

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Insertion of a double balloon catheter for induction of labour in pregnant women without previous caesarean section

In late pregnancy, if the cervix does not dilate fully, several methods can be used to encourage the cervix to open and induce labour. In this procedure, a thin plastic tube (catheter) is passed through the cervix from the vagina to the uterus. Two small balloons on the catheter are inflated either side of the cervix, one inside the uterus and one in the vagina, with the aim of causing the cervix to dilate and inducing labour.

The National Institute for Health and Care Excellence (NICE) is examining insertion of a double balloon catheter for induction of labour in pregnant women and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about insertion of a double balloon catheter for induction of labour in pregnant women.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 27 April 2015

Target date for publication of guidance: July 2015

1 Provisional recommendations

- 1.1 Current evidence on the efficacy and safety of insertion of a double catheter balloon device for induction of labour in women without previous caesarean section is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

2 Indications and current treatments

- 2.1 Induction of labour is the most commonly performed obstetric intervention. It is done in up to 20% of pregnancies in the UK and is generally carried out when the risks of continuing pregnancy outweigh the benefits. It is usually more painful than spontaneous labour, and epidural analgesia and assisted delivery are more likely to be needed. Maternal and fetal indications for induction of labour include pregnancy-induced hypertensive disorders, diabetes, post-term pregnancy, estimated large-for-date fetus, thrombophilia, intra-uterine fetal growth restriction, oligohydramnios, non-reassuring fetal status and fetal death.
- 2.2 Various methods are used to ripen and dilate the cervix and successfully induce labour in women when the cervix is unfavourable for induction. These include pharmacological methods (prostaglandins in the form of vaginal gels or tablets, or pessaries, and oxytocin as a slow intravenous infusion), surgical methods (amniotomy, alone or with oxytocin) and mechanical methods (laminaria tents and balloon catheters introduced through the cervix into the cervical canal and the extra-amniotic space). The aim of mechanical interventions is to ripen and dilate the cervix and promote onset of labour by applying pressure on the internal cervical os, by indirectly increasing local secretion of prostaglandin and oxytocin, or both. Also, mechanisms that involve neuroendocrine reflexes may promote the onset of uterine contractions. A standard Foley urinary catheter is commonly used, with the balloon inflated in the extra-amniotic space and the catheter then put under tension to pull back against the cervical os. Sometimes saline solution is infused into the extra-amniotic space as an adjunct.

3 The procedure

- 3.1 Insertion of a double balloon catheter for induction of labour at term in pregnant women aims to facilitate induction through causing dilation of the cervix when the cervix is unfavourable for induction. The double balloon is claimed to stimulate local prostaglandin release, which leads to cervical ripening, through the 2 balloons squeezing the cervix.
- 3.2 The procedure is usually done with the woman in a lithotomy or supine position. A sterile speculum is inserted into the vagina to gain access to the cervix. The cervix is then prepared by cleaning with an appropriate antiseptic solution before inserting the device. A double balloon catheter (with a uterine balloon and a vaginal balloon) is inserted through the cervical canal and into the uterus, so that the tip of the catheter lies in the extra-amniotic space. The uterine balloon is then inflated with a small amount of saline and the catheter is gently pulled back until the uterine balloon lies against the internal cervical os. The vaginal balloon is also inflated with saline so that it lies against the external cervical os. Both the balloons are inflated with alternative increments of small amounts of saline. When the balloons are fully inflated and in place on both sides of the cervix, the speculum is removed. The external end of the device is loosely taped to the woman's inner thigh.
- 3.3 Following the insertion of the double balloon, a fetal non-stress test is done and sometimes extra-amniotic saline is infused at the same time. The mother and fetus are monitored and the device is left in place for up to about 12 hours. If labour begins, or spontaneous device expulsion or rupture of membranes have occurred, or if fetal distress is suspected, the balloons are deflated and the device is

removed to facilitate labour management. If labour does not begin spontaneously, the membranes are ruptured artificially and oxytocin infusion is started.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 A nested study (n=186) within a quasi-randomised controlled trial (RCT) of 188 pregnant women, comparing double balloon catheter (DBC) plus extra-amniotic saline infusion (EASI; n=60) against single balloon catheter (SBC) plus EASI (n=126) reported that 'ripening success' (defined as an increase in Bishop score of 2 points or more with or without cervical dilation of 3 cm or more) was similar between the DBC and SBC groups (96% versus 93% respectively; p=0.55).
- 4.2 An RCT of 330 nulliparous pregnant women with unfavourable cervixes compared 3 methods (DBC [n=107], versus SBC [n=110] versus prostaglandin gel [dinoprostone, n=113]) for induction of labour at term. The induction-to-delivery interval was longer in the DBC group (median 24.5 hours, 95% confidence interval [CI] 23.7 to 30.6) than the SBC group (median 23.2 hours, 95% CI 20.8 to 25.8) or the prostaglandin gel group (23.8 hours, 95% CI 21.7 to 26.8) (a single p value of 0.043 was cited). A quasi-RCT of 188 women at term with singleton pregnancy comparing DBC (n=100) against SBC plus EASI (n=88) for induction of labour reported that time from device insertion to delivery was significantly longer in the DBC group compared with the SBC plus EASI group

(20.5 hours versus 17.3 hours respectively; $p=0.03$). The nested study ($n=186$) in this RCT, comparing DBC plus EASI ($n=60$) against SBC plus EASI ($n=126$) reported balloon insertion to delivery interval was significantly shorter in the DBC plus EASI group compared with the SBC plus EASI group (14.2 hours versus 15.5 hours respectively; $p=0.04$).

- 4.3 The RCT of 330 nulliparous pregnant women with unfavourable cervixes comparing 3 methods (DBC [$n=107$], versus SBC [$n=110$] versus prostaglandin gel [$n=113$]) reported no difference in caesarean delivery rates between any of the groups (DBC 43% versus SBC 36% versus prostaglandin gel 37%; a single p value of 0.567 was cited). The nested study ($n=186$) within the quasi-RCT of 188 women, comparing DBC plus EASI ($n=60$) against SBC plus EASI ($n=126$), reported that caesarean section delivery rate was significantly lower in the DBC group than the SBC group (8% versus 20% respectively; $p=0.05$).
- 4.4 An RCT of 210 pregnant women with unfavourable cervixes, comparing DBC ($n=105$) against prostaglandin gel ($n=103$), reported that more women in the DBC group had a vaginal delivery within 24 hours than those in the prostaglandin gel group (69% versus 49% respectively; odds ratio 2.22; 95% CI, 1.26 to 3.91). An RCT of 326 pregnant women with an unfavourable cervix at term comparing DBC plus oral misoprostol ($n=162$) against oral misoprostol alone ($n=151$) reported that the rate of spontaneous vaginal delivery within 48 hours did not differ significantly between the groups (80% [$101/162$] versus 85% [$90/106$] respectively; $p=0.29$).

- 4.5 The nested study (n=186) within the quasi-RCT of 188 patients, comparing DBC plus EASI (n=60) against SBC plus EASI (n=126), reported that there was no significant difference in maternal satisfaction (assessed on a scale of 1–10, with higher scores indicating greater satisfaction; 7.7 in the DBC group versus 7.0 in the SBC group, p=0.42). An RCT of 122 women, comparing DBC plus oral misoprostol (n=59) against oral misoprostol alone (n=63) reported that women were not ‘bothered’ by the placement of DBC (70% [28/40], p=0.017) or by the presence of the catheter (75% [30/40], p=0.002). They also reported a significant positive birth experience (on the German language version of Salmon Item List score) in the DBC plus misoprostol group compared with the misoprostol alone group (87.7 versus 79.3 respectively; p=0.030).
- 4.6 In the RCT of 326 pregnant women comparing DBC plus oral misoprostol (n=162) against oral misoprostol alone (n=151) Apgar scores of less than 7 (at 5 minutes) were reported more in the DBC plus oral misoprostol group than in the oral misoprostol alone group (8 versus 1 respectively; p=0.04). In the quasi-RCT of 188 patients and the nested study (n=186), Apgar scores of less than 7 (at 5 minutes) were similar between the study groups.
- 4.7 The specialist advisers listed efficacy outcomes as the proportion of women having a vaginal birth or caesarean delivery; the interval from commencement of induction to delivery; and the change in Bishop’s score to enable artificial rupture of membranes (a score of 8 or more indicates that the cervix is ripe).

