calculated that 2210 patients in total were needed (based on alpha of 0.05 and 80% power). Eligible patients were randomised using a coin toss. Women in both arms had IV access secured after admission and labour in lateral or semi-Fowler position. There was one nurse for each woman in both groups. External fetal monitoring was performed using a tocodynamometer for recording uterine contractions and a Doppler ultrasound to monitor fetal heart rate. External monitoring was continued for as long as satisfactory tracings were obtained. Direct monitoring, by the insertion of a fetal scalp electrode, was indicated if the quality of the trace was not satisfactory. If the EFM trace was satisfactory, the decision to use internal monitoring was left to the managing clinician. The initial FHR trace was assessed at least every 15 minutes during the first stage of labour and every 5 minutes during the second stage. Women assigned to auscultation were monitored using a Doppler ultrasound device. The baseline heart rate was counted between contractions and then auscultated every 15 minutes during the first stage and every 5 minutes during the second stage. The FHR was measured during and immediately after the contraction, for at least 30 seconds afterwards. The auscultation lasted 1 minute. Uterine contraction was evaluated using palpation. In the EFM group, non-reassuring heart rate patterns were defined as: - late decelerations unrelated to supine hypotension or regional anaesthesia, which failed to respond to conservative measures - persistent prolonged decelerations of less than 80 beats per minute (bpm) lasting more than 2 minutes - severe variable decelerations (70 bpm or fewer lasting 60 seconds or more) - variable decelerations with a rising baseline and loss of variability - persistent fetal tachycardia (more than 160 bpm) associated with decreased variability (less than 5 bpm) - persistent decreased variability - sinusoidal FHR pattern (three to five cycles per minute, amplitude 5 to 15 bpm) In the auscultation group, non-reassuring heart rate patterns were defined if one or more of the following was present:	**Results** **Mode of birth (n (%))** a. Spontaneous vaginal Auscultation: 561 (82.2) EFM: 571 (76.5) b. Vacuum extraction Auscultation: 58 (8.5) EFM: 101 (13.5) c. Low forceps Auscultation: 2 (0.3) EFM: 3 (0.4) d. Mid forceps Auscultation: 2 (0.3) EFM: 0 (0) e. Caesarean section Auscultation: 59 (8.6) - for fetal distress: 16 - reasons other than suspected fetal distress: 43 EFM: 71 (9.5) - for fetal distress: 40 - reasons other than suspected fetal distress: 31 **Admission to NICU (n (%))** a. Total Auscultation: 102 (14.9) EFM: 104 (13.9) b. Unrelated to prematurity Auscultation: 69/625 (11) EFM: 72/698 (10.3) **Cord arterial pH < 7.10 (n/total (%))** Auscultation: 18/680 (2.6) EFM: 31/739 (4.1) **Neonatal complications (n (%))** a. None Auscultation: 594 (87.1) EFM: 639 (85.6) b. Hypoxic ischaemic encephalopathy Auscultation: 2 (0.3) EFM: 1 (0.1) c. Intraventricular haemorrhage Auscultation: 1 (0.1) EFM: 0 (0) d. Seizures Auscultation: 2 (0.3) EFM: 0 (0) **e. Respiratory distress** Auscultation: 40 (5.8) EFM: 55 (7.3) f. Hypotonia* Auscultation: 3 (0.4) EFM: 3 (0.4) g. Necrotizing enterocolitis*	**Limitations** The trial was stopped after the third periodic review due to increasing mortality rates. Appropriate randomisation: Yes Allocation concealment: Yes Groups comparable at baseline: Yes. There were significant differences between the two groups in the proportion of women having spontaneous labour (higher in auscultation arm), augmented labour (higher in EFM arm) and induction of labour (higher in EFM arm). The duration of labour was also significantly longer in the EFM arm. However, the authors reported that this should have put the EFM arm at a disadvantage. Groups received same care (apart from intervention): Yes Blinding of participants: No Blinding of staff providing care: No Blinding of outcome assessors: No for maternal outcomes, yes for neonatal outcomes, unclear for cord blood gas values (but unlikely to cause bias for this outcome, because it is biochemical) Missing data/loss to follow-up: Generally not; 0.6% of women had missing data for cord arterial pH Precise definition of outcomes: Yes Valid and reliable method of outcome assessment: Yes Intention-to-treat analysis performed: Yes Indirectness: This was not a completely low-risk population: 12.8% of women had antepartum risk factors, 7.4% labours were preterm and 12% were induced. (As these conditions are not mutually exclusive, the total proportion was considered low enough not to exclude the study) **Other information** CTG: monitoring was external for as long as traces were satisfactory **Duration of labour (mean ± SD)** a. First stage / hours Auscultation: 5.5 ± 3.7 EFM: 6.1 ± 4.3 (p = 0.006) b. Second stage / minutes Auscultation: 26.9 ± 16.9 EFM: 29.4 ± 18.6 (p = 0.01)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	EFM: 238 (31.9) (p = 0.0001) - Augmented* Auscultation: 260 (38.1) EFM: 391 (58.4) (p = 0.0001) - Induced Auscultation: 48 (7) EFM: 117 (15.6) * The higher use of oxytocin for augmentation in the EFM group was related to the longer labours in the EFM arm **Inclusion criteria** Singleton living fetus Gestational age of 26 weeks or more Admitted in spontaneous labour or for induction of labour **Exclusion criteria** Known fetal congenital or chromosomal abnormalities		- FHR during and immediately after a contraction repeatedly below 100 bpm, even if there was recovery to 120-160 before the next contraction (moderate decelerations when FHR was 80-99 and severe when it was less than 80) - persistent baseline rate (between contractions) of less than 100 bpm - persistent baseline rate of more than 160 bpm In the presence of non-reassuring patterns, groups were managed similarly. Management was initially conservative, for example, stopping oxytocin, administering maternal oxygen, changing position, or increasing IV fluids. Fetal scalp pH, or crossing patients over from one group to another were not used. If the non-reassuring pattern persisted after 20 minutes of trying conservative methods, a surgical intervention (forceps, vacuum extraction or caesarean section) was performed. A data sheet was completed by the attending physicians which recorded maternal characteristics, and outcomes for the woman and baby. Most neonatal outcomes were collected by neonatologists blinded to allocation. Obstetric records and FHR data from both arms of the trial were reviewed throughout by two authors blinded to monitoring method. This was aimed at determining whether interpretation and management of FHR had been appropriate. If there was delayed or absent intervention after persistent non-reassuring patterns, or surgical intervention in the presence of reassuring patterns, this was recorded as 'failure to comply with protocol'. Data were reviewed every 3 months to detect trends in mortality. The continuing trend of increasing death in the auscultation group was compared with the year before the study, which did not show any peaks, and the study was stopped after the third review. Statistical analysis was done using chi-squared, Fisher's exact test, Student's t tests, ANOVA, and Mann-Whitney tests, where appropriate; $p < 0.05$ was considered significant. **Outcomes reported** 1. Mode of birth: recorded on a data sheet by attending physician 2. Admission to NICU: data collected by neonatologists blinded to allocation 3. Neonatal morbidity: data collected by neonatologists blinded to allocation on development of complications such as neonatal death, ischaemic encephalopathy, neurologic abnormalities, seizures, intraventricular haemorrhage, sepsis, necrotising enterocolitis, respiratory distress syndrome (need for supplemental oxygen for over 24 hours), hyperbilirubinemia, hyperglycemia, and metabolic or other problems 4. Cord blood gas values: following the birth, the cord was clamped and blood gases were measured from the artery and vein within 10 minutes of birth. Who collected these data was not clearly reported	Auscultation: 0 (0) EFM: 2 (0.2) h. Sepsis* Auscultation: 2 (0.3) EFM: 3 (0.4) i. Hyperbilirubinemia* Auscultation: 26 (3.8) EFM: 31 (4.1) j. Hypoglycemia* Auscultation: 4 (0.6) EFM: 5 (0.6) k. Other (including congenital abnormalities)* Auscultation: 2 (0.3) (Note: Congenital heart disease; gastroschisis) EFM: 7 (0.9) (Note: Congenital heart disease (n = 2); cleft lip/palate (n = 1; duodenal atresia (n = 1); no further details given) * reported here as morbidities, as reported in the paper, but not reported in the GRADE table as they are unlikely to be affected by method of intrapartum monitoring **Need for neonatal resuscitation (n (%))** Auscultation: 65 (9.5) EFM: 63 (8.4) **Death of baby (n (%))** a. Intrapartum fetal death Auscultation: 2 (0.3) EFM: 0 (0) b. Neonatal death Auscultation: 7 (1) EFM: 2 (0.26) c. Total perinatal death† Auscultation: 9 (1.3) EFM: 2 (0.26) † of these, 6 in the auscultation group and 0 in the EFM group were reported as being due to fetal hypoxia. Note: the 2 deaths in the EFM group could not have been prevented by monitoring: one baby died of complex congenital heart disease and the other of haemorrhage and DIC due to trauma at the base of the tongue during intubation attempt for meconium suctioning; among the 9 deaths in the auscultation group, there was compliance with trial protocol and vaginal delivery in all 9. Details of deaths are reported below Clinical characteristics of the nine perinatal deaths in the auscultation group: Intrapartum (n = 2) - Both women were at term (39 weeks; 41 weeks) - Neither woman had risk factors and both were vertex presentation - One had meconium staining Neonatal (n = 7) - 2 out of 7 were preterm (26.3 weeks; 30 weeks) - Risk factors were present in 6 out of 7 (prematurity [2], PROM [3], gastroschisis [1]) and the presentation of the remaining baby was breech.	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				- 3 had meconium staining - The two premature babies and the case of gastroschisis were considered to be deaths that were not related to hypoxia	
Full citation Wood,C., Renou,P., Oats,J., Farrell,E., Beischer,N., Anderson,I., A controlled trial of fetal heart rate monitoring in a low-risk obstetric population, American Journal of Obstetrics and Gynecology, 141, 527-534, 1981 **Ref Id** 164094 **Country/ies where the study was carried out** Australia **Study type** Randomised controlled trial **Aim of the study** To determine the effects of fetal heart rate monitoring in low-risk women **Study dates** Not reported **Source of funding** None reported	**Sample size** N = 989 **Characteristics** There were no significant differences in maternal age, parity, injections of opiate, use of other drugs, or ketones between the two groups **Inclusion criteria** None of the exclusion criteria **Exclusion criteria** Past history of stillbirth or neonatal death Antepartum haemorrhage in more than one pregnancy Eclampsia Previous birth before 37 weeks' gestation Clinical signs of fetal distress of meconium stained liquor and fetal heart rate above 160 or below 12 between contractions Medical and obstetric complications of hypertension (145/90 mmHg) Proteinuria (on boiling) Proven renal disease, cyanotic heart disease, rhesus isoimmunisation, diabetes, jaundice of hepatosis, anaemia (Hb 9g/100 ml) at any stage of pregnancy Antepartum haemorrhage Low estriol excretion Polyhydramnios Multiple pregnancy Breech presentation Premature labour (37 weeks) Prolonged pregnancy (42 weeks) Prolonged labour (24 hours) Known fetal malformation	**Interventions** Standard care (n = 482) Electronic fetal monitoring (n = 507)	**Details** Randomisation was by randomised cards. In one of the study sites this did not work effectively because a significantly higher proportion of low parity patients were in the EFM group compared to the auscultation group. Cards were not in sealed envelopes. Parity was corrected by random elimination, leaving 927 of the original 989 patients in the trial. Results were analysed for both 927 and 989 patients, and the results were the same, so the former were reported by the study authors. Control women were managed by staff in the standard way. Women randomised to EFM were managed in a similar way, with the addition of fetal monitoring. Management of labour and birth was the responsibility of the attending medical staff. If complications in labour indicated the need for monitoring among those randomised to standard care, this was performed, but the women remained in the standard care group for the analysis. Following randomisation, external CTG was performed until the time at which either an amniotomy was performed for obstetric reasons or vaginal examination was performed after the membranes had ruptured. At that point, a scalp electrocardiocographic electrode was applied. FHR tracings were examined by a skilled, unbiased observer who reported on their type and significance to the medical staff, who then made the final decision concerning management of the labour. All staff were trained in the recognition and significance of FHR abnormalities, but there were very few incidences of abnormal traces.	**Results** **<u>Mode of birth (n/total (%))</u>** <u>a. Normal</u> Standard: 371/482 (77.0) EFM: 307/445 (69.0) <u>b. Forceps</u> Standard: 101/482 (21.0) EFM: 120/445 (27.0) <u>c. Caesarean section</u> Standard: 10/482 (2.1) EFM: 18/445 (4.0) **<u>Neonatal death</u>** Standard: 0/482 EFM: 1/445 (Note: the authors reported the following details: normal labour (9 hours), type 1 dips present in contractions for a couple of hours before delivery with the FHR slowing to 100 bpm. The baby was delivered by forceps, with the head being rotated when the cord prolapsed. The baby was born in poor condition, with Apgar scores of 1 and 3, and died after 2 days in the intensive care. Cause of death was shown to be hypoxic brain damage) **<u>Neurological symptoms and/or signs (n/total (%))</u>** Standard: 3/495 (0.6) EFM: 1/479 (0.2) (Note: the data reported for this outcome appear not to exclude the women that the authors reported that they would, because N = 974) **<u>Care of the baby (n/total (%))</u>** <u>a. Need for isolette*</u> Standard: 29/480 (6.0) EFM: 40/443 (9.0) <u>b. Need for nursery*</u> Standard: 48/474 (10.1) EFM: 59/443 (13.3) <u>c. Need for phototherapy</u> Standard: 4/480 (0.8) EFM: 16/443 (3.6) * The article reported the proportion of babies spending 0, 1, 2 and ≥3 days in isolette/nursery; therefore, the proportion of babies not spending 0 days is reported above	**Limitations** Appropriate randomisation: Allocation was by randomised cards Allocation concealment: No, cards were not in sealed envelopes Groups comparable at baseline: This was reported for the denominator of most of the outcomes, but for neurological symptoms/signs, due to issues with randomisation, there may be a difference in the proportion of primigravidas Groups received same care (apart from intervention): Yes (according to study authors) Blinding of participants: Not reported Blinding of staff providing care: Not reported Blinding of outcome assessors: Not reported Missing data/loss to follow-up: There are small amounts of missing data (< 2%) for need for isolette, need for nursery. and neurological signs and symptoms Precise definition of outcomes: Type of neurological symptoms or signs were not reported (and the denominator does not match what the authors stated that they would analyse/report in the methods section) Valid and reliable method of outcome assessment: Unclear for neurological symptoms and signs as no details were reported Intention to treat analysis performed: Yes No details of what standard care involved were reported. However, judging by the discussion section of the article, this has been assumed to be by intermittent auscultation. This is supported by assumptions made by Cochrane reviewers, who included this study in a review of intermittent auscultation compared with EFM **Other information** CTG was external until membranes ruptured, and then internal. 49 women in the standard care group received EFM due to meconium in the amniotic fluid or FHR abnormality detected by auscultation. No caesarean sections were prompted by the results of the traces. Babies with early, mid or late dips were delivered by forceps

G.3 Intermittent auscultation compared with cardiotocography in the presence of meconium stained liquor

Study Details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Alfirevic,Zarko, Devane,Declan, Gyte,Gillian ML, Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour, Cochrane Database of Systematic Reviews, -, 2013 **Ref Id** 200781 **Country(ies) where the study was done** Various **Study type** Systematic review **Aim of the study** To evaluate the effectiveness of continuous cardiotocography during labour **Study dates** Assessed as up-to-date: January 2013 **Source of funding** Not reported	**Sample size** n = 500 from two studies (Pakistan 1989, Melbourne 1976) **Characteristics** Twelve studies included in the systematic review but only two studies consisted of right population for this review: Pakistan 1989 Randomisation: women selecting sealed unnumbered envelopes Participants: high-risk women all with meconium stained liquor Intervention: cardiotocography (CTG) versus intermittent auscultation Outcomes: neonatal mortality, mode of birth, Apgar score Study period: 1988 - 1989 Melbourne 1976 Randomisation: cards in sealed numbered envelopes Participants: high-risk women (40% with meconium stained liquor) Intervention: continuous CTG versus intermittent auscultation Outcomes: mode of birth, oxytocin use, analgesia use, maternal infection, neonatal mortality and morbidity, umbilical cord blood gas Study period: April 1974 - April 1975 **Inclusion criteria** Randomised and quasi-randomised controlled trials **Exclusion criteria** Not specified	**Intervention** Intermittent auscultation: intermittent monitoring undertaken either by listening to the baby's heart rate using a fetal stethoscope (Pinard) or a hand-held Doppler device Continuous fetal monitoring: electronic fetal heart rate monitoring by means of cardiotocograph	**Details** Electronic searches The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by contacting the Trials Search Co-ordinator. CENTRAL, MEDLINE were searched, and hand searching of 30 journals and conference proceedings was done. No language restrictions were applied. Selection of studies Two review authors independently assessed the full text of all potential studies for inclusion and methodological quality. Data extraction and management Two authors extracted the data separately and double checked it for discrepancies. Statistical analysis was done using RevMan. Where information was unclear, the reviewers attempted to contact the original authors. Assessment of risk of bias Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Selection bias - Allocation concealment - Blinding - Incomplete outcome data - Sequence generation - Other sources of bias Measures of effect Dichotomous outcomes were presented risk ratios with 95% confidence intervals. For continuous data, weighted mean differences were used. Fixed-effect analysis was performed in the absence of significant heterogeneity. In the presence of heterogeneity sensitivity analysis followed by random effects analysis was performed. Dealing with missing data The authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis, with the denominator being set as the number randomised minus any participants whose outcomes were known to be missing. Analysis If high levels of heterogeneity (> 50%) were identified, prespecified sensitivity analysis was performed according to the quality of the trials. Planned subgroup analyses: 1. low risk (absence of identified risk factors) 2. high risk of perinatal mortality and morbidity 3. spontaneous onset of labour 4. induction of labour 5. preterm 6. term 7. singleton/twin pregnancy 8. with and without fetal blood sampling (FBS) 9. parity	**Results** Caesarean section Continuous fetal monitoring: n = 74/275 (26.9%) Intermittent auscultation: n = 36/275 (13.1%) RR 2.11 (1.19 to 3.74) Caesarean section for abnormal FHR pattern and/or acidosis Continuous fetal monitoring: n = 47/275 (17.1%) Intermittent auscultation: n = 21/275 (7.6%) RR 2.24 (1.38 to 3.64) Instrumental vaginal birth Continuous fetal monitoring: n = 108/275 (39.3%) Intermittent auscultation: n = 94/275 (34.2%) RR 1.16 (0.88 to 1.54) Spontaneous vaginal birth not achieved Continuous fetal monitoring: n = 182/275 (66.2%) Intermittent auscultation: n = 130/275 (47.3%) RR 1.4 (1.2 to 1.63) Perinatal death Continuous fetal monitoring: n = 5/275 (1.8%)* Intermittent auscultation: n = 6/275 (2.2%)* RR 0.83 (0.26 to 2.67) NICU admission Continuous fetal monitoring: n = 11/175 (6.3%) Intermittent auscultation: n = 30/175 (17.1%) RR 0.37 (0.19 to 71) Infection/damage from scalp electrode Continuous fetal monitoring: n = 1/100 (1%) Intermittent auscultation: n = 0/100 (0%) RR 3.00 (0.12 to 72.77)	**Limitations** Pakistan 1989: - data extracted from unpublished trial lodged with Cochrane centre - no allocation concealment **Other information** The systematic review is available online at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006066.pub2/full

Study Details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Neonatal seizure Continuous fetal monitoring: n = 0/175 (0%) Intermittent auscultation: n = 4/175 (2.3%) RR 0.11 (0.01 to 2.05)	

G.4 Interpretation of cardiotocograph traces

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Cibils,L.A., Clinical significance of fetal heart rate patterns during labor. II. Late decelerations, American Journal of Obstetrics and Gynecology, 123, 473-494, 1975 **Ref Id** 195117 **Country/ies where the study was carried out** USA **Study type** Cohort **Aim of the study** To evaluate fetal heart rate (FHR) changes and patterns in two groups (with decelerations, no decelerations) in order to predict fetal condition at birth **Study dates** June 1970 to 1974 **Source of funding** Not reported	**Sample size** n = 1304 records reviewed: n = 598 had no accelerations, n = 147 had late decelerations **Characteristics** Women in the no decelerations group were younger than women in the late decelerations group (22.8 years versus 25.1 years). Gestational age and duration of FHR recording were similar in the two groups **Inclusion criteria** Singleton pregnancy Cephalic presentation Direct or internal monitoring Minimum of 60 minutes recording prior to 2nd stage/decision to perform a caesarean section **Exclusion criteria** Not reported	**Interventions** 60 minutes of FHR trace analysis (available prior to second stage of labour)	**Details** During the study period n = 1,304 records were reviewed manually and coded (details provided in a previously published paper). n = 598 (46%) had no decelerations of FHR which could be correlated in time with uterine contractions. n = 147 (11%) had FHR late decelerations	**Results** There is low likelihood of neonatal problems when there is no deceleration of FHR: <u>Neonatal morbidity and/or death*</u> Late decelerations group: 7% No decelerations group: 0.5% p < 0.0001 * no further details on neonatal mortality reported High numbers of mortality and morbidity present in neonates with low birthweight with late decelerations: <u>Neonatal morbidity and/or death in low birthweight babies < 2500g</u> Late decelerations group: 15% No decelerations group: 5% p = ns A high percentage of babies with FHR late decelerations (50%) were distressed during labour and 33% born depressed (clinical distress defined as presence of meconium stained liquor, tachycardia, markedly irregular heat beat, no definition for "depressed" babies given)	**Limitations** Limited outcome data No exclusion criteria specified hence high risk of selection bias Women's demographic characteristics not reported Unclear how and by whom data were analysed No statistical analysis of data reported **Other information** Normal baseline FHR defined as 120 to 150 beats per minute (bpm) Tachycardia: > 150 beats per minute
Full citation Cibils,L.A., Clinical significance of fetal heart rate patterns during labor. V. Variable decelerations, American Journal of Obstetrics and Gynecology, 132, 791-805, 1978 **Ref Id** 195119 **Country/ies where the study was carried out** USA **Study type** Cohort **Aim of the study** To evaluate fetal heart rate (FHR) changes and patterns in two groups (with decelerations, variable	**Sample size** n = 1304 records reviewed. n= 598 had no decelerations, n = 312 had variable decelerations **Characteristics** Women in the no decelerations group were significantly younger than women in the late decelerations group (22.8 yr vs. 24.4 yr), had higher gestational age (39.4 wk vs. 38.6 wk) and longer duration of FHR recording (252 minutes vs. 223 minutes). Fetal weight was significantly higher in the no decelerations group compared with the variable decelerations group (3236 g vs. 2988 g). There were fewer normal and hypertensive women in the variable decelerations group, but there was a higher rate of women with other pathological conditions such as premature rupture of membranes. **Inclusion criteria** Singleton labours	**Interventions** FHR: variable decelerations variable decelerations with late component ('variable with hypoxic component')	**Details** From n = 1,304 records that were reviewed manually and coded (details provided in a previously published paper): n = 598 (46%) had no decelerations of FHR which could be correlated in time with uterine contractions; n = 312 had FHR variable decelerations (n = 18 women had variable decelerations with a component of late deceleration in the recovery period, all of these cases had umbilical cord problems). The maternal condition and neonatal outcomes were compared in order to ascertain the clinical value of observed changes in FHR pattern.	**Results** Cases with variable decelerations n = 312 Cases with no deceleration n = 598 Association between variable deceleration and baseline alterations (tachycardia, saltatory or fixed FHR baselines): <u>Saltatory fixed</u> No deceleration: 39% Variable decelerations: 25% p = ns <u>Tachycardia</u> No decelerations: 5% Variable decelerations: 21% p < 0.0005 <u>Sustained</u> No decelerations: 8% Variable decelerations: 21% p < 0.0005 <u>Fetal distress</u> No decelerations: 4%	**Limitations** Limited outcome data No exclusion criteria specified hence high risk of selection bias Women's demographic characteristics not reported Unclear how and by whom data were analysed **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
decelerations) in order to predict fetal condition at birth **Study dates** Not specified **Source of funding** Not specified	60 minutes of FHR trace available prior to second stage **Exclusion criteria** Not specified			Variable decelerations: 23% p < 0.0005 <u>Neonatal death</u> No decelerations: 0.2% Variable decelerations: 2.2% p < 0.0005 Significant association between variable decelerations (with a hypoxic [late] component) and baseline alterations (tachycardia, saltatory or fixed FHR baselines): <u>Saltatory fixed</u> Variable decelerations with late component: 39% Variable decelerations: 25% p < 0.0005 <u>Tachycardia</u> Variable decelerations with late component: 61% Variable decelerations: 21% p < 0.0005 <u>Sustained</u> Variable decelerations with late component: 67% Variable decelerations: 21% p < 0.0005 <u>Fetal distress</u> Variable decelerations with late component: 78% Variable decelerations: 23% p < 0.0005 <u>Neonatal death</u> Variable decelerations with late component: 11% Variable decelerations: 2.2% p = ns	
Full citation Cibils,L.A., Clinical significance of fetal heart rate patterns during labor. VI. Early decelerations, American Journal of Obstetrics and Gynecology, 136, 392-398, 1980 **Ref Id** 195120 **Country/ies where the study was carried out** USA **Study type** Cohort **Aim of the study** To evaluate fetal heart rate (FHR) changes and patterns in two groups (no decelerations, early decelerations) in order to predict fetal condition at birth **Study dates**	**Sample size** n = 1304 records reviewed. n= 598 had no accelerations, n = 247 had early decelerations **Characteristics** Women in the no decelerations group were younger than women in the early decelerations group (22.8 yr vs. 23.6 yr), had similar gestational ages (39.4 wk vs. 38.2 wk) and longer durations of FHR recording (252 minutes vs. 231 minutes). Fetal weight was significantly higher in the no decelerations group compared with the early decelerations group (3236 g vs. 3129 g). **Inclusion criteria** Singleton labours 60 minutes of FHR trace available prior to second stage **Exclusion criteria** Not specified	**Interventions** FHR: No decelerations Early decelerations	**Details** From n = 1,304 records that were reviewed manually and coded (referred to a previous published paper): n = 598 (46%) had no decelerations of FHR which could be correlated in time with uterine contractions; n = 247 had FHR early decelerations prior to 2nd stage of labour. The maternal condition and neonatal outcomes were compared in order to ascertain the clinical value of observed changes in FHR pattern.	**Results** <u>Transient tachycardia</u> Early decelerations group: 10% No decelerations groups: 5% <u>Fetal distress (no definition provided)</u> Early decelerations group: 5% No decelerations groups: 4% <u>Neonatal death</u> Early decelerations group: n = 1 (congenital heart disease) No decelerations groups: n = 1 (congenital malformation)	**Limitations** Limited outcome data No exclusion criteria specified hence high risk of selection bias Women's demographic characteristics not reported Unclear how and by whom data were analysed **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Not specified **Source of funding** Not specified					
Full citation Cibils,L.A., Votta,R., Clinical significance of fetal heart rate patterns during labor. IX: Prolonged pregnancy, Journal of Perinatal Medicine, 21, 107-116, 1993 **Ref Id** 195122 **Country/ies where the study was carried out** USA **Study type** Case series **Aim of the study** To evaluate fetal heart rate (FHR) changes and patterns in women with prolonged labour in order to diagnose early fetal compromise **Study dates** July 1980 to December 1984 **Source of funding** Not specified	**Sample size** 707 post-term pregnancies (> 14 days post estimated date of delivery [EDD]) **Characteristics** No characteristics specified. It is specified that the relevant clinical informations has been reported in a previously published paper. **Inclusion criteria** Post-term pregnancies (> 14 days post EDD) **Exclusion criteria** Not specified	**Interventions** Fetal heart rate records	**Details** n = 707 pregnancies that passed the estimated date of delivery by 14 days were included in the study. This was assessed in women with good menstrual histories, who had dating examinations or confirmed by an ultrasound in the first trimester of pregnancy. All women had either internal or external continuous fetal monitoring. Data for this study were gathered prospectively. The observation was based on the interpretation of fetal heart rate and uterine contraction and their value as a tool to diagnose early fetal compromise or to prevent fetal deterioration by early intervention. Statistical analysis was performed using χ^2 method.	**Results** No significant correlation between abnormal FHR patterns and pH: n = 598 no decelerations n = 147 traces with late decelerations <u>Deceleration pattern</u> Variable decelerations: 55% No or early decelerations: 23% Late deceleration: 17% <u>Baseline frequency</u> Normal: 71% Tachycardia: 26% Bradycardia: 4% <u>Baseline pattern</u> Normal: 75% Fixed: 8% Saltatory: 17% Acidemia (pH ≤ 7.20) could not be predicted from deceleration patterns in FHR trace: <u>FHR and umbilical cord pH</u> pH ≤ 7.20 Total n = 46 pH ≥ 7.21 Total n = 108 <u>No or early decelerations</u> pH ≤ 7.20 n = 11 (23%) pH ≥ 7.21 n = 25 (23%) <u>Variable decelerations</u> pH ≤ 7.20 n = 17 (36%) pH ≥ 7.21 n = 48 (44%) <u>Late decelerations</u> pH ≤ 7.20 n = 18 (39%) pH ≥ 7.21 n = 35 (32%)	**Limitations** No exclusion criteria specified hence high risk of selection bias Women's demographic characteristics not reported Unclear how and by whom data were analysed **Other information**
Full citation Low,J.A., Cox,M.J., Karchmar,E.J., McGrath,M.J., Pancham,S.R., Piercy,W.N., The prediction of intrapartum fetal metabolic acidosis by fetal heart rate monitoring, American Journal of Obstetrics and Gynecology, 139, 299-305, 1981 **Ref Id** 195666 **Country/ies where the study was carried out** Canada **Study type** Case series	**Sample size** n = 200 term infants with significant metabolic acidosis (base buffer < 36.1 mEq/l) n = 200 term infants without metabolic acidosis (base buffer > 36.1 mEq/l) **Characteristics** Not specified **Inclusion criteria**	**Interventions** All FHR variables	**Details** FHR characteristics during the 8 hours prior to delivery were studied in 200 women in whom the baby had evidence of a metabolic acidosis at birth (base buffer < 36.1 mEq/l), and compared to those in 200 women in whom the baby had a normal acid-base at birth (base buffer > 36.1 mEq/l). Fetal heart rate records were scored for each 20 minute period for a maximum of 24 twenty-minute cycles (8 hours) prior to birth. All records were assessed by one of the two authors. The assessment was performed without knowledge of the clinical or laboratory data. In each 20 minute cycle the following characteristics were scored: baseline fetal heart rate, baseline FHR long term	**Results** There was no statistically significant difference between the two groups in regard to decrease frequency or absence of FHR accelerations in the 12 FHR trace cycles (4 hours before birth) indicating that fetal heart rate accelerations (as an independent variable) were not predictive of fetal acidosis (no synthesis of the statistical data provided). Total decelerations and variable decelerations in last hour prior to birth were significantly associated with acidosis. Late decelerations in the last hour prior to birth were significantly associated with neonatal acidosis. Variable decelerations only in last 20 minutes prior to birth were significantly associated with acidosis:	**Limitations** No analysis on combining factors for prediction. **Other information** Baseline heart rate classified as normal: 120 to 160 beats per minute (bpm) Bradicardia: < 120 bpm Tachycardia: > 160 bpm Baseline variability: amplitude of oscillation as normal (6 to 25 bpm), decreased (3 to 5 bpm) and absent (< 3 bpm) Accelerations: at least 15 bpm above the baseline. Normal (≥ 2 acceleration in 20 min), decreased (1 acceleration in 20 min), absent (no accelerations in 20 min) Decelerations: fall in FHR in excess of 15 bpm. Total deceleration

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To evaluate the fetal heart rate (FHR) characteristics in predicting the presence of a metabolic acidosis **Study dates** Not specified **Source of funding** Not specified	Women admitted and monitored in the intrapartum intensive-care unit. **Exclusion criteria** Not specified		variability, FHR accelerations, FHR variable decelerations and FHR late decelerations.	<u>Cycle 1 (20 min FHR trace 20 min before birth)</u> Total decelerations: Index: n = 51/200 Control: n = 33/200 p = 0.001 <u>Cycle 1 (20 min FHR trace 20 min before birth)</u> Variable decelerations: Index: n = 38/200 Control: n = 30/200 p = 0.01 <u>Cycle 1 (20 min FHR trace 20 min before birth)</u> Late decelerations: Index: n = 78/200 Control: n = 23/200 p = 0.001 <u>Cycle 2 (20 min FHR trace 40 min before birth)</u> Total decelerations: Index: n = 42/200 Control: n = 30/200 p = 0.001 <u>Cycle 2 (20 min FHR trace 40 min before birth)</u> Variable decelerations: Index: n = 30/200 Control: n = 26/200 p = 0.2 <u>Cycle 2 (20 min FHR 40 min trace before birth)</u> Late decelerations: Index: n = 59/200 Control: n = 21/200 p = 0.001 <u>Cycle 3 (20 min FHR trace 60 min before birth)</u> Total decelerations: Index: n = 35/200 Control: n = 26/200 p = 0.006 <u>Cycle 3 (20 min FHR trace 60 min before birth)</u> Variable decelerations: Index: n = 26/200 Control: n = 24/200 p = 0.3 <u>Cycle 3 (20 min FHR 60 min trace before birth)</u> Late decelerations: Index: n = 42/200 Control: n =21/200 p = 0.01	patterns were classified on the basis of frequency of contraction in 20 minute period. None (0% or 4% contractions associated with a deceleration), moderate (5% to 30% contractions associated with a deceleration), marked (> 30% contractions associated with a deceleration)
Full citation Low,J.A., Pancham,S.R., Piercy,W.N., Intrapartum fetal asphyxia: Clinical characteristics, diagnosis, and significance in relation to pattern of development, American Journal of	**Sample size** Total n = 587	**Interventions** All FHR variables	**Details** Fetal heart rate records (obtained via a scalp electrode) were reviewed for each two hour period prior to birth in n = 587 women. Based on the serial acid base observations (maternal venous blood acid base,	**Results** There were no statistically significant differences between the two groups (asphyxia and normal group) at mid-labour (> 2 hours prior to birth) in regard to pH, buffer base, and oxygen or carbon dioxide tension. However, the maternal pH, buffer base, and oxygen tension in the asphyxia group were all significantly lower compared to the normal group at two hours, one hour	**Limitations** Unclear how and by who the records were assessed. **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Obstetrics and Gynecology, 129, 857-872, 1977 **Ref Id** 196822 **Country/ies where the study was carried out** Canada **Study type** Case series **Aim of the study** To examine clinical circumstances related to development of intrapartum fetal asphyxia **Study dates** Not specified **Source of funding** Supported by Ministry of Health grant	n = 122 with significant metabolic acidosis (base buffer < 36.1 mEq/l) n = 465 without metabolic acidosis (base buffer > 36.1 mEq/l) **Characteristics** <u>Parity 0</u> Normal group: 61% Asphyxia terminal: 67% Asphyxia/one hour: 55% Asphyxia/two hours: 72% <u>Parity ≥ 1</u> Normal group: 39% Asphyxia terminal: 33% Asphyxia one/hour: 45% Asphyxia two/hours: 28% <u>Preterm neonates</u> Normal group: 11% Asphyxia terminal: 0% Asphyxia one/hour: 15% Asphyxia two/hours: 3% <u>Preterm neonates</u> Normal group: 10% Asphyxia terminal: 0% Asphyxia one/hour: 15% Asphyxia two/hours: 3% <u>Post term gestation</u> Normal group: 10% Asphyxia terminal: 13% Asphyxia one/hour: 20% Asphyxia two/hours: 14% <u>Medical complication (hypertension, diabetes, other)</u> Normal group: 15% Asphyxia terminal: 12% Asphyxia one/hour: 9% Asphyxia two/hours: 33% <u>Meconium stained liquor</u> Normal group: 33% Asphyxia terminal: 35% Asphyxia one/hour: 45% Asphyxia two/hours: 50% <u>Regional or local anaesthesia</u> Normal group: 90% Asphyxia terminal: 85% Asphyxia one/hour: 75% Asphyxia two/hours: 80% **Inclusion criteria** Women admitted and monitored in the intrapartum intensive-care unit. The criteria for		lactate, and pyruvate characteristics during the labour and birth, fetal acid base characteristics during the last half of labour and fetal acid base, lactate and pyruvate characteristics during the labour and birth), women were divided into the normal group or the asphyxia group. FHR observations were made on the total decelerations, and late decelerations in relation to the contractions in each two hour period. The baseline FHR was observed at six 20-minute intervals in a two hour period. The normal acid base group as determined by a serial acid base study during birth included n = 465 women with a fetus with capillary blood buffer base of > 1 SD below the normal mean, i.e. ≥ 40 mEq/l, and umbilical artery buffer base at delivery of > 1 SD below the normal mean, i.e. ≥ 38.6 mEq/l. The fetal asphyxia group included n = 122 women in whom the baby at delivery had an umbilical artery buffer base of < 2 SD below the normal mean, i.e. < 36.1 mEq/L. Duration of metabolic acidosis during labour were determined by the available serial fetal acid base observation in the second half of labour for each case. The criteria of developing metabolic acidosis during labour were a capillary blood buffer base of < 1 SD below the normal mean in the last hour of labour, i.e. < 40 mEq/l. The asphyxia group were divided into three groups based on the acid base characteristics during labour and delivery: terminal asphyxia (just before birth); asphyxia/one hour (one hour before birth); asphyxia/two hours (two hours before birth).	and 5 minutes prior to birth. The umbilical artery and vein buffer base was also significantly lower in the asphyxia group when compared with the normal group. Normal group n = 465 Asphyxia group n = 122 (terminal n = 46, one hour n = 40, two hours n = 36) <u>Perinatal death</u> Normal group: n = 29/465 (16%) Asphyxia terminal: n = 1/46 (2%) Asphyxia one/hour: n = 0/40 (0%) Asphyxia two/hours: n = 1/36 (3%) **<u>Mode of birth</u>** <u>Spontaneous low forceps</u> Normal group: n = 270/465 (58%) Asphyxia terminal: n = 14/46 (30%) Asphyxia/one hour: n = 14/40 (35%) Asphyxia/two hours: n = 11/36 (30%) <u>Mid-forceps</u> Normal group: n = 133/465 (29%) Asphyxia terminal: n = 28/46 (61%) Asphyxia/one hour: n = 14/40 (35%) Asphyxia/two hours: n = 8/36 (22%) <u>Caesarean section</u> Normal group: n = 55/465 (12%) Asphyxia terminal: n = 3/46 (6%) Asphyxia/one hour: n = 9/40 (22%) Asphyxia/two hours: n = 16/36 (44%) <u>Marked patterns of total decelerations (8 hours prior to birth)</u> Normal group: 9% Asphyxia terminal: 29% Asphyxia/one hour: not reported Asphyxia/two hours: 20% <u>Marked patterns of total decelerations (6 hours prior to birth)</u> Normal group: 13% Asphyxia terminal: 21% Asphyxia/one hour: 14% Asphyxia/two hours: 20% <u>Marked patterns of total decelerations (4 hours prior to birth)</u> Normal group: 19%	Baseline heart rate classified as normal: 120 to 160 beats per minute (bpm) bradycardia: < 120 bpm, tachycardia: > 160 bpm Baseline variability: amplitude of oscillation as normal (6 to 25 bpm), decreased (3 to 5 bpm) and absent (< 3 bpm) Accelerations: at least 15 bpm above the baseline. Normal (≥ 2 accelerations in 20 min), decreased (1 acceleration in 20 min), absent (no accelerations in 20 min) Decelerations: fall in FHR in excess of 15 bpm. Total deceleration patterns were classified on the basis of frequency of contractions in 20 minute period. None (0% or 4% contractions associated with a deceleration), moderate (5% to 30% contractions associated with a deceleration), marked (> 30% contractions associated with a deceleration) Total decelerations defined as percentage of contractions associated with a deceleration in each two-hour period. It was classified as moderate (5% to 29% of contractions were associated with a deceleration) and marked (> 30% of contractions were associated with a deceleration) Late decelerations defined as percentage of contractions associated with a late deceleration in each two-hour period. It was classified as moderate (< 10% of contractions were associated with a late deceleration) and marked (≥ 10% of contractions were associated with a late deceleration)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	admission were maternal, fetal, or labour risk factors that could have been predictive of fetal asphyxia. **Exclusion criteria** Not specified			Asphyxia terminal: 30% Asphyxia/one hour: 37% Asphyxia/two hours: 39% <u>Marked patterns of total decelerations (2 hours prior to birth)</u> Normal group: 34% Asphyxia terminal: 54% Asphyxia/one hour: 52% Asphyxia/two hours: 61% <u>Moderate or marked patterns of late decelerations (8 hours prior to birth)</u> Normal group: 15% Asphyxia terminal: 9% Asphyxia/one hour: not reported Asphyxia/two hours: not reported <u>Moderate or marked patterns of late decelerations (6 hours prior to birth)</u> Normal group: 18% Asphyxia terminal: 31% Asphyxia/one hour: 8% Asphyxia/two hours: 16% <u>Moderate or marked patterns of late decelerations (4 hours prior to birth)</u> Normal group: 21% Asphyxia terminal: 26% Asphyxia/one hour: 26% Asphyxia/two hours: 27% <u>Moderate or marked patterns of late decelerations (2 hours prior to birth)</u> Normal group: 31% Asphyxia terminal: 59% Asphyxia/one hour: 59% Asphyxia/two hours: 68%	
Full citation Maso,G., Businelli,C., Piccoli,M., Montico,M., De,Seta F., Sartore,A., Alberico,S., The clinical interpretation and significance of electronic fetal heart rate patterns 2 h before delivery: an institutional observational study, Archives of Gynecology and Obstetrics, 286, 1153-1159, 2012 **Ref Id** 275105	**Sample size** n = 198 **Characteristics** Not specified **Inclusion criteria** - Singleton - Term - Spontaneous and operative vaginal birth - External continuous FHR monitoring during	**Interventions** Intrapartum electronic fetal monitoring	**Details** Data collected (retrospective for 6 months) from a labour database of Maternal and Child Institute Burlo Garofolo in Italy. Based on the inclusion criteria, all cases with the last 2 hours continuous electronic fetal monitoring (EFM) before birth were included in the study. An obstetrician, blinded to neonatal outcomes, retrospectively reviewed the included cases. The tracings were interpreted as normal, suspicious or pathological, according to specific guidelines of	**Results** Umbilical artery pH value of 7.20 chosen as the cut off to define neonatal acidemia. **<u>Three EFM groups: normal, suspicious, pathological</u>** <u>Normal</u> If all four FHR variables (baseline, variability, decelerations, accelerations) fells into reassuring category (see 'Other information') <u>Suspicious</u> If one of the variables presented non reassuring characteristics and the reminder variables were reassuring (see 'Other information') <u>Pathological</u>	**Limitations** - Women characteristics not reported - Selective data reported **Other information** **<u>Categorisation of FHR:</u>** <u>Reassuring</u> Baseline: 100-180 Variability: ≥ 5 Decelerations: none Accelerations: present

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Italy **Study type** Case series **Aim of the study** To evaluate the clinical significance of intrapartum fetal heart rate (FHR) monitoring in low-risk pregnancies **Study dates** Not specified **Source of funding** Not specified	the last 2 hours of labour was available - Short term neonatal outcomes were available - Low risk pregnancy (defined as cases without risk factors for the development of acidosis, cerebral palsy, perinatal death, and neonatal encephalopathy) **Exclusion criteria** Cases with risk factors for the development of acidosis, cerebral palsy, perinatal death, and neonatal encephalopathy		EFM and by grouping the different FHR patterns considering baseline, variability, presence of decelerations and bradycardia (see 'Other information' section). Analysis: Comparisons between groups were performed with Kruskal-Wallis test. Differences among categorical variables were evaluated using Fisher's exact test.	If more than two non-reassuring or more than one abnormal variable was respectively (see 'Other information') **Mean pH values in the three EFM groups:** Normal pH 7.30 (95% CI 7.28 to 7.32) Suspicious pH 7.25 (95% CI 7.23 to 7.27) Pathological pH 7.20 (95% CI 7.17 to 7.13) p < 0.001 (for all pairwise comparisons) **Mean BD mmol/L values in the three EFM groups:** Normal -3.35 (95% CI -4.19 to -2.50) Suspicious -5.62 (95% CI -6.43 to -4.81) Pathological -7.50 (95% CI -8.50 to -6.50) p < 0.001 (for all pairwise comparisons) **Composite dverse outcomes*:** Normal n = 0/51 (0%) Suspicious n = 5/88 (5.7%) Pathological n = 6/59 (10.1%) p = 0.005 (normal vs. pathological) **Normal variability:** pH < 7.20 n = 3/51 (5.9%) pH < 7.10 n = 0/51 (0%) PH < 7.00 n = 0/51 (0%) BD mmol/l 0/51 (0%) **Normal variability and typical variable decelerations:** pH < 7.20 n = 18/63 (28.6%) pH < 7.10 n = 6/63 (9.5%) PH < 7.00 n = 1/63 (1.6%) BD mmol/l 5/63 (7.9%) **Normal variability and atypical variable decelerations:** pH < 7.20 n = 13/27 (48.2%) pH < 7.10 n = 2/27 (7.4%) PH < 7.00 n = 0/27 (0%) BD mmol/l 0/27 (0%) **Moderate bradycardia** pH < 7.20 n = 6/17 (35.3%) pH < 7.10 n = 0/17 (0%) PH < 7.00 n = 0/17 (0%) BD mmol/l 0/17 (0%)	Non-reassuring Baseline: 110 -160 Variability: < 5 for ≥ 40 but < 90 min Decelerations: - repetitive (≥ 3) typical variable decelerations with over 50% of contractions - single prolonged < 3 min Accelerations: the absence of accelerations with an otherwise normal FHR tracing is of uncertain significance Abnormal Baseline: - 161 - 180 - < 100 - >180 - sinusoidal pattern - ≥ 10 min Variability: < 5 for ≥ 40 to ≥ 90 min Decelerations: - either repetitive (≥ 3) atypical variable decelerations or late decelerations, with over 50% of contractions - single prolonged deceleration > 3 min Accelerations: the absence of accelerations with an otherwise normal FHR tracing is of uncertain significance **Normal, suspicious, pathological** Normal If all four FHR variables (baseline, variability, decelerations, accelerations) fells into reassuring category Suspicious If one of the variables presented non reassuring characteristics and the reminder variables were reassuring Pathological If more than two non-reassuring or more than one abnormal variable was respectively **FHR features definitions:** Atypical variable Defined in the presence of at least one of the following conditions: loss of primary or secondary rise in the baseline rate; slow return to baseline FHR after the contraction; prolong secondary rise in the baseline rate; biphasic deceleration; loss of variability during deceleration; continuation of baseline rate at lower level Bradycardia Defined as moderate or severe if persistent fall of baseline between 100 and 109 bpm was respectively observed over a time period of 5 to 10 min.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Severe bradycardia pH < 7.20 n = 7/15 (46.7%) pH < 7.10 n = 4/15 (26.7%) PH < 7.00 n = 1/15 (6.7%) BD mmol/l 2/15 (13.3%) *Composite neonatal outcomes: umbilical artery pH < 7 and/or APGAR score < 7 at 5 min and/or neonatal resuscitation in delivery room and admission to neonatal intensive care unit for distress at birth.	
Full citation Cahill,A.G., Caughey,A.B., Roehl,K.A., Odibo,A.O., Macones,G.A., Terminal fetal heart decelerations and neonatal outcomes, Obstetrics and Gynecology, 122, 1070-1076, 2013 **Ref Id** 298858 **Country/ies where the study was carried out** USA **Study type** Retrospective cohort study **Aim of the study** To examine the incidence and characteristics of terminal fetal heart rate decelerations and to estimate their association with acidemia **Study dates** Between 2004 and 2008 **Source of funding** Not specified	**Sample size** Terminal deceleration: n = 951 No terminal deceleration n = 4,437 **Characteristics** Groups were similar with respect to: - maternal age and race - body mass index - gestational age at delivery - use of regional anesthesia - induction in labour Women with a terminal deceleration were more likely to be nulliparous and, they were less likely to have a spontaneous vaginal birth. The mean BMI in both groups was > 31. **Inclusion criteria** - singleton - vertex gestation at term (at or after 37 0/7 weeks), - labored, and reached complete dilation. **Exclusion criteria** - Multiple gestation - Fetus with a known congenital anomaly - Did not have sufficient electronic fetal monitoring (EFM) recording during the 30 minutes before birth (less than 10 minutes of EFM during the 30 minutes before birth).	**Interventions** Electronic fetal monitoring	**Details** Data collected from all consecutive births at Washington University in St. Louis Medical Center during the study period. The institutional policy is one of universal EFM during labor and arterial umbilical cord gas pH level birth. Women's EFM trace from 30 minutes before birth was interpreted by two formally trained obstetric research nurses certified in EFM interpretation and blinded to clinical data and outcomes.. Electronic fetal monitoring was interpreted using the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the American College of Obstetricians and Gynecologists three-tiered category system. Terminal deceleration, defined as a prolonged deceleration (15 bpm or more below baseline for 120 seconds (2 min) or more and fewer than 10 minutes) or bradycardia (< 110 bpm for 10 minutes or more). The comparison made between women who had a terminal deceleration and those who did not. Interval interobserver reliability was performed. For presence of terminal decelerations, kappa coefficient was consistently more than 0.9. Detailed maternal and pregnancy data including obstetric history, pregnancy course and complications, medication exposure and acute events (including placental abruption, umbilical cord prolapse, and uterine rupture), physical examination, anesthesia type, delivery, and neonatal outcomes were also extracted.Use of internal monitors for fetal heart rate monitoring and contractions and umbilical cord gas arterial pH level, as well as CO_2 and base excess, also were recorded. The primary outcome was acidemia, defined as arterial umbilical cord gas pH level of 7.10 or less. Secondary outcomes included arterial umbilical cord gas pH level 7.05 or less, base excess more than −8, metabolic acidemia (pH level 7.10 or less and	**Results** **Terminal deceleration and neonatal outcomes** Arterial umbilical cord pH level of 7.10 or less Terminal deceleration n = 12/951 (1.3%) Not terminal deceleration n = 45/4437 (1.0%) Adjusted* OR 1.2 (95% CI 0.6 to 2.3) P = 0.49 Arterial umbilical cord pH level of 7.05 or less Terminal deceleration n = 4/951 (0.4%) Not terminal deceleration n = 13/4437 (0.3%) Adjusted* OR 1.4 (95% CI 0.5 to 4.4) P = 0.52 Arterial umbilical cord pH level of 7.10 or less and base excess < -8.0 Terminal deceleration n = 11/951 (1.2%) Not terminal deceleration n = 39/4437 (0.9%) Adjusted* OR 1.3 (95% CI 0.7 to 2.6) P = 0.45 Apgar score less than 7 at 5 minutes Terminal deceleration n = 4/951 (0.4%) Not terminal deceleration n = 51/4437 (1.2%) Adjusted* OR 0.4 (95% CI 0.1 to 1.1) P = 0.05 Special care or NICU admission Terminal deceleration n = 42/951 (4.4%) Not terminal deceleration n = 228/4437 (5.2%) Adjusted* OR 0.8 (95% CI 0.6 to 1.2) P = 0.35 Abruption composite Terminal deceleration n = 10/951 (1.1%) Not terminal deceleration n = 18/4437 (0.4%) Adjusted* OR 2.6 (95% CI 1.2 to 5.6) P = 0.2 **Terminal deceleration characteristics by acidemia:** Number of babies born with acidemia. n = 12/951 (1.3%) Number of babies born with no acidemia. n = 939/951 (1.3%) Median time to birth (min SD) Acidemia 6.7 (SD 3.7 to 12.7) No academia	**Limitations** - Uneven number of participants in two groups - 30 min EFM traces just before birth were analysed - if trace was lost or discontinuous after the initiation of the terminal deceleration, it was assumed that duration of terminal deceleration was until birth **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			base excess more than −8), admission to the neonatal intensive care unit (level IV) or admission to the special care unit (level II), and Apgar score less than 7 at 5 minutes. Analysis: For continuous variables Student *t* tests and Mann-Whitney *U* tests were used and χ^2 and for dichotomous variables Fisher exact tests were used as appropriate.Stratified analyses were performed to identify potentially confounding factors, which were considered in multivariable analyses. To refine estimates of association between terminal decelerations and acidemia by eliminating nonsignificant factors, multivariable logistic regression was performed. To explore the risk of acidemia and other adverse outcomes among women with terminal bradycardia a secondary analysis was performed. Linear regression was then used to estimate the incremental association between increasing terminal deceleration duration beyond 2 minutes and decreasing arterial umbilical cord pH level. To estimate the predictive ability of terminal deceleration duration and risk of acidemia, Receiver-operator characteristic curve analysis was used. STATA 10 special edition was used for the all analysis.	3.2 (SD 2.5 to 4.6) P<.01 For every additional 120 seconds of duration of the terminal deceleration beyond the first 120 seconds, there was a corresponding decrease in arterial umbilical cord pH level by 0.042 (95% CI 0.040 to 0.048; *P*<.01). However, terminal deceleration characteristics, such as median or greatest depth and variability within the nadir, were not associated with risk of acidemia **Baradicardia and terminal deceleration** Risk associated with Bradycardia among women with terminal deceleration: Bradycardia duration of 10 minutes or more n = 31/951 Bradycardia duration of < 10 minutes n = 930/951 Risk of acidemia (pH level of 7.10 or less): Bradycardia duration of 10 minutes or more n = 4/31 (12.9%) Bradycardia duration of < 10 minutes n = 8/920 (0.9%) Adjusted OR 18.6 (5.0 to 68.9) P < 0.01 Risk of acidemia (pH level of 7.05 or less): Bradycardia duration of 10 minutes or more n = 2/31 (6.5%) Bradycardia duration of < 10 minutes n = 2/920 (0.2%) Adjusted* OR 46.0 (5.7 to 373.0) P < 0.01 Apgar score < 7 at 5 min: Bradycardia duration of 10 minutes or more n = 2/31 (6.5%) Bradycardia duration of < 10 minutes n = 2/920 (0.2%) Adjusted* OR 67.0 (8.4 to 536.6) P < 0.01 Special care and NICU admission: Bradycardia duration of 10 minutes or more n = 3/31 (10%) Bradycardia duration of < 10 minutes n = 8/920 (0.9%) Adjusted* OR 11.4 (3.2 to 40.7) P < 0.01 * Adjusted for nulliparity Presence of bradycardia (10 minutes or more) was poorly predictive of acidemia, with a sensitivity of 33.3%, a specificity of 97.0%, and a positive predictive value of only 12.9%. **Duration of terminal deceleration** Predictive value of duration of terminal deceleration beyond 2 minutes for academia (pH level of 7.10 or less) AUC (area under the curve) 0.78 (95% CI 0.60–0.94) Predictive value of duration of terminal deceleration cut-off of 4 minutes or more for academia (pH level of 7.10 or less) Sensitivity: 75.0% (95% CI 74.2 to76.3%) Specificity: 64.0% (95% CI 62.8–65.1%)	
Full citation Graham,E.M., Adami,R.R., McKenney,S.L., Jennings,J.M., Burd,I., Witter,F.R., Diagnostic accuracy of fetal heart rate monitoring in the identification of neonatal	**Sample size** N=39 cases (neonates treated with whole-body hypothermia for suspected hypoxic-ischaemic encephalopathy) N=78 controls (matched to each neonate in the case group in a two-to-one fashion using the two subsequent births in the same hospital	**Interventions** Non-computer-assisted interpretation of the last hour of EFM tracing before birth	**Details** The last 1 hour of EFM tracing was reviewed independently by three obstetricians blinded to outcome using the National Institute of Child Health and Human Development and the American College of	**Results** **Odds ratio* (OR) with 95% CI of the following EFM features in the case group. (Last 1 hour tracing before birth.)** Reactive: OR 0.50 (0.22-1.12) Late decelerations: OR 1.10 (1.00-1.21) Early decelerations: OR 0.58 (0.35-0.94) Debt 30: 1.00 (1.00-1.00)	**Limitations** **Assessed with QUADAS-2 (for measures of diagnostic accuracy):** **Patient selection:** High risk (case-control design) **Index test(s)** (The index test in the study is the interpretation of the last hour of EFM tracing prior to birth): Low risk (3 reviewers

<table>
<tr><th>Study details</th><th>Participants</th><th>Interventions</th><th>Methods</th><th>Outcomes and Results</th><th>Comments</th></tr>
<tr>
<td>encephalopathy, Obstetrics and Gynecology, 124, 507-513, 2014

Ref Id

346212

Country/ies where the study was carried out

USA

Study type

Case-control study

Aim of the study

To estimate the diagnostic accuracy of electronic heart rate abnormalities in the identification of neonates with encephalopathy treated with whole-body hypothermia

Study dates

Between January 1, 2007 and July 1, 2013

Source of funding

None reported</td>
<td>matched by gestational age within 1 weeks and mode of birth)

Characteristics

There was no difference in the following characteristics in the case and control groups: maternal age, parity, race, receiving oxytocin, pre-eclampsia, intrauterine growth restriction, oligohydramnios, abruption, histologic chorioamnionitis, histologic funisities, histologic placental infarcts, birthweight, gender.
The case group more often had clinical chorioamnionitis, nonreassuring fetal heart rate, and meconium, 1-minute Apgar score of less than 7, 5-minute Apgar score of less than 7, cord pH <7.0 or base deficit >12mM, respiratory distress, positive blood cultures, seizures and longer stay length of stay at hospital

Inclusion criteria

All neonates born with suspected hypoxic-ischaemic encephalopathy at two hospitals and treated with whole-body hypothermia within 6 hours of birth during the 6.5-year period from January 1, 2007 to July 1, 2013. Neonates were eligible for treatment with whole-body hypothermia if moderate to severe encephalopathy was present at birth (manifested by lethargy, stupor, coma, decreased or no activity, distal flexion, complete extension, decerebrate posture, hypotonia or flaccidity, abnormal primitive reflexes, bradycardia, periodic breathing, apnoea, or seizures) and had a cord gas or early neonatal gas at less than 1 hour with pH 7.0 or less or base deficit greater than 16 mM. They were also eligible if the cord or early neonatal gas at less than 1 hour showed pH 7.01-7.15 and base deficit 10-15.9 mM if moderate to severe encephalopathy was present with evidence of an acute sentinel event, 10-minute Apgar score less than 5, or there was need for assisted ventilation initiated at birth with continuation for at least 10 minutes.

Neonates in the control group were matched to each neonate in the case group in a two-to-one fashion using the two subsequent births in the same hospital matched by gestational age to within 1 week and mode of birth).

