

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section

Complications during childbirth may result in the need for an emergency caesarean section. This can be difficult if the baby's head becomes fixed low down in the mother's pelvis. In this procedure, a silicone balloon device is inserted into the vagina and then inflated to help lift the baby's head and dislodge it from the pelvis, before starting the caesarean section.

The National Institute for Health and Care Excellence (NICE) is examining the insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section 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 the insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section.

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- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 19 December 2014

Target date for publication of guidance: March 2015

1 Provisional recommendations

- 1.1 Current evidence on the efficacy and safety of inserting a balloon device to disimpact an engaged fetal head before an emergency caesarean section is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance and audit or research.

1.2 Clinicians wishing to insert a balloon device to disimpact an engaged fetal head before an emergency caesarean section should take the following actions.

- Inform the clinical governance leads in their NHS trusts.
- [Audit](#) [*URL to audit tool to be added at publication*] and review clinical outcomes of all patients treated by the insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section (see section 7.1).

1.3 Further research and data collection should report the impact of performing the procedure on the time taken from the decision to perform a caesarean section to delivery of the baby. Technical failures, including the need for repositioning of the device and for subsequent manual disimpaction of the fetal head; and any complications resulting from use of the procedure should be recorded. Fetal outcomes should also be reported. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Obstructed labour poses considerable risks to a mother and her baby, often leading to the need for an emergency caesarean section. This can be difficult if the fetal head is fixed (engaged) deep within the mother's pelvis.

2.2 Two approaches are commonly used to disimpact an engaged fetal head. One involves the surgeon or midwife placing a hand through the vagina and pushing the baby's head back up the pelvis. This is often associated with vaginal tissue trauma. The other approach (reverse breech extraction) involves the surgeon delivering the baby's feet through the uterine incision, and then delivering the

head. This method is associated with fetal hip injury, shoulder injury and facial or neck trauma, and is avoided whenever possible. Difficulties in disimpacting an engaged fetal head often delay the delivery of an already compromised fetus. There is a risk of the complications described above and also risks of obstetric haemorrhage, injury to uterine vessels and trauma to the urinary tract.

3 The procedure

- 3.1 Insertion of a balloon device to disimpact an engaged fetal head aims to elevate the fetal head, without trauma, immediately before an emergency caesarean section, usually at full dilatation.
- 3.2 A disposable soft silicone balloon device is inserted vaginally, using a lubricant. It is pushed posteriorly towards the coccyx and placed between the pelvic floor and the fetal head, usually at full dilatation of the cervix. The balloon surface is in contact with the fetal head, while the base plate of the device rests on the anococcygeal ligament, preventing any downward movement during inflation. This is similar to the placement of a ventouse cup. Once the device is in position, the mother's legs are placed flat on the operating table, and the balloon is inflated using sterile saline via a tube connected to a two-way tap. The balloon is designed to inflate only in an upward direction. The engaged fetal head is elevated out of the pelvis by a few centimetres. The intention is to allow the surgeon to site the uterine incision slightly higher up on the lower segment of the uterus, on a wider and thicker part of the segment, so avoiding trauma to the utero-vesical reflection and making the delivery easier, with less manipulation. Immediately after delivery the balloon is deflated by opening the two-way tap, and the device is

removed from the vagina by traction. Following the procedure, the vagina is inspected for trauma.

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](#) *[add URL]*.

4.1 The review of evidence identified 1 non-randomised comparative study that compared women who had a balloon device inserted to disimpact an engaged fetal head before a caesarean section (n=50) against unmatched historical controls (n=124): women who had a second stage caesarean section. No other peer-reviewed studies were identified. All outcomes were considered to relate to efficacy unless they were safety outcomes that seemed to relate directly to the balloon device.

4.2 Maternal outcomes

4.2.1 No maternal deaths were reported in women in the balloon device group whereas maternal deaths were reported in 2% (2/124) of women in the control group (p=0.51).

4.2.2 The mean time between uterine incision and delivery was 2.79±0.4 minutes in the balloon device group and 8.43±1.7 minutes in the control group (p<0.001).

4.2.3 The mean time taken to complete caesarean sections was 31.8±4.6 minutes in the balloon device group and 52.1±10.7 minutes in the control group (p<0.001).

- 4.2.4 Extensions of uterine incisions that resulted in increased operating times, blood loss, or extensions that involved 1 or more uterine arteries, the cervix, vagina or other organs, were reported in 4% (2/50) of women in the balloon device group and 15% (19/124) in the control group ($p=0.03$).
- 4.2.5 Blood loss of more than 1 litre was reported in 2% (1/50) of women in the balloon device group and 8% (10/127) of women in the control group ($p=0.18$). Blood transfusions were needed for 2% (1/50) of women in the balloon device group and 5% (6/127) of women in the control group ($p=0.36$).
- 4.3 **Neonatal outcomes**
- 4.3.1 There were no neonatal deaths in the balloon device group and 2 neonatal deaths (2%, 2/124) in the control group ($p=0.51$).
- 4.3.2 Apgar scores of less than 3 at 5 minutes were reported in 4% (2/50) of babies in the balloon device group and 3% (4/124) of babies in the control group ($p=0.55$).
- 4.3.3 Admission to an intensive care unit for more than 24 hours was needed for 6% (3/50) of babies in the balloon device group and 10% (12/124) of babies in the control group ($p=0.33$).
- 4.3.4 Seizure was reported in 2% (1/50) of babies in the balloon device group and 2% (3/124) of babies in the control group ($p=0.68$). No further details were provided.
- 4.3.5 Intubation was not needed in any babies in the balloon device group whereas it was needed in 4% (5/124) of babies in the control group ($p=0.18$).

4.3.6 Neonatal injury was not reported in any babies in the balloon device group whereas it was reported in 5% (6/124) of babies in the control group ($p=0.12$). No further details were provided.

4.3.7 Infection was not reported in any babies from the balloon device group whereas it was reported in 6% (7/124) of babies from the control group ($p=0.09$). Timing of infection was not reported.

4.4 **Specialist advice**

4.4.1 Specialist advisers listed key efficacy outcomes as the interval between uterine incision and delivery of the infant, and the avoidance of outcomes associated with delayed delivery, including fetal asphyxia or acidosis. They also listed the avoidance of trauma to the mother and her baby, including the avoidance of haemorrhage, vaginal laceration, cervical laceration, trauma to the maternal bladder, trauma to the lower segment of the uterus, and trauma to the fetal head (including skull fracture). Other key efficacy outcomes listed by specialist advisers were the avoidance of extension of uterine incision, reduction in intensive care unit or neonatal intensive care unit admission and reduction in postoperative recovery times.

5 **Safety**

For more detailed information on the evidence, see the [interventional procedure overview](#) *[add URL]*.

5.1 The review of evidence identified 1 non-randomised comparative study that compared women who had a balloon device inserted to disimpact an engaged fetal head before a caesarean section (n=50) against unmatched historical controls (n=124): women who

had a second stage caesarean section. No other peer-reviewed studies were identified. The non-randomised comparative study described no safety outcomes directly related to the use of the balloon device: all outcomes were described in the study as efficacy outcomes.

- 5.2 One specialist adviser highlighted uterine rupture as an anecdotal adverse event. Advisers stated that theoretical adverse events could include infection, and trauma to the mother's genital tract or fetal head during device insertion or as a result of excessive pressure following device inflation.

6 Committee comments

- 6.1 The Committee recognised the potential for insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section to be widely used if further evidence shows it to be safe and efficacious. This was an important reason for the recommendations for further evidence in sections 1.3 and 1.4.
- 6.2 The Committee noted that the emergency and often unexpected circumstances in which this device would be used preclude any recommendation about special arrangements for consent.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance requires that clinicians performing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

Bruce Campbell

Chairman, Interventional Procedures Advisory Committee

November, 2014