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more
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detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Uterine tachysystole was significantly lower in the double balloon catheter (DBC) group than the prostaglandin gel group (5% [3/67] versus 17% [10/59] respectively, $p=0.04$), as was non-reassuring fetal heart rate (2% [1/67] versus 15% [9/59] respectively; $p=0.01$) in a randomised controlled trial (RCT) of 126 women with oligohydramnios and unfavourable cervixes.
- 5.2 'Fetal malpresentation after catheter removal' was reported in 2 women in the DBC group (1 had a fetus with face presentation and 1 had a fetus with a transverse lie) in an RCT of 302 pregnant women (293 in the final analysis) comparing DBC ($n=148$) against single balloon catheter (SBC; $n=145$). One woman had a vaginal delivery after an external cephalic version was performed and 1 had a caesarean section.
- 5.3 Cord prolapse was reported in 1 woman in the DBC group in the RCT of 302 pregnant women comparing DBC ($n=148$) against SBC ($n=145$). She had an emergency caesarean delivery.
- 5.4 Cord blood pH was lower in the prostaglandin gel group than the DBC and SBC groups (median arterial pH: prostaglandin gel group 7.25, DBC group 7.26, SBC 7.26; a single p value of 0.05 was cited) in an RCT of 330 nulliparous pregnant women.
- 5.5 There was no statistically significant difference in the incidence of postpartum haemorrhage (that is, more than 1000 ml blood loss) between the DBC, SBC and prostaglandin gel groups (DBC 5% [5/107], SBC 5% [5/110], prostaglandin gel group 11% [12/113]; a

single p value of 0.143 was cited) in the RCT of 330 nulliparous pregnant women.

5.6 Birth canal injury was reported in 1 and 5 women respectively in the DBC and prostaglandin gel groups ($p=0.10$) in the RCT of 126 pregnant women.

5.7 Postpartum endometritis after caesarean section occurred in 1 woman in the DBC plus oral misoprostol group ($n=59$) and in no women in the oral misoprostol alone group ($n=63$) in an RCT of 122 pregnant women with unfavourable cervixes at term. Intrapartum fever was reported in 8 and 2 women respectively in the DBC and SBC groups ($p=0.10$) in the RCT of 302 pregnant women comparing DBC ($n=148$) against SBC ($n=145$).

5.8 Infection of the newborn occurred in 4 women in the DBC plus oral misoprostol group ($n=162$) and in 1 woman in the oral misoprostol alone group ($n=151$) in an RCT of 326 pregnant women with unfavourable cervixes at term (p values not reported).

5.9 Statistically significant differences in women's reported pain during cervical ripening (assessed on a visual analogue scale 0 to 10, higher scores representing maximum pain) between the DBC, SBC and prostaglandin gel groups (a pain score of more than 4 was reported in 55% of women in the DBC group, 36% in the SBC group, and 63% in the prostaglandin gel group, single p value <0.001 was cited) were described in the RCT of 330 nulliparous pregnant women. Pain perception during the insertion procedure was similar in the DBC plus extra-amniotic saline infusion (EASI) and the SBC plus EASI groups (assessed on a visual analogue scale of 1–10, higher scores representing worst pain; mean scores were 3.1 and 3.7 respectively; $p=0.19$) in a nested study ($n=186$)

within a quasi-RCT of 188 patients comparing DBC plus EASI (n=60) against SBC plus EASI (n=126). Maternal discomfort due to the device was reported in 5 patients in the DBC group (n=107) in the RCT of 330 women; 2 women were unable to void, 2 women had decreased balloon volume and, in 1 woman, the device was removed.

- 5.10 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: failed induction of labour and prolonged interval from 'commencement of induction to delivery'. They considered that the following were theoretical adverse events: rupture of membranes, scar rupture (if used in woman with previous caesarean section), infection, procedural pain and pain after insertion, bleeding and placental abruption.

6 Committee comments

- 6.1 The Committee noted that, in 1 study of insertion of a double catheter balloon device for induction of labour in women without previous caesarean section, using extra amniotic saline infusion may have conferred an advantage.
- 6.2 The Committee noted that randomised trials are in progress comparing this procedure against other methods for induction of labour.

7 Further information

7.1 For related NICE guidance, see the [NICE website](#).

Bruce Campbell

Chairman, Interventional Procedures Advisory Committee

March 2015