



# Balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour

Interventional procedures guidance Published: 23 April 2025

www.nice.org.uk/guidance/ipg800

# 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.

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG744 and IPG515.

#### 1 Recommendations

- 1.1 More research is needed on balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour before it can be used in the NHS.
- 1.2 This procedure should only be done as part of a formal research study, and a research ethics committee needs to have approved its use.
- 1.3 The procedure should only be done by staff trained in managing an emergency caesarean birth when the baby's head is impacted.
- 1.4 Centres already using this procedure may continue to do so but are encouraged to collect data or do further research on the outcomes listed in recommendation 1.5.

#### What research is needed

- 1.5 More research, including randomised controlled trials or a registry, is needed on:
  - how the procedure compares with other options
  - patient selection, such as the characteristics of the woman, trans man or

non-binary person giving birth, and risk factors

• longer-term (beyond the immediate postpartum period and after hospital discharge) safety and efficacy outcomes for the woman, trans man or non-binary person giving birth, and the baby.

#### Why the committee made these recommendations

Several publications that provided supporting evidence for NICE's interventional procedures guidance on balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour have been retracted since the guidance was published. This includes a key study that was retracted because the journal's research integrity team found several inconsistencies in the results presented. There is now a lack of high-quality evidence to show whether the procedure improves outcomes for either the woman, trans man or non-binary person giving birth, or the baby. But there are no major safety concerns. So, this procedure can be used in research.

# 2 The condition, current treatments, unmet need and procedure

#### The condition

- A caesarean during the second stage of labour is associated with an increased risk of adverse perinatal outcomes compared with an elective caesarean or a caesarean during the first stage of labour. Delivery of the baby can be more difficult if the head is impacted deep within the pelvis, further increasing the risks to the woman, trans man or non-binary person giving birth, and to the baby. The definition of impaction of a baby's head is subjective. But a UK survey published in 2023 proposed the definition: 'A cesarean birth where the obstetrician is unable to deliver the fetal head with their usual delivering hand, and additional maneuvres and/or tocolysis are required to disimpact and deliver the fetal head' (Cornthwaite et al. 2023).
- Difficulties in disimpacting a deeply engaged baby's head can delay the birth of a baby that is already at risk. For the woman, trans man or non-binary person

giving birth, there is an increased risk of complications such as:

- extension of the uterine incision
- haemorrhage
- infection
- bladder injury.

For the baby, complications include:

- umbilical artery acidosis
- skull or limb fracture
- hypoxic ischaemic encephalopathy
- brachial plexus injury.

#### **Current treatments**

2.3 Two main approaches are commonly used to disimpact an engaged baby's head. One involves the surgeon or an assistant placing fingers of a cupped hand through the vagina and pushing the baby's head back up the pelvis. This can be associated with vaginal tissue trauma. The other approach (reverse breech extraction) involves the surgeon delivering the baby's feet first through the uterine incision, and then delivering the head. The Patwardhan technique and the modified Patwardhan technique are modifications of the reverse breech extraction method. They involve delivering a shoulder or both shoulders of the baby first, followed by the body and, lastly, the head.

#### Unmet need

Impaction of the baby's head makes a caesarean delivery more difficult and is associated with an increased risk of complications. There is no clear consensus on the safest and most effective technique to support disimpacting the baby's

head before or at an emergency caesarean. The situation is also affected by the baby's position. The aim of balloon disimpaction is to elevate the baby's head and make a caesarean delivery during the second stage of labour less traumatic and quicker.

### The procedure

- 2.5 Balloon disimpaction is usually done immediately before an emergency caesarean, at full dilation, during the second stage of labour.
- 2.6 A disposable soft silicone balloon device is inserted into the vagina, using a lubricant. The balloon is pushed back towards the coccyx and placed between the pelvic floor and the baby's head. The balloon surface is placed in contact with the head. The base plate of the device rests on the posterior vaginal wall and anorectum, opposite the anococcygeal ligament. This is to prevent downward displacement when the device is inflated. Once the device is in position, the balloon is inflated using sterile saline using a tube connected to a 2-way tap. The balloon is designed to inflate only in an upward direction. Inflating the balloon helps to elevate the head out of the pelvis by a few centimetres. The intention is to:
  - make the delivery easier, with less manipulation through the abdominal wound
  - reduce the risk of injury.

Immediately after delivery, the balloon is deflated by opening the 2-way tap and then removed from the vagina by traction. After the caesarean, the vagina is inspected for trauma.

#### 3 Committee considerations

#### The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 1 systematic review, 5 retrospective cohort studies, 2 randomised controlled trials, 1 prospective non-randomised comparative study and 2 case reports. Both the randomised controlled trials and all the cohort studies except 1 were also included in the systematic review. The evidence is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- The professional experts and the committee considered the key efficacy outcomes to be:
  - outcomes for the woman, trans man or non-binary person giving birth:
    - reduced time from the decision to have a caesarean to birth
    - reduced time from uterine incision to birth
    - reduced need for extension of uterine incision
    - less blood loss
    - fewer operative complications
  - outcomes for the baby:
    - improved Appar scores
    - improved umbilical artery pH
    - less sepsis
    - reduced need for admission to a special care baby unit or newborn intensive care unit

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- less need for intubation
- fewer deaths.
- The professional experts and the committee considered the key safety outcomes to be trauma to the vagina or baby's head, and infection.
- A submission was received from a patient organisation, which was considered by the committee. This highlighted the potentially severe and long-lasting effects of having a caesarean when the baby's head is impacted. They noted that the few women who had experience of balloon disimpaction of the baby's head were positive about it and had successful outcomes.

#### Committee comments

- The committee was told about a new programme funded by the Department of Health and Social Care called <u>Avoiding Brain Injury in Childbirth (ABC)</u>. The aim of the programme is to improve outcomes for women, trans men or non-binary people giving birth, and their babies by implementing national clinical protocols, tools and multiprofessional training. This will include training on how to manage impaction of the baby's head during a caesarean birth.
- The committee noted that some of the evidence described the balloon disimpaction device being used at a caesarean during the second stage of labour but not necessarily when there was impaction of the baby's head.
- 3.7 The committee was told that the balloon disimpaction device may be useful for less experienced staff, and that the procedure is being taught to newer staff in some centres.

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## **Endorsing organisation**

This guidance has been endorsed by Healthcare Improvement Scotland.