Exclusion criteria

Exclusion criteria for whole-body hypothermia treatment included greater than 6 hours of life, gestational age less than 35 weeks, severe growth restriction (birthweight less than 1800 g), major congenital anomaly, severe persistent pulmonary hypertension with anticipated need for extracorporeal membrane</td>
<td></td>
<td>Obstetricians and Gynecologists three-tiered category system and definitions. Each reviewer assessed the last hour of tracing and assigned a category based on the most non-reassuring portion of the tracing and the final category was assigned based on consensus among the reviewers.
Each reviewer recorded the fetal heart rate (FHR), time with FHR greater than 160 bpm (tachycardia), or less than 110 bpm (bradyvcardia), number of accelerations, reactivity, total number of decelerations, and number of late, variable, or early decelerations. Reactivity was defined as the presence of at least two FHR accelerations that peaked (but did not necessarily remain) at least 15 bpm above the baseline and lasted 15 seconds during a 20-minute period that occurred any time during the last hour before birth. Variability was classified as absent (undetectable), minimal (amplitude range 5 bpm or less), moderate (amplitude range from 6-25 bpm) or marked (amplitude range greater than 25 bpm). Absent or minimal were considered as decreased variability. The number of prolonged decelerations lasting 2-10 minutes was recorded as well as the nadir and length of the most severe prolonged deceleration.
Severe variable decelerations were those with a drop to less than 70 bpm or lasting greater than 60 seconds. The number of contractions in the last hour before birth were counted, and the ratio of late decelerations per contractions and variable decelerations per contractions were expressed as a percentage. Total deceleration area was calculated as the sum of the area within all decelerations in the final 30 minutes (debt30) and final 60 minutes (debt60) of the tracing as a measure of both quantity and severity. The area within each deceleration was approximated as one-half (width in seconds x depth in bpm).
Multiple variable logistic regression models were used to determine the diagnostic accuracy of EFM parameters in the identification of neonates with encephalopathy treated with whole-body hypothermia. Variables significant at a p-value of <0.10 in bivariate analyses were used in the multiple variable regression</td>
<td>Debt 60: 1.00 (1.00-1.00)
*Adjusted for chorioamnionitis

Diagnostic accuracy (95% CI) of the following EFM features or classifications to detect cases with whole-body hypothermia treatment for suspected hypoxic-ischaemic encephalopathy
<u>Early decelerations</u>
<table>
<tr><th></th><th>Suspected hypoxic-ischaemic encephalopathy</th><th>No suspected encephalopathy</th><th>Totals</th></tr>
<tr><td>Early decelerations</td><td>NR</td><td>NR</td><td>NR</td></tr>
<tr><td>No early decelerations</td><td>NR</td><td>NR</td><td>NR</td></tr>
<tr><td>Totals</td><td>NR</td><td>NR</td><td>NR</td></tr>
</table>
Sensitivity 23.1% (11.7-39.7%)
Specificity 94.9% (86.7-98.3%)
Positive likelihood ratio** 4.53
Negative likelihood ratio** 0.81

<u>Category III (versus category I)</u>
<table>
<tr><th></th><th>Suspected encephalopathy</th><th>No suspected encephalopathy</th><th>Totals</th></tr>
<tr><td>Category III</td><td>5</td><td>1</td><td>6</td></tr>
<tr><td>Category I (normal)</td><td>4</td><td>7</td><td>11</td></tr>
<tr><td>Totals</td><td>9</td><td>8</td><td>17</td></tr>
</table>
Sensitivity** 55.6% (22.7-84.7%)
Specificity** 87.5% (46.7-99.3%)
Positive likelihood ratio** 4.44 (0.65-30.44)
Negative likelihood ratio** 0.51 (0.24-1.09)

<u>Category II (versus category I)</u>
<table>
<tr><th>a</th><th>Suspected encephalopathy</th><th>No suspected encephalopathy</th><th>Totals</th></tr>
<tr><td>Category II</td><td>30</td><td>70</td><td>100</td></tr>
</table>
</td>
<td>assessed the trace and they were blinded to the results of the reference standard)
Reference standard (The reference standard in the study is the assessment of suspected hypoxic-ischaemic encephalopathy within 6 hours of birth): Low risk (the reference standard is likely to correctly classify the target condition)
Flow and timing: High risk (index test was performed before birth, reference tests were performed after birth, this means that differences in outcomes may be due to events in-between the two tests)
Overall risk of bias: very serious risk of bias
Assessed with NICE 2012 guideline manual checklist for prognostic studies (for ORs):
<table>
<tr><td>The study sample represents the population of interest with regard to key characteristics, sufficient to limit potential bias to the results
All neonates born at two hospitals with suspected hypoxic-ischaemic encephalopathy treated with whole-body hypothermia within 6 hours of birth during the 6.5-year period from January 1, 2007 to July 1, 2013 were included.
Neonates in the control group were matched to each neonate in the case group in a two-to-one fashion using the subsequent two deliveries in the same hospital matched by gestational age within 1 weeks and mode of birth</td><td><u>Yes</u></td><td>No</td><td>Unclear</td></tr>
</table>
</td>
</tr>
</table>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	oxygenation, coagulopathy with active bleeding, and suspected sepsis with severe hemodynamic compromise requiring large doses of pressors				

Category I (normal)	4	7	11
Totals	34	77	111

Sensitivity** 88.2% (71.6-96.2%)
Specificity** 9.1% (4.0-18.4%)
Positive likelihood ratio** 0.97 (0.84-1.12)
Negative likelihood ratio** 1.29 (0.40-4.19)

Decreased variability

	Suspected encephalopathy	No suspected encephalopathy	Totals
Decreased variability	13	15	18
No decreased variability	26	63	89
Totals	39	78	117

Sensitivity** 33.3% (19.6-50.3%)
Specificity** 80.8% (70.0-88.5%)
Positive likelihood ratio** 1.73 (0.92-3.27)
Negative likelihood ratio** 0.83 (0.66-1.04)

Reactivity

	Suspected encephalopathy	No suspected encephalopathy	Totals
Reactivity	16	48	64
No reactivity	23	30	53
Totals	39	78	117

Sensitivity** 41.0% (26.0-57.8%)
Specificity** 38.5% (27.9-50.2%)
Positive likelihood ratio** 0.67 (0.44-1.01)
Negative likelihood ratio** 1.53 (1.13-2.07)

**Calculated by the NGA technical team using http://vassarstats.net/clin1.html

Comments			
Loss to follow-up is unrelated to key characteristics (that is, the study data adequately represent the sample), sufficient to limit potential bias N/A	Yes	No	Unclear
The prognostic factor of interest is adequately measured in study participants, sufficient to limit potential bias 3 reviewers assessed the trace and they were blinded to the results of the reference standard using the NICHD classification. The reviewers were an obstetric resident (RRA), and two maternal-fetal medicine attendings, all of whom had passed the required EFM course. Categorical EFM tracing parameters were determined by consensus among the three reviewers, and continuous parameters were averaged.	**Yes**	No	Unclear
The outcome of interest is adequately	**Yes**	No	Unclear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments			
					measured in study participants, sufficient to limit potential bias Clear and comprehensive criteria to assess moderate to severe encephalopathy at birth and eligibility for treatment with whole-body hypothermia due to suspected encephalopathy			
					Important potential confounders are appropriately accounted for, limiting potential bias with respect to the prognostic factor of interest ORs were adjusted for the presence of clinical chorioamnionitis, however not for other factors such as demographic characteristics or presence of meconium	Yes	**No**	Unclear
					The statistical analysis is appropriate for the design of the study, limiting potential for the presentation of invalid results Multivariable logistic regression was appropriately conducted.	**Yes**	No	Unclear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Risk of bias: No serious risk of bias / **Serious risk of bias** / Very serious risk of bias **Other information**
Full citation Holzmann, M., Wretler, S., Cnattingius, S., Nordstrom, L., Cardiotocography patterns and risk of intrapartum fetal acidemia, Journal of Perinatal Medicine, 43, 473-479, 2015 **Ref Id** 446285 **Country/ies where the study was carried out** Sweden **Study type** Prospective observational cohort study **Aim of the study** To identify cardiotocography patterns associated with increased risk of intrapartum fetal acidaemia **Study dates** February 2009-February 2011 **Source of funding** Not reported	**Sample size** N= 1070 women in labour, 2134 fetal blood samples (FBSs) **Characteristics** Women who underwent FBS due to a CTG trace that was assessed as 'non-reassuring' by the attending physician during labour at Karolinska University Hospital, Stockholm. Median maternal age: 31 (range: 15 to 47) Median gestational age (weeks+days): 40+3 (range:34+1 to 42+4) Thick meconium: 75 (7.0%) Mode of birth: Spontaneous: 421 (39.4%); Ventouse: 349 (32.6%); Caesarean section: 300 (28.0%) **Inclusion criteria** Singleton pregnancy, >=34 weeks of gestation, cephalic presentation, and indication for FBS according to the attending doctor **Exclusion criteria** For the last sample in a particular woman, an exclusion criterion was active pushing prior to sampling	**Interventions** **Intervention 1** Interpretation of cardiotocography tracing for the last 60 minutes prior to first FBS **Intervention 2** Interpretation of cardiotocography tracing for the last 60 minutes prior to last FBS	**Details** All women had an admission CTG; with a normal test result and the woman being considered to be at low risk, intermittent CTG monitoring every 2 hours was recommended. Women considered to be at high risk, having epidural analgesia or oxytocin augmentation had continuous CTG monitoring. CTG interpretation followed the guidelines of the Swedish Society of Obstetrics and Gynecology (SFOG), based on the international classification system of the International Federation of Gynecology and Obstetrics (FIGO) from 1987. The attending physician decided upon FBS if the CTG trace was visually interpreted as non=reassuring. FBS was performed according to clinical routine; 5 µl of fetal scalp blood was collected after wiping dry from amniotic fluid and applying silicone gel. Analysis was done at the bedside using Lactate Pro™ (KDK Corp., Kyoto, Japan), calibrated every 50th analysis. Half of the women had more than one FBS. The study authors, therefore, included results for both the first sample, including the total population that met the inclusion criteria, and included results from the last sample unless this failed to meet the inclusion criteria. A senior obstetrician (LN), blinded to the lactate concentration at sampling, interpreted all CTG tracings with focus on the last 60 minutes prior to each FBS. The study authors documented baseline FHR, variability, accelerations, type of decelerations, and duration of CTG pattern prior to FBS. Definitions published by FIGO were used, i.e. FHR (normal) 110–150 beats per minute (bpm), bradycardia <110 bpm, and tachycardia >150 bpm. Variability: normal 5–25 bpm, reduced: 2–4 bpm, absent: <2 bpm, and increased: >25 bpm, accelerations: transient increase in	**Results** **Diagnostic accuracy (95% CI) of the following EFM features to detect fetal lactacidaemia (lactate>4.8 mmol/l) at <u>first</u> FBS (negative test result is 'normal baseline and variability')** <u>Reduced variability</u> |	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
---	---	---	---
Reduced variability	4	150	154
Normal baseline and variability	6	236	242
Totals	10	386	396 | Sensitivity 40.00% (13.69% to 72.63%) Specificity 61.14% (56.06% to 66.00%) Positive likelihood ratio 1.03 (0.48 to 2.22) Negative likelihood ratio 0.98 (0.59 to 1.63) <u>Absent variability</u> |	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
---	---	---	---
Absent variability	4	28	32
Normal baseline and variability	6	236	242		**Limitations** **Assessed with QUADAS-2:** **Patient selection**: High risk (All women included in the study had received FBS, and FBS was only recommended by the attending physician if the CTG was non-reassuring. Therefore, even if some of the CTGs were later classified as normal when re-evaluated for the study by a senior obstetrician, they may have not been representative of the 'average' normal CTG) **Index test**: High risk (Even if the senior obstetrician interpreting the CTGs was blinded to the outcome, it is known that FHR trace interpretation is difficult and can be subjective and therefore introduce bias; other studies rely on consensus across multiple reviewers for trace interpretation) **Reference standard**: Low risk (For the last FBS, an exclusion criterion was active pushing prior to sampling because active pushing is known to increase the lactate concentration) **Flow and timing**: Low risk (CTG trace interpretation was applied to the last 60 minutes prior to each FBS; both the index test and the reference standard were applied before birth) **Overall risk of bias**: Very serious **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

FHR of ≥15 bpm for ≥15 seconds, and decelerations: transient episodes of slowing of FHR below baseline level of ≥15 bpm lasting ≥15 seconds.
Severe variable decelerations were defined as having a variable shape, an abrupt fall from baseline FHR to nadir of deceleration, and a duration >60 seconds. Late decelerations were defined as start of deceleration after a peak of contraction, uniform shape, and gradual fall to nadir of deceleration. Bradycardic episodes were defined as baseline FHR <110 bpm for >3 minutes occurring within 30 minutes before sampling, including prolonged decelerations lasting <10 minutes and bradycardia for >10 minutes. Simple variable decelerations (duration <60 seconds) and early decelerations (starting before peak of contraction) were referred to the normal group

Totals	10	264	274

Sensitivity 40.00% (13.69% to 72.63%)
Specificity 89.39% (84.88% to 92.72%)
Positive likelihood ratio 3.77 (1.63 to 8.70)
Negative likelihood ratio 0.67 (0.40 to 1.11)

Increased variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Increased variability	2	8	10
Normal baseline and variability	6	236	242
Totals	8	244	252

Sensitivity 25.00 % (4.45% to 64.42%)
Specificity 96.72% (93.40% to 98.47%)
Positive likelihood ratio 7.63 (1.92 to 30.31)
Negative likelihood ratio 0.78 (0.52 to 1.16)

Bradycardic episode

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Bradycardic episode	10	36	46
Normal baseline and variability	6	236	242
Totals	16	272	288

Sensitivity 62.50 % (35.87% to 83.72%)
Specificity 86.76% (82.02% to 90.44%)
Positive likelihood ratio 4.72 (2.90 to 7.68)
Negative likelihood ratio 0.43 (0.23 to 0.81)

Tachycardia

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Tachycardia	10	114	124
Normal baseline and variability	6	236	242
Totals	16	350	366

Sensitivity 62.50% (35.87% to 83.72%)
Specificity 67.43% (62.21% to 72.26%)
Positive likelihood ratio 1.92 (1.28 to 2.89)
Negative likelihood ratio 0.56 (0.29 to 1.05)

Tachycardia+reduced variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Tachycardia+reduced variability	9	140	149
Normal baseline and variability	6	236	242
Totals	15	376	391

Sensitivity 60.00% (32.89% to 82.54%)
Specificity 62.76% (57.64% to 67.63%)
Positive likelihood ratio 1.61 (1.04 to 2.49)
Negative likelihood ratio 0.64 (0.34 to 1.19)

Severe variable decelerations

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Severe variable decelerations	18	109	127
Normal baseline and variability	6	236	242
Totals	24	345	369

Sensitivity 75.00 % (52.95% to 89.40%)
Specificity 68.41 % (63.17% to 73.22%)
Positive likelihood ratio 2.37 (1.80 to 3.14)
Negative likelihood ratio 0.37 (0.18 to 0.73)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Late decelerations

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Late decelerations	8	50	58
Normal baseline and variability	6	236	242
Totals	14	286	300

Sensitivity 57.14% (29.65% to 81.19%)
Specificity 82.52% (77.50% to 86.64%)
Positive likelihood ratio 3.27 (1.95 to 5.49)
Negative likelihood ratio 0.52 (0.28 to 0.95)

Severe variable decelerations+reduced variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Severe variable decelerations+reduced variability	4	24	28
Normal baseline and variability	6	236	242
Totals	10	260	270

Sensitivity 40.00% (13.69% to 72.63%)
Specificity 90.77% (86.41% to 93.88%)
Positive likelihood ratio 4.33 (1.85 to 10.13)
Negative likelihood ratio 0.66 (0.40 to 1.10)

Late decelerations+reduced variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Late decelerations+reduced variability	3	22	25
Normal baseline and variability	6	236	242

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Totals	9	258	267

Sensitivity 33.33% (9.04% to 69.08%)
Specificity 91.47% (87.20% to 94.46%)
Positive likelihood ratio 3.91 (1.43 to 10.70)
Negative likelihood ratio 0.73 (0.46 to 1.16)

Severe variable decelerations+tachycardia

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Severe variable decelerations+tachycardia	8	24	32
Normal baseline and variability	6	236	242
Totals	14	260	274

Sensitivity 57.14% (29.65% to 81.19%)
Specificity 90.77% (86.41% to 93.88%)
Positive likelihood ratio 6.19 (3.42 to 11.20)
Negative likelihood ratio 0.47 (0.26 to 0.87)

Late decelerations+tachycardia

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Late decelerations+tachycardia	6	24	30
Normal baseline and variability	6	236	242
Totals	12	260	272

Sensitivity 50.00% (22.29% to 77.71%)
Specificity 90.77% (86.41% to 93.88%)
Positive likelihood ratio 5.42 (2.74 to 10.72)
Negative likelihood ratio 0.55 (0.31 to 0.97)

Diagnostic accuracy (95% CI) of the following EFM features to detect fetal lactacidaemia (lactate>4.8 mmol/l) at last FBS (negative test result is 'normal baseline and variability')

Reduced variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Reduced variability	5	108	113
Normal baseline and variability	9	178	187
Totals	14	286	300

Sensitivity 35.7% (14.1-63.9%)
Specificity 62.2% (61.2-63.6%)
Positive likelihood ratio 0.95 (0.36-1.76)
Negative likelihood ratio 1.03 (0.57-1.40)

Absent variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Absent variability	7	25	32
Normal baseline and variability	9	178	187
Totals	16	203	219

Sensitivity 43.8% (20.8-69.4%)
Specificity 87.7% (82.2-91.7%)
Positive likelihood ratio 3.55 (1.83-6.91)
Negative likelihood ratio 0.64 (0.42-0.99)

Increased variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Increased variability	2	5	7
Normal baseline and variability	9	178	187
Totals	11	183	194

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Sensitivity 18.2% (3.2-52.2%) Specificity 97.3% (93.4-99.0%) Positive likelihood ratio 6.65 (1.45-30.51) Negative likelihood ratio 0.84 (0.64-1.11) Bradycardic episode	

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Bradycardic episode	12	24	36
Normal baseline and variability	9	178	187
Totals	21	202	223

Sensitivity 57.1% (34.4-77.4%)
Specificity 88.1% (82.6-92.1%)
Positive likelihood ratio 4.81 (2.84-8.15)
Negative likelihood ratio 0.49 (0.30-0.80)

Tachycardia

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Tachycardia	16	90	106
Normal baseline and variability	9	178	187
Totals	25	268	293

Sensitivity 64.0% (42.6-81.3%)
Specificity 66.4% (60.4-72.0%)
Positive likelihood ratio 1.91 (1.36-2.67)
Negative likelihood ratio 0.54 (0.32-0.92)

Tachycardia + reduced variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Tachycardia + reduced variability	7	121	128
Normal baseline and variability	9	178	187
Totals	16	299	315

Sensitivity 43.8% (20.8-69.4%)
Specificity 59.3% (53.7-65.1%)
Positive likelihood ratio 1.08 (0.61-1.92)
Negative likelihood ratio 0.94 (0.61-1.46)

Severe variable decelerations

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Severe variable decelerations	21	76	97
Normal baseline and variability	9	178	187
Totals	30	254	284

Sensitivity 70.0% (50.4-84.6%)
Specificity 70.1% (64.0-75.6%)
Positive likelihood ratio 2.34 (1.73-3.16)
Negative likelihood ratio 0.43 (0.25-0.74)

Late decelerations

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Late decelerations	11	38	49
Normal baseline and variability	9	178	187
Totals	0	216	236

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Sensitivity 55.0% (32.0-76.2%) Specificity 82.4% (76.5-87.1%) Positive likelihood ratio 3.13 (1.91-5.10) Negative likelihood ratio 0.55 (0.34-0.89) Severe variable decelerations and + reduced variability	

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Severe variable decelerations and + reduced variability	8	20	28
Normal baseline and variability	9	178	187
Totals	17	198	215

Sensitivity 47.1% (23.9-71.5%)
Specificity 89.9% (84.6-93.6%)
Positive likelihood ratio 4.66 (2.42-8.95)
Negative likelihood ratio 0.59 (0.38-0.92)

Late decelerations + reduced variability

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Late decelerations + reduced variability	10	24	34
Normal baseline and variability	9	178	187
Totals	19	202	221

Sensitivity 52.6% (29.5-74.8%)
Specificity 88.1% (82.6-92.1%)
Positive likelihood ratio 4.43 (2.51-7.82)
Negative likelihood ratio 0.54 (0.33-0.86)

Severe variable decelerations + tachycardia

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Severe variable decelerations + tachycardia	16	17	33
Normal baseline and variability	9	178	187
Totals	25	195	220

Sensitivity 64.0% (42.6-81.3%)
Specificity 91.3% (86.2-94.7%)
Positive likelihood ratio 7.34 (4.27-12.61)
Negative likelihood ratio 0.39 (0.23-0.67)

Late decelerations + tachycardia

	Lactate >4.8 mmol/l	Lactate ≤4.8 mmol/l	Totals
Late decelerations + tachycardia	10	20	30
Normal baseline and variability	9	178	187
Totals	19	198	217

Sensitivity 52.6% (29.5-74.8%)
Specificity 89.9% (84.6-93.6%)
Positive likelihood ratio 5.21 (2.87-9.45)
Negative likelihood ratio 0.53 (0.33-0.85)

Sensitivity, specificity and likelihood ratios calculated by the NGA technical team using http://vassarstats.net/clin1.html

Full citation	Sample size	Interventions	Details	Results	Limitations
Liu, L., Tuuli, M. G., Roehl, K. A., Odibo, A. O., Macones, G. A., Cahill, A. G., Electronic fetal monitoring patterns associated with respiratory morbidity in term neonates, American Journal of	N=4736 **Characteristics** Compared to the group who had no respiratory morbidity (n=4561), the group that	EFM patterns in the last 30 minutes before birth	EFM was performed with the use of internal or external monitoring as clinically indicated. The primary outcome was neonatal respiratory morbidity, which was defined as either any oxygen requirement at or after 6 hours of life	**Adjusted* odds ratio (aOR) with 95% confidence interval (CI) of neonatal respiratory morbidity** in the presence of the following EFM characteristics in the last 30 minutes before birth in the whole sample (n=4736)** Ever baseline bradycardia <110bpm: aOR 0.5 (0.1-3.4) Ever baseline <120 bpm: aOR 0.7 (0.4-1.3)	According to NICE 2012 guidelines manual checklist for prognostic studies **The study sample represents the** Yes / No / **Unclear**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments			
Obstetrics & Gynecology, 213, 681.e1-6, 2015 **Ref Id** 446299 **Country/ies where the study was carried out** USA **Study type** Prospective cohort study **Aim of the study** To identify electronic fetal monitoring patterns that are associated with neonatal respiratory morbidity **Study dates** The study was conducted after approval from the Washington University School of medicine Human Research Protection Office (approval in 11/2014) **Source of funding** Supported in part by the National Institute of Child Health and Human Development	had respiratory morbidity (n=175) more often had pre-eclampsia, pregestational diabetes, were nulliparous, had had previous caesarean section, had received prostaglandin, had not had vaginal birth, had caesarean birth, and had had maternal fever. No difference between the groups was observed in maternal age, gestational age at birth, labour type (spontaneous, augmented or induced), birthweight, percentage of maternal black race, percentage of gestational diabetes, and use of regional anaesthesia, Foley bulb, and oxytocin **Inclusion criteria** Term, vertex, non-anomalous singleton pregnancies during labour at Washington University in St. Louis Missouri, USA **Exclusion criteria** Neonates with <10 minutes of EFM in the 30 minutes before birth. Gestational age <37 weeks. Postnatal anomaly diagnosis		or any mechanical ventilation in the first 24 hours. Because caesarean birth and maternal fever are both risk factors for increased neonatal respiratory morbidity, secondary analyses were performed that excluded those women who underwent caesarean birth and those with fever. Because mechanical ventilation is the most severe acute respiratory morbidity for a term infant, analyses were repeated to estimate which EFM patterns were associated with mechanical ventilation compared with those without morbidity. Multivariable logistic regression was performed in a backward step-wise fashion to refine estimates of the association between EFM characteristics and neonatal respiratory morbidity by controlling for confounding factors. Model fit of the final model (adjusted for maternal fever, parity, pregestational diabetes, previous caesarean birth, and pre-eclampsia) was tested with the Hosmer-Lemeshow goodness-of-fit test	Ever baseline tachycardia >160 bpm: aOR 2.9 (1.9-4.4) Ever absent or minimal variability: aOR 1.3 (0.9-1.8) Mostly absent or minimal variability: aOR 1.1 (0.8-1.6) Always absent or minimal variability: aOR 1.2 (0.8-1.7) Mostly moderate variability: aOR 0.7 (0.5-1.0) Always moderate variability: aOR 0.7 (0.5-0.9) Ever marked variability: aOR 2.7 (1.5-5.0) Accelerations present: aOR 0.6 (0.4-0.9) Decelerations present: aOR 0.8 (0.5-1.2) Early decelerations: aOR 0.4 (0.1-1.1) Variable decelerations: aOR 0.8 (0.5-1.1) Late decelerations: aOR 0.8 (0.6-1.1) Prolonged decelerations: aOR 1.7 (1.3-2.4) **Adjusted* OR (95% CI) of neonatal respiratory morbidity** in the presence of the following EFM characteristics in the last 30 minutes before birth <u>excluding caesarean birth (n=3994)</u> Ever baseline tachycardia >160 bpm: aOR 3.0 (1.8-5.1) Always moderate variability: aOR 0.7 (0.5-1.1) Ever marked variability: aOR 2.7 (1.3-5.7) Accelerations present: aOR 0.8 (0.5-1.2) Variable decelerations: aOR 3.4 (1.2-9.5) Prolonged decelerations: aOR 1.8 (1.2-2.8) **Adjusted* OR (95% CI) of neonatal respiratory morbidity** in the presence of the following EFM characteristics in the last 30 minutes before birth <u>excluding women with maternal fever (n=4647)</u> Ever baseline tachycardia >160 bpm: aOR 2.9 (1.9-4.6) Always moderate variability: aOR 0.7 (0.5-1.0) Ever marked variability: aOR 3.1 (1.7-5.7) Accelerations present: aOR 0.6 (0.4-0.9) Prolonged decelerations: aOR 1.8 (1.3-2.5) **Adjusted* OR (95% CI) of neonatal <u>mechanical ventilation</u> (versus no respiratory morbidity) in the presence of the following EFM characteristics in the last 30 minutes before birth(n=4605)** Ever baseline tachycardia >160 bpm: aOR 3.1 (1.4-6.7) Always moderate variability: aOR 0.8 (0.4-1.40) Ever marked variability: aOR 2.2 (0.7-7.2) Accelerations present: aOR 0.4 (0.2-0.9) Prolonged decelerations: aOR 2.6 (1.4-4.7) *Adjusted for maternal fever, parity, pregestational diabetes, previous caesarean birth, pre-eclampsia **Neonatal respiratory morbidity defined as either any oxygen requirement at or after 6 hours of life or any mechanical ventilation in the first 24 hours after birth	**population of interest with regard to key characteristics, sufficient to limit potential bias** Consecutive singleton, vertex, non-anomalous pregnancies were included. Mean gestational weeks in the sample was 38.9 (±1.3) and 38.9 (±1.2) (depending on the outcome finding) so a small portion of the births might be preterm. Also, the population is of both low- and high-risk pregnancies			
					Loss to follow-up is unrelated to key characteristics (that is, the study data adequately represent the sample), sufficient to limit potential bias N/A	<u>Yes</u>	No	Unclear
					The prognostic factor of interest is adequately measured in study participants, sufficient to	Yes	No	<u>Unclear</u>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments			
					limit potential bias EFM interpretation is known to be difficult and can be subject to bias. It is not reported if more than reviewer interpreted each tracing. Only the last 30 minutes of the EFM before birth was considered			
					The outcome of interest is adequately measured in study participants, sufficient to limit potential bias	**Yes**	No	Unclear
					Important potential confounders are appropriately accounted for, limiting potential bias with respect to the prognostic factor of interest	**Yes**	No	Unclear
					The statistical analysis is appropriate for the design of the study, limiting potential for the presentation of invalid results Multiple variable logistic regression was conducted appropriately.	**Yes**	No	Unclear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

However, it is unclear why the crude outcome was reported as relative risk and the adjusted one as odds ratio				
Risk of bias:	**No serious risk of bias**	Serious	Very serious	

Other information

Full citation

Sharbaf,F.R., Amjadi,N., Alavi,A., Akbari,S., Forghani,F., Normal and indeterminate pattern of fetal cardiotocography in admission test and pregnancy outcome, Journal of Obstetrics and Gynaecology Research, 40, 694-699, 2014

Ref Id

324863

Country/ies where the study was carried out

Iran

Study type

Prospective comparative study

Aim of the study

To evaluate the prognostic value of normal and indeterminate patterns of cardiotocography in admission tests and pregnancy outcomes

Study dates

March 2010 to February 2011

Source of funding

None reported

Sample size

N=818 total (including both low- and high-risk populations, 328 high risk and 497 low risk)
n=659 normal tracing
n=159 intermediate tracing

N=492 low-risk sample
n=410 normal tracing in low-risk sample
n=82 intermediate tracing in low-risk sample

N=326 high-risk sample
n=249 normal tracing in high-risk sample
n=77 intermediate tracing in high-risk sample

Characteristics

The mean age of the women was 26.6 (+-5.1) years. The median gestational age at birth was 39 (34-42) weeks. Admission tests were: 659 (80.4%) normal, 159 (19.4%) indeterminate and two (0.2%) abnormal. 60% of the women were categorised as low-risk and 40% were categorised as high-risk. Obstetric characteristics of the women (n=818):

	%
Nulliparous	64.2
Preterm <37 wks	8.1
Post-date >41 wks	0.9
Pregnancy-induced hypertension	8.3

Interventions

Fetal heart rate (FHR) tracings obtained with a non-stress test machine in early labour during a 20-40 minute period

Details

The FHR tracings were interpreted by two obstetricians according to NICHD recommendations resulting in normal, indeterminate, or abnormal categories based on baseline fetal heart rate, variability, acceleration and types of deceleration. Obstetricians were blinded to clinical conditions in order to avoid biased findings. When there was a disagreement, consensus was obtained with a perinatologist. Unfavourable outcome related to the women was only caesarean section due to non-reassuring fetal heart rate pattern. Non-reassuring fetal heart rate pattern was defined as abnormal patterns according to the NICHD recommendation. Fetal complications (neonatal death, umbilical cord artery pH <=7.2, 5-minute Apgar <7, thick meconium staining in liquor, admission to the neonatal intensive care unit, neonatal mortality and low birthweight) were assessed and compared in both groups

Results

Relative risk (RR) of the following perinatal outcomes in low- and high-risk and overall populations with indeterminate FHR tracing (according to NICHD classification)

CS due to non-reassuring fetal heart rate pattern
Overall: RR 3.8 (2.5-5.6)
Low-risk group: RR 3.7 (2.1-6.9)
High-risk group: RR 3.4 (2.0-5.7)

Umbilical artery pH <=7.2
Overall: RR 1.5 (0.8-2.8)
Low-risk group: RR 1.05 (0.4-3.0)
High-risk group: RR 1.9 (0.8-4.5)

NICU admission
Overall: RR 2.3 (1.2-4.2)
Low-risk group: RR 1.0 (0.3-3.4)
High-risk group: RR 3.2 (1.5-6.9)

NICU admission after excluding preterm birth
Overall: RR 2.0 (1.0-4.1)
Low-risk group: RR 0.7 (0.2-3.1)
High-risk group: RR 3.6 (1.4-9.2)

Diagnostic accuracy of indeterminate FHR tracing (NICHD classification) on different perinatal outcomes (NR = not reported)

CS
Mixed population (including both low- and high-risk samples)

a	CS	No CS	Totals
Indeterminate FHR category	NR	NR	NR
Normal FHR category	NR	NR	NR

Limitations

Assessed with QUADAS-2:
-Not described whether all women fitting the inclusion/exclusion criteria during the study period were selected.
-The study included gestational ages 35-36 weeks (preterm), while the guideline review is looking at term only (37-42 weeks).

-Even though there were two independent FHR tracing reviewers who were blinded to clinical conditions, it is known that FHR tracing interpretation is difficult and can be subjective and therefore introduce bias.

-Unlikely that the 'diagnosis' of outcomes would have been blinded to the FHR tracing interpretation.

-Index test (CTG tracing) performed before birth and reference test (usual ascertainment of outcome) performed during/after birth might mean that differences in the test results are due to events after the index test.

Assessed with NICE 2012 guidelines manual checklist for prognostic studies:

1.1	**The study sample represents the population of interest with regard to key characteristics, sufficient to limit potential bias to the results** The study population included singleton pregnancies with more than 34 weeks of gestation, intact membranes with both low- and high-risk pregnancies. However, since the proportion of preterm births (<37 weeks of gestation) in the study	**Yes**	No	Unclear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Participants

Pre-eclampsia	8.4
Gestational diabetes	4.5
Intrauterine growth restriction	3.9
Decreased fetal movement	15.2
Decreased amniotic fluid	11.7
Thick meconium staining	14.1
Non-reassuring fetal heart rate pattern	11.4
Caesarean section (CS)	33.3
CS due to non-reassuring fetal heart rate pattern	10.3

Inclusion criteria

Women admitted to to the labour ward at the Women's Hospital, Tehran University of Medical Sciences between March 2010 and February 2011 with singleton pregnancies with gestational age of more than 34 weeks and intact membranes.
Pregnancies were considered 'high risk' when there was a post-dated pregnancy (>41 weeks), oligohydramnios (amniotic fluid index <=5), pregnancy-induced hypertension, gestational diabetes, pre-eclampsia, intra-uterine growth restriction or decreased fetal movements

Exclusion criteria

Women with active phase of labour, <34 weeks of gestation and those with twin pregnancies, hydramnios or previous caesarean section who were not candidates for vaginal birth

Outcomes and Results

Totals	NR	NR	NR

Sensitivity 30.9%
Specificity 86.3%
Positive likelihood ratio* 2.26
Negative likelihood ratio* 0.80

Low-risk population

	CS	No CS	Totals
Indeterminate FHR category	NR	NR	NR
Normal FHR category	NR	NR	NR
Totals	NR	NR	NR

Sensitivity 28.6%
Specificity 87.7%
Positive likelihood ratio* 2.33
Negative likelihood ratio* 0.81

High-risk population

	CS	No CS	Totals
Indeterminate FHR category	NR	NR	NR
Normal FHR category	NR	NR	NR
Totals	NR	NR	NR

Sensitivity 33.1%
Specificity 83.4%
Positive likelihood ratio* 1.99
Negative likelihood ratio* 0.80

Umbilical artery pH <=7.2
Mixed population (including both low- and high-risk samples)

	Umbilical artery pH <=7.2	Umbilical artery pH >7.2	Totals
Indeterminate FHR category	13	55	68
Normal FHR category	19	127	146

Comments

	population is small (8.1%), and only includes late preterm births (35-36 weeks of gestation), this was not considered a serious risk of bias/serious indirecteness. The findings are presented in the whole population (mix of low- and high-risk) as well as for low- and high-risk populations separately			
1.2	**Loss to follow-up is unrelated to key characteristics (that is, the study data adequately represent the sample), sufficient to limit potential bias** N/A	**Yes**	No	Unclear
1.3	**The prognostic factor of interest is adequately measured in study participants, sufficient to limit potential bias** Only 20-40 minutes of trace in 'early labour' were considered. The tracings were interpreted by two obstetricians who were blinded to the clinical conditions. In case of disagreement of interpretation between the obstetricians, a consensus view would be provided by a perinatologist. Interpretation of CTG tracing is known to be difficult and can be subject to bias, however, two (and potentially three) different persons reviewed each tracing	Yes	No	**Unclear**
1.4	**The outcome of interest is adequately measured in study participants, sufficient to limit potential bias**	**Yes**	No	Unclear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Totals	32	182	214		

Sensitivity 40.6% (24.2-59.2%)
Specificity 69.8% (62.5-76.2%)
Positive likelihood ratio* 1.34 (0.84-2.16)
Negative likelihood ratio* 0.85 (0.64-1.14)

Low-risk population

	Umbilical artery pH <=7.2	Umbilical artery pH >7.2	Totals
Indeterminate FHR category	4	78	82
Normal FHR category	22	388	410
Totals	26	466	492

Sensitivity 26.7% (8.9-55.2%)
Specificity 83.7% (80.0-86.8%)
Positive likelihood ratio* 1.63 (0.69-3.87)
Negative likelihood ratio* 0.88 (0.65-1.19)

High-risk population

	Umbilical artery pH <=7.2	Umbilical artery pH >7.2	Totals
Indeterminate FHR category	9	68	77
Normal FHR category	8	241	249
Totals	17	309	326

Sensitivity 52.9% (28.5-76.1%)
Specificity 80.0% (72.9-82.4%)
Positive likelihood ratio**2.41 (1.47-3.95)
Negative likelihood ratio* 0.60 (0.36-1.00)

NICU admission
Mixed population (including both low- and high-risk samples)

	NICU admission	No NICU admission	Totals
Indeterminate FHR category	15	144	159

1.5	**Important potential confounders are appropriately accounted for, limiting potential bias with respect to the prognostic factor of interest** Statistical methods for deriving relative risks were not described at all and whether or not the model adjusted for potential confounders is not reported. Presumably, the estimates are crude and therefore might be subject to serious risk of bias	Yes	**No**	Unclear
1.6	**The statistical analysis is appropriate for the design of the study, limiting potential for the presentation of invalid result** Statistical methods for deriving relative risks were not described at all and whether or not the model adjusted for potential confounders is not reported. Presumably, the estimates are crude and therefore might be subject to serious risk of bias	Yes	**No**	Unclear
	Overall risk of bias (for RR data):	No serious risk of bias	Serious risk of bias	**Very serious risk of bias**

Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Normal FHR category	27	632	659
Totals	42	776	818

Sensitivity 35.7% (22.0-52.0%)
Specificity 81.4% (78.5-84.1%)
Positive likelihood ratio* 1.92 (1.25-2.96)
Negative likelihood ratio* 0.79 (0.63-1.00)

Low-risk population

	NICU admission	No NICU admission	Totals
Indeterminate FHR category	3	79	82
Normal FHR category	15	395	410
Totals	18	474	492

Sensitivity 16.7% (4.4-42.2%)
Specificity 83.3% (79.6-86.5%)
Positive likelihood ratio* 1.00 (0.35-2.86)
Negative likelihood ratio* 1.00 (0.81-1.23)

High-risk population

	NICU admission	No NICU admission	Totals
Indeterminate FHR category	12	65	77
Normal FHR category	12	237	249
Totals	24	302	326

Sensitivity 50.0% (29.6-70.4%)
Specificity 78.5% (73.3-82.9%)
Positive likelihood ratio* 2.32 (1.47-3.66)
Negative likelihood ratio* 0.64 (0.43-0.95)

<u>NICU admission excluding preterm birth</u>
Mixed population (including both low- and high-risk samples)

	NICU admission excluding preterm birth	No NICU admission excluding preterm birth	Totals

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Indeterminate FHR category	NR	NR	NR
Normal FHR category	NR	NR	NR
Totals	NR	NR	NR

Sensitivity 31.3%
Specificity 81.9%
Positive likelihood ratio* 1.73
Negative likelihood ratio* 0.84

Low-risk population

	NICU admission excluding preterm birth	No NICU admission excluding preterm birth	Totals
Indeterminate FHR category	NR	NR	NR
Normal FHR category	NR	NR	NR
Totals	NR	NR	NR

Sensitivity 12.5%
Specificity 83.2%
Positive likelihood ratio* 0.74
Negative likelihood ratio* 1.05

High-risk population

	NICU admission excluding preterm birth	No NICU admission excluding preterm birth	Totals
Indeterminate FHR category	NR	NR	NR
Normal FHR category	NR	NR	NR
Totals	NR	NR	NR

Sensitivity 50.0%
Specificity 79.9%
Positive likelihood ratio* 2.49

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Negative likelihood ratio* 0.63

Neonatal death

Mixed population (including both low- and high-risk samples)

	Neonatal death	No neonatal death	Totals
Indeterminate FHR category	2	157	159
Normal FHR category	0	659	659
Totals	2	816	818

Sensitivity 100% (19.8-100%)
Specificity 80.8% (77.8-83.4%)
Positive likelihood ratio* 5.2 (4.52-5.98)
Negative likelihood ratio* 0 (NA)

Low-risk population

	Neonatal death	No neonatal death	Totals
Indeterminate FHR category	0	82	82
Normal FHR category	0	410	410
Totals	0	492	492

Sensitivity NA**
Specificity 83.3% (79.7-86.5%)**
Positive likelihood ratio 0 (NA)**
Negative likelihood ratio 1.20 (NA)**

High-risk population

	Neonatal death	No neonatal death	Totals
Indeterminate FHR category	2	75	77
Normal FHR category	0	249	249
Totals	2	324	326

Sensitivity 100% (19.8-100%)
Specificity 76.9% (71.8-81.3%)
Positive likelihood ratio* 4.32 (3.54-5.27)
Negative likelihood ratio* 0 (NA)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				* Calculated by the NGA technical team.using http://vassarstats.net/clin1.html ** Calculated by the NGA technical team using https://www.medcalc.org/calc/diagnostic_test.php Confidence intervals (CIs) calculated by the NGA technical team using http://vassarstats.net/clin1.html	

Full citation

Soncini, E., Paganelli, S., Vezzani, C., Gargano, G., Giovanni Battista, L. S., Intrapartum fetal heart rate monitoring: evaluation of a standardized system of interpretation for prediction of metabolic acidosis at delivery and neonatal neurological morbidity, Journal of Maternal-Fetal & Neonatal Medicine, 27, 1465-9, 2014

Ref Id

446330

Country/ies where the study was carried out

Italy

Study type

Retrospective comparative study

Aim of the study

To assess the ability of the intrapartum fetal heart rate interpretation system developed in 2008 by the National Institute of Health and Human Development (NICHD) to predict fetal metabolic acidosis at delivery and neonatal neurological morbidity

Study dates

August 2007 to May 2011

Source of funding

None reported

Sample size

N=314

Characteristics

The chartacteristics of the sample:

	n=314
Maternal age in years, mean (SD)	30 (5.2)
Parity 1, %	75.5
Gravidity 1, %	53.5
Gestational age (GA) in weeks, mean (SD)	40 (1.2)
Spontaneous birth, %	37.6
Vacuum extraction, %	25.8
Caesarean section (CS), %	36.6
Birthweight in g, mean (SD)	3411 (483)
Small for gestational age (SGA), %	12.7
1-minute Apgar <7, %	17.8
5-minute Apgar <7, %	2.5

Interventions

Continuous cardiotocography at least 1 hour and up to 5 hours before birth

Details

FHR tracings were obtained by external transducer ultrasound and recorded Philips Series 50A fetal monitor and Philips Avalon FM 20 fetal monitor; the paper sliding speed was 1 cm/minute.
All tracings recorded prior to birth were reviewed by a single expert observer who was blinded to umbilical blood pH, gas values and neonatal outcome. The analysis included both the dilitant period and the expulsive period, if available.
In accordance with NICHD recommendations, both qualitative and quantitative analysis of the FHR tracing was performed. Baseline heart rate, baseline variability, presence of accelerations and decelerations, and uterine contractions were assessed.
Tracings were further classified using a three-tier system: Category I (normal), Category II (indeterminate), Category III (abnormal). Trends in FHR patterns over time were quantified in minutes. Abnormal FHR patterns lasting longer than 30 minutes fell into Category III. Indeterminate FHR patterns lasting longer than 30 minutes fell within Category II. Otherwise, tracings were classified as Category I. When both indeterminate and abnormal FHR patters were present in the same tracing, with each FHR pattern lasting under 30 minutes but overall total more than 30 minutes, it was classified as Category II.
Category II was further divided into two subcategories according to the 2010 American College of Obstetricians and Gynecologists management guidelines. Within this study, the authors denoted the two subcategories Category IIA and IIB. Tracings with moderate FHR variability or FHR accelerations were classified as Category IIA and tracings with minimal/absent baseline FHR variability and no FHR accelerations were classified as Category IIB.
To assess the reproducibility of heart rate readings, a second and a third investigator further reviewed

Results

Diagnostic accuracy of FHR tracing classifications on different perinatal outcomes with 95% CI (calculated by the NGA technical team)
Category III (abnormal) versus Category I (normal)
NICU admission

	NICU admission	No NICU admission	Totals
Category III (abnormal)	12	19	27
Category I (normal)	0	108	108
Totals	12	127	135

Sensitivity 100% (69.9-100%)
Specificity 85.0% (77.4-90.5%)
Positive likelihood ratio 6.68 (4.42-10.12)
Negative likelihood ratio 0 (NA)

Neonatal encephalopathy

	Neonatal encephalopathy	No neonatal encephalopathy	Totals
Category III (abnormal)	8	23	31
Category I (normal)	0	108	108
Totals	8	131	139

Sensitivity 100% (59.8-100%)
Specificity 82.4% (74.6-88.3%)
Positive likelihood ratio 5.70 (3.93-8.25)
Negative likelihood ratio 0 (NA)

Moderate-severe neonatal encephalopathy

Limitations

The study was assessed using QUADAS-2 checklist.
-The study sample was selected and analysed retrospectively with specific inclusion/exclusion criteria, no random sampling
-In the study setting, continuous CTG was only performed for labouring women with antenatal or intrapartum risk factors.
Also umbilical cord blood sampling was only performed in cases of continuous fetal monitoring and operative birth. Therefore, it is assumed that all the included women are high risk, however, the details of the reason for 'high risk' were not reported
-The interpretation of CTG tracings is known to be difficult and subjective and since only one expert reviewed the tracings (two others reviewed 10% of the tracings with good/excellent inter-observer agreement, kappa=0.77) it could be a biased interpretation
-The diagnosis of outcomes was likely not done blinded to the index test (CTG tracing), thus, might introduce bias
-Index test (CTG tracing) was performed before birth and reference test (ascertainment of outcome) performed during/after birth which might mean that events after the index test influenced the outcome independently of the index test

Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Participants

Meconium-stained amniotic fluid, %	36.6
NICU admission, %	7.6
Neonatal encephalopathy, %	3.5
Moderate-severe neonatal encephalopathy, %	1.6
Death before NICU discharge, %	1.0

The proportion of FHR tracings was as follows: Category I 34.4%, Category IIA 37.6%, Category IIB 18.2%, and Category III 9.8%. No statistically significant differences were found between groups in terms of parity, gestational age, oligohydramniuos, induction of labour or mode of birth. Rate of operative delivery for suspected fetal distress increased significantly with worsening FHR pattern

Inclusion criteria

All labouring women, monitored with continuous cardiotocography, carrying singleton fetuses with cephalic presentation at >=37 weeks of gestation whose umbilical artery blood gas and acid-base analysis at birth was available

Exclusion criteria

Cases with fetal malformation, arrhythmia, elective caesarean section, or absence of significant uterine contractions (fewer than 3 contractions in 10 minutes).
Cases with no fetal heart rate tracing available in the last hour prior to birth

Methods

tracings independently in 10% of cases

Outcomes and Results

	Moderate-severe neonatal encephalopathy	No moderate-severe neonatal encephalopathy	Totals
Category III (abnormal)	4	27	31
Category I (normal)	0	108	108
Totals	4	135	139

Sensitivity 100% (39.6-100%)
Specificity 80.0% (72.1-86.2%)
Positive likelihood ratio 5.00 (3.57-7.01)
Negative likelihood ratio 0 (NA)

Instrumental birth

	Instrumental birth	No instrumental birth	Totals
Category III (abnormal)	19	12	31
Category I (normal)	74	34	108
Totals	93	46	139

Sensitivity 20.4% (13.0-30.3%)
Specificity 73.9% (58.6-85.2%)
Positive likelihood ratio 0.78 (0.42-1.47)
Negative likelihood ratio 1.08 (0.96-1.21)

Instrumental birth for suspected fetal distress

	Instrumental birth for suspected fetal distress	No instrumental birth for suspected fetal distress	Totals
Category III (abnormal)	18	13	31

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Category I (normal)	24	84	108
Totals	42	97	139

Sensitivity 42.9% (28.1-58.9%)
Specificity 86.6% (77.8-92.4%)
Positive likelihood ratio 3.20 (1.73-5.91)
Negative likelihood ratio 0.66 (0.51-0.86)

Death before NICU discharge

	Death before NICU discharge	No death before NICU discharge	Totals
Category III (abnormal)	3	28	31
Category I (normal)	0	108	108
Totals	3	136	139

Sensitivity 100% (31.0-100%)
Specificity 79.4% (71.4-85.7%)
Positive likelihood ratio 4.86 (3.49-6.76)
Negative likelihood ratio 0 (NA)

pH <7

	pH <7	pH ≥7	Totals
Category III (abnormal)	17	14	31
Category I (normal)	0	108	108
Totals	17	122	139

Sensitivity 100% (77.1-100%)
Specificity 88.5% (81.2-93.3%)
Positive likelihood ratio 8.71 (5.32-14.27)
Negative likelihood ratio 0 (NA)

Base excess (BE) <=-12 mmol/l

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

	BE <=-12 mmol/l	BE >-12 mmol/l	Totals
Category III (abnormal)	19	12	31
Category I (normal)	3	105	108
Totals	22	117	139

Sensitivity 86.4% (64.0-96.4%)
Specificity 89.7% (82.4-94.4%)
Positive likelihood ratio 8.42 (4.80-14.76)
Negative likelihood ratio 0.15 (0.05-0.44)

pH <7 and BE <=-12 mmol/l

	pH <7 and BE <=-12 mmol/l	pH ≥7 and BE >-12 mmol/l	Totals
Category III (abnormal)	14	17	31
Category I (normal)	0	108	108
Totals	14	125	139

Sensitivity 100% (73.2-100%)
Specificity 86.4% (78.8-91.6%)
Positive likelihood ratio 7.35 (4.73-11.44)
Negative likelihood ratio 0 (NA)

Category IIB (indeterminate B) versus Category I (normal)
NICU admission

	NICU admission	No NICU admission	Totals
Category IIB	9	48	57

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Category I (normal)	0	108	108
Totals	9	156	165

Sensitivity 100% (62.9-100%)
Specificity 69.2% (61.3-76.2%)
Positive likelihood ratio 3.25 (2.57-4.11)
Negative likelihood ratio 0 (NA)

Neonatal encephalopathy

	Neonatal encephalopathy	No Neonatal encephalopathy	Totals
Category IIB	3	54	57
Category I (normal)	0	108	108
Totals	3	162	a

Sensitivity 100% (31.0-100%)
Specificity 66.7% (58.8-73.8%)
Positive likelihood ratio 3.00 (2.41-3.73)
Negative likelihood ratio 0 (NA)

Moderate-severe neonatal encephalopathy

	Moderate-severe neonatal encephalopathy	No moderate-severe neonatal encephalopathy	Totals
Category IIB	1	56	57
Category I (normal)	0	108	108
Totals	1	164	165

Sensitivity 100% (5.5-100%)
Specificity 65.9% (58.0-73.0%)
Positive likelihood ratio 2.93 (2.37-3.62)
Negative likelihood ratio 0 (NA)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Instrumental birth

	Instrumental birth	No instrumental birth	Totals
Category IIB	30	27	57
Category I (normal)	74	34	108
Totals	104	61	165

Sensitivity 28.9% (20.6-38.7%)
Specificity 55.7% (42.5-68.2%)
Positive likelihood ratio 0.65 (0.43-0.98)
Negative likelihood ratio 1.28 (1.10-1.48)

Instrumental birth for suspected fetal distress

	Instrumental birth for suspected fetal distress	No instrumental birth for suspected fetal distress	Totals
Category IIB	29	28	57
Category I (normal)	24	84	108
Totals	53	112	165

Sensitivity 54.7% (40.6-68.2%)
Specificity 75.0% (65.8-82.5%)
Positive likelihood ratio 2.19 (1.46-3.28)
Negative likelihood ratio 0.60 (0.45-0.82)

Death before NICU discharge

	Death before NICU discharge	No death before NICU discharge	Totals

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Category IIB	0	57	57
Category I (normal)	0	108	108
Totals	0	165	165

Sensitivity NA*
Specificity 65.5% (57.7-72.7%)*
Positive likelihood ratio 0 (NA)*
Negative likelihood ratio 1.53 (NA)*

pH <7

	pH <7	pH ≥7	Totals
Category IIB	7	50	57
Category I (normal)	0	108	108
Totals	7	158	165

Sensitivity 100% (56.1-100%)
Specificity 68.4% (60.4-75.4%)
Positive likelihood ratio 3.16 (2.51-3.97)
Negative likelihood ratio 0 (NA)

BE <=-12 mmol/l

	BE <=-12 mmol/l	BE >-12 mmol/l	Totals
Category IIB	14	43	57
Category I (normal)	3	105	108
Totals	17	148	165

Sensitivity 82.4% (55.8-95.3%)
Specificity 71.0% (62.8-78.0%)
Positive likelihood ratio 2.83 (2.03-3.96)
Negative likelihood ratio 0.25 (0.09-0.70)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

pH <7 and BE <=-12 mmol/l

	pH <7 and BE <=-12 mmol/l	pH ≥7 and BE >-12 mmol/l	Totals
Category IIB	4	53	57
Category I (normal)	0	108	108
Totals	4	161	165

Sensitivity 100% (39.6-100%)
Specificity 67.1% (59.2-74.2%)
Positive likelihood ratio 3.04 (2.44-3.79)
Negative likelihood ratio 0 (NA)

Category IIA (indeterminate A) versus Category I (normal)
NICU admission

	NICU admission	No NICU admission	Totals
Category IIA	3	115	118
Category I (normal)	0	108	108
Totals	3	223	226

Sensitivity 100% (31.0-100%)
Specificity 48.4% (41.7-55.2%)
Positive likelihood ratio 1.94 (1.71-2.20)
Negative likelihood ratio 0 (NA)

Neonatal encephalopathy

	Neonatal encephalopathy	No neonatal encephalopathy	Totals
Category IIA	0	118	118

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Category I (normal)	0	108	108
Totals	0	226	226

Sensitivity NA*
Specificity 47.8% (41.1-54.5%)*
Positive likelihood ratio 0 (NA)*
Negative likelihood ratio 2.09 (NA)*

Moderate-severe neonatal encephalopathy

	Moderate-severe neonatal encephalopathy	No moderate-severe neonatal encephalopathy	Totals
Category IIA	0	118	118
Category I (normal)	0	108	108
Totals	0	226	226

Sensitivity NA*
Specificity 47.8% (41.1-54.5%)*
Positive likelihood ratio 0 (NA)*
Negative likelihood ratio 2.09 (NA)*

Instrumental birth

	Instrumental birth	No instrumental birth	Totals
Category IIA	73	45	118
Category I (normal)	74	34	108
Totals	147	79	226

Sensitivity 49.7% (41.4-58.0%)
Specificity 43.0% (32.1-54.6%)
Positive likelihood ratio 0.87 (0.68-1.12)
Negative likelihood ratio 1.17 (0.96-1.42)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Instrumental birth for suspected fetal distress

	Instrumental birth for suspected fetal distress	No instrumental birth for suspected fetal distress	Totals
Category IIA	50	68	118
Category I (normal)	24	84	108
Totals	74	152	226

Sensitivity 67.6% (55.6-77.7%)
Specificity 55.3% (47.0-63.3%)
Positive likelihood ratio 1.51 (1.19-1.91)
Negative likelihood ratio 0.59 (0.42-0.82)

Death before NICU discharge

	Death before NICU discharge	No death before NICU discharge	Totals
Category IIA	0	118	118
Category I (normal)	0	108	108
Totals	0	226	226

Sensitivity NA*
Specificity 47.8% (41.1-54.5%)*
Positive likelihood ratio 0 (NA)*
Negative likelihood ratio 2.09 (NA)*

pH <7

	pH <7	pH ≥7	Totals

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Category IIA	0	118	118
Category I (normal)	0	108	108
Totals	0	226	226

Sensitivity NA*
Specificity 47.8% (41.1-54.5%)*
Positive likelihood ratio 0 (NA)*
Negative likelihood ratio 2.09 (NA)*

BE <=-12 mmol/l

	BE <=-12 mmol/l	BE >-12 mmol/l	Totals
Category IIA	2	116	118
Category I (normal)	3	105	108
Totals	5	221	226

Sensitivity 40.0% (7.3-83.0%)
Specificity 47.5% (40.8-54.3%)
Positive likelihood ratio 0.76 (0.26-2.25)
Negative likelihood ratio 1.26 (0.61-2.61)

pH <7 and BE <=-12 mmol/l

	pH <7 and BE <=-12 mmol/l	pH ≥7 and BE >-12 mmol/l	Totals
Category IIA	0	118	118
Category I (normal)	0	108	108
Totals	0	226	226

Sensitivity NA*

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Specificity 47.8% (41.1-54.5%)* Positive likelihood ratio 0 (NA)* Negative likelihood ratio 2.09 (NA)* Sensitivity, specificity and likelihood ratios calculated by the NGA technical team using http://vassarstats.net/clin1.html unless marked with * *Sensitivity, specificity and likelihood ratios calculated by the NGA technical team using https://www.medcalc.org/calc/diagnostic_test.php	
Full citation Berkus,M.D., Langer,O., Samueloff,A., Xenakis,E.M., Field,N.T., Electronic fetal monitoring: what's reassuring?, Acta Obstetricia et Gynecologica Scandinavica, 78, 15-21, 1999 **Ref Id** 196611 **Country/ies where the study was carried out** USA **Study type** Cohort **Aim of the study** To determine which combinations of fetal heart rate (FHR) pattern abnormalities are associated with normal outcome in term pregnancies **Study dates** From March to August 1991 **Source of funding** Not specified	**Sample size** n = 2200 consecutive singleton term pregnancies n = 484/2200 (26%) with normal FHR trace during the last 30 minutes prior to delivery **Characteristics** There were no significant differences observed between the reassuring and non-reassuring group in fetal gestational age, sex, birth weight, and fetal complications. Women with non-reassuring tracing were significantly older, more often primigravida, had more maternal illness (cardiovascular, thyroid, kidney disease or diabetes) and more caesarean section and instrumental birth. However, there was no statistically significant differences in pregnancy complications (hypertension, infection, post-date, substance abuse, meconium stained liquor). **Inclusion criteria** Term pregnancy (> 36 weeks or birth weight > 2500g) Live birth Singleton pregnancy **Exclusion criteria** Choriamnionitis Major congenital abnormalities	**Interventions** **Normal** Baseline 120–160 bpm Variability > 5 bpm Presence of accelerations No variable or late decelerations **Abnormal** Baseline 90–120 bpm or > 160 bpm Variability < 5 bpm No accelerations Any decelerations Prolonged bradycardia or any combination	**Details** A cohort of n = 2200 consecutive birth was examined and the fetal heart rate tracings analysed. Arterial blood gas was collected from 97.5% of the study population. Blood sample was drawn immediately after birth and analysed within 30 minutes of birth. Every women entering the delivery room had FHR trace performed. The last 30 minutes of trace segment prior to delivery was analysed. All traces were obtained by scalp electrocardiography, and observers that analysed the data were blinded to birth outcomes.	**Results** Association between abnormal FHR tracing patterns and immediate adverse outcome (1st stage n = 224) Mild or moderate variable deceleration: not significant (ns) Decreased variability: ns Mild bradycardia: ns Tachycardia: ns Prolonged bradycardia: OR 1.9 (95% CI 1.3 to 3.7) Severe variable deceleration: ns late deceleration: ns Association between abnormal FHR tracing patterns and cord pH < 7.15 & 5 min apgar score < 7 (first stage n = 224) Mild or moderate variable deceleration: ns Decreased variability: ns Mild bradycardia: ns Tachycardia: ns Prolonged bradycardia: ns Severe variable deceleration: ns Late deceleration: ns Association between abnormal FHR tracing patterns and immediate adverse outcome (second stage n = 1635) Mild or moderate variable deceleration: ns Decreased variability: ns Mild bradycardia: ns Tachycardia: OR 1.9 (95% CI 1.2 to 2.8) Prolong bradycardia: ns Severe variable deceleration: ns Late deceleration: ns Association between abnormal FHR tracing patterns and cord pH < 7.15 & 5 min apgar score < 7 (second stage n = 1635) Mild or moderate variable deceleration: ns Decreased variability: ns Mild bradycardia: ns Tachycardia: ns Prolonged bradycardia: OR 3.6 (95% CI 1.2 to 11) Severe variable deceleration: OR 2.4 (95% CI 1.2 to 4) Late deceleration: OR 6.9 (95% CI 2.1 to 23) Decreased variability: ≤ 5 bpm Mild bradycardia: 90 < FHR < 120 bpm Tachycardia: 120 < FHR< 160 bpm Prolonged bradycardia: < 90 bpm, > 2.5 min	**Limitations** No separate data for Apgar and pH **Other information** Reassuring (normal) trace defined as: Any tracing with acceleration Had mild variables Had decreased variability Had mild bradycardia Had any above combination Non-reassuring (abnormal) trace defined as: No acceleration Severe or late deceleration Prolonged bradycardia Tachycardia any above combination Neonates were assessed to have immediate adverse outcomes if they: were admitted to level III, neonatal intensive care unit for > 24 hours and required oxygen support (intubation > 6 hrs, or > 24 hrs of > 40% oxygen supplementation) had significant complications (intracranieal haemorrahge, neonatal death) experienced neurological sequelae (seizure, persistent hypotonia at discharge)
Full citation Cardoso,C.G., Graca,L.M., Clode,N., A study on second-stage cardiotocographic patterns and umbilical blood acid-base balance in cases with first-stage normal fetal heart	**Sample size** n = 293 singleton term pregnancies. Normal 1st stage traces, analysed on all of second stage. Classified on modified Melchior and Barnard classification. n = 103 type 0 used as controls.	**Interventions** Type 0 Stable FHR during entire second stage Type 1a	**Details** n = 293 cases in which FHR monitoring was obtained during the last hour of the 1st stage and entire 2nd stage were evaluated. Arterial and venous umbilical blood was	**Results** **Umbilical artery acid base pH (2nd stage CTG types)** Type 0 7.24 ± 0.06 Type 1a	**Limitations** Unusual scoring system. Analysis not based on specific FHR abnormalities. Small numbers in more severe categories (2b: n = 13, 3: n = 14).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
rates, Journal of Maternal-Fetal Investigation, 5, 144-147, 1995 **Ref Id** 197264 **Country/ies where the study was carried out** Portugal **Study type** Cohort **Aim of the study** To examine the correlation between fetal heart rate (FHR) patterns during the 2nd stage of labour and umbilical blood acid based parameters **Study dates** Not specified **Source of funding** Not specified	**Characteristics** Instrumental vaginal birth performed in 10 cases of 0 type (9.7%), n =11 of type 1a (11.8%), n = 6 of type 1b (31.5%), n = 6 of 2a (16.6%), n = 9 of type 2b (69%), n = 10 of type 3 (71%) and n = 2 of type 4 (13.4). No other characteristics specified. **Inclusion criteria** Singleton pregnancy Term pregnancy (37-42 weeks gestation) No maternal and fetal pathology Vertex birth Spontanous or instrumental vaginal birth Normal fetal monitoring trace during the last hour of 2nd stage (FHR between 120 and 160 beats/min, variability > 5 beats/min, and absence of periodic pattern) **Exclusion criteria** Not specified	Mild variable decelerations <u>Type 1b</u> Moderate to severe variable decelerations or late decelerations with each contraction, returning to baseline inbetween <u>Type 2a</u> Baseline 90–120 bpm with decelerations <u>Type 2b</u> Basal FHR below 90 bpm, usually with reduced variability <u>Type 3</u> Basal FHR below 90 bpm, low variability, accelerations with contractions <u>Type 4</u> Basal FHR below 90bpm during final moments of 2nd stage only	obtained in all cases. n = 103 cases were included in type 0 (absence of FHR abnormalities during the 2nd stage) were used as a control group. FHR tracing was recorded via a spiral electrode applied to the fetal head and uterine contractions were measured by tocodynametery. Paper speed of the monitor was 1cm/min. <u>Analysis</u> Analysis of the tracing was independently interpreted and classified by two investigators that were blinded to the information regarding umbilical cord pH and cases. Acidemia was diagnosed when pH levels were more than one standard deviation below the mean level obtained in the control group. The 2nd stage of labour never exceeded 45 min	7.15 ± 0.07 p = ns <u>Type 1b</u> 7.19 ± 0.07 p = 0.0001 <u>Type 2a</u> 7.19 ± 0.06 p = 0.0001 <u>Type 2b</u> 7.06 ± 0.07 p = 0.0001 <u>Type 3</u> 7.09 ± 0.06 p = 0.0001 <u>Type</u> 4 7.19 ± 0.07 p = 0.01 **<u>Umbilical vein acid base pH (2nd stage CTG types)</u>** <u>Type 0</u> 7.30 ± 0.06 <u>Type 1a</u> 7.29 ± 0.07 p = ns <u>Type 1b</u> 7.22 ± 0.07 p = 0.0001 <u>Type 2a</u> 7.26 ± 0.06 p = 0.001 <u>Type 2b</u> 7.12 ± 0.07 p = 0.0001 <u>Type 3</u> 7.15 ± 0.06 p = 0.0001 <u>Type 4</u> 7.24 ± 0.06 p = 0.004 **<u>Early neonatal morbidity was found in n = 3 neonates:</u>** <u>Case 1</u> CTG pattern 1b Arterial pH 7.07 Morbidity: resuscitation Days in NICU: 2 <u>Case 2</u> CTG pattern 2b Arterial pH 7.00 Morbidity: grunting Days in NICU: 7 <u>Case 3</u> CTG pattern 2b Arterial pH 7.09 Morbidity: resuscitation Days in NICU: 4 Arterial and venous pH values significantly lower in types 1b and below compared with controls. Mean pH only < 7.20 in types 2b and 3.	**Other information** Beginning of 2nd stage: Defined as the moment of the initiation of pushing effort and full cervical dilatation
Full citation	**Sample size**	**Interventions**	**Details**	**Results**	**Limitations**
Dellinger,E.H., Boehm,F.H., Crane,M.M., Electronic fetal heart rate monitoring: early neonatal outcomes associated with normal rate, fetal	n = 898 Normal pattern n = 627	<u>Normal pattern</u> 110–160 bpm, minimal to moderate variability, with or without accelerations	Fetal heart rate data from all labouring women monitored at 2 institutions were examined. Tracings in the final hour before delivery were	Total normal n = 627 Total stress n =236 Total distress n = 8	Underpowered cohort due to imbalance between groups. Analysis between distress and normal for pH and Apgar highly specific but interpret with caution in view of numbers in each group.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
stress, and fetal distress, American Journal of Obstetrics and Gynecology, 182, 214-220, 2000 **Ref Id** 170635 **Country/ies where the study was carried out** USA **Study type** Cohort **Aim of the study** To examine the ability of well-defined classification system for electronic fetal heart rate (FHR) tracing to predict early neonatal outcome **Study dates** One hospital: July 1993 to February 1994 One hospital: February to June 1995 **Source of funding** Not specified	Stress pattern n = 263 Distress pattern n = 8 **Characteristics** Comparative characteristics not reported **Inclusion criteria** Singleton pregnancy > 32 weeks gestation **Exclusion criteria** Presence of anomalies or arrhythmias Multiple pregnancy Gestational age < 32 weeks Caesarean section before onset of labour Inability to obtain an adequate FHR tracing Traces were excluded from the study if ≥ 15 min during the final hour went untraced	<u>Stress pattern</u> > 160 bpm for > 5 minutes, minimal to moderate variability, moderate to severe variable decelerations, late decelerations or sinusoidal pattern <u>Distress pattern</u> < 110 bpm for > 5 minutes, moderate to severe variable decelerations with absent variability, late decelerations with absent variability, 110–160 bpm with absent variability and no accelerations	defined as normal, fetal stress, or fetal distress. Based on the standard care of the hospital all labouring women received electronic fetal heart monitoring. All tracings were stored after birth and reviewed at the later date by an observer blinded to the birth outcomes. The FHR tracing was evaluated for the one hour period preceding the birth.	<u>Umbilical pH < 7.00</u> Normal n = 0/627 Stress n = 2/263 (1.6%) Distress n = 2/8 (28.5%) p > 0.001 <u>NICU admission</u> Normal n = 29 Distress/Stress n = 25 <u>LSCS rate</u> Normal n = 75 Distress/Stress n = 4 <u>Stress/distress vs. normal</u> Sensitivity 68% Specificity 71% PPV 5% NPV 99%. Umbilical cord pH < 7.00 <u>Stress/distress vs. normal</u> Sensitivity 100% Specificity 66% PPV 3% NPV 100% <u>Results also on distress vs. normal</u> NPV for all outcomes > 98%	**Other information**

Full citation	Sample size	Interventions	Details	Results	Limitations
Ellison,P.H., Foster,M., Sheridan-Pereira,M., MacDonald,D., Electronic fetal heart monitoring, auscultation, and neonatal outcome, American Journal of Obstetrics and Gynecology, 164, 1281-1289, 1991 **Ref Id** 164084 **Country/ies where the study was carried out** Ireland **Study type** Retrospective cohort study **Aim of the study** To examine the relationship between a number of maternal, labour and delivery variables (including fetal heart rate [FHR] patterns) to neonatal outcomes	Original cohort from Dublin RCT. Two groups of FHR traces: electronic fetal monitoring (EFM) alone n = 2362 and EFM plus neurological examination n = 135 **Characteristics** Not specified **Inclusion criteria** Not specified **Exclusion criteria** Heavily stained meconium liquor Decreased amniotic fluid Abnormal heart rate on admission	All FHR variables	Data in this study are from a randomised control trial conducted in Dublin (comparing the effectiveness of electronic fetal monitoring and auscultation in improving the health of fetus during delivery and birth). For the purpose of this review only data on electronic fetal monitoring will be reported. Data for electronic fetal heart monitoring were available for both the 1st and 2nd stages of labour. The fetal heart rate monitoring was interpreted by an obstetrician who was blinded to the women's characteristics and neonatal birth outcomes. All newborns were examined physically and neurologically by a physician. FHR patterns were recorded separately. <u>Analysis</u> Frequencies were reviewed for all variables, as well as distributions and skews. Pearson correlation and biserial correlations for dichotomous variables were obtained and reviewed for each sample.	Correlation of specific fetal heart patterns to neonatal convulsions (n = 135): <u>1st stage of labour</u> Late deceleration r = 0.38, p < 0.001 Severe variable deceleration r = -0.04, p = ns Marked tachycardia r = -0.02 Moderate variable decelerations r = -0.02 Early decelerations r = 0.01 Normal baseline and variability r = -0.05 <u>2nd stage of labour</u> Late decelerations r = 0.38, p < 0.001 Early decelerations r = 0.01	No specifics of scoring for neurological examination specified **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates March 1981 to April 1983 **Source of funding** Not specified					
Full citation Gaffney,G., Flavell,V., Johnson,A., Squier,M., Sellers,S., Cerebral palsy and neonatal encephalopathy, Archives of Disease in Childhood Fetal and Neonatal Edition, 70, F195-F200, 1994 **Ref Id** 196440 **Country/ies where the study was carried out** UK **Study type** Retrospective cohort study **Aim of the study** To test the hypothesis that children born at term with cerebral palsy with signs of neurological dysfunction preceded by depression at birth (termed neonatal encephalopathy) differ from those without such signs in the frequency of antenatal and perinatal factors, and in the severity and characteristics of their impairment and disability **Study dates** 1984 to 1987 **Source of funding** Funded by Oxford Regional Health Authority	**Sample size** 141 case of cerebral palsy; UK hospital **Characteristics** No significant differences observed between the two groups (with neonatal encephalopathy [NE] and without neonatal encephalopathy) marital status, maternal disease, recurrent abortion, poor obstetric history, previous preterm birth, maternal smoking habit, and maternal age. More women in the 'without NE' group were primigravida compared with the 'with NE' group. Half the mothers of infants with neonatal encephalopathy (51/100) and mothers of infants with neonatal encephalopathy (20/41), had one or more complicating factors (antenatal infection, premature rupture of membranes, pre-eclampsia, severe pre-eclampsia, antepartum haemorrhage, previous infertility, induced conception, raised maternal serum alpha fetoprotein, polyhydramnios, reduced fetal movement, or complicated antenatal course). More women in the neonatal encephalopathy group had post-date pregnancy (> 41 weeks), induction of labour, 2nd stage of labour exceeding > 2 hours, meconium stained liquor, caesarean section or instrumental birth. There was no significant difference in augmentation use between the two groups. **Inclusion criteria** Singleton pregnancy Term pregnancy **Exclusion criteria** Children with major congenital abnormality Children in whom there was a definite postnatal cause for cerebral palsy such as meningitis or trauma	**Interventions** Ominous FHR pattern	**Details** Children with cerebral palsy born during the study period were identified from the Oxford health regional register of childhood impairment. The children with cerebral palsy were divided into those with signs of neonatal encephalopathy (with NE) and those without (without NE). This was based on the information recorded in the neonatal case notes. The clinical characteristics of the children in the study were described in terms of distribution of tone changes, as walking and non walking, and with or without intellectual deficit, vision loss, seizures, involuntary movement, or bulbar signs such as difficulty in swallowing.	**Results** **<u>Findings on cardiotocograph (CTG) in mothers of children with cerbral palsy with or without neonatal encephalopathy</u>** <u>Ominous first stage CTG</u> Without NE: n = 4/48 (8%) With NE: n = 13/27 (48%) OR 10.2 (2.9 to 36.4) <u>Ominous second stage CTG</u> Without NE: n = 19/45 (42%) With NE: n = 21/25 (84%) OR 7.2 (2.1 to 24.4) <u>Median duration of first stage abnormality (min)</u> Without NE: 48.5 (38 to 287) With NE: 200.0 (15 to 480) p = 0.3 <u>Median duration of second stage abnormality (min)</u> Without NE: 38 (8 to 287) With NE: 100.0 (12 to 480) p = 0.003 Follow-on data: significant association with major and minor impairment in encephalopathy group. Quadraplegia (OR 4.8; 95% CI 2.2 to 10.5) Hemiplegia (OR 0.3; 95% CI 0.1 to 0.8)	**Limitations** **Other information** Neonatal encephalopathy defined as: Depression at birth, based on a one minute apgar score of less than or equal to 6. Followed by evidence of neonatal neurological abnormality such as lethargy, coma, impaired respiration, seizures, and/or tone change
Full citation Giannubilo,S.R., Buscicchio,G., Gentilucci,L., Palla,G.P., Tranquilli,A.L., Deceleration area of fetal heart rate trace and fetal acidemia at delivery: A case-control study, Journal of Maternal-Fetal and Neonatal Medicine, 20, 141-144, 2007	**Sample size** Total n = electronic fetal monitoring (EFM) traces of 236 pregnancy n = 56 pregnancies met the inclusion criteria (Acidemia n = 26, Control = 30) **Characteristics**	**Interventions** EFM traces	**Details** From n = 410 third trimester cardiotocograph (CTG) tracings performed at the department of obstetrics and gynaecology, Belcolle Hospital during the study period, n = 236 with performed cord gas analysis were selected for inclusion. n = 56 pregnancies met the inclusion criteria (Acidemia n = 26,	**Results** <u>Number of decelerations (> 15bpm/15s) during the second stage of labour</u> Acidemia: 8.03 ± 3.77 Control: 4.64 ± 3.84) <u>Total deceleration area/cm^2/hour</u> Acidemia: 35.56 ± 11.87 Control: 17.81 ± 9.38	**Limitations** Small study with a large drop out **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 158821 **Country/ies where the study was carried out** Italy **Study type** Retrospective cohort **Aim of the study** To assess the correlation between the total deceleration area of the fetal heart rate (FHR) pre-delivery trace and intrapartum fetal acid-base status in a low risk population. **Study dates** January to August 2004 **Source of funding** Not reported	<u>Maternal</u> There were no significant differences observed between the two groups (normal and abnormal pH at birth) in maternal age, gestational age at delivery, primiparity, length of second stage of labour or operative delivery rate. The length of first stage of labour was statistically significantly longer in controls compared with acidemic group p < 0.001. <u>Neonatal</u> There were also no significant differences observed in birth weight, baby's sex, apgar score 1 min < 7 and apgar score 5 min < 7, or cord arterial pH. Cord base deficit was significantly higher in the acidemic group compared with controls p < 0.001. <u>CTG parameter (Acidemic n = 26, Control n = 30)</u> <u>Baseline heart rate</u> Acidemic 131.25 ± 9.19 Control 136.25 ± 10.14 <u>Number of decelerations > 15 bpm/15</u> Acidemic 8.03 ± 3.77 Control 4.64 ± 3.84 <u>Fetal deceleration area cm^2/h</u> Acidemic 17.81 ± 9.38 Control 35.56 ± 11.87 **Inclusion criteria** Normal FHR pattern (normal variability, presence of accelerations) Singleton pregnancy Caucasian race Vertex presentation Vaginal birth, no labour augmentation Term birth > 37 wks **Exclusion criteria** Technically uninterpretable trace Required emergency caesarean section (CS) because of maternal or fetal conditions (such as sign of placental insufficiency, cephalo-pelvic distribution) Previous CS Pre-existing heart or lung disease Carrying a baby with growth restriction or malformation		Control = 30). CTG was performed during second stage of labour at least one hour without interruption. Umbilical blood gas performed by collecting blood samples from cord artery and the pH < 7.2 was considered abnormal. A base deficit ≥ 12 mmol/l was considered the threshold of the fetal metabolic acidosis at delivery. Hospital records of each newborn were evaluated for Apgar, weight and neonatal complication. <u>Analysis</u> The deceleration area was calculated, after digital analysis, with Autocad System 2004. Statistical analysis performed with SPSS version 0.8 statistical package. Chi-square or Fisher's exact tests were used for comparison of proportions. Student's t-test was applied for comparisons of means.		
Full citation	**Sample size**	**Interventions**	**Details**	**Results**	**Limitations**
Gilstrap,L.C.,III, Hauth,J.C., Hankins,G.D., Beck,A.W., Second-	n = 277 cases with known arterial cord pH samples and satisfactory second stage traces	Uncomplicated bradycardia or tachycardia	Cord pH was determined within 5 minutes of birth and specimens	**<u>Correlation of normal and abnormal traces and cord pH (mean ± SD)</u>**	Unclear for how long abnormalities were present for

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
stage fetal heart rate abnormalities and type of neonatal acidemia, Obstetrics and Gynecology, 70, 191-195, 1987 **Ref Id** 195342 **Country/ies where the study was carried out** USA **Study type** Cohort study **Aim of the study** To examine the incidence and type of acidaemia, degree of buffer base deficit, and immediate neonatal outcome in relation to baseline second stage fetal heart rate (FHR) patterns before delivery **Study dates** June 1985 to April 1986 **Source of funding** Not specified	**Characteristics** White race: 83% Maternal age 20-29 years old: 71% Primiparous: 51% **Inclusion criteria** Term birth Vaginal birth Vertex presentation **Exclusion criteria** <u>Women with complication such as:</u> Diabetes Chronic hypertension Preeclampsia Acute chorioamnionitis Significant medical illness Women with abnormal FHR such as late decelerations, moderate or severe variable decelerations, bradycardia and tachycardia		were obtained from either the umbilical artery or vein. Acidosis defined as a arterial cord pH of less than 7.20. Fetal heart rate tracings were obtained during the second stage via a scalp electrode. The tracing during the 2nd stage (before expulsion of head) was evaluated for baseline FHR abnormality and variability. Only women with either a normal FHR pattern or obvious baseline changes, consisting of bradycardia or tachycardia, were included. Analysis The FHR trace was independently analysed by both authors without knowledge of blood gas results. Traces were only included if the interpretation was in agreement (there was disagreement in < 2% of the traces)	Normal (n = 129) 7.29 ± 0.6 Tachycardia (n = 32) 7.25 ± 0.5 p < 0.05 Mild bradycardia (n = 53) 7.23 ± 0.7 p < 0.05 Moderate or severe bradycardia (n = 63) 7.22 ± 0.7 p < 0.05	Not consecutive cases, hence subject to selection bias **Other information** <u>Uncomplicated bradycardia:</u> Mild (90–119 bpm) Moderate (60–89 bpm) Severe (< 60 bpm) Tachycardia (> 160 bpm)
Full citation Gilstrap,L.C.,III, Hauth,J.C., Toussaint,S., Second stage fetal heart rate abnormalities and neonatal acidosis, Obstetrics and Gynecology, 63, 209-213, 1984 **Ref Id** 195341 **Country/ies where the study was carried out** USA **Study type** Prospective cohort study **Aim of the study** To examine the correlation of baseline fetal heart rate (FHR) abnormalities in the last 10 minutes of the second stage of labour with neonatal acid-base status	**Sample size** n = 833 cases with cord pH samples and interpretable traces in the last 10 minutes of labour **Characteristics** **<u>Demographic characteristics:</u>** White race: 75% Maternal age 20-29 years old: 65% Primiparous: 85% Term pregnancy: 98% **Inclusion criteria** If a cord pH was obtained If there was satisfactory fetal heart tracing during the last minutes of 2nd stage	**Interventions** Uncomplicated bradycardia Uncomplicated tachycardia	**Details** All infants during the study period, whose delivery was by forceps, were included in the study. Cord pH was determined within 5 minutes of birth and specimens were obtained from either the umbilical artery or vein. Acidosis was defined as a pH of less than 7.20. Fetal heart rate tracings were obtained during the second stage via a scalp electrode. The tracing during the last 10 mins of delivery (before expulsion of the head) was evaluated for FHR abnormalities. Only women with either a normal FHR pattern or obvious baseline changes, consisting of bradycardia or tachycardia, were included.	**Results** **Correlation of n = 833 normal and abnormal traces and cord pH** Acidosis: Normal n = 19/430 (4%) Abnormal n = 80/403 (20%) p < 0.001 **Association of mild bradycardia and umbilical cord pH** Acidosis: Normal n = 19/430 (4%) Abnormal (with mild bradycardia [present 1-3 min in 17% and > 3 in 20%]) n = 30/165 (18%) p < 0.001 Association of moderate bradycardia and umbilical cord pH Acidosis: Normal n = 19/430 (4%) Abnormal (with mild bradycardia [present 1-3 min in 25% and > 3 in 29%]) n = 33/121 (27%) p < 0.001 Association of tachycardia (mild and marked) and umbilical cord pH Acidosis: Normal n = 19/430 (4%) Abnormal (with mild or marked tachycardia) n = 17/117 (18%) p < 0.001	**Limitations** Not consecutive cases, high risk of selection bias Unclear how and by whom data were analysed Blood for cord pH was taken from umbilical artery or vein. **Other information** **Uncomplicated bradycardia:** Mild (90–119 bpm) Moderate (60–89 bpm) Severe (< 60 bpm) **Uncomplicated tachycardia** Mild (160–179 bpm) Marked (> 180 bpm)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates August 1979 to January 1983 **Source of funding** Not specified	**Exclusion criteria** Women with significant FHR abnormalities during the 1st stage of labour such as: Decelerations Persistent pattern of bradycardia Tachycardia Women with significant FHR abnormalities, such as late or moderate or severe variable decelerations were excluded from the analysis			**Umbilical artery pH < 7.20** Mild tachycardia: < 3 minutes: 4/42 (10%) > 3 minutes: 9/54 (17%) Marked tachycardia: < 3 minutes: 2/5 (40%) > 3 minutes: 2/16 (13%) Mild bradycardia: < 3 minutes: 19/110 (17%) > 3 minutes: 11/55 (20%) Moderate to severe bradycardia: < 3 minutes: 19/72 (26%) > 3 minutes: 14/49 (29%)	
Full citation Hadar,A., Sheiner,E., Hallak,M., Katz,M., Mazor,M., Shoham-Vardi,I., Abnormal fetal heart rate tracing patterns during the first stage of labor: Effect on perinatal outcome, American Journal of Obstetrics and Gynecology, 185, 863-868, 2001 **Ref Id** 169256 **Country/ies where the study was carried out** Israel **Study type** Cohort **Aim of the study** To evaluate perinatal outcomes of infants who had pathologic fetal heart rate (FHR) tracings during the first stage of labour, in comparison with pregnancies with normal tracings. **Study dates** January to June 2000 **Source of funding** Not specified	**Sample size** n = 601 FHR tracing (pregnancies); n = 301 abnormal pattern, n = 300 normal pattern **Characteristics** Women with abnormal tracing were more often nulliparous and delivered infants with significantly lower birth weight, compared with women with normal tracing. There were no significant differences observed in FHR patterns in maternal age, ethnic origin, gravidity, gestational age and sex of the baby. Women with abnormal tracing had a significantly higher rate of oligohydramnios and oxytocin augmentation in labour. Women with abnormal FHR patterns had a significantly longer duration of 1st stage labour, and a higher incidence of thick meconium stained amniotic fluid. **Inclusion criteria** Low risk women Fetus at vertex presentation Normal FHR pattern Women with interpretable external fetal monitoring tracing during the labour and birth Cases with values taken immediately after birth **Exclusion criteria** Congenital abnormalities Preexisting maternal heart or lung disease Fetuses with intrauterine growth retardation Women in need of emergency caesarean section	**Interventions** Fetal heart rate tracing (normal vs. abnormal)	**Details** The perinatal outcomes of 301 infants born at 37 to 42 weeks of gestation with pathologic fetal heart rate patterns during the first stage of labour were compared with 300 infants with normal fetal heart rate tracing patterns. Data were collected prospectively and demographic information was obtained on each woman's admission to the hospital. The labour room team evaluated each woman's FHR tracing hourly and documented the results. The same obstetrician collected the data after assessing the FHR tracing and the delivery chart. The data were collected prospectively. Tracings were interpreted with the use of the National Institute of Child Health and Human Development fetal heart rate monitor guidelines. Umbilical cord blood was collected immediately after birth and all blood gas analysis performed within 10 minutes of birth. Analysis SPSS version 8.0 package was used for the analysis. Chi square test used for comparison between the two groups for the categorical variable and Student's t-test was used for continuous variables with normal distribution. Multiple logistic regression was used to investigate the independent contribution of obstetric factors to abnormal fetal heart patterns and to investigate the contribution of those factors to the occurrence of fetal acidosis (pH 7.2 and base deficit ≥ 12)	**Results** Arterial pH 7.2 Abnormal FHR n = 48/301 (16%) Normal FHR n = 14/300 (4.7%) p < 0.001 Arterial pH 7.1 Abnormal FHR n = 10/301 (3.3%) Normal FHR n = 2/300 (0.7%) p < 0.02 Base deficit ≥ 12 Abnormal FHR n = 25/301 (8.3%) Normal FHR n = 7/300 (2.3%) p = 0.001 Admission to NICU Abnormal FHR n = 4/301 (1.3%) Normal FHR n = 4/300 (1.3%) p < 0.343 Vacuum birth Abnormal FHR n = 33/301 (11.0%) Normal FHR n = 12/300 (4%) Caesarean birth Abnormal FHR n = 46/301 (15%) Normal FHR n = 20/300 (6.3%) Spontaneous vaginal birth Abnormal FHR n = 222/301 (73.8%) Normal FHR n = 268/300 (89.3%) Factors associated with pathologic fetal heart rate monitoring during the first stage of labour in a multivariable analysis Hydramnios: odds ratio 7.68 (95% CI, 1.75% to 33.63%), Oligohydramnios: odds ratio 2.74 (95% CI, 1.01% to 7.39%), Presence of meconium-stained amniotic fluid: odds ratio 1.91 (95% CI, 1.03% to 3.3%) Pathological fetal heart patterns during the 1st stage of labour (compared with normal tracing n = 300 associated with fetal acidosis (pH < 7.2 and base deficit ≥ 12) Late deceleration (yes/no): odds ratio 17.5 (95% CI, 1.6 to 185.7) p = 0.01 Variable deceleration < 70 bpm (yes/no): odds ratio 3.9 (95% CI, 1.3 to 11.7) p = 0.01 Pathologic FHR during the 1st stage of labour (yes/no): odds ratio 2.86 (95% CI, 0.3 to 24.4) p = 0.336	**Limitations** **Other information** Tracings were interpreted with the use of National Institute of Child Health Development Research Planing Workshop Guideline (NICHD) Abnormal pH was defined as: pH 7.2 in 2 separate analyses Base deficit of ≥ 12 mmol/l was considered to be diagnostic of fetal metabolic acidosis at birth

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Previous Caesarean section				
Full citation Heinrich,J., Elective fetal monitoring and obstetrical operative frequency, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 14, 143-152, 1982 **Ref Id** 196602 **Country/ies where the study was carried out** Germany **Study type** Cohort **Aim of the study** To evaluate the influence of fetal monitoring on obstetric operation rates with emphasis on fetal heart frequency (FHF). **Study dates** 1977 to 1978 and 1979 to 1981 (additional group) **Source of funding** Not specified	**Sample size** n = 2694 unselected deliveries n = 5000 elective monitored women (additional group) **Characteristics** Unclear gestation range/risk range **Inclusion criteria** Not specified **Exclusion criteria** Not specified	**Interventions** All FHR variables. Grouped into scoring system <u>Normal</u> Baseline 120–160 bpm; constant mild bradycardia; variability 10– 25 bpm; sporadic variable declarations; accelerations; mild variable deceleration <u>Warning</u> Tachycardia; variability < 10 bpm or > 25 bpm; periodic accelerations; moderate variable decelerations; early decelerations <u>Severe</u> Transient bradycardia; severe variable decelerations; prolonged decelerations <u>Hypoxia</u> Final bradycardia; variability 0–5 bpm; typical late decelerations	**Details** Digital display fetal monitors were used recording several tocometric parameters such as amplitude, frequency, base tonus and Montevideo units of labor. If the measured values exceeded an upper limit, an automatic alarm signal was activated. Arterial umbilical pH was carried out for all liveborns. The collected data included identification of the patient, results of medical history as well as of clinical and laboratory examinations and a final review of the course of pregnancy, delivery and post-partum period. The validity of the FHF-classification was demonstrated in 2694 unselected deliveries (June 1977/1978) by comparison with postnatal measurement of acid-base balance and Apgar scoring. The relation of obstetric operation rate, values of acid-base balance in umbilical arteria and FHF-parameters were also studied in an additional group of 5000 elective monitored patients (November 1979-1981). Data analysis The automated data analysis was made by means of a digital computer system (ES 1040).	**Results** <u>Umbilical artery pH</u> Significant difference at pH < 7.20 between severe and hypoxic categories compared to warning and normal categories. **<u>FHF parameter in the 2nd stage of labour (30 min antepartum) and pH of umbilical arteria</u>** <u>Normal classification (n = 1080)</u> Normal pH (pH > 7.20): 1043/1080 (96.6%) Preacidosis (pH 7.25 - 7.20): 27/1080 (2.5%) Acidosis (pH < 7.20): 10/1080 (0.9) <u>Warning symptoms (n = 1133)</u> Normal pH (pH > 7.20): 1095/1133 (96.7%) Preacidosis (pH 7.25 - 7.20): 27/1133 (2.4%) Acidosis (pH < 7.20): 11/1133 (0.9) <u>Severe functional hemodynamic (n = 431)</u> Normal pH (pH > 7.20): 357/431 (93.0%) Preacidosis (pH 7.25 - 7.20): 48/431 (11%) Acidosis (pH < 7.20): 26/451 (6.0%) <u>Hypoxia (n = 50)</u> Normal pH (pH > 7.20): 30/50 (60.0%) Preacidosis (pH 7.25 - 7.20): 11/50 (22%) Acidosis (pH < 7.20): 9/50 (18%)	**Limitations** Small numbers in hypoxic category Not possible to determine gestation or risk categories **Other information**
Full citation Honjo,S., Yamaguchi,M., Umbilical artery blood acid-base analysis and fetal heart rate baseline in the second stage of labor, Journal of Obstetrics and Gynaecology Research, 27, 249-254, 2001 **Ref Id** 195455 **Country/ies where the study was carried out** Japan **Study type** Cohort **Aim of the study** To evaluate the correlation between umbilical arterial acidemia and second-stage baseline fetal heart rate (FHR)	**Sample size** n = 365 **Characteristics** All subjects in the study were Japanese, no further characteristics were specified **Inclusion criteria** Term pregnancy (37 - 42 weeks) Vertex presentation Vaginal birth **Exclusion criteria** Women with complication such as: Diabetes Pre-eclampsia Multiple gestation	**Interventions** FHR tracing with either normal or baseline abnormality consisting of bradycardia or tachycardia during the 2nd stage of labour	**Details** Data were collected from n = 365 newborns, born during the study period in maternity ward of a hospital in Takasaki city. Based on the hospital policy, umbilical cord artery blood was taken from all newborns for blood gas determinations within 5 minutes of birth. FHR monitoring was performed in the second stage. Fetal heart rate tracings were obtained for as long as possible during the second stage of labour. Babies with marked periodic FHR abnormalities were excluded from the analysis. Therefore, in this study FHR tracings with either normal or baseline abnormality consisting of bradycardia or tachycardia were evaluated. The cord was clamped immediately after birth, and the blood samples were taken as soon afterwards as possible.	**Results** Umbilical arterial acidemia occurred in 54.1% of the newborns with moderate to severe bradycardia, in 27.3% with mild bradycardia, and in 19.3% with tachycardia, compared with only 1.3% of those with a normal FHR (p < 0.001). **<u>Umbilical cord pH and blood gas analysis in newborn with normal and abnormal FHR tracing</u>** <u>pH</u> Normal (n = 236) 7.31 ± 0.05 Tachycardia (n = 57) 7.22 ± 0.11 (p < 0.001 as compared with normal) Mild bradycardia (n = 11) 7.25 ± 0.06 (p < 0.01 as compared with normal) Moderate to severe bradycardia (n = 61) 7.18 ± 0.06 (p < 0.001 as compared with normal) <u>Base excess</u> Normal (n = 236) - 5.2 ± 2.8 Tachycardia (n = 57) - 9.5 ± 4.5 (p < 0.001 as compared with normal) Mild bradycardia (n = 11) -8.7 ± 4.4 (p < 0.05 as compared with normal) Moderate to severe bradycardia (n = 61) -10.2 ± 3.5 (p < 0.001 as compared with normal)	**Limitations** **Other information** The FHR definition proposed by the National Institue of Child Health and HUman Development Research Planing Workshop was used: Abnormal tracing: - Baseline 110 - 160 bpm - Variability < 5 bpm - No periodic deceleration - The baseline FHR was taken as approx. mean FHR rounded to increments of 5 bpm duing a 10 minute segment The baseline tachycardia and bradycardia was defined as: - Mild bradycardia: baseline FHR between 90 - 109 bpm for ≥ 10 minutes - Moderate to severe bradycardia: baseline FHR < 90 bpm for ≥ 10 minutes - Tachycardia: baseline FHR of 160 bpm for ≥10 minutes The decrease from the baseline was taken as ≥ 15 bpm, lasting ≥ 2 minutes, but < 10 minutes. Newborn acidemia was defined as umbilical cord pH < 7.2, a pCO_2 65 mmHg or lower, and bicarbonate 17.3 mmol/l or lower

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
abnormalities in Japanese newborn infants. **Study dates** 1998 to 1999 **Source of funding** Not specified	Chronic hypertension Chorioamnionitis Significant medical illness Other pregnancy complications Newborns with fetal heart rate abnormality during the 1st stage of labour including: Late deceleration Moderate or severe variable deceleration Any presistant nonperiodic patterns of bradycardia, or tachycardia			<u>Number of newborns with an umbilical arterial pH < 7.2 in different FHR patterns</u> Normal FHR pattern n = 3/236 (1.3%) Tachycardia n = 11/57 (19.3%) Mild bradycardia n = 3/11 (27.3%) Moderate to severe bradycardia n = 33/61 (54.1%) p < 0.001 (all 3 groups compared with normal group)	Metabolic acidemia was defined as an umbilical pH < 7.2, a pCO_2 49.2 mmHg or lower, and bicarbonate 17.3 mmol/l, or lower
Full citation Krebs,H.B., Petres,R.E., Dunn,L.J., Smith,P.J., Intrapartum fetal heart rate monitoring. VI. Prognostic significance of accelerations, American Journal of Obstetrics and Gynecology, 142, 297-305, 1982 **Ref Id** 159500 **Country/ies where the study was carried out** USA **Study type** Cohort study **Aim of the study** To assess the prognostic value of accelerations in early labour and just prior to delivery **Study dates** January 1975 to June 1977 **Source of funding** Not reported	**Sample size** n = 1996 fetal heart rate (FHR) traces **Characteristics** Not specified **Inclusion criteria** Term, singleton pregnancies > 34 weeks gestation **Exclusion criteria** Not specified	**Interventions** Periodic variable and uniform accelerations	**Details** Fetal tracings were obtained from women in labour during the study period. The time of monitoring exceeded 2 hours and included at least 30 minutes of the first stage of labour. The FHR tracings were reviewed by the senior author. The average monitoring time was 6.2 hours. Indications for monitoring were preeclampsia and eclampsia (10.2%), meconium stained liquor (14.2%), premature rupture of membranes (16.8%), and other high risk factors such as post-datism, intrauterine growth retardation, diabetes (7.1%), and oxytocin for indicated induction or augmentation (23%). Monitoring was elective in 46% of the women. The first and last 30 minutes of FHR tracing obtained from women in labour were evaluated.	**Results** Mode of birth: Caesarean section: 16.2% (n = 241 in the 1st stage of labour, n = 83 in the second stage of labour) **<u>Prognostic significance of sporadic accelerations in the first 30 minutes of monitored labour: ≥ 3 accelerations per 30 minutes</u>** <u>Perinatal mortality</u> Elective n = 2 (0.2%) Non elective (with high risk factors) n = 4 (0.4%) P > 0.5 **<u>Prognostic significance of sporadic accelerations in the first 30 minutes of monitored labour: < 3 accelerations per 30 minutes</u>** <u>Perinatal mortality</u> Elective n = 3 (2.8%) Non elective (with high risk factors) n = 12 (9.8%) P < 0.05	**Limitations** Unbalanced cohort with only 86 (4%) adverse outcomes. Not clear if the outcome assessors were blinded to outcomes. Unclear data analysis. **Other information** FHR scoring for internal FHR monitoring; for each of the criteria 0 to 2 points may be given so that a score of 0 to 10 may be obtained <u>Baseline FHR</u> < 100, > 180 = 0 score 100 - 119, 161 - 180 = 1 score 120 - 160 = 2 score <u>Variability (oscillatory amplitude [bpm])</u> < 3 = 0 score 3 - 5 > 25 = 1 score 6 - 25 = 2 score <u>Variability (frequency [bpm])</u> < 3 = 0 score 3 - 6 = 1 score > 6 = 2 score <u>Acceleration/30 min</u> 0 = 0 score period, 1 - 4 sporadic = 1 score ≥ 5 sporadic = 2 score <u>Deceleration/30 min</u> Late, severe variable, atypical variable = 0 score Mild variable, moderate variable = 1 score None, early deceleration, dip 0 = 2 score Acceleration defined: Transient increase in the FHR bpm above the baseline FHR. Sporadic accelerations occur independently from uterine contractions. Uniform sporadic accelerations have a rounded configuration, whereas variable sporadic accelerations differ from one another and abruptly leave and return to the baseline FHR. Periodic accelerations occur during the uterine contractions and are

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					called uniform periodic accelerations. Variable accelerations are varied in shape and often develop notching, which widen, deepen, and progress into variable decelerations.
Full citation Larma,J.D., Silva,A.M., Holcroft,C.J., Thompson,R.E., Donohue,P.K., Graham,E.M., Intrapartum electronic fetal heart rate monitoring and the identification of metabolic acidosis and hypoxic-ischemic encephalopathy, American Journal of Obstetrics and Gynecology, 197, 301-308, 2007 **Ref Id** 121224 **Country/ies where the study was carried out** USA **Study type** Case controlled study **Aim of the study** To determine whether electronic fetal monitoring (EFM) can identify fetuses with metabolic acidosis and hypoxic-ischemic encephalopathy **Study dates** April 1991 to February 2006 **Source of funding** Not specified	**Sample size** Cases n = 107 Control n = 107 **Characteristics** The gestational age distribution: Born ≥ 37 weeks: 64% Born 29 - 36 weeks: 30% Born 24 - 28 weeks: 6 % Born by caesarean section: 71% **Inclusion criteria** All infants born with metabolic acidosis **Exclusion criteria** Not specified	**Interventions** Electronic fetal monitoring	**Details** Infants who were born with metabolic acidosis born in a single university were identified. The cases were 107 non anomalous chromosomally normal fetuses with an umbilical arterial pH < 7.0 and base excess < or = 12 mmol/l. Controls were the subsequent delivery that was matched by gestational age and mode of delivery. The last hour of the electronic fetal monitoring before delivery was evaluated by 3 obstetricians who were blinded to the outcome using a guideline developed by National Institute of Child Health and Human Development (NICHD) research planning workshop. Within the case group, n = 13 neonates had neurological complications (including 8 with seizures, n = 1 with grade 3 intra ventricular haemorrhage, n= 4 died). All 13 infants had clinical features that were consistent with at least Sarnat stage 2 (moderate hypoxic ischemic encephalopathy [HIE]). The EFM tracings of these 13 infants were compared with those of the other 94 infants with metabolic acidosis who had no neurologic injury.	**Results** Cases had a significant increase in late and prolonged decelerations/hour and late decelerations/contractions. Those fetuses with HIE had significant increases in bradycardia, decreased variability, and non reactivity but no difference in late or variable decelerations/hour. **<u>Identification of HIE (FHR parameters during the last hour before delivery)</u>** <u>Time baselines < 110 beats/min</u> Area under receiver operating characteristic curve: 0.56 Sensitivity: 15.4% Specificity: 98.9% Positive predictive values (PPV): 66.7%, Negative predictive values (NPV): 89.4% <u>Baseline variability < 5 beats/min</u> Area under receiver operating characteristic curve: 0.69 Sensitivity: 53.8% Specificity: 79.8% PPV: 26.9% NPV: 92.6% <u>Non-reactive</u> Area under receiver operating characteristic curve: 0.65 Sensitivity: 92.3% Specificity: 61.7% PPV: 2.7% NPV: 82.9% <u>all 3 abnormalities</u> Area under receiver operating characteristic curve: 0.82 Sensitivity: 7.7% Specificity: 98.9% Positive predictive values: 50.0% Negative predictive values: 88.6%	**Limitations** **Other information** Fetal metabolic acidosis and HIE are associated with significant increases in electronic fetal monitoring abnormalities, but their predictive ability to identify these conditions is low.
Full citation Low,J.A., Pickersgill,H., Killen,H., Derrick,E.J., The prediction and prevention of intrapartum fetal asphyxia in term pregnancies, American Journal of Obstetrics and Gynecology, 184, 724-730, 2001 **Ref Id** 197178 **Country/ies where the study was carried out** Canada **Study type** Cohort	**Sample size** n = 166 term pregnancies with confirmed fetal asphyxia **Characteristics** **Inclusion criteria** Term pregnacies base deficit > 12mmol/l **Exclusion criteria**	**Interventions** Fetal heart rate patterns	**Details** The outcomes of n = 166 term pregnancies with biochemically confirmed fetal asphyxia (umbilical artery base deficit at delivery, > 12 mmol/l) were examined. The population included n = 83 women who delivered by caesarean section matched with 83 women delivered vaginally. Antepartum and intrapartum clinical risk factors and neonatal complications were documented. Fetal assessments included fetal heart rate patterns in the fetal heart rate record and fetal capillary blood gas and acid-base assessments. Each caesarean birth was matched with a vaginal birth on the basis of gestational age (± 1 week), birth weight (± 100g) and umbilical artery acid base deficit > 12 mmol/l in the same year. The assessment of electronic FHR	**Results** Fetal asphyxial exposures were as follows: mild, n = 140; moderate, n = 22; and severe, n = 4. <u>Mode of birth in mild feta asphyxia</u> Caesarean section n = 67 (n 24/67 had meconium stained amniotic fluid) vaginal birth n = 73 (n = 32/67 had meconium stained amniotic fluid) <u>Mode of birth in moderate or severe fetal asphyxia</u> Caesarean section n = 16 (n = 4/16 had meconium stained amniotic fluid) vaginal birth n = 10 (n = 4/10 had meconium stained amniotic fluid) **<u>Predictive and non-predictive FHR patterns according to mild fetal asphyxia vrsus moderate or severe fetal asphyxia</u>** <u>Mild asphyxia</u> predictive pattern n = 89 Nonpredictive FHR pattern n = 25 No record n = 26	**Limitations** **Other information** Fetal asphyxia was classified as mild, moderate, or severe on the basis of umbilical artery base deficit (cutoff > 12 mmol/l) and neonatal encephalopathy and other organ system complications **<u>FHR criteria predictive of fetal asphyxia:</u>** Absent or minimal baseline variability and late or prolong decelerations The FHR patterns are based on the findings in six 10 minute cycle of FHR recording: - Absent baseline variability, usually with repretitive cycles (≥ 2) of the late or prlonged deceleration - Repretitive cycles (≥ 2) of both minimal baseline variability and late or prolong decelerations - Repretitive cycles (≥ 2) of either minimal baseline variability or late or prolonged deceleration - One cycle of either mimnimal baseline variability or late or prolong decelerations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To examine the roles of clinical risk scoring, electronic fetal heart rate monitoring, and fetal blood gas and acid-base assessment in the prediction and prevention of intrapartum fetal asphyxia in term pregnancies. **Study dates** Not reported **Source of funding** Not specified			record was the interpretation of clinician in charge (outlined by medical record). Analysis Statistical analysis included Student's t test. No further details provided	Moderate or severe asphyxia predictive pattern n = 20 Nonpredictive FHR pattern n = 4 No record n = 2 Classification of FHR patterns in 26 pregnancies with moderate or severe asphyxia Predictive n = 13 Suspect n = 7 Nonpredictive n = 3 No FHR monitoring record n = 3	- no cycle of either minimal baseline variability or late or prolonged decelerations **Criteria for classification of FHR as predictive, suspect, and nonpredictive of fetal asphyxia on the basis of a 10 minute cycle of FHR recordings** Predictive Absent (cycle) ≥ 1 and late or prolong decelerations ≥ 2 or Minimal (cycle) ≥ 2 and late or prolong decelerations ≥ 2 Suspect Minimal (cycle) ≥ 2 and late or prolong decelerations ≥ 0/1 or Minimal (cycle) ≥ 0/1 and late or prolong decelerations ≥ 2 Nonpredictive Minimal (cycle) 1 and late or prolong decelerations 0 or Minimal (cycle) 0 and late or prolong decelerations 1 or Minimal (cycle) 0 and late or prolong decelerations 0 **Classification of intrapartum fetal asphyxia** Mild asphyxia Metabolic acidosis (base deficit ≥ 12): present Encephalopathy: minor* present or not present Cardiovascular, repiratory and renal complications: minor† present or not present Moderate asphyxia Metabolic acidosis (Base deficit ≥ 12): present Encephalopathy: moderate** present Cardiovascular, repiratory and renal complications: moderate †† or severe††† present or not present Severe asphyxia Metabolic acidosis (Base deficit ≥ 12): present Encephalopathy: severe* present** Cardiovascular, repiratory and renal complications: moderate †† or severe†† present * Irritability or jitteriness ** Profound lethargy or abnormal tone *** Coma or abnormal tone with seizure † Cardiovascular: with bradycardia (≤ 100 beats/min) or tachycardia (≥ 100 beats/min), repiratory: supplementary oxygen was required, †† Cardiovascular: with hypertention or hypotention, respiratory: if positive pressure or ventilation > 24 hours were required, renal: elevation of serum creatinine level (> 100 mmol/l) ††† With abnormal electrocardiographic or echocardiographic findings, respiratory: if mechanical ventilation >24 hours were required, renal: anuria or oliguria (< 1 ml/kg per hour)
Full citation Low,J.A., Victory,R., Derrick,E.J., Predictive value of electronic fetal monitoring for intrapartum fetal asphyxia with metabolic acidosis, Obstetrics and Gynecology, 93, 285-291, 1999 **Ref Id** 196968 **Country/ies where the study was carried out**	**Sample size** n = 71 term infants with base deficits > 16 mmol/l n = 71 term infants with base deficits < 8 mmol/l Studied over 4 hours prior to delivery (divided into 10-minute cycles) **Characteristics** No significant differences between the asphyxia and control group observed in maternal age, parity, medical and obstetric history or birth characteristics. Higher rate of	**Interventions** All FHR variables	**Details** A matched case control study conducted during the study period. n = 142 term infants who had the blood gas and acid base assessment at delivery were selected. Each case in the asphyxia group (infants with umbilical artery > 16 mmol/l) was matched with a control infant whose umbilical artery base deficit was < 8 mmol/l. Matching was performed based on the birth weights (± 150 g) and gestational age (± 1 week). The control infant was the next one after	**Results** Predictive value of abnormal FHR variables for acidosis Absent baseline variability (> 10 minutes) with late and/or prolonged decelerations: sensitivity - 17% specificity - 98% positive predictive value (PPV) - 18 negative predictive value (NPV) - 98.3 Minimal baseline variability (> 20 minutes) and late and/or prolonged decelerations (> 20 minutes): sensitivity - 46% specificity - 89% PPV - 8 NPV - 98.7	**Limitations** Good NPV for all features individually. Poor specificity in combination. Baseline tachycardia, variable and early decelerations not discriminative features **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Case control study **Aim of the study** To examine the predictive value of each fetal heart rate (FHR) variable and of patterns of FHR variables for fetal asphyxia during labour **Study dates** May 1984 to May 1996 **Source of funding** Not specified	meconium stained liquor in the asphyxia group compared with the control group (23/71 vs. 12/71 p = 0.05). <u>Mean birth weight</u> Asphyxia group 3,412 ± 472 Control group 3,426 ± 459 <u>Caesarean section rate</u> Asphyxia group 23/71 Control group 11/71 p = 0.01 **Inclusion criteria** For infants in the asphyxia group: - Umbilical artery base deficit > 16 mmol/l Infants in control group: - Umbilical artery base deficit < 8 mmol/l **Exclusion criteria** Not specified		the asphyxia case that met the criteria. The severity of asphyxia was classified as mild (n = 41), moderate (n = 17) or severe (n = 13) on the basis of short term outcome or expressed by newborn encephalopathy and other newborn organ system complications.	<u>Minimal baseline variability (> 20 minutes) or late decelerations and/or prolonged decelerations (> 20 minutes):</u> sensitivity - 75% specificity - 57% positive predictive value - 3.5 negative predictive value - 99.1 <u>Minimal baseline variability (10 minutes) and/or late and/or prolonged decelerations (10 minutes):</u> sensitivity - 93% specificity - 29% PPV - 2.6 NPV - 99.5	
Full citation Menihan,C.A., Phipps,M., Weitzen,S., Fetal heart rate patterns and sudden infant death syndrome, JOGNN - Journal of Obstetric, Gynecologic, and Neonatal Nursing, 35, 116-122, 2006 **Ref Id** 117077 **Country/ies where the study was carried out** USA **Study type** Retrospective case control study **Aim of the study** To determine differences in electronic fetal monitoring patterns between infants who died of sudden infant death syndrome (SIDS) and controls. **Study dates** Between 1990 and 1998 **Source of funding** Association of Women's Health, Obstetrics, and neonatal Nurses Philips Grant	**Sample size** Cases n = 29 Controls n = 98 **Characteristics** There were no significant differences observed between the two groups in previous live birth, any obstetric and medical conditions (mixed population), maternal surgeries, medication and vitamins taken during pregnancy and prior infant birth weight < 2500g. Compared with controls (n = 98), the mothers whose infants subsequently died of SIDS (n = 29), were younger (22 vs. 28 years; p < 0.01), were more likely to receive Medicaid health insurance (odds ratio 4.6; confidence interval 1.9 to 11.2), were more likely to be unmarried (odds ratio 5.2; confidence interval 2.1 to 12.8), had less intention to breastfeed (26% vs. 57%), and were more likely to smoke (odds ratio 4.6; confidence interval 9 to 11.2). **Inclusion criteria** Infants born between 1990 and 1998 who subsequently died of sudden infant death syndrome (SIDS) and controls. **Exclusion criteria** Not specified	**Interventions** Electronic fetal heart monitoring (EFM)	**Details** Data were obtained from 127 infants born during the study period at Women and Infants Hospital in Rhode Island. Thirty two infants (n = 32) who had been born at the hospital were chosen as potential cases and and the control infants for each of 32 SIDS cases were selected by computer, matching the day of birth for each case (unclear if mode of birth was matched). A total of 96 infants were identified for the control group. The birth certificates of each of 32 SIDS babies were reviewed by one of the researchers for confirmation of autopsy result. 29/32 infants were confirmed as SIDS and included in the study. The reasons for death in three other infants were unclear - SIDS was listed as a possible diagnosis in their death certificate. <u>Sample size</u> For the sample size calculation it assumed 50% of SIDS victims would have minimal or absent variability in the EFM readings, and 20% of controls would have minimal or absent variability in their EFM readings. Therefore 3 control per case incorporated and an alpha error of 0.05 and beta error of 20 included. Based on these assumptions, a sample size of 112 (28 cases and 84 controls) was needed for the study. <u>Data analysis</u> Data were analysed using Student's	**Results** **FHR measures among foetuses ≥ 32 weeks** **<u>Baseline variability in 1st hour of tracing</u>** <u>Increased or moderate</u> Cases n = 15 (57%) Controls n = 56 (78%) Unadjusted OR: not reported (NR) <u>Minimal or absent</u> Cases n = 5 (45%) Controls n = 16 (23%) Unadjusted OR 1.2 (95% CI: NR) **<u>Baseline variability in last hour of tracing</u>** <u>Increased or moderate</u> Cases n = 9 (45%) Controls n = 35 (49%) Unadjusted OR: NR <u>Minimal or absent</u> Cases n = 11 (55%) Controls n = 36 (51%) Unadjusted OR 1.2 (95% CI 0.4 to 3.2) **<u>Fetal sleep cycles during tracing</u>** <u>Present throughout tracing</u> Cases n = 1 (5%) Controls n = 14 (20) Unadjusted OR: NR <u>50% -75% of tracing</u> Cases n = 7 (35%) Controls n = 24 (34%) Unadjusted OR 4.1 (95% CI 0.5 to 52.3) <u>25% - 49% of tracing</u> Cases n = 4 (20%) Controls n = 11 (16%) Unadjusted OR 5.1 (95% CI 0.5 to 43.4)	**Limitations** **Other information** Statistical differences were found in demographic characteristics between sudden infant death syndrome mother-infant couples and their controls. However, no differences were detected in the intrapartum electronic fetal monitoring records, specifically in variability and sleep/wake cycles.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			t test for continuous variables and chi-square and Fisher's exact test for categorical variables.	<u>< 25% of tracing</u> Cases n = 6 (30%) Controls n = 18 (26%) Unadjusted OR 4.7 (95% CI 0.6 to 139.6) <u>Not present during tracing</u> Cases n = 2 (10%) Controls n = 3 (5%) Unadjusted OR 9.3 (95% CI: NR) **<u>Fetal sleep cycles (dichotomised)</u>** <u>50% - 100% of tracing</u> Cases n = 8 (40%) Controls n = 38 (54%) Unadjusted OR: NR <u>0% - 49% of tracing</u> Cases n = 12 (60%) Controls n = 32 (46%) Unadjusted OR 1.8 (95% CI 0.6 to 4.0)	
Full citation Murphy,K.W., Russell,V., Collins,A., Johnson,P., The prevalence, aetiology and clinical significance of pseudo-sinusoidal fetal heart rate patterns in labour, British Journal of Obstetrics and Gynaecology, 98, 1093-1101, 1991 **Ref Id** 122221 **Country/ies where the study was carried out** UK **Study type** Prospective Cohort **Aim of the study** To investigate the prevalence of sinusoidal and pseudo-sinusoidal fetal heart rate (FHR) patterns in labour and the relation between the characteristics of the FHR pattern and fetal outcome. **Study dates** September 1987 to February 1988 **Source of funding** Not specified	**Sample size** n = 1520 women who had fetal monitoring during labour for various reason were reviewed Intervention n = 230 Control n = 100 **Characteristics** The reasons for monitoring were (high risk and low risk population): Oxytocin (31%) Hypertensive disorder and intrauterine growth retardation (22%) Epidural analgesia (15%) Breech (4%) Irregular FHR on auscultation (3%) Others (16%) **Inclusion criteria** All women who had fetal monitoring in labour during the study time (49% of all labours were monitored). Only cardiotocographs (CTG) with pseudo-sinusoidal pattern which persisted ≥ 10 min were included **Exclusion criteria** Not specified	**Interventions** Sinusoidal and pseudo-sinusoidal patterns	**Details** Study conducted in John Radcliffe Hospital, Oxford, over a 6 month period in which all women who had continuous FHR monitoring in labour had their intrapartum CTGs inspected for the presence of sinusoidal or pseudo-sinusoidal FHR patterns. Control: Every tenth women who was monitored during the study period and who did not have a sinusoidal or pseudo-sinusoidal FHR pattern was selected as a control. Intrapartum ultrasonography was undertaken in a small pseudo-sinusoidal episode in order to look for fetal sucking or mouth movements. Analysis: Both internal (electrocardiographic) and external (ultrasonic) recordings of FHR were analysed. The intrapartum CTGs were reviewed immediately after recordings were made. To compare the results between the study group and the control group univariate analyses were performed. The reviewers examined the association between the presence of pseudo-sinusoidal patterns and some variables. Multivariate analyses (logistic regression analysis) were performed.	**Results** Intervention n = 230 with pseudo-sinusoidal patterns (n = 219 were minor and n = 11 intermediate patterns) Control n = 100 with no sinusoidal pattern <u>Minor pseudo-sinusoidal n = 65/219 (30%)</u> Control group n = 26/100 (26%) <u>Frequency distribution of minor pseudo sinusoidal patterns in the study group</u> Number of pseudo sinusoidal episodes per subject n = 1 Number of subjects n = 94 (42%) Number of pseudo sinusoidal episodes per subject n =2 Number of subjects n = 71 (32%) Number of pseudo sinusoidal episodes per subject n = 3 Number of subjects n = 38 (17%) Number of pseudo sinusoidal episodes per subject n > 4 Number of subjects n = 18 (8%) <u>Caesarean section rates</u> Minor pseudo-sinusoidal n = 22/219 (10%) Control group n = 12/100 (12%) p = ns <u>Instrumenal vaginal birth</u> Minor pseudo-sinusoidal n = 65/219 (30%) Control group n = 26/100 (26%) p = ns <u>Fetal sleep pattern present</u> Minor pseudo-sinusoidal n = 125/219 (57%) Control group n = 51/100 (51%) p = ns <u>Umbilical artery pH < 7.12 (measured in 67% of intervention group and 57% of the control group)</u> Minor pseudo-sinusoidal n = 20/147 (14%) Control group n = 5/57 (9%) p = ns <u>Admission to special care</u> Minor pseudo-sinusoidal n = 19 (9%) Control group n = 4 (4%) p = ns	**Limitations** Unclear how and by whom data were analysed and if the assessor was blinded to the outcomes **Other information** Pseudo-sinusoidal pattern classification: - Minor when the amplitude of the oscillations was 5-15 beats/min - Intermediate at 16-24 beats/min - Major when the amplitude was ≥ 25 cycle frequency was 2-5 cycles/min for minor and intermediate patterns and 1-2 cycles/min for major patterns CTG classified as normal or abnormal according to the criteria suggested by Steer et al. (1989) Uterine hyper-stimulation: - When more than 15 contractions were present during a 30 min period Data on pseudo sinusoidal traces divided into minor, moderate and severe categories depending on amplitude of oscillations and frequency of cycles. CTGs were classified as normal or abnormal according to criteria suggested by Steer et al. (1989)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Significant association with epidural analgesia (RR 1.84; 95% CI 1.24 to 2.76) and pethidine administration (RR 1.84; 95% CI 1.31 to 2.59) from multivariate analysis.	
Full citation Nelson,K.B., Dambrosia,J.M., Ting,T.Y., Grether,J.K., Uncertain value of electronic fetal monitoring in predicting cerebral palsy, New England Journal of Medicine, 334, 613-618, 1996 **Ref Id** 171881 **Country/ies where the study was carried out** USA **Study type** Case control study **Aim of the study** To investigate the usefulness of fetal monitoring as interpreted by the obstetrician at the time of birth of infants who were diagnosed with cerebral palsy **Study dates** From 1983 to 1985 **Source of funding** Supported in part by a cooperative agreement with the Center for Environmental Health and Injury Control, Centers for Disease Control and Prevention, in part by funds from the Comprehensive Environmental Response, Compensation, and Liability Act Trust Fund through an interagency agreement with the Agency for Toxic Substances and Disease Registry, Public Health Service, and in part by a training grant from the Department of Health and Human Services, Maternal and Child Health Bureau.	**Sample size** n = 95 infants with cerebral palsy (CP) at aged 3 years with n = 378 matched controls **Characteristics** <u>Maternal parity (nulliparous)</u> Children with CP: n = 42 (54%) Controls: n = 144 (48%) <u>Maternal gestational age (means)</u> Children with CP: 40 weeks Controls: n = 40 weeks <u>Maternal age (mean)</u> Children with CP: 28 yr Controls: 27 yr <u>Induction of labour</u> Children with CP: n = 13 (17%) Controls: n = 48 (16%) <u>Internal monitoring</u> Children with CP: n = 45 (58%) Controls: n = 170 (57%) **Inclusion criteria** Singleton infants with birth weight of 2500 grams or more **Exclusion criteria** Children in whom cerebral palsy was acquired after the first 28 days of life or through non-accidental head trauma in the first month and children with mild involvement or isolated hypotonia were not included.	**Interventions** Continuous electronic fetal monitoring (EFM) (except in 9% of CP cases and 13% of controls)	**Details** Data were collected from singleton children born during the three-year study period in four counties in the San Francisco area. All weighed 2500 g or more at birth, survived to the age of three years, and had moderate or severe cerebral palsy. The inclusion or exclusion of each identified child was determined by means of a standardised clinical examination or extensive review of the medical records. Controls were randomly selected from the singleton children who met all the criteria for the case children except the diagnosis of cerebral palsy. Demographic data were extracted by nurses working at the California Birth Defects Monitoring Program who did not know whether the records were those of case or control children and did not know that the study was about cerebral palsy. The findings on fetal monitoring record were those noted in the birth records, as indicated by the physicians attending the deliveries. No monitoring strips were available for this study. Data collected on the highest fetal heart rate above 160 or 180 beats per minute, the lowest fetal heart rate below 100 or 80 beats per minute, and the presence or absence of multiple late decelerations (commonly defined as bradycardia occurring well after the onset of uterine contractions, although in this study the term was recorded as used by the clinicians involved) and decreased beat-to-beat variability in heart rate. Multiple late decelerations and decreased beat-to-beat variability were then combined into a single variable indicating the occurrence of either or both during labor.	**Results** **<u>Heart rate patterns according to presence (n = 78) or absense of cerebral palsy (n = 300)</u>** <u>Tachycardia > 160 bpm</u> Children with CP: n = 22 (28%) Control: n = 85 (28.3)% Odds ratio 1.0 (0.6 to 1.7) <u>Tachycardia > 180 bpm</u> Children with CP: n = 5 (6.4%) Control: n = 16 (5.3%) Odds ratio 1.3 (0.4 to 3.4) <u>Bradycardia < 100 bpm</u> Children with CP: n = 27 (34.6%) Control: n = 75 (25%) Odds ratio 1.5 (0.9 to 2.5) <u>Bradycardia < 80 bpm</u> Children with CP: n = 13 (16.7%) Control: n = 35 (11.7%) Odds ratio 1.5 (0.8 to 3) <u>Mutiple late decelerations</u> Children with CP: n = 11 (14.1%) Control: n = 12 (4.0%) Odds ratio 3.9 (1.7 to 9.3) <u>Decreased beat to beat variability</u> Children with CP: n = 13 (16.7%) Control: n = 21 (7%) Odds ratio 2.7 (1.1 to 5.8) <u>MLD/DV</u> Children with CP: n = 21 (26.9%) Control: n = 28 (9.3%) Odds ratio 3.6 (1.9 to 6.7) <u>Association between multiple late decelerations, decreased variability or both with cerebral palsy in high and low risk populations</u> <u>Low</u> Sensitivity: 13.8 Specificity: 91.3 PPV: 0.05 <u>High</u> Sensitivity: 13.8 Specificity: 89.1 PPV: 0.25	**Limitations** The findings on fetal monitoring record were those noted in the birth records, as indicated by the physicians attending the deliveries. No monitoring strips were available for this study. No actual definition of reduced beat-to-beat variability or multiple late decelerations. Duration of monitoring or specific heart-rate patterns not specified in the analysis. **Other information** Cerebral palsy defined as chronic disability originating from central nervous system, characterised by aberrant control of movement or posture, appearing in early life, and not resulting from progressive disease
Full citation Ozden,S., Demirci,F., Significance for fetal outcome of poor prognostic features in fetal heart rate traces with variable decelerations, Archives of Gynecology and Obstetrics, 262, 141-149, 1999	**Sample size** 167 'randomly' selected FHR traces Study group n = 76 with variable decelerations. Divided to two groups poor cases with poor prognostic features (PPFs) (n = 45) and poor cases without PPFs (n = 31) Control group n = 91 normal traces	**Interventions** Variable deceleration classified into 7 subtypes according to PPFs 1. Loss of primary acceleration 2. Loss of secondary acceleration	**Details** Data for the study were collected from n = 167 randomly selected women with a singleton pregnancy at term. n = 96 women who had an FHR trace without pathological features were selected as a control group. The remaining 76 women had variable decelerations and their	**Results** **<u>Mode of birth</u>** <u>Vaginal birth</u> Study group: poor (PPFs) n = 25/45 (55.6%); poor (- PPFs) n = 18/31 (58%) Control group n = 65/91 (71.4%) P = ns <u>Caesarean section</u>	**Limitations** Complex analysis Small sample size **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 197028 **Country/ies where the study was carried out** Turkey **Study type** Cohort **Aim of the study** To determine the clinical significance of the existence of poor prognostic features in fetal heart rate (FHR) traces with variable decelerations. **Study dates** From January 1995 to January 1996 **Source of funding** Not specified	**Characteristics** No significant differences observed between the two group in maternal age, gravidity, parity, and cervical dilatation. **Inclusion criteria** Singleton Term pregnancy **Exclusion criteria** Poorly documented gestational age Premature birth Multiple pregnancy	3. Loss of variability during deceleration 4. Slow return to baseline 5. Biphasic deceleration 6. Prolonged secondary acceleration 7. Prolonged deceleration	FHR traces were analysed for the existence of poor prognostic features. All the traces were analysed by one study author. Umbilical cord pH were taken for included women and pH < 7.20 were defined as acidemia. <u>Analysis</u> Statistical analysis performed using SPSS. Kruscall Wallis one way ANOVA was used to compare cord blood gas value among the three groups.	Study group: poor (PPFs) n = 20/45 (44.4%); poor (- PPFs) n = 13/31 (41.9%) Control group n = 26/91 (28.6%) P = ns <u>pH</u> Study group: poor (PPFs) n 7.18 - 0.08 poor (- PPFs) 7.24 - 0.08 Control group 7.27 - 0.06 P = 0.00001 **<u>Comparison of vriable deceleration subgroups to the number of poor prognostic features for the neonatal outcomes</u>** <u>Vaginal birth</u> Study group: PPF0 n = 18/31 (58%); PPF1 n = 9/13 (69%); PPF2 n = 7/12 (58%); PPF3 n = 5/8 (62%); PPF 4 4/12 (33%) p = ns (comparison between the group without PPF n = 31 and with PPF n = 45) <u>Caesarean section</u> Study group: PPF0 n = 13/31 (42%); PPF1 n = 4/13 (31%); PPF2 n = 5/12 (42%); PPF3 n = 3/8 (37%); PPF 4 8/12 (67%) Caesarean section <u>PH</u> Study group: PPF0 7.24 - 0.08; PPF1 7.20 - 0.06; PPF2 7.15 - 0.09; PPF3 7.18 - 0.08; PPF 4 7.18 - 0.01 p = 0.02	

Full citation	Sample size	Interventions	Details	Results	Limitations
Powell,O.H., Melville,A., MacKenna,J., Fetal heart rate acceleration in labor: excellent prognostic indicator, American Journal of Obstetrics and Gynecology, 134, 36-38, 1979 **Ref Id** 196676 **Country/ies where the study was carried out** USA **Study type** Cohort study **Aim of the study** To examine correlation between fetal heart rate (FHR) acceleration and neonatal outcomes **Study dates** January 1976 to December 1976 **Source of funding** Not specified	n = 1677 monitored labours **Characteristics** Not specified **Inclusion criteria** Not specified **Exclusion criteria** Not specified	Uniform accelerations (> 3 in 15 minutes > 15 beats for > 15s)	Infants born during the study period in a teaching hospital of the Eastern Virginia Medical school, who met the inclusion criteria, were included in the study. All labouring women had electronic fetal monitoring (EFM) routinely. 65% of the study population gave birth in the private section and 35% in the usual section of the clinic. Only traces with uniform FHR acceleration patterns were included. The accelerations occurring in association with decelerations were excluded.	Mortality rate of the hospital during the study period: 18.6/1000 Mortality rate of group of monitored women during the study period: 14.9/1000 Acceleration present in 935 women who were monitored <u>Perinatal mortality</u> Acceleration present: n = 4 per 1000 Acceleration not present: n = 20 per 1000 The 4 deaths in the "acceleration" group were due to pneumonia in one case (a term infant), due to intracranial haemorrhage in one case (a 37 week infant delivered by midforceps), and due to respiratory distress syndromes in two babies. In the 20 babies who died in the "no accelerations" group, the deaths were often associated with hypoxia (such as: diabetes, post maturity, sepsis, preeclampsia) that were demonstrable in 16 babies. Two (n = 2) died from respiratory distress syndrome and two died with congenital abnormality syndrome. There was no difference in the presence of accelerations in vertex and non vertex presentations. n = 91 women had breech presentation. n = 76 were monitored and only n = 2 failed to show acceleration in labour. There was one death among breech births which was due to severe hypoxia in a vaginal birth and there were no accelerations present during labour for this baby.	No population data presented. Unclear how and by whom the data were analysed. No inclusion/exclusion criteria specified. Unclear what percentage of premature labour and high risk pregnancies were included. **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Roy,K.K., Baruah,J., Kumar,S., Deorari,A.K., Sharma,J.B., Karmakar,D., Cesarean section for suspected fetal distress, continuous fetal heart monitoring and decision to delivery time, Indian Journal of Pediatrics, 75, 1249-1252, 2008 **Ref Id** 60814 **Country/ies where the study was carried out** India **Study type** Prospective observational study **Aim of the study** To find out the efficacy of continuous fetal heart monitoring by analysing the cases of ceasarean section for non reassuring fetal heart in labour, detected by cardiotocography (CTG) and correlating these cases with perinatal outcome. **Study dates** March 2002 to March 2007 **Source of funding** Not specified	**Sample size** Total n = 217 **Characteristics** Not specified **Inclusion criteria** Gestational age ≥ 36 No fetal anomalies Non reassuring CTG not responding to conservative management (including changing the maternal position, intravenous hydration, and oxygen administration) **Exclusion criteria** Abnormal presentation Multiple pregnancy Intrauterine growth restriction (IUGR) Caesarean section for other primary indications	**Interventions** Caesarean section for non reassuring fetal heart rate (FHR) detected by cardiotocograph (CTG)	**Details** During the study period, a total of 3,148 women delivered in a maternity unit of whom 217 (6.8%) women underwent cesarean section for non-reassuring fetal heart trace in labor. The percentage of caesarean sections for various indications was 16.2%. The maternal demographic profile, specific types of abnormal fetal heart rate tracing and the decision to delivery time interval were noted. The decision time to perform a caesarean section was defined as when the senior resident on duty took the decision to perform the caesarean and exact delivery time. The adverse immediate neonatal outcomes in terms of Apgar score < 7 at 5 minutes, umbilical cord pH < 7.10, neonates requiring immediate ventilation and NICU admissions were recorded. The correlation between non-reassuring fetal heart, decision to delivery interval and neonatal outcome were analysed. Data analysis Statistical analysis was done using Student's t-test and chi square test where appropriate.	**Results** **Various fetal heart abnormalites indicated by CTG and its relation to immediate adverse neonatal outcomes** Persistent bradycardia n = 106/217 (48.8%) 5 minutes Apgar < 7 n = 16/106 Umbilical cord pH < 7.10 n = 4/106 NICU admission n = 16/106 Recurrent late deceleration n = 56 (25.8%) 5 minutes Apgar < 7 n = 10/56 Umbilical cord pH < 7.10 n = 5/56 NICU admission n = 10/56 Variable deceleration n = 38/217 (17.5%) 5 minutes Apgar < 7 n = 7/38 Umbilical cord pH < 7.10 n = 4/38 NICU admission n = 7/38 Decreased variability n= 17/217 (7.8%) 5 minutes Apgar < 7 n = nil Umbilical cord pH < 7.10 n = nil NICU admission n = nil **Overall findings for non- reassuring CTG and its relation to the neonatal outcomes** Decision to delivery interval (DDI): DDI ≤ 30 min n = 121/217 DDI > 30 min n = 96/217 5 minutes apgar < 7 DDI ≤ 30 min n = 18/121 (14.8%) DDI > 30 min n = 15/96 (15.6%) p = ns Arterial cord pH < 7.10 DDI ≤ 30 min n = 8/121 (6.6%) DDI > 30 min n = 5/96 (5.2%) p = ns NICU admission for suspected birth asphyxia DDI ≤ 30 min n = 26/121 (21.4%) DDI > 30 min n = 7/96 (7.2%) p < 0.05 Fresh stillbirth DDI ≤ 30 min n = 1*/121 (0.8%) DDI > 30 min n = nil p < 0.05 *Death was due to placental abruption Born healthy n = 184 (84.7%)	**Limitations** No definition for bradycardia, deceleration and non reassuring CTG provided. Unclear if the outcome assessors were blinded to the study groups allocation. Women's demographic characteristics not reported. **Other information** Non-reassuring fetal heart rate detected by CTG did not correlate well with adverse neonatal outcome.
Full citation Salim,R., Garmi,G., Nachum,Z., Shalev,E., The impact of non-significant variable decelerations appearing in the latent phase on delivery mode: a prospective cohort study, Reproductive Biology and Endocrinology, 8, 81-, 2010 **Ref Id** 109319	**Sample size** Category I n = 251 Category II NSV n = 186 Category II SV n = 76 **Characteristics** There were no significant differences observed between the three groups in maternal age, parity and polyhydramnios.	**Interventions** Electronic fetal monitoring (EFM)	**Details** Variable deceleration was defined according to 2008 National Institute of Child Health and Human Development workshop. Variable decelerations were categorised as significant (SV) if fetal heart rate (FHR) reached 70 beats/min for one minute or more but less than 2 minutes, otherwise they were categorised as non-significant (NSV) Women were divided into three groups. All had a fetal heart rate	**Results** Total n = 1005 Category II-NSV tracings (study group) n = 186 Category II-SV n = 76 Category I tracings n = 251 **Mode of birth** There was a statistically significant differences observed between the three groups in method of birth (category II-SV versus category I and category II-NSV) (p = 0.0001) Spontaneous vaginal birth Control group (Category I): n = 238 (94.8%)	**Limitations** **Other information** Fetal Heart interpretation categorisation from National Institute of Child Health and Human Development workshop 2008 (Macones et al., 2008): **Category I** Category I fetal heart rate (FHR) tracings include all of the following: Baseline rate: 110–160 beats per minute (bpm) Baseline FHR variability: moderate Late or variable decelerations: absent

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Israel **Study type** Prospective cohort **Aim of the study** To estimate the impact of non-significant variable decelerations (NSV) appearing during the latent phase of labour on delivery mode and neonatal outcome. **Study dates** January to April 2009 **Source of funding** Not specified	**Inclusion criteria** Term pregnancy (≥ 37) In the latent phase of labour (defined as interval between the start of regular contractions combined with any cervical dynamics [dilating > 4 cm]) Singleton pregnancy **Exclusion criteria** Fetal heart tracing abnormalities during the latent phase Caesarean section without a trial of labour Women gave birth to infants with major malformation		tracing with normal baseline and variability: Study group (Category II NSV): women who had Category II tracing based on Institute of Child Health and Human Development (NICHD) categorisation system; women with NSV, episodic or recurrent, and normal base line and moderate variability Control group (Category I): women who had category I tracing based on NICHD categorisation Second control group (Category II-SV): women who had category II-SV tracing based on NICHD categorisation; women with significant variables (SV) <u>Sample size</u> In order to show a difference of 10% in the rate of operative birth between the category I and category II-NSV tracing with an alpha of 0.05 and a power of 80% a sample size of 160 per group was required <u>Analysis</u> One-way analysis of variance was used to compare the continuous demographic and clinical variables of the three groups. Significant group differences were tested (post-hoc). Backwards stepwise logistic regression using significant invariables was performed to determine which predicted operative delivery. P < 0.05 was considered significant. <u>Assessment</u> All traces were assessed by two obstetricians at the same time, both were blinded to the groups allocation and neonatal outcomes.	Study group (Category II NSV): n = 166 (89.2%) Second control group (Category II SV): n = 40 (52.6%) <u>Vacuum</u> Control group (Category I): n = 6 (2.4%) Study group (Category II NSV): n = 8 (4.3%) Second control group (Category II SV): 11 (14.5%) <u>Caesarean</u> Control group (Category I): n = 7 (2.8%) Study group (Category II NSV): n = 12 (6.5%) Second control group (Category II SV): n = 25 (32.9%) <u>Reasons for vacuum or caesarean delivery</u> There was a statistically significant difference observed between the three groups in reasons for vacuum or ceasarean delivery (category II-SV versus category I and category II-NSV) (p = 0.0001) <u>Indication for CS (not reassuring FHR monitoring)</u> Control group (Category I): n = 3 (23.1%) Study group (Category II NSV): n = 5 (25%) Second control group (Category II SV): n = 20 (55.6%) <u>Indication for CS (failure to progress in the active or second stage)</u> Control group (Category I): n = 10 (76.9%) Study group (Category II NSV): n = 15 (75.0%) Second control group (Category II SV): n = 16 (44.4%) **<u>Neonatal outcomes</u>** <u>Neonatal weight (g)</u> Control group (Category I): mean 3329 ± 392 Study group (Category II NSV): mean 3397 ± 439 Second control group (Category II SV): mean 3130 ± 487 p = 0.002 (category II-SV versus category I and category II-NSV) <u>Neonatal born < 2500 g</u> Control group (Category I): n = 2 (0.8%) Study group (Category II NSV): n = 1 (0.5%) Second control group (Category II SV): n = 4 (5.3%) p = 0.0001 (category II-SV versus category II-NSV) <u>Apgar score at 5 min (out of 10)</u> Control group (Category I): mean 9.96 ± 0.23 Study group (Category II NSV): mean 9.90 ± 0.31 Second control group (Category II SV): mean 9.86 ± 0.39 p = 0.01 <u>Mean cord PH</u> Control group (Category I): 7.31 ± 0.07 Study group (Category II NSV): 7.31 ± 0.07 Second control group (Category II SV): 7.30 ± 0.08 p = 0.5 <u>Cord pH between 7.0 to 7.1</u> Control group (Category I): n = 2 (0.8%) Study group (Category II NSV): n = 7 (3.8%) Second control group (Category II SV): n = 4 (5.3%) <u>Meconium stained amniotic fluid</u> Control group (Category I): n = 22(8.8%) Study group (Category II NSV): n = 26 (14%) Second control group (Category II SV): n = 15 (19.7%) <u>Nuchal cord or true knot</u> Control group (Category I): n = 23 (9.2%)	Early decelerations: present or absent Accelerations: present or absent **<u>Category II</u>** Category II FHR tracings include all FHR tracings not categorized as Category I or Category III. Category II tracings may represent an appreciable fraction of those encountered in clinical care. Examples of Category II FHR tracings include any of the following: <u>Baseline rate</u> Bradycardia not accompanied by absent baseline variability Tachycardia <u>Baseline FHR variability</u> Minimal baseline variability Absent baseline variability not accompanied by recurrent decelerations Marked baseline variability **Accelerations** Absence of induced accelerations after fetal stimulation **Periodic or episodic decelerations** Recurrent variable decelerations accompanied by minimal or moderate baseline variability Prolonged deceleration ≥ 2 minutes but ≤ 10 minutes Recurrent late decelerations with moderate baseline variability Variable decelerations with other characteristics, such as slow return to baseline, "overshoots," or "shoulders" **<u>Category III</u>** <u>Category III FHR tracings include either:</u> Absent baseline FHR variability and any of the following: Recurrent late decelerations Recurrent variable decelerations Bradycardia Sinusoidal pattern

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Study group (Category II NSV): n = 19 (10.2%) Second control group (Category II SV): n = 12 (15.8%) p = 0.3 <u>Neonatal death</u> Control group (Category I): n = 0 Study group (Category II NSV): n = 0) Second control group(Category II SV): n = 0	
Full citation Sameshima,H., Ikenoue,T., Predictive value of late decelerations for fetal acidemia in unselective low-risk pregnancies, American Journal of Perinatology, 22, 19-23, 2005 **Ref Id** 157246 **Country/ies where the study was carried out** Japan **Study type** Retrospective cohort study **Aim of the study** To evaluate the clinical significance of late decelerations (LD) of intrapartum fetal heart rate (FHR) monitoring to detect low pH (< 7.1) in low-risk pregnancies. **Study dates** 1995 to 2000 **Source of funding** Supported in part by Grant-in-Aid for Scientific Research from Ministry of Education, Japan	**Sample size** Carditocograph (CTG) trace of n = 5522 women with low-risk pregnancies **Characteristics** <u>Average maternal age</u> No decelerations 28.4 ± 4.8 Occasional LD 30.0 ± 4.9 Recurrent LD 38.8 ± 2.0 p = ns <u>Avarage gestational age</u> No decelerations 38.5 ± 1.8 Occasional LD 38.8 ± 2.0 Recurrent LD 38.1 ± 2.5 Average parity of the three groups 0.6 ± 0.9 **Inclusion criteria** Low risk pregnancies Cases with recurrent and occasional late deceleration (LD) **Exclusion criteria** Premature birth < 32 wk Multiple pregnancy Hypertensive disorders Pre-eclampsia or eclampsia Chronic hypertension Collagen diseases Diabetes mellitus Thyroid dysfunction Cardiac, repiratory, renal disease Epilepsy Placenta praevia Coagulation disorders Intrauterine infection and chorioamnionitis Intrauterine growth restriction	**Interventions** FHR via cardiotocograph (CTG) trace	**Details** Cliinical significance of late decelerations (LD) of intrapartum fetal heart rate (FHR) monitoring to detect low pH (< 7.1) in low-risk pregnancies was evaluated. Data collected from two secondary and two tertiary-level institutions where 10,030 women delivered. Among them, 5522 were low-risk pregnancies. The last 2 hours of FHR patterns before delivery were interpreted according to the guidelines of the National Institute of Child Health and Human Development. The correlation between the incidence of LD (occasional, < 50%; recurrent, ≥ 50%) and severity (reduced baseline FHR accelerations and variability) of LD, and low pH (< 7.1) wasevaluated. <u>Statistical analyses</u> Included a contingency table with chi^2 and Fisher's exact test, and one-way analysis of variance with the Bonferroni/Dunn test.	**Results** Occasional LD n = 301/5522 Recurrent LD n = 99/5522 <u>Recurrent LD n = 99</u> Moderate variability and acceleration n = 64/99 Moderate variability without acceleration n = 16/99 Acceleration with minimal variabiliy n = 3/99 Minimal variability without accelerations n = 16/99 Blood gases and pH values deteriorated as the incidence of LD increased and as baseline accelerations or variability decreased. Positive predictive value for low pH (< 7.1) was exponentially elevated from 0% at no decelerations, 1% in occasional LD, and > 50% in recurrent LD with no baseline FHR accelerations and reduced variability.	**Limitations** Poor reporting of results Unclear if the outcome assessor was blinded to the outcomes **Other information** In low-risk pregnancies, information on LD combined with acceleration and baseline variability enables us to predict the potential incidence of fetal acidemia.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Fetal abnormalities Anomalies Hydrops fetalis Metabolic disorders Known congenital syndromes				
Full citation Samueloff,A., Langer,O., Berkus,M., Field,N., Xenakis,E., Ridgway,L., Is fetal heart rate variability a good predictor of fetal outcome?, Acta Obstetricia et Gynecologica Scandinavica, 73, 39-44, 1994 **Ref Id** 196845 **Country/ies where the study was carried out** USA **Study type** Cohort **Aim of the study** To investigate whether fetal heart rate (FHR) variability serves as a reliable single predictor of fetal outcome **Study dates** During 1991 **Source of funding** not specified	**Sample size** n = 2220 consecutive deliveries **Characteristics** Maternal age (mean ± SD) 27.4 ± 6.04 Complication in pregnancy (hypertension, diabetes, abrupto placenta, placenta previa, chorioamnionitis, previous caesarean section): 27. 34% Epidural: 47.3% **Inclusion criteria** Not specified **Exclusion criteria** < 37 weeks gestation Twins Fetal malformation Stillbirth	**Interventions** Scoring FHR variability using 5 scoring systems: A. FHR amplitude variability ≥ 3 bpm < 3 bpm B. FHR amplitude ≥ 5bpm < 5 bpm C. FHR frequency of oscillations ≥ 3 bpm < 3/min D. FHR frequency of oscillations ≥ 5 bpm < 5/min E. Combination of (amplitude frequency)/2. Value < 3 scored as low and ≥ 3 as high	**Details** Data were collected from follow up of n = 2200 consecutive births during 1991 from a teaching hospital. Based on the hospital policy, every women entering the labour ward was connected to a fetal heartt monitor. Fetal heart variability data were obtained from n = 1816 women (the missing 7.8% of variability data was due to either imminent birth in which obtaining a trace was not possible or lost tracing). <u>Analysis</u> Three sections of the trace were analysed: 1. early in labour for a period of 30 minutes, 2. 30 minutes of tracing in the active phase 3. throughout the entire 2nd stage in segments of 30 minutes (a maximum of three segments). In all deliveries with 2nd stage longer than 90 minutes, the last tracing prior to the delivery was analysed. A total of 4361 tracing segments were analysed by five maternal-fetal faculty members blinded to the maternal and neonatal outcomes.	**Results** pH ≥ 7.20, <7.20 Scoring method A: sensitivity 10.99%, specificity 93.80%, positive predictive value (PPV) 25.20%, negative predictive value (NPV) 84.74% Scoring method B: sensitivity 26.24%, specificity 78.93%, PPV 19.12%, NPV 84.93% Scoring method C: sensitivity 6.78%, specificity 95.18%, PPV 23.17%, NPV 84.48% Scoring method D: sensitivity 25.35%, specificity 90.52%, PPV 19.72%, NPV 85.11% Scoring method E: sensitivity 7.44%, specificity 96.30%, PPV 27.63%, NPV 84.58% Both amplitude and frequency methods poorly sensitive at lower limits (< 3). Sensitivity increased by increasing limit to 5 in both scores but consequent drop in specificity. Combination method has low sensitivity.	**Limitations** Variability not single useful predictor of outcome. Division of cases into normal and abnormal not balanced as non-matched. Hence, performance of tests affected. **Other information**
Full citation Sheiner,E., Hadar,A., Hallak,M., Katz,M., Mazor,M., Shoham-Vardi,I., Clinical significance of fetal heart rate tracings during the second stage of labor, Obstetrics and Gynecology, 97, 747-752, 2001 **Ref Id** 196075 **Country/ies where the study was carried out** Israel **Study type**	**Sample size** n = 601 **Characteristics** Women with abnormal FHR patterns were of significantly lower birth order and more often carried male fetuses compared with women with normal FHR patterns. The women with abnormal FHR tracings during the second stage of labour had a significantly higher rate of oligohydramnios and a non-significantly higher rate of hydramnios. No other significant differences were seen between the groups for anesthesia use, first and second stage duration, presence of meconium in amniotic fluid, cord problems, and birth weight.	**Interventions** Abnormal fetal heart rate tracing	**Details** Women were examined at the delivery suite. Based on the hospital policy, all labouring women had continuous fetal monitoring and the monitor patterns were checked and the findings dcumented hourly. The same obstetrician collected the data after carefully evaluating both the monitor files and the flow charts. Tracings were interpreted using the guidelines of the National Institute of Child Health and Human Development Research Planning Workshop. The cumulative depth of decelerations or bradycardia was	**Results** **<u>Pathologic FHR patterns during 2nd stage of labour (compared with normal tracing) associated with pH < 7.2 (n = 57) and base deficit of ≥ 12 (n = 28)</u>** <u>Variable decelerations ≥ 70 bpm</u> pH < 7.2 OR 5.1 (95% CI 1.4 to 21.4) p = 0.008 Base deficit of ≥ 12 OR 3.5 (95% CI 0.8 to 15.8) p = 0.101 <u>Variable decelerations < 70 bpm</u> pH < 7.2 OR 16.3 (95% CI 3.8 to 80.5) p < 0.001 Base deficit of ≥ 12 OR 10.5 (95% CI 1.9 to 56.4) p = 0.006	**Limitations** Unclear if the assessors were blinded to the outcomes **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Cohort **Aim of the study** To examine the importance of abnormal FHR patterns during the second stage of labor in terms of pregnancy outcome **Study dates** January to June 2000 **Source of funding** Not specified	**Inclusion criteria** Low risk pregnancy Singleton gestation Vertex presentation Term delivery (greater than 37 completed weeks gestation) **Exclusion criteria** Uninterpretable tracings Immediate caesarean because of maternal or fetal indications, such as clinical evidence of cephalopelvic disproportion or placental insufficiency Previous caesarean section Pre-existing heart or lung disease Fetuses with known growth restriction or malformations		classified by a nadir of less than 100 but at least 70 beats per minute, and decelerations with a nadir less than 70 beats per minute. Information was collected about labor duration, performance of an episiotomy, mode of delivery (spontaneous, vacuum, or caesarean), neonatal sex, birth weight, presence of cord problems (nuchal cord or true knot of the cord), Apgar scores, and acid-base status (in particular, metabolic acidosis). The umbilical cord was clamped immediately after delivery. Arterial blood was drawn into a 2-ml plastic syringe that was flushed with heparin, and then transferred to the pH machine located in the delivery ward. The pH was considered abnormal when it was lower than 7.2. Base deficit of 12 mmol/l or greater was considered the threshold of fetal metabolic acidosis at delivery. Newborn morbidity included admission to the intensive care unit or delayed discharge from the hospital because of fetal indications. The local ethics institutional review board approved the study. Analysis Comparison of group means was performed with the SPSS version 8.0 statistical package (SPSS Inc., Chicago, IL). Chi-square or Fisher's exact test was used for comparison of proportions. Student's t-test was applied for comparison of means. P < 0.05 was considered statistically significant. Multiple logistic regression models were used to investigate the independent contributions of obstetric factors to abnormal FHR patterns during the second stage of labor and to investigate the contributions of those patterns to selected fetal outcomes. Odds ratios (ORs) and their 95% confidence intervals (CIs) were calculated from the regression coefficients.	Late decelerations pH < 7.2 OR 15.2 (95% CI 2.8 to 91.4) p < 0.001 Base deficit of ≥ 12 OR 17.3 (95% CI 2.9 to 101.9) p = 0.002 Bradicardia ≥ 70 bpm pH < 7.2 OR 2.3 (95% CI 0.3 to 17.1) p = 0.390 Base deficit of ≥ 12 OR 3.8 (95% CI 0.3 to 44.2) p = 0.282 Bradycardia < 70 bpm pH < 7.2 OR 26.6 (95% CI 5.2 to 150.3) p < 0.001 Base deficit of ≥ 12 OR 5.2 (95% CI 0.8 to 31.9) p = 0.007 Bradycardia < 70 bpm pH < 7.2 OR 2.2 (95% CI 0.3 to 17.1) p = 0.728 Base deficit of ≥ 12 OR 5.1 (95% CI 0.6 to 46.1) p =0.098 **Pathologic FHR patterns during 2nd stage of labour (compared with normal tracing) associated with fetal acidosis (pH < 7.2 and base deficit of ≥ 12) n = 28** Late decelerations OR 3.9 (95% CI 1.1 to 13.1) p = 0.029 Abnormal tracing during the 1st stage OR 3.4 (95% CI 1.3 to 8.7) p = 0.011 Bradycardia < 70 bpm OR 3.0 (95% CI 1.02 to 8.6) p = 0.045	
Full citation Spencer,J.A., Badawi,N., Burton,P., Keogh,J., Pemberton,P., Stanley,F., The intrapartum CTG prior to neonatal encephalopathy at term: a case-control study, British Journal of Obstetrics and Gynaecology, 104, 25-28, 1997 **Ref Id**	**Sample size** Cases n = 55 Controls n = 39 **Characteristics** Not specified	**Interventions** Fetal heart rate patterns	**Details** All cases of neonatal encephalopathy developing during the first seven days of life in term infants were identified from five hospitals (two teaching and three peripheral) in Perth, Western Australia. One control per case was subsequently selected by matching	**Results** Comparison of first and last sections of CTG between cases of neonatal encephalopathy and controls. Individual parameters and Krebs' score derived from 30 min sections. FIGO classification derived from 60 min sections. First CTG section Cases n = 38 Controls n = 35 **Late decelerations**	**Limitations** Low intra-observer agreement No exclusionn criteria or women's characteristics reported **Other information** **FIGO FHR pattern**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
197160 **Country/ies where the study was carried out** Australia **Study type** Case control **Aim of the study** To compare cardiotocograph (CTG) records during labour in cases of neonatal encephalopathy and matched controls. **Study dates** Eight months during 1992 **Source of funding** British council and The Royal Society and The Royal College of Obstetrician and Gynaecologists (Ethicon travel grant)	**Inclusion criteria** One or more of the following features present during the first week of life: - Seizures - Absent or altered responsiveness - Abnormal muscular tone, feeding difficulties of central origin - Difficulty with central control of respiration **Exclusion criteria** Not specified		for hospital of delivery, time and day of the week, sex, and maternal insurance status. All cases and controls had a neurological examination within the first seven days of birth. Clinical data were obtained from the obstetric case notes and a maternal questionnaire. The selected CTG traces were interpreted without knowledge of the outcome. A note was made of baseline rate, amplitude and frequency of the variability, presence of accelerations, and presence and type of decelerations. Krebs' intrapartum CTG score 9 for the first and last 30 min of the trace was calculated, as defined. The total score for each section of CTG was considered abnormal (score 0-3), suspicious (score 4-6) or normal (score 7-10) and these classifications were reduced to two groupings for analyses. The FIGO classification 3 was also determined for the first and last hour of each CTG. Half of the traces were reviewed on a second occasion, at least 10 days later. Intra-observer reproducibility was evaluated using Cohen's Kappa. Analysis Associations between case-control status and binary explanatory variables were assessed using the x2 test for association, or Fisher's exact test if the expected cell count was 5 or less.	Cases Yes n = 2 No n = 36 Controls Yes n = 0 No n = 35 **FHR acceleration** Cases Yes n = 16 No n = 22 Controls Yes n = 8 No n = 27 **FHR variability** Cases ≤ 5bpm n = 4 > 5 bpm n = 34 Controls ≤ 5bpm n = 2 > 5 bpm n = 33 **Krebs' score** Cases 0-3 n = 2 4-10 n = 36 Controls 0-3 n = 1 4-10 n = 34 **FIGO Classification** Cases Abnormal n =19 Normal n = 19 Control Abnormal n = 9 Normal n = 26 First CTG section Cases n = 38 Controls n = 35 **Late decelerations** Cases Yes n = 17 No n = 19 Controls Yes n = 8 No n = 23 **FHR acceleration** Cases Yes n = 26 No n = 10 Controls Yes n = 15 No n = 16 **FHR variability** Cases ≤ 5bpm n = 14 > 5 bpm n = 22	Abnormal (pathological) Baseline FHR: < 100, > 170 Variability (amplitude bpm): < 5 for 40 min Deceleration: severe variable, severe repeated early, prolonged, late or sinusoidal Suspicious Baseline FHR: 100 – 110, 150 - 170 Variability (amplitude bpm): 5 – 10 for 40 min > 25 Deceleration/30 min: variable Normal Baseline FHR: 120 - 150 Variability (amplitude bpm): 6 - 25 Deceleration/30 min: none FHR scoring for internal FHR monitoring; for each of the criteria 0 to 2 points may be given so that a score of 0 to 10 may be obtained Abnormal: score 0 – 3 Suspicious: score 4 – 6 Normal: score 7 – 10 Score 0 Baseline FHR: < 100, > 180 Variability (amplitude bpm): < 3 Variability (frequency bpm): < 3 Acceleration/30 min: 0 Deceleration/30 min: late, severe variable, atypical variable = 0 score Score 1

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Controls ≤ 5bpm n = 4 > 5 bpm n = 27 **Krebs' score** Cases 0-3 n = 19 4-10 n = 17 Controls 0-3 n = 10 4-10 n = 21 **IGO Classification** Cases Abnormal n =32 Normal n = 4 Control Abnormal n = 16 Normal n = 15 Intra-observer reproducibility using Cohen's Kappa for the 1st and last sections of CTG traces (Krebs' score) First section: 0.58 (95% CI 0.30 to 0.87) Last section 0.40 (95% CI 0.16 to 0.62) Intra-observer reproducibility using Cohen's Kappa for the 1st and last sections of CTG traces (FIGO classification) First section: 0.47 (95% CI 0.24 to 0.70) Last section 0.33 (95% CI 0.12 to 0.55)	Baseline FHR: 100 - 119, 161 -180 Variability (amplitude bpm): 3 - 5 > 25 Variability (frequency bpm): 3 - 6 Acceleration/30 min: 1 -4 Deceleration/30 min: moderate variable Score 2 Baseline FHR: 120 - 160 Variability (amplitude bpm): 6 - 25 Variability (frequency bpm): > 6 Acceleration/30 min: > 4 Deceleration/30 min: none, early
Full citation Spencer,J.A., Johnson,P., Fetal heart rate variability changes and fetal behavioural cycles during labour, British Journal of Obstetrics and Gynaecology, 93, 314-321, 1986 **Ref Id** 174553 **Country/ies where the study was carried out** UK **Study type** Case control study **Aim of the study** To evaluate the cycle of low and high fetal heart rate (FHR) and fetal behavioural cycles **Study dates** March 1983 to July 1983 **Source of funding**	**Sample size** n = 301 consecutive fetal heart rate (FHR) recording **Characteristics** Prostagladine/oxytocin Cycle present n = 163 (93%) No cycle present n = 110 (88%) pethidine/epidural Cycle present n = 159 (90%) No cycle present n = 117 (94%) **Inclusion criteria** Term birth **Exclusion criteria** Not specified	**Interventions** FHR variability	**Details** During the study period all 1st stage cardiotocograph (CTG) recordings with ≥ 6 hour duration were analysed for cycles of low and high FHR variability episodes. Each episode was visually identified by the change in long term variability of ≥ 5 beats per minute maintained for ≥ 5 minutes duration. A complete cycle required both low and high FHR variability episodes with changes before and after. The actual variability during the quiet episode (episodes of low FHR variability) of cycles was recorded as > 5 or < 5 beats/min, and the predominant variability of CTG without cycle was also recorded as > 5 or < 5 beats/min. A minimum of two cycles required before a CTG was regarded as showing evidence of fetal behavioural state changes. Analysis: The CTG analysis was performed independently by two observers without knowledge of detail s of labour outcomes. All information were coded and SPSS were used for data analysis. Statistical comparison made using Student's t-test and chi square.	**Results** Mode of birth in presence and on presence of FHR variability cycles Instrumental vaginal birth Cycle present n = 159 (90%) No cycle present n = 117 (94%) Caesarean section Cycle present n = 70 (40%) No cycle present n = 51 (41%)	**Limitations** No demographic data reported. **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Grant from DHSS and the MRC					
Full citation Williams,K.P., Galerneau,F., Intrapartum fetal heart rate patterns in the prediction of neonatal acidemia, American Journal of Obstetrics and Gynecology, 188, 820-823, 2003 **Ref Id** 174581 **Country/ies where the study was carried out** Canada **Study type** Cohort **Aim of the study** To correlate changes in the intrapartum electronic fetal heart rate patterns with the development of significant neonatal acidemia. **Study dates** January 1997 to January 2000 **Source of funding** Not specified	**Sample size** n = 488 fetuses **Characteristics** Not specified **Inclusion criteria** Term pregnancy (> 37 weeks) Birth of neonates within 30 minutes of the bradycardia Continous electronic fetal monitoring for 2 hours before the delivery Umbilical cord artery and cord blood gases done at birth **Exclusion criteria** Fetal anomality Multiple gestation	**Interventions** Fetal heart rate patterns	**Details** Study population consisted of n = 488 women who had continuous electronic fetal monitoring during labor for the last 2 hours. Umbilical artery cord gas analysis performed at birth. One investigator blinded to the cord gas outcome reviewed all 488 tracings using the National Institute of Child Health and Human Development guidelines for fetal heart rate monitoring. The women were placed in six groups, depending on the absence or presence of normal variability (amplitude > 5 beats) during the last hour of monitoring combined with the absence of decelerations or the presence of variable or late decelerations. The relationship between changes in variability and the outcome variables of pH and base deficit in the six groups was assessed with analysis of variance and Chi Square test. Significance was set at the P < 0.05 level.	**Results** Women with normal variability and accelerations, even in the presence of late decelerations or variable decelerations, maintained an umbilical artery pH 7.0 or greater in more than 97% of cases. In the presence of minimal/absent variability (amplitude < 5) for at least an hour, the incidence of significant acidemia (pH < 7.0) ranged from (12%-31%): **Outcome variable corelated with different intrapartum electronic fetal monitoring parameters** Group 1 (normal variability) n = 42 Umbilical artery pH (mean ± SD) 7.24 ± 0.07 Base deficit (mean ± SD) 3.62 ± 3.16 Incidence of pH < 7.0: 0% (p < 0.05 vs. group 1, 2, 3) Incidence of pH < 7.1: 9.5% Incidence of base deficit < 16: 0% Incidence of base deficit < 12: 2.4% Group 2 (normal variability and late decelerations) n = 173 Umbilical artery pH (mean ± SD) 7.18 ± 0.07 Base deficit (mean ± SD) -6.17 ± 3.14 Incidence of pH < 7.0: 1.7% Incidence of pH < 7.1: 13.3% Incidence of base deficit < 16: 0% Incidence of base deficit < 12: 4.6% Group 3 (normal variability and and variable decelerations) n = 219 Umbilical artery pH (mean ± SD) 7.18 ± 0.08 Base deficit (mean ± SD) -6.24 ± 3.6 Incidence of pH < 7.0: 23% Incidence of pH < 7.1: 9.1% Incidence of base deficit < 16: 0.91% Incidence of base deficit < 12: 5.5% Group 4 (decreased variability) n = 13 Umbilical artery pH (mean ± SD) 7.07 ± 0.2 Base deficit (mean ± SD) -9.8 ± 7.7 (p < 0.05 vs. group 4 and 5) Incidence of pH < 7.0: 31% (p < 0.05 vs. group 1, 2, 3 and 6) Incidence of pH < 7.1: 38.5% (p < 0.05 group 1, 2, 3 and 6) Incidence of base deficit < 16: 23.1% (p < 0.05 group 1, 2, 3 and 6) Incidence of base deficit < 12: 38.5% (p < 0.05 group 1, 2, 3 and 6) Group 5 (decreased variability and late deceleration) n = 25 Umbilical artery pH (mean ± SD) 7.01 ± 0.14 Base deficit (mean ± SD) -9.58 ± 6.14 (p < 0.05 vs. group 4 and 5) Incidence of pH < 7.0: 24% (p < 0.05 vs. group 1, 2, 3 and 6) Incidence of pH < 7.1: 44% (p < 0.05 group 1, 2, 3 and 6) Incidence of base deficit < 16: 24% (p < 0.05 group 1, 2, 3 and 6) Incidence of base deficit < 12: 32% (p < 0.05 group 1, 2, 3 and 6) Group 6 (decreased variability and varable decelerations) n = 16 Umbilical artery pH (mean ± SD) 7.19 ± 0.14 (p < 0.05 vs. group 2, 3, 4 and 5) Base deficit (mean ± SD) 3.37 ± 5.07 Incidence of pH < 7.0: 12.5% Incidence of pH < 7.1: 18.8%	**Limitations** **Other information** Fetal Heart rate traces were assessed based on the National Institute of Child Health and Human Development guidelines for FHR monitoring Neonatal acidosis defined as a pH of less than 7.0 at birth

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Incidence of base deficit < 16: 12.5% Incidence of base deficit < 12: 12.5% **<u>Umbilical artery blood gas value in the absence of accelerations</u>** <u>Group 4 n = 8</u> Umbilical artery pH (mean ± SD) 6.97 ± 0.17 Base deficit (mean ± SD) -13.06 ± 7.07 Incidence of pH < 7.0: 62.5% Incidence of pH < 7.1: 62.5% Incidence of base deficit < 16: 37.5% Incidence of base deficit < 12: 62.5% <u>Group 5 n = 19</u> Umbilical artery pH (mean ± SD) 7.01 ± 0.13 Base deficit (mean ± SD) -13.15 ± 6.64 Incidence of pH < 7.0: 31.6% Incidence of pH < 7.1: 52.6% Incidence of based deficit < 16: 26.3% Incidence of based deficit < 12: 42.1% <u>Group 6 n = 8</u> Umbilical artery pH (mean ± SD) 7.08 ± 0.2 Base deficit (mean ± SD) -9.95 ± 6.25 Incidence of pH < 7.0: 25% Incidence of pH < 7.1: 37.5% Incidence of base deficit < 16: 25% Incidence of base deficit < 12: 25%	
Full citation Williams,K.P., Galerneau,F., Fetal heart rate parameters predictive of neonatal outcome in the presence of a prolonged deceleration, Obstetrics and Gynecology, 100, 951-954, 2002 **Ref Id** 174549 **Country/ies where the study was carried out** Canada **Study type** Cohort **Aim of the study** To correlate the presence of baseline variability and the duration of a prolonged deceleration/bradycardia in intrapartum fetal heart rate (FHR) tracings with the development of neonatal acidemia **Study dates** January 1997 to January 2000 **Source of funding** Not specified	**Sample size** n = 186 women **Characteristics** Not specified **Inclusion criteria** Term pregnancy (> 37 weeks) An identified prolonged deceleration/bradycardia for > 2 minutes with fall < 100 bpm Birth of neonates within 30 minutes of the bradycardia Continous electronic fetal monitoring (EFM) for 2 hours before the delivery Umbilical cord artery and cord blood gases done at birth **Exclusion criteria** Not specified	**Interventions** Fetal heart rate tracing	**Details** Study's population consisted of n = 186 women with term gestations who had continuous electronic fetal monitoring for at least 2 hours before delivery, with an identified bradycardia during that period. Each woman had umbilical artery cord analysis done and delivery within 30 minutes of that bradycardia. The last hour of all electronic monitoring tracings was reviewed by one investigator blinded to the cord gas outcome reviewed using the National Institute of Child Health and Human Development guidelines for FHR monitoring. The presence or absence of variability before the bradycardia and recovery or no recovery of the bradycardia were assessed and women were categorised into four groups. Group 1 (n = 128 women) with normal variability and recovery before 10 minutes , group 2 (n = 40 women) with normal variability and no recovery within 10 minutes, group 3 (n = 9 women) with decreased variability and recovery within 10 minutes, and group 4 (n = 9 women) with decreased variability and no recovery within 10 minutes. Two cutoffs were used to define abnormal pH; a pH < 7.0 and a pH < 7.1. Two cutoffs were also used for base deficit, a base deficit > -16 and a base deficit > -12.	**Results** **<u>Outcome variable correlated with different intrapartum electronic fetal monitoring parameters</u>** <u>Group 1 (normal variability and recovery) n = 128</u> Umbilical artery pH (mean ± SD) 7.17 ± 0.09 Base deficit (mean ± SD) -6.54 ± 3.9 Incidence of pH < 7.0: 2% (p < 0.05 vs. group 2 and 3) Incidence of pH < 7.1: 22% Incidence of pH < 7.0: 1% Incidence of pH < 7.0: 5% P < 0.001 <u>Group 2 (normal variability and no recovery) n = 40</u> Umbilical artery pH (mean ± SD) 7.13 ± 0.15 Base deficit (mean ± SD) -7.15 ± 5.1 Incidence of pH < 7.0: 18% Incidence of pH < 7.1: 33% Incidence of pH < 7.0: 8% Incidence of pH < 7.0: 13% P < 0.001 <u>Group 3 (decreased variability and recovery) n = 9</u> Umbilical artery pH (mean ± SD) 7.11 ± 0.11 Base deficit (mean ± SD) -10.32 ± 3.68 Incidence of pH < 7.0: 44% Incidence of pH < 7.1: 56% Incidence of pH < 7.0: 11.1% Incidence of pH < 7.0: 22% P < 0.001 <u>Group 4 (decreased variability and no recovery) n = 9</u> Umbilical artery pH (mean ± SD) 6.83 ± 0.16 (p < 0.05 vs. group 1,2,3) Base deficit (mean ± SD) -20.17. ± 6.0 (p < 0.05 vs. group 1,2,3) Incidence of pH < 7.0: 78% (p < 0.05 vs. group 1 and 2) Incidence of pH < 7.1: 89% (p < 0.05 vs. group 1) Incidence of pH < 7.0: 78% (p < 0.05 vs. group 1 and 2)	**Limitations** **Other information** Fetal heart rate traces were assessed based on the National Institute of Child Health and Human Development guidelines for FHR monitoring Neonatal acidosis defined as a pH of less than 7.0 at birth Prolonged deceleration/bradycardia: > 2 minutes with a fall to < 100 bpm

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			Analysis Analysis of variance and the chi^2 test were used to asses the relationship between the various groups. A multiple logistic regression model was developed with the parameters of amplitude and recovery used to predict pH at birth.	Incidence of pH < 7.0: 89% (p < 0.05 vs. group 1 and 2) P < 0.001	
Full citation Williams,K.P., Galerneau,F., Comparison of intrapartum fetal heart rate tracings in patients with neonatal seizures vs. no seizures: what are the differences?, Journal of Perinatal Medicine, 32, 422-425, 2004 **Ref Id** 121348 **Country/ies where the study was carried out** USA **Study type** Case control **Aim of the study** To examine which intrapartum fetal heart rate parameters in the presence of severe neonatal acidosis (pH < 7.0) appropriately predicts the development of neonatal seizures in the context of hypoxic ischemic encephalopathy (HIE). **Study dates** January 1997 to January 2000 **Source of funding** Not specified	**Sample size** Seizure n = 25 No seizure (controls) n = 25 **Characteristics** There were no significant differences observed between the seizure and no seizure group in maternal age (32 ± 5 vs 34 ± 3), gravidity (2 ± 1 vs 2 ± 2), gestational age (39 ± 2 vs 38 ± 3) and neonatal birth weight. **Inclusion criteria** Singleton pregnancy Term ≥ 37 weeks Presence of neonatal convulsions with 24 - 48 hours of birth secondary to hypoxic ischemic encephalopathy **Exclusion criteria** Not specified	**Interventions** Fetal heart rate parameters	**Details** The neonatal and antenatal records of the women who fit the inclusion criteria were reviewed. The cases with confirmed diagnoses of HIE (based on the clinical criteria and nureo-imaging) and cord pH < 0.7 were chosen for the study. The intrapartum fetal heart rate tracings of neonates who developed neonatal seizures secondary to HIE were compared with matched neonates with similar pH (pH < 0.7) and gestational age (> 37) who did not develop seizures. All women had at least 2 hours of intrapartum fetal heart rate patterns available for review. The fetal heart rate parameters (prolonged deceleration, variable and late decelerations, variability, accelerations, fetal heart rate baseline and duration of the fetal heart rate abnormality) were reviewed. Analysis Comparison between the groups was done using chi-square and Fisher's exact test for nominal data, and Student's t-test for continuous data.	**Results** **Incidence of fetal heart rate parameters (seizure n = 25, no seizure n = 25)** Bradycardia Seizure n = 14 (56%) No seizure n = 21 (84%) Odds ratio 0.24 (0.06 to 0.92) p = 0.062 Variable deceleration Seizure n = 9 (36%) No seizure = 15 (50%) Odds ratio 0.38 (0.12 to 1.18) p = 0.156 Late decelerations Seizure n = 8 (32%) No seizure n = 13 (52%) Odds ratio 0.43 (0.14 to 1.37) p = 0.256 Minimal/absent variability Seizure n = 16 (64%) No seizure n = 9 (36%) Odds ratio 3.16 (1 to 10.03) p = 0.080 Accelerations Seizure n = 6 (24%) No seizure = 12 (36%) Odds ratio 0.34 (0.10 to 1.15) p = 0.140 Duration of abnormal FHR(min) Seizure 72 ± 12 No seizure 36 ± 18 p < 0.001 Baseline FHR (beats/min) Seizure 143 ± 11 No seizure 146 ± 16 p = 0.444	**Limitations** Exclusion criteria not specified No definitions for all FHR features and abnormal FHR given **Other information** The tracing was reviewed in two 1 hour segments according to NICHD classification Minimal baseline variability: amplitude variation of ≤ 5 bpm Absent baseline variability: no amplitude variation

G.5 Care in labour as a result of cardiotocography

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Clark, S. L., Meyers, J. A., Frye, D. K., Garthwaite, T., Lee, A. J., Perlin, J. B., Recognition and response to electronic fetal heart rate patterns: impact on newborn outcomes and primary cesarean delivery rate in women undergoing induction of labor, American Journal of Obstetrics & Gynecology, 212, 494.e1-6, 2015 **Ref Id** 391386 **Country/ies where the study was carried out** USA **Study type** Retrospective cohort study **Aim of the study** To examine the clinical impact of specific fetal monitoring related procedures during induced labour **Study dates** April to September 2013 **Source of funding** Not reported	**Sample size** N = 14398 charts reviewed in total **Characteristics** Not reported **Inclusion criteria** Singleton, term (≥ 37 weeks) pregnancies, undergoing induction of labour with oxytocin **Exclusion criteria** None reported	**Interventions** The protocol for intervention advocated a reduction in the dose of oxytocin according to the fetal heart rate pattern, or according to features of the uterine contractions. Safety checks for fetal heart rate pattern In any 30 minute segment of CTG there should be: -at least one acceleration of 15 bpm for 15 seconds, or adequate variability present for at least 10 minutes -no more than one late deceleration -no more than 2 variable decelerations exceeding 60 seconds in duration and decreasing for more than 60 bpm Safety checks for uterine contractions: In any 30 minute segment of CTG there should be: -no more than 5 contractions in 10 minutes, for any 20 minute interval -no two contractions exceeding 120 seconds in duration -the uterus should palpate as soft between contractions -if an intrauterine pressure catheter is in place, the Montevideo units must calculate less than 300 mmHg and the baseline resting tone must be < 25mmHg	**Details** Chart reviews were conducted for all pregnancies which met the inclusion criteria. Each chart was examined by a regional nurse who was certified as a fetal heart rate monitor instructor by the Association of Women's Health, Obstetric and Neonatal Nurses. Each 30 minute section of CTG recorded during the infusion of oxytocin was examined for specific features (as described above). For every segment in which these reassuring features were not present, the chart was reviewed to assess whether oxytocin had been reduced or not. The chart was regarded as compliant if the oxytocin infusion had been reduced. The chart was regarded as non-compliant if the dose of oxytocin was not reduced, despite the absence of reassuring features. Charts had to be compliant throughout the entire duration of oxytocin infusion. The proportion of babies with adverse outcome (NICU admission; 1 minute Apgar score of < 7; 5 minute Apgar score of < 7 or primary caesarean section) was compared in the groups in whom oxytocin was reduced appropriately, to those in whom the oxytocin had not been reduced despite non-reassuring CTG features	**Results** In the traces with non-reassuring fetal heart rate features: **NICU admission** Group in whom oxytocin was decreased, n/N: 91/2354 (3.8%) Group in whom oxytocin was not decreased, n/N: 276/5272 (5.2%) RR 0.74 (95% CI 0.58-0.93) **Primary caesarean section** Group in whom oxytocin was decreased, n/N: 630/2364 (26.6%) Group in whom oxytocin was not decreased, n/N: 923/5272 (17.5%) RR 1.52 (95% CI 1.39-1.66) Risk ratios (RRs) calculated by the NGA technical team using Review Manager version 5.3.	**Limitations** **Other information** NICE 2012 guidelines manual checklist for cohort studies **A. Selection bias** A1 The method of allocation to treatment groups was unrelated to potential confounding factors: Unclear - Although participants were not 'allocated' to treatment groups, they were assigned to the groups retrospectively based on the interpretation of CTGs and data extraction from case notes. It is not clear whether those responsible for allocating CTGs to the two groups were aware of the neonatal outcome at the time of allocation. This could affect how cases were allocated as compliant or non-compliant A2 Attempts were made within the design or analysis to balance the comparison groups for potential confounders: No - RRs were calculated by the NGA technical team based on the n/N provided by the study, therefore, the RRs are unadjusted for potential confounding factors and can cause high risk of bias A3 The groups were comparable at baseline, including all major confounding and prognostic factors: Unclear - no baseline characteristics reported Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect? High risk of bias **B. Performance bias** B1 The comparison groups received the same care apart from the intervention(s) studied: Unclear B2 Participants receiving care were kept 'blind' to treatment allocation: n/a B3 Individuals administering care were kept 'blind' to treatment allocation: n/a Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect? Unclear or unknown risk **C. Attrition bias** C1 All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up) Yes C2 a. How many participants did not complete treatment in each group? n/a b. The groups were comparable for treatment completion: n/a C3 a. For how many participants in each group were no outcome data available? - No Apgar data for 12 participants in the compliant group, and 18 in the non-compliant group (with regard to fetal heart rate) - No Apgar data for 3 participants in the compliant group, and 9 in the non-compliant group (with regard to contractions).

<table>
<tr><th>Study details</th><th>Participants</th><th>Interventions</th><th>Methods</th><th>Outcomes and Results</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>b. The groups were comparable with respect to the availability of outcome data: Yes
Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?
Low risk of bias
D. Detection bias
D1 The study had an appropriate length of follow-up: Yes
D2 The study used a precise definition of outcome: Yes
D3 A valid and reliable method was used to determine the outcome: Yes
D4 Investigators were kept 'blind' to participants' exposure to the intervention: No
D5 Investigators were kept 'blind' to other important confounding and prognostic factors: No
Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?
Low risk of bias</td></tr>
<tr><td>Full citation

Lowe, B., Beckmann, M., Involving the consultant before fetal blood sampling, Australian & New Zealand Journal of Obstetrics & Gynaecology, 14, 14, 2016

Ref Id

458053

Country/ies where the study was carried out

Australia

Study type

Retrospective cohort study

Aim of the study

To compare neonatal outcomes following a change in hospital policy to consultant review of all CTG traces prior to collection of a fetal blood sample (FBS)

Study dates

Period 1: 1st May 2011 to 30th April 2012
Period 2 (following implementation of the new protocol): 1st May 2012 to 30th April 2013

Source of funding

None reported</td><td>Sample size

N = 4712
n = 2225 births prior to the new protocol being implemented
n = 2487 births after the protocol was implemented

Characteristics

<table><tr><th>Characteristic</th><th>Before protocol introduction</th><th>After protocol introduction</th><th>p value</th></tr><tr><td>Maternal age, mean (SD)</td><td>29.4 (5.6)</td><td>29.6 (5.4)</td><td>0.18</td></tr><tr><td>BMI, median (IQR)</td><td>23.1 (20.3, 27.0)</td><td>23.1 (20.4, 26.9)</td><td>0.56</td></tr><tr><td>Nulliparity, n (%)</td><td>1287 (57.8)</td><td>1440 (57.9)</td><td>0.97</td></tr><tr><td>Gestational age at birth, mean (SD)</td><td>39.5 (1.2)</td><td>39.4 (1.2)</td><td>0.08</td></tr><tr><td>Birthweight (g), mean (SD)</td><td>3497 (489)</td><td>3479 (494)</td><td>0.22</td></tr><tr><td>Induction of labour, n (%)</td><td>964 (43.3)</td><td>1100 (44.2)</td><td>0.53</td></tr><tr><td>Oxytocic augmentation, n (%)</td><td>550 (24.7)</td><td>531 (21.3)</td><td>0.01</td></tr><tr><td>Epidural, n (%)</td><td>1106 (49.7)</td><td>1262 (50.7)</td><td>0.48</td></tr></table></td><td>Interventions

A new hospital protocol was instigated whereby CTGs had to be reviewed by a consultant prior to a fetal blood sample being collected</td><td>Details

Prior to the new protocol, CTGs were not routinely reviewed by a consultant before a fetal blood sample was collected. After implementing the new protocol, all CTGs were reviewed remotely by a consultant prior to the decision to collect a fetal blood sample. The criterion for fetal blood sampling was a pathological CTG</td><td>Results

Fetal blood samples performed
Before protocol, n/N (%): 79/2225 (3.6)
After protocol implemented, n/N (%): 43/2487 (1.7)
RR 0.49 (95% CI 0.34-0.70)

Acidosis (pH <7.1)
Before protocol, n/N (%): 49/2225 (2.2)
After protocol implemented, n/N (%): 20/2487 (0.8)
RR 0.37 (95% CI 0.22-0.61)

Admission to NICU
Before protocol, n/N (%): 98/2225 (4.4)
After protocol implemented, n/N (%): 106/2487 (4.3)
RR 0.97 (95% CI 0.74-1.27)

Emergency caesarean section
Before protocol, n/N (%): 537/2225 (24.1)
After protocol implemented, n/N (%): 559/2487 (22.5)
RR 0.93 (95% CI 0.84-1.03)

Instrumental birth
Before protocol, n/N (%): 445/2225 (20)
After protocol implemented, n/N (%): 439/2487 (17.6)
RR 0.88 (95% CI 0.78-0.99)

Emergency caesarean section due to fetal distress
Before protocol, n/N (%): 181/2225 (8.1)
After protocol implemented, n/N (%): 165/2487 (6.6)
RR 0.82 (95% CI 0.67-1.00)</td><td>Limitations

Other information

NICE 2012 guidelines manual checklist for cohort studies
A. Selection bias
A1 The method of allocation to treatment groups was unrelated to potential confounding factors: No
- The two separate groups comprised women giving birth during different time periods, therefore there are potentially confounders as well as the change in protocol that the study aimed to assess
A2 Attempts were made within the design or analysis to balance the comparison groups for potential confounders: No
- Multiple variable analysis was done on only one outcome, otherwise ORs/RRs not reported and were calculated by the NGA technical using n/N reported. Therefore, most results are presenting unadjusted RRs and can be subject to bias since no adjustments for possible confounding variables were made
A3 The groups were comparable at baseline, including all major confounding and prognostic factors: No
- The majority of characteristics were not significantly different between the two groups. However, there was a significant reduction in the use of oxytocin during the second time period, which could affect the possible need for FBS, as well as potentially affecting neonatal outcome
Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect?
High risk of bias - potential confounders should be accounted for in the analysis

B. Performance bias</td></tr>
</table>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<table><tr><td>FBS performed, n (%)</td><td>79 (3.5)</td><td>43 (1.7)</td><td><0.01</td></tr><tr><td>Cord gas completed, n (%)</td><td>1006 (45.2)</td><td>1112 (44.7)</td><td>0.73</td></tr></table> **Inclusion criteria** All publically funded women with continuous CTG during labour, who gave birth during the study period **Exclusion criteria** Preterm birth (< 37 weeks), fetal death in utero, known congenital abnormalities and multiple pregnancy			**Emergency caesarean section due to failure to progress** Before protocol, n/N (%): 230/2225 (10.3) After protocol implemented, n/N (%): 253/2487 (10.2) RR 0.98 (95% CI 0.83-1.17) **Emergency caesarean section due to other reasons** Before protocol, n/N (%): 126/2225 (5.7) After protocol implemented, n/N (%): 141/2487 (5.7) RR 1.00 (95% CI 0.79-1.26) **Normal vaginal birth** Before protocol, n/N (%): 1231/2225 (55.3) After protocol implemented, n/N (%): 1460/2487 (58.7) RR 1.06 (95% CI 1.01-1.12) **Fetal scalp lactate > 4.8 mmol/l** Before protocol, n/N (%): 56/2225 (2.5) After protocol implemented, n/N (%): 36/2487 (1.4) RR 0.58 (95% CI 0.38-0.87) Risk ratios calculated by the NGA technical team using Review Manager version 5.3	B1 The comparison groups received the same care apart from the intervention(s) studied: Unclear - As above, the different time periods mean that care may have changed in other ways for the later group B2 Participants receiving care were kept 'blind' to treatment allocation: n/a B3 Individuals administering care were kept 'blind' to treatment allocation: No Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect? Unclear or unknown risk **C. Attrition bias** C1 All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up): Yes C2 a. How many participants did not complete treatment in each group? n/a b. The groups were comparable for treatment completion: n/a C3 a. For how many participants in each group were no outcome data available? None reported b. The groups were comparable with respect to the availability of outcome data: Yes Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect? Low risk of bias **D. Detection bias** D1 The study had an appropriate length of follow-up: Yes D2 The study used a precise definition of outcome: Yes D3 A valid and reliable method was used to determine the outcome: Yes D4 Investigators were kept 'blind' to participants' exposure to the intervention: No D5 Investigators were kept 'blind' to other important confounding and prognostic factors: No Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect? Low risk of bias
Full citation Katsuragi, S., Parer, J. T., Noda, S., Onishi, J., Kikuchi, H., Ikeda, T., Mechanism of reduction of newborn metabolic acidemia following application of a rule-based 5-category color-coded fetal heart rate management framework, Journal of Maternal-Fetal and Neonatal Medicine, 28, 1608-1613, 2015 **Ref Id** 446292 **Country/ies where the study was carried out**	**Sample size** N = 3907 overall. Number of women included in each of the two groups is not clear **Characteristics** Not reported **Inclusion criteria** All births in a single institution during the study period **Exclusion criteria** Delivery by planned caesarean section	**Interventions** A 6 month training period was undertaken, during which time members of staff were trained in a new CTG management system. This was based on the NICHD categorisation and rule management system. CTGs were categorised into five colour coded tiers (with increasing severity: green, blue, yellow, orange and red) using 134 different combinations of variability, heart rate and graded decelerations. Each colour coded level had corresponding suggested interventions (ranging from patient positioning to immediate birth). The colour framework provides decision support only, without dictating the decision All healthcare staff were trained with the new system over a 6 month period. Pre- and post-intervention assessment was not undertaken	**Details** CTGs showing variable decelerations during the 10 minutes before birth were chosen for further analysis. The acid-base status of these neonates was compared before and after the training programme	**Results** **Acidosis (pH <7.15)** Before training, n/N (%): 11/688 (1.6) After training, n/N (%): 2/744 (0.2) RR 0.17 (95% CI 0.04-0.76) **Acidosis (BE < -12 mmol/l)** Before training, n/N (%): 11/688 (1.6) After training, n/N (%): 2/744 (0.2) RR 0.17 (95% CI 0.04-0.76)	**Limitations** **Other information** NICE 2012 guidelines manual checklist for cohort studies: **A. Selection bias** A1 The method of allocation to treatment groups was unrelated to potential confounding factors: No – different time periods were studied A2 Attempts were made within the design or analysis to balance the comparison groups for potential confounders: No RRs calculated by the NGA technical team, therefore, the RRs are unadjusted and are subject to bias because there is no adjustment for potential confounders

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Japan **Study type** Retrospective cohort study **Aim of the study** To assess neonatal outcomes before and after training with a rule-based, 5 category management system for CTG interpretation **Study dates** Baseline data were from 2003 to 2004. Follow up data were from 2006 to 2007 (following a 6 month training period in 2005) **Source of funding** Institutional funding only				Risk ratios (RRs) calculated by the NGA technical team using Review Manager version 5.3	A3 The groups were comparable at baseline, including all major confounding and prognostic factors: Unclear Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect? High risk of bias **B. Performance bias** B1 The comparison groups received the same care apart from the intervention(s) studied: Unclear B2 Participants receiving care were kept 'blind' to treatment allocation: n/a B3 Individuals administering care were kept 'blind' to treatment allocation: n/a Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect? Low risk of bias **C. Attrition bias** C1 All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up): Yes C2 a. How many participants did not complete treatment in each group? n/a b. The groups were comparable for treatment completion: n/a C3 a. For how many participants in each group were no outcome data available? Not reported b. The groups were comparable with respect to the availability of outcome data: Unclear Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect? Unclear risk of bias **D. Detection bias** D1 The study had an appropriate length of follow-up: Yes D2 The study used a precise definition of outcome: Yes D3 A valid and reliable method was used to determine the outcome: Yes D4 Investigators were kept 'blind' to participants' exposure to the intervention: Unclear D5 Investigators were kept 'blind' to other important confounding and prognostic factors: Unclear Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect? Low risk of bias

G.6 Fetal scalp stimulation

Anyaegbunam,A.M., Ditchik,A., Stoessel,R., Mikhail,M.S., Vibroacoustic stimulation of the fetus entering the second stage of labor, Obstetrics and Gynecology, 83, 963-966, 1994

Bibliographic details

Full citation

Anyaegbunam,A.M., Ditchik,A., Stoessel,R., Mikhail,M.S., Vibroacoustic stimulation of the fetus entering the second stage of labor, Obstetrics and Gynecology, 83, 963-966, 1994

Ref Id

202123

Country/ies where the study was carried out

USA

Aim of the study

To evaluate the fetal heart rate response to vibroacoustic stimulation of fetuses entering the second stage of labour as a predictor of neonatal outcome

Study type

Study dates

July 1991 - July 1992

Source of funding

Not reported

Participants

Sample size

N = 632
Vibroacoustic stimulation (VAS) = 316
Sham stimulation = 316

Characteristics

Maternal age (years) - mean ± SD
VAS = 26 ± 4
Sham = 24 ± 3

Nulliparous
VAS = 40.5%
Sham = 44.6%

Gestational age at delivery (weeks) - mean ± SD
VAS = 39 ±1
Sham = 38 ± 2

Birthweight (g) - mean ± SD
VAS = 3430 ± 438
Sham = 3363 ± 381

Low arterial pH (<7.20)
VAS = 5.7%
Sham = 4.7%

Inclusion Criteria

Gestational age ≥37 weeks, singleton fetus, reassuring heart rate patterns, cephalic presentation, absence of heavy meconium and fully dilated cervix

Exclusion Criteria

Not reported

Tests

Tests

5 seconds of fetal vibroacoustic stimulation

Methods

Methods

Consecutive volunteers who met the study criteria were included. Women were assigned to the study or control group based on a pre-generated list of random numbers - allocation was to VAS if the next number was odd, and to sham stimulation if the number was even.

A 5c electronic larynx (AT&T, Special Needs Center, Parsippany, NJ) was placed above the symphysis on the mother's abdomen. The larynx was activated for 5 seconds, 30 seconds after a uterine contraction, and the fetal heart rate (FHR) trace was marked and the response recorded. In the sham stimulation group the artifiical larynx was not activated but the FHR trace was marked in a similar fashion.

FHR traces were interpreted by an investigator blinded to group allocation. An acceleration was defined as an increase over baseline of at least 15 bpm for at least 15 seconds. Those receiving VAS were stratified into 3 groups: acceleration, initial acceleration followed by immediate deceleration, and no response.

Samples of umbilical artery and vein blood were obtained at birth and tested for pH, carbon dioxide pressure, oxygen pressure and base defecit

Outcomes and results

Results

Prevalence of acidosis (umbilical) pH < 7.20
18/316 (6%)

a. For umbilical cord pH <7.20
All values calculated by NCC from data in Table 3
Sensitivity: 22.2% (3.02 to 41.43)
Specificity: 77.18% (72.42 to 81.95)
PPV: 5.56% (0 to 10.85)
NPV: 94.26% (91.34 to 97.18)
LR+: 0.97 (0.40 to 2.37)
LR-: 1.01 (0.78 to 1.30)

b. For Apgar score < 7 at 5 minutes
All values calculated by NCC from data in Table 3
Sensitivity: 30% (1.60 to 58.40)
Specificity: 77.45% (72.77 to 82.13)
PPV: 4.17% (0 to 8.78)
NPV: 97.13% (95.04 to 99.23)
LR+: 1.33 (0.50 to 3.51)
LR-: 0.90 (0.60 to 1.36)

Cord pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	4	68
Predictive Test -ve	14	230

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	3	69
Predictive Test -ve	7	237

Comments

Limitations

Only outcome data reported for those receiving the active intervention (VAS) - case series
Allocation concealment unclear
Period of FHR observation for qualifying acceleration following stimulus not reported
Indirectness: All participants had reassuring FHR traces; unclear whether any women were considered high risk

Other information

Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics)
For 2x2 table acceleration and acceleration followed by deceleration were considered a negative stimulation test result

Arulkumaran,S., Ingemarsson,I., Ratnam,S.S., Fetal heart rate response to scalp stimulation as a test of fetal well-being in labour, Asia-Oceania Journal of Obstetrics and Gynaecology, 13, 131-135, 1987

Bibliographic details

Full citation

Arulkumaran,S., Ingemarsson,I., Ratnam,S.S., Fetal heart rate response to scalp stimulation as a test of fetal well-being in labour, Asia-Oceania Journal of Obstetrics and Gynaecology, 13, 131-135, 1987

Ref Id

201763

Participants

Sample size

N = 50

Characteristics

Suspicious trace = 32/50 (64%)
Ominous trace = 18/50 (36%)

Tests

Tests

Fetal scalp stimulation for 15 seconds carried out with Allis' tissue forceps (closed to first ratchet)

Methods

Methods

Fetal heart rate was monitored with a scalp electrode and the trace interpreted by two senior members of staff.

Suspicious trace defined as: no accelerations and reduced baseline variability (5-10 bpm) or abnormal baseline rate or flat baseline (< 5 bpm) or variable decelerations without ominous features. Ominous trace defined as: flat baseline and abnormal baseline rate or repeated late decelerations or reperated variable decelerations with ominous feautres (duration > 60

Outcomes and results

Results

Prevalence of acidosis
4% (2/50)

Predictive accuracy of no acceleration following fetal scalp stimulation (Allis clamp)
a. For FBS pH < 7.20
All values calculated by NCC from data in Table 1
Sensitivity: 100% (100 to 100)

Comments

Limitations

Study sample represents population: unclear whether consecutive women were included, length of study period not reported
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: period of fetal heart rate observation for qualifying acceleration following stimulus not reported
Outcome of interest is sufficiently measured in participants: yes

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>Country/ies where the study was carried out

Singapore

Aim of the study

To evaluate the response of the fetus to painful pinch stimulation of the scalp and its relation to fetal acid base balance when a suspicious or ominous fetal heart rate was encountered

Study type

Study dates

Not reported

Source of funding

Not reported</td>
<td>Inclusion Criteria

Women in the first stage of labour with cephalic presentation

Exclusion Criteria

Not reported</td>
<td></td>
<td>seconds, beat loss > 60 beats, slow recovery, rebound tachycardia, late deceleration component). Fetal heart rate changes were so classified if it persisted after corrective measures of alteration of position of the mother, hydration, oxygen inhalation and omission of oxytocin infusion.

Scalp stimulation was carried out for 15 seconds when the fetal heart rate recording was at the baseline rate. The presence or absence of immediate fetal heart tate acceleration was noted. Acceleration was defined as at least 15 beats above the baseline for at least 15 seconds duration.

Within 20 min of the test stimulation fetal blood sampling was performed with the mother in in the left lateral position. Management was according to FBS results and continued CTG trace.</td>
<td>Specificity: 83.33% (72.79 to 93.88)
PPV: 20% (0 to 44.79)
NPV: 100% (100 to 100)
LR+: 6 (3.19 to 11.30)
LR-: 0 (NC)

<u>b. For caesarean section</u>
All values calculated by NCC from data in Table 2
Sensitivity: 60% (29.64 to 90.36)
Specificity: 90% (80.70 to 99.30)
PPV: 60% (29.64 to 90.36)
NPV: 90% (80.70 to 99.30)
LR+: 6 (2.08 to 17.29)
LR-: 0.44 (0.21 to 0.96)

FBS pH
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>2</td><td>8</td></tr>
<tr><td>Predictive Test -ve</td><td>0</td><td>40</td></tr>
</table>
Caesarean section
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>6</td><td>4</td></tr>
<tr><td>Predictive Test -ve</td><td>4</td><td>36</td></tr>
</table>
</td>
<td>Important potential confounders are accounted for: time between stimulation, fetal blood sample and delivery not reported
Statistical analysis is appropriate for study design: yes
Indirectness: unclear whether women were considered high risk

Other information

Authors define an acceleration as a positive stimulation test but do not report any accuracy statistics calculated using this definition. NCC calculated predictive values using no acceleration as definition of positive stimulation test, in line with other included studies.
Two babies who had negative tests and acidotic scalp pH values had cord arterial pH values below 7.20 at birth but none had low Apgar score (< 7) at 5 minutes.</td>
</tr>
<tr>
<td>Full citation

Bartelsmeyer,J.A., Sadovsky,Y., Fleming,B., Petrie,R.H., Utilization of fetal heart rate acceleration following vibroacoustic stimulation in labor to predict fetal acidemia and base deficit levels, Journal of Maternal-Fetal Medicine, 4, 120-125, 1995

Ref Id

202115

Country/ies where the study was carried out

USA

Aim of the study

To evaluate if vibroacoustic stimulation can predict fetal scalp blood base defecit levels in addition to pH levels.</td>
<td>Sample size

N = 104

Characteristics

<u>Gestational age (weeks) - mean ± SD, N</u>
15bpm x 15 sec acceleration = 38.8 ± 1.7, 52
10bpm x 10 sec acceleration = 39.2 ± 2.3, 23
No acceleration = 37.7 ± 3.1, 29

<u>Birth weight (g) - mean ± SD</u>
15bpm x 15 sec acceleration = 3343 ± 482, 52
10bpm x 10 sec acceleration = 3339 ± 507, 23
No acceleration = 2855 ± 872, 29</td>
<td>Tests

5 seconds of continuous fetal vibroacoustic stimulation (VAS)</td>
<td>Methods

Women having FBS were studied over a 24 month period. Immediately prior to FBS fetal VAS was performed using a model 5C electronic artificial larynx (AT&T Consumer Products, USA) which produces a mixed frequency sound of 81 Hz and 81 db measured at 1 m in air. A single stimulus was applied continuously for 5 seconds to the maternal abdomen one-third of the distance from the symphysis pubis to the umbilicus.

Accelerations of the fetal heart rate (FHR) occurring within 20 seconds of VAS were recorded as a positive response. The amplitude and duration of acceleratory response was recorded and FHR trcaes interpreted by either of two investigators. FHR responses were classified in to three groups: FHR response of at least 15 bpm for 15 seconds, FHR response of at least 10 bpm for 10 seconds but less than 15 bpm for 15 seconds and no response.

FHR was recorded by an internal scalp electrode. FBS was performed immediately following VAS.</td>
<td>Results

<u>Prevalence of acidosis</u>
14/104 (13%)

<u>Predictive value of no acceleration following VAS</u>
<u>a. For fetal blood sample pH < 7.20</u>
All values calculated by NCC from data in Table 4 (corresponds to sensitivity reported in text of paper)
Sensitivity: 79% (57.08 to 100)
Specificity: 52.22% (41.9 to 62.54)
PPV: 20.37% (9.63 to 31.11)
NPV: 94% (87.42 to 100)
LR+: 1.64 (1.12 to 2.33)
LR-: 0.41 (0.15 to 1.14)

<u>b. For Apgar score < 7 at 5 min</u>
All values calculated by NCC from data in Table 2
Sensitivity: 83.33% (53.51 to 100)
Specificity: 52.04% (42.15 to 61.93)</td>
<td>Limitations

Study sample represents population: unclear whether consecutive women were included
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome
Outcome of interest is sufficiently measured in participants: yes
Important potential cofounders are accounted for: time between VAS and delivery not reported
Statistical analysis is appropriate for study: yes
Indirectness of population: based on gestational age mean and SD for 'no acceleration' population not all fetuses were delivered at term; unclear whether any women were considered high risk

Other information</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Study type **Study dates** 24-month period (study dates not reported) **Source of funding** Not reported	**Inclusion Criteria** Women having fetal scalp blood sampling (FBS) **Exclusion Criteria** Not reported			PPV: 9.62% (1.6 to 17.63) NPV: 98.08% (94.34 to 100) LR+: 1.74 (1.15 to 2.62) LR-: 0.32 (0.05 to 1.93) **FBS pH** **Apgar score**	Authors' definition of positive stimulation test: no acceleration For 2x2 table no response and FHR response of at least 10 bpm for 10 seconds but less than 15 bpm for 15 seconds were considered a positive stimulation test result

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	11	43
Predictive Test -ve	3	47

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	5	47
Predictive Test -ve	1	51

Full citation	Sample size	Tests	Methods	Results	Limitations
Full citation Chauhan,S.P., Hendrix,N.W., Devoe,L.D., Scardo,J.A., Fetal acoustic stimulation in early labor and pathological fetal acidemia: a preliminary report, Journal of Maternal-Fetal Medicine, 8, 208-212, 1999 **Ref Id** 201734 **Country/ies where the study was carried out** USA **Aim of the study** To determine if a non-reactive response to fetal acoustic stimulation in early labour can predict a significantly higher risk of umbilical arterial pH < 7.10 or < 7.00 **Study type** **Study dates** 6-month period (dates not reported) **Source of funding** Not reported	**Sample size** N = 271 **Characteristics** Maternal age (years) - mean ± SD 24.4 ± 6.0 Nulliparous 104/271 (82%) Mean gestational age (weeks) - mean ± SD 39.1 ± 1.5 Mean birth weight (g) - mean ± SD 3328 ± 486 **Inclusion Criteria** 1] Singleton gestation 2] In early active labour (cervical dilation of 5 cm or less) 3] no contraindication to continue labour 4] vertex presentation 5] no narcotics 6] umbilical arterial blood gas anaylsis within 30 min of delivery 7] ≥ 37 weeks' gestational age	3-seconds of vibroacoustic stimulation (VAS)	3-second fetal VAS was performed by placing the stimulator unit (Corometrics model 146, Wallingford, CT) over the symphysis. If no acceleration of fetal heart rate (FHR) occurred within 1 min of stimulation, additional pulses were applied at 1-min intervals with a maximum of 3 pulses. If 10 min after the third stimuli there was no acceleration (acceleration defined as an increase of 15 bpm lasting for at least 15 seconds) of FHR then the response was considered non-reactive. Immediately after birth a segment of umbilical cord was doubly clamped and umbilical arterial and venous blood samples were collected. Blood gas analyses were performed within 30 min of delivery. Caesarean delivery for fetal distress was undertaken if fetal bradycardia, late decelerations, or moderate to severe variable decelerations occurred and were unresponsive to conservative management such as changes in maternal position, hydration, supplemental oxygenation, transcervical amnioinfusion and use of tocolytics for intrauterine resuscitation. Scalp stimulation was performed prior to proceeding with urgent caesarean delivery for abnormal FHR. Scalp pH was not obtained due to nonavailability of the machine. Results of VAS were not used in the management of the woman's labour.	**Results** **Prevalence of acidosis** a. pH < 7.10 8/271 (3.3%) b. pH < 7.00 4/271 (1.6%) **Predictive value of no acceleration following VAS** a. For umbilical pH < 7.10 Values as reported in Table 2; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 44% (11.98 to 76.91) Specificity: 91% (87.79 to 94.65) PPV: 15% (1.41 to 28.21) NPV: 97.95 (96.17 to 99.73) LR+: 5.06 (2.21 to 11.59) LR-: 0.61 (0.34 to 1.09) b. For umbilical pH < 7.00 Values as reported in Table 2; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 50% (1 to 99) Specificity: 91% (87.14 to 94.13) PPV: 7% (0 to 17.29) NPV: 99.18 (98.05 to 100) LR+: 5.34 (1.87 to 15.24) LR-: 0.55 (0.21 to 1.47) c. For cesearean section Values as reported in Table 2; NCC calculated LR+, LR- and all confidence intervals	**Limitations** Study sample represents population: not consecutive (women only included when one of the study authors was available) Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: 10-minute window for reaction to 3rd stimulus, compared with 1-min window for reaction to 1st and 2nd stimuli Outcome of interest is sufficiently measured in participants: results reported for pH < 7.10 and < 7.00 (standard definition is < 7.20) Important potential confounders are accounted for: yes Statistical analysis is appropriate for study design: yes Indirectness: unclear whether any women were considered high risk **Other information** Authors' definition of positive stimulation test: no acceleration Number of stimulations applied One stimulation = 214/271 (78.9%) Two stimulations = 19/271 (7%) Three stimulations = 38/271 (14%)

<table>
<tr>
<th>Bibliographic details</th>
<th>Participants</th>
<th>Tests</th>
<th>Methods</th>
<th>Outcomes and results</th>
<th>Comments</th>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria

Not reported</td>
<td></td>
<td></td>
<td>Sensitivity: 37% (3.95 to 71.05)
Specificity: 92% (87.39 to 94.35)
PPV: 11% (0 to 22.97)
NPV: 97% (96.17 to 99.73)
LR+: 4.11 (1.55 to 10.87)
LR-: 0.69 (0.40 to 1.18)

Umbilical cord pH
<table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>Predictive Test +ve</td><td>4</td><td>23</td></tr><tr><td>Predictive Test -ve</td><td>5</td><td>239</td></tr></table>
Umbilical cord pH
<table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>Predictive Test +ve</td><td>2</td><td>25</td></tr><tr><td>Predictive Test -ve</td><td>2</td><td>242</td></tr></table>
Caesarean section
<table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>Predictive Test +ve</td><td>3</td><td>24</td></tr><tr><td>Predictive Test -ve</td><td>5</td><td>239</td></tr></table></td>
<td>Of the 38 fetuses who received three stimulations, only 11 had an acceleration with 10 min of last VAS application (definition of response)

<u>Interval between first VAS to delivery</u>
Full study population = 7.9 ± 6.9 hours
Caesarean section for distress = 7.3 ± 4.3 hours vs. No caesarean section = 7.9 ± 6.9 hours
Umbilical arterial pH < 7.10 = 7.2 ± 6.0 hours vs. umbilical arterial pH ≥ 7.10 = 7.9 ± 6.6 hours
Umbilical arterial pH < 7.00 = 9.5 ± 8.0 hours vs. umbilical arterial pH ≥ 7.00 = 8.0 ± 6.9 hours</td>
</tr>
<tr>
<td>Full citation

Clark,S.L., Gimovsky,M.L., Miller,F.C., Fetal heart rate response to scalp blood sampling, American Journal of Obstetrics and Gynecology, 144, 706-708, 1982

Ref Id

201761

Country/ies where the study was carried out

USA

Aim of the study</td>
<td>Sample size

N = 200

Characteristics

Not reported

Inclusion Criteria

Not reported

Exclusion Criteria

Not reported</td>
<td>Tests

Endoscope placement and fetal scalp blood sampling (scalp puncture served as fetal scalp stimulation)</td>
<td>Methods

The labour records of women who delivered at Los Angeles County/University of Southern California Women's Hospital during a 2-year period were reviewed. Intrapartum fetal heart rate tracings of 200 women who had undergone fetal scalp blood sampling were chosen sequentially.
Fetal heart rate tracings were reviewed blindly, without knowledge of the pH values obtained at the time of sampling. They were judged to be either reactive (demonstrating fetal heart rate acceleration of 15 bpm lasting 15 seconds) or non-reactive in response to endscope placement and scalp puncture.</td>
<td>Results

<u>Prevalence of FBS pH < 7.21</u>
19/200 (10%)

<u>Predictive value of no acceleration following fetal scalp puncture for FBS pH < 7.21</u>
All values calculated by NCC using data in Table I
Sensitivity: 100% (100 to 100)
Specificity: 93.37% (89.75 to 96.99)
PPV: 61.29% (44.14 to 78.44)
NPV: 100% (100 to 100)
LR+: 15.08 (8.73 to 26.06)
LR-: 0 (NC)</td>
<td>Limitations

Study sample represents population: unclear whether consecutive women were included
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: period of fetal heart rate observation for qualifying acceleration following stimulus not reported
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: time between stimulation, fetal blood sampling and delivery not reported
Statistical analysis is appropriate for study design: yes</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
To ascertain the correlation between fetal acid-base status and the ability of the fetus to manifest a reassuring fetal heart rate pattern in response to tactile stimulation provided by fetal blood sampling **Study type** **Study dates** A 2-year period (dates not reported) **Source of funding** Not reported				**FBS pH** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 19 / 12 **Predictive Test -ve**: 0 / 169	Indirectness: gestational age not reported - at least one woman was in pre-term labour (32 to 33 weeks' gestation); unclear whether any women were considered high risk **Other information** Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics) All FBS was performed during the first stage of labour. Mean (range) scalp pH Acceleration in response to stimulation = 7.32 (7.21 to 7.42) No acceleration in response to stimulation = 7.16 (6.95 to 7.31)
Full citation Clark,S.L., Gimovsky,M.L., Miller,F.C., The scalp stimulation test: a clinical alternative to fetal scalp blood sampling, American Journal of Obstetrics and Gynecology, 148, 274-277, 1984 **Ref Id** 202086 **Country/ies where the study was carried out** USA **Aim of the study** To compare the correlation between heart rate accelerations in response to non-invasive tactile stimulation of the fetal scalp and subsequent pH obtained at scalp blood sampling **Study type** **Study dates** Not reported **Source of funding** Not reported	**Sample size** N = 100 **Characteristics** Gestational age Preterm (33 to 35 weeks) = 4/100 (4%) Term (37 to 41 weeks) = 76/100 (76%) Post-term (≥ 42 weeks) = 20/100 (20%) **Inclusion Criteria** Fetuses with heart rate tracings indicating possible acidosis mandating scalp blood sampling **Exclusion Criteria** Not reported	**Tests** 15 seconds of gentle digital pressure on the scalp through the dilated cervix, followed by transvaginal application on fetal scalp of Allis clamp closed to first ratchet and left in place for 15 seconds	**Methods** 100 fetuses with heart tracings indicating possible acidosis were prospectively enrolled by the clinical resident on the labour and delivery floor after review of the woman's clinical course and fetal heart rate (FHR) pattern. FHR response to each stimulation (15 seconds of gentle digital pressure followed by 15 seconds application of Allis clamp) was observed, followed by scalp blood sampling in the usual manner. Each tracing was reviewed by one of the authors without knowledge of the fetal scalp pH and was judged to be reactive or non-reactive to each stimulus as well as to the stimulus of the scalp puncture itself. Reactive response was defined as an acceleration of fetal heart rate of 15 bpm lasting at least 15 seconds	**Results** **Prevalence of acidosis pH < 7.20** 19/64 (30%) **Predictive accuracy of no acceleration following fetal scalp stimulation (FSS) (Allis clamp) for FBS pH < 7.20 [only in those fetuses who had not responded to initial digital FSS]** All values calculated by NCC from data presented in Fig 2 Sensitivity: 100% (100 to 100) Specificity: 33.33% (19.56 to 47.11) PPV: 38.78% (25.13 to 52.42) NPV: 100% (100 to 100) LR+: 1.5 (1.22 to 1.84) LR-: 0 (NC) **FBS pH** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 19 / 30 **Predictive Test -ve**: 0 / 15	**Limitations** Study sample represents population: unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: period of FHR observation for qualifying acceleration following stimulus not reported Outcome of interest is sufficiently measured in participants: results not adequately reported digital stimulation Important potential confounders are accounted for: time between stimulation, FBS and delivery not reported Statistical analysis is appropriate for study design: yes - although data not sufficiently reported for digital scalp stimulation Indirectness of population: 76% of fetuses were delivered at term; fetuses had failed to respond to digital stimulation; unclear whether any women were considered high risk **Other information** Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics). 2x2 table could not be calculated for digitial fetal scalp stimulation. 2x2 table could be calculated for predictive accuracy of response to Allis clamp stimulation for the 64 fetuses who did not respond with an acceleration to digital stimulation. Data not reported for response to stimulation of scalp puncture. Data reported in Fig 2 (used to caclulate 2x2 table) specifiy percentage of fetuses with pH < 7.20 and percentage of fetuses with pH > 7.20. Unclear in which group fetuses with a pH of 7.20 were included. All women were in the first stage of labour.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Full citation Edersheim,T.G., Hutson,J.M., Druzin,M.L., Kogut,E.A., Fetal heart rate response to vibratory acoustic stimulation predicts fetal pH in labor, American Journal of Obstetrics and Gynecology, 157, 1557-1560, 1987 **Ref Id** 201764 **Country/ies where the study was carried out** USA **Aim of the study** To examine the relationship between vibratory acoustic stimulation, direct fetal scalp stimulation, and fetal scalp blood pH **Study type** **Study dates** March 1985 - March 1986 **Source of funding** Not reported	**Sample size** N = 188 responses N = 127 women **Characteristics** Not reported **Inclusion Criteria** ≥ 34 weeks' gestation, active labour with ruptured membranes, and evidence of abnormal fetal heart rate tracings **Exclusion Criteria** Not reported	**Tests** 3 seconds of fetal vibroacoustic stimulation (VAS) followed by the inicision of fetal scalp blood sampling (FBS) serving as fetal scalp stimulation.	**Methods** FBS was performed where fetal heart rate (FHR) tracings were suspicious or equivocal. FBS was also performed with meconium plus FHR abnormality such as decreased beat-to-beat variability or fetal tachycardia. FHR was monitored continuously by Corometrics 112 fetal heart rate monitor. 60 seconds before FBS a single 3-second VAS was applied over the fetal vertex with the Western Electric Model 5c electronic artificial larynx. FHR was observed for 60 seconds and FBS was performed by standard puncture technique and analysed on a Corometrics 220 pH system. FHR response to both VAS and fetal scalp stimulation was recorded and correlated with pH value obtained. An acceleration was defined as an increase in FHR above the baseline of 15bpm sustained for 15 seconds occurring within 60 seconds after either stimulation.	**Results** **Prevalence of acidosis pH < 7.20** 6/188 (3%) [acidotic samples, not fetuses] **1. Predictive accuracy of an acceleration** a. Following vibroacoustic stimulation for FBS pH > 7.20 As reported in Table II and text of paper; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 63.7% (56.75 to 70.72) Specificity: 100% (100 to 100) PPV: 100% (100 to 100) NPV: 8.33% (1.95 to 14.72) LR+: NC LR-: 0.36 (0.30 to 0.44) b. Following fetal scalp stimulation for FBS pH > 7.20 As reported in Table II and text of paper; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 43.4% (36.21 to 50.61) Specificity: 100% (100 to 100) PPV: 100 % (100 to 100) NPV: 5.5% (1.22 to 9.79) LR+: NC LR-: 0.57 (0.50 to 0.64) **2. Predictive accuracy of no acceleration** a. Following vibroacoustic stimulation for FBS pH < 7.20 All values calculated by NCC using data presented in Table II Sensitivity:100% (100 to 100) Specificity: 63.74% (56.75 to 70.72) PPV: 8.33% (1.95 to 14.72) NPV: 100% (100 to 100) LR+: 2.76 (2.27 to 3.24) LR-: 0 (NC) b. Following fetal scalp stimulation for FBS pH < 7.20 All values calculated by NCC using data presented in Table II Sensitivity: 100% (100 to 100) Specificity: 43.41% (36.21 to 50.61) PPV: 5.5% (1.22 to 9.79) NPV: 100% (100 to 100) LR+: 1.77 (1.56 to 2.01) LR-: 0 (NC) **FBS pH** |	**Reference Test +ve**	**Reference Test -ve**
---	---	---
Predictive Test +ve	116	0
Predictive Test -ve	66	6	 **FBS pH**	**Limitations** Study sample represents population: unclear how many women were in preterm labour, unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome; Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: unclear whether any women were considered high risk **Other information** Responses to both VAS and fetal scalp stimulation were recorded in 188 instances in 127 women Authors' definition of positive stimulation test: acceleration Authors' definition of positive fetal scalp test: no acidosis pH > 7.20 First set of predictive accuracy results in evidence table are as reported in the study Second set of predictive accuracy results were calculated by NCC with a recalculated 2x2 table using a definition of positive stimulation test being no acceleration and definition of positive fetal scalp test of acidosis pH < 7.20, in line with other studies included in this review.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	79	0
Predictive Test -ve	103	6

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	6	66
Predictive Test -ve	0	116

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	6	103
Predictive Test -ve	0	79

Full citation

Elimian,A., Figueroa,R., Tejani,N., Intrapartum assessment of fetal well-being: a comparison of scalp stimulation with scalp blood pH sampling, Obstetrics and Gynecology, 89, 373-376, 1997

Ref Id

201856

Country/ies where the study was carried out

USA

Aim of the study

To determine if and to what extent the need for scalp pH sampling is decreased by the scalp stimulation test and whether redefinition of reactivity and presence of fetal heart rate (FHR) variability preceding scalp stimulation further decreased the need for fetal scalp blood sampling

Study type

Sample size

N = 108

Characteristics

Mean gestational age
39.2 ± 1.7 weeks

Mean birthweight
3240 ± 579 g

Mean maternal age
24.2 ± 5.9 years

Nulliparous
73/108 (68%)

Indications for FBS*
Moderate to severe variable decelerations = 84/108 (78%)
Late decelerations = 12/108 (11%)
Baseline tachycardia = 5/108 (5%)
Baseline bradycardia = 3/108 (3%)
Decreased variability = 4/108 (4%)

Tests

15 seconds of gentle digital fetal scalp stimulation

Methods

108 consecutive women were enterted prospectively in to the study. The decision to perform fetal scalp blood sampling (FBS) was made by the attending senior resident in the labour and delivery suite after review of the woman's clinical course and FHR trace.

15 seconds of digital fetal scalp stimulation was performed through the dilated cervix, followed 1 to 2 minutes later by FBS in the usual manner. Each FHR trace was marked at the time of both stimulations and judged to be reactive or non-reactive in response to both digital stimulation and scalp puncture.

Reactive response defined as an acceleration of 15 bpm lasting at least 15 seconds. FHR reaction was then correlated with scalp blood pH values (using 220 pH system, Corometrics Medical Systems, Wallingford, CT, USA). Fetal acidosis defind as scalp pH < 7.20

Results

Prevalence of acidosis pH < 7.20
15/108 (14%)

Predictive value of no acceleration following digital fetal scalp stimulation (FSS) (first FSS intervention) for fetal blood sample pH < 7.20
All values calculated by NCC from data in Table 1 (corresponds to sensitivity, specificity, PPV reported in text of paper)
Sensitivity: 100% (100 to 100)
Specificity: 54.84% (44.72 to 64.95)
PPV: 26.32% (14.88 to 37.75)
NPV: 100% (100 to 100)
LR+: 2.21 (1.77 to 2.77)
LR-: 0 (NC)

Predictive value of no acceleration following scalp puncture (second FSS intervention) for fetal blood sample pH < 7.20
Calculated by NCC from data in Table 1 (corresponds to sensitivity, specificity, PPV reported in text of paper)
Sensitivity: 100% (100 to 100)
Specificity: 53.76% (43.63 to 63.9)

Limitations

Study sample represents population: yes
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome; period of FHR observation for qualifying acceleration following stimulus not reported
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: time between stimulation, FBS and delivery not reported
Statistical analysis is appropriate for study design: yes

Indirectness: 5% of women were in pre-term labour (34-36 weeks); unclear whether any women were considered high risk

Other information

Authors' definition of positive stimulation test: no acceleration.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Study dates January - September 1995 **Source of funding** Not reported	*percentage calculated by NCC-WCH, do not add up to 100% due to rounding up **Inclusion Criteria** FHR patterns, recorded by fetal scalp electrode, suggestive of possible acidosis **Exclusion Criteria** 1] HIV positive or positive for hepatitis B surface antigen 2] Herpes virus lesions 3] Women in whom scalp was inaccessible for sampling			PPV: 25.86% (14.59 to 27.13) NPV: 100% (100 to 100) LR+: 2.16 (1.73 to 2.69) LR-: 0 (NC) **FBS pH** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 15 / 42 **Predictive Test -ve**: 0 / 51 **FBS pH** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 15 / 43 **Predictive Test -ve**: 0 / 50	5/108 (4.6%) had a gestational age of 34-36 weeks. Where there was more than one FBS only the last sample was used for analysis. Variability of FHR was performed before scalp stimulation and confirmed by two of the authors blinded to scalp pH results - it is unclear whether FHR response (reactive or non-reactive) to stimulation was also assessed blindly.
Full citation Ingemarsson,I., Arulkumaran,S., Reactive fetal heart rate response to vibroacoustic stimulation in fetuses with low scalp blood pH, British Journal of Obstetrics and Gynaecology, 96, 562-565, 1989 **Ref Id** 202006 **Country/ies where the study was carried out** Unclear **Aim of the study** To describe fetal heart rate responses to vibroacoustic stimulation of the fetus in labour **Study type** **Study dates** Not reported **Source of funding** Not reported	**Sample size** N = 33 **Characteristics** Not reported **Inclusion Criteria** Women undergoing fetal blood sampling because of suspicious or ominous fetal heart rate (FHR) traces in the first stage of labour **Exclusion Criteria** Not reported	**Tests** 5 seconds of fetal vibroacoustic stimulation (VAS)	**Methods** Women between 35 and 42 gestational weeks received fetal blood sampling (FBS). Before FBS a model 5C electronic artifical larynx (Western Electric, Bell Telephone) was applied to the maternal abdomen in the region of the fetal head for 5 seconds. A response was defined as reactive if the FHR showed an acceleration of 15 bpm for 15 seconds immediately after the sound stimulation. FBS was taken by one of the authors within 20 minutes of sound stimulation with the woman in the left lateral position. Cord artery blood was taken at caesarean section in 15 women when FBS was not possible due to high head and inadequate dilatation of the cervix. Acidosis was defined as pH < 7.20 Suspicious or omnious FHR traces showed late decelerations (intermittently or repeatedly), pronounced variable decelerations (depth > 60 bpm or lasting for > 60 seconds or both), tachycardia with late or variable decelerations, or reduced variability (< 5 bpm lasting for > 60 min) indicative of possible fetal acidosis	**Results** **Prevalence of acidosis pH <7.20** 4/51 (8%) **Predictive accuracy of no acceleration following VAS** a. For FBS pH <7.20 All values calculated by NCC using data presented in Table 1 and 2 Sensitivity: 50% (1 to 99) Specificity: 68.97% (52.13 to 85.80) PPV: 18.18% (0 to 40.97) NPV: 90.91% (78.90 to 100) LR+: 1.61 (0.53 to 4.94) LR-: 0.73 (0.26 to 1.99) **FBS pH** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 2 / 9 **Predictive Test -ve**: 2 / 20	**Limitations** Study sample represents population: unclear, characteristics not reported; unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between stimulation, FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: unclear whether any women were considered high risk **Other information** Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics). 51 women were recruited in to the study but data for both stimulation test plus FBS test only reported for 33 women. Individual data are reported for 11 fetuses with no FHR response to VAS and and no FHR response to

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					FBS (the scalp puncture acting as the stimulus). These data were used to caclulate predictive accuracy statistics for VAS (FBS pH < 7.20). Results were the same for FBS and so predictive accuracy statistics for FBS (FBS pH < 7.20) were not calculated.
Full citation Irion,O., Stuckelberger,P., Moutquin,J.M., Morabia,A., Extermann,P., Beguin,F., Is intrapartum vibratory acoustic stimulation a valid alternative to fetal scalp pH determination?, British Journal of Obstetrics and Gynaecology, 103, 642-647, 1996 **Ref Id** 201885 **Country/ies where the study was carried out** Switzerland **Aim of the study** To determine the validity of fetal heart rate accelerations, either spontaneous or induced by vibratory acoustic stimulation, as an indicator of fetal wellbeing according to subsequent scalp pH values **Study type** **Study dates** Over a 15 month period (dates not reported) **Source of funding** Not reported	**Sample size** N = 421 samples N = 253 women **Characteristics** <u>Maternal age (years) - mean ± SD</u> 28.3 ± 4.4 <u>Gestational age (weeks) - mean ± SD</u> 39.1 ± 1.6 <u>Operative delivery for fetal distress</u> 106/253 (42%) Forceps or vacuum extractor = 75/253 (30%) Caesarean section = 30/253 (12%) [one operative delivery not accounted for in text of study] **Inclusion Criteria** Abnormal intrapartum fetal heart rate tracings at > 30 weeks' pregnancy **Exclusion Criteria** No cases were excluded	**Tests** 5 seconds of fetal vibroacoustic stimulation (VAS)	**Methods** All fetal scalp blood samplings (FBS) for abnormal intrapartum fetal heart rate (FHR) tracings at > 30 pregnancy weeks were consecutively included in the study. FHR abnormalities were the presence of at least one of the following: late decelrations, decreased baseline variability (beat-to-beat variability < 5 bpm for 20 min), severe variable decelerations, moderate or severe bradycardia (< 100 bpm for 3 min), tachycardia (baseline rate > 160 bpm). Every time FBS was deemed necessary, VAS was performed by applying a model 5C electronic artificial larynx (Western Electric, New York) to the maternal abdominal wall above the fetal vertex for 5 sec. FHR tracing was observed for at least 60 sec after VAS. FBS was performed by scalp puncture for pH determination within 5 min. Reactivity was defined as FHR acceleration of at least 15 bpm above the baseline level, lasting for at least 15 sec. Tracings were blindly assessed by one author for the presence of VAS-induced reactivity prior to FBS.	**Results** **<u>Prevalence of acidosis</u>** 31/421 (7.4%) **<u>1. Predictive accuracy of an acceleration following VAS</u>** <u>a. For FBS pH > 7.20</u> As reported in Table 3 of paper Sensitivity: 52% (47 to 57) Specificity: 77% (63 to 92) PPV: 97% (94 to 99) NPV: 11% (7 to 16) LR+: 2.29 (1.19 to 4.43) LR-: 0.62 (0.50 to 0.77) <u>b. For FBS pH > 7.25</u> As reported in Table 3 of paper Sensitivity: 56% (51 to 62) Specificity: 65% (57 to 74) PPV: 78% (73 to 84) NPV: 40% (33 to 47) LR+: 1.63 (1.26 to 2.11) LR-: 0.67 (056 to 0.80) **<u>2. Predictive accuracy of no acceleration following VAS</u>** <u>a. For FBS pH < 7.20</u> All values calculated by NCC using data presented in Table 2 Sensitivity: 77.42% (62.70 to 92.14) Specificity: 51.54% (46.58 to 56.50) PPV: 11.27% (7.02 to 15.51) NPV: 96.63% (94.18 to 99.09) LR+: 1.60 (1.29 to 1.98) LR-: 0.44 (0.23 to 0.85) <u>b. For FBS pH < 7.25</u> All values calculated by NCC using data presented in Table 2 Sensitivity: 65.38% (57.21 to 73.56) Specificity: 56.01% (50.31 to 61.72) PPV: 39.91% (33.33 to 46.48) NPV: 78.37% (72.77 to 83.96) LR+: 1.49 (1.24 to 1.78) LR-: 0.62 (0.48 to 0.80) **FBS pH** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 201 / 7 **Predictive Test -ve**: 189 / 24	**Limitations** Study sample represents population: yes Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: unclear how many women were in preterm labour, unclear whether any women were considered high risk **Other information** Responses to both VAS and fetal scalp stimulation were recorded in 421 instances in 253 consecutive women Authors' definition of positive stimulation test: acceleration Authors' definition of positive fetal scalp test: no acidosis pH > 7.20 First set of predictive accuracy results in evidence table are as reported in the study Second set of predictive accuracy results were calculated by NCC with a recalculated 2x2 table using a definition of positive stimulation test being no acceleration and definition of positive fetal scalp test of acidosis pH < 7.20, in line with other studies included in this review.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	163	45
Predictive Test -ve	128	85

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	24	189
Predictive Test -ve	7	201

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	85	128
Predictive Test -ve	45	163

Full citation

Lazebnik,N., Neuman,M.R., Lysikiewicz,A., Dierker,L.R., Mann,L.I., Response of fetal heart rate to scalp stimulation related to fetal acid-base status, American Journal of Perinatology, 9, 228-232, 1992

Ref Id

202013

Country/ies where the study was carried out

USA

Aim of the study

To determine whether fetal scalp stimulation during active labour results in a fetal heart response, and whether the magnitude and direction of any change is related to fetal acid-base status

Sample size

N = 104

Characteristics

Not reported

Inclusion Criteria

Not reported

Exclusion Criteria

Not reported

Tests

The incision of fetal scalp blood sampling (FBS) served as fetal scalp stimulation

Methods

Term fetuses during labour were studied by scalp pH. All fetuses were monitored by an internal scalp electrode and intrauterine pressure catheter. The timing of stimulation was marked on fetal heart tracings.

Recordings of fetal heart rate (FHR) were digitised by tracing the curves on a digitising tablet (Houston Instruments DT-114). Data were then run through a computer program that sampled it every 0.5 seconds. The FHR was recorded, digitised and sampled for 15 to 25 minutes before and after FBS. The 5 minutes immediately preceding FBS were omitted from the analysis. FHR was averaged for 5 minutes before the beginning of preparations for the FBS procedure and over 1 minute immediately following FBS to obtain pre- and post-stimulation mean heart rates.

The effect of fetal scalp stimulation was examined by setting the time of scalp incision at zero and determining the FHR at 0.5 second intervals before and after the scalp incision from the digitised heart rate recordings.

Results

Prevalence of acidosis pH <7.20
15/104 (14%)

Predictive value of mean change in heart rate < 15bpm following fetal scalp stimulation for fetal blood sample pH < 7.20
As reported in Table 4 of paper; NCC calculated confidence intervals, LR+ and LR-
Sensitivity: 73% (50.95 to 95.71)
Specificity: 17% (9.08 to 24.63)
PPV: 13% (5.81 to 20.08)
NPV: 79% (60.62 to 97.28)
LR+: 0.88 (0.64 to 1.21)
LR-: 1.58 (0.61 to 4.12)

FBS pH

Limitations

Study sample represents population: unclear whether consecutive women were included
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: yes
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: time between FBS and delivery was recorded but not reported
Statistical analysis is appropriate for study design: yes

Indirectness of outcome: standard definition of acceleration not used; net difference in heart rate of more than 15 bpm was applied; population and inclusion and exclusion criteria not sufficiently reported to assess indirectness of population

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Study type **Study dates** Not reported **Source of funding** Not reported			Subjects were divided in to three groups according FBS pH and mean and standard error of the heart rate for each group was determined for each 0.5 second sample point. These values were then plotted as a function of time for each group.	<table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>**Predictive Test +ve**</td><td>11</td><td>74</td></tr><tr><td>**Predictive Test -ve**</td><td>4</td><td>15</td></tr></table>	**Other information** Authors' definition of positive stimulation test: mean increase in FHR <15 bpm. Some fetuses underwent more than one scalp blood sampling; only the first sampling was used to avoid the effect of habituation. All fetuses with FBS pH < 7.20 were tested at delivery for acidosis by cord blood gas analysis.
Full citation Lin,C.C., Vassallo,B., Mittendorf,R., Is intrapartum vibroacoustic stimulation an effective predictor of fetal acidosis?, Journal of Perinatal Medicine, 29, 506-512, 2001 **Ref Id** 201886 **Country/ies where the study was carried out** USA **Aim of the study** The hypothesis is that intrapartum vibroacoustic stimulation is an effective predictor of fetal acidosis during labour **Study type** **Study dates** 1 July 1995 - 30 April 1997 **Source of funding** Not reported	**Sample size** N = 113 **Characteristics** <u>Stage of labour</u> First stage = 53 Second stage = 60 <u>Gestational age</u> Term (≥ 37 weeks) = 94 Pre-term (≥ 34, < 37 weeks) = 13 Very pre-term (< 34 weeks) = 6 **Inclusion Criteria** Singleton gestations in active phase of first or second stage of labour and exhibiting abnormal fetal heart rate (FHR) patterns (moderate to severe variable decelerations or late decelerations, with or without baseline tachycardia or significantly decreased baseline variability). Women with known medical or obstetric complications, such as diabetes, hypertension, preeclampsia or fetal growth restriction were included. **Exclusion Criteria** Multiple gestation, congenital fetal malformations, gestational age < 28 weeks and administration of narcotic analgesia to the mother within the last 3 hours	**Tests** 3 seconds of fetal vibroacoustic stimulation (VAS)	**Methods** 3-seconds of VAS using an artificial larynx (model 5E, AT&T, Van Nuys, CA, USA) was applied to the maternal abdomen directly over the fetal head. For women in the second stage of labour VAS was applied to the suprapubic area, or if the fetal head was at plus two station or lower, directly to the fetal head on parietal or occiput area with a sterile latex glove covered VAS applicator. FHR response was monitored; a positive response was defined as 15bpm acceleration above baseline for a duration ≥ 15 seconds. No response or a deceleration after VAS suggested an acidotic fetus. A biphasic repsonse, defined as an acceleration followed by a deceleration was considered equivocal. Scalp blood was obtained immediately following VAS testing during the first stage of labour. During the second stage of labour, one or several VAS testings were performed, so that the time intervals between the last VAS testing and the delivery of the fetus were within 15 minutes. Umbilical blood sample was obtained at delivery for fetal blood pH and blood gas analysis in every case by a Corometric 220 pH System (Wallingford, CT). The decision to perform fetal scalp blood sampling or caeserean section was made by the attending physician or senior resident assessing the FHR tracing and reviewing the clinical course.	**Results** **<u>Prevalence of acidosis</u>** 31/113 (27%) **<u>Predictive value of no acceleration following VAS</u>** <u>a. For fetal blood sample pH < 7.20</u> Values as reported in Table II; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 39% (21.56 to 55.86) Specificity: 93% (87.05 to 98.32) PPV: 67% (44.89 to 88.44) NPV: 80% (71.96 to 88.04) LR+: 5.29 (2.18 to 12.86) LR-: 0.66 (0.50 to 0.88) <u>b. For Apgar score < 7 at 5 minutes</u> Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 100% (100 to 100) Specificity: 86% (79.95 to 92.78) PPV: 17% (0 to 33.88) NPV: 100% (100 to 100) LR+: 7.33 (4.58 to 11.74) LR-: 0 (NC) <u>c. For NICU admission</u> Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 55% (33.20 to 76.80) Specificity: 92% (87.11 to 97.84) PPV: 61% (38.59 to 83.63) NPV: 91% (84.64 to 96.42) LR+: 7.31 (3.23 to 16.51) LR-: 0.49 (0.30 to 0.79) <u>d. For neonatal morbidity</u> Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 71% (37.96 to 105) Specificity: 88% (81.49 to 93.98) PPV: 28% (7.09 to 48.47) NPV: 98% (95.01 to 101) LR+: 5.82 (2.91 to 11.63) LR-: 0.33 (0.10 to 1.05) **FBS pH**	**Limitations** Study sample represents population: unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcom; period of FHR observation for qualifying acceleration following stimulus was not reported Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between FBS and delivery for women in first stage of labour unclear Statistical analysis is appropriate for study design: yes Indirectness of population: 17% of women were in pre-term labour; high risk women were included (numbers not reported) **Other information** While authors state a positive stimulation test was FHR acceleration, statistics reported are for no acceleration predicting acidosis (< 7.20). Authors' definition of positive stimulation test: no acceleration. When more than one fetal blood pH value was obtained, only the last one was used for analysis.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	12	6
Predictive Test -ve	19	76

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	3	15
Predictive Test -ve	0	95

NICU admission

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	11	7
Predictive Test -ve	9	86

Neonatal morbidity

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	5	13
Predictive Test -ve	2	93

Full citation	Sample size	Tests	Methods	Results	Limitations
Polzin,G.B., Blakemore,K.J., Petrie,R.H., Amon,E., Fetal vibro-acoustic stimulation: magnitude and duration of fetal heart rate accelerations as a marker of fetal health, Obstetrics and Gynecology, 72, 621-626, 1988 **Ref Id** 201800	N = 100 **Characteristics** Gestational age (weeks) - mean ± SD, N 15 bpm x 15 sec acceleration = 39.4 ± 1.9, 57 10 bpm x 10 sec acceleration = 39.1 ± 2.5, 20 No acceleration = 38.3 ± 3.1, 23	5 seconds of continuous fetal vibroacoustic stimulation (VAS)	Over a period of 20 months, when one of the study authors was available, 100 women were studied using the standard indications for fetal scalp blood sampling (FBS; late, moderate or severe variable fetal heart rate (FHR) decelerations, fetal tachycardia or bradycardia, or poor FHR variability longer than 30 minutes). Immediately before FBS, VAS was performed using a Model 5C electronic artificial larynx (AT&T Consumer Products, USA), which produced a mixed-frequency sound of 81 Hz and 81 db at 1 m in air. A single stimulus	**Prevalence of acidosis < 7.20** 10/100 (10%) **Predictive value of no acceleration following VAS** a. For fetal blood sample pH < 7.20 All values calculated by NCC from data presented in Table 4 (see Other information) Sensitivity: 90% (71.41 to 100) Specificity: 84.44% (76.96 to 91.93) PPV: 39.13% (19.88 to 59.08)	Study sample represents population: not consecutive (women only included when one of the study authors was available) Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for:

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Country/ies where the study was carried out USA **Aim of the study** To evaluate whether there are significant differences in the intrapartum fetal acid-base status according to the magnitude and duration of fetal heart rate accelerations in response to fetal vibroacoustic stimulation. The predictive value of these responses in the detection of the acidotic versus non-acidotic fetus during labour was also examined. **Study type** **Study dates** Over a 20 month period (dates not reported) **Source of funding** Not reported	<u>Birth weight (g) - mean ±SD, N</u> 15 bpm x 15 sec acceleration = 3289 ± 527, 57 10 bpm x 10 sec acceleration = 3043 ± 588, 20 No acceleration = 2703 ± 909, 23 **Inclusion Criteria** Active phase of labour, singleton gestation, vertex presentation **Exclusion Criteria** Not reported		was applied continuously for 5 seconds to the maternal abdomen one-third of the distance from the symphysis pubis to the umbilicus. FHR accelerations, if they occurred, began within 20 seconds of the stimulus. FHR responses were classified in to three groups: FHR acceleration of ≥ 15 bpm lasting ≥ 15 seconds, 10-15 bpm lasting 10-15 seconds, or no acceleration. FBS was performed immediately after VAS, usually in the left lateral position. Mean pH values were derived from logarithmic tables.	NPV: 98.70 % (96.17 to 100) LR+: 5.79 (3.43 to 9.77) LR-: 0.11 (0.02 to 0.76) <u>b. For fetal blood sample pH < 7.25</u> All values calculated by NCC from data presented in Table 4 (see Other information) Sensitivity: 45.45% (24.65 to 66.26) Specificity: 83.33% (75.06 to 91.60) PPV: 43.48% (23.22 to 63.74) NPV: 84.41% (76.31 to 92.52) LR+: 2.73 (1.39 to 5.36) LR-: 0.65 (0.44 to 0.97) <u>c. For Apgar score < 7 at 5 minutes</u> All values calculated by NCC from data presented in Table 2 Sensitivity: 50% (9.99 to 90.01) Specificity: 57.45% (47.45 to 67.44) PPV: 6.98% (1 to 14.59) NPV: 94.74% (88.94 to 100) LR+: 1.18 (0.51 to 2.71) LR-: 0.87 (0.38 to 1.97) **FBS pH** |	Reference Test +ve	Reference Test -ve
---	---	---
Predictive Test +ve	9	14
Predictive Test -ve	1	76	 **FBS pH** 		Reference Test +ve	Reference Test -ve
---	---	---
Predictive Test +ve	10	13
Predictive Test -ve	12	65	 **Apgar score** 		Reference Test +ve	Reference Test -ve
---	---	---
Predictive Test +ve	3	40
Predictive Test -ve	3	54		time between FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: based on gestational age mean and SD for 'no acceleration' population not all fetuses were delivered at term; unclear whether any women were considered high risk **Other information** Authors' definition of positive stimulation test: no acceleration. Predictive accuracy statistics presented in Table 3 of study report do not account for the full study population - data for 10bpm x 10sec population not included with the no acceleration population. Therefore, data extracted for full study population from Table 4 and all statistics calculated by NCC. For the 2x2 table no acceleration and FHR acceleration ≥ 10 bpm and 10 sec but < 15 bpm and 15 sec were considered a positive stimulation test result. In nearly all cases FHR was recorded by internal scalp electrode.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Full citation Sarno,A.P., Ahn,M.O., Phelan,J.P., Paul,R.H., Fetal acoustic stimulation in the early intrapartum period as a predictor of subsequent fetal condition, American Journal of Obstetrics and Gynecology, 162, 762-767, 1990 **Ref Id** 201730 **Country/ies where the study was carried out** USA **Aim of the study** To evaluate the usefulness of fetal acoustic stimulation in the early intrapartum period as a predictor of subsequent fetal condition **Study type** **Study dates** 1 August 1987 - 1 November 1987 **Source of funding** Not reported	**Sample size** N = 201 **Characteristics** Maternal age (years) - mean ± SD 25.9 ± 5.5 Nulliparous 74/201 (37%) Gestational age (weeks) - mean ± SD 40.1 ± 2.2 Duration of ruptured membranes (hours) - mean ± SD 14.2 ± 17.0 Duration of labour (hours) - mean ± SD 17.4 ± 8.5 **Inclusion Criteria** Gestational age ≥ 37 weeks, singleton fetus, vertex presentation, latent phase of labour (cervical dilatation ≤ 4 cm) **Exclusion Criteria** Not reported	**Tests** 3 seconds of fetal vibroacoustic stimulation (VAS)	**Methods** Consecutive women who met inclusion criteria were included over the study period, during periods of availability of the first author. Following admission electronic fetal monitoring was instituted. A 40-min baseline fetal heart rate (FHR) monitor tracing was obtained, then VAS was performed using a fetal acoustic stimulator (Corometrics model 146, Wallingford, CT, USA), sound level 82 dB at 1 m in air. The acoustic stimulator was placed on the maternal abdomen over the fetal vertex and a 3-second pulse of stimulation applied. If no acceleration of FHR was noted within 1 min an additional pulse was administered to a maximum of three pulses, each 1 minute apart. A reactive response was defined as one or more accelerations of the FHR 15 bpm from baseline, persisting for 15 seconds. A non-reactive response was defined as failure to elicit a qualifying acceleration after any of three separate stimuli and for 10 minutes after the last stimulus. Care was taken not to perform acoustic stimulation during or immediately after a uterine contraction to avoid periods of transient fetal hypoxia and for standardisation of the technique. The result of stimulation was blinded from the physcians who managed the woman's labour. All FHR tracings were read by a single examiner without knowledge of the prior fetal acoustic stimulation results. Outcome was assessed by incidences of meconium staining, fetal distress requiring caesarean delivery, Apgar scores < 7 at 1 and 5 minutes, subsequent abnormal FHR patterns and perinatal mortality.	**Results** **Predictive value of no acceleration following VAS** a. For Apgar score < 7 at 1 minute Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 24.1% (8.56 to 39.71) Specificity: 95.9% (92.98 to 98.88) PPV: 50% (23.81 to 76.19) NPV: 88.2% (83.62 to 92.85) LR+: 5.93 (2.25 to 15.66) LR-: 0.79 (0.64 to 0.97) b. For Apgar score < 7 at 5 minutes Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 33.3% (0 to 71.05) Specificity: 93.8% (90.47 to 97.22) PPV: 14.3% (0 to 32.62) NPV: 97.9% (95.79 to 99.93) LR+: 5.42 (1.54 to 19.05) LR-: 0.71 (0.40 to 1.25) c. For caesarean delivery for fetal distress Values as reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 31.2% (8.54 to 53.96) Specificity: 95.1% (92.04 to 98.24) PPV: 35.7% (10.61 to 60.81) NPV: 94.1% (90.75 to 97.49) LR+: 6.42 (2.44 to 16.89) LR-: 0.72 (0.52 to 1.01) **Apgar score** |	Reference Test +ve	Reference Test -ve
---	---	---
Predictive Test +ve	7	7
Predictive Test -ve	22	165	 **Apgar score** 		Reference Test +ve	Reference Test -ve
---	---	---
Predictive Test +ve	2	12
Predictive Test -ve	4	183	 **Caesarean section**	**Limitations** Study sample represents population: included women who were considered high risk Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential cofounders are accounted for: time between VAS and delivery not reported Statistical analysis is appropriate for study: yes Indirectness of population: 118/201 (59%) had one or more complications of pregnancy [complications not reported] **Other information** Authors' definition of positive stimulation test: no acceleration.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				<table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>**Predictive Test +ve**</td><td>5</td><td>9</td></tr><tr><td>**Predictive Test -ve**</td><td>11</td><td>176</td></tr></table>	
Full citation Smith,C.V., Nguyen,H.N., Phelan,J.P., Paul,R.H., Intrapartum assessment of fetal well-being: a comparison of fetal acoustic stimulation with acid-base determinations, American Journal of Obstetrics and Gynecology, 155, 726-728, 1986 **Ref Id** 201855 **Country/ies where the study was carried out** USA **Aim of the study** To compare acoustically evoked accelerations of the fetal heart rate (FHR) with fetal acid-base status **Study type** **Study dates** Not reported **Source of funding** Not reported	**Sample size** N = 64 **Characteristics** <u>FHR abnormality indicating need for fetal blood sampling</u> Intermittent late decelerations = 20/64 (31%) Severe variable decelerations = 14/64 (22%) Absent variability = 12/64 (19%) Tachycardia = 11/64 (17%) Repetitive late decelerations = 7/64 (11%) **Inclusion Criteria** Women with FHR tracings sufficiently abnormal to merit either fetal blood sampling (FBS) or immediate caesarean delivery for fetal distress **Exclusion Criteria** Not reported	**Tests** ≤ 3 seconds of fetal vibroacoustic stimulation (VAS)	**Methods** Immediately before fetal blood sampling (FBS) with the woman in the dorsal lithotomy position, transabdominal acoustic stimulation of the fetus was accomplished by a Model 5C electronic artificial larynx (Western Electric). The artificial larynx produces a vibratory acoustic stimulus of approximately 80 Hz and 82 dB, measured at 1 m in air. The stimulus was applied overlying the fetal vertex for ≤ 3 seconds. The response was termed reactive if an immediate acceleration of 15 bpm and 15 seconds was evident. If a qualifying acceleration was not present, the stimulus was repeated at 1-minute intervals for a maximum of three times. Fetal scalp sampling was then accomplished by existing protocol. In 15 cases where scalp sampling was not possible immediate cesearean delivery was performed. In all cases the fetus was delivered within 15 minutes of the stimulus. The arithmetic mean of the umbilical arterial and venous pH determinations was calculated.	**Results** **<u>Prevalence of acidosis pH < 7.25</u>** 18/64 (28%) <u>Predictive value of no acceleration following VAS for fetal blood sample pH < 7.25</u> All values calculated by NCC from data in Table II Sensitivity: 100% (100 to 100) Specificity: 65.22% (51.45 to 78.98) PPV: 52.94% (36.16 to 69.72) NPV: 100% (100 to 100) LR+: 2.88 (1.94 to 4.27) LR-: 0 (NC) **FBS pH** <table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>**Predictive Test +ve**</td><td>18</td><td>16</td></tr><tr><td>**Predictive Test -ve**</td><td>0</td><td>30</td></tr></table>	**Limitations** Study sample represents population: unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome Outcome of interest is sufficiently measured in participants: yes Important potential cofounders are accounted for: length of stimulation not standardised (≤ 3 seconds); time between VAS and deliveries that were not caesarean births not reported Statistical analysis is appropriate for study: yes Indirectness: unclear whether any women were considered high risk **Other information** Definition of positive stimulation test: no acceleration (selected by NCC, authors do not define positive stimulation test and do not report predictive accuracy statistics). Five fetuses that failed to respond to VAS did respond to the stimulus of FBS scalp puncture (data for scalp puncture not sufficiently reported to construct 2x2 table).
Full citation Spencer,J.A., Predictive value of a fetal heart rate acceleration at the time of fetal blood sampling in labour, Journal of Perinatal Medicine, 19, 207-215, 1991 **Ref Id** 196967 **Country/ies where the study was carried out** UK **Aim of the study** To present the results of a 1-year audit of all cases requiring fetal scalp blood sampling during labour at a major teaching hospital, with particular emphasis on the relationship between the fetal	**Sample size** N = 138 **Characteristics** <u>Gestation ≥ 37 weeks</u> 133/138 (96%) <u>Nulliparous</u> 110/138 (80%) <u>Mode of delivery</u> Normal vaginal delivery = 38/138 (27%) Operative vaginal delivery = 60/138 (43%) Caesarean section = 40/138 (30%) **Inclusion Criteria** Not reported	**Tests** The incision of fetal scalp blood sampling served as fetal scalp stimulation	**Methods** Data were collected from all cases that required intrapartum fetal scalp blood sampling (FBS) due to concerns regarding the CTG during 1 year at the John Radcliffe Maternity Hospital, Oxford. Fetal heart rate (FHR) records were derived from the fetal electrocardiogram using a spiral electrode and an HP 8040 fetal monitor (Hewlett Packard, Uxbridge, UK). FHR reaction to FBS was noted to be either an acceleration (transient rise above baseline of more than 15 bpm for longer than 15 seconds), no response or a deceleration (transient fall below baseline of more than 15 bpm for longer than 15 seconds). Fetal scalp blood was collected into heparinised capillary tubes for immediate blood gas analysis using an ABL 3 (Radiometer, Copenhagen). Fetal pH was related to the FHR before the FBS and to the FHR reaction at the time.	**Results** **<u>Prevalence of acidosis < 7.20</u>** 6/138 (4%) **<u>1. Predictive value of an acceleration following fetal scalp stimulation</u>** <u>a. For fetal blood sample pH ≥ 7.20</u> As reported in Table V; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 52.3% (43.75 to 60.79) Specificity: 100% (100 to 100) PPV: 100% (100 to 100) NPV: 8.7% (2.05 to 15.34) LR+: NC LR-: 0.48 (0.40 to 0.57) <u>b. For fetal blood sample pH ≥ 7.25</u> All values calculated by NCC from data in Table IV Sensitivity: 53.57% (44.33 to 62.81) Specificity: 65.38% (47.10 to 83.67)	**Limitations** Study sample represents population: yes Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: unclear whether assessor blinded to outcome; period of FHR observation for qualifying acceleration following stimulus was not reported Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between stimulation, FBS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness: 96% delivered at term; unclear whether any women were considered high risk

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
heart rate reaction at the time of fetal scalp blood sampling and the fetal scalp pH **Study type** **Study dates** Not reported **Source of funding** Not reported	**Exclusion Criteria** Not reported			PPV: 86.96% (79.01 to 94.90) NPV: 24.64% (14.47 to 34.81) LR+: 1.55 ((0.89 to 2.70) LR-: 0.71 (0.50 to 1.00) **2. Predictive value of no acceleration following fetal scalp stimulation** a. For fetal blood sample pH < 7.20 All values calculated by NCC from data in Table IV Sensitivity: 100% (100 to 100) Specificity: 52.27% (43.75 to 60.79) PPV: 8.70% (2.05 to 15.34) NPV: 100% (100 to 100) LR+: 2.10 (1.75 to 2.50) LR-: 0 (NC) b. For fetal blood sample pH < 7.25 All values calculated by NCC from data in Table IV Sensitivity: 65.38% (47.10 to 83.67) Specificity: 53.57% (44.33 to 62.81) PPV: 24.64% (14.47 to 34.81) NPV: 86.96% (79.01 to 94.90) LR+: 1.41 (1.00 to 1.98) LR-: 0.87 (0.79 to 0.95) c. For Apgar score < 7 at 1 minute All values calculated by NCC from data in Table III Sensitivity: 54.00% (40.19 to 67.81) Specificity: 52.27% (41.84 to 62.71) PPV: 39.13% (27.61 to 50.65) NPV: 66.67% (55.54 to 77.79) LR+: 1.13 (0.81 to 1.58) LR-: 0.88 (0.61 to 1.26) d. For Apgar score < 7 at 5 minutes Calculated by NCC from data in Table III Sensitivity: 100% (100 to 100) Specificity: 50.36% (41.99 to 58.74) PPV: 1.45% (0 to 4.27%) NPV: 100% (100 to 100) LR+: 2.01 (1.70 to 2.38) LR-: 0 (NC) **FBS pH** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 69 / 0 **Predictive Test -ve**: 63 / 6 **FBS pH**	**Other information** Authors' definition of positive stimulation test: acceleration (≥ 15 bpm above baseline for ≥ 15 seconds) Authors' definition of positive FBS pH; a. no acidosis ≥7.20; b. no acidosis ≥ 7.25 First set of predictive accuracy results in evidence table are as reported in the study. Second set of predictive accuracy results were calculated by NCC with a recalculated 2x2 table using a definition of positive stimulation test being no acceleration and definition of positive fetal scalp test of a. acidosis pH < 7.20 and b. acidosis pH < 7.25 in line with other studies included in this review. Data for Apgar score < 7 at 1 and 5 minutes was calculated from Apgar ≥ 7 at 1 and 5 minutes reported in Table III, to be in line with other studies included in this review. Approximately 50% of labours were monitored by CTG because of perceived risk factors or the use of epidural analgesia. Only the first FBS on any single patient was included in the analysis.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	60	9
Predictive Test -ve	52	17

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	6	63
Predictive Test -ve	0	69

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	17	52
Predictive Test -ve	9	60

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	27	42
Predictive Test -ve	23	46

Apgar score

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	1	68

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Predictive Test -ve 0 69	
Full citation Tannirandorn,Y., Wacharaprechanont,T., Phaosavasdi,S., Fetal acoustic stimulation for rapid intrapartum assessment of fetal well-being, Journal of the Medical Association of Thailand, 76, 606-612, 1993 **Ref Id** 201731 **Country/ies where the study was carried out** Thailand **Aim of the study** To evaluate the usefulness of fetal acoustic stimulation in the early intrapartum period as a rapid screening test to predict subsequent fetal condition **Study type** **Study dates** Not reported **Source of funding** Not reported	**Sample size** N = 140 **Characteristics** <u>Nulliparous</u> 88/140 (63%) <u>Gestational age (weeks) - mean (range)</u> 39.5 (37 - 43) <u>Antenatal risk factors</u> Post-term (≥ 42 weeks) = 14/140 (10%) Poor weight gain = 11/140 (7.8%) Pre-eclampsia = 9/140 (6.4%) No antenatal care = 5/140 (3.6%) Oligohydraminos = 1/140 (0.7%) Others (poor obstetric history, intrauterine growth restriction, diabetes etc.) = 5/140 (3.6%) **Inclusion Criteria** Gestational age ≥ 37 weeks, cephalic presentation, latent phase of labour (cervical dilatation ≤ 3 cm), intact membranes **Exclusion Criteria** Women with spurious labour who had not been delivered within 24 hours of admission and those with twin pregnancies or known fetal abnormalities were excluded from analysis	**Tests** 3-seconds of fetal vibroacoustic stimulation (VAS)	**Methods** After admission to the delivery room, blood pressure was monitored at 10-min intervals and a tocodynamometer and Doppler FHR transducer (Sonic Aid FM 3, Oxford, UK) were applied to the abdomen and adjusted for best signal. Fetal heart rate (FHR) and uterine contractions were recorded for 15 to 20 min. Acoustic stimulation was then performed using a fetal acoustic stimulator (Corometrics 146, CT, USA; sound level 82 dB at 1 m in air) placed on the maternal abdomen over the fetal head and a 3-sec pulse of sound stimulation was applied. If no acceleration of the FHR was noted within 30 sec an additional pulse was administered to a maximum of 3 pulses, 30 seconds apart. Care was taken not to perform acoustic stimulation during or immediately after uterine contractions to avoid periods of transient fetal hypoxia and for standardisation of the technique. A reactive response to VAS was defined as one or more accelerations of FHR ≥ 15 bpm from the baseline persisting for 15 seconds. A non-reactive response was defined as a failure to elicit a qualifying acceleration after any of three separate stimuli and for 15 min after the last stimulus. All VAS results were interpreted by a single examiner without knowledge of the perinatal outcome. Obstetricians managing the woman's labour were not informed of the results of VAS. Perinatal outcome was considered poor when there was perinatal death, a 5-min Apgar score < 7, fetal distress requiring caesarean section, thick meconium stained amniotic fluid or admission to the neonatal intenstive care unit.	**Results** **<u>Predictive value of no acceleration following VAS for poor perinatal outcome</u>** Values as reported in Table 4; NCC caclulcated LR+, LR- and all confidence intervals Sensitivity: 71.4% (37.96 to 100) Specificity: 99.2% (97.78 to 100) PPV: 83.3% (53.51 to 100) NPV: 98.5% (96.45 to 100) LR+: 95 (12.75 to 707.63) LR-: 0.29 (0.09 to 0.93) **Poor perinatal outcome** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve** 5 1 **Predictive Test -ve** 2 132	**Limitations** Study sample represents population: unclear whether consecutive women were included Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: 15-minute window for reaction to 3rd stimulus, compared with 30-sec window for reaction to 1st and 2nd stimuli; time between VAS and delivery not reported Statistical analysis is appropriate for study design: yes Indirectness of population: 32% of women had one or more antenatal complication (10% had a gestational age ≥ 42 weeks) Indirectness of outcome: composite of poor perinatal outcome **Other information** Authors' definition of positive stimulation test: no acceleration
Full citation Trochez,R.D., Sibanda,T., Sharma,R., Draycott,T., Fetal monitoring in labor: are accelerations good enough?, Journal of Maternal-Fetal and Neonatal Medicine, 18, 349-352, 2005 **Ref Id** 201769 **Country/ies where the study was carried out** UK **Aim of the study** To investgate whether accelerations evoked by fetal scalp stimulation from routine vaginal examination prior to fetal blood sampling (FBS) predicted the absence of fetal acidosis at the time of the FBS	**Sample size** N = 54 **Characteristics** <u>Mode of delivery</u> Spontaneous vertex = 17/54 (31%) Instrumental = 22/54 (41%) Emergency caesarean section = 15/54 (28%) **Inclusion Criteria** Term (> 37 weeks gestation) singleton fetuses where FBS was obtained in labour **Exclusion Criteria** Not reported	**Tests** Fetal scalp stimulation during vaginal examination (method and duration of stimulation not reported)	**Methods** 69 fetuses were identified during the study period but information retrieval was only possible in 54 (78%), in whom 70 scalp blood sample procedures were performed. The CTG traces for all of these fetuses were reviewed by an investigator blind to the outcome. A portion of the trace starting from the point of the vaginal examination, as indicated by routine markings made on the CTG by the attending midwife, was reviewed for accelerations. Accelerations were defined as an increase in fetal heart rate above the baseline of at least 15bpm for at least 15 seconds. The position of the presenting part was determined and recorded in all cases ensuring scalp stimulation.	**Results** **<u>Prevalence of acidosis ≤ 7.20</u>** 5/70 (7%) **<u>Predictive value of no acceleration fetal scalp stimulation</u>** <u>a. For fetal blood sample pH ≤ 7.20</u> As reported in Table I and Table II of paper Sensitivity: 40% (7.26 to 82.96) Specificity: 69.23% (56.4 to 79.76) PPV: 9.09% (2.52 to 27.81) NPV: 93.75% (83.16 to 97.85) LR+: 1.3 (0.27 to 6.24) LR-: 0.87 (0.44 to 1.70) <u>b. For cord pH ≤ 7.20</u> Calculated by NCC from data in Table III Sensitivity: 40% (-2.94 to 82.94) Specificity: 75.86% (60.29 to 91.44) PPV: 22.22% (-4.94 to 49.38) NPV: 88% (75.26 to 100) LR+: 1.66 (0.47 to 5.80) LR-: 0.79 (0.38 to 1.67)	**Limitations** Study sample represents population: yes Loss to follow-up is unrelated to key characteristics: no loss to follow up Prognostic factor is adequately measured in participants: period of FHR observation for qualifying acceleration following stimulus not reported Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: time between stimulation, FBS and delivery reported only for acidotic babies, not whole study population Statistical analysis is appropriate for study design: yes Indirectness: unclear whether any women were considered high risk **Other information**

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>Study type

Study dates

November 2002 - November 2003

Source of funding

Not reported</td>
<td></td>
<td></td>
<td></td>
<td><u>c. For Apgar score < 7 at 5 minutes</u>
Calculated by NCC from data in Table III
Sensitivity: 50% (1 to 99)
Specificity: 69.57% (56.27 to 82.86)
PPV: 12.5% (-3.71 to 28.71)
NPV: 94.12% (86.21 to 102.03)
LR+: 1.64 (0.56 to 4.80)
LR-: 0.72 (0.26 to 1.95)

FBS pH
<table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>Predictive Test +ve</td><td>2</td><td>20</td></tr><tr><td>Predictive Test -ve</td><td>3</td><td>45</td></tr></table>
Cord pH
<table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>Predictive Test +ve</td><td>2</td><td>7</td></tr><tr><td>Predictive Test -ve</td><td>3</td><td>22</td></tr></table>
Apgar score
<table><tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr><tr><td>Predictive Test +ve</td><td>2</td><td>14</td></tr><tr><td>Predictive Test -ve</td><td>2</td><td>32</td></tr></table></td>
<td>Authors' definition of positive stimulation test: no acceleration

43/54 (80%) had one scalp sampling, 6/54 (11%) had two and 5/54 (9%) had 3, giving a total of 70 FBS procedures.

48/54 (89%) of women were in the first stage of labour with dilatation ranging from 5 to 9cm; 6/54 (11%) were at full dilatation.

The five acidotic fetuses were all delivered within 30 minutes of scalp blood sampling; 4 by caesarean section and one by instrumental delivery.

Cord pH data were not available for 16 fetuses; 7/16 had a positive FSS test result (no CTG acceleration), 9/16 had a negative FSS results (CTG acceleration)</td>
</tr>
<tr>
<td>Full citation

Umstad,M., Bailey,C., Permezel,M., Intrapartum fetal stimulation testing, Australian and New Zealand Journal of Obstetrics and Gynaecology, 32, 222-224, 1992

Ref Id

201865

Country/ies where the study was carried out

UK</td>
<td>Sample size

N = 60

Characteristics

All fetuses were at least 36 weeks' gestation

Inclusion Criteria

Fetal heart rate (FHR) tracing significantly abnormal such that fetal scalp blood sampling (FBS) was indicated</td>
<td>Tests

3 seconds of fetal vibroacoustic stimulation (VAS) followed by the incision of FBS serving as fetal scalp stimulation</td>
<td>Methods

Several minutes prior to FBS, a 3-second VAS was applied over the fetal head via a Corometrics Fetal Acoustic Stimulator (model 146), which generates a sound level of 82 db at 1 m in air.

FBS was performed in the usual manner in either lithotomy (with appropriate tilt) or left lateral positions. A Corometrics Model 220 pH Analyzer was used to assess pH of both fetal capillary and umbilical artery blood samples.

FHR traces were reported by one of the study authors who was blinded to the results of FBS, Apgar scores,</td>
<td>Results

<u>Prevalence of acidosis < 7.20</u>
8/60 (13%)

<u>Prevalence of acidosis < 7.25</u>
23/60 (38%)

<u>Predictive value of no FHR acceleration following VAS</u>
<u>a. For fetal blood sample pH < 7.20</u>
As reported in Table 4; NCC calculated LR+, LR- and all confidence intervals
Sensitivity:100% (100 to 100)
Specificity: 59.6% (46.28 to 72.95)</td>
<td>Limitations

Study sample represents population: yes
Loss to follow-up is unrelated to key characteristics: no loss to follow up
Prognostic factor is adequately measured in participants: yes - assessor blinded to outcome
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: time between FBS and delivery not reported
Statistical analysis is appropriate for study design: yes
Indirectness: unclear whether any women were considered high risk</td>
</tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Aim of the study To evaluate the usefulness of intrapartum fetal stimulation tests in routine clinical practice **Study type** **Study dates** 6-month period (dates not reported) **Source of funding** The Royal Women's Hospital/3AW Clinical Research Foundation	**Exclusion Criteria** Not reported		mode of delivery and umbilical artery cord pH values. A reactive FHR response was defined as an acceleration ≥ 15bpm for ≥ 15 seconds occuring within 60 seconds of the stimulus. Fetal scalp stimulation responses were assessed by determining the reaction to fetal scalp puncture with the guarded scalpel blade during FBS.	PPV: 27.6% (11.32 to 43.85) NPV: 100% (100 to 100) LR+: 2.48 (1.78 to 3.45) LR-: 0 (NC) b. For fetal blood sample pH < 7.25 As reported in Table 3; NCC calculated LR+, LR- and all confidence intervals Sensitivity: 100% (100 to 100) Specificity: 83.8% (71.91 to 95.66) PPV: 79.3% (64.57 to 94.05) NPV: 100% (100 to 100) LR+: 6.17 (2.96 to 12.83) LR-: 0 (NC) **Predictive value of no FHR acceleration following fetal scalp stimulation (scalp puncture)** c. For fetal blood sample pH < 7.20 As reported in Table 6 NCC calculated LR+, LR- and all confidence intervals Sensitivity: 62.5% (28.95 to 96.05) Specificity: 67.3% (54.56 to 80.06) PPV: 22.7% (5.22 to 40.24) NPV: 92.1% (83.53 to 101) LR+: 1.91 (0.98 to 3.71) LR-: 0.56 (0.22 to 1.39) d. For fetal blood sample pH < 7.25 As reported in Table 5 NCC calculated LR+, LR- and all confidence intervals Sensitivity: 82.6% (67.12 to 98.10) Specificity: 91.9% (83.10 to 100) PPV: 86.4% (72.02 to 100) NPV: 89.5% (79.72 to 99.23) LR+: 10.19 (3.39 to 30.63) LR-: 0.19 (0.08 to 0.46) **FBS pH** |	**Reference Test +ve**	**Reference Test -ve**
---	---	---
Predictive Test +ve	8	21
Predictive Test -ve	0	31	 **FBS pH** 		**Reference Test +ve**	**Reference Test -ve**
---	---	---
Predictive Test +ve	23	6
Predictive Test -ve	0	31		**Other information** Authors' definition of positive stimulation test: no acceleration. Results of fetal stimulation tests were not used in the obstetric management of the women.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	5	17
Predictive Test -ve	3	35

FBS pH

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	19	3
Predictive Test -ve	4	34

G.7 Fetal blood sampling as an adjunct to cardiotocography

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Alfirevic,Z., Devane,D., Gyte,G.M., Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. [55 refs]Updated, Cochrane Database of Systematic Reviews, 5, CD006066-, 2013 **Ref Id** 65685 **Country/ies where the study was carried out** Various **Study type** Systematic review of RCTs **Aim of the study** To evaluate the effectiveness and safety of continuous cardiotocography (CTG) when used as a method to monitor fetal wellbeing during labour **Study dates** Assessed as up-to-date May 2013 <u>Included studies:</u> **Athens 1993** Study period: October 1990 to June 1991 **Copenhagen 1985** Study period: January 1981 to January 1982 (date women expected to give birth) **Dallas 1986** Study period: not reported **Denver 1976** Study period: not reported **Denver 1979** Study period: July 1975 to July 1977 **Dublin 1985** Study period: March 1981 to April 1983 **Lund 1994** Study period: October 1989 to May 1991 **Melbourne 1976** Study period: March 1974 to April 1975 **Melbourne 1981** Study period: not reported	**Sample size** Total number of studies included n = 13 Number of studies reporting outcomes for CTG plus fetal blood sampling (FBS) intervention n = 8 **Characteristics** **Athens 1993** RCT; randomisation by tossing a coin on admission; women and obstetricians not blinded; neonatologists collecting data on neonatal outcomes were blinded Population: n = 1428 Inclusion: mixed-risk, women with a singleton pregnancy at ≥ weeks' gestation admitted in spontaneous labour or for induction of labour Exclusion: women with known fetal congenital or chromosomal abnormalities Intervention: continuous CTG without FBS n = 746 Comparison: intermittent auscultation (IA) n = 682 CTG: external unless trace poor when internal CTG used **Copenhagen 1985** RCT; randomisation by random sampling; method of randomisation unclear Population n = 969 women, high- and low-risk women, only women with diabetes excluded; 3 twin pairs in CTG group and 6 twin pairs in IA group Intervention: continuous CTG in conjunction with FBS (CTG: external or internal) n = 482 Comparison: IA n = 487 **Dallas 1986** Quasi RCT; randomisation by alternate months; selective monitoring (policy of using monitoring only in high-risk pregnancies) versus universal monitoring (use of a monitor for every pregnancy in which the fetus was considered viable, i.e. irrespective of risk status) Population: n = 34,995 women; data were extracted for 14,618 women with low-risk pregnancies; 7288 in universal monitoring group where all women monitored by CTG, and 7330 in selective monitoring where low-risk women monitored by IA Intervention: Continuous CTG (CTG: no information on external or internal) n = 7288 Comparison: IA n = 7330 **Denver 1976** RCT; randomised by sealed envelope Population n = 483; high-risk women; those with meconium stained fluid, needing oxytocin or abnormal fetal heart tones during labour were eligible to participate Intervention: continuous CTG without FBS versus (CTG: internal) n = 242 Comparison: IA n = 241	**Interventions** Intervention: continuous CTG during labour Control: no fetal heart monitoring Intermittent auscultation of fetal heart rate with Pinard or Doppler Intermittent CTG	**Details** <u>Electronic searches</u> The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by contacting the Trials Search Coordinator. CENTRAL, MEDLINE, EMBASE were searched and hand searching of journals and conference proceedings was performed. Dissertation abstracts and National Research Register was searched for accessing grey literature. No language restrictions were applied. <u>Selection of studies</u> Two review authors independently assessed all potential studies for inclusion. There was no disagreement regarding the eligibility for inclusion that needed to be resolved through consultation with a third person. <u>Data extraction and management</u> A form was designed to extract data, and two authors extracted them. Data were analysed in RevMan. Where information was unclear, the reviewers attempted to contact the original authors. <u>Assessment of risk of bias</u> Two review authors independently assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Selection bias (allocation concealment) - Attrition bias - Blinding: lack of blinding was not considered to undermine the validity of the study - Incomplete outcome data - Other sources of bias <u>Measures of effect</u> Dichotomous outcomes were presented as a risk ratios (RRs) with 95% confidence intervals (CIs). For continuous data, weighted mean differences and their 95% CI were used. <u>Dealing with missing data</u> The review authors investigated the effect of including trials with high levels of attrition using sensitivity analysis. Outcomes were assessed on an intention-to-treat basis, with the denominator being the number randomised minus any participants whose outcomes were known to be missing. For the purpose of the sensitivity analysis 'high quality' was defined as a trial having allocation concealment classified as 'adequate'. <u>Analysis</u> If high levels of heterogeneity (> 50%) were identified, prespecified sensitivity analysis was done according to the quality of the trials. A random effects model was used as an overall summary where appropriate.	**Results** **Thirteen studies were identified and included in the systematic review but only eight (8) studies had CTG plus FBS as an intervention. Therefore outcomes related to those studies are reported here.** **<u>Continuous CTG and FBS versus IA</u>** <u>Neonatal seizures</u> No. studies: 5 n = 15004 Continuous CTG and FBS n = 7542 IA n = 7462 RR 0.49 (95% CI 0.29 to 0.84) <u>Cerebral palsy</u> No. studies: 2 n = 13252 Continuous CTG and FBS n = 6609 IA n = 6643 RR 1.74 (95% CI 0.97 to 3.11) <u>Caesarean section</u> No. studies: 6 n = 15074 Continuous CTG and FBS n = 7582 IA n = 7492 RR 1.50 (1.10 to 2.06) <u>Instrumental vaginal birth</u> No. studies: 5 n = 14828 Continuous CTG and FBS n = 7460 IA n = 7368 RR 1.25 (1.13 to 1.38) <u>Cord blood acidosis</u> No. studies: 1 n = 1075 Continuous CTG and FBS n = 540 IA n = 535 RR 0.45 (0.16 to 1.29) <u>Any pharmacological analgesia</u> No. studies: 2 n = 828 Continuous CTG and FBS n = 482 IA n = 367 RR 0.99 (0.90 to 1.07)	**Limitations** <u>Attrition bias reported by the review authors for the included studies</u> **Athens 1993** Attrition bias: (A) less than 3% of participants excluded Allocation concealment: no **Copenhagen 1985** Attrition bias: (B) 3% to 9.9% of participants excluded (1061 women agreed to participate; 92 excluded) Allocation concealment: unclear **Dallas 1986** Attrition bias: information not available Allocation concealment: no **Denver 1976** Attrition bias: (A) less than 3% of participants excluded Allocation concealment: unclear **Denver 1979** Attrition bias: (A) less than 3% of participants excluded Allocation concealment: unclear **Dublin 1985** Attrition bias: (A) less than 3% of participants excluded FBS was performed when the duration of labour exceeded 8 hours. This occurred in 77/6474 (1.2%) of women in the CTG arm and 139/6486 (2.1%) of women in the IA arm **Lund 1994** Attrition bias: (A) less than 3% of participants excluded Allocation concealment: unclear **Melbourne 1976** Attrition bias: information not available; one obstetrician withdrew his participants from the trial; it was not clear whether this was pre- or post-randomisation nor how may participants were withdrawn Allocation concealment: yes **Melbourne 1981** Attrition bias: (B) 3% to 9.9% of participants excluded Allocation concealment: no **New Delhi 2006** No good information on study methodology **Pakistan 1989** Attrition bias: (A) less than 3% of participants excluded Allocation concealment: no Data extracted from unpublished trial lodged with Cochrane centre **Seattle 1987** Attrition bias: (D) more than 20% of participants excluded Allocation concealment: unclear **Sheffield 1978** Attrition bias: (A) less than 3% of participants excluded Allocation concealment: unclear **Other information** The systematic review is available online at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006066.pub2/full

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
New Delhi 2006 No good information on study methodology **Pakistan 1989** Study period: 1988 to 1989 **Seattle 1987** Study period: November 1981 to February 1985 **Sheffield 1978** Study period: July 1976 to June 1977 **Source of funding** Not reported	**Denver 1979** RCT; randomisation by random numbers in sealed envelopes Population: n = 690 high-risk women participating with 5 pairs of twins Intervention 1: continuous CTG with FBS (CTG: external until internal feasible) n = 229 Intervention 2: continuous CTG without FBS (CTG: external until internal feasible) n = 230 Comparison: IA n = 231 **Dublin 1985** RCT; randomisation by opaque, sealed envelopes Population: n = 12,964; mixed risked women at > 28 weeks' gestation, in labour; total of 12,964 women participated Intervention: continuous CTG in conjunction with FBS versus (CTG: internal) n = 6474 Comparison: IA n = 6490 Attrition bias: (A) less than 3% of participants excluded Study period: March 1981 to April 1983 **Lund 1994** RCT; randomisation by shuffled opaque envelopes Population: n = 4044 women with low to moderate risk factors during labour Intervention: continuous CTG with FBS versus (CTG: no information on external or internal) n = 2029 Comparison: intermittent CTG with FBS (CTG: no information on external or internal) n = 2015 **Melbourne 1976** RCT; randomised by cards in sealed numbered envelopes Population: n = 350 high-risk women Intervention: continuous CTG with FBS (CTG: external) n = 175 Comparison: intermittent auscultation n = 175 **Melbourne 1981** RCT; randomisation by cards; envelopes unsealed; biased randomisation in one of the participating hospitals; 62 low-parity women excluded post hoc to correct for inequality in randomisation Population: n = 989 low-risk women Intervention: continuous CTG without FBS (CTG: external until membranes ruptured then internal) n = 445 Comparison: intermittent auscultation n = 482 **New Delhi 2006** RCT; no details on how this was undertaken Population: n = 100 women who had had one previous low-transverse caesarean section; for this pregnancy, singleton and cephalic Intervention: continuous CTG n = 50 Comparison: IA n = 50 **Pakistan 1989** RCT; randomisation by woman selecting a sealed, unnumbered envelope		Fixed-effect meta-analysis was used in the absence of substantial heterogeneity between the trials. Random effects meta-analyses were used where heterogeneity was present or suspected		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Population: n = 200 high-risk women (all participants had meconium stained liquor) Intervention: continuous CTG with FBS (external) n = 100 Comparison: IA n = 100 Attrition bias: (A) less than 3% of participants excluded Study period: 1988 to 1989 **Seattle 1987** RCT; randomisation by numbered, sealed envelopes Population: n = 386 high-risk women Preterm labour (28-32 weeks' gestation), estimated fetal weight 700-1750 g Intervention: continuous CTG with FBS (CTG: external until rupture of membranes then internal) n = 188 Comparison: IA n = 188 **Sheffield 1978** RCT; randomisation by sealed envelopes; details not reported Population: n = 504 women with mixed risk Intervention: continuous CTG without FBS versus (CTG: internal) n = 253 Comparison: IA n = 251 **Inclusion criteria** Randomised and quasi randomised studies comparing continuous cardiotocography (CTG) with or without fetal blood sampling (FBS) with a) no fetal monitoring b) intermittent auscultation of the fetal heart rate using a Pinard stethoscope or hand-held Doppler device or intermittent CTG. Studies using less robust methods of allocation (for example, alternation) were not included **Exclusion criteria** Not reported				
Full citation Noren,H., Luttkus,A.K., Stupin,J.H., Blad,S., Arulkumaran,S., Erkkola,R., Luzietti,R., Visser,G.H., Yli,B., Rosen,K.G., Fetal scalp pH and ST analysis of the fetal ECG as an adjunct to cardiotocography to predict fetal acidosis in labor--a multi-center, case controlled study, Journal of Perinatal Medicine, 35, 408-414, 2007 **Ref Id** 121268 **Country/ies where the study was carried out** Norway **Study type** Retrospective cohort	**Sample size** Cases n = 97 (marked acidosis n = 53, moderate acidaemia n = 44) Control n = 97 **Characteristics** There were statistically significant differences observed in two groups (cases and controls) on antenatal factors, primigravidae and cord pH. Significantly more operative births were observed in marked acidosis and moderate acadaemia cases compared with controls. Admission to neonatal care unit was significantly higher in marked acidosis cases compared with the matched control **Inclusion criteria**	**Interventions** STAN analysis plus electronic fetal monitoring (EFM) plus FBS	**Details** From a European Union multicentre study on clinical implementation of STAN methodology, 911 cases were identified where a scalp pH had been obtained. A total of n = 6999 cases were recorded during the study period in maternity units and 911 cases were identified where a FBS was performed. Each ward had a research midwife responsible for education and data collection. The decision for need of FBS was left to the clinician in charge and time and pH reading was recorded. In 53 cases, marked cord artery acidosis was found (cord artery pH < 7.06) and 44 cases showed moderate acidaemia at birth (pH 7.06-7.09). Comparisons were made with 97 control cases (pH ≥ 7.20). Intervention: Clinical management was guided by CTG interpretation supported by computerised ST waveform assessment (ST log) and or FBS	**Results** **Time between onset of significant ST events (FHR plus ST indication to intervene) and birth** FHR+ST events recorded within 16 minutes of birth (cord artery pH ≥ 7.20) n = 17/28(61%) STAN indications recorded >16 minutes (cord artery pH ≥ 7.20) n = 13/69 (19%) OR 6.66 (2.53 to 17.55) P < 0.001 **Distribution of FBS and ST guideline indication to intervene (marked acidosis)** Women with abnormal FBS Marked acidosis n = 24/53 (45%) Control n = 4/53 (7.5%) Number of samples with scalp pH > 7.19	**Limitations** Data from a previously published study used. Not clear how the observers assessed the data. Results reported poorly and inconsistently **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the relationship between scalp pH (fetal blood sampling [FBS]) and ST analysis in situations of acidosis with special emphasis on the timing of cardiotocography (CTG), FBS and ST changes during labour **Study dates** October 2000 to June 2002 **Source of funding** Not reported	Pregnancy > 36 weeks, high-risk pregnancy, women with suspicious or abnormal external CTG, induced or oxytocin-augmented labour or meconium stained liquor **Exclusion criteria** Not reported		according to the study protocol. The ST log automatically notified the staff if any ST events occurred and intervention was required in case of combined CTG and ST changes. Intervention was also indicated by occurrence of preterminal CTG (complete loss of variability and reactivity). No intervention was recommended if CTG was normal, irrespective of the ST. During the first stage of labour identification and alleviation of the cause of hypoxia was the intervention. If that was not possible operative birth was recommended. In the second stage of labour, if the ST changes appeared, immediate birth was recommended. In the event of abnormal CTG and normal ST during the second stage of labour, a maximum of 90 minutes was recommended before birth. FBS was optional during the first and second stages of labour. In the cases with no indication to intervene, the recording continued until the birth. Analysis: The results were evaluated with medical statistical software. Student's t test or Mann-Whitney test were used for testing continuous variables. Fisher's exact test was used for discrete variables	Marked acidosis n = 43 Control n = 53 Number of samples with scalp pH 7.15 - 7.19 Marked acidosis n = 6 Control n = 1 Number of samples with scalp pH < 7.15 Marked acidosis n s 21 Control n = 3 Number of adequately monitored Marked acidosis n = 46/53 (86.8%) Control n = 42/53 (79.2%) ST indication Marked acidosis n = 41/53 (77.4%) Control n = 20/53 (37.7%) No ST indication (adequately monitored) Marked acidosis n = 5/46 (11%) Control n = 22/42 (52.4%) **Distribution of FBS and ST guideline indication to intervene (moderate acidaemia)** Women with abnormal FBS Moderate acidaemia n = 24/53 (45%) Control n = 4/53 (7.5%) Number of samples with scalp pH > 7.19 Moderate acidaemia n = 57 Control n = 61 Number of samples with scalp pH 7.15 - 7.19 Moderate acidaemia n = 10 Control n = 0 Number of samples with scalp pH < 7.15 Moderate acidaemia n = 13 Control n = 0 Number of adequately monitored Moderate acidaemia n = 40/44 (91%) Control n = 32/44 (72.7%) ST indication Moderate acidaemia n = 24/44 (54.5%) Control n = 10/44 (22.7%) No ST indication (adequately monitored) Moderate acidaemia n = 16/40 (40%) Control n = 22/32 (68.8%) **Cases with abnormal CTG and their relation to FBS and ST** Abnormal CTG patterns Normal ST n = 60/121 (49.6%) Abnormal ST n = 61/121 (50.4%) Cases with an abnormal CTG and cord artery pH < 7.10 n = 84/121 (69%): Abnormal ST n = 70/84 (83%) Abnormal FBS (< 7.20) Normal ST n = 7*/60 (11.7%) Abnormal ST n = 29/61 (47.5%)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Normal FBS Normal ST n = 50/60 (83.3%) Abnormal ST n = 12†/61 (19.7%) No FBS in conection with abnormal CTG Normal ST n = 3‡/60 (5%) Abnormal ST n = 20/61 (32.8%) *All had FBS taken in the second stage of labour; n = 6 had respiratory acidosis with normal neonatal period; n = 1 had cord pH >= 7.20 †n = 5/12 developed acidosis subsequently and n = 7 had a normal cord acid base ‡All developed acidosis **FBS and ST indication of abnormality in cases with CTG changes noted at the start of ST recording** Total ST findings with normal FBS Normal ST n = 43/44 (97.7%) Abnormal ST n = 1/44 (2.3%) Total ST findings with abnormal FBS Normal ST n = 3/17 (17.6%) Abnormal ST n = 14/17 (82.4%) ST findings with normal FBS (marked acidosis) Normal ST n = 14*/14 (100%) Abnormal ST n = 0/14 (0%) Total ST findings with abnormal FBS (marked acidosis) Normal ST n = 2/7 (28.6%) Abnormal ST n = 5/7 (71.4%) ST findings with normal FBS (marked acidaemia) Normal ST n = 29†/30 (96.7%) Abnormal ST n = 1/30 (3.3%) ST findings with abnormal FBS (marked acidaemia) Normal ST n =1/10 (10%) Abnormal ST n = 9/10 (90%) Special care baby unit was associated with low Apgar scores (< 7 at 5 minutes) Marked acidosis: 15/26 (58%) Moderate acidosis: 4/14 (26%) The corresponding rate for control group was 1 of 12 (8%) * n =11/14 subsequently developed ST changes and those that did not, ST changes were inadequately recorded † n = 2 developed subsequent ST changes	
Full citation Stein,W., Hellmeyer,L., Misselwitz,B., Schmidt,S., Impact of fetal blood sampling on vaginal delivery and neonatal outcome in deliveries complicated by pathologic fetal heart	**Sample size** n = 49,560 births, 26% underwent FBS	**Interventions** EFM plus FBS	**Details** Data collection Data about the woman, pregnancy and birth were collected from the perinatal birth register of Hense, using an evaluated 76 item	**Results** Spontaneous birth (no presence of additional risk factor) EFM + FBS n = 2191 (82%)	**Limitations** Choice of treatment unrelated to confounders (selection bias): unclear Groups comparable at baseline: unclear Groups received same/similar care (apart from intervention): unclear Blinding of those assessing outcomes: no

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
rate: a population based cohort study, Journal of Perinatal Medicine, 34, 479-483, 2006 **Ref Id** 121315 **Country/ies where the study was carried out** Germany **Study type** Population-based cohort study **Aim of the study** To compare the impact of electronic fetal monitoring (EFM) alone versus EFM with additional fetal blood sampling (FBS) in vaginal births complicated by pathologic fetal heart rate (FHR) **Study dates** All births in Hesse between 1990 and 2000 **Source of funding** Not reported	**Characteristics** No significant differences observed between the two groups in neonatal sex, birthweight < 2.5 kg, birthweight > 4 kg and maternal risk in pregnancy. Gestational age > 40 weeks, maternal age > 35 years, and additional risk factors at birth were significantly associated with FBS **Inclusion criteria** Pathologic fetal heart rate Singleton pregnancy Vaginal birth Cephalic presentation **Exclusion criteria** Not reported		questionnaire. From 1990 to 2000, the perineal birth register of Hense recorded data of 589,609 births > 35 weeks. Of these, 49,450 births fulfilled the inclusion criteria. Analysis Bivariate analyses between the usage of FBS and the characteristics of the newborn, woman and birth were performed only on those records with no missing values for any maternal covariates. To assess the effect of FBS in the births with pathological FHR on mode of birth and neonatal outcomes, univariate regression analysis was performed and odds ratios (ORs) and their corresponding 95% confidence intervals (95% CIs) were calculated	EFM alone n = 7678 (76.7%) OR 1.41 (95% CI 1.27 to 1.58) Spontaneous birth (in presence of additional risk factor) EFM + FBS n = 5912 (57.8%) EFM alone n = 13974 (52.4%) OR 1.24 (95% CI 1.19 to 1.30) Vaginal assisted birth (no presence of additional risk factor) EFM + FBS n = 472 (16.8%) EFM alone n = 2336 (23.3%) OR not reported Vaginal assisted birth (in presence of additional risk factor) EFM + FBS n = 4318 (42.2%) EFM alone n = 12679 (47.6%) OR not reported **Neonatal outcomes** Severe fetal acidosis (umbilical artery pH < 7.0) EFM + FBS n = 64 (0.5%) EFM alone n = 307 (0.91%) OR 0.55 (95% CI 0.42 to 0.72) Apgar score < 5 after 7 minutes EFM + FBS n = 78 (0.61%) EFM alone n = 314 (0.86%) OR 0.71 (95% CI 0.55 to 0.90) Admission to neonatal unit EFM + FBS n = 1025 (8.0%) EFM alone n = 3220 (8.8%) OR 0.90 (95% CI 0.83 to 0.96) Reanimation EFM + FBS n = 652 (5.1%) EFM alone n = 3220 (8.8%) OR 0.80 (95% CI 0.73 to 0.88)	Missing data/loss to follow-up: unclear Precise definition of outcomes: yes Valid and reliable method of outcome assessment: unclear Intention-to-treat analysis performed: no **Other information**
Full citation Becker,J.H., Westerhuis,M.E., Sterrenburg,K., van den Akker,E.S., van,Beek E., Bolte,A.C., van Dessel,T.J., Drogtrop,A.P., van Geijn,H.P., Graziosi,G.C., van Lith,J.M., Mol,B.W., Moons,K.G., Nijhuis,J.G., Oei,S.G., Oosterbaan,H.P., Porath,M.M., Rijnders,R.J., Schuitemaker,N.W., Wijnberger,L.D., Willekes,C., Visser,G.H., Kwee,A., Fetal blood sampling in addition to intrapartum ST-analysis of the fetal electrocardiogram: evaluation of the recommendations in the Dutch STAN[REGISTERED] trial, BJOG: An International Journal of Obstetrics and Gynaecology, 118, 1239-1246, 2011 **Ref Id** 156994 **Country/ies where the study was carried out**	**Sample size** At least one FBS performed for n = 301 women; n = 224 complete ST recordings were available for assessment **Characteristics** Not reported **Inclusion criteria** Women in labour with a high-risk singleton pregnancy in cephalic position at term **Exclusion criteria** Not reported	**Interventions** FBS in conjunction with electronic fetal monitoring (EFM) and ST wave analysis	**Details** Data were used from women monitored in the STAN arm of a previously published multicentre randomised controlled trial; participants had been randomly assigned to monitoring by cardiotocography (CTG) combined with ST-analysis of the fetal electrocardiogram (ECG; index group) or CTG without ST-analysis (control group). This study was on the women randomised to the index group in whom FBS was undertaken. In women in the index group, a scalp electrode was applied to the fetal head and connected to a STAN S21 or S31 fetal heart monitor (Neoventa Medical, Gothenburg, Sweden). Clinical management was guided by the STAN clinical guidelines. In the study protocol FBS was recommended in three situations: (1) start of STAN registration with an intermediary or abnormal CTG trace (2) abnormal CTG trace for more than 60	**Results** **FBS in births monitored by ST-analysis of the fetal ECG related to the trial protocol** Number of FBS According to trial protocol n = 171 Not according to trial protocol n = 126 pH > 7.25 According to trial protocol n = 112/171 (65.5%) Not according to trial protocol n = 96/126 (76.2%) pH 7.20 - 7.25 According to trial protocol n = 33/171 (19.3%) Not according to trial protocol n = 15/126 (12%) pH < 7.20 According to trial protocol n = 17/171 (10%) Not according to trial protocol n = 10/126 (7.9%)	**Limitations** A large number of women in whom at least one FBS was performed were excluded from the analysis for various reasons that were not reported. Data from a previously published trial were used **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Netherlands **Study type** Prospective cohort study **Aim of the study** To evaluate recommendations for additional fetal blood sampling (FBS) when using ST-analysis of the fetal electrocardiogram **Study dates** January 2006 to July 2008 **Source of funding** Funded by a grant from ZonMW, the Dutch Organisation for Health Research and Development			minutes without ST-events (3) poor ECG signal quality in the presence of an intermediary or abnormal CTG trace. Poor signal quality was defined as absence of ST-information for more than 4 minutes or less than one average ECG-complex per minute within a period of 10 minutes. If FBS showed a pH < 7.20, an immediate birth was advised. If the pH was between 7.20 and 7.25 the advice was to repeat FBS after 30 minutes. If the pH was > 7.25, the fetal condition was considered well enough to continue labour. Presence of STAN abnormalities (defined in the protocol) was also an indication for immediate birth. Data analysis All STAN recordings of women in the index group in which at least one FBS was performed were assessed by two observers who examined whether or not additional FBS was performed according to the trial protocol. When there was disagreement, the opinion of a third observer was decisive. The observers were only provided with information on the timing of FBS, without knowledge of its result, other clinical parameters obtained during labour, or the neonatal outcome. For each FBS the following items had to be scored: (1) classification of the CTG as normal, intermediary, abnormal or (pre)terminal within a 60-minute period before performance of FBS (2) duration of an intermediary, abnormal or (pre)terminal CTG in minutes (3) interpretation of any ST-events; and (4) judgement of whether FBS was performed according to the randomised controlled trial protocol. Observers evaluated whether the FBS was performed according to the trial protocol, and assessed the relation between pH result measured by FBS and the reason to perform FBS was described. In the cases of protocol violation (FBS not performed according to the trial protocol) the relation between pH results of FBS and ST-waveform interpretation regarding fetal indications to intervene, was evaluated. Fetal acidosis was defined as an FBS pH < 7.20. Women were classified as being treated 'not according to trial protocol' if at least one of the FBSs was not performed according to the trial protocol. Metabolic acidosis for neonates was defined as an umbilical cord artery pH < 7.05 and base deficit > 12 mmol/l	Missing pH According to trial protocol n = 9/171 (5.3%) Not according to trial protocol n = 5/126 (4%) **FBS in births monitored by ST-analysis of the fetal ECG related to reasons according to the trial protocol** Number of FBS Total n = 171 Abnormal CTG (cardiotocography) at start n = 18 Intermediary CTG at start n = 9 Abnormal CTG > 60 min without ST events n = 111 Poor ECG signal quality n = 33 pH > 7.25 Total n = 112 Abnormal CTG at start n = 9 Intermediary CTG at start n = 9 Abnormal CTG > 60 min without ST events n = 69 Poor ECG signal quality n = 25 pH 7.20 - 7.25 Total n = 33 Abnormal CTG at start n = 5 Intermediary CTG at start n = 0 Abnormal CTG > 60 min without ST events n = 24 Poor ECG signal quality n = 4 pH < 7.20 Total n = 17 Abnormal CTG at start n = 2 Intermediary CTG at start n = 0 Abnormal CTG > 60 min without ST events n = 12 Poor ECG signal quality n = 3 Missing pH Total n = 9 Abnormal CTG at start n = 2 Intermediary CTG at start n = 0 Abnormal CTG > 60 min without ST events n = 6 Poor ECG signal quality n = 1 **Relation of presence or absence of significant ST-events and preterminal CTG with results of FBS not taken according to protocol** Indication to intervene (at least on significant ST events) Total n = 34 pH < 7.20 n = 8 (23.5%) pH 7.20 - 7.25 n = 5 (14.7 %) pH > 7.25 n = 19 (60%) Missing value n = 2 (5.9 %) No indication to intervene (total n = 92) pH < 7.20 n = 2 (2.2%) pH 7.20 - 7.25 n = 10 (11%) pH > 7.25 n = 77 (83.7%) Missing value n = 3 (3.2%) Preterminal CTG (total n = 1) pH < 7.20 n = 1 (100%) pH 7.20 - 7.25 n = 0	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				pH > 7.25 n = 0 Missing value n = 0 **<u>Neonatal outcomes</u>** **FBS was taken according to the trial protocol** <u>Neonates with metabolic acidosis at birth</u> n = 3 One out of the three women had abnormal CTG for 36 minutes plus poor ECG quality before FBS with pH 7.9. In the other women (n=2), FBS was performed because of abnormal CTG > 60 minutes and result of FBS was normal but CTG abnormalities persisted. For one woman the time between FBS and birth was only 20 minutes; in the other it was 9 hours with an abnormal CTG for the last 115 minutes (FBS pH 7.32, umbilical cord artery pH 6.93) **FBS was performed not according to the trial protocol** <u>Neonates with metabolic acidosis at birth</u> n = 3 In all three women earlier intervention was recommended based on significant ST-events. In one of these women multiple FBSs were performed because of an abnormal CTG-pattern (pH 7.38, 7.33, 7.31, 7.28 and 7.28). The final two FBSs were both preceded by a significant ST-event. Abnormalities on CTG persisted thereafter and ST-analysis showed one more significant ST-event 76 minutes after the last FBS, during the second stage of labour. The time between the last FBS and birth was 114 minutes; after a failed vacuum extraction, caesarean section was performed and the baby was born with cord pH 6.95 and died because of severe asphyxia and encephalopathy	

G.8 Fetal blood sampling – time to result

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Annappa,R., Campbell,D.J., Simpson,N.A., Fetal blood sampling in labour and the decision to delivery interval, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 141, 10-12, 2008 **Ref Id** 92285 **Country/ies where the study was carried out** England **Study type** Prospective case series of consecutive attempts at fetal blood sampling (FBS) **Aim of the study** To determine the time interval from the decision to the result for fetal blood sampling (FBS) and the time from an abnormal pH to the birth of the baby **Study dates** April 1st 2006 to August 1st 2006 **Source of funding** None reported	**Sample size** N = 107 (This was the number of attempts to do FBS, involving 72 women) **Characteristics** **BMI (n/total (%))** ≤ 25: 44/72 (61.1) > 25: 28/72 (38.9) **Cervical dilatation in cm (n/total (%))** ≤ 5: 27/72 (37.5) > 5: 45/72 (62.5) **Operator grade (n/total (%))** SHO/SSHO: 41/72 (56.9) SPR/Senior Registrar: 31/72 (43.1) **Inclusion criteria** Consecutive attempts at FBS **Exclusion criteria** None reported	**Interventions** Fetal blood sampling	**Details** Consecutive attempts at FBS over the study period were reported. Operators performed the procedure with women in either lithotomy or left lateral position. Fetal capillary blood samples were collected in a heparinised glass tube and analysed using a Bayer Rapid Lab 840 blood gas analyser. All details were recorded in a document designed for this audit. If a sample was taken but judged to be inadequate, another sample was taken; 107 attempts yielded 177 samples due to the need for repeat samples. The time interval was taken from the decision to perform FBS to the result of a successfully attained sample. Non-parametric tests were used for the analysis. The time from the decision to the result was compared for each factor using Mann-Whitney tests. Regression analysis was undertaken to investigate the factor, while controlling for other factors	**Results** **Time from decision to the result of the FBS** a. Median/minutes (IQR): 17 (11 - 22) b. Time taken > 30 minutes (n/total (%)): 5/107 (4.7) [Note: the median time for preparation was 8 minutes (IQR 7 - 15), and the median time to perform the procedure was 10 minutes (IQR 9 - 16)] **Factors affecting the time interval between decision to result of FBS/minutes (median (IQR))** a. BMI ≤ 25: 13 (11 - 17) > 25: 17 (14 - 22) ($p < 0.001$) b. Cervical dilatation ≤ 5: 22 (16 - 25) > 5: 15 (10 - 17) ($p < 0.0001$) c. Operator grade SHO/SSHO: 17 (17 - 22) SPR/Senior Registrar: 13 (10 - 17) ($p < 0.001$) These were all independent predictors in the regression model, when including all factors. No valid comparisons for position or epidural could be performed because 95% of women had epidural and 95% of women had FBS taken in the left lateral position **Number of samples needed (n)** One: 46 Two: 52 Three: 9 Failed to obtain sample: 2 (Note: 23/177 (13%) of samples were inadequate for analysis)	**Limitations** Inclusion or exclusion criteria and characteristics of the study population were not reported in detail; therefore, it is not possible to establish whether women had low-risk pregnancies **Other information**
Full citation Tuffnell,D., Haw,W.L., Wilkinson,K., How long does a fetal scalp blood sample take?, BJOG: An International Journal of Obstetrics and Gynaecology, 113, 332-334, 2006 **Ref Id** 158858 **Country/ies where the study was carried out** UK **Study type** Case series (consecutive, prospective) **Aim of the study**	**Sample size** N=74 women and 100 samples **Characteristics** No description of the study population **Inclusion criteria** A series of 100 consecutive FBSs on vertex-presenting fetuses **Exclusion criteria**	**Interventions** FBS	**Details** The cases, including the timing of each result, were collected daily from the record in the micro blood analyser database. The clinical staff were aware of the audit and recorded time of decision to perform the test, the time the procedure was started and the operator grade. The operator also recorded the number of attempts for each FBS in the case notes. Those women in whom an FBS was attempted but an inadequate sample obtained were also included in the analysis	**Results** 100 fetal scalp pH results on 74 babies were reviewed; 89 were successful and 11 were inadequate for the analysis. The median time interval between decision to perform the test and the results was 18 min (IQR 12–25). In 35 (39.5%) of the successful FBS, the time taken was > than 20 minutes, and in eight (9%), it took > than 30 minutes	**Limitations** Inclusion or exclusion criteria and characteristics of the study population were not reported in detail; therefore, it is not possible to establish whether women had low-risk pregnancies **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To identify the time from a decision to perform a fetal blood sample (FBS) to the result of the test being available **Study dates** May 2004 to September 2004 **Source of funding** Not reported	Not reported				
Full citation Rimmer, S., Roberts, S. A., Heazell, A. E., Cervical dilatation and grade of doctor affects the interval between decision and result of fetal scalp blood sampling in labour, Journal of Maternal-Fetal & Neonatal Medicine, 29, 2671-4, 2016 **Ref Id** 451292 **Country/ies where the study was carried out** UK **Study type** Case series (consecutive, retrospective) **Aim of the study** To determine the average time interval between decision to perform a fetal scalp blood sample (FSBS) and obtaining the result in a sufficiently large sample so that other influences on the speed of sampling such as cervical dilatation or grade of operator could be assessed **Study dates** April 2013 to May 2014 **Source of funding** None reported	**Sample size** N=119 (n=207 procedures); n=112 (199) included in the analysis **Characteristics** No description of the study population **Inclusion criteria** All women who had a FSBS between April 2013 and May 2014 were eligible **Exclusion criteria** Not reported	**Interventions** FSBS	**Details** From women who were eligible, 119 were selected randomly using a computer-generated randomisation list until at least 20 participants had been sampled from each grade of clinician and a minimum of 150 procedures overall. The case notes were identified and relevant information collected from these and the K2 Guardian electronic labour record system (Version 2.050.056.001, K2 Medical Systems, Plymouth, UK) using a standardised proforma. Seven participants for whom complete case notes could not be located were excluded from the study	**Results** The median time interval from the decision for FSBS to obtaining the result was 10 minutes (range 2–39 minutes). Fifteen samples (7.5%) took >=20 min to obtain the sample. In four of these cases, the delay resulted from a senior grade of doctor having to perform the procedure after a junior doctor had been unsuccessful	**Limitations** Inclusion or exclusion criteria and characteristics of the study population were not reported in detail; therefore, it is not possible to establish whether women had low-risk pregnancies **Other information**

G.9 Predictive value of fetal blood sampling

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Full citation

Bakr,A.F., Al-Abd,M., Karkour,T., Fetal pulse oximetry and neonatal outcome: a study in a developing country, Journal of Perinatology, 25, 759-762, 2005

Ref Id

121095

Country/ies where the study was carried out

Egypt

Study type

Aim of the study

To compare the diagnostic value of fetal pulse oximetry with that of fetal scalp blood gas for an abnormal neonatal outcome in cases with abnormal fetal heart rate tracings

Study dates

June 2001 to May 2002

Source of funding

None, institutional resources
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Sample size

N = 150

Characteristics

None reported

Inclusion Criteria

Abnormal fetal heart rate tracing (criteria not reported)

Complete screening panel (fetal pulse oximetry, fetal scalp blood gas and umbilical cord blood gas)

Exclusion Criteria

None reported
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Tests

Fetal scalp pH analysis
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Methods

Informed consent was given by all participants before enrolment. Routine care was given to all patients. Women were monitored with a fetal oxygen saturation monitor and an average value of 30 minutes reading was calculated. A fetal scalp blood gas was taken. An umbilical cord gas sample was obtained shortly following birth, prior for the baby being moved from the delivery area.

Abnormal neonatal outcome was defined as having any of the following:
- Apgar score ≤ 7 at 5 minutes
- Secondary respiratory distress
- Transfer to NICU
- Neonatal arterial blood pH ≤ 7.15
- Neonatal death

The diagnostic value of fetal blood sampling (FBS) and fetal pulse oximetry were compared for their ability to predict umbilical cord blood pH ≤ 7.15 and abnormal neonatal outcome. Sensitivity, specificity and predictive values were calculated. (Note: this review deals only with FBS; therefore, data for fetal pulse oximetry are not reported)
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Results

Predictive value of pH ≤ 7.20 (95% CI)
a. For umbilical artery pH ≤ 7.15
Sensitivity: 72% (58 to 82)
Specificity: 53% (42 to 63)
PPV: 57% (48 to 65)* [NCC: 51% (40 to 61)]
NPV: 43% (35 to 51)* [NCC: 74% (63 to 85)]
LR+: 1.54 (1.17 to 2.02)†
LR-: 0.53 (0.34 to 0.83)†

b. For abnormal neonatal outcome
Sensitivity: 82% (65 to 91)
Specificity: 52% (42 to 61)
PPV: 57% (48 to 64)* [NCC: 36% (26 to 47)]
NPV: 43% (35 to 51)* [NCC: 89% (82 to 97)]
LR+: 1.69 (1.33 to 2.16)†
LR-: 0.36 (0.18 to 0.71)†

* values reported here are as reported in the study; however, the PPV and NPV values do not match the 2x2 data reported in the study. NCC calculations are reported in square brackets following study data.
† calculated by the NCC-WCH technical team, as likelihood ratios were not reported in the study

pH <= 7.2 for UA pH <= 7.15

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	43	42
Predictive Test -ve	17	48

pH <= 7.2 for abnormal neonatal outcome

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	31	54
Predictive Test -ve	7	58
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Limitations

Study sample represents population: unclear - no characteristics of the study population are reported
Loss to follow-up is unrelated to key characteristics: no loss to follow-up
Prognostic factors is adequately measured in participants: yes
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for: no details about mode of birth or when they intervened are reported
Statistical analysis is appropriate for study design: yes

For PPV and NPV, calculations reported in the study are not consistent with the 2x2 data that are reported.

Indirectness of population: not reported whether women were low risk in pregnancy. Also, it is likely that some women had an interval of longer than 1 hour between FBS and birth; however, the mean and SD suggest that the vast majority will have been an under an hour which is why the study was included

Other information

The mean time lag between the fetal blood gas analysis and birth was 36.7 ± 15.3 minutes.
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Full citation

East,Christine E., Leader,Leo R., Sheehan,Penelope, Henshall,Naomi E., Colditz,Paul B., Intrapartum fetal scalp lactate sampling for fetal assessment in the presence of a non-reassuring fetal heart rate trace, Cochrane Database of Systematic Reviews, -, 2011

Ref Id

151307

Country/ies where the study was carried out

Sweden
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Sample size

N = 2 trials

N = 3348 mother and baby pairs

Characteristics

Westgren 1998
N = 341
Inclusion criteria: abnormal fetal heart rate during labour and fetal blood sample (FBS) deemed necessary by the attending physician

Interventions:
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Tests

pH analysis

Lactate analysis
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Methods

Searching and identification of studies
The Trials Search Co-ordinator was contacted to search the Cochrane Pregnancy and Childbirth Group's Trials Register (November 2009). At least 2 review authors independently assessed all potential studies for inclusion.

Data extraction and management
A form was designed to extract data. Two review authors did data extraction and data was entered into RevMan and checked for accuracy. If any data was unclear, an attempt was made to contact the study authors to provide details.

Two review authors assessed risk of bias using
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Results

ALL SAMPLES
Mode of birth (n/total)
a. Spontaneous vaginal birth
Lactate: 709/1667
pH: 709/1652

RR 0.91 (95% CI 0.67 to 1.24)
Heterogeneity: I^2 = 64% [therefore, random effects model was used]
Test for overall effect: Z = 0.62 (p = 0.54)

[2 studies: Westgren 1998; Wiberg-Itzel 2008]

b. Assisted vaginal birth
Lactate: 415/1667
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Limitations

This systematic review does not have any limitations.

Indirectness: it is unclear whether these women had low risk pregnancies; for most outcomes, time interval between FBS and birth is not reported.

The following represent the review authors assessment of the risk of bias of the included studies:

Westgren 1998
Adequate sequence generation: unclear, method not reported
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Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Study type **Aim of the study** To evaluate the effectiveness and risks of fetal scalp lactate sampling in the assessment of fetal well-being during labour, compared with no testing or alternative testing **Study dates** Review content was assessed as up-to-date in February 2010 **Source of funding** Department of Obstetrics and Gynaecology and Pregnancy Research Centre, Department of Perinatal Medicine, University of Melbourne, Royal Women's Hospital, Australia School of Women's and Children's Health, University of New South Wales, Royal Hospital for Women, Randwick, Australia Perinatal Research Centre, University of Queensland, Royal Brisbane & Women's Hospital, Australia	- pH analysis was performed in the delivery ward (35 microlitres using ABL 510) - lactate analysis was performed at bedside (5 microlitres using Lactate card) Cut-off action values: pH < 7.20; lactate 2.9 - 3.09 mmol/l was deemed suspicious, and > 3.08 mmol/l was deemed abnormal. No standard advice was given regarding action, so that clinician would consider whole clinical picture, not just one value **Wiberg-Itzel 2008** N = 3007 randomised; N = 2992 analysed Inclusion criteria: singleton pregnancy, cephalic presentation at 34 or more weeks, clinical indication for fetal scalp blood analysis during labour Post-randomisation exclusion: multiple pregnancy, gestational age < 34 weeks Interventions: - pH analysis was done using different blood gas analysers - Lactate was measured with the Lactate Pro Cut-off action values: - pH: normal > 7.25, pre-acidaemia 7.21 - 7.25, acidaemia < 7.21 - Lactate: normal < 4.2 mmol/l, pre-acidaemia 4.2 - 4.8 mmol/l, acidaemia > 4.8 mmol/l Following pre-acidaemia, the recommendation was for further sampling 20 - 30 minutes later if no other indications for intervention. Following acidaemia, management decisions were made by the attending clinicians **Inclusion Criteria** Published and unpublished randomised and quasi-randomised trials comparing fetal scalp lactate testing with no testing or alternative additional tests (e.g. pH, fetal pulse oximetry) to evaluate fetal status in the presence of a non-reassuring cardiotocograph (CTG) during labour **Exclusion Criteria** None reported		criteria outlined in the Cochrane Handbook: - The method used to generate the allocation sequence - Allocation concealment - Blinding - Incomplete outcome data, including attrition and exclusions - Selective reporting bias - Other sources of bias **Data analysis** Fixed-inverse variance meta-analysis was used for combining data, where the authors judged the trials' populations and methods to be sufficiently similar. Where there was suspected clinical or methodological heterogeneity between studies, sufficient to suggest that treatment effects could differ, the authors planned to use random effects meta-analysis. Where substantial heterogeneity was identified in a fixed effects meta-analysis, the analysis was repeated using random effects. There were planned sub-group analyses by stage of labour, gestation, and concurrent use of alternative tests; however, there were not sufficient data to do this.	pH: 455/1652 RR 0.90 (95% CI 0.81 to 1.01) Heterogeneity: I^2 = 0.0% Test for overall effect: Z = 1.73 (p = 0.084) [2 studies: Westgren 1998; Wiberg-Itzel 2008] c. Caesarean section Lactate: 472/1667 pH: 432/1652 RR 1.09 (95% CI 0.97 to 1.22) Heterogeneity: I^2 = 0.0% Test for overall effect: Z = 1.50 (p = 0.13) [2 studies: Westgren 1998; Wiberg-Itzel 2008] d. Operative delivery for non-reassuring fetal status Lactate: 580/1496 pH: 571/1496 RR 1.02 (95% CI 0.93 to 1.11) Heterogeneity: NA Test for overall effect: Z = 0.34 (p = 0.74) [1 study: Wiberg-Itzel 2008] **Neonatal death*** Lactate: 0/1496 pH: 3/1496 RR 0.14 (95% CI 0.01 to 2.76) Heterogeneity: NA Test for overall effect: Z = 1.29 (p = 0.20) [1 trial: Wiberg-Itzel 2008] * Based on data reported in the full text of the trial, the causes of death were lung hypoplasia due to diaphragmatic hernia (n = 2) and congenital cardiac fibrosis (n = 1). **Neonatal encephalopathy (n/total)†** Lactate: 6/1496 pH: 6/1496 RR 1.00 (95% CI 0.32 to 3.09) Heterogeneity: NA Test for overall effect: Z = 0.0 (p = 1.0) [1 trial: Wiberg-Itzel 2008] † Based on data reported in the full text of the trial, this was hypoxic ischaemic encephalopathy. In the lactate group, 5 cases were mild and one was moderate. In the pH group, 4 cases were mild and 2 were moderate. **Admission to NICU (n/total)** Lactate: 167/1496 pH: 164/1496 RR 1.02 (95% CI 0.83 to 1.25) Heterogeneity: NA Test for overall effect: Z = 0.17 (p = 0.86) [1 trial: Wiberg-Itzel 2008] **Apgar score < 7 at 5 minutes (n/total)**	Adequate allocation concealment: yes Blinding: No blinding of participants; blinding of clinicians not feasible; no blinding of outcome assessors reported Incomplete outcome data: excludes women with protocol violations (n = 1 from lactate group, n = 13 from pH group Selective reporting: unclear Other bias: unclear **Wiberg-Itzel 2008** Adequate sequence generation: yes Adequate allocation concealment: yes Blinding: No blinding of participants; blinding of clinicians not feasible; no blinding of outcome assessors reported Incomplete outcome data: There were post-randomisation exclusions for 8 of lactate group (twins n = 7, < 34 weeks n = 5) and 7 of the pH group (twins n = 3, < 34 weeks n = 4). All other data reported by intention to treat, but FBS was not undertaken in all women due to: - sampling or analysis failure (lactate: 18, pH: 155) - rapid delivery, need for expedited delivery, reassuring CTG, withdrew consent, no reason given (lactate: 81, pH: 106) There was incomplete umbilical cord blood gas analysis for the following outcomes: - metabolic acidaemia: lactate group 9%, pH group 12% - pH: lactate group 8%, pH group 12% Selective reporting: unclear Other bias: unclear **Other information** **Success rate of fetal blood sampling (n/total (%))** Lactate: 1478/1496 (97.8%) pH: 1341/1496 (89.6%) [1 trial: Wiberg-Itzel 2008]

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Lactate: 50/1667 pH: 44/1652 RR 1.13 (95% CI 0.76 to 1.68) Heterogeneity: I^2 = 0.0% Test for overall effect: Z = 0.59 (p = 0.56) [2 trials: Westgren 1998; Wiberg-Itzel 2008] **Metabolic acidaemia (umbilical artery pH < 7.05 + base deficit > 12 mmol/l)** Lactate: 44/1360 pH: 47/1315 RR 0.91 (95% CI 0.60 to 1.36) Heterogeneity: NA Test for overall effect: Z = 0.48 (p = 0.63) [1 trial: Wiberg-Itzel 2008] **Cord blood gas values at birth** a. Umbilical artery pH < 6.98 (n/total) Lactate: 4/171 pH: 8/156 RR 0.46 (95% CI 0.14 to 1.49) Heterogeneity: NA Test for overall effect: Z = 1.30 (p = 0.19) [1 trial: Westgren 1998] b. Umbilical artery pH < 7.00 (n/total) Lactate: 21/1376 pH: 24/1322 RR 0.84 (95% CI 0.47 to 1.50) Heterogeneity: NA Test for overall effect: Z = 0.59 (p = 0.56) [1 trial: Wiberg-Itzel 2008] c. Umbilical artery pH < 7.10 (n/total) Lactate: 121/1376 pH: 131/1322 RR 0.89 (95% CI 0.70 to 1.12) Heterogeneity: NA Test for overall effect: Z = 0.99 (p = 0.32) [1 trial: Wiberg-Itzel 2008] d. Umbilical artery lactate > 4.68 mmol/l (n/total)‡ Lactate: 20/171 pH: 29/156 RR 0.63 (95% CI 0.37 to 1.07) Heterogeneity: NA Test for overall effect: Z = 1.72 (p = 0.085) [1 study: Westgren 1998] e. Umbilical artery base deficit (mean ± SD) Lactate: 8 ± 3.8 [n = 171] pH: 8.7 ± 4.6 [n = 156] MD - 0.70 (95% CI - 1.62 to 0.22) Heterogeneity: NA Test for overall effect: Z = 1.49 (p = 0.14)	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				[1 study: Westgren 1998] f. Umbilical artery base deficit > 19.2‡ Lactate: 1/171 pH: 3/156 RR 0.30 (0.03 to 2.89) Heterogeneity: NA Test for overall effect: Z = 1.04 (p = 0.30) [1 study: Westgren 1998] ‡ According to the original trial paper, the thresholds used by Westgren were chosen according to the 1st or 99th centile of normal values, which are reported in another study **SUB-GROUP ANALYSIS OF FBS TAKEN WITHIN 60 MINUTES OF DELIVERY** **Operative delivery for non-reassuring fetal status** Lactate: 380/684 pH: 257/508 RR 1.10 (95% CI 0.98 to 1.22) Heterogeneity: NA Test for overall effect: Z = 1.68 (p = 0.092) [1 study: Wiberg-Itzel et al., 2008) **Apgar score < 7 at 5 minutes** Lactate: 28/684 pH: 21/508 RR 0.99 (95% CI 0.57 to 1.72) Heterogeneity: NA Test for overall effect: Z = 0.03 (p = 0.97) [1 study: Wiberg-Itzel et al., 2008) **Metabolic acidaemia (umbilical artery pH < 7.05 + base deficit > 12 mmol/l) (n/total)** Lactate: 25/684 pH: 20/508 RR 0.93 (95% CI 0.52 to 1.65) Heterogeneity: NA Test for overall effect: Z = 0.25 (p = 0.80) [1 study: Wiberg-Itzel et al., 2008) **Umbilical artery pH < 7.00 (n/total)** Lactate: 10/684 pH: 11/508 RR 0.68 (95% CI 0.29 to 1.58) Heterogeneity: NA Test for overall effect: Z = 0.59 (p = 0.56) [1 study: Wiberg-Itzel et al., 2008)	
Full citation Hon,E.H., Khazin,A.F., Paul,R.H., Biochemical studies of the fetus. II. Fetal pH and apgar scores, Obstetrics and Gynecology,Obstet.Gynecol., 33, 237-255, 1969	**Sample size** N = 194 patients **Characteristics**	**Tests** pH analysis	**Methods** Patients were monitored using electrocardiogram (ECG), fetal heart rate (FHR) patterns, monitoring of uterine contractions and blood pressure monitoring. Biochemical measures included maternal, fetal and neonatal pH, pO_2, pCO_2, base deficit, lactate,	**Results** **Correlation between 1 minute Apgar scores and fetal blood pH at different intervals before birth** All samples Apgar 7-10 - Time interval (mean ± SD): 80.35 ± 114.50	**Limitations** No 2x2 data are available for samples taken within an hour of birth. Study sample represents population: unclear, as very few details are given

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Ref Id 159922 **Country/ies where the study was carried out** USA **Study type** **Aim of the study** Not reported **Study dates** Not reported **Source of funding** Supported in part by grants from the National Institute of Child Health and Human Development	No details given **Inclusion Criteria** None reported **Exclusion Criteria** None reported		pyruvates and haemoglobin. 1392 fetal scalp samples were obtained in total, of which 1117 samples were included in the study (194 patients). At the start of the study, pH was determined twice, once in early labour and once during late labour. However, during the later parts of the study, more frequent sampling was done, and reached as high as 28 per person. Apgar score was assessed as follows: - 7 - 10 was considered high - 6 or less was considered low A pH of 7.20 was used as the pH threshold.	- Apgar (mean ± SD): 8.56 ± 0.64 - pH (mean ± SD): 7.28 ± 0.058 - r: 0.0812 - number of samples: 851 - p-value: < 0.05 Apgar 1-6 - Time interval (mean ± SD): 144.65 ± 171.49 - Apgar (mean ± SD): 3.63 ± 2.03 - pH (mean ± SD): 7.26 ± 0.082 - r: 0.3395 - number of samples: 257 - p-value: < 0.005 <u>Within 60 minutes</u> Apgar 7-10 - Time interval (mean ± SD): 14.70 ± 13.64 - Apgar (mean ± SD): 8.56 ± 0.64 - pH (mean ± SD): 7.27 ± 0.059 - r: -0.0004 - number of samples: 530 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 19.22 ± 15.23 - Apgar (mean ± SD): 3.13 ± 2.04 - pH (mean ± SD): 7.23 ± 0.093 - r: 0.4402 - number of samples: 106 - p-value: < 0.005 <u>Within 45 minutes</u> Apgar 7-10 - Time interval (mean ± SD): 12.49 ± 10.49 - Apgar (mean ± SD): 8.54 ± 0.65 - pH (mean ± SD): 7.27 ± 0.060 - r: 0.0037 - number of samples: 500 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 15.51 ± 10.31 - Apgar (mean ± SD): 3.20 ± 2.00 - pH (mean ± SD): 7.23 ± 0.089 - r: 0.4248 - number of samples: 96 - p-value: < 0.005 <u>Within 30 minutes</u> Apgar 7-10 - Time interval (mean ± SD): 10.05 ± 7.15 - Apgar (mean ± SD): 8.57 ± 0.64 - pH (mean ± SD): 7.27 ± 0.060 - r: 0.0203 - number of samples: 456 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 13.50 ± 8.50 - Apgar (mean ± SD): 3.23 ± 2.06 - pH (mean ± SD): 7.22 ± 0.089 - r: 0.4608 - number of samples: 87 - p-value: < 0.005 <u>Within 15 minutes</u> Apgar 7-10 - Time interval (mean ± SD): 7.28 ± 4.18	Loss to follow-up is unrelated to key characteristics: unclear Prognostic factors are adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: mode of birth is not reported Statistical analysis is appropriate for study design: yes **Other information** This study population appears to be the same as Khazin et al., but different data are reported

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				- Apgar (mean ± SD): 8.61 ± 0.64 - pH (mean ± SD): 7.27 ± 0.064 - r: 0.0111 - number of samples: 371 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 7.64 ± 4.25 - Apgar (mean ± SD): 3.53 ± 2.17 - pH (mean ± SD): 7.21 ± 0.104 - r: 0.5490 - number of samples: 53 - p-value: < 0.005 <u>Within 5 minutes</u> Apgar 7-10 - Time interval (mean ± SD): 2.87 ± 1.35 - Apgar (mean ± SD): 8.58 ± 0.68 - pH (mean ± SD): 7.25 ± 0.073 - r: 0.0154 - number of samples: 142 - p-value: > 0.05 Apgar 1-6 - Time interval (mean ± SD): 2.71 ± 1.32 - Apgar (mean ± SD): 3.47 ± 2.07 - pH (mean ± SD): 7.23 ± 0.083 - r: 0.7376 - number of samples: 17 - p-value: < 0.005 **<u>Correlation between 5 minute Apgar scores and fetal blood pH at different intervals before birth</u>** <u>All samples</u> Apgar 7-10 - Time interval (mean ± SD): 89.85 ± 118.90 - Apgar (mean ± SD): 8.99 ± 0.74 - pH (mean ± SD): 7.28 ± 0.060 - r: 0.04343 - number of samples: 1029 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 164.83 ± 240.04 - Apgar (mean ± SD): 4.20 ± 1.57 - pH (mean ± SD): 7.23 ± 0.097 - r: 0.3485 - number of samples: 79 - p-value: <0.005 <u>Within 60 minutes:</u> Apgar 7-10 - Time interval (mean ± SD): 15.52 ± 14.31 - Apgar (mean ± SD): 9.11 ± 0.69 - pH (mean ± SD): 7.27 ± 0.061 - r: 0.0607 - number of samples: 595 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 14.48 ± 8.69 - Apgar (mean ± SD): 4.00 ± 1.82 - pH (mean ± SD): 7/18 ± 0.098 - r: 0.3880 - number of samples: 41 - p-value: <0.01	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				<u>Within 45 minutes:</u> Apgar 7-10 - Time interval (mean ± SD): 12.87 ± 10.63 - Apgar (mean ± SD): 9.12 ± 0.68 - pH (mean ± SD): 7.27 ± 0.06 - r: 0.0019 - number of samples: 555 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 14.48 ± 8.69 - Apgar (mean ± SD): 4.00 ± 1.82 - pH (mean ± SD): 7/18 ± 0.098 - r: 0.3880 - number of samples: 41 - p-value: <0.01 <u>Within 30 minutes:</u> Apgar 7-10 - Time interval (mean ± SD): 10.33 ± 7.35 - Apgar (mean ± SD): 9.15 ± 0.67 - pH (mean ± SD): 7.27 ± 0.06 - r: 0.0044 - number of samples: 503 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 14.06 ± 8.38 - Apgar (mean ± SD): 3.95 ± 1.81 - pH (mean ± SD): 7.18 ±0.096 - r: 0.3591 - number of samples: 40 - p-value: < 0.05 <u>Within 15 minutes:</u> Apgar 7-10 - Time interval (mean ± SD): 7.27 ± 4.17 - Apgar (mean ± SD): 9.22 ± 0.63 - pH (mean ± SD): 7.27 ± 0.063 - r: -0.0120 - number of samples: 400 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 8.31 ± 4.44 - Apgar (mean ± SD): 4.21 ± 1.84 - pH (mean ± SD): 7.16 ± 0.114 - r: 0.4261 - number of samples: 24 - p-value: < 0.05 <u>Within 5 minutes:</u> Apgar 7-10 - Time interval (mean ± SD): 2.83 ± 1.34 - Apgar (mean ± SD): 9.18 ± 0.65 - pH (mean ± SD): 7/25 ± 0.071 - r: -0.0534 - number of samples: 151 - p-value: p > 0.05 Apgar 1-6 - Time interval (mean ± SD): 3.31 ± 1.44 - Apgar (mean ± SD): 4.25 ± 1.58 - pH (mean ± SD): 7.18 ± 0.080 - r: 0.6171 - number of samples: 8 - p-value: < 0.05	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Full citation Kerenyi,T.D., Falk,S., Mettel,R.D., Walker,B., Acid-base balance and oxygen saturation of fetal scalp blood during normal and abnormal labors, Obstetrics and Gynecology, 36, 398-404, 1970 **Ref Id** 169762 **Country/ies where the study was carried out** USA **Study type** **Aim of the study** Not stated **Study dates** Not reported **Source of funding** None reported	**Sample size** N = 33 (However, only 23 were taken within 1 hour of delivery and hence constitute the population of interest) **Characteristics** Of the study population who had a fetal blood sample (FBS) taken within an hour of birth: 8 had normal labours and gave birth to babies with an Apgar score of 6 or better, following a blood sample taken within 1 hour of birth (range 10 minutes to 55 minutes). Dilatation was rim in one woman, 6-9 in 5 women and full in 2 women. 7 had complicated labours and gave birth to babies with an Apgar score of 6 or better after an FBS within an hour of birth (range 1 minute - 40 minutes): Case 5: abnormal fetal heart rate (FHR), pitocin drip, secondary uterine inertia, - Full dilatation Case 15: Toxemia - Full dilatation Case 22: Relative cephalopelvic disproportion, eclamptic - Full dilatation Case 23: premature (2300 g), fetal tachycardia - Full dilatation Case 27: meconium staining - Full dilatation Case Elm 4: toxemia, relative chronic pulmonary diseaese (CPD), premature rupture of membranes (RoM), tachycardia, rim and full dilatation - Full dilatation Case 26: Class D diabetes - Full dilatation 8 had complicated labours and gave birth to depressed babies within an hour of FBS (range 16 minutes to 40 minutes): Case 3: relative CPD, pitocin drip - 7 cm dilatation Case 12: CPD - Full dilatation Case 14: meconium staining, fetal tachycardia - 5-6 cm dilatation Case 18: fetal distress, irregular and slow FHR [still born] - Full dilatation Case 19: CPD, fetal distress, FHR 60, cord around shoulder - Full dilatation Case 24: prolonged RoM, amniotis, fetal sepsis - Full dilatation Case Elm 3: toxemia, type II dips, CPD - Full dilatation	**Tests** pH analysis within 60 minutes of birth	**Methods** Fetal blood sampling was done with the patient in the lithotomy position, after the membranes had either been ruptured artificially or had spontaneously ruptured. An endoscope was put through the os and pressed against the head. The scalp was cleaned and at the time of a contraction was sprayed with ethyl chloride to produce hyperaemia. A silicone preparation was applied to enhance blood beading. A puncture was made with a 2mm blade and blood was collected in a heparinised tube after suction was applied by mouth. The sample was immediately analysed. Samples were taken periodically during labour. If any value was abnormal, the analysis was immediately repeated and the result compared to the maternal blood. As the series went on, maternal acid-base status was found to be a useful tool in determining whether acidosis started in the mother or the baby. At delivery, blood samples from the cord were collected before clamping. The clinical status of the baby was evaluated at 1 minute and 5 minutes. All patients delivered under local or regional anaesthesia, where possible. Patients received varying amounts of meperidine and scopolamine for analgesia.	**Results** The following predictive value measures were calculated by the technical team, based on data reported in tables 1 - 3 of the paper. The calculations only include fetal scalp samples that were taken within 1 hour of birth (n = 23). There is missing data for 2 arterial samples. **Predictive value of pH < 7.10 (95% CI)** a. For Apgar score < 7 at 1 minute Sensitivity: 25.00% (0.50 to 49.50) Specificity: 100 (NC) PPV: 100 (NC) NPV: 55.00% (33.20 to 76.80) LR+: infinite LR-: 0.75 (0.54 to 1.04) b. For Apgar score < 7 at 5 minutes Sensitivity: 66.67% (13.32 to 100) Specificity: 95.00% (85.45 to 100) PPV: 66.67% (13.32 to 100) NPV: 95.00% (85.45 to 100) LR+: 13.33 (1.68 to 105.79) LR-: 0.35 (0.07 to 1.74) c. For umbilical artery pH < 7.10 Sensitivity: 33.33% (0 to 86.68) Specificity: 94.44% (83.86 to 100) PPV: 50.00% (0 to 100) NPV: 89.47% (75.67 to 100) LR+: 6.00 (0.50 to 72.21) LR-: 0.71 (0.31 to 1.58) **Predictive value of pH ≤ 7.20 (95% CI)** a. For Apgar score < 7 at 1 minute Sensitivity: 58.33% (30.44 to 86.23) Specificity: 72.73% (46.41 to 99.05) PPV: 70.00% (41.60 to 98.40) NPV: 61.54% (35.09 to 87.99) LR+: 2.14 (0.73 to 6.28) LR-: 0.57 (0.27 to 1.23) b. For Apgar score < 7 at 5 minutes Sensitivity: 66.67% (13.32 to 100) Specificity: 60.00% (38.53 to 81.47) PPV: 20.00% (0 to 44.79) NPV: 92.31% (77.82 to 100) LR+: 1.67 (0.64 to 4.37) LR-: 0.56 (0.11 to 2.86) c. For umbilical artery pH < 7.1 Sensitivity: 100% (NC) Specificity: 66.67% (44.89 to 88.44) PPV: 33.33% (2.5 to 64.13) NPV: 100% (NC) LR+: 3.00 (1.56 to 5.77) LR-: 0.00 (NC) **Predictive value of pH ≤ 7.25 (95% CI)** a. For Apgar score < 7 at 1 minute Sensitivity: 75.00% (50.50 to 99.50) Specificity: 9.09% (0 to 26.08) PPV: 47.37% (24.92 to 69.82) NPV: 25.00% (0 to 67.44) LR+: 0.83 (0.57 to 1.20) LR-: 2.75 (0.33 to 22.69)	**Limitations** Study sample represents population: Many of the women were not low risk; inclusion and exclusion criteria are not reported Loss to follow-up is unrelated to key characteristics: No loss to follow-up Prognostic factors are adequately measured in participants: There are missing data for between 4 and 5 (17 - 22%) out of the 23 women for base deficit values. Outcome of interest is sufficiently measured in participants: There are missing data for 2/23 arterial pH measurements Important potential confounders are accounted for: Mode of birth is not reported Statistical analysis is appropriate for study design: Yes **Other information** **Further information about cases of low Apgar score at 5 minutes** **Case 14:** - Meconium staining, fetal tachycardia - Tested at 19 minutes before birth - Apgar of 2 at 1 minute and 5 at 5 minutes **Case 18:** - Fetal distress, irregular and slow FHR - Tested at 25 minutes before birth - Baby was stillborn **Case 30:** - Cephalopelvic disproportion, irregular FHR, caesarean section - Tested at 40 minutes before birth - Apgar of 4 at 1 minute and 6 at 5 minutes **Further information about cases of low arterial pH (< 7.10) at birth** **Case 12:** - Cephalopelvic disproportion - Tested at 16 minutes before birth and had pH of 7.12 - Artery pH of 7.06 **Case 18:** - Fetal distress, irregular and slow FHR - Tested at 25 minutes before birth and had pH of 6.64 - Baby was stillborn and had arterial pH of 6.81 **Case Elm 3:** - Toxemia, type II dips, cephalopelvic disproportion - Tested at 25 minutes before birth and had pH of 7.15 - Artery pH of 7.08

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	Case 30: CPD, irregular FHR, caesarean - 7 cm dilatation **Inclusion Criteria** None reported **Exclusion Criteria** None reported			b. For Apgar score < 7 at 5 minutes Sensitivity: 66.67% (13.32 to 100) Specificity: 15.00% (0 to 30.65) PPV: 10.53% (0 to 24.33) NPV: 75.00% (32.56 to 100) LR+: 0.78 (0.35 to 1.78) LR-: 2.22 (0.33 to 15.01) c. For umbilical artery pH < 7.1 Sensitivity: 100% (NC) Specificity: 22.22% (3.02 to 41.43) PPV: 17.65% (0 to 35.77) NPV: 100% (NC) LR+: 1.29 (1.00 to 1.65) LR-: 0 (NC) **Predictive value of base deficit > 10 mEq/l (95% CI)** a. For Apgar score < 7 at 1 minute Sensitivity: 25.00% (0 to 55.01) Specificity: 90.91% (73.92 to 100) PPV: 66.67% (13.32 to 100) NPV: 62.50% (38.78 to 86.22) LR+: 2.75 (0.30 to 25.35) LR-: 0.83 (0.53 to 1.28) **b. For Apgar score < 7 at 5 minutes** Sensitivity: 0 (NC) Specificity: 83.33% (66.12 to 100) PPV: 0 (NC) NPV: 93.75% (81.89 to 100) LR+: 0 (NC) LR-: 1.20 (0.98 to 1.48) c. For umbilical artery pH < 7.10 Sensitivity: 0 (NC) Specificity: 81.25% (62.12 to 100) PPV: 0 (NC) NPV: 86.67% (69.46 to 100) LR+: 0 (NC) LR-: 1.23 (0.97 to 1.56) **Predictive value of base deficit > 12 mEq/l (95% CI)** a. For Apgar score < 7 at 1 minute Sensitivity: 25.00% (0 to 55.01) Specificity: 100% (NC) PPV: 100 (NC) NPV: 64.71% (41.99 to 87.42) LR+: infinite LR-: 0.75 (0.51 to 1.12) b. For Apgar score < 7 at 5 minutes Sensitivity: 0 (NC) Specificity: 88.89% (74.37 to 100) PPV: 0 (NC) NPV: 94.12 (82.93 to 100) LR+: 0 (NC) LR-: 1.13 (0.96 to 1.32) c. For umbilical artery pH < 7.10 Sensitivity: 0 (NC) Specificity: 87.50% (71.29 to 100) PPV: 0 (NC) NPV: 87.50% (71.29 to 100) LR+: 0 (NC) LR-: 1.14 (0.95 to 1.38) **Predictive value of base deficit > 12.5 mEq/l (95% CI)** a. For Apgar score < 7 at 1 minute	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Sensitivity: 12.50% (0 to 35.42) Specificity: 100 (NC) PPV: 100 (NC) NPV: 61.11% (38.59 to 83.63) LR+: infinite LR-: 0.88 (0.67 to 1.14) b. For Apgar score < 7 at 5 minutes Sensitivity: 0 (NC) Specificity: 94.44% (83.86 to 100) PPV: 0 (NC) NPV: 94.44% (83.86 to 100) LR+: 0 (NC) LR-: 1.06 (0.95 to 1.18) c. For umbilical artery pH < 7.10 Sensitivity: 0 (NC) Specificity: 93.75% (81.89 to 100) PPV: 0 (NC) NPV: 88.24% (72.92 to 100) LR+: 0 (NC) LR-: 1.07 (0.94 to 1.21) **FBS pH < 7.1 for Apgar < 7 at 1 minute** | | Reference Test +ve | Reference Test -ve | | --- | --- | --- | | **Predictive Test +ve** | 3 | 0 | | **Predictive Test -ve** | 9 | 11 | **FBS pH < 7.1 for arterial pH < 7.10** | | Reference Test +ve | Reference Test -ve | | --- | --- | --- | | **Predictive Test +ve** | 1 | 1 | | **Predictive Test -ve** | 2 | 17 | **FBS pH <= 7.20 for arterial pH < 7.1** | | Reference Test +ve | Reference Test -ve | | --- | --- | --- | | **Predictive Test +ve** | 3 | 6 | | **Predictive Test -ve** | 0 | 12 | **FBS pH <= 7.20 for Apgar < 7 at 1 minute** | | Reference Test +ve | Reference Test -ve | | --- | --- | --- | | **Predictive Test +ve** | 7 | 3 |	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

Predictive Test -ve	5	8

FBS pH <= 7.20 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	2	8
Predictive Test -ve	1	12

FBS pH <= 7.25 for arterial pH < 7.1

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	3	14
Predictive Test -ve	0	4

FBS pH <= 7.25 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	9	10
Predictive Test -ve	3	1

FBS <= 7.25 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	2	17
Predictive Test -ve	1	3

FBS base deficit > 10 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	2	1
Predictive Test -ve	6	10

FBS base deficit > 10 for Apgar < 7 at 5 minutes

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	0	3
Predictive Test -ve	1	15

FBS base deficit > 10 for arterial pH < 7.10

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	0	3
Predictive Test -ve	2	13

FBS base deficit > 12 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	2	0
Predictive Test -ve	6	11

FBS base deficit > 12 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	0	2
Predictive Test -ve	1	16

FBS base deficit > 12 for arterial pH < 7.10

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	0	2
Predictive Test -ve	2	14

FBS base deficit > 12.5 for Apgar < 7 at 1 minute

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	1	0
Predictive Test -ve	7	11

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				FBS base deficit > 12.5 for Apgar < 7 at 5 minutes | | Reference Test +ve | Reference Test -ve | | Predictive Test +ve | 0 | 1 | | Predictive Test -ve | 1 | 17 | **FBS base deficit > 12.5 for arterial pH < 7.10** | | Reference Test +ve | Reference Test -ve | | Predictive Test +ve | 0 | 1 | | Predictive Test -ve | 2 | 15 |	
Full citation Khazin,A.F., Hon,E.H., Quilligan,E.J., Biochemical studies of the fetus. 3. Fetal base and Apgar scores, Obstetrics and Gynecology, 34, 592-609, 1969 **Ref Id** 170426 **Country/ies where the study was carried out** USA **Study type** **Aim of the study** Not reported **Study dates** Not reported **Source of funding** Supported in part by research grants from the National Institute of Child Health and Human Development, USPHS, and a grant from the Health Sciences Computing Facility	**Sample size** N = 194 **Characteristics** 80 patients had complications of pregnancy such as toxemia, Rh sensitisation, diabetes, premature rupture of membranes, clinically diagnosed fetal distress or post-dates (proportions of each are not reported) **Inclusion Criteria** Not reported **Exclusion Criteria** Not reported	**Tests** pH analysis	**Methods** Fetal blood samples were collected according to Saling's technique, but glass capillary tubes were used instead of plastic. Patients were monitored using electrocardiogram (ECG), fetal heart rate (FHR) patterns, monitoring of uterine contractions and blood pressure monitoring. Biochemical measures included maternal, fetal and neonatal pH, pO_2, pCO_2, base deficit, lactate, pyruvates and haemoglobin. Umbilical artery and vein blood was obtained before the first breath of the infant, from a doubly clamped segment of the umbilical cord. A radiometer microelectrode was done to determine pH. Fetal scalp blood samples were obtained during different stages of labour, and between 1 and 35 samples were taken per patient. Fetal base determinations were done on 602 samples taken from 140 patients (1 - 17 per patient). Apgar score at 1 and 5 minutes were taken. 1 - 6 was considered low, and 7 - 10 was considered high. This was first done for all samples, and then restricted to samples taken within the last 30 minutes of labour. To determine the impact of time interval between fetal base determination and birth on predictive values, correlation coefficients were taken for all samples, then restricted to those in the last 60, 45, 30, 15 and 5 minutes preceding birth.	**Results** The following calculations were performed by the technical team, based on 2x2 data reported in the text for 130 **babies** who had samples taken within 30 minutes of birth: **Predictive accuracy (95% CI) of a fetal base deficit of > 12.5 mEq/l for:** a. 1-minute Apgar score < 7 Sensitivity: 31.82% (12.35 to 51.28) Specificity: 92.59% (87.65 to 97.53) PPV: 46.67% (21.42 to 71.91) NPV: 86.96% (80.80 to 93.11) LR+: 4.30 (1.74 to 10.62) LR-: 0.74 (0.55 to 0.98) b. 5-minute Apgar score < 7 Sensitivity: 42.86% (6.20 to 79.52) Specificity: 90.24% (85.00 to 95.49) PPV: 20.00% (0 to 40.24) NPV: 96.52% (93.17 to 99.87) LR+: 4.39 (1.60 to 12.06) LR-: 0.63 (0.33 to 1.21) **Correlation between 1 minute Apgar score and fetal base-deficit at different intervals before birth** All samples - Apgar 7 - 10 Time interval (mean ± SD): 86.06 ± 111.55 Apgar (mean ± SD): 8.53 ± 0.63 Base deficit / mEq/l (mean ± SD): 7.91 ± 2.80 number of samples: 472 r: -0.1459 p-value: < 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 194.54 ± 225.81 Apgar (mean ± SD): 3.29 ± 2.08 Base deficit / mEq/l (mean ± SD): 8.26 ± 3.39 number of samples: 130 r: +0.0387 p-value: > 0.05 60 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 15.75 ± 15.05	**Limitations** Study sample represents population: 80/194 women had complications in labour; very few other details about the population are reported Loss to follow-up is unrelated to key characteristics: no loss to follow-up Prognostic factors are adequately measured in participants: very few details about what happened to the babies during labour Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: mode of birth is not reported Statistical analysis is appropriate for study design: yes **Other information** **Further information about the false negatives (i.e. base deficit ≤ 12.5 mEq/l but with a low Apgar score at 1 minute, table 5 in paper)** 1. - 2 samples taken, at 20 minutes and 16 minutes prior to birth - BD 11.1 - 11.3 - Late decelereations (+++), hyperactivity (+++) - Apgar scores: 2, 5 2. - 5 samples taken, at between 320 and 18 minutes prior to birth - BD 8.8 - 10.3 - Variable decelerations (++), Caput (+++) - Forceps applied with traction for 7 minutes - Apgar scores: 4, 7 3. - 3 samples taken, at between 12 and 9 minutes prior to birth - BD 9.4 - 12.4 - Variable decelerations (+) - Shoulder dystocia, midforceps - Apgar scores: 6, 9

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Apgar (mean ± SD): 8.48 ± 0.67 Base deficit / mEq/l (mean ± SD): 8.27 ± 2.95 number of samples: 277 r: -0.2002 p-value: <0.005 - Apgar 1 - 6 Time interval (mean ± SD): 19.70 ± 12.05 Apgar (mean ± SD): 3.16 ± 2.03 Base deficit / mEq/l (mean ± SD): 9.75 ± 3.85 number of samples: 45 r: -0.2056 p-value: > 0.05 <u>45 minutes before birth</u> - Apgar 7 - 10 Time interval (mean ± SD): 12.80 ± 11.04 Apgar (mean ± SD): 8.47 ± 0.67 Base deficit / mEq/l (mean ± SD): 8.32 ± 2.99 number of samples: 257 r: -0.1817 p-value: <0.005 - Apgar 1 - 6 Time interval (mean ± SD): 18.38 ± 10.59 Apgar (mean ± SD): 3.26 ± 2.03 Base deficit / mEq/l (mean ± SD): 9.72 ± 3.68 number of samples: 43 r: -0.2167 p-value: > 0.05 <u>30 minutes before birth</u> - Apgar 7 - 10 Time interval (mean ± SD): 9.94 ± 7.50 Apgar (mean ± SD): 8.52 ± 0.66 Base deficit / mEq/l (mean ± SD): 8.39 ± 2.98 number of samples: 230 r: -0.1825 p-value: < 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 14.59 ± 7.43 Apgar (mean ± SD): 3.31 ± 2.15 Base deficit / mEq/l (mean ± SD): 10.43 ± 3.31 number of samples: 35 r: -0.2664 p-value: > 0.05 <u>15 minutes before birth</u> - Apgar 7 - 10 Time interval (mean ± SD): 6.84 ± 4.06 Apgar (mean ± SD): 8.58 ± 0.66 Base deficit / mEq/l (mean ± SD): 8.28 ± 2.98 number of samples: 185 r: -0.1812 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 8.58 ± 4.36 Apgar (mean ± SD): 3.44 ± 2.55 Base deficit / mEq/l (mean ± SD): 10.57 ± 3.36 number of samples: 18 r: -0.3553 p-value: > 0.05 <u>5 minutes before birth</u> - Apgar 7 - 10 Time interval (mean ± SD): 3.01 ± 1.37	4. - 2 samples taken at between 24 and 22 minutes prior to birth - BD 7.2 - Variable decelerations (++) - Twin A, variable decelerations with delivery - Apgar scores: 5, 9 [Note: there was one further case, but the sample was taken outside the time of interest; therefore details have not been reported here]

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Apgar (mean ± SD): 8.61 ± 0.68 Base deficit / mEq/l (mean ± SD): 8.49 ± 2.46 number of samples: 81 r: -0.0590 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 1.75 ± 0.50 Apgar (mean ± SD): 2.50 ± 2.38 Base deficit / mEq/l (mean ± SD): 10.68 ± 1.08 number of samples: 4 r: -0.9259 p-value: **Correlation between 5 minute Apgar score and fetal base-deficit at different intervals before birth** All samples - Apgar 7 - 10 Time interval (mean ± SD): 94.26 ± 114.80 Apgar (mean ± SD): 9.01 ± 0.70 Base deficit / mEq/l (mean ± SD): 7.97 ± 2.92 number of samples: 559 r: -0.0918 p-value: < 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 307.45 ± 326.20 Apgar (mean ± SD): 4.65 ± 1.25 Base deficit / mEq/l (mean ± SD): 8.11 ± 3.27 number of samples: 43 r: -0.3210 p-value: < 0.05 60 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 16.31 ± 14.94 Apgar (mean ± SD): 9.08 ± 0.68 Base deficit / mEq/l (mean ± SD): 8.35 ± 3.06 number of samples: 309 r: -0.0960 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 16.31 ± 7.99 Apgar (mean ± SD): 4.62 ± 1.76 Base deficit / mEq/l (mean ± SD): 11.47 ± 3.18 number of samples: 13 r: -0.8362 p-value: < 0.005 45 minutes before birth - Apgar 7 - 10 Time interval (mean ± SD): 13.48 ± 11.25 Apgar (mean ± SD): 9.08 ± 0.68 Base deficit / mEq/l (mean ± SD): 8.38 ± 3.06 number of samples: 287 r: -0.0663 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 16.31 ± 7.99 Apgar (mean ± SD): 4.62 ± 1.76 Base deficit / mEq/l (mean ± SD): 11.47 ± 3.18 number of samples: 13 r: -0.8362 p-value: < 0.005 30 minutes before birth	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				- Apgar 7 - 10 Time interval (mean ± SD): 10.34 ± 7.61 Apgar (mean ± SD): 9.11 ± 0.64 Base deficit / mEq/l (mean ± SD): 8.51 ± 3.03 number of samples: 253 r: -0.1383 p-value: < 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 15.13 ± 7.05 Apgar (mean ± SD): 4.50 ± 1.78 Base deficit / mEq/l (mean ± SD): 11.84 ± 3.02 number of samples: 12 r: -0.8359 p-value: < 0.005 <u>15 minutes before birth</u> - Apgar 7 - 10 Time interval (mean ± SD): 6.91 ± 4.07 Apgar (mean ± SD): 9.21 ± 0.58 Base deficit / mEq/l (mean ± SD): 8.36 ± 2.98 number of samples: 197 r: -0.1454 p-value: > 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 9.75 ± 4.45 Apgar (mean ± SD): 4.33 ± 2.58 Base deficit / mEq/l (mean ± SD): 12.42 ± 4.12 number of samples: 6 r: -0.9366 p-value: < 0.005 <u>5 minutes before birth</u> - Apgar 7 - 10 Time interval (mean ± SD): 2.96 ± 1.37 Apgar (mean ± SD): 9.21 ± 0.62 Base deficit / mEq/l (mean ± SD): 8.55 ± 2.44 number of samples: 84 r: -0.1517 p-value: 0.05 - Apgar 1 - 6 Time interval (mean ± SD): 2.00 (NA) Apgar (mean ± SD): 6 (NA) Base deficit / mEq/l (mean ± SD): 11.80 (NA) number of samples: 1 r: NA p-value: NA **FBS base deficit > 12.5 for Apgar < 7 at 1 minute** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 7 / 8 **Predictive Test -ve**: 15 / 100 **FBS base deficit > 12.5 for Apgar < 7 at 5 minutes**	

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>3</td><td>12</td></tr>
<tr><td>Predictive Test -ve</td><td>4</td><td>111</td></tr>
</table>
</td><td></td></tr>
<tr><td>Full citation

Kubli,F.W., Influence of labor on fetal acid-base balance, Clinical Obstetrics and Gynecology, 11, 168-191, 1968

Ref Id

169765

Country/ies where the study was carried out

USA

Study type

Aim of the study

Not reported

Study dates

1966 - 1967

Source of funding

Supported in part by Public Health Service Research Grant from the National Heart Institute and a Grant from DFG (Deutsche Forschungsgemeinschaft)</td><td>Sample size

N = 77

Characteristics

none reported

Inclusion Criteria

Not reported

Exclusion Criteria

Not reported</td><td>Tests

pH within 30 minutes of birth</td><td>Methods

Very few details are reported, as this is a further analysis of another study by Hon (referenced as not published). 77 patients were selected in whom the last sample was done 30 minutes before birth. However, the authors report including 5 further patients with an abnormal pH value with or without depression.

For all patients, continuous fetal heart rate monitoring was done and amniotic fluid pressure was recorded.</td><td>Results

The following measures were calculated based on 2x2 data reported in table 2a of the paper.

<u>Predictive value of pH < 7.20 for an Apgar < 7 (reported as ≤ 6) at 1 minute</u>
Sensitivity: 57.14% (31.22 to 83.07)
Specificity: 84.13% (75.10 to 93.15)
PPV: 44.44% (21.49 to 67.40)
NPV: 89.83% (82.12 to 97.54)
LR+: 3.60 (1.74 to 7.45)
LR-: 0.51 (0.28 to 0.94)

<u>Correlation of fetal scalp measurements with umbilical cord measurements (r value)*</u>
a. pH: 0.76

b. Base excess: 0.90

Note: this relates to 31 samples from uncomplicated, spontaneous births where the FBS was done within 5 minutes of birth

* There is some discrepancy between data reported in the text and in the figures; data from the text have been reported here

FBS pH < 7.20 for Apgar < 7 at 1 minute
<table>
<tr><th></th><th>Reference Test +ve</th><th>Reference Test -ve</th></tr>
<tr><td>Predictive Test +ve</td><td>8</td><td>10</td></tr>
<tr><td>Predictive Test -ve</td><td>6</td><td>53</td></tr>
</table></td><td>Limitations

Study sample represents population: Unclear, exclusion and inclusion criteria are not reported and there are no characteristics reported
Loss to follow-up is unrelated to key characteristics: Unclear
Prognostic factors are adequately measured in participants: Yes
Outcome of interest is sufficiently measured in participants: Yes
Important potential confounders are accounted for: No, there are very few details and mode of birth is not reported
Statistical analysis is appropriate for study design: Unclear

They restricted sample to those within 30 minutes, but then added a further 5 patients as they didn't have sufficient data. In general, this study is very badly reported.

Other information

<u>Additional details about babies with low scalp pH but born vigorous ('false positives')</u>
Note: The detail provided about the 'false positives' does not use the same threshold for high Apgar as the rest of the data reported; therefore, not all of the false positives have extra data reported for them.

Out of the 7 babies with abnormal pH but an Apgar of at least 8:
- 2 had unknown causes
- In one, there was transient uterine hypertonus due to oxytocin over-dosage, which was associated with marked and prolonged late decelerations.
- In the remaining 4 cases, the presence of severe or moderate cord compression was suggested.</td></tr>
<tr><td>Full citation

Wiberg-Itzel,E., Lipponer,C., Norman,M., Herbst,A., Prebensen,D., Hansson,A., Bryngelsson,A.L., Christoffersson,M., Sennstrom,M., Wennerholm,U.B., Nordstrom,L., Determination of pH or lactate in fetal scalp blood in management of intrapartum fetal distress: randomised controlled multicentre trial, BMJ, 336, 1284-1287, 2008

Ref Id

116763

Country/ies where the study was carried out

Sweden</td><td>Sample size

N = 3007 randomised

Characteristics

<u>Maternal age/years (mean (range))</u>
pH: 33.0 (19 - 49)
Lactate: 32.5 (19 - 48)

<u>Parity (n (%))</u>
- Nulliparous
pH: 1179 (78.8)
Lactate: 1155 (77.2)

- Multiparous
pH: 317 (21.2)</td><td>Tests

pH analysis

Lactate analysis

[data are reported for within 60 minutes of birth]</td><td>Methods

Antenatal clinics gave information about the study to women who were late in pregnancy, and requested consent either then or when the woman was admitted in labour. If consent was not obtained, or the woman was distressed, she was cared for according to the protocols of the department she was in. 3007 women were randomised, and then 15 were excluded as per exclusion criteria.

An internet based system was used for randomisation and data entry. Randomisation was stratified by department, and also by the use of electrocardiogram (ECG) as an adjunct to cardiotocography (CTG). At the point that the clinician decided to sample fetal scalp blood, the woman was randomised to either pH or lactate</td><td>Results

The following data was reported in the trial, and this was used to calculate the diagnostic accuracy data below.

<u>Incidence of metabolic acidaemia (n/total (%))</u>
<u>a. Split by pH status</u>
> 7.25: 7/281 (2.5)
7.25 - 7.21: 3/92 (3.3)
< 7.21: 10/135 (7.4)

<u>b. Split by lactate status</u>
< 4.2: 6/344 (1.7)
4.2 - 4.8: 0/73 (0)
> 4.8: 19/267 (7.1)

<u>Incidence of pH < 7.00 at birth (n/total (%))</u>
<u>a. Split by pH status</u></td><td>Limitations

Study sample represents population: unclear whether these women were definitely low risk during their pregnancy
Loss to follow-up is unrelated to key characteristics: Not applicable because there was no loss to follow-up. However, there are some missing data: samples for cord pH measurement were missing in 174 in pH arm and 120 in lactate arm; however, it is unclear whether these came from the subset of the study population with measurements done within 60 minutes of birth.
Prognostic factors is adequately measured in participants: yes
Outcome of interest is sufficiently measured in participants: yes
Important potential confounders are accounted for:</td></tr>
</table>

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Study type **Aim of the study** To examine the effectiveness of pH analysis of fetal scalp blood compared with lactate analysis in identifying hypoxia in labour to prevent acidaemia at birth **Study dates** December 2002 to December 2005 **Source of funding** Signhild Engqvists Stiftelse, Almanna BB's Minnesfond, the regional city council research and development foundations, the health and medical committee of the region Vastra Gotaland, and Medexa, Lomma, Sweden	Lactate: 341 (22.8) **Gestational age/weeks+days (mean (range))** pH: 40+2 (34+0 - 44+2) Lactate: 40+3 (34+0 - 43+6) **Fetal weight** a. Mean/grams (range) pH: 3575 (1590 - 5680) Lactate: 3566 (1860 - 6110) b. Proportion with fetal weight < 2500 (n/total) pH: 39/1496 Lactate: 36/1496 **Use of STAN monitor (n (%))** pH: 393 (26.2) Lactate: 392 (26.2) **Inclusion Criteria** Singleton pregnancy Cephalic presentation Gestational age ≥ 34 weeks Non-reassuring fetal heart rate trace that the clinician in charge considered to be an indication for FBS **Exclusion Criteria** Multiple pregnancy Gestational age < 34 weeks		analysis. If sampling or analysis failed, management was based on other clinical information. Any crossover was regarded as a protocol violation. Scalp blood was sampled one to nine times for each fetus. In the pH group, successful sampling or analysis was performed in 1008 fetuses, with a total of 1628 analyses of pH. In the lactate group, successful sampling was done in 1355 fetuses, with a total of 2301 analyses. End points were metabolic acidaemia in cord blood (defined as a pH < 7.05 and base deficit > 12 mmol/l) and pH < 7.00. Base deficit was calculated with the algorithm used by Radiometer blood gas analysers. Lactate was measured using a microvolume test strip device (Lactate Pro). Various pH analysers were used, but regular quality checks were performed. Guidelines for interpreting blood gas were: - pH > 7.25 or lactate < 4.2 mmol/l: normal - pH 7.21 - 7.25 or lactate 4.2 - 4.8 mmol/l: pre-acidaemia - pH < 7.21 or lactate > 4.8 mmol/l: acidaemia The guidelines for pre-acidaemia were to repeat the sample in 20-30 minutes if there was no other indication for intervention. For fetuses with acidaemia, the decision about delivery was left to the clinician. A sample size calculation calculated that a total of 2872 participants would be needed to detect a 100% increase in metabolic acidaemia with lactate, compared to a prevalence of 1.6% in the pH arm, with 80% power. To show a 50% reduction, 2907 cases in each arm would be needed. For the endpoint of pH < 7.00, 1141 cases in each arm were needed to detect a 50% decrease or increase. Interim analyses were done after 1400 and 2400 randomised cases. Following the second analysis, the independent steering committee recommended stopping the trial after 3000 cases. Data was analysed on an intention-to-treat basis. Chi-squared and relative risks were used to compared pH and lactate groups. p < 0.05 was considered significant.	> 7.25: 4/281 (1.4) 7.25 - 7.21: 2/92 (2.2) < 7.21: 5/135 (3.7) b. Split by lactate status < 4.2: 0/344 (0) 4.2 - 4.8: 0/73 (0) > 4.8: 10/267 (3.7) **Incidence of Apgar < 7 at 5 minutes (n/total (%))** a. Split by pH status > 7.25: 9/281 (3.2) 7.25 - 7.21: 2/92 (2.2) < 7.21: 10/135 (7.4) b. Split by lactate status < 4.2: 4/344 (1.2) 4.2 - 4.8: 1/73 (1.4) > 4.8: 23/267 (8.6) The following diagnostic accuracy measures were calculated by the technical team, based on the above data. They refer to fetuses in whom fetal scalp blood was collected within 60 minutes of birth. **Predictive accuracy of scalp pH < 7.21** a. For metabolic acidaemia Sensitivity: 50.00% (28.09 to 71.91) Specificity: 74.39% (70.51 to 78.26) PPV: 7.41% (2.99 to 11.83) NPV: 97.32% (95.68 to 98.96) LR+: 1.95 (1.23 to 3.10) LR-: 0.67 (0.43 to 1.05) b. For umbilical artery pH < 7.00 Sensitivity: 45.45% (16.03 to 74.88) Specificity: 73.84% (69.98 to 77.71) PPV: 3.70% (0.52 to 6.89) NPV: 98.39% (97.11 to 99.67) LR+: 1.74 (0.89 to 3.38) LR-: 0.74 (0.43 to 1.27) c. For Apgar < 7 at 5 minutes Sensitivity: 47.62% (26.26 to 68.98) Specificity: 74.33% (70.45 to 78.21) PPV: 7.41% (2.99 to 11.83) NPV: 97.05% (95.33 to 98.77) LR+: 1.86 (1.16 to 2.98) LR-: 0.70 (0.47 to 1.06) **Diagnostic accuracy of scalp pH ≤ 7.25** a. For metabolic acidaemia Sensitivity: 65.00% (44.10 to 85.90) Specificity: 56.15% (51.74 to 60.55) PPV: 5.73% (2.70 to 8.75) NPV: 97.51% (95.69 to 99.33) LR+: 1.48 (1.06 to 2.08) LR-: 0.62 (0.34 to 1.14) b. For umbilical artery pH < 7.00 Sensitivity: 63.64% (35.21 to 92.06) Specificity: 55.73% (51.37 to 60.10) PPV: 3.08% (0.83 to 5.33) NPV: 98.58% (97.19 to 99.96) LR+: 1.44 (0.91 to 2.27) LR-: 0.65 (0.30 to 1.43) c. For Apgar < 7 at 5 minutes	not really applicable - women were randomised to receive lactate or pH Statistical analysis is appropriate for study design: yes **Other information** This study is also included in the Cochrane review (East et al., 2010) which has been included in this review. However, further data are available from the full text of the trial. Data that have been reported in the Cochrane review will not be reported here. There were 155 protocol violations in the pH group (146 failed FBS and 9 failed analysis) and 18 in the lactate group (all failed sampling). However, data for these women would not be incorporated in this data, as they could not be classified by pH or lactate value. No fetal scalp blood was collected in 106 women in the pH arm and 81 in the lactate arm. In most cases a reason was not provided, however, some were as a result of rapid delivery, expedited delivery, reassuring CTG or the withdrawal of consent.

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Sensitivity: 57.14% (35.98 to 78.31) Specificity: 55.85% (51.44 to 60.26) PPV: 5.29% (2.38 to 8.2) NPV: 96.80% (94.74 to 98.86) LR+: 1.29 (0.88 to 1.90) LR-: 0.77 (0.47 to 1.27) **Diagnostic accuracy of scalp lactate > 4.8 mmol/l** a. For metabolic acidaemia Sensitivity: 76.00% (59.26 to 92.74) Specificity: 62.37% (58.67 to 66.07) PPV: 7.12% (4.03 to 10.2) NPV: 98.56% (97.42 to 99.70) LR+: 2.02 (1.59 to 2.57) LR-: 0.38 (0.19 to 0.78) b. For umbilical artery pH < 7.00 Sensitivity: 100% (100 to 100) Specificity: 61.87% (58.20 to 65.54) PPV: 3.75% (1.47 to 6.02) NPV: 100% (100 to 100) LR+: 2.62 (2.38 to 2.89) LR-: 0.00 (not calculable [NC]) c. For Apgar < 7 at 5 minutes Sensitivity: 82.14% (67.96 to 96.33) Specificity: 62.80% (59.11 to 66.50) PPV: 8.61% (5.25 to 11.98) NPV: 98.80% (97.76 to 99.85) LR+: 2.21 (1.81 to 2.70) LR-: 0.28 (0.13 to 0.63) **Diagnostic accuracy of scalp lactate ≥ 4.2 mmol/l** a. For metabolic acidaemia Sensitivity: 76.00% (59.26 to 92.74) Specificity: 51.29% (47.47 to 55.11) PPV: 5.59% (3.15 to 8.03) NPV: 98.26% (96.87 to 99.64) LR+: 1.56 (1.24 to 1.97) LR-: 0.47 (0.23 to 0.94) b. For umbilical artery pH < 7.00 Sensitivity: 100% (100 to 100) Specificity: 51.04% (47.26 to 54.81) PPV: 2.94% (1.15 to 4.74) NPV: 100% (100 to 100) LR+: 2.04 (1.89 to 2.21) LR-: 0.00 (NC) c. For Apgar < 7 at 5 minutes Sensitivity: 85.71% (72.75 to 98.68) Specificity: 51.83% (48.01 to 55.65) PPV: 7.06% (4.34 to 9.78) NPV: 98.84% (97.70 to 99.97) LR+: 1.78 (1.50 to 2.11) LR-: 0.28 (0.11 to 0.69) **Operative delivery due to fetal distress in women in whom fetal scalp blood was taken within 60 minutes of delivery (n/total (%))** a. In women randomised to pH analysis pH > 7.25: 81/281 (28.8) pH 7.21 - 7.25: 58/92 (63.0) pH < 7.21: 118/135 (87.4) **b. In women randomised to lactate analysis** Lactate < 4.2: 79/334 (23.0)	

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Lactate 4.2 - 4.8: 50/73 (68.5) Lactate > 4.8: 251/267 (94.0) **FBS < 7.21 for metabolic acidaemia** **FBS < 7.21 for UA pH < 7.00** **FBS < 7.21 for Apgar < 7 at 5 minutes** **FBS <= 7.25 for metabolic acidaemia** **FBS <= 7.25 for pH < 7.00** **FBS <= 7.25 for Apgar < 7 at 5 minutes**	

FBS < 7.21 for metabolic acidaemia

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	10	125
Predictive Test -ve	10	363

FBS < 7.21 for UA pH < 7.00

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	5	130
Predictive Test -ve	6	367

FBS < 7.21 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	10	125
Predictive Test -ve	11	362

FBS <= 7.25 for metabolic acidaemia

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	13	214
Predictive Test -ve	7	274

FBS <= 7.25 for pH < 7.00

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	7	220
Predictive Test -ve	4	277

FBS <= 7.25 for Apgar < 7 at 5 minutes

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	12	215
Predictive Test -ve	9	272

Lactate > 4.8 for metabolic acidaemia

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	19	248
Predictive Test -ve	6	411

Lactate > 4.8 for UA pH < 7.00

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	10	257
Predictive Test -ve	0	417

Lactate > 4.8 for Apgar < 7 at 5 minutes

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	23	244
Predictive Test -ve	5	412

Lactate >= 4.2 for metabolic acidaemia

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	19	321
Predictive Test -ve	6	338

Lactate >= 4.2 for UA pH < 7.00

	Reference Test +ve	Reference Test -ve
Predictive Test +ve	10	330
Predictive Test -ve	0	344

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Lactate >= 4.2 for Apgar < 7 at 5 minutes | | Reference Test +ve | Reference Test -ve | | Predictive Test +ve | 24 | 316 | | Predictive Test -ve | 4 | 340 |	
Full citation Young,D.C., Gray,J.H., Luther,E.R., Peddle,L.J., Fetal scalp blood pH sampling: its value in an active obstetric unit, American Journal of Obstetrics and Gynecology,Am.J.Obstet.Gynecol., 136, 276-281, 1980 **Ref Id** 159915 **Country/ies where the study was carried out** Canada **Study type** **Aim of the study** To determine: - indications for fetal blood pH sampling - the incidence of fetal acidosis with each indication - incidence of neonatal depression related to fetal acidosis - complications of fetal blood sampling (FBS) - number of caesarean sections avoided - number of asphyxiated infants born less than 1 hour after fetal blood sampling **Study dates** January 1st 1978 to September 30th 1978 **Source of funding** Life Insurance Association of Canada	**Sample size** N = 232 women (Note: the last scalp sample was taken less than 1 hour before birth in 95 women, and they constitute the true population of interest) **Characteristics** **Time between last FBS and birth (n (%))** < 1 hour: 95 (40.9) 1 - 2 hours: 67 (28.9) > 2 hours: 70 (30.2) **Obstetric characteristics (n (%))** Pre-eclampsia toxaemia: 37 (16) Premature rupture of membranes: 23 (10) intrauterine growth restriction (IUGR): 19 (8) Prematurity: 9 (4) Post-maturity: 32 (14) Meconium-stained fluid: 77 (33) Oxytocin induced labour: 103 (44) Oral prostaglandin: 16 (7) Nulliparous: 162 (70) Epidural: 175 (75) Parenteral narcotic < 6 hours: 53 (23) **Indication for fetal blood sampling (n (%))** Baseline: - Tachycardia: 14 (6) - Bradycardia: 15 (6) Decreased variability: 24 (10) Variable decelerations: - Mild: 22 (10) - Moderate: 84 (36) - Severe: 38 (16) Late decelerations: - Mild: 19 (8) - Moderate: 5 (2) Early decelerations: 7 (3) Other indications: 4 (2) **Inclusion Criteria** All patients having fetal scalp blood pH sampling (98% were due to fetal heart rate changes)	**Tests** Fetal scalp pH	**Methods** 232 women had a total of 335 pH determinations done (mean 1.5 per patient, range 1 to 5). 98% of sampling was due to changes in fetal heart rate. 95% of the samples in the study were done with the patients in a modified Sims' position. A Monoject Sterile Disposable Fetal Blood Sampling Kit was used for sample collection, and results were available within 10 minutes of sampling. The fetal heart trace in the hour before FBS were analysed and classified using ACOG Technical Bulletin 32, and in addition as follows: - Mild decelerations: less than 30 bpm in depth - Moderate decelerations: 30 - 60 bpm in depth - Severe decelerations: greater than 60 bpm in depth - Persistent decelerations: longer than 30 minutes and with more than 50% of contractions - Variable decelerations that did not return to baseline were considered indicative of late recovery The FHR tracings were reviewed by members of the Perinatal Medicine Division without knowledge of pH values, to try and estimate whom they would have performed a caesarean on without knowledge of pH values. For this, only patients with less than full dilatation of the cervix and who subsequently delivered vaginally were included. Fetal acidosis was classified as: - Mild: pH 7.20 - 7.24 - Severe: < 7.20 Neonatal depression was defined as one of: - 1 minute Apgar less than 7 and the need for positive pressure resuscitation - 5 minute Apgar less than 7	**Results** The following diagnostic accuracy measures have been calculated by the technical team, based on 2x2 data that was reported in the study. The data only relate to babies born within 1 hour of the fetal pH measurement. 136 babies who had a pH ≥ 7.25 and were born over an hour after the measurement were not included for these calculations: **Diagnostic accuracy for neonatal depression (95% CI)** a. pH < 7.20 Sensitivity: 37.50% (3.95 to 71.05) Specificity: 96.59% (92.80 to 100) PPV: 50.00% (9.99 to 90.01) NPV: 94.44% (89.71 to 99.18) LR+: 11.00 (2.64 to 45.84) LR-: 0.65 (0.38 to 1.11) b. pH < 7.25 Sensitivity: 50.00% (15.35 to 84.65) Specificity: 81.82% (73.76 to 89.88) PPV: 20.00% (2.47 to 37.53) NPV: 94.74% (89.72 to 99.76) LR+: 2.75 (1.21 to 6.26) LR-: 0.61 (0.30 to 1.23) The GDG report that neonatal depression was more frequent in babies with severe fetal acidosis. However, it was not more frequent in babies with mild acidosis when compared to normal scalp pH. They state that this may reflect the use of intrauterine resuscitation (oxygen by mask, repositioning, discontinuation of oxytocin, etc.). The following data relate to the entire study population: **Proportion of women having caesarean section (n/total (%))** pH < 7.20: 6/6 (100) - all 6 born within 1 hour of pH measurement pH 7.20 - 7.24: 7/14 (50) - all 14 born within 1 hour of pH measurement pH ≥ 7.25: 40/212 (19) - 76 born within 1 hour, 66 born within 1-2 hours, 70 born over 2 hours later Note: the overall CS rate was 23%, of which 25% were performed for fetal distress. **Complications of fetal blood sampling (n (%)** Bleeding: - Haematoma: 6 (2.6) - Abrasions: 3 (1.3) - Ecchymosis: 1 (0.4) - Anaemia of unknown etiology: 1 (0.4)	**Limitations** Study sample represents population: there was a high proportion of women who would not be considered low risk Loss to follow-up is unrelated to key characteristics: there was no loss to follow up Prognostic factor is adequately measured in participants: yes Outcome of interest is sufficiently measured in participants: yes Important potential confounders are accounted for: there were differences in the proportion of babies born by CS, and this is not reported for the sub-group of babies with normal pH but who were born within an hour Statistical analysis is appropriate for study design: yes Indirectness of population: yes, a high proportion of women were not low risk **Other information** **Further information regarding babies with severe fetal acidosis (pH < 7.20) in labour** **True positives (depressed at birth)** Baby 1 - had severe pre-eclamptic toxaemia - fetal pH of 7.12 - 32 minutes before birth - Apgar of 1 at 1 minute and 3 at 5 minutes - FHR tracing decelerations: persistent, mild, late - cord pH 7.21/7.11 Baby 2 - had meconium and died at about 4 hours - fetal pH of 6.74 - 37 minutes before birth - Apgar of 0 at 1 minute and 1 at 5 minutes - FHR tracing decelerations: persistent, moderate, late - cord pH 6.79/6.60 Baby 3 - post-mature, hypertension, prior stillbirth - fetal pH of 6.94 - 41 minutes before birth - Apgar of 1 at 1 minute and 4 at 5 minutes - FHR tracing decelerations: occasional severe, variable, late recovery, decreasing variability - cord pH 7.14/7.09 **False positives (normal Apgar scores)** Baby 4

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	Exclusion Criteria None reported			Infection: - Abscess: 1 (0.4) - Cellulitis: 1 (0.4) - Erythema: 1 (0.4) - Herpes: 1 (0.4) Total: 15 (6.5) **FBS pH < 7.20 for neonatal depression** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 3 / 3 **Predictive Test -ve**: 5 / 85 **FBS pH < 7.25 for neonatal depression** **Reference Test +ve** / **Reference Test -ve** **Predictive Test +ve**: 4 / 16 **Predictive Test -ve**: 4 / 72	- chronic active hepatitis - fetal pH of 7.19 - 58 minutes before birth - Apgar of 9 at 1 minute and 10 at 5 minutes - FHR tracing decelerations: persistent, moderate, variable late recovery - cord pH Baby 5 - true knot in cord - fetal pH of 7.19 - 45 minutes before birth - Apgar of 9 at 1 minute and 10 at 5 minutes - FHR tracing decelerations: persistent mild late - cord pH 7.26/7.20 Baby 6 - 32 weeks, pre-eclamptic toxaemia, abruptio placentae - fetal pH of 7.16 - 38 minutes before birth - Apgar of 7 at 1 minute and 8 at 5 minutes - FHR tracing decelerations: persistent mild late - cord pH 7.19/7.17 **Further information regarding babies whose pH was ≥ 7.25 but were born depressed (false negatives)** Baby 1 - meconium, analgesic at 3 hours - fetal pH of 7.36 - 54 minutes before birth (vaginal birth) - Apgar of 4 at 1 minute and 6 at 5 minutes - FHR tracing decelerations: moderate variable late recovery - cord pH 7.27/7.11 Baby 2 - meconium aspiration - fetal pH of 7.34 - 50 minutes before birth (vaginal birth) - Apgar of 4 at 1 minute and 8 at 5 minutes - FHR tracing decelerations: moderate variable - cord pH 7.14/7.10 Baby 3 - IUGR - fetal pH of 7.25 - 38 minutes before birth (vaginal birth) - Apgar of 4 at 1 minute and 6 at 5 minutes - FHR tracing decelerations: moderate variable late recovery - cord pH 7.25/7.02 Baby 4 - meconium - fetal pH of 7.37 - 45 minutes before birth (vaginal birth) - Apgar of 6 at 1 minute and 9 at 5 minutes - FHR tracing decelerations: mild early - cord pH 7.37/7.34

G.10 Women's experience of fetal monitoring

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Parisaei,M., Harrington,K.F., Erskine,K.J., Maternal satisfaction and acceptability of foetal electrocardiographic (STAN[REGISTERED]) monitoring system, Archives of Gynecology and Obstetrics, 283, 31-35, 2011 **Ref Id** 134248 **Country/ies where the study was carried out** UK **Study type** Prospective questionnaire-based study **Aim of the study** To assess the acceptability of the fetal electrocardiographic (STAN®) monitoring system by women at a London Hospital **Study dates** November 2003 to June 2005 **Source of funding** Not reported	**Sample size** Total n = 125 **Characteristics** Population consisted of women with high-risk pregnancy (diabetes, pre-eclampsia, previous caesarean section) or intrapartum risk factors (meconium stained liquor, oxytocin augmentation); 78% were believed to be low risk at their antenatal booking appointment Mean age (years): 28.8 (SD 6.3) Nulliparous: 75% Spoke English fluently: 83% Ethnicity African: 40% White: 30% Asian: 10% Other: 20% Intrapartum characteristics in cohort of women being monitored by STAN Induction of labour: 37% Meconuim stained liquor: 50% Epidural use: 80% Fetal blood sampling performed: 13% Syntocinon infusion utilised: 67% Spontaneous vaginal birth: 29% Emergency caesarean section (CS): 54% (215 of these were for fetal distress according to STAN clinical protocol) **Inclusion criteria** Term pregnancy (> 37 weeks' gestation) Singleton pregnancy **Exclusion criteria** Multiple pregnancy Women with viral infection (HIV or hepatitis B and C)	**Interventions** Fetal electrocardigraphic (STAN) monitoring	**Details** A questionnaire was designed to assess women's acceptability for STAN. The study was conducted in a university hospital in East London with 4000 births per year. Women who had STAN monitoring were provided with information sheets about the study. Women were asked to fill in the questionnaire after the birth (the majority of women filled in the questionnaire on the day of the birth). The information sheet and the questionnaire were reviewed by a clinical psychologist; n = 125 women were monitored with STAN during the study period. The questionnaire consisted of 7 yes/no questions and space was provided for further comments. Analysis: Dichotomous and categorical data were summarised using percentages and hypothesis tests. Continuous data were summarised using mean for normally distributed data and median for non-normal data	**Results** 1) Did the midwife(s) looking after you in labour explain the reasons why your baby was monitored continuously in labour? Yes: 93% (CI 85% to 98%) 2) Did the doctor(s) looking after you in labour explain the reasons why your baby was monitored continuously in labour? Yes: 99% (CI 83% to 99.9%) 3) Did you understand how the STAN system monitors your baby's wellbeing in labour? Yes: 95% (CI 87% to 99%) 4) Did you think the STAN system is an acceptable additional way of monitoring your baby in labour? Yes: 95% (CI 87% to 99%) 5) Did you feel reassured by having the STAN system as well as the CTG monitor in labour? Yes: 96% (CI 89% to 99%) 6) Would you have the STAN system again in future labours if we needed further information about your baby's wellbeing in labour? Yes: 93% (CI 85% to 98%) 7) Would you recommend the STAN system to your friends who are going to be mothers? Yes: 89% (CI 80% to 95%); the majority would only do so if they were high risk and there was a need for continuous fetal monitoring	**Limitations** Unclear whether the questionnaire was a validated tool or not Unclear how the questionnaire was developed and by whom Questionnaire response rate was 61% (77/125) Unclear how the data were analysed and by whom Unclear what explanation was given to women about the reasons why the baby was monitored continuously in labour 13.3% of study population had a language problem Unclear whether women received unbiased information about STAN and how it assesses the baby's wellbeing **Other information**
Full citation Hindley,C., Hinsliff,S.W., Thomson,A.M., Pregnant women's views about choice of intrapartum monitoring of the fetal heart rate: a questionnaire survey, International Journal of Nursing Studies, 45, 224-231, 2008 **Ref Id** 136975 **Country/ies where the study was carried out** UK **Study type** Qualitative exploratory/descriptive	**Sample size** Total n = 63 **Characteristics** **Antepartum sample Total n = 63** Gestational age when questionnaire completed 34-36 weeks 6 days n = 45 37-40 weeks n = 18 Age (years) Under 20 n = 3 20-24 n = 14 25-29 n = 20 30-34 n = 20 35-39 n = 6 Ethnicity White n = 49	**Interventions** Intrapartum electronic fetal monitoring (EFM)	**Details** A total of 63 pregnant women at low obstetric risk were approached to complete antepartum and postpartum questionnaires. The sample was recruited from two maternity hospitals (centre 1 n = 30; centre 2 n = 33). After gaining informed consent, women were asked to complete the first questionnaire between 34 and 40 weeks of pregnancy. Sixty-three (n = 63) women completed the antepartum questionnaire; 38 of them also completed the postpartum questionnaire. Questionnaire A validated tool (from an informed choice across maternity care) was modified and used for women's preferences of fetal monitoring. The developed questionnaire was piloted with a small sample and modified	**Results** **Women's preference for electronic fetal monitoring (EFM)** Antenatal survey (n = 63) Women did not prefer one specific option. The majority preferred a combination of intermittent and continuous EFM n = 35/63 (56%) Postnatal survey (n = 38) Number of women received EFM n = 23/38 (61%) **Women's preference for mobility during labour** Antenatal survey Stay mobile or off the bed n = 46/63 (73%) Postnatal survey Women reported staying in bed n = 16/38 (40%) **Women's preference for decision making on fetal monitoring** Antenatal survey Women wanted the final decision after considering	**Limitations** Participants recruited from two different hospitals, the influence of different setting should be considered when interpreting the data **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To investigate women's view on intrapartum fetal monitoring techniques and informed choice **Study dates** Not specified **Source of funding** NHS, Northern region Research and Development Directorate	Other n = 12 Missing n = 2 Jarman deprivation score Low deprivation (30 - 39.99) n = 14 Not deprived (below 30) n = 48 Missing n = 1 Educational qualifications No recorded qualification n = 2 Secondary education qualification n = 9 Further education qualification n = 38 Higher education n = 14 Parity Primigravida n = 31 Multigravida n = 32 **Postpartum sample n = 38** Completion of questionnaire in weeks postpartum 0-2 weeks n = 24 3-4 weeks n = 8 > 5 weeks n = 5 Missing n = 1 Type of birth Normal Instrumental Emergency caesarean section Analgesia Epidural n = 8 Narcotic n = 12 Entonox n = 11 Other n = 3 None n = 4 Age (years) Under 20 n = 1 20-24 n = 5 25-29 n = 10 30-34 n = 17 35-39 n = 5 Ethnicity White n = 30 Others n = 7 Missing n = 1 Jarman deprivation score Low deprivation (30 - 39.99) n = 7 Not deprived (below 30) n = 30 Missing n = 1 Parity Primigravida n = 16 Multigravida n = 22 **Inclusion criteria** Women with no underlying medical condition (low-risk pregnancy) Predicted a vaginal birth **Exclusion criteria** Not reported		according to the results. Themes chosen for the questionnaire were identified from a background literature review. The antepartum questionnaire contained 28 items and aimed to elicit information on women's knowledge and preferences of intrapartum fetal monitoring. The postpartum questionnaire had 21 items and asked for information about monitoring preferences for labour and actual monitoring outcomes Data collection Women were approached at 34 weeks of their pregnancy at the antenatal clinic. The midwife was the first point of contact, referring suitable women to the researcher to discuss the study in detail. An information pack plus the questionnaire and a stamped envelope were given to women. Women who did not return their questionnaire were approached in their next antenatal visit and reminded about the study (only one reminder was permitted based on ethics committee's approval). Following women's birth of a healthy infant, they were sent the postpartum questionnaire and stamped addressed envelope, together with a letter of congratulations. Women were not followed up if they failed to respond. Data analysis The data were analysed using SPSS 10.1. The analysis of data was descriptive. Frequency count and cross-tabulations were used.	midwife's view: antepartum n = 35/63 (56%); intrapartum n = 28/63 (44%) Postnatal survey Women had conceded decision making to midwife in intrapartum period n = 14/38 (38%) **Choice/control preference** Antenatal survey Felt choice of being in control is important n = 61/63 (97%) Felt midwives did not facilitate a choice in intrapartum fetal method antenataly n = 59/63 (94%) Not received enough information and discussion to make a choice regarding fetal monitoring method n = 25/63 (40%) **Importance of information** Antenatal survey Women were aware of different types of monitoring n = 59/63 (94%) Knew all types of monitoring except Pinard sthethoscope n = 46/63 (73%) Felt it is very important to have information on intrapartum fetal monitoring n = 54/63 (86%) Postnatal survey Felt it is very important to have information on intrapartum fetal monitoring n = 15/38 (39%) **Sources of information** Antenatal survey Felt midwife had not explicitly given any information on monitoring n = 41/63 (65%) Felt had the information from media n = 36/63 (57%) Women relied on past experience n = 29/63 (46%) Felt had informed choice or partially had informed choice n = 25/63 Postnatal survey Felt that they have been given informed choice n = 15/38 (39%)	
Full citation Shields,D., Fetal and maternal monitoring: maternal reactions to fetal monitoring, American Journal of Nursing, 78, 2110-2112, 1978	**Sample size** Total n = 30	**Interventions** Internal electronic fetal monitoring	**Details** The time that women were monitored ranged from 1 hour to 12 hours (no more details about the monitoring machine reported). To assess the general attitudes of women	**Results** Scores Women in positive range: n = 22 Women in negative range: n = 8	**Limitations** Data and results poorly reported. Very old study, advances in technology should be considered when interpreting the data. A self-developed scale used

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 170538 **Country/ies where the study was carried out** Canada **Study type** Prospective observational study **Aim of the study** To examine women's experience and reaction to fetal monitoring **Study dates** Not reported **Source of funding** Not reported	**Characteristics** Age: ranged from 17 to 42 years Married: n = 19, single: n = 9, separated: n = 2 White: n = 16 Black: n = 14 Primiparous: n = 18 Multiparous: n = 12 <u>Reason women were monitored</u> Failure to progress and oxytocin stimulation: n = 7 Induced labour: n = 18 Poor obstetrical history: n = 1 Research on normal labour: n = 4 <u>Mode of birth</u> Spontaneous vaginal birth: n = 8 Forceps delivery: n = 13 Vacuum extraction: n = 2 Caesarean section: n = 7 <u>Mean length of labour</u> Multiparous: n = 6 hours and 26 min Nulliparous: n = 12 hours and 9 min Mean duration of monitoring: 5 hours and 16 min **Inclusion criteria** Women who had internal fetal monitoring during labour and gave birth at term **Exclusion criteria** Not reported		regarding fetal monitoring, the study author developed a 'mood and feeling inventory'. The scale consisted of a list of adjectives that women marked according to their feelings in a scale ranging from 1 (not at all) to 6 (very much). The negative scale consisted of eight words; apprehensive, uneasy, tense, frightened, worried, upset, nervous. The positive scale consisted of six words; relaxed, confident, peaceful, comfortable, optimistic, calm. Women were asked to mark the scale regarding their feelings during fetal monitoring retrospectively (as they remembered). Women were interviewed by the author within 48 hours of the birth. Their positive or negative attitudes toward the monitoring experience were assessed. Interviews were carried out using an open-ended questionnaire. <u>Analysis</u> A positive and a negative response for each woman was tabulated and a mean score was calculated. The negative score was subtracted from the positive score and the difference served as an indication of an overall positive or negative reaction. The maximum difference of 5 that could happen between the positive and negative scores of an individual woman were divided into high, medium, or low, positive or negative and women were placed by their scores in those categories	Highly negative category: n = 2 Highly positive category: n = 3 One woman had a high negative score (-3.46). She expressed a high degree of negativity throughout the interview. She expressed that she received 'too little information about the equipment', and did not like the idea of attaching it to the baby's head. She felt that, the monitoring was not a good indicator of what was happening; while she was in severe pain, she was told by the nurse that the equipment showed mild pain. She also expressed that 'the head is the most important part and I was worried about brain damage because of the clamp'. The woman with the highest negative score (-3.75) said she 'felt like a battery being charged with all those wires and connections'. From three women who had a high positive score, one woman with a score of 4.17, said she 'Knew exactly what was going on and therefore was not afraid'. A woman with a score of 4.45, was a 'little frightened' but thought it was an 'exciting idea' compared with other labours and felt that 'monitoring seemed to make it shorter and more interesting'. The woman with the highest positive score of 4.87 thought monitoring was 'a fantastic, good idea'. No differences were observed between these five women with the rest of the study's population. When a Chi- square computation was performed between the inventory scores and the age, race, parity, marital status length labour and length of monitoring, no significant difference in the results were observed. <u>Understanding the reason for monitoring</u> (determined by comparing women's response to the reason for monitoring, to the reason given in the women's charts): Good understanding: n = 27 Partially understood: n = 3 (n = 2/3 were women with high negative score) <u>Information received</u> Adequate: n = 27 (20 said they had full information and 7 said they received as much as they requested) No adequate information received: n = 3 <u>Nurse's presence</u> All women expressed their desire about wanting nurses to stay with them all the time; n = 17 wanted nurses for supportive care; n = 6 expressed a desire for the nurse's presence as a person that could intervene in some way if necessary. <u>Worries about monitoring</u> No worries: n =7 Some worries (not the same as those during pregnancy): n = 11 (4 expressed fears related to the electrodes) Some worries (the same as those during pregnancy): n = 12 (fearing that baby would be deformed in some way or die) <u>Complain about monitoring</u> Getting comfortable: the most frequent complaint	with unclear validity; 18/30 women were multiparous **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				was with regard to difficulty in getting comfortable. Some women were annoyed about the fact that when the electrode fell off, an additional vaginal examination was needed to reapply the electrode. Complaints about vaginal examination mainly related to privacy and too many people being present in the room. Noise of fetal heart beat: was considered discomforting by 2 women because of fears that it would stop (one expressed that she 'worried the whole time that the baby's heart would stop if the machine stopped'). <u>Caregiveres</u> Four (n = 4) women expressed that the clinicians were the cause of some discomfort for them. Two of these women considered the facial expression of the physician frightening. The other 2 women thought that some staff were unfamiliar with the machine and they found this disquieting. One woman thought that the clinician had more interest in the machine than they did with her, she said 'they all came with the machine and they all left with the machine'	
Full citation Hansen,P.K., Smith,S.F., Nim,J., Neldam,S., Osler,M., Maternal attitudes to fetal monitoring, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 20, 43-51, 1985 **Ref Id** 171177 **Country/ies where the study was carried out** Denmark **Study type** Prospective observational study **Aim of the study** To examine women's views on of intrapartum fetal surveillance methods **Study dates** January to August 1981 **Source of funding** Not reported	**Sample size** Total n = 655 **Characteristics** A: preferred auscultation (AUS-P), B: preferred electronic fetal monitoring (EFM-P), C: undecided (UD), p (A:B), p (a:b:c) <u>Number</u> AUS-P: n = 212 EFM-P: n = 259 UD: 184 <u>Age (mean ± SD)</u> AUS-P: 27.8 ± 4.7 EFM-P: 28.1 ± 5.1 UD: 26.3 ± 5.6 p (A:B) = ns p (A:B:C) < 0.001 <u>Pathological obesity</u> AUS-P: n = 0 EFM-P: n = 9 UD: n = 8 p (A:B) < 0.01 p (A:B:C) < 0.05 <u>High-risk pregnancy</u> AUS-P: n = 46 EFM-P: n = 109 UD: n = 49 p (A:B) < 0.001 p (A:B:C) < 0.001 There were no statistically significant differences observed between the three groups on pre-eclampsia, bleeding in pregnancy, twins, anaemia, pathological HPL, pathological estriol, diabetes, previous sterility **Inclusion criteria** Not reported	**Interventions** EFM versus auscultation	**Details** Parallel to a randomised clinical trial concerning alternative methods of intrapartum fetal surveillance (electronic fetal monitoring [EFM] and auscultation [AUS]) an investigatory interview was carried conducted to examine women's views on fetal monitoring. The first interview was conducted when women were at 36 weeks' gestation. In the first semi-structured interview women were told about the study and consent was obtained. They were asked about their knowledge of fetal monitoring during labour and their source of information. They were also asked about their preference and asked to state the advantages and disadvantages of the two different methods. The interview lasted about 20 minutes. Out of 665 participants, 655 were interviewed initially (ten declined to participate) and 385 were interviewed again. Women were asked to state their preference for EFM or AUS and also state the advantages and disadvantages of the two methods. All women who had the pre-birth interview, were interviewed again on the 2nd or 3rd day after the birth. The person that performed the 2nd interview was blinded to the women's preference stated at the first interview regarding fetal monitoring. The women were asked how their labour was monitored, what the advantages or disadvantages were of the method used and how they would want the fetal heart monitored in future labours/births. <u>Analysis</u> Analysis of variance was used for the statistical evaluation of age and parity. Elsewhere X^2 statistics were used	**Results** **Women's preference** EFM (electronic fetal monitoring) n = 39.5% AUS (auscultation) n = 32.4% UD (undecided) n = 28% **Sources of information** <u>Antenatal classes</u> Total number: n = 326 AUS-P: 40% EFM-P: 38% UD: 22% <u>Books</u> Total number: n = 130 AUS-P: 47% EFM-P: 35% UD: 22% <u>Newspaper</u> Total number: n = 100 AUS-P: 45% EFM-P: 40% UD: 15% <u>Doctors</u> Total number: n = 90 AUS-P: 59% EFM-P: 32% UD: 9% <u>Parents (a monthly magazine from a lay/support movement)</u> Total number: n = 59 AUS-P: 66% EFM-P: 24% UD: 11% <u>Radio and TV</u> Total number: n = 56 AUS-P: 36% EFM-P: 46% UD: 19%	**Limitations** Unclear if the outcome assessors were blinded to the study groups allocation 41% of study population were not available for the second interview; the reason was not reported Inclusion and exclusion criteria not reported Significantly more women in EFM-P group had high-risk pregnancy No subgroup analysis performed based on parity (nuliparous and multiparous women) **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Not reported			<u>All with information of EFM</u> Total number: n = 560 AUS-P: 35% EFM-P: 41% UD: 24% <u>Not heard of EFM</u> Total number: n = 95 AUS-P: 18% EFM-P: 32% UD: 51% **Distribution of preference related to place of antenatal classes** <u>The department</u> Total number: n = 321 AUS-P: 31% EFM-P: 42% UD: 27% <u>Women's liberation</u> Total number: n = 64 AUS-P: 70% EFM-P: 20% UD: 9% <u>Public schools</u> Total number: n = 35 AUS-P: 35% EFM-P: 37% UD: 27% <u>Private institution</u> Total number: n = 31 AUS-P: 26% EFM-P: 48% UD: 26% <u>No birth preparing courses</u> Total number: n = 213 AUS-P: 21% EFM-P: 42% UD: 36% **Advantages and disadvantages of AUS mentioned postpartum by AUS-P (n = 85) and EFM-P (n = 94) groups who had their labour monitored by auscultation** <u>No pain to the baby</u> AUS-P: 11% EFM-P: 3% p <0.05 <u>No discomfort from sensors and belt</u> AUS-P: 58% EFM-P: 30% p <0.05 <u>Increased contact with personnel</u> AUS-P: 25% EFM-P: 15% p <0.05 <u>More natural childbirth</u> AUS-P: 72% EFM-P: 45% p <0.05 **Advantages and disadvantages of EFM mentioned postpartum by AUS-P (n = 36) and**	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				EFM-P (n = 66) groups who had their labour monitored by EFM EFM promoting husband involvement AUS-P: 25% EFM-P: 45% p < 0.05 More positively influenced by EFM signal/trace AUS-P: 31% EFM-P: 67% p < 0.01 Possibility of quick intervention AUS-P: 44% EFM-P: 62% p <0.05 Continuous precise surveillance AUS-P: 45% EFM-P: 70% p < 0.05 Enforced mobility AUS-P: 22% EFM-P: 20% p < 0.05 Technical milieu AUS-P: 25% EFM-P: 3% p <0.05 Disturbance from EFM signals AUS-P: 20% EFM-P: 3% p < 0.05 Fear of the trauma to the baby AUS-P: 5% EFM-P: 2% p < 0.05	
Full citation Mangesi,L., Hofmeyr,G.J., Woods,D.L., - Assessing the preference of women for different methods of monitoring the fetal heart in labour, - South African Journal of Obstetrics and Gynaecology, 15, 2009- **Ref Id** 187897 **Country/ies where the study was carried out** South Africa **Study type** Prospective cross-sectional study **Aim of the study** To assess which method of fetal monitoring was preferred by labouring women	**Sample size** Total n = 100 women **Characteristics** Not reported **Inclusion criteria** Women in first stage of active labour **Exclusion criteria** Women in second stage of labour Twin pregnancy Preterm labour Evidence of fetal distress	**Interventions** Fetal stethoscope, cardiotocography (CTG), Doppler ultrasound monitor (fetal heart rate monitor [FHRM])	**Details** Convenience sampling was used; women who were in the active phase of the first stage of labour were recruited from a hospital (in the Eastern Cape province, South Africa) after the study was explained and verbal consent obtained (no further details were reported). A researcher spent approximately 30 minutes with each woman; 10 minutes were spent explaining the study and obtaining consent, 10 minutes were spent monitoring the fetal heart with the stereoscope and a Doppler device (FHRM), and for the last 10 minutes the fetal heart was monitored with a cardiotocograph and if the tracing was unsatisfactory a doctor was notified. Participants were asked to indicate their first and second preferred method. Data analysis Data were recorded in a collecting sheet and then entered into Epi_Info 2002 computer software (no further detail reported)	**Results** First maternal preference: Fetal stethoscope: 13/97 FHRM: 72/97 CTG: 12/97 Second maternal preference: Fetal stethoscope: 58/97 FHRM: 17/97 CTG: 22/97 n = 2 women were unable to decide n = 1 loss of data The fetal stereoscope was disliked because of causing discomfort during the examination and CTG was disliked because it often confined women to the bed and the securing belt of the carditocograph restricted the woman's movement	**Limitations** No details of the women's characteristics reported Women provided with the study's information when they were in labour Consent obtained verbally Intervention applied over very short period of time Not clear when participants were asked about their preference Poor reporting with limited information provided **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Not reported **Source of funding** Not reported					
Full citation McCourt, C., Technologies of birth and models of midwifery care, Revista Da Escola de Enfermagem Da Usp, 48 Spec No, 168-77, 2014 **Ref Id** 446553 **Country/ies where the study was carried out** UK **Study type** Qualitative (the study author reported that she relied on questionnaire responses too, but the findings included for this review were obtained using qualitative methodology) **Aim of the study** The article focuses on the theme of birth technology and discusses the impact on women's embodiment in birth and sources of information women use about the status of their bodies, their labour and the babies. The overarching study explored how the impact of birth on women's experiences may be mediated by a relational model of support achieved through a caseload model of midwifery care **Study dates** The study was conducted over a 2-year period from 1994 to 1996* *This information was reported in the companion paper: McCourt, C., Page, L., Hewison J., Vail, A., Evaluation of One-to-One Midwifery: Women's Responses to Care, Birth, 25:2, 73-80, 1998 **Source of funding** Not reported	**Sample size** N=1403 (survey); 44 women were interviewed (20 had responded to the survey, 24 had not) **Characteristics** Not reported for the group of women that replied to the questionnaire. For the group that did not respond to the questionnaire, the authors targeted women in minority ethnic groups and young mothers **Inclusion criteria** For the interviews the author wrote to all women returning questionnaires in a particular time period including all those who were contactable until 20 interviews had been arranged.* The second group were women who had not returned the questionnaires but had not declined consent to take part. Because the author was concerned about possible skews in response patterns, she targeted women who were less likely to respond to a written questionnaire – women in minority ethnic groups and young mothers (under 21 years*). All such women, who had not declined consent but had not returned a questionnaire, were contacted by letter, and all those who responded by letter or could be contacted by telephone were included.* *This information was reported in the paper: McCourt, C., Page, L., Hewison J., Vail, A., Evaluation of One-to-One Midwifery: Women's Responses to Care, Birth, 25:2, 73-80, 1998 **Exclusion criteria** Not reported	**Interventions** Continuous electronic fetal monitoring	**Details** The article draws on the evaluation of a pilot scheme for caseload midwifery, which was implemented in response to UK government policy recommendations on woman-centred care in 1993. The evaluation was performed using both a survey and semi-structured interviews.* The survey of women's responses to care was based on a detailed structured postal questionnaire about how women experience their care and whether the pattern of care affects their wellbeing. The study authors* also interviewed two groups of women, chosen as subsamples from the survey, using semi-structured interviews.The first group were women who had responded to the survey by completing questionnaires. The other interviews were conducted for the group who had not returned the questionnaires but had not declined consent to take part, including one interview involving assistance of an interpreter. The interviews used a narrative approach; women were asked to tell their stories from first contact with maternity services. They were asked to reflect what they found most helpful or would like to change about each stage of care. The article used analysis of women's narrative accounts of labour and birth. Transcripts of interview tapes were analysed with computer-assisted text analysis.* The article is based mainly on analysis of the interviews but is also informed by the analysis of women's questionnaire responses, which provided less depth but covered a broader scope of women. The article focuses mainly on women's experiences of birth and differences in the ways in which women recounted these experiences according to whether they were attended by a caseload midwife and whether they received a high or low level of technological intervention. The overall findings had been published previously by a larger group of authors but this article focused on a different aspect: birth technology. *This information is reported in the companion paper: McCourt, C., Page, L., Hewison J., Vail, A., Evaluation of One-to-One Midwifery: Women's Responses to Care, Birth, 25:2, 73-80, 1998	**Results** The following quotations were cited from two interviews. "I could tell he was OK by the monitor I think" (Standard care, 418). "I kept asking questions though… but otherwise it was just through my husband… he was in the delivery suite and in the operating theatre… he had had quite a good idea, he had been able to look at the graphs, baby's heartbeat and my contractions, and even though maybe not knowing exactly what to read into the graphs" (Standard care, 424). The comments above were chosen by the author of the article as examples of her impression that the baby and the labour were perceived to some extent as being in the monitor, not as part of the woman's body. The author specified that she built her impression from listening to the women's narratives and from observation of medical staff, although the impressions were rarely articulated by the women. The authors wrote that many women and partners, and medical staff, focused attention on the monitor screen to try to understand their labour. This tendency was increased for women who had an epidural (these women could not feel their contractions and watched the monitor to see when contractions were taking place) and for women in standard care (these women were less satisfied with the information and support they received than those who experienced the caseload model of midwifery care) In addition to the main outcomes, the study authors reported that responses to CTG monitoring were ambiguous. In questionnaire responses women were least likely to be critical of receiving CTG monitoring since they perceived this to be important for the safety of the baby; however, no quotations from the women who participated in the study were reported in support of this	**Limitations** Aims of the research: Low risk of bias (clearly explained, with comprehensive background and rationale) Qualitative methodology: Low risk of bias (qualitative research is an appropriate methodology for the research goal) Research design: Low risk of bias (in relation to the group of women who had already responded to a questionnaire, the study author reported that interviews were carried out not only to check the validity of closed questionnaire responses but also to give a greater depth of response than could be obtained through a structured questionnaire) Recruitment strategy: Unclear risk of bias (in relation to the group of women that were interviewed, the study authors reported that all women returning the first postal questionnaire during a particular time period were contacted and asked to participate until 20 interviews had been arranged,* however the time period was not specified and the authors did not specify how they chose this time period) Data collection: Low risk of bias (semi-structured interviews*) Relationship between researcher and participants: Unclear risk of bias (it was not reported whether the relationship between the researcher and the participants had been considered) Ethical issues: Low risk of bias (the original study was approved by the ethics committee of the hospitals concerned) Data analysis: Low risk of bias (the study authors reported that transcripts of all interviews were analysed with computer-assisted text analysis and that key emergent themes were developed through open coding; responses were then sorted to log the number of women providing comments in each category and the nature of the responses*) Statement of findings: Low risk of bias (the findings are explicit and there is adequate discussion of the evidence) Research value: Unclear risk of bias (the study author did not discuss whether or how the findings could be transferred to other populations, and they did not identify new areas where research would be necessary) Overall quality rating based on the aforementioned considerations: Moderate *This information was reported in the companion paper: McCourt, C., Page, L., Hewison J., Vail, A., Evaluation of One-to-One Midwifery: Women's Responses to Care, Birth, 25:2, 73-80, 1998 Note: limitations were assessed using the Critical Appraisal Skills Programme (CASP) Qualitative Research Checklist as recommended in the 2012 NICE guidelines manual

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Other information The article includes only limited information relating to the methods employed in the study, however the author of the article reported that she used interviews from which overall findings had been published previously. Therefore it was possible to obtain more information from the following companion paper as referred to above: McCourt, C., Page, L., Hewison J., Vail, A., Evaluation of One-to-One Midwifery: Women's Responses to Care, Birth, 25:2, 73-80, 1998

G.11 Cardiotocography with electrocardiogram analysis compared with cardiotocography alone

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Belfort, M. A., Saade, G. R., Thom, E., Blackwell, S. C., Reddy, U. M., Thorp, J. M., Tita, A. T. N., Miller, R. S., Peaceman, A. M., McKenna, D. S., Chien, E. K. S., Rouse, D. J., Gibbs, R. S., El-Sayed, Y. Y., Sorokin, Y., Caritis, S. N., VanDorsten, J. P., A randomized trial of intrapartum fetal ECG ST-segment analysis, New England Journal of Medicine, 373, 632-641, 2015 **Ref Id** 446127 **Country/ies where the study was carried out** USA **Study type** Multicentre randomised controlled trial (RCT) **Aim of the study** To assess whether intrapartum fetal ECG ST-segment analysis in addition to conventional CTG modifies intrapartum and neonatal outcomes **Study dates** Recruitment from November 2010 to March 2014 **Source of funding** Grants from NICHD and funding from Neoventa Medical	**Sample size** See Neilson 2015 **Characteristics** 11,108 randomised women with a single fetus >36 weeks of gestation who were attempting vaginal birth and had cervical dilation between 2 and 7 cm; trial conducted at 16 university-based clinical centres in Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network Intervention: CTG plus fetal ECG (ST-segment analysis) (n=5532) versus CTG only (n=5576). Monitoring device used was STAN S31 (Neoventa Medical) **Inclusion criteria** Women with a singleton fetus >36 weeks of gestation who were attempting vaginal birth and had cervical dilation of between 2 and 7 cm **Exclusion criteria** Noncephalic presentation, planned caesarean birth, need for immediate birth, absent fetal heart-rate variability (amplitude range undetectable) or a sinusoidal pattern, minimal fetal heart-rate variability in the 20 minutes before randomization, or other fetal or maternal conditions that would preclude trial of labour or placement of scalp electrode	**Interventions** Intervention: CTG plus fetal ECG-ST analysis, n=5532 Control: CTG only, n=5576	**Details** See Neilson 2015	**Results** See Neilson 2015 for other outcomes <u>1. Spontaneous vaginal birth</u> CTG plus fetal ECG-ST analysis: 4269/5532 CTG only: 4348/5576 <u>2. Apgar score ≤ 3 at 5 minutes</u> CTG plus fetal ECG-ST analysis: 17/5532 CTG only: 6/5576	**Limitations** Risk of bias: no details of randomisation procedure reported Participant blinding: not possible Outcome assessment blinding: protocol subcommittee that was unaware of study group assignment conducted chart review of all cases that met primary outcome criteria Attrition bias: full clinical data and valid umbilical blood gas results obtained from 96.5% of neonates **Other information** See Neilson 2015
Full citation Neilson, J. P., Fetal electrocardiogram (ECG) for fetal monitoring during labour, Cochrane Database of Systematic Reviews, 12, CD000116, 2015 **Ref Id** 446197 **Country/ies where the study was carried out** **Study type** Cochrane systematic review **Aim of the study**	**Sample size** Total n = 27403 Electrocardiogram (ECG) plus cardiotocograph (CTG) n = 13711 CTG alone n = 13692 **Characteristics** <u>Amer-Wahlin 2001</u> 4966 women in labour at > 36 weeks with singleton pregnancies, cephalic presentation and perceived need for continuous fetal heart rate monitoring via a fetal scalp electrode; high-risk pregnancies, suspicious or abnormal cardiotocography, induced labour, oxytocin augmentation, meconium-stained amniotic fluid or epidural analgesia. The trial took place between 1998 and 2000 in 3 Swedish centres, Lund, Malmo, Gothenburg.	**Interventions** Intervention: CTG plus ECG (ST or PR analysis) Control: CTG only	**Details** <u>Electronic searches</u> The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by the Trials Search Coordinator (September 23, 2015). CENTRAL, MEDLINE, EMBASE were searched, and hand searching of journals and conference proceedings was conducted. No language restrictions were applied. Weekly current awareness alert for a further of 44 journals, plus monthly BidMed Central email alters, were also considered. <u>Selection of studies</u> The review author (JPN) assessed all potential identified studies for inclusion. <u>Data extraction and management</u> A form was designed to extract data and JPN extracted the data using the agreed form. The data were analysed in RevMan. Where information was unclear, JPN contacted the original authors for further details.	**Results** <u>1 Caesarean section</u> No. of studies: 7 total n = 27403 <u>1.1 ST analysis:</u> No. of studies: 6 n = 26446 ECG plus CTG n = 1810/13229 CTG alone n = 1779/13217 RR 1.02 (95% CI 0.96 to 1.08) <u>1.2 PR analysis:</u> No. of studies: 1 n = 957 ECG plus CTG n = 79/482 CTG alone n = 98/475	**Limitations** **<u>Quality of review</u>** 1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criteria? No 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? No 11. Was the conflict of interest included? Yes **<u>Details of individual studies</u>** **Amer-Wahlin 2001**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To compare the effects of analysis of fetal ECG waveform during labour with alternative methods of fetal monitoring **Study dates** Updated to 23 September 2015 **Source of funding** Supported by NIHR via Cochrane Infrastructure funding to Cochrane Pregnancy and Childbirth	Intervention: CTG plus ST analysis of fetal ECG (2519 women) versus CTG alone (2477). The monitoring device was the STAN S21 (Neoventa Medical, Gothenburg) which incorporates an 'expert system' to provide advice to clinical staff. In this, it constitutes a technically more advanced system than used in the Westgate 1993 trial. <u>Belfort 2015</u> 11,108 randomised women with a single fetus >36 weeks of gestation who were attempting vaginal birth and had cervical dilation between 2 and 7 cm. Trial conducted at 16 university-based clinical centres in Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network. Intervention: CTG plus fetal ECG (ST-segment analysis) (n=5532) versus CTG alone (n=5576). Monitoring device was STAN S31 (Neoventa Medical). <u>Ojala 2006</u> 1483 women randomised; 11 exclusions; clinical data available but blood gas data missing for 36. In labour at ≥ 36 weeks with singleton fetus, cephalic presentation, decision to perform amniotomy, no contraindication to scalp electrode. Sample size based on 50% reduction of umbilical artery pH < 7.10 Intervention: CTG plus ECG waveform analysis (STAN) (733 women) versus CTG (739 women). Fetal scalp sampling for pH estimation an option in either group. Recruitment in tertiary referral hospital in Finland 2003-4 <u>Strachan 2000</u> 957 women in labour with perceived need for continuous fetal heart rate monitoring (age > 35 years, maternal disease, adverse obstetric history, prematurity, suspected fetal growth restriction, antepartum haemorrhage, breech presentation, multiple pregnancy, epidural analgesia, induction or augmentation of labour, abnormal cardiotocography, meconium, previous caesarean section). Results were only available for 957 women (92%) for reasons that are unclear. The trial took place in 5 centres: Nottingham and Dundee (UK), Hong Kong, Amsterdam (Netherlands) and Singapore Intervention: CTG plus fetal ECG (n = 482) versus CTG alone (n = 475). <u>Vayssiere 2007</u> 799 women in labour at 36 weeks or more, with a		<u>Assessment of risk of bias</u> JPN assessed risk of bias using criteria from the Cochrane Handbook for Systematic Reviews of Interventions: - Sequence generation - Allocation concealment - Blinding - Incomplete outcome data - Selective reporting bias - Other sources of bias <u>Measures of effect</u> Dichotomous outcomes were presented as risk ratios (RR) with 95% confidence intervals (CIs). No continuous data analysed. <u>Dealing with missing data</u> Levels of attrition noted for included studies. Impact of including studies with high levels of missing data will be explored in future updates. Outcomes were assessed on an intention-to-treat basis as far as possible. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing. <u>Analysis</u> Heterogeneity was regarded high if I^2 > 30% and either $Tau^2 > 0$ or there was a low P value (< 0.10) in the Chi^2 test. A fixed-effect model was used for combining data where studies were assumed estimating the same underlying treatment effect. If substantial clinical or statistical heterogeneity was detected, a random effects meta analysis was used. Fixed-effect meta-analysis was used where trials were comparing the same intervention and the populations and methods were judged to be similar enough. Random effects meta-analyses were used where heterogeneity was present or suspected. If substantial heterogeneity was detected, it was investigated using subgroup and sensitivity analysis	RR 0.79 (95% CI 0.61 to 1.04) <u>2 Cord pH < 7.05 + base deficit >12 mmol/l</u> No. of studies: 6 n = 25682 <u>2.1 ST analysis:</u> No. of studies: 6 n=25682 ECG plus CTG n = 81/12850 CTG alone n = 121/12832 RR 0.72 (95% CI 0.43 to 1.2) <u>2.2 PR analysis:</u> No. of studies: 0 <u>3 Neonatal encephalopathy</u> No. of studies: 6 n = 26410 <u>3.1 ST analysis:</u> n = 26410 ECG plus CTG n = 12/13210 CTG alone n = 20/13200 RR 0.61 (95% CI 0.3 to 1.22) <u>3.2 PR analysis:</u> No. of studies: 0 <u>4 Fetal blood sampling</u> <u>No. of studies: 5 n = 10628</u> <u>4.1 ST analysis:</u> No. of studies: 4 n = 9671 ECG plus CTG n = 449/4870 CTG alone n = 503/4801 RR 0.61 (95% CI 0.41 to 0.9) <u>4.2 PR analysis:</u> No. of studies: 1 n = 957 ECG plus CTG n = 81/482 CTG alone n = 88/475 RR 0.91 (95% CI 0.69 to 1.19)	A modified intention to treat analysis performed excluding non cephalic and preterm babies from the analysis. **Belfort 2015** Unclear random sequence generation. Blinding of participants and study personnel not possible. Protocol subcommittee unaware of group assignment conducted chart review of all cases that met primary outcome criteria. **Ojala 2006** n = 5 in CTG group and n = 78 in the ECG group had technical difficulties in achieving satisfactory monitoring. **Strachan 2000** For unclear reason the results are reported for 92.2% of study's population. Subgroup analysis of babies born with a low arterial pH showed no action for fetal distress had been taken in nearly 75% of cases, suggesting study protocol violation within the trial groups. **Westerhuis 2010** There was no blinding for women or clinicians, and a secondary analysis on 61 babies with adverse outcomes (metabolic acidosis in umbilical cord artery, pH < 7.00, sign of severe hypoxic ischaemic encephalopathy [HIE] and perinatal death) showed the trial protocol was violated in 11 (42%) and 13 (19%) cases of study and control group respectively. **Other information** The systematic review is available online at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000116.pub5/full

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	single fetus with cephalic presentation, and either abnormal cardiotocographic trace or thick meconium-stained amniotic fluid. Exclusions included maternal infections that contraindicated scalp electrode attachment (e.g. HIV), cardiac malformation, severely abnormal cardiotocography at the time of recruitment was an option in both groups Intervention: CTG + fetal ECG (n = 399) versus CTG alone (n = 400). Scalp sampling for pH estimation Westerhuis 2010 5681 women in labour with a singleton fetus in vertex position, a gestational age 36 weeks or greater and a medical indication for electronic fetal monitoring defined by either a high-risk pregnancy (induction or augmentation of labour, epidural anaesthesia, meconium-stained amniotic fluid) or non-reassuring fetal heart rate Intervention group: CTG and ST-analysis. Control group: CTG. Westgate 1993 2434 pregnant women, 1215 in cardiotocography alone arm, 1219 ST waveform and CTG arm. (More than 34 weeks of gestation with no gross fetal abnormality.) Intervention: CTG plus ST analysis (n =1219) versus CTG alone (n = 1215). **Inclusion criteria** Trials comparing analysis of any component of the fetal electrocardiographic (ECG) during labour with alternative fetal monitoring methods. Studies using less robust methods of allocation (for example, alternation) were not included **Exclusion criteria**			5 Instrumental vaginal birth 5.1 ST analysis No. of studies = 6 n = 26,446 ECG plus CTG n = 1810/4870 CTG alone n = 1489/13217 RR 1.02 (95% CI 0.96 to 1.08) 5.2 PR analysis No. of studies = 1 n = 957 ECG plus CTG n = 116/482 CTG alone n = 122/475 RR 0.94 (95% CI 0.75 to 1.17) 6 Neonatal intubation No. of studies: 3 n=13501 6.1 ST analysis No. of studies = 2 n = 12544 ECG plus CTG n = 51/6246 CTG alone n = 36/6298 RR 1.37 (95% CI 0.89 to 2.11) 6.2. PR analysis No. of studies = 1 n = 957 ECG plus CTG n = 6/482 CTG alone n = 8/475 RR 0.74 (95% CI 0.26 to 2.11) 7 Admission to neonatal care unit No. of studies: 7 n = 27367 7.1 ST analysis: No. of studies: 6 n=26410 ECG plus CTG n = 1113/13210 CTG alone n = 1155/13200 RR 0.96 (95% CI 0.89 to 1.04) 7.2 PR analysis No. of studies: 1 n = 957 ECG plus CTG n = 22/482	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				CTG alone n = 28/475 RR 0.77 (95% CI 0.45 to 1.33) <u>8 Fetal, perinatal or neonatal death</u> No. of studies: 7 n = 26446 <u>8.1 ST analysis</u> <u>Fetal or neonatal death</u> No. of studies: 6 n = 15338 ECG plus CTG n = 11/13229 CTG alone n = 6/13217 RR 1.71 (95% CI 0.67 to 4.33) <u>8.2 PR analysis</u> <u>Perinatal death</u> No. of studies: 1 n = 957 ECG plus CTG n = 1/482 CTG alone n = 0/475 RR 2.96 (95% CI 0.12 to 72.39) <u>9 Apgar score <7 at 5 minutes</u> No. of studies: 6 n = 16259 <u>9.1 ST analysis</u> No. of studies: 5 n = 15302 ECG plus CTG n = 103/7678 CTG alone n = 1078/7624 RR 0.95 (95% CI 0.73 to 1.24) <u>9.2 PR analysis</u> No. of studies: 1 n = 957 ECG plus CTG n = 3/482 CTG alone n = 7/475 RR 0.42 (95% CI 0.11 to 1.62)	
Full citation Olofsson, P., Ayres-de-Campos, D., Kessler, J., Tendal, B., Yli, B. M., Devoe, L., A critical appraisal of the evidence for using cardiotocography plus ECG ST interval analysis for fetal surveillance in labor. Part I: the randomized controlled trials, Acta Obstetricia et Gynecologica Scandinavica, 93, 556-68; discussion 568-9, 2014 **Ref Id** 446200	**Sample size** No. of studies: 5, n=15363 CTG plus fetal ECG-ST (n=7702) versus CTG only (n=7661) **Characteristics** <u>Westgate 1993</u> 2434 pregnant women, 1215 cardiotocography alone arm, 1219 ST waveform and CTG arm. (More than 34 weeks of gestation with no gross fetal abnormality.)	**Interventions** Intervention: CTG plus fetal ECG-ST analysis Control: CTG only	**Details** No details reported of how studies were selected. Includes revised data from Amer-Wahlin 2011 and Westerhuis 2011. Review addressed: (1) Power calculations, (2) Prestudy training, inclusion criteria, randomisation and recruitment pace, (3) Intrapartum management protocols, (4) Intrapartum interventions, (5) Cord blood and early neonatal metabolic acidosis, (6) Neonatal outcomes	**Results** <u>1. Spontaneous vaginal birth</u> No. of studies: 5, n=15363 CTG plus fetal ECG-ST (n=7702) versus CTG only (n=7661) <u>Westgate 1993</u> CTG plus fetal ECG-ST: 875/1219 CTG only: 832/1215 RR 1.05 (95%CI 0.995, 1.1) <u>Amer-Wahlin 2001/2011</u>	**Limitations** **<u>Quality of review</u>** 1. Was an ‘a priori’ design provided? No 2. Was there duplicate study selection and data extraction? No 3. Was a comprehensive literature search performed? No 4. Was the status of publication (i.e. grey literature) used as an inclusion criteria? No 5. Was a list of studies (included and excluded) provided? Not applicable, not a systematic review 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out **Study type** Critical review of CTG plus fetal ECG-ST analysis randomised controlled trials (RCTs) **Aim of the study** To assess the quality of 5 RCTs evaluating CTG plus fetal ECG ST analysis **Study dates** From 1993 to 2011 **Source of funding** None reported	Intervention: CTG plus ST analysis (n =1219) versus CTG alone (n = 1215). CTG plus fetal ECG-ST (n=1219) versus CTG only (n=1215) Amer-Wahlin 2001/2011 4966 women in labour at > 36 weeks with singleton pregnancies, cephalic presentation and perceived need for continuous fetal heart rate monitoring via a fetal scalp electrode; high-risk pregnancies (suspicious or abnormal cardiotocography, induced labour, oxytocin augmentation, meconium-stained amniotic fluid or epidural analgesia). The trial took place between 1998 and 2000 in 3 Swedish centres, Lund, Malmo, Gothenburg Intervention: CTG plus ST analysis of fetal ECG (2519 women) versus CTG alone (2477). The monitoring device was the STAN S21 (Neoventa Medical, Gothenburg) which incorporates an 'expert system' to provide advice to clinical staff. In this, it constitutes a technically more advanced system than used in the Westgate 1993 trial. CTG plus fetal ECG-ST (n=2519) versus CTG only (n=2447) Ojala 2006 1483 women randomised; 11 exclusions; clinical data available but blood gas data missing for 36. In labour at ≥ 36 weeks with singleton fetus, cephalic presentation, decision to perform amniotomy, no contraindication to scalp electrode. Sample size based on 50% reduction of umbilical artery pH < 7.10 Intervention: CTG plus ECG waveform analysis (STAN) (733 women) versus CTG (739 women). Fetal scalp sampling for pH estimation an option in either group. Recruitment in tertiary referral hospital in Finland 2003-4 CTG + fetal ECG-ST (n=733) versus CTG only (n=739) Vayssiere 2007 799 women in labor at 36 weeks or more, with a single fetus with cephalic presentation, and either abnormal cardiotocographic trace or thick meconium-stained amniotic fluid. Exclusions included maternal infections that contraindicated scalp electrode attachment (e.g. HIV), cardiac malformation, severely abnormal cardiotocography at the time of recruitment was an option in both groups Intervention: CTG + fetal ECG (n = 399) versus CTG alone (n = 400). Scalp sampling for ph estimation CTG + fetal ECG-ST (n=399) versus CTG only (n=400) Westerhuis 2010/2011 5681 women in labour with a singleton fetus in vertex position, a gestational age 36 weeks or greater and a medical indication for electronic fetal monitoring. A medical indication is defined by either a high-risk pregnancy, induction or augmentation of labour, epidural anaesthesia, meconium-stained amniotic fluid or non-reassuring fetal heart rate Intervention group: CTG and ST-analysis. Control group: CTG.			CTG plus fetal ECG-ST: 2065/2519 CTG only: 1947/2447 RR 1.03 (95%CI 1.003, 1.059) Ojala 2006 CTG plus fetal ECG-ST: 616/733 CTG only: 625/739 RR 0.99 (95%CI 0.95, 1.04) Vayssiere 2007 CTG plus fetal ECG-ST: 183/399 CTG only: 179/400 RR 1.02 (95%CI 0.88, 1.19) Westerhuis 2010/2011 CTG plus fetal ECG-ST: 2038/2827 CTG only: 2018/2840 RR 1.01 (95%CI 0.98, 1.05) **Overall (not reported in review article; calculated by NGA technical team in RevMan)** CTG plus fetal ECG-ST: n=7702 CTG only: n=7661 RR 1.02 (95%CI 1.0, 1.04)	9. Were the methods used to combine the findings of studies appropriate? Not applicable, meta-analysis not conducted 10. Was the likelihood of publication bias assessed? No 11. Was the conflict of interest included? Yes **Details of individual studies:** **Amer-Wahlin 2001** A modified intention to treat analysis performed excluding non-cephalic and preterm babies from the analysis. **Ojala 2006** n = 5 in CTG group and n = 78 in the ECG group had technical difficulties in achieving satisfactory monitoring. **Strachan 2000** For unclear reason the results are reported for 92.2% of the study's population. Subgroup analysis of babies born with a low arterial pH showed no action for fetal distress had been taken in nearly 75% of cases, suggesting study protocol violation within the trial groups. **Westerhuis 2010** There was no blinding for women or clinicians, and a secondary analysis on 61 babies with adverse outcomes (metabolic acidosis in umbilical cord artery, pH < 7.00, sign of severe hypoxic ischaemic encephalopathy [HIE] and perinatal death) showed the trial protocol was violated in 11 (42%) and 13 (19%) cases of study and control group respectively. **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	CTG + fetal ECG-ST (n=2832) versus CTG only (n=2849) **Inclusion criteria** RCT of CTG plus fetal ECG-ST analysis studies **Exclusion criteria** None reported				
Full citation van Wijngaarden,W.J., Sahota,D.S., James,D.K., Farrell,T., Mires,G.J., Wilcox,M., Chang,A., Improved intrapartum surveillance with PR interval analysis of the fetal electrocardiogram: a randomized trial showing a reduction in fetal blood sampling, American Journal of Obstetrics and Gynecology, 174, 1295-1299, 1996 **Ref Id** 196803 **Country/ies where the study was carried out** UK, Hong Kong **Study type** Randomised prospective trial **Aim of the study** To test potential reduction in unnecessary fetal blood sampling in sample of high-risk labours using CTG plus fetal ECG-PR interval analysis versus CTG only **Study dates** Not reported clearly **Source of funding** None reported	**Sample size** N=214. CTG plus fetal ECG-PR interval analysis, n=112 (Included in analyses, n=84; >37 week=76, 27-37 week=8) CTG only, n=102 (Included in analyses, n=100; >37 week=92, 27-37 week=8) Excluded: Inability to obtain analysable fetal ECG waveform signal, n=8; non-availability of umbilical artery gas measurements, n=4; discontinuation of trial at woman's request, n=1; erroneous fetal ECG analyser settings by labour suite staff resulting in inverted waveform that did not provide any fetal ECG data, n=17 **Characteristics** Compared fetal blood sampling rate and results in 214 'high-risk' paturients (where the fetus was at risk of acidosis) monitored by CTG plus fetal ECG-PR interval analysis or by CTG only in 3 teaching hospitals over period of 10 months (Queens Medical Centre, Nottingham, UK), 8 months (Ninewells Hospital, Dundee, UK) and 3 months (Prince of Wales Hospital, Hong Kong). Randomisation using PC-random number generator. All participants monitored by fetal ECG analyser system. Fetal ECG signal obtained by Copeland's fetal scalp electrode (Surgicraft, Redditch, UK) or a spiral scalp electrode (Corometrics Medical Systems, Wallingford, CT, USA), processed, and analysed with Nottingham fetal ECG analyser. Time-interval parameters displayed on video display in CTG plus fetal ECG-ST analysis group, whilst only electronic fetal monitoring information displayed in CTG only group. Labour management and decision making sole responsibility of on-call labour ward staff. Intervention with fetal blood sampling or birth in CTG only group according to established International Federation of Gynecology and Obstetrics (FIGO) guidelines in use at labour suites of each unit. Management in CTG plus ECG-ST analysis group based on: (1) electronic fetal monitoring; (2) conduction index: positive index >20 minutes defined as 'abnormal'; (3) ratio index >4% defined as 'abnormal'. If CTG became abnormal (e.g. prolonged profound bradycardia), then an 'opt-out clause' allowing management based only on CTG was allowed	**Interventions** No. of participants, N=214 Intervention: CTG plus fetal ECG-PR interval analysis, n=112 Control: CTG only, n=102	**Details** Randomisation using PC-random number generator. All participants monitored by fetal ECG analyser system. Fetal ECG signal obtained by Copeland's fetal scalp electrode (Surgicraft, Redditch, UK) or a spiral scalp electrode (Corometrics Medical Systems, Wallingford, CT, USA), processed, and analysed with Nottingham fetal ECG analyser. Time-interval parameters displayed on video display in CTG plus fetal ECG-PR interval analysis group, whilst only electronic fetal monitoring information displayed in CTG only group. Labour management and decision making sole responsibility of on-call labour ward staff. Intervention with fetal blood sampling or birth in CTG only group according to established International Federation of Gynecology and Obstetrics (FIGO) guidelines in use at labour suites of each unit. Management in CTG plus ECG-PR interval analysis group based on: (1) electronic fetal monitoring; (2) conduction index: positive index >20 minutes defined as 'abnormal'; (3) ratio index >4% defined as 'abnormal'. If the CTG became abnormal (e.g. prolonged profound bradycardia) then an 'opt-out clause' allowing management based only on CTG was allowed. Abnormal fetal blood sampling result: pH<=7.25 Normal fetal blood sampling result: pH>7.25 Acidosis at birth: arterial umbilical cord pH<=7.15 (1 SD below mean of population studied)	**Results** <u>1 Number undergoing fetal blood sampling</u> CTG plus fetal ECG-PR interval analysis: 5/84 CTG only: 21/100 Intention to treat: CTG plus fetal ECG-PR interval analysis: 5/112 CTG only: 21/103 <u>2 Acidotic infants</u> CTG plus fetal ECG-PR interval analysis: 8/84 CTG only: 14/100 Intention to treat: CTG plus fetal ECG-PR interval analysis: 8/112 CTG only: 14/102 <u>3 Assisted births</u> CTG plus fetal ECG-PR interval analysis: 36/84 CTG only: 42/100 Intention to treat: CTG plus fetal ECG-PR interval analysis: 36/112 CTG only: 42/102 <u>4 Assisted births for presumed fetal distress</u> CTG plus fetal ECG-PR interval analysis: 7/84 CTG only: 16/100 Intention to treat CTG plus fetal ECG-PR interval analysis: 7/112 CTG only: 16/102	**Limitations** Allocation concealment: no details reported Participant blinding: not possible Outcome assessment blinding: all labour records, CTG, fetal ECG data, and biochemcial data were reviewed and scrutinised according to signal quality, protocol adherence, and sample quality by a research fellow and research engineer at Queen's Medical Centre before analysis of outcomes Attrition bias: full clinical data available for 86% of sample **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria High-risk paturients. Since there was only one ECG analyser at each centre, if there was more than one eligible participant then the one thought to have greatest risk of fetal compromise was approached for recruitment. Definition of 'high risk': (1) Maternal factors: age <16 or >35 years; weight <45 kg or >90 kg; any disease with potential adverse effect on fetus. (2) Obstetric factors: poor obstetric history; intrauterine growth restriction; prematurity; antepartum haemorrhage. (3) Intrapartum factors: breech presentation; epidural anaesthesia; induction or augmentation of labour with oxytocin; trial of scar with labour; cardiotocographic abnormalities; meconium. **Exclusion criteria** Women giving birth by elective caesarean section; cases in which <1 hour of interpretable data expected; woman did not consent to trial; fetal ECG analyser at site not available				

G.12 Automated interpretation of cardiotocograph traces

<table>
<tr><th>Bibliographic details</th><th>Participants</th><th>Tests</th><th>Methods</th><th>Outcomes and results</th><th>Comments</th></tr>
<tr>
<td>Full citation

Chen, C. Y., Yu, C., Chang, C. C., Lin, C. W., Comparison of a novel computerized analysis program and visual interpretation of cardiotocography, PLoS ONE [Electronic Resource], 9, e112296, 2014

Ref Id

446257

Country/ies where the study was carried out

Taiwan

Study type

Retrospective cohort study

Aim of the study

To compare new computerised CTG analysis software with visual interpretation of the CTG

Study dates

CTGs were recorded between March and September 2011

Source of funding

No funding or support reported</td>
<td>Sample size

N = 62 CTG traces

Characteristics

Mean gestational age 38 weeks (range 37-40)
No other characteristics reported

Inclusion Criteria

Singleton pregnancies of ≥ 37 weeks' gestation. No medical complications in the woman and no known congenital abnormalities in the fetus

Exclusion Criteria

None reported</td>
<td>Tests

A computerised algorithm for interpretation of the CTG was developed using LabVIEW 2010 software. This enabled detection of the baseline fetal heart rate, variability, accelerations and decelerations (number and timing). The NICHD 3 tier system for the classification of CTGs was used to define the traces as normal (category I), indeterminate (category II) or abnormal (category III)</td>
<td>Methods

62 admission CTGs were obtained from a database including women admitted in early labour to a tertiary care univerisity hospital. The duration of each trace was between 20 and 30 minutes. They were independently examined by 8 obstetricians with between 3 and 6 years of experience.
Observers were asked to record the baseline heart rate, variability, number of accelerations, number and type of decelerations, uterine contractions and category of CTG (according to the NICHD criteria)</td>
<td>Results

Agreement between the computer algorithm and the eight obstetricians
Baseline fetal heart rate, ICC (95% CI): 0.91 (0.88 - 0.94)
Baseline variability, κ statistic (95% CI): 0.68 (0.51 - 0.84)
Accelerations, ICC (95% CI): 0.85 (0.80 - 0.90)
Early decelerations, ICC (95% CI): 0.78 (0.71 - 0.84)
Late decelerations, ICC (95% CI): 0.67 (0.59 - 0.76)
Variable decelerations, ICC (95% CI): 0.60 (0.51 - 0.70)
Prolonged deceleration, κ statistic (95% CI): 0.82 (0.58 - 1.00)
Recurrent deceleration, κ statistic (95% CI): 0.82 (0.67 - 0.97)
Contraction frequency, ICC (95% CI): 0.97 (0.96 - 0.98)
<u>CTG categories</u>
Category I, κ statistic (95% CI): 0.91 (0.81 - 1.00)
Category II, κ statistic (95% CI): 0.78 (0.63 - 0.93)
Category III, κ statistic (95% CI): 0.50 (0.17 - 0.83)
Overall categorisation, κ statistic (95% CI): 0.80 (0.67 - 0.94)

Agreement between the eight obstetricians only
Baseline fetal heart rate, ICC (95% CI): 0.91 (0.88 - 0.94)
Baseline variability, κ statistic (95% CI): 0.67 (0.51 - 0.83)
Accelerations, ICC (95% CI): 0.84 (0.79 - 0.89)
Early decelerations, ICC (95% CI): 0.78 (0.71 - 0.84)
Late decelerations, ICC (95% CI): 0.65 (0.56 - 0.74)
Variable decelerations, ICC (95% CI): 0.59 (0.50 - 0.69)
Prolonged deceleration, κ statistic (95% CI): 0.82 (0.58 - 1.00)
Recurrent deceleration, κ statistic (95% CI): 0.82 (0.66 - 0.97)
Contraction frequency, ICC (95% CI): 0.97 (0.96 - 0.98)
<u>CTG categories</u>
Category I, κ statistic (95% CI): 0.90 (0.81 - 1.00)
Category II, κ statistic (95% CI): 0.78 (0.62 - 0.93)
Category III, κ statistic (95% CI): 0.48 (0.15 - 0.80)
Overall categorisation, κ statistic (95% CI): 0.80 (0.66 - 0.93)</td>
<td>Limitations

Other information

QUADAS criteria
1. Patient selection – high risk; selection of CTGs was not reported to be random or consecutive; cases were apparently chosen to ensure different classes of CTG were included
2. Index tests – low risk
3. Reference standard – low risk
4. Flow and timing – low risk</td>
</tr>
<tr>
<td>Full citation

Chung,T.K., Mohajer,M.P., Yang,Z.J., Chang,A.M., Sahota,D.S., The prediction of fetal acidosis at birth by computerised analysis of intrapartum cardiotocography, British Journal of Obstetrics and Gynaecology, 102, 454-460, 1995

Ref Id

197179

Country/ies where the study was carried out</td>
<td>Sample size

n = 73 CTG traces

Characteristics

<table>
<tr><th>Characteristic</th><th>Number</th><th>Mean (range)</th></tr>
<tr><td>Maternal</td><td></td><td></td></tr>
<tr><td>Maternal age (years)</td><td></td><td>26.6 (15-40)</td></tr>
<tr><td>Primiparous</td><td>50</td><td></td></tr>
</table>
</td>
<td>Tests

A CTG interpretation algorithm was designed by the study authors, which classified traces as normal or abnormal. An abnormal trace was defined by one or more of the following criteria.

1. Tachycardia (fetal heart rate >160 bpm) for more than 30 minutes during labour
2. Bradycardia (fetal heart rate <110 bpm) for more than 30 minutes during labour
3. Low variation (standard deviation of the fetal</td>
<td>Methods

The categorisation of CTG traces as normal or abnormal by the computer algorithm was compared to the outcome of fetal acidosis.
Acidosis was defined by an umbilical artery pH of less than 7.15, or by a base excess (BE) of less than -8mmol/l at birth.
Results were reported as overall accuracy of the algorithm, as well as sensitivity and specificity</td>
<td>Results

Diagnostic accuracy of computer algorithm for fetal acidosis, as defined by umbilical arterial pH of <7.15
Sensitivity, % (95%CI): 87.5 (46.7 - 99.3)*
Specificity, % (95% CI): 75.4 (62.9 - 84.9)*
Positive likelihood ratio (95% CI): 3.55 (2.16 - 5.86)*
Negative likelihood ratio (95% CI): 0.17 (0.03 - 1.05)*
<table>
<tr><th colspan="2" rowspan="2"></th><th colspan="2">Computer diagnosis</th><th rowspan="2">Total</th></tr>
<tr><th>Abnormal CTG</th><th>Normal CTG</th></tr>
<tr><td>Reference standard</td><td>Acidosis (pH < 7.15)</td><td>7</td><td>1</td><td>8</td></tr>
</table>
</td>
<td>Limitations

Selection of cases for CTG interpretation not well reported, and it was unclear whether a consecutive or random sampling approach was taken. Thresholds for fetal acidosis used differed from those pre-defined by the guideline committee as clinically significant

Other information

QUADAS 2 criteria
1. Patient selection: Unclear risk - it is not clear</td>
</tr>
</table>

Bibliographic details	Participants			Tests	Methods	Outcomes and results	Comments
UK **Study type** Retrospective cohort study **Aim of the study** To assess the ability of a computer software interpretation program to predict fetal acidosis at birth **Study dates** Not reported **Source of funding** Not reported	Multiparous	23		heart rate of ≤3 bpm) for more than 60 minutes during labour 4. More than five late decelerations (minima of the fetal heart rate occurring 20-60 seconds after the maxima of the contraction) during labour 5. More than 10 variable decelerations (minima of the FHR occurring more than 20 seconds prior to, or 60 seconds after, the maxima of the contraction) during labour			how CTG traces were selected for assessment 2. Index test(s): Low risk 3. Reference standard: Unclear risk - thresholds differ from those suggested by the guideline committee 4. Flow and timing: Low risk
	Labour and birth						
	Induction of labour	36					
	Duration of labour (hours)		9.53 (3-17)				
	Epidural anaesthesia	57					
	Nitrous oxide only	7					
	Other analgesia	9					
	Normal birth	39					
	Forceps birth	25					
	Caesarean section	9					
	Infant						
	Birthweight (g)		3226.25 (1500-4580)				
	Male infants	40					
	Female infants	33					
	Indication for fetal monitoring						
	Intrauterine growth restriction	10					
	Pregnancy induced hypertension	9					
	Prolonged rupture of membranes	2					
	Polyhydramnios	2					
	Maternal anaemia	3					
	Post term	14					
	Meconium stained amniotic fluid	6					
	Suspicious antepartum CTG	9					

	No acidosis (pH ≥ 7.15)	16	49	65
Total		23	50	73

Diagnostic accuracy of computer algorithm for fetal acidosis, as defined by base excess of less than -8mmol/l
Sensitivity, % (95% CI): 76.5 (49.8 - 92.2)*
Specificity, % (95% CI): 82.1 (69.2 - 90.7)*
Positive likelihood ratio (95% CI): 4.28 (2.30 - 7.96)*
Negative likelihood ratio (95% CI): 0.29 (0.12 - 0.68)*

		Computer diagnosis		Total
		Abnormal CTG	Normal CTG	
Reference standard	Acidosis (BE < -8 mmol/l)	13	4	17
	No acidosis (BE ≥ -8mmol/l)	10	46	56
Total		23	50	73

*Sensitivity, specificity and likelihood ratios calculated by the NGA technical team using http://vassarstats.net/clin1.html

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	<table><tr><td>Decreased fetal movements</td><td>6</td><td></td></tr><tr><td>Other</td><td>12</td><td></td></tr></table> **Inclusion Criteria** CTG traces were selected from women recruited at the University Hospital of Nottingham. Eligible women had a recognised indication for continuous fetal monitoring (in accordance with local management guidelines) and a labour that lasted for more than 3 hours **Exclusion Criteria** Not reported				
Full citation Costa, A., Santos, C., Ayres-de-Campos, D., Costa, C., Bernardes, J., Access to computerised analysis of intrapartum cardiotocographs improves clinicians' prediction of newborn umbilical artery blood pH, BJOG : an international journal of obstetrics and gynaecology, 117, 1288-1293, 2010 **Ref Id** 446136 **Country/ies where the study was carried out** Portugal **Study type** Randomised controlled study **Aim of the study** To assess whether access to computerised CTG analysis improves clinicians' prediction of neonatal outcomes (umbilical artery pH and 5 minute Apgar score) **Study dates** Not reported **Source of funding**	**Sample size** N = 204 CTG traces n = 104 randomised to receive computer analysis n = 100 randomised to receive no computer analysis **Characteristics** <table><tr><td>Characteristic</td><td>Visual assessment n = 100</td><td>Computerised assessment n = 104</td></tr><tr><td>Gestational age, weeks, mean (SD)</td><td>39 (1)</td><td>39 (1)</td></tr><tr><td>Birth weight, g, mean (SD)</td><td>3362 (446)</td><td>3282 (427)</td></tr><tr><td>Male births, n (%)</td><td>50 (50)</td><td>46 (44)</td></tr><tr><td>Duration of assessed trace, minutes, median (minimum - maximum)</td><td>227 (60-770)</td><td>213 (64-780)</td></tr><tr><td>Cord artery pH, mean (SD) [21 missing values]</td><td>7.25 (0.08)</td><td>7.22 (0.08)</td></tr><tr><td>5-mniute Apgar scores, median (minimum - maximum)</td><td>10 (8 - 10)</td><td>10 (6 - 10)</td></tr><tr><td>Caesarean birth, n (%)</td><td>12 (12)</td><td>15 (14)</td></tr></table> **Inclusion Criteria** Singleton pregnancies of more than 36 weeks' gestation, cephalic presentation, absence of known fetal malformations, active phase of labour, generally accepted indication for internal fetal heart rate monitoring (poor signal quality, heavy	**Tests** The Omniview-SisPorto 3.5 system was used for CTG analysis	**Methods** Using computergenerated random numbers, traces were assigned to receive computer analysis by the Omniview SisPorto 3.5 system, or to no analysis (control group). The tracing printout in the study group had the baseline drawn on the fetal heart rate graph. Accelerations, decelerations, contractions and periods with abnormal short term and long term variability were highlighted. The last alert elicited by the system was also displayed underneath the tracing. Traces in the control group showed only the standard fetal heart rate and uterine contraction signals. All traces were presented independently to three obstetricians with more than 5 years of experience in CTG interpretation. With the information that tracings had been recorded in term pregnancies, and that timings to birth were those previously mentioned (5 minutes for vaginal birth, 20 minutes for caesarean birth), the obstetricians were asked to estimate the newborns' umbilical arterial pH (to 2 decimal places) and 5 minute Apgar scores. A predicted pH of within 0.1 of the actual result was considered to be accurate, as was an Apgar score of within 1	**Results** **Accuracy of observers' prediction of umbilical arterial pH (within a margin of 0.1)** For traces without computerised CTG analysis (control): correct prediction of pH in 46% of cases (95% CI: 35% - 56%) intraclass correlation coefficient = 0.29 (0.08 - 0.47) For traces with computerised CTG analysis (intervention): correct prediction of pH in 70% of cases (95% CI: 61% - 79%) intraclass correlation coefficient = 0.52 (0.34 - 0.66) **Agreement between the three observers in prediction of umbilical arterial pH** For traces without computerised CTG analysis (control): intraclass correlation coefficient = 0.43 (0.21 - 0.60) For traces with computerised CTG analysis (intervention): intraclass correlation coefficient = 0.70 (0.61 - 0.77) (Study authors reported that the difference between these results was statistically significant; a p value was not reported) **Agreement between the three observers in prediction of 5 minute Apgar score** For traces without computerised CTG analysis (control): intraclass correlation coefficient = 0.42 (0.25 to 0.57) For traces with computerised CTG analysis (intervention): intraclass correlation coefficient = 0.55 (0.37 to 0.68) (Study authors reported that the difference between these results was statistically significant; a p value was not reported)	**Limitations** **Other information** ***QUADAS 2 criteria*** 1. Patient selection: Low risk 2. Index tests: Low risk 3. Reference standard: Low risk 4. Flow and timing: Low risk

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Not financially supported	meconium staining, high-risk pregnancy etc), a minimum of 60 minutes of trace duration, signal loss in the last hour < 20%, no complications with the potential to influence fetal oxygenation occurring between tracing end and delivery (difficult vaginal or abdominal fetal extractions, cord prolapse, maternal hypotension, shoulder dystocia etc), and no anaesthetic complications taking place at the time of surgery **Exclusion Criteria** Time interval between tracing end and vaginal delivery exceeded 5 minutes, or interval between tracing end and caesarean birth exceeded 20 minutes				
Full citation Costa, M. A., Ayres-de-Campos, D., Machado, A. P., Santos, C. C., Bernardes, J., Comparison of a computer system evaluation of intrapartum cardiotocographic events and a consensus of clinicians, Journal of Perinatal Medicine, 38, 191-5, 2010 **Ref Id** 457633 **Country/ies where the study was carried out** Portugal **Study type** Retrospective cohort study **Aim of the study** To compare computer analysis of intrapartum CTG features using the Omniview SisPorto 3.5 system with interpretation by clinicians **Study dates** Not reported **Source of funding** None reported	**Sample size** n = 50 CTG traces **Characteristics** Not reported **Inclusion Criteria** Singleton pregnancies of more than 36 weeks' gestation. Traces were recorded as part of a previously conducted randomised controlled trial. Included CTGs were of more than 60 minutes' duration with less than 10% signal loss **Exclusion Criteria** None reported	**Tests** The Omniview SisPorto 3.5 system was used to analyse the CTG traces and determine baseline fetal heart rate, accelerations, decelerations and contractions	**Methods** Three clinicians (all with > 5 years' experience of CTG interpretation) initially assessed the traces independently. A second round of assessment was promoted for discordant segments of CTG, but without informing the clinicians of the other observers' results. Finally, a consensus meeting was held between all three clinicians to review the second round discordant segments. CTG segments which remained discordant after the third round were discarded from further analysis. Determination of agreement in baseline rate was assessed using the intraclass correlation coefficient, the proportions of specific agreement and the limits of agreement. Agreement in determining accelerations, decelerations and contractions was assessed using the proportions of specific agreement and 95% confidence interval (CI)	**Results** **Agreement on baseline estimation** Agreement between observers, ICC (95% CI): 0.87 (0.84 - 0.90) Observer 1 and computer, ICC (95% CI): 0.79 (0.48 - 0.89) Observer 2 and computer, ICC (95% CI): 0.88 (0.74 - 0.93) Observer 3 and computer, ICC (95% CI): 0.78 (0.27 - 0.91) Consensus of observers and computer, ICC (95% CI): 0.85 (0.46 - 0.93) **Agreement on accelerations** Agreement between observers, proportion of agreement (95% CI): 60% (48 - 66) Observer 1 and computer, proportion of agreement (95% CI): 68% (52 - 75) Observer 2 and computer, proportion of agreement (95% CI): 69% (55 - 76) Observer 3 and computer, proportion of agreement (95% CI): 65% (50 - 71) Consensus of observers and computer, proportion of agreement (95% CI): 71% (69 - 73) **Agreement on decelerations** Agreement between observers, proportion of agreement (95% CI): 65% (57 - 69) Observer 1 and computer, proportion of agreement (95% CI): 63% (51 - 68) Observer 2 and computer, proportion of agreement (95% CI): 62% (49 - 65) Observer 3 and computer, proportion of agreement (95% CI): 61% (51 - 68) Consensus of observers and computer, proportion of agreement (95% CI): 68% (66 - 70) **Agreement on contractions** Agreement between observers, proportion of agreement (95% CI): 93% (90 - 95) Observer 1 and computer, proportion of agreement (95% CI): 86% (83 - 88) Observer 2 and computer, proportion of agreement (95% CI): 84% (83 - 87) Observer 3 and computer, proportion of agreement (95% CI): 85% (81 - 90) Consensus of observers and computer, proportion of agreement (95% CI): 87% (85 - 89)	**Limitations** **Other information** ***QUADAS criteria*** 1. Patient selection - low risk 2. Index tests - low risk 3. Reference standard - low risk 4. Flow and timing - low risk
Full citation Keith, R. D., Beckley, S., Garibaldi, J. M., Westgate, J. A., Ifeachor, E. C., Greene, K. R., A multicentre comparative study of 17 experts and an intelligent computer system for managing labour using the	**Sample size** n = 50 CTG traces **Characteristics** Characteristic | n	**Tests** The computerised system used in this study was developed by the study authors to assist clinical staff in their interpretation of CTG and consequent labour management. The system extracts relevant data from the CTG using numerical algorithms (including signal quality, baseline	**Methods** A panel of 17 experts was asked to independently score the CTGs to provide a reference standard for comparison with the computerised system. The experts were asked to score 15 minute segments of CTG trace according to the following five-point protocol.	**Results** Agreement in scoring between the computerised system and experts: κ = 0.31 Consistency in scoring for the computerised system: κ = 0.98 The computer system identified the need for intervention for 2/3 cases of birth asphyxia, 2/4 cases of metabolic acidosis and 2/5 cases of acidosis. The computer system recommended no unnecessary intervention in all of the 11 cases with a good perinatal outcome (normal vaginal birth with an arterial pH >7.15, venous pH >7.20 and 5 minute Apgar score ≥ 9 with no resuscitation)	**Limitations** The system used in this article incorporated both CTG data and clinical information **Other information** ***QUADAS 2 criteria***

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
cardiotocogram, British Journal of Obstetrics & Gynaecology, 102, 688-700, 1995 **Ref Id** 457998 **Country/ies where the study was carried out** UK **Study type** Retrospective cohort study **Aim of the study** To investigate whether computer software which integrates CTG interpretation and clinical features has a performance comparable to experts in the management of labour **Study dates** Not reported **Source of funding** The Mason Medical Research Foundation, the Northcott Devon Medical Foundation, the Science and Engineering Research Council, the South Western Region Health Authority and the Polytechnic Central Funding Council	<table><tr><td>Mode of birth</td><td></td></tr><tr><td>Vaginal birth</td><td>21</td></tr><tr><td>Forceps birth</td><td>13</td></tr><tr><td>Caesarean section</td><td>16</td></tr><tr><td>Outcome</td><td></td></tr><tr><td>Birth asphyxia[1]</td><td>3</td></tr><tr><td>Metabolic acidosis[2]</td><td>4</td></tr><tr><td>Acidosis[3]</td><td>5</td></tr></table> [1] Cord arterial pH < 7.05, base deficit ≥ 12 and Apgar score at 5 minutes of ≤7 with neonatal morbidity [2] Cord arterial pH < 7.05, base deficit ≥ 12 and Apgar score at 5 minutes of >7 with no neonatal morbidity [3] Cord arterial pH < 7.05 and base deficit <12 with no neonatal morbidity **Inclusion Criteria** CTGs were selected from a database of 2400 high risk labours in which cord blood gas analysis and Apgar scores had been recorded **Exclusion Criteria** Cases which had been previously reviewed by the computerised system or used to build its knowledge.	heart rate, heart rate variability, accelerations, the magnitude and timing of decelerations). These features are classified using additional algorithms and a small neural net. Relevant clinical information (such as cervical dilatation, risk factors and analgesia) is then considered. The system interprets all of these features using a database of over 400 rules which are used to recommend action	1. I am not concerned for this fetus 2. I have concerns for this fetus, but they are not sufficient to request fetal blood sampling (FBS); I may take some remedial action 3. I am sufficiently concerned to request FBS or, if possible, a simple vaginal birth 4. The information I have leads me to be seriously concerned for this fetus; I am not going to recommend immediate birth although I am thinking of expediting birth and will do so if things deteriorate further 5. I am so concerned for this fetus that I want immediate birth A method was derived to identify agreement between any two sets of scoring sequences. This gave a value of 0 if no similarity was seen, and 1 if perfect concordance was present. The method incorporated a weighted agreement matrix which rewarded similar scores given to a particular segment, but heavily penalised widely differing scores. The method also awarded a partial agreement when two experts took a major decision close to each other, but not within the same segment of CTG. The agreement between the system and each of the 17 experts was calculated for each case and averaged		1. Patient selection: Unclear risk - selection of cases is not fully reported 2. Index tests: Low risk 3. Reference standard: Low risk 4. Flow and timing: High risk - unclear how the system performed with regard to women who had an intervention for birth but a normal perinatal outcome
Full citation Mongelli,M., Dawkins,R., Chung,T., Sahota,D., Spencer,J.A., Chang,A.M., Computerised estimation of the baseline fetal heart rate in labour: the low frequency line, British Journal of Obstetrics and Gynaecology, 104, 1128-1133, 1997 **Ref Id** 196506 **Country/ies where the study was carried out**	**Sample size** n = 60 CTG traces **Characteristics** <table><tr><td>Characteristic</td><td>%</td><td>Mean (SD)</td></tr><tr><td>Nulliparous</td><td>57</td><td></td></tr><tr><td>Induction of labour</td><td>25</td><td></td></tr><tr><td>Operative birth</td><td>55</td><td></td></tr></table>	**Tests** The fetal electrocardiogram signal was collected using a fetal scalp electrode. A computer algorithm was developed to estimate the baseline fetal heart rate, with an aim to produce a low frequency line that would be stable under noisy conditions yet responsive to both sudden and gradual changes. Values outside the range of 30 to 240 bpm were considered as noise and excluded from analysis	**Methods** Sixty 40-minute segments of intrapartum CTG records were selected from 60 different women. Traces were chosen on the grounds of complexity and potential difficulty in interpretation. The tracings were reproduced and sent to 12 clinical experts for their estimation of the baseline. Of these, 8 were NHS consultants or senior academics, and 4 were of senior registrar/lecturer status	**Results** The intraclass correlation between the computer and the panel of experts was in excess of 0.9. The 95% confidence interval (CI) for the difference in baseline between computer and experts was -12 to 15 bpm. The 95% CI for the difference in baseline between experts was -10 to 10 bpm	**Limitations** **Other information** ***QUADAS 2 criteria*** 1. Patient selection - low risk 2. Index test - low risk 3. Reference standard - low risk 4. Flow and timing - low risk

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
UK **Study type** Retrospective cohort study **Aim of the study** To develop a computerised algorithm for the determination of fetal heart rate baseline during labour **Study dates** Not reported **Source of funding** Not reported	<table><tr><td>Gestational age, weeks</td><td></td><td>39.8 (1.8)</td></tr><tr><td>Birthweight, g</td><td></td><td>3373 (447)</td></tr></table> **Inclusion Criteria** All women had electronic fetal monitoring because of perceived high fetal risks. Traces for this study were selected because of complexity and potential difficulty in interpretation **Exclusion Criteria** Not reported				
Full citation Nielsen, P. V., Stigsby, B., Nickelsen, C., Nim, J., Computer assessment of the intrapartum cardiotocogram. II. The value of compared with visual assessment, Acta Obstetricia et Gynecologica Scandinavica, 67, 461-4, 1988 **Ref Id** 454968 **Country/ies where the study was carried out** Denmark **Study type** Retrospective cohort study **Aim of the study** To compare the accuracy of a computer Cardiotocographic Assessment System (CAS) with that of four very skilled obstetricians' using the same set of CTGs **Study dates** Not reported **Source of funding**	**Sample size** Not reported; 50 CTG records **Characteristics** Pregnant women in the first stage of labour **Inclusion Criteria** Not reported **Exclusion Criteria** Not reported	**Tests** The computer Cardiotocographic Assessment System (CAS)	**Methods** The CTGs were assessed both by 4 obstetricians and the computer system as being normal or pathological. The 4 obstetricians, all experienced in EFM, had been working in the same department, using EFM routinely in all births. They were informed of the incidence of compromised infants (one-third). The newborn was declared compromised if the 1-minute Apgar score was below 7, or the umbilical arterial blood was acidotic (pH < 7.15 or standard base excess below -10 meq/l), or primary resuscitation was needed. The CAS operates as follows. 1) The first program automatically detects the CTG patterns (decelerations, accelerations, uterine contractions, baseline and resting tone) and describes these patterns by 17 variables (duration, amplitude, and area of each acceleration, deceleration, and contraction; level of baseline and resting tone; baseline variability; slope of the descending part of the deceleration, recovery time, and residual area for the ascending part; lag time and latency time. 2) The second program calculates 1) the number , 2) the mean value, 3) standard deviation, 4) and trend of each of the 17 variables for a chosen epoch of the CTG. This calculation results in 17x4=68 subvariables but 12 of these	**Results** Compared with individual obstetricians the computer system achieved the highest accuracy, and compared with the obstetrician obtaining the best accuracy, the result of the computer was significantly better. Computer assessment of 50 CTGs compared with 4 obstetricians' visual assessment <table><tr><td></td><td></td><td>**Fetal outcome**</td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td>**Normal**</td><td>**Compromised**</td><td>**Total**</td><td>**Fisher's test**</td><td>**Accuracy**</td></tr><tr><td>**Computer**</td><td>**N**</td><td>**32**</td><td>**5**</td><td>**37**</td><td>**<0.001**</td><td>**86%**</td></tr><tr><td></td><td>**P**</td><td>**2**</td><td>**11**</td><td>**13**</td><td></td><td></td></tr><tr><td>**Obstetricians**</td><td>**1 N**</td><td>**24**</td><td>**9**</td><td>**33**</td><td>**0.2**</td><td>**62%**</td></tr><tr><td></td><td>**1 P**</td><td>**10**</td><td>**7**</td><td>**17**</td><td></td><td></td></tr><tr><td></td><td>**2 N**</td><td>**28**</td><td>**11**</td><td>**39**</td><td>**0.2**</td><td>**66%**</td></tr><tr><td></td><td>**2 P**</td><td>**6**</td><td>**5**</td><td>**11**</td><td></td><td></td></tr><tr><td></td><td>**3 N**</td><td>**18**</td><td>**5**</td><td>**23**</td><td>**0.1**</td><td>**58%**</td></tr></table>	**Limitations** ***QUADAS 2 criteria*** 1. Patient selection - High risk; selection of CTGs was not reported to be random or consecutive 2. Index tests - High risk; not clear if the index test was interpreted without knowledge of the results of the reference standard 3. Reference standard - Low risk 4. Flow and timing - Low risk **Other information**

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
The development of the computer system was supported by the Danish Medical Research Council, grant numbers 12-3832, 5.52.13.16 and 12-3202			contain only duplicate information, leaving 56 subvariables to be considered in the assessment of the CTG. 3) The third program calculates the probability of the CTG belonging to a compromised infant. This probability is calculated by a discriminant function, and a CTG is considered pathological if the probability is above 0.5. The computer system's calculation of the probability of a compromised infant was for each CTG based on the experience from the other 49 CTG thus excluding the possibility of 'self-recognition'. The best combination of subvariables was found by minimising the average probability of misclassification		

	3 P	**16**	**11**	**27**		
	4 N	**20**	**11**	**31**	**8.8**	**50%**
	4 P	**14**	**5**	**19**		
Total		**34**	**16**	**50**		

N=CTGs assessed as normal; P=CTGs assessed as pathological

	Sensitivity (95% CI)	Specificity (95%)	LR+ (95% CI)	LR- (95% CI)
Computer	68.8 (41.48-87.87)	94.12 (78.94-98.97)	11.7 (2.93-46.67)	0.33 (0.16-0.69)
Obs 1	43.75 (20.75-69.45)	70.59 (52.33-84.29)	1.49 (0.69-3.19)	0.8 (0.50-1.26)
Obs 2	31.3 (12.113-58.52)	82.4 (64.83-92.61)	1.77 (0.63-4.95)	0.83 (0.59-1.18)
Obs 3	68.8 (41.48-87.87)	52.9 (35.40-69.84)	1.5 (0.90-2.38)	0.6 (0.27-1.29)
Obs 4	31.3 (12.13-58.52)	58.8 (40.83-74.87)	0.8 (0.33-1.74)	1.2 (0.81-1.69)

"Sensitivity, specificity and likelihood ratios calculated by the NGA technical team using http://vassarstats.net/clin1.html"

Full citation	Sample size	Tests	Methods	Results	Limitations
Parer,J.T., Hamilton,E.F., Comparison of 5 experts and computer analysis in rule-based fetal heart rate interpretation, American Journal of Obstetrics and Gynecology, 203, 451-457, 2010 **Ref Id** 169819 **Country/ies where the study was carried out** USA	N = 30 CTG traces **Characteristics** Not reported **Inclusion Criteria** Singleton, term pregnancies with umbilical blood gas analysis present **Exclusion Criteria** Not reported	PeriCALM computer software was used for CTG analysis. This software follows a strict rule-based system to classify the CTG based on fetal heart rate baseline, variability, and decelerations (depth, duration and timing). The scoring system results in a five-level classification system for CTGs. For a CTG to be coded as green (category 1) all features must be within normal limits. Progressively abnormal traces are coded as blue, yellow, orange and red.	The CTGs were shown to five experts who were asked to follow the same strict, rule-based system to interpret the traces. The experts were given a copy of the rules and encouraged to follow them, even if they disagreed with them, as the purpose of the study was to assess concordance when using the rules. The percentage of exact agreement (where the computer assigned exactly the same colour category as the observers) was calculated, using the individual scores of each expert. The percentage of majority agreement was also	**Exact agreement with all clinical decisions** Computer software, % (95% CI): 44.9% (43.4 - 46.5)* Experts (average agreement for all experts), % (95% CI): 45.5% (42.1 - 48.4) **Exact agreement with majority clinical decisions** Computer software, % (95% CI): 56.8% (52.6 - 61.0)* Computer software, κ statistic: 0.52 (no CI reported) Experts (average agreement for all experts), % (95% CI): 56.7% (49.4 - 63.9) Experts, κ statistic (95% CI): 0.58 (0.48 - 0.68) **Close agreement with majority clinical decisions** Computer software, % (95% CI): 83.1% (79.7 - 86.1)* Experts (average agreement for all experts), % (95% CI): 88.6% (80.8 - 96.4) * Confidence interval (CI) calculated by the NGA technical team using http://statpages.info/confint.html	**Other information** ***QUADAS 2 criteria*** 1. Patient selection - high risk; selection of CTGs is not well reported, and it may not represent the population in whom this method would be used 2. Index tests - low risk 3. Reference standard - unclear risk; a specific 'rule-based' system was used by the experts to interpret the CTG for this study; this is likely to differ from how experts interpret

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Study type Retrospective cohort study **Aim of the study** To measure agreement between five expert clinicians and a computerised method with a strict rule-based method of CTG interpretation **Study dates** Not reported **Source of funding** No external funding reported			calculated to assess how often the computer agreed with the score given by the majority of experts for any particular CTG segment. Finally, the percentage of 'close' agreement was calculated (when the computer assigned scores ± 1 category of the majority agreement). Agreement between experts was calculated in the same way		the CTG in clinical practise 4. Flow and timing - low risk
Full citation Taylor,G.M., Mires,G.J., Abel,E.W., Tsantis,S., Farrell,T., Chien,P.F., Liu,Y., The development and validation of an algorithm for real-time computerised fetal heart rate monitoring in labour, BJOG: An International Journal of Obstetrics and Gynaecology, 107, 1130-1137, 2000 **Ref Id** 197103 **Country/ies where the study was carried out** UK **Study type** Prospective cohort study **Aim of the study** To develop and validate a computerised algorithm for the interpretation of the characteristics of the intrapartum CTG **Study dates** Not reported **Source of funding** Not reported	**Sample size** n = 24 CTG traces taken from a total of 30 labours **Characteristics** Characteristic / n/N / median (range) / mean (SD) Induction of labour / 16/30 / / Maternal age, years / / 27.5 (18-35) / Primiparous / 16/30 / / Duration of labour, minutes / / 484 (143 - 1155) / Operative vaginal birth / 6/30 / / Caesarean section / 7/30 / / Birthweight, g / / / 3538 (526) Gestational age, weeks / / / 40.1 (1.6) Admission to SCBU / 0/30 / / SCBU: special care baby unit **Inclusion Criteria** Women in active labour or undergoing induction of labour	**Tests** Cardiotocograms were recorded using a fetal scalp electrode. A computer algorithm was developed to identify key features of the CTG, including baseline fetal heart rate, fetal heart variability, accelerations and decelerations	**Methods** The cardiotocograms were analysed independently by 7 reviewers, all of whom were senior obstetric staff (consultants or senior specialist registrars) who were actively involved in the labour ward. Each reviewer assessed the baseline heart rate, the number of accelerations and the number and type of decelerations. The inter-rater reliability of the components of the CTG for the expert reviewers, and the validity of the computer algorithm were assessed with the intra-class correlation coefficient for continuous variables (baseline heart rate, number of accelerations, number of decelerations), and by the kappa statistic for dichotomous variables (baseline variability). 24 CTGs were randomly chosen for review	**Results** **Inter-rater reliability between expert reviewers** Baseline fetal heart rate: intraclass correlation coefficient 0.93 Number of decelerations: intraclass correlation coefficient 0.93 Number of late decelerations: intraclass correlation coefficient 0.79 Number of accelerations: intraclass correlation coefficient 0.27 Baseline variability: κ statistic 0.27 **Validity of computerised algorithm when compared to expert reviewers** Baseline fetal heart rate: intraclass correlation coefficient 0.91 to 0.98 Number of decelerations: intraclass correlation coefficient 0.82 to 0.92 Number of late decelerations: intraclass correlation coefficient 0.68 to 0.85 Number of accelerations: intraclass correlation coefficient 0.06 to 0.80 Baseline variability: κ statistic 0.00 to 0.34	**Limitations** **Other information** ***QUADAS 2 criteria*** 1. Patient selection - Unclear risk; methods of participant recruitment are not reported 2. Index tests - Low risk 3. Reference standard - Low risk 4. Flow and timing - Unclear risk; it is not clear why 30 CTGs were recorded, but only 24 'randomly' selected for use in the study; methods for random selection are not reported

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	Exclusion Criteria Not reported				
Full citation Todros,T., Preve,C.U., Plazzotta,C., Biolcati,M., Lombardo,P., Fetal heart rate tracings: observers versus computer assessment, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 68, 83-86, 1996 **Ref Id** 196732 **Country/ies where the study was carried out** Italy **Study type** Retrospective cohort study **Aim of the study** To assess the reproducibility of CTG interpretation among observers and between observers and a computerised system **Study dates** Not reported **Source of funding** The Italian National Research Council	**Sample size** N = 63 CTG recordings **Characteristics** Not reported **Inclusion Criteria** High- and low-risk pregnancies between 30 and 41 weeks of gestation **Exclusion Criteria** Not reported	**Tests** A 25 minute strip of CTG from each of 63 tracings was randomly chosen. The 2CTG computerised system was used to analyse the traces. The computer output variables included in the analysis were: baseline heart rate, the amplitude bandwidth around the baselines (a measure of long-term variability), the number of accelerations, and the number and timing of decelerations	**Methods** Four observers independently assessed the CTG traces for the same variables. Two of the observers were consultants with experience of reading CTGs (experts) and 2 were residents with 1 year of experience (non-experts)	**Results** **Reproducibility among observers** Baseline fetal heart rate: κ statistic 0.65 Variability: κ statistic 0.38 Accelerations: κ statistic 0.58 Number of decelerations: κ statistic 0.67 Type of decelerations: κ statistic 0.05 **Concordance between expert observers and the computer system** Baseline fetal heart rate: κ statistic 0.18 to 0.48 Variability: κ statistic 0.16 to 0.74 Accelerations: κ statistic 0.58 to 0.64 Number of decelerations: κ statistic 0.41 to 0.45 **Concordance between non-expert observers and the computer system** Baseline fetal heart rate: κ statistic 0.24 to 0.36 Variability: κ statistic 0.65 to 0.69 Accelerations: κ statistic 0.37 to 0.48 Number of decelerations: κ statistic 0.54	**Limitations** CTG traces used were from women at 30 to 41 weeks of gestation. It is unclear whether the recordings were all made intrapartum, or whether some were taken antenatally **Other information** ***QUADAS 2 criteria*** 1. Patient selection - high risk; CTGs included those from premature gestations, and it is unclear whether all women were in labour at the time of monitoring 2. Index tests - low risk 3. Reference standard - low risk 4. Flow and timing - low risk
Full citation Wolfberg,A.J., Derosier,D.J., Roberts,T., Syed,Z., Clifford,G.D., Acker,D., Plessis,A.D., A comparison of subjective and mathematical estimations of fetal heart rate variability, Journal of Maternal-Fetal and Neonatal Medicine, 21, 101-104, 2008 **Ref Id** 169793	**Sample size** n = 30 CTG traces **Characteristics** Apgar scores for all infants were greater than 6 at both 1 and 5 minutes, and there were no neonatal complications for any of the newborns **Inclusion Criteria** Women in labour who had a fetal scalp electrode positioned for clinical indications. Singleton pregnancies, between 35 and 41 weeks' gestation **Exclusion Criteria** Not reported	**Tests** Mean fetal heart rate was calculated over a 10 minute period for each of the CTG recordings. The variance was then calculated for the same period. The standard deviation was used as the computed measure of fetal heart rate variability	**Methods** Four perinatologists with recognised expertise in CTG interpretation were asked to assess the variability for the same 10 minute segments of CTG. They were asked to give a value for the variability (to the closest integer, not a range) and to rate the variability according to NICHD criteria as absent, minimal, moderate, marked or sinusoidal	**Results** **Correlation between the computer analysis and the (average) expert interpretation of variability** Intraclass correlation coefficient 0.62 (range 0.27 to 0.68) **Correlation between the expert interpretation of variability** Intraclass correlation coefficient 0.44 (range 0.33 to 0.72)	**Limitations** Correlation was reported for determining the absolute variability for the fetal heart rate (i.e. a specific value). The computerised results were not further categorised into categories of variability according to the NICHD criteria. Therefore the correlation between the computer and experts for different categories of variability was not reported **Other information**

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Country/ies where the study was carried out USA **Study type** Retrospective cohort study **Aim of the study** To develop a computer algorithm to determine baseline fetal heart rate variability, and compare it to clinicians' interpretation **Study dates** Not reported **Source of funding** Not reported					***QUADAS 2 criteria*** 1. Patient selection – unclear risk; insufficient data were reported with regard to selection of participants 2. Index tests – low risk 3. Reference standard – low risk 4. Flow and timing – low risk