NICE National Institute for Health and Care Excellence

2017 surveillance of caesarean section (NICE guideline CG132)

Surveillance report

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Contents

Surveillance decision

We will plan an update of the following clinical areas:

- Woman-centred care
- Procedural aspects

We will amend the following recommendations:

1. Recommendation 1.4.5.4

- A footnote is to be added with reference to the HES products drug safety update.

2. Recommendation 1.4.5.6

- A footnote is to be added explaining that proton pump inhibitors are not licensed for this indication.

3. Recommendation 1.6.3.1

- A footnote is to be added explaining that injectable formulations of diamorphine aren't licensed for intrathecal or epidural use (off-label).

4. Recommendation 1.7.1.2

- A footnote is to be added explaining two MHRA warnings related to the use of codeine and ibuprofen.

Reason for the decision

We found 307 new studies through surveillance of this guideline. New evidence that could affect recommendations was identified. Topic experts, including those who helped to develop the guideline, advised us about whether the following sections of the guideline should be updated and new questions added:

Woman-centred care

- Planning mode of birth – what are the risks and benefits of planned caesarean section (CS) compared with planned vaginal birth for both women and babies?

Topic experts highlighted there is a need to consider long-term outcomes when planning the mode of birth. Evidence was identified about CS and its impact on maternal outcomes (risk of future ectopic pregnancy, stillbirth or miscarriage, sub-fertility) and infant outcomes (cerebral palsy, childhood obesity, asthma, bowel disease, and iron-related haematological indices).

Decision: This question should be updated.

Procedural aspects

- Surgical techniques for CS – use of antibiotics – methods to reduce infectious morbidity at CS.

New evidence was identified in three areas: preoperative skin preparation, vaginal preparation, and of intra-abdominal irrigation. Topic experts advised that this area should be updated.

Decision: This question should be updated.

- New review question – procedures to prevent and manage hypothermia and shivering in women having a CS.

NICE guideline CG132 does not include guidance about prophylaxis and management of hypothermia and shivering in women undergoing to CS. Evidence was identified around procedures to prevent and manage hypothermia and shivering in women having a CS. In NICE guideline CG65 hypothermia: prevention and management in adults having surgery, pregnant women are out of scope. In the previous surveillance review of NICE guideline CG65 they considered that the best place to address this issue is in NICE guideline CG132.

Decision: This question should be added.

Other clinical areas

We also found new evidence that was not thought to have an effect on current

recommendations. This evidence related to provision of information, planned CS, factors reducing the likelihood of CS, procedural aspects of CS, surgical techniques for CS, care of the baby born by CS, care of the women after CS, recovery following CS; and pregnancy and childbirth after CS.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all the new evidence and views of topic experts, we decided that a partial update is necessary for this guideline.

See how we made the decision for further information.

Commentary on selected new evidence

With advice from topic experts we selected 3 studies for further commentary.

Woman-centred care – planning mode of birth

We selected three systematic reviews for a full commentary: Bruce A et al. (2014), Darmasseelane K et al. (2014) and Huang L et al. (2015). We selected these because they assessed the impact of caesarean section (CS) on three different long-term outcomes for the baby: bowel disease (Bruce A et al.), obesity (Darmasseelane K et al.), and asthma (Huang L et al.). When we identified more than one systematic review for the same outcome, we selected the systematic review with the highest quality.

What the guideline recommends

NICE guideline CG132 (1.1.2.1) recommends to discuss with women the risk and benefits of CS and vaginal delivery (VD) including their circumstances, concerns, priorities and plans for future pregnancies. Linked to the recommendation there is box that describes the impact of CS on different maternal and neonatal outcomes including: perineal and abdominal pain during birth and three days postpartum, injury to vagina, early postpartum haemorrhage, obstetric shock, admission to neonatal intensive care unit, hospital stay, hysterectomy caused by postpartum haemorrhage, and cardiac arrest.

Bruce A et al. (2014) – Impact of caesarean section on risk of inflammatory bowel disease

Methods

The systematic review by Bruce A et al. (2014) assessed the impact of CS on the risk of development of inflammatory bowel disease (IBD). The definition of IBD included the development of Crohn's disease (CD) or ulcerative colitis (UC). A protocol of the study was published before the review was conducted. Searches were conducted in three databases and the search terms (and years) used were described in the text. These searches were supplemented by reviewing the references of relevant articles identified. Two authors independently selected studies for inclusion. They included cohort, case-control or trial

design in which CS was included as an exposure or intervention. Only published studies that included development of IBD (CD or UC) and the diagnosis was confirmed or reported by the patient were included.

Information about the data extraction process was not described in the paper. It included information about study characteristics and results. They assessed the risk of bias of each included study using the CASP quality assessment tool.

The authors performed a meta-analysis of the risk of developing IBD after CS compared with vaginal delivery (VD). They calculated unadjusted odd ratios (OR) and 95% confidence intervals (95% CI) for this outcome. The selection of the model to calculate the pooled risk ratios and 95% CI and the methods to assess and explore potential causes of statistical heterogeneity were not described. They did sensitivity analysis to explore the effect size (and direction) by study design or the sources of data used. A risk assessment for publication bias was also performed but the funnel plot or statistical analyses used were not reported.

Results

Seven observational studies (four retrospective cohorts and three case-control studies) covering 4,058,117 people were included in the systematic review. The included studies varied in their methodology and follow-up time. All the included studies adjusted their results by confounding factors.

The biases identified in the included studies were those inherent to the study design. Two studies were conducted in Germany, one in Denmark, one in Australia, one in Norway, one in Sweden, and one in the UK. Five studies used population-based registers and two studies were in patients with IBD attending ambulatory care clinics.

CS was not associated with a significant increase in the risk of IBD including UC or CD (OR 1.00, 95% CI 0.75 to 1.33, 7 studies). There was a minor discrepancy between the results of the I^2 test reported in the text (89%) and in the forest plot (90%). The systematic review conducted sensitivity analysis by population-based studies including cohort and case-control studies or only cohort studies. The sensitivity analyses found similar results. However, a significant association between CS and an increased risk of IBD was identified when the analysis were restricted to case-control studies using questionnaires to collect the data.

The authors detected risk of publication bias of small studies with positive results but they did not consider that these findings affected their results.

Strengths and limitations

Strengths

- The review followed a protocol previously published.
- More than two databases were searched and the references of relevant studies found were reviewed.
- Two reviewers selected the included studies.
- CASP quality assessment tool was used to assess the quality of the included studies.
- Authors assessed the risk of publication bias.

Limitations

- It was unclear if two reviewers did the data extraction.
- A validated tool was used to assess the quality of the included studies but the results were not well documented.
- It was unclear the methods followed to calculate the pooled risk ratios and 95% CI or how they assessed the statistical heterogeneity. In some of the analysis, the values of I^2 identified may represent substantial statistical heterogeneity (I^2=89%) but authors considered them as low heterogeneity and they did not describe strategies for exploring any potential sources for heterogeneity. There is a discrepancy between the results described in the text and the results showed in the figures.
- It was unclear how different characteristics of the interventions assessed impacted on the results including for example type of CS (planned or emergency CS), type of VD (spontaneous or instrumental VD) or if the results varied by type of IBD (CD or ID).

Darmasseelane K et al. 2014 – Impact of caesarean section on risk of obesity

Methods

The systematic review evaluated the impact of CS compared with VD on baby body mass index (BMI), and development of overweight (BMI more than 25) and obesity (BMI more then 30) in life.

The study followed a protocol published before the review was conducted. Searches were conducted in three databases and no language or study type filters were applied. The search terms (and years) used were described in the text. The searches were supplement by reviewing the references in the studies found. Two authors independently selected studies for inclusion. The studies were included if they reported data related to delivery mode and BMI in the adulthood, delivery mode with follow-up until adulthood, or adult BMI with birth characteristics.

Two reviewers did the data extraction. The data extracted included information about general characteristics of the studies and results. They used the modified Newcastle–Ottawa scale to assess the risk of bias of each included study.

The authors performed a meta-analysis for the risk of being overweight or obese associated with the mode and calculated the mean BMI difference associated to mode of delivery using the inverse-variance method. Only unadjusted estimates were reported. The statistical heterogeneity was assessed and if it was considered to have an impact on the result a random-effects model was preferred. Pre-specified subgroup analyses were performed by gender and type of CS. An extension of subgroup analyses was performed through meta-regression analyses to investigate the impact of offspring age on the results. The risk of publication bias was also assessed.

Results

Fifteen studies were included covering 163,753 people. Ten studies were conducted in European countries, one in USA, and the others in China (one), India (one), Brazil (two).

CS was associated with an increased BMI compared with VD (unadjusted mean difference 0.44 $kg.m^{-2}$,95% CI 0.17 to 0.72,12 studies, n=37,798, I^2=39%). CS was also associated with higher risk of overweight (unadjusted OR 1.26, 95% CI 1.16 to 1.38, 12 studies, n=37,338,

I^2=0%) and obesity compared with VD (unadjusted OR 1.22, 95% CI 1.05 to 1.42, 11 studies, n=37,622, I^2=22%).

Similar findings were identified when the results were analysed by gender. In men CS was associated with an increased BMI and higher risk of overweight and obesity compared with VD. In women no differences were identified in the BMI, however CS was associated with an increased higher risk of overweight and obesity. This gender difference was not statistically significant in the meta-regression analysis. No differences were identified when comparing emergency CS with VD or planned CS with VD in BMI, overweight and obesity. Sensitivity analysis by studies including siblings or errors in data collection was performed and their exclusion did not affect the findings. The impact of the quality of included studies on the results was also explored. High quality studies were associated with a higher effect estimates in all the outcomes assessed.

Strengths and limitations

Strengths

- The review followed a protocol previously published.
- Authors performed a comprehensive literature research.
- Two reviewers participated in the selection process of the included studies and two reviewers did the data extraction.
- Quality of the included studies was assessed and documented.
- They used appropriate methods for combining findings. They assessed and explored the causes of heterogeneity. Sensitivity analyses were performed to determine the impact of the quality of the studies on the results.
- They assessed the risk of publication bias.

Limitations

- Most of the studies included the CS being conducted before the 1990s, so these might not represent the current practice.
- Unadjusted estimates were used and the impact of confounding factors on the results remains unclear. Thus, conclusions need to be interpreted with caution.

Huang L et al. 2014 – Impact of caesarean section on risk of asthma

Methods

The systematic review by Huang L et al. (2014) assessed impact of CS on the risk of asthma in children. Searches were conducted in four databases. Two reviewers independently selected studies for inclusion. Primary studies that reported relevant data in children were included. Two reviewers did the data extraction. The data extracted included information about general characteristics of the studies and their results. Authors did not report if they did a risk of bias assessment of the included studies.

Adjusted and unadjusted estimates were used. The authors performed a meta-analysis for the risk of asthma associated with delivery mode. Methods to pool the effect estimates were described and the authors assessed the statistical heterogeneity of the results founded. Potential sources of heterogeneity were explored using a meta-regression analysis. Authors included in the model the study design, year of publication, outcome definition, and age of diagnosis. A risk assessment for publication bias was also carried out using a funnel plot.

Results

A total of 26 cohort studies were included (n=not reported) most of them conducted in European countries. Five studies were conducted in UK, four in Netherlands, four in Sweden, three in Finland, and other five in other European countries (Norway, Denmark, and Sweden). Three studies conducted in US, one in New Zealand and one in Korea were also included.

CS section was associated with increased risk of asthma in children (OR 1.16, 95% CI 1.14 to 1.19, 26 studies, I^2=24.6%). Six of the included studies in this meta-analysis reported only crude odds ratios. No risk of publication bias was detected for this outcome. Both planned CS and emergency CS were associated with an increased risk of asthma in children compared with VD. The OR for planned CS was 1.21 (95% CI 1.17 to 1.25, I^2=39.9%) and for emergency CS was 1.23 (95% CI 1.19 to 1.26, I^2=84.8%). Studies with unadjusted estimates were included in these meta-analyses as well. The heterogeneity in the emergency CS pooled estimate was explored. Subgroup analyses showed higher effect estimates in studies in which the diagnosis was made by a physician than those using self-reported questionnaires, and in retrospective cohort studies than in prospective cohort

studies.

Instrumental VD was also associated with an increased risk of asthma compared with spontaneous VD in children (OR 1.07, 95% CI 1.01 to 1.11, seven studies, I^2=54.9%). No risk of publication bias was detected for this outcome.

Strengths and limitations

Strengths

- The impact of different type of delivery mode (planned CS, elective CS, spontaneous VD or instrumental VD) on the results was assessed.
- They assessed the risk of publication bias for the main important outcomes studied.

Limitations

- The authors did not explain if a protocol was set before the systematic review was started, so reporting bias could not be excluded.
- The search was limited in the terms used and the inclusion criteria were not clearly defined.
- Two reviewers did the abstract sifting but the full text review process was not reported.
- Authors did not mention if they did a risk of bias assessment of the included studies, therefore it is unclear if the included studies were at a high risk of bias.
- The authors included studies that provided information about mode of delivery and risk of asthma regardless if it was the primary aim of the study or not. But this information was not reported in the results section.
- Adjusted and crude effect estimates were included in the same meta-analyses. The authors explored causes of heterogeneity by study designs, year of publication, outcome definition, and age. However, other analyses by type of effect estimate (adjusted or unadjusted) were not performed.
- All the included studies were published after 2000 but in twenty studies the year of birth was before 2000, so these might not represent the current practice.

Impact on guideline

These three systematic reviews assessed the impact of CS on three different long-term outcomes for the baby. All the systematic reviews included observational studies, most of the included studies were conducted in European countries. Therefore their results could be considered relevant to the guideline. However these studies also have important limitations that could have an impact on the results. The studies are not well enough designed to give reliable evidence on causation, all have important methodological limitations and therefore their results most be interpreted with caution.

Topic experts highlighted that it is important to discuss with women these and other long-term outcomes when considering the benefits and risk of CS and other alternatives. Long-term outcomes for babies are not currently included in NICE guideline CG132, therefore the new evidence identified could have an impact on current NICE guideline CG132 recommendations.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on surveillance 4 years after the publication of caesarean section (2011) NICE guideline CG132.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

New evidence

We found 284 new studies in a search for randomised controlled trials and systematic reviews published between 25 September 2012 and 19 January 2016. We also considered 3 additional studies identified by members of the guideline committee who originally worked on this guideline.

Evidence identified in a previous evidence update (2013), surveillance review (2014), and rapid review (2015) was also considered. This included 16 studies identified in the evidence update (2014) and surveillance review (2014), and 4 studies identified in the rapid review (2015).

From all sources, 307 studies were considered to be relevant to the guideline.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review of the guideline.

See appendix A for all new evidence considered.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline and other correspondence we have received since the publication of the guideline. This included a workshop with experts to discuss potential areas for update.

Views of stakeholders

Stakeholders are consulted only if we decide not to update the guideline following checks at 4 and 8 years after publication. Because this was a 4-year surveillance review, and the decision was to update, we did not consult on the decision.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

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