NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg515

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 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 advance that they intend to perform the procedure when necessary.
- Audit and review clinical outcomes of all women treated by the insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section (see section 7.2).

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 2-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 2-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.

4.1 The review of evidence identified 1 non-randomised comparative study. It 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), that is, women who had a caesarean section during the second stage of labour. 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.

Maternal outcomes

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

4.3 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).

4.4 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).

4.5 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) of women in the control group (p=0.03).

4.6 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).

Neonatal outcomes

4.7 No neonatal deaths were reported in the balloon device group whereas neonatal deaths were reported in 2% (2/124) of babies in the control group (p=0.51).

4.8 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).

4.9 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).

4.10 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.

4.11 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).

4.12 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.

4.13 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.

Specialist advice

4.14 The specialist advisers listed key efficacy outcomes as the interval between uterine incision and delivery of the baby, and avoiding outcomes associated with delayed delivery, including fetal asphyxia or acidosis. They also listed avoiding trauma to the mother and her baby, including 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 avoiding extension of the uterine incision, reducing intensive care unit or neonatal intensive care unit admission and reducing postoperative recovery times.

5 Safety

For more detailed information on the evidence, see the interventional procedure overview.

5.1 The review of evidence identified 1 non-randomised comparative study. It 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), that is, women who had a caesarean section during the second stage of labour. 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 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 event: uterine rupture. They considered that the following were theoretical adverse events: 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 become widely used if further evidence shows it to be safe and efficacious. This was an important reason for the recommendation for further evidence in section 1.3.

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.

6.3 The Committee noted that there is ongoing research evaluating the safety and efficacy of this procedure.

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

June 2023: A more recent publication on this topic (IPG744) has been withdrawn, following the retraction of a paper used in committee decision making. This topic will be returning to committee for re-discussion and the schedule will be shared once confirmed. In the meantime, please refer to this particular interventional procedure (IPG515) for guidance on this topic.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation