Interventional procedure overview of balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour

Contents

Table 1 Abbreviations

Abbreviation	Definition
CI	Confidence interval
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
IQR	Interquartile range
OR	Odds ratio
RR	Risk ratio/relative risk
SD	Standard deviation

Indications and current treatment

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 an impacted 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 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 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.

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

An impacted 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. Balloon disimpaction aims to elevate the baby's head and make a caesarean delivery during the second stage of labour less traumatic and quicker.

What the procedure involves

Balloon disimpaction of an engaged baby's head aims to elevate the head, with reduced risk of trauma. It is usually done immediately before an emergency caesarean, at full dilation, during the second stage of labour.

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. The procedure is similar to the placement of a ventouse cup. 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 and to reduce the risk of injury. 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 caesarean, the vagina is inspected for trauma.

Outcome measures

The main maternal outcomes reported in the evidence included uterine incision extension, uterine wall rupture, blood loss, operative time (including incision to delivery time) and length of hospital stay. The main neonatal outcomes included Apgar score, admission to neonatal intensive care, umbilical cord arterial pH and birth trauma. The measures used are detailed in the following paragraphs.

Apgar score

The Apgar score is used to assess the clinical status of newborn infants after delivery. The score has 5 components: skin colour, heart rate, reflexes, muscle tone, and respiration, each of which is given a score of 0, 1, or 2. The score is reported at 1 minute and 5 minutes after birth for all infants, and subsequently if needed. An Apgar score of 7 or above is usually considered to be reassuring.

Umbilical cord arterial pH

Low arterial umbilical cord pH is associated with neonatal mortality and morbidity. Acidosis is usually defined as pH 7.0 or lower.

Evidence summary

Population and studies description

This interventional procedures overview is based on about 3,000 people included in studies on balloon disimpaction, from 1 systematic review (Cornthwaite 2024), 5 retrospective cohort studies (Sadler 2024, Sacre 2021, Hanley 2020, Chooi 2022, Safa 2016), 2 randomised controlled trials (Lassey 2020, Dutta 2019), 1 prospective non-randomised comparative study (Barman 2015) and 2 case reports (Jordan 2022, Mumtaz 2023). Both the randomised controlled trials and all the cohort studies except 1 (Sadler 2024) were also included in the systematic review. Of the 3,000 people included in the studies, 986 had the procedure. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This overview presents 11 studies as the key evidence in table 2 and table 3, and lists 7 other relevant studies in appendix B, table 5.

Studies were from Australia, India, New Zealand, UK and US. The systematic review included 24 studies, 7 of which used balloon disimpaction (Cornthwaite 2024). Of the 7 studies, 6 have been included in the key evidence tables to give details of all the reported outcomes. The remaining study was a non-randomised comparative study that has been retracted since the systematic review was prepared. The systematic review assessed certainty of evidence across outcomes using GRADE and avoided pooling data for meta-analysis when there was high heterogeneity. It excluded a randomised controlled trial that had been retracted because of concerns about scientific integrity. It used a sensitivity

analysis that excluded the non-randomised study that has also since been retracted. According to GRADE criteria, the certainty of evidence was very low.

A recently published large retrospective cohort study in New Zealand compared outcomes within and between 2 centres (Sadler 2024). In 1 centre, outcomes were compared before and after the balloon disimpaction device was introduced and outcomes were compared with and without its use. The outcomes in this centre were then compared with the outcomes in a centre that didn't have the device available. The primary outcome was uterine incision extension. There were statistically significant differences in demographic and clinical characteristics between the comparison groups, including parity, fetal head station and attempted assisted vaginal birth, suggesting that balloon disimpaction was used for more difficult deliveries. There were statistically significant differences in maternal ethnicity between the comparison groups. In the unit where the balloon disimpaction device was available, there was a higher proportion of people of Indian ethnicity (33%) and a lower proportion of people of Maori ethnicity (11%) in the group where the device was used compared to the group in which the device was not used (26% Indian and 16% Maori). When the 2 units were compared, the unit with the balloon device had a higher proportion of people with a specific ethnicity recorded (14% Maori, 25% Pacific, 29% Indian, 11% other Asian and 22% 'Other') compared with the unit without the balloon device (5% Maori, 6% Pacific, 16% Indian, 25% other Asian, and 48% 'Other').

The 2 randomised controlled trials were both small and 1 was published in a journal that was identified in the systematic review as being 'potentially predatory' (Dutta 2019). This trial was based in India and compared balloon disimpaction (n=25) with the modified Patwardhan technique (n=25). Although the paper describes the trial as a prospective comparative trial rather than a randomised controlled trial in the title and methods, it does describe a process of randomising treatment allocation. The primary outcome measure was not specified. The trial by Lassey et al. (2020) was based in the US and compared outcomes in

nulliparous women having caesarean delivery in the second stage of labour using an inflated balloon disimpaction device (n=30) with those using a non-inflated device (n=30). The study assessed the use of the device in the second stage of labour and did not specifically address its use with impacted fetal head. The original trial description stated the estimated enrolment was 200 but the actual enrolment was 60. The primary outcome measure was time (in seconds) from hysterotomy to delivery of the neonate.

The remaining 4 retrospective cohort studies were based in the UK and Australia. The study by Sacre et al. (2021) included 391 caesarean births, 170 (44%) of which used balloon disimpaction based on the individual clinician's decision. There were no statistically significant differences between the groups in maternal age, body mass index, ethnicity, onset of labour, or fetal position. Most of the women (87%) were described as Caucasian. The proportion of nulliparous women was higher in the balloon disimpaction group as was the proportion of fetal head station reported below the ischial spines. There was a higher number of deliveries for fetal distress in the group without balloon disimpaction. The study by Hanley et al. (2020) included 174 caesarean births, 114 (66%) of which used balloon disimpaction. There were no statistically significant differences in baseline characteristics between the groups. The primary outcome of interest was operative complications, which included uterine incision extension, need for breech extraction, use of vertical incision and bladder, ureter or bowel injury. The study by Chooi et al. (2023) included all caesarean births where balloon disimpaction was used (n=53) and randomly selected a similar number of caesarean births without balloon disimpaction (n=48). Maternal and neonatal baseline characteristics were similar between the 2 groups. The study by Safa et al. (2016) compared all caesarean births done at full dilation using balloon disimpaction with those using the hand-push technique to disimpact the fetal head. Maternal baseline characteristics were similar between the groups.

The prospective non-randomised comparative study by Barman et al. (2015) was not included in the systematic review by Cornthwaite et al. (2024). It compared 75 caesarean deliveries using balloon disimpaction with 72 deliveries using the Patwardhan technique. Assignment to each group was done alternately. Maternal baseline characteristics were similar between the groups.

The case report by Jordan et al. (2022) describes uterine and bladder rupture when balloon disimpaction was used at a full dilation caesarean in a woman who had had a previous caesarean delivery at full dilation for obstructed labour. The case report by Mumtaz et al. (2023) describes 2 cases of posterior uterine wall rupture identified at caesarean immediately after balloon disimpaction was used.

Table 2 presents study details.

Figure 1 Flow chart of study selection

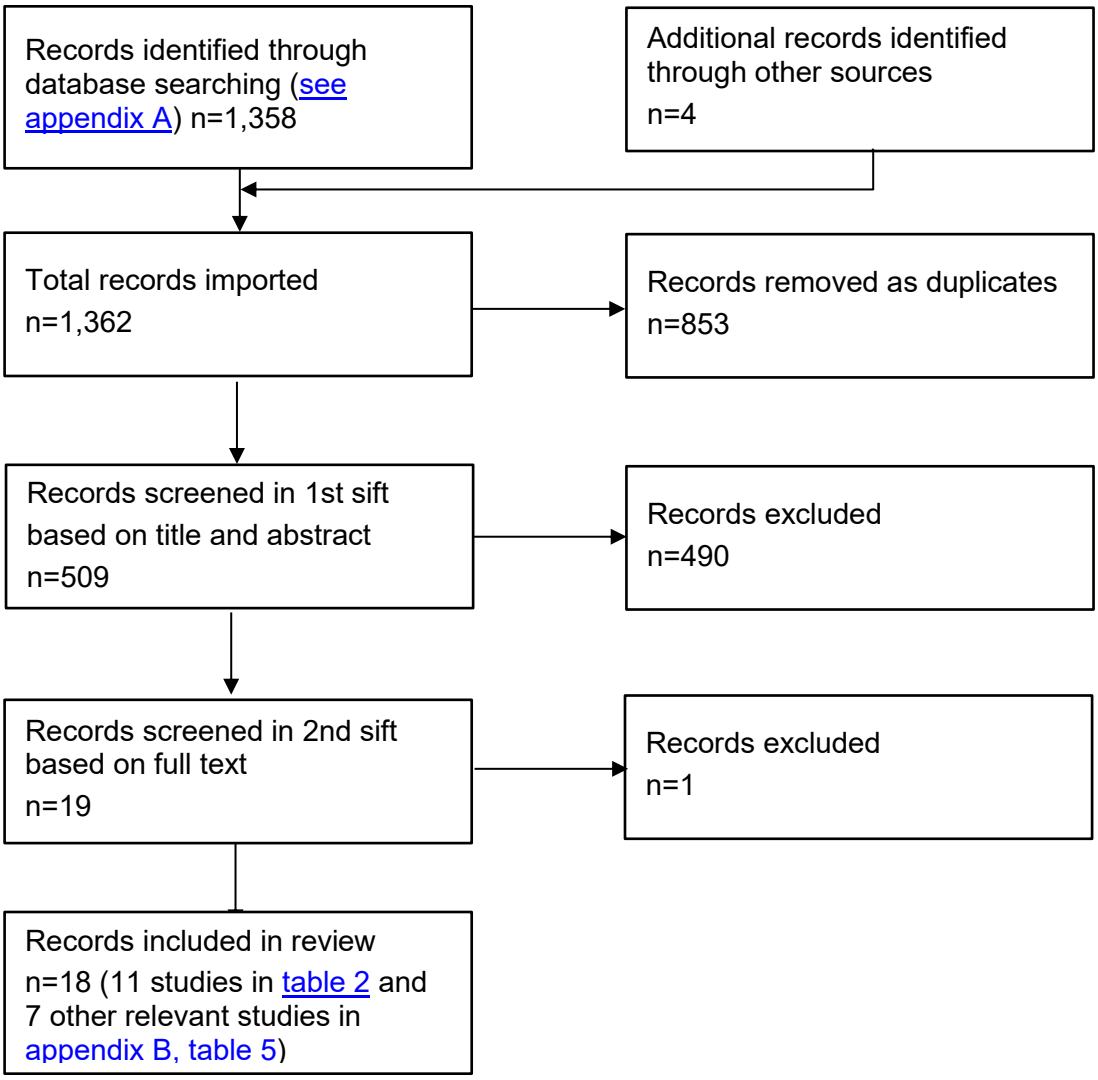

Table 2 Study details

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
1	Cornthwaite K, 2024 Studies on balloon disimpaction were from Australia, India, UK and US	n=3,558 (24 studies) Of the 7 studies on balloon disimpaction (n=1,110), 6 included women with 10 cm cervical dilation and 1 study included women with cervical dilation 7 cm or more.	Systematic review, including 7 studies on balloon disimpaction. Of the 7 studies, 2 were randomised controlled trials and 5 were non-randomised comparative studies. The risk of bias was low in 1 of the randomised controlled trials and high in the other. All non-randomised studies were at serious or critical risk of bias. The certainty of evidence using GRADE was low or	Studies comparing techniques or adjunctive measures to prevent or manage impacted fetal head at emergency caesarean birth (first or second stage). All randomised controlled trials of any size and non-randomised comparative prospective or retrospective cohort studies with 30 or more people per treatment arm were included. A trial that was retracted because of concerns about scientific integrity was excluded. Another trial with similar authors, data and methods was considered to be at risk of retraction and was	The Fetal Pillow device was used in the intervention arm of all 7 studies on balloon disimpaction (n=533). The comparators were no pillow (n=453), non-inflated pillow (n=30), vaginal disimpaction (n=69) or Patwardhan technique (n=25).	Not reported

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			very low for all outcomes.	excluded during sensitivity analysis.		
2	Sadler L, 2024 New Zealand	n=1,703 caesareans in second stage (375 with balloon disimpaction) When comparing use and non-use of balloon disimpaction, there was a higher proportion of use in nulliparous compared to parous women (82% versus 73%) and when the fetal head was at or below the ischial spines (station 0 to +3) (57% versus 44%), and after attempted operative vaginal birth (14% versus 7%).	Retrospective cohort (2 centres), comparing outcomes with or without balloon disimpaction. There were 3 comparisons: 2 were within a centre, before and after introduction of balloon device and with or without use of balloon device. The third compared the centre that used the device with a centre that did not use it. Study period: 2016 to 2021	Singleton, cephalic, term (37 weeks or more) pregnancies with caesarean in second stage. Cases were ascertained from maternity electronic records at 2 tertiary maternity units.	Second stage caesarean deliveries with (n=375) or without (n=1,328) balloon disimpaction using the Fetal Pillow device.	6 weeks
3	Lassey S, 2020 US	n=60 (30 with balloon disimpaction) nulliparous women who had caesarean	Double blind randomised controlled trial	At least 18 years old with a full term (37 weeks of gestation or greater) singleton fetus in cephalic presentation.	The Fetal Pillow device (Safe Obstetric Systems UK) was used in all deliveries. It	To hospital discharge

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		delivery in the second stage of labour Median maternal age (years): • Inflated group=33.0 • Non-inflated group=30.5	Analysis was by intention to treat. Recruitment period: 2018 to 2019	Women were excluded if there was a contraindication to a vaginal delivery, prior caesarean delivery, or presence of congenital fetal anomaly. Non-English speaking women were also excluded.	was inflated in the treatment group (n=30) and not inflated in the control group (n=30). Most women had a low transverse caesarean delivery (93%).	
4	Dutta S, 2019 India	n=50 (25 with balloon disimpaction) Full dilation Mean age=25 years 60% of whole cohort were nulliparous. 46% were at fetal station 2 and 30% were at fetal station 1.	Randomised controlled trial Study period is unclear: most of the text refers to a period between 2016 and 2017 but some text refers to 2014. The abstract refers to the centre as West Bengal but the rest of the paper states the study was done in North Bengal.	Women with singleton pregnancies at least 36 weeks gestation having caesarean at full dilation, with a deeply engaged fetal head. Patients with active genital infections, fetal malpresentation, non-cephalic presentation were excluded.	The Fetal Pillow device (Safe Obstetrics Systems UK) was used in 25 (50%) deliveries. The comparator was the modified Patwardhan technique (n=25).	To hospital discharge
5	Sacre H, 2021 UK	n=391 (170 with balloon disimpaction) Full dilation	Retrospective cohort study	Full dilation caesareans.	The Fetal Pillow device (Safe Obstetrics	To hospital discharge

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Median maternal age=30 years 87% Caucasian 87% of those in the balloon disimpaction group were nulliparous compared with 73% in the control group (p=0.0009). There were statistically significant differences in station with fewer people in the balloon disimpaction group reported as above the ischial spines (RR 0.37, 95% CI 0.25 to 0.57, p<0.0001) and more below the ischial spines (RR 2.34, 95% CI 1.68 to 3.26, p<0.0001).	Study period: 2014 to 2018	Twin pregnancies and breech presentations were excluded. All outcomes were obtained from the hospital electronic patient record systems Meditech and neonatal outcomes were obtained from Badger.net.	Systems UK) was used in 170 (44%) deliveries. The decision to use the device or not was left to the individual clinician.	
6	Hanley I, 2020 Australia	n=174 (114 with balloon disimpaction) Full dilation Mean maternal age=28.0 years (balloon disimpaction),	Retrospective cohort study Study period: 2014 to 2018	All patients who had a caesarean delivery at full dilation or with the use of a balloon disimpaction device pillow were reviewed for this study.	The Fetal Pillow device (Safe Obstetrics Systems UK) was used in 114 (66%) deliveries. Use of	To hospital discharge

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		26.6 years (control), p=0.1 Mean parity=0.41 (balloon disimpaction), 0.47 (control), p=0.35 Most were at fetal station 0 or 1.		Any cases that used balloon disimpaction at less than full dilation were excluded. The study data were extracted from the study institution's electronic record system.	the device depended on obstetrician preference or situation-specific factors (such as urgency of delivery).	
7	Chooi K, 2023 Australia	n=101 (53 with balloon disimpaction) Cervical dilation 7 cm or above Mean maternal age=30.4 years 76% of whole cohort were nulliparous.	Retrospective cohort study Study period: 2018 to 2019 All caesarean births where balloon disimpaction was used and a similar number of births where caesarean birth occurred at full dilatation and balloon disimpaction was not used were included. These were randomly selected from the hospital database as they were coded	Women who had a singleton pregnancy requiring caesarean birth at term gestation in the second stage of labour. Women were excluded if they were identified as fully dilated on coding but their medical records documented that they were less than 7 cm dilated. Women who were 7 cm dilated and above, but not fully dilated, remained in the study.	The Fetal Pillow device (Safe Obstetrics Systems UK) was used in 53 (53%) deliveries.	To hospital discharge

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			as 'emergency caesarean' and 'full dilatation' across the same time period.			
8	Safa H, 2016 Australia	n=160 (91 with balloon disimpaction) Full dilation Mean maternal age (years): • Balloon disimpaction=29.9 • Hand-push method=31, p=0.39 75% of whole cohort were nulliparous. Fetal station was not reported.	Retrospective cohort study Study period: 2013 to 2015	Women who had singleton pregnancies and had caesarean delivery at full dilation at 37 week of pregnancy or later during the study period. Only deliveries where balloon disimpaction or the hand-push method were used were included in the analyses. Multiple pregnancies, pregnancies that resulted in fetal death in utero, and any major fetal congenital anomalies were excluded.	The Fetal Pillow device (Safe Obstetrics Systems UK) was used in 91 (57%) deliveries. The comparator was the hand-push technique (n=69).	To hospital discharge
9	Barman S, 2015	n=147 (75 with balloon disimpaction)	Non-randomised comparative study	Women with single fetus with cephalic presentation at late stage	• Fetal pillow (Safe Obstetric	Not reported

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
	India	Mean maternal age (years): • Balloon disimpaction=21.9 • Patwardhan=22.4 Station of head +1 or below: • Balloon disimpaction=45% • Patwardhan=54%	Women were alternately allocated to study or control group. Study period: 2012 to 2013	of labour when head was deep in pelvis and needing emergency caesarean.	Systems UK), n=75 • Patwardhan technique, n=72	
10	Jordan A, 2022 Australia	n=1 Full dilation 32-year old (parity 1) Fetal head was at station 1	Case report	Case report: uterine and bladder rupture	The Fetal Pillow device (Safe Obstetrics Systems UK) was used.	Not reported
11	Mumtaz H, 2023 UK	n=2 40-year old (parity 1) and 36-year old (parity 2) women	Case report	Case reports of posterior uterine rupture	The Fetal Pillow (Cooper Surgical) was used.	Not reported

Table 3 Study outcomes

First author, date	Maternal outcomes	Neonatal outcomes
Cornthwaite 2024	Pooled analysis that included balloon disimpaction device compared with no device, non-inflated device or vaginal disimpaction demonstrated no or equivocal differences in maternal outcomes based on very low or low certainty evidence. **Uterine incision extension** (balloon disimpaction compared with no balloon) RR=0.79 (95% CI 0.52 to 1.19); 4 studies, I^2=31% After excluding a study at risk of retraction in sensitivity analysis, the RR was 0.90 (95% CI 0.67 to 1.23, I^2=0%). GRADE assessment showed very low certainty for this outcome, with and without the study at risk of retraction. **Postpartum haemorrhage** (balloon disimpaction compared with no balloon) RR=1.10 (95% CI 0.81 to 1.49); 4 studies, I^2=0% After excluding a study at risk of retraction in sensitivity analysis, the RR was 1.13 (95% CI 0.83 to 1.54, I^2=0%). **Operative time** Although 1 non-randomised study reported a statistically significantly shorter operative time when using balloon disimpaction compared with no balloon (mean difference 20.81 [95% CI 22.31 to 19.31] minutes), it was at serious	**Infant birth trauma** (balloon disimpaction compared with no balloon) OR=1.02 (95% CI 0.46 to 2.24); 2 studies, I^2=68% After excluding the study at risk of retraction in sensitivity analysis, the OR was 1.44 (95% CI 0.60 to 3.48) in the remaining study (Chooi 2022). GRADE assessment showed very low certainty for this outcome, with and without the study at risk of retraction. **Apgar score less than 7 at 5 minutes** (balloon disimpaction compared with no balloon) RR=1.01 (95% CI 0.84 to 1.21); 3 studies, I^2=0%

First author, date	Maternal outcomes	Neonatal outcomes
	risk of bias with risk of retraction and very low certainty in the effect estimates.	
Sadler, 2024	**Comparison 1: after versus before introduction of balloon disimpaction device to centre** **Any uterine incision extension (primary outcome)** • After introduction of device=24.8% (219/883) • Before introduction of device=26.8% (84/314) Adjusted OR=0.88 (95% CI 0.65 to 1.19) For nulliparous women, adjusted OR=1.13 (95% CI 0.78 to 1.62) For parous women, adjusted OR=0.47 (95% CI 0.26 to 0.82) **Major uterine incision extension** • After introduction of device=7.7% (68/883) • Before introduction of device=6.4% (20/314) Adjusted OR=1.20 (95% CI 0.71 to 2.04) **Comparison 2: use versus non-use of balloon disimpaction device after introduction** **Any uterine incision extension (primary outcome)** • Device used=26.1% (98/375) • Device not used=23.8% (121/508) Adjusted OR=1.14 (95% CI 0.83 to 1.57) **Major uterine incision extension**	**Comparison 1: after versus before introduction of balloon disimpaction device to centre** **Composite neonatal outcome** (including perinatal death, hypoxic ischaemic encephalopathy (Sarnat moderate or severe), any neonatal seizure, birth trauma, acidosis (cord pH less than 7.10) or neonatal intensive care unit admission for at least 48 hours) • After introduction of device=4.3% (38/883) • Before introduction of device=4.1% (13/314) Adjusted OR=1.07 (95% CI 0.55 to 2.06) **Comparison 2: use versus non-use of balloon disimpaction device after introduction** **Composite neonatal outcome** • Device used=4.8% (18/375) • Device not used=3.9% (20/508) Adjusted OR=1.01 (95% CI 0.51 to 1.99)

First author, date	Maternal outcomes	Neonatal outcomes
	• Device used=8.5% (32/375) • Device not used=7.1% (36/508) Adjusted OR=1.35 (95% CI 0.80 to 2.27) Balloon disimpaction was used more frequently with nulliparous than parous women (82.4% versus 73.0%) and when the fetal head was at or below the ischial spines (station 0 to +3) (56.7% versus 43.9%), and after attempted operative vaginal birth (13.6% versus 6.9%). **Comparison 3: unit with versus unit without availability of balloon disimpaction device** **Any uterine incision extension (primary outcome)** • Unit with device available=24.2% (139/574) • Unit without device available=29.2% (148/506) Adjusted OR=0.73 (95% CI 0.54 to 0.99) **Major uterine incision extension** • Unit with device available=7.1% (41/574) • Unit without device available=6.5% (33/506) Adjusted OR=1.35 (95% CI 0.80 to 2.27) The following potential confounders, and predictors, of maternal and neonatal morbidity were included in multivariable models using logistic regression: maternal body mass index, ethnicity, parity, previous caesarean status, length of second stage, attempted assisted vaginal	**Comparison 3: unit with versus unit without availability of balloon disimpaction device** **Composite neonatal outcome** • Unit with device available=4.7% (27/574) • Unit without device available=6.5% (33/506) Adjusted OR=0.73 (95% CI 0.39 to 1.36)

First author, date	Maternal outcomes	Neonatal outcomes
	delivery, station of head at last vaginal assessment, urgency of caesarean, neonatal birthweight and gestational age.	
Lassey, 2020	**Median time from hysterotomy to delivery (primary outcome)** • Inflated device=31 seconds • Non-inflated device (control)=54 seconds, p<0.01 Mean difference=-38.2 seconds (95% CI -56.1 to -20.3) **Uterine incision extension** • Inflated device=20% (6/30) • Non-inflated device (control)=43% (13/30), p=0.05 Of the 13 extensions in the non-inflated group, 4 were into the cervix, vagina or bladder compared with none in the inflated group. **Median blood loss (ml)** • Inflated device=800 • Non-inflated device (control)=900 Mean difference=-191.7, p=0.09 There were 3 blood transfusions in the non-inflated group and none in the inflated group. Maternal fever, intensive care unit admission, prolonged length of hospital stay and readmission were rare events and not different between groups.	There were no differences in neonatal outcomes between the groups, including birth weight, Apgar scores, neonatal intensive care, unit admission, intubation and other fetal morbidity. The median Apgar score at 1 minute was 8 in both groups. At 5 minutes, the median score was 9 in both groups.

First author, date	Maternal outcomes	Neonatal outcomes
	Ease of delivery Healthcare providers described 80% (24/30) of deliveries in the inflated group as 'easy' or 'very easy' compared with 43% (13/30) in the not-inflated group. None of the deliveries in the inflated group were described as 'difficult' or 'very difficult' compared with 37% (11/30) in the not-inflated group (p<0.01). 97% (29/30) of healthcare providers in the inflated group would use the balloon elevation device again or recommend it to others compared with 77% (22/30) in the not-inflated group (p=0.03).	
Dutta 2019	**Extension of uterine incision** • Balloon disimpaction=8% • Modified Patwardhan technique=24%, p=0.001 **Operating time (skin to skin), p=0.02** **30 to 40 minutes** • Balloon disimpaction=80% • Modified Patwardhan technique=64% **40 to 50 minutes** • Balloon disimpaction=12% • Modified Patwardhan technique=28% **50 to 60 minutes** • Balloon disimpaction=8%	**Admission to special newborn care unit** • Balloon disimpaction=12% • Modified Patwardhan technique=60%, p=0.04 Out of the 15 babies admitted to the special newborn care unit in the modified Patwardhan group, 1 had bruises over the back and abdomen and died on day 11 (early neonatal death). **Occurrence of neonatal seizure** • Balloon disimpaction=0% • Modified Patwardhan technique=4%, p=0.03

First author, date	Maternal outcomes	Neonatal outcomes
	• Modified Patwardhan technique=4% **More than 1 hour** • Balloon disimpaction=0% • Modified Patwardhan technique=4% **Uterine incision to delivery time, p=0.04** **0 to 2 minutes** • Balloon disimpaction=52% • Modified Patwardhan technique=8% **2 to 4 minutes** • Balloon disimpaction=48% • Modified Patwardhan technique=44% **4 to 6 minutes** • Balloon disimpaction=0% • Modified Patwardhan technique=48% **Number of mops soaked in blood, p=0.02** • 1: balloon disimpaction=12%, modified Patwardhan technique=0% • 2: balloon disimpaction=72%, modified Patwardhan technique=80% • More than 2: balloon disimpaction=16%, modified Patwardhan technique=20%	

First author, date	Maternal outcomes	Neonatal outcomes
	Need for blood transfusion • Balloon disimpaction=0% • Modified Patwardhan technique=16%, p=0.002	
Sacre, 2021	**Median estimated blood loss, ml (interquartile range)** • Balloon disimpaction=600 (500 to 900) • Control=600 (500 to 800) **Estimated blood loss more than 1,000 ml** • Balloon disimpaction=22.9% (39/170) • Control=18.6% (41/221) RR=1.24 (95% CI 0.84 to 1.83), p=0.29 **Estimated blood loss more than 1,500 ml** • Balloon disimpaction=8.8% (15/170) • Control=6.3% (14/221) RR=1.39 (95% CI 0.69 to 2.81), p=0.35 **Blood transfusion** • Balloon disimpaction=5.4% (8/170) • Control=4.1% (9/221) RR=1.16 (95% CI 0.46 to 2.9), p=0.76 **Uterine incision extension** • Balloon disimpaction=21.8% (37/170)	**Median birthweight, g (interquartile range)** • Balloon disimpaction=3,658 (3,350 to 3,958) • Control=3,650 (3,328 to 4,030) **Apgar score less than 7 at 5 minutes** • Balloon disimpaction=7.1% (12/170) • Control=5.4% (12/221) RR 1.30 (95% CI 0.60 to 2.82), p=0.51 **Arterial pH less than 7.1** • Balloon disimpaction=7.1% (12/170) • Control=13.1% (29/221) RR 0.54 (95% CI 0.28 to 1.02), p=0.06 **Admission to neonatal intensive care unit** • Balloon disimpaction=8.8% (15/170) • Control=12.2% (27/221) RR 0.72 (95% CI 0.40 to 1.31), p=0.29

First author, date	Maternal outcomes	Neonatal outcomes
	• Control=21.3% (43/221) RR=1.02 (95% CI 0.70 to 1.50), p=0.91 **Subgroup analysis: deliveries at the ischial spines or lower** **Median estimated blood loss, ml (interquartile range)** • Balloon disimpaction=600 (500 to 887.5) • Control=600 (500 to 800) **Estimated blood loss more than 1,000 ml** • Balloon disimpaction=23.0% (32/139) • Control=14.2% (18/126) RR=1.61 (95% CI 0.95 to 2.72), p=0.07 **Estimated blood loss more than 1,500 ml** • Balloon disimpaction=8.6% (12/139) • Control=3.2% (4/126) RR=2.72 (95% CI 0.90 to 8.22), p=0.08 **Blood transfusion** • Balloon disimpaction=5.6% (8/139) • Control=3.2% (4/126) RR=1.81 (95% CI 0.56 to 5.88), p=0.32	**Subgroup analysis: deliveries at the ischial spines or lower** **Apgar score less than 7 at 5 minutes** • Balloon disimpaction=7.2% (10/139) • Control=5.6% (7/126) RR 1.30 (95% CI 0.51 to 3.30), p=0.59 **Arterial pH less than 7.1** • Balloon disimpaction=7.2% (10/139) • Control=18.3% (23/126) RR 0.39 (95% CI 0.20 to 0.80), p=0.001 **Admission to neonatal intensive care unit** • Balloon disimpaction=7.9% (11/139) • Control=11.9% (15/126) RR 0.67 (95% CI 0.31 to 1.39), p=0.28

First author, date	Maternal outcomes	Neonatal outcomes
	Uterine incision extension • Balloon disimpaction=21.6% (30/139) • Control=24.6% (31/126) RR=0.87 (95% CI 0.56 to 1.36), p=0.56	
Hanley, 2020	**Need to use 'hand push' technique** • Balloon disimpaction=0.9% (1/114) • Control=10.0% (6/60), p=0.007 **Operative complications** (including uterine incision extension, need for breech extraction, use of vertical incision, and bladder, ureter or bowel injury) – primary outcome • Balloon disimpaction=16.7% (19/114) • Control=25.0% (15/60) OR=0.56 (95% CI 0.26 to 1.22), p=0.146 **Mean estimated blood loss (ml)** • Balloon disimpaction=730 • Control=725, p=0.98 **Estimated blood loss more than 1 litre** • Balloon disimpaction=13.2% (15/114) • Control=11.7% (7/60) OR=1.15 (95% CI 0.44 to 3.00), p=0.77	**Mean Apgar score at 5 minutes** • Balloon disimpaction=8.65 • Control=8.63, p=0.87 **Apgar score more than 7 at 5 minutes** • Balloon disimpaction=92.9% (105/113) • Control=93.3% (56/60) OR=1.07 (95% CI 0.31 to 3.70), p=0.91 **Neonatal intensive care unit stay** • Balloon disimpaction=33.0% (37/112) • Control=40.0% (24/60) OR=0.76 (95% CI 0.39 to 1.47), p=0.41 **Mean duration of stay in neonatal intensive care unit** • Balloon disimpaction=1 hour • Control=1.5 hours, p=0.24 **Mean umbilical cord arterial pH**

First author, date	Maternal outcomes	Neonatal outcomes
	Need for blood transfusion • Balloon disimpaction=0.9% (1/114) • Control=5.2% (3/60) OR=0.22 (95% CI 0.03 to 1.64), p=0.14 **Mean length of hospital stay** • Balloon disimpaction=65.8 hours • Control=72.6 hours, p=0.71	• Balloon disimpaction=7.25 • Control=7.19, p=0.0001
Chooi 2023	**Uterine incision extension** • Balloon disimpaction=20.8% (11/53) • Control=25.0% (12/48) RR=0.83 (95% CI 0.40 to 1.72), p=0.61 **Blood transfusion** • Balloon disimpaction=3.8% (2/53) • Control=2.1% (1/48) RR=1.81 (95% CI 0.18 to 38.3), p=0.62 **Admission to high dependency unit** • Balloon disimpaction=11.3% (6/53) • Control=10.4% (5/48) RR=1.09 (95% CI 0.35 to 3.56), p=0.88	**Need for resuscitation** • Balloon disimpaction=28.3% (15/53) • Control=25.5% (12/47) RR=1.11 (95% CI 0.58 to 2.18), p=0.76 **Apgar score below 7 at 1 minute** • Balloon disimpaction=15.1% (8/53) • Control=18.8% (9/48) RR=0.81 (95% CI 0.33 to 1.94), p=0.62 **Apgar score below 7 at 5 minutes** • Balloon disimpaction=3.8% (2/53) • Control=6.2% (3/48) RR=0.60 (95% CI 0.08 to 3.50), p=0.57

First author, date	Maternal outcomes	Neonatal outcomes
	Mean blood loss, ml • Balloon disimpaction=699.1 (SD 393.9) • Control=797.9 (SD 488.3) Mean difference=-98.9 (95% CI -273.3 to 75.6), p=0.26 **Blood loss more than 1,000 ml** • Balloon disimpaction=26.4% (14/53) • Control=29.2% (14/48) RR=0.91 (95% CI 0.48 to 1.72), p=0.76 **Mean length of hospital stay, days** • Balloon disimpaction=3.22 (SD 1.4) • Control=3.45 (SD 1.2) Mean difference=-0.23 (95% CI -0.75 to 0.29), p=0.39	**Mean cord arterial lactate** • Balloon disimpaction=4.19 (SD 1.76) • Control=4.41 (SD 1.74) Mean difference=-0.22 (95% CI -0.98 to 0.54), p=0.56 **Mean cord arterial pH** • Balloon disimpaction=7.25 (SD 0.06) • Control=7.24 (SD 0.08) Mean difference=-0.00 (95% CI -0.03 to 0.03), p=0.92 **Admission to special care baby unit or neonatal intensive care** • Balloon disimpaction=30.2% (16/53) • Control=46.8% (22/47) RR=0.64 (95% CI 0.38 to 1.07), p=0.09 **Jaundice** • Balloon disimpaction=28.3% (15/53) • Control=42.6% (20/47) RR=0.67 (95% CI 0.38 to 1.14), p=0.14 **Seizures or jitters**

First author, date	Maternal outcomes	Neonatal outcomes
		• Balloon disimpaction=0% (0/53) • Control=8.5% (4/47), p=0.045 **Neonatal trauma (soft tissue injury, bony trauma or intracranial bleed)** • Balloon disimpaction=30.2% (16/53) • Control=23.4% (11/47) RR=1.29 (95% CI 0.67 to 2.59), p=0.45
Safa 2016	**Mean estimated blood loss, ml** • Balloon disimpaction=273 (SD 145) • Hand-push technique=403 (SD 199), p=0.026 **Blood transfusion** • Balloon disimpaction=3% (3/91) • Hand-push technique=3% (2/69), p=0.75 **Uterine angle extension** • Balloon disimpaction=20% (18/91) • Hand-push technique=35% (24/69), p=0.061 **Mean length of hospital stay, hours** • Balloon disimpaction=77.9 (SD 19.6) • Hand-push technique=97.8 (SD 27.6), p=0.002	**Apgar score below 7 at 5 minutes** • Balloon disimpaction=3% (3/91) • Hand-push technique=6% (4/69), p=0.44 **Need for endotracheal intubation** • Balloon disimpaction=0% (0/91) • Hand-push technique=3% (2/69), p=0.10 **Admission to neonatal intensive care unit** • Balloon disimpaction=15% (14/91) • Hand-push technique=25% (17/69), p=0.14

First author, date	Maternal outcomes	Neonatal outcomes
		Mean cord arterial pH • Balloon disimpaction=7.24 (SD 0.06) • Hand-push technique=7.19 (SD 0.09), p=0.003
Barman 2015	**'Easy' delivery of fetal head** • Balloon disimpaction=76.0% (57/75) • Patwardhan technique=31.9% (23/72) OR=6.75 (95% CI 3.08 to 14.95) **Mean baby delivery time (seconds)** • Balloon disimpaction=180 (SD 29) • Patwardhan technique=270 (SD 50), p<0.0001 **Mean total operative time (skin to skin; minutes)** • Balloon disimpaction=36.8 (SD 7) • Patwardhan technique=40.2 (SD 7), p=0.004 **Extension of uterine angle** • Balloon disimpaction=25.3% (19/75) • Patwardhan technique=18.1% (13/72), p=0.285 **Uterine artery tear** • Balloon disimpaction=20.0% (15/75)	**Admission to neonatal intensive care unit** • Balloon disimpaction=17.3% (13/75) • Patwardhan technique=33.3% (24/72), p=0.025 **Mean Apgar score at 1 minute** • Balloon disimpaction=6.23 (SD 2.15) • Patwardhan technique=3.93 (SD 2.13), p<0.0001 **Mean Apgar score at 5 minutes** • Balloon disimpaction=7.79 (SD 2.03) • Patwardhan technique=5.96 (SD 2.29), p<0.0001 2 babies in the Patwardhan technique group were stillborn.

First author, date	Maternal outcomes	Neonatal outcomes
	• Patwardhan technique=9.7% (7/72), p=0.081 **Need for blood transfusion** • Balloon disimpaction=5.3% (4/75) • Patwardhan technique=6.9% (5/72)	
Jordan 2022	Caesarean at full dilation, for obstructed labour with the fetal head at station 1. The woman had a previous caesarean delivery at full dilation for obstructed labour. As soon as the balloon disimpaction device was inserted frank blood was seen in the catheter and the urinary bag. Intraoperatively, there were extensive adhesions and a Bandl's ring. The lower segment of the uterus had ruptured into the bladder, with fetal parts present within the bladder cavity and abdomen. Surgical repair involved the urology team. Total maternal blood loss was 3.1 litres. After resuscitation, the immediate and long term recovery were uneventful. The authors noted that there was a weakened zone because of a previous caesarean section scar. This ruptured when elevation of the fetal head caused a shift in pressure to the weakest point.	A live male infant weighing 3,850 g was delivered in good condition (Apgar score 9).
Mumtaz 2023	Case 1: 40-year old woman of Asian origin with a history of caesarean section 7 years previously because of failure to progress. Labour progressed smoothly until full cervical dilation was reached. There were concerns about fetal distress during active pushing and it was decided to proceed with an emergency caesarean (station at 0 and left occiput transverse position). A balloon disimpaction device was inserted vaginally. Intraoperatively haemoperitoneum	Both babies were delivered in good condition (Apgar scores 8 and 10, and 9 and 10, respectively).

First author, date	Maternal outcomes	Neonatal outcomes
	was noted. The anterior uterine wall was intact. The baby was delivered through a lower-segment transverse incision and was in good condition. A vertical full thickness uterine posterior wall rupture was noted, which was repaired with sutures. Total estimated blood loss was 1,000 ml. The immediate and long-term recovery were uneventful. Case 2: 36-year old woman of African origin with a history of 2 previous vaginal deliveries. After 2 hours of active pushing at full cervical dilation, the fetal head was in direct occiput anterior position, station at ischial spines and caput+2. A decision was made to proceed with an emergency caesarean section. A