

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures

Patient Organisation Submission

IP1217/2 - Balloon disimpaction of fetal head at emergency caesarean delivery

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template, and ask if you would like to attend as a patient expert at the bottom of the form. You do not have to answer every question – they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

About you	
1. Your name	Kim Thomas
2. Name of organisation	Birth Trauma Association
3. Job title or position	CEO
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	Charity supporting parents psychologically traumatised by birth. Currently all funding is through donations or occasional grants. No formal membership structure, but we have a Facebook group with 18,000 members.
<p>5. How did you gather the information about the experiences of patients and carers to help your submission?</p> <p>We asked a question about women's experiences of balloon disimpaction in our Facebook support group. We have also, over the years, received accounts from thousands of women about their birth experiences, some of them through the Facebook group, others through our enquiries or support inbox.</p>	

Living with the condition

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

The consequences of experiencing an impacted fetal head during caesarean can be severe and long-lasting. In one case related to us, the woman experienced an impacted fetal head during the caesarean, but there was no balloon device/fetal pillow, so the baby was pulled out manually. The woman suffered a cut that led to her losing nine litres of blood, and doctors performed a hysterectomy in an attempt to stop the blood flow. This was devastating and life-changing.

In another example, a book by the influencer Louise Thompson recounts her experience of having an emergency section while her baby's head was wedged in her pelvis, and had to be manually pushed up. The surgeon nicked an artery, she lost 3 ½ litres of blood and suffered a rupture to the uterus. After returning home, she suffered another, near-fatal, haemorrhage and was in hospital for six weeks. The psychological and physical effects of her trauma were profound, and she continues to feel the effects two years on.

Another woman told us of how, during her birth experience, three attempts at forceps failed, and an emergency c-section was attempted. Because the fetal head was so far down the birth canal, the baby had to be delivered by forceps during the c-section, leaving the mother with pelvic pain that has lasted 10 years.

Finally, another woman said that in her case an emergency c-section was attempted at 4cm dilation. When the incision was made, however, she was fully dilated and the baby's head had started to descend. The baby's head was severely impacted, resulting in brain damage, and the baby had to go for cooling. The woman who shared this story thinks that the balloon device is not used enough.

Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are? Why do you consider it to be innovative?

In the examples we heard, women have told us that the balloon device could have made the birth easier. In the first example given in answer to question 6, the device might have enabled the baby to be pulled out more easily, thereby avoiding the haemorrhage and the hysterectomy. In the fourth example, the baby might have avoided brain damage.

We also heard from a few women who had experience of the balloon device being used. These were all positive stories, in that the device successfully freed the baby's head, and the baby was born safely. One said she felt that it was "much safer" than the alternative option of the baby being pulled down the birth canal.

8. Does this procedure have the potential to change the current pathway or patient outcomes? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

A procedure that could successfully move the baby's head before the c-section would lead to better outcomes for mother and baby. Earlier this year, an article in *AJOG* entitled Management of impacted fetal head at cesarean delivery¹ made it clear that the evidence on the fetal pillow is limited and contradictory, and therefore we cannot be sure that it leads to better outcomes than other methods. However, as the article shows, the evidence on the other methods is similarly limited. It is clear that more research is needed but our feeling is that all maternity units should have a fetal pillow so that it is available to clinicians as an option.

Disadvantages of the procedure or operation

9. What do patients (or carers) think the disadvantages of the procedure or operation are?

Cases of impacted fetal head (IFH) are growing in number: according to the *AJOG* article, at least 5% of caesarean deliveries are at full cervical dilatation, which means that the baby's head may be wedged low in the pelvis. One estimate is that up to one in 10 caesarean sections in the UK are affected by IFH. This can have devastating consequences for both mother and baby, so research into interventions that might improve outcomes would be welcome. Our view is that this situation should not arise in the first place, and that prevention should be the first course of action. In cases where a woman has a high risk of impacted fetal head because of pelvic disproportion or fetal malposition, we believe women should be offered a choice between vaginal delivery and caesarean section. Some of the women who told us that they'd received the balloon procedure commented that they were left to labour for too long and their requests for caesarean were ignored. One, for example, said doctors attempted Ventouse and forceps delivery before eventually using a c-section aided by the balloon device – she lost two litres of blood, and her baby spent five days in NICU. Another laboured for 56 hours, including two hours of pushing.

We understand that prevention is not in the remit of this committee, but we would nonetheless like to have our view on the record. Late second-stage caesareans are highly risky, and in many cases, offering women a c-section earlier in the second stage would lead to far better outcomes.

When it comes to the balloon procedure itself, it is difficult to know for certain what the advantages or disadvantages are based purely on the stories women have told us. Those who received the balloon procedure were positive, while those who didn't receive it felt it could have led to better outcomes in their case. Obviously it is hard to be certain from a small number of stories, and it is clear that much more research is urgently needed in this area.

¹ Cornthwaite, Katie R. et al. Management of impacted fetal head at cesarean delivery
American Journal of Obstetrics & Gynecology, Volume 230, Issue 3, S980 - S987

Patient population
<p>10. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.</p> <p>If the balloon device is shown to be safe and effective, then it would benefit those women at higher risk of experiencing impacted fetal head.</p>
Safety and efficacy
<p>11. What are the uncertainties about how well this procedure works and how safe it is?</p> <p>Research seems inconclusive on whether the procedure is more or less effective than other procedures for disengaging the fetal head. On the issue of safety, while some studies have apparently shown an associated decrease in risk of PPH, others have shown an increased risk. Clearly, however, there are also risks from other measures that might be used, such as manually trying to release the fetal head.</p>
Equality
<p>10. Are there any potential equality issues that should be taken into account when considering this topic?</p> <p>Black women and South Asian women have significantly worse maternal outcomes than white women, and it may be that they are more affected by IFH than other groups, though there is a lack of research in the area.</p>
Other issues
<p>11. Are there any other issues that you would like the Committee to consider?</p> <p>From our very small sample, it seems that women themselves were not consulted about the method used to free the baby's head. We believe that informed consent is important in childbirth, and therefore perhaps the Committee could consider this when revising the guideline.</p>

Key messages
<p>12. In no more than 5 bullet points, please summarise the key messages of your submission.</p> <ol style="list-style-type: none"> 1. The health outcomes for women and babies when they experience impacted fetal head can be devastating. 2. The evidence on the effectiveness and safety of the balloon device compared with other methods of disimpaction appears to be mixed. 3. Our small sample suggests that balloon disimpaction can be an effective way of freeing the baby's head, and we believe the option ought at least to be open to clinicians. 4. Informed consent is important, so that if women are offered balloon disimpaction, the benefits and risks should be explained to them.
Committee meeting
<p>13. Would you be willing to attend the interventional procedures committee meeting to provide the view from your organisation in person?</p> <p>Yes</p>

Thank you for your time.

Please return your completed submission to helen.crosbie@nice.org.uk and ip@nice.org.uk.