

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of 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.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in June 2014 and updated in December 2014

Procedure name

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

Specialist societies

- Royal College of Obstetricians and Gynaecologists
- Royal College of Midwives
- Royal College of Paediatrics and Child Health

Description

Indications and current treatment

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.

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.

What the procedure involves

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.

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.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section. Searches were conducted of the following databases, covering the period from their commencement to 4 December 2014: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Women undergoing a caesarean section at full dilatation.
Intervention/test	Insertion of a balloon device to disimpact the engaged fetal head.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 174 women from 1 non-randomised comparative study.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section

Study 1 Seal SL (2014)

Details

Study type	Non-randomised comparative study
Country	India
Recruitment period	October 2011 to February 2012
Study population and number	Women undergoing caesarean section at full dilatation n=174 (50 balloon device vs 124 unmatched historical controls)
Age and sex	Balloon device group: mean age, 23.1 years Control group: mean age, 24.2 years
Patient selection criteria	Inclusion criteria: Women with singleton uterine pregnancies who needed caesarean sections at full dilatation were included. Exclusion criteria: Women with active genital infections, major fetal abnormalities, pregnancy induced hypertension, intrauterine growth restriction or diabetes were excluded.
Technique	The balloon device was inserted vaginally and inflated with 180 ml of sterile saline to elevate the fetal head out of the pelvis. No further details were provided as to how caesarean sections were performed.
Follow-up	Not reported
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: No patients were lost to follow-up.

Study design issues: Procedures were performed by registrars (number not specified) who had at least 4 years training in obstetrics and gynaecology. All participating clinicians were instructed in the use of the device by watching an animated training video.

Study population issues: Women in the control group were unmatched historical controls: women who had a caesarean section during the second stage of labour, whose results were obtained from a previous study by the same author. There were no significant differences in maternal age, maternal weight, gestational age, and fetal weight between groups. Indications for caesarean section included failure-to-progress (balloon device group, 74.0%; control group, 77.4%), fetal distress (balloon device group, 16.0%; control group, 12.0%) and failed instrumental delivery (balloon device group, 10.0%; control group, 10.4%). It is unclear what methods were used to disimpact fetal heads in the control group.

Other issues: Apgar score is used to assess a newborn's health by assessing 5 domains: appearance, pulse, responsiveness, muscle activity, and breathing. Each domain is scored from 0 to 2; thus, total scores range from 0 to 10 with higher scores indicating better health.

- Clinical grading system for extensions of uterine incisions during caesarean section
 - Grade I – Extension of the incision that does not increase the operating time or blood loss.
 - Grade II – Extension that increases the operating time and blood loss.
 - Grade III – Extension that involves 1 or more uterine arteries, the cervix, vagina or other organs.

Key efficacy and safety findings

Efficacy				Safety																																																																						
Number of women analysed: 174 (50 balloon device vs 124 historical controls) The average elevation of the fetal head, after device inflation, was 4 cm (p<0.001). Maternal outcomes <table><tr><th>Outcome</th><th>Balloon device</th><th>Control</th><th>p value</th></tr><tr><td>Total caesarean time (minutes)</td><td>31.8±4.6</td><td>52.1±10.7</td><td><0.001</td></tr><tr><td>Time from uterine incision to delivery (minutes)</td><td>2.79±0.4</td><td>8.43±1.7</td><td><0.001</td></tr><tr><td>Proportion with grade II or III extensions of uterine incisions (%)</td><td>4.0 (2/50)</td><td>15.2 (19/124)</td><td>0.03</td></tr><tr><td>Blood loss > 1 litre</td><td>2.0 (1/50)</td><td>8.0 (10/127)</td><td>0.18</td></tr><tr><td>Blood transfusion</td><td>2.0 (1/50)</td><td>4.8 (6/127)</td><td>0.36</td></tr><tr><td>Admission to intensive care unit</td><td>0</td><td>4.0 (5/124)</td><td>0.18</td></tr><tr><td>Length of stay (days)</td><td>4.1</td><td>6.4</td><td><0.001</td></tr><tr><td>Maternal death</td><td>0</td><td>1.6 (2/124)</td><td>0.51</td></tr></table> Neonatal outcomes <table><tr><th rowspan="2">Outcome</th><th colspan="2">% (n/N)</th><th rowspan="2">p value</th></tr><tr><th>Balloon device</th><th>Control</th></tr><tr><td>Babies with Apgar scores <3 at 5 minutes</td><td>4.0 (2/50)</td><td>3.2 (4/124)</td><td>0.55</td></tr><tr><td>Admission to intensive care unit for more 24 hours</td><td>6.0 (3/50)</td><td>9.6 (12/124)</td><td>0.33</td></tr><tr><td>Neonatal death</td><td>0</td><td>1.6 (2/124)</td><td>0.51</td></tr><tr><td>Neonatal seizure</td><td>2.0 (1/50)</td><td>2.4 (3/124)</td><td>0.68</td></tr><tr><td>Intubation</td><td>0</td><td>4.0 (5/124)</td><td>0.18</td></tr><tr><td>Neonatal injury</td><td>0</td><td>4.8 (6/124)</td><td>0.12</td></tr><tr><td>Infection</td><td>0</td><td>5.6 (7/124)</td><td>0.09</td></tr></table>				Outcome	Balloon device	Control	p value	Total caesarean time (minutes)	31.8±4.6	52.1±10.7	<0.001	Time from uterine incision to delivery (minutes)	2.79±0.4	8.43±1.7	<0.001	Proportion with grade II or III extensions of uterine incisions (%)	4.0 (2/50)	15.2 (19/124)	0.03	Blood loss > 1 litre	2.0 (1/50)	8.0 (10/127)	0.18	Blood transfusion	2.0 (1/50)	4.8 (6/127)	0.36	Admission to intensive care unit	0	4.0 (5/124)	0.18	Length of stay (days)	4.1	6.4	<0.001	Maternal death	0	1.6 (2/124)	0.51	Outcome	% (n/N)		p value	Balloon device	Control	Babies with Apgar scores <3 at 5 minutes	4.0 (2/50)	3.2 (4/124)	0.55	Admission to intensive care unit for more 24 hours	6.0 (3/50)	9.6 (12/124)	0.33	Neonatal death	0	1.6 (2/124)	0.51	Neonatal seizure	2.0 (1/50)	2.4 (3/124)	0.68	Intubation	0	4.0 (5/124)	0.18	Neonatal injury	0	4.8 (6/124)	0.12	Infection	0	5.6 (7/124)	0.09	Adverse events NB: Authors reported all outcomes as efficacy outcome measures.
				Outcome	Balloon device	Control	p value																																																																			
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Efficacy

The rapid 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 caesarean section during the second stage of labour.

Maternal outcomes

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).

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).

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).

Extensions of uterine incisions that resulted in increased operating times or 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).

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).

Admission to an intensive care unit was needed for no women in the balloon device group and 4.0% (5/124) of women in the control group (p=0.18).

Neonatal outcomes

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).

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).

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).

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.

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 ($p=0.18$).

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.

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.

Safety

No safety outcomes directly related to the use of balloon devices were reported in the non-randomised comparative study.

Validity and generalisability of the studies

- Only 1 peer reviewed article was identified that assessed the efficacy of insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section.
- There was a possibility of selection bias; the study compared women who received the intervention with unmatched historical controls.
- Authors did not adequately state exclusion criteria.
- Authors did not explicitly state if any of the women from the control group had undergone alternative methods to disimpact engaged fetal heads before caesarean sections.
- Authors reported all outcome measures as efficacy outcomes since the intention of the procedure was to reduce caesarean section-related morbidities and mortalities in mothers and newborns.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

Clinical guidelines

- Caesarean section. NICE clinical guideline CG132 (2011). Available from <http://www.nice.org.uk/guidance/cg132>

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their specialist society or royal college. The advice received is their individual opinion and does not represent the view of the society.

Dr Ruta Deshpande, Ms Beverly Gordon (Royal College of Midwives); Mr Tim Overtan, Dr Sikhar Sircar, Professor Gordon Smith (Royal College of Obstetricians and Gynaecologists)

- One specialist adviser performs the procedure regularly whereas the other 4 specialist advisers have never performed the procedure; 1 of whom stated that he had significant experience disimpacting engaged fetal heads but had not used a balloon device.
- All specialist advisers described the procedure as novel and of uncertain safety and efficacy.
- Two specialist advisers stated that more than 50% of specialists were engaged in this area of work while 3 specialist advisers could not give estimates on what proportion of specialists perform the procedure.
- Specialist advisers stated that comparators include reverse breech extraction and vaginal disimpaction by pushing the baby's head back up the pelvis. One specialist adviser identified the less commonly used Patwardhan technique (delivery of anterior shoulder first through a lower uterine incision) as a possible comparator.
- Specialist advisers did not highlight any adverse events reported in the literature.
- 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.
- 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.
- Specialist advisers stated that uncertainties surrounding the efficacy of the procedure are associated with the risk of infection and the potential delay in performing a caesarean section because of difficulty inserting the balloon device. The specialist adviser who regularly performed the procedure alluded to potential concerns about patient selection: he stated that he had to select women that were suitable for treatment by the device rather than select all women needing caesarean section at full dilatation.
- Three specialist advisers considered the procedure to have a moderate impact on the NHS whereas 1 adviser believed the procedure would have a major impact and another adviser believed the procedure would have a minor impact.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- No ongoing trials were identified from standard IP sources.

References

1. Seal SL, Dey A, Barman SC, Kamilya G, Mukherji J. (2014) Does elevating the fetal head prior to delivery using a fetal pillow reduce maternal and fetal

complications in a full dilatation caesarean section? A prospective study with historical controls. *Journal of Obstetrics & Gynaecology*. 34(3):241-4

Appendix A: Additional papers on insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Mufti NM, Thomas TT, Sircar SS (2013) The Fetal Pillow (FP): A novel intervention to reduce maternal and fetal complications in caesarean sections at full dilatation (CSFD). Archives of disease in childhood: fetal and neonatal edition: 98, Supplement 1.	Non-randomised comparative study n=34 (16 balloon device vs 18 controls) Follow-up: not reported	The mean operating time was 41.6 minutes in the balloon device group and 70 minutes in the control group. Mean blood loss was 698 ml in balloon device group and 829 ml in the control group. Uterine extensions were observed in 31% of patients in the balloon device group and 33% of patients in the control group.	Journal abstract that does not highlight additional efficacy outcome measures or adverse events.
Papanikolaou N, Tillisi A, Louay L, Singh M, Ikomi A, Varma R. (2009) Reducing complications related to Caesarean section (CS) in second stage: UK experience in the use of fetal disimpacting system (FDS). International Journal of Gynecology & Obstetrics 107S2: S93–S396	Case series n=28 Follow-up: not reported	Mean blood loss was 700 ml (range 300–1200 ml). No trauma to the fetal head or maternal vaginal tissues was reported. No extension of uterine incisions was required in 85.7% (24/28) of patients.	Journal abstract that does not highlight additional efficacy outcome measures or adverse events.

Appendix B: Related NICE guidance for insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section.

Guidance	Recommendations
Clinical guidelines	Caesarean section. NICE clinical guideline CG132 (2011). 1.1.1 Provision of information 1.1.1.1 Pregnant women should be offered evidence-based information and support to enable them to make informed decisions about childbirth. Addressing women's views and concerns should be recognised as being integral to the decision-making process. [2004] 1.1.1.2 Give pregnant women evidence-based information about caesarean section (CS) during the antenatal period, because about 1 in 4 women will have a CS. Include information about CS, such as: • indications for CS (such as presumed fetal compromise, 'failure to progress' in labour, breech presentation) • what the procedure involves • associated risks and benefits • implications for future pregnancies and birth after CS. [new 2011] 1.1.1.3 Communication and information should be provided in a form that is accessible to pregnant women, taking into account the information and cultural needs of minority communities and women whose first language is not English or who cannot read, together with the needs of women with disabilities or learning difficulties. [2004] 1.1.2 Planning mode of birth 1.1.2.1 Discuss the risks and benefits of CS and vaginal birth with women, taking into account their circumstances, concerns, priorities and plans for future pregnancies (including the risks of placental problems with multiple CS) (see box A and 1.7.1.8). [new 2011] 1.1.2.2 Consent for CS should be requested after providing pregnant women with evidence-based information and in a manner that respects the woman's dignity, privacy, views and culture, while taking into consideration the clinical situation.

	[2004] 1.1.2.3 A pregnant woman is entitled to decline the offer of treatment such as CS, even when the treatment would clearly benefit her or her baby's health. Refusal of treatment needs to be one of the woman's options. [2004, amended 2011] 1.1.2.4 When a decision is made to perform a CS, a record should be made of all the factors that influence the decision, and which of these is the most influential. [2004, amended 2011]
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Appendix C: Literature search for insertion of a balloon device to disimpact an engaged fetal head before an emergency caesarean section

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	04/12/2014	Issue 12 of 12, December 2014
Database of Abstracts of Reviews of Effects – DARE (Cochrane Library)	04/12/2014	Issue 4 of 4, October 2014
HTA database (Cochrane Library)	04/12/2014	Issue 4 of 4, October 2014
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	04/12/2014	Issue 11 of 12, November 2014
MEDLINE (Ovid)	04/12/2014	1946 to November Week 3 2014
MEDLINE In-Process (Ovid)	04/12/2014	December 03, 2014
EMBASE (Ovid)	04/12/2014	1974 to 2014 Week 48
CINAHL (NLH Search 2.0)	04/12/2014	1981 to present
PubMed	04/12/2014	n/a
JournalTOCS	04/12/2014	n/a

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	balloon dilation/
2	(balloon* adj4 (dilat* or expand* or inflat* or device*)).tw.
3	((elevat* or (disimpact* or dis-impact*)) adj4 (fetal or foetal or fetus or foetus) adj4 (head* or system*)).tw.
4	((fetal or foetal or fetus or foetus) adj4 (pillow* or balloon* or cushion*)).tw.
5	or/1-4
6	cesarean section/
7	(caesarian or cesarian or caesarean or cesarean).tw.
8	(c-section or c section).tw.
9	(cephalopelvi* adj4 disproportion*).tw.
10	dystocia.tw.
11	((engage* or impact*) adj4 (fetal or foetal or fetus or foetus) adj4 head*).tw.

12	(full* adj4 dilat*).tw.
13	or/6-12
14	5 and 13
15	animals/ not humans/
16	14 not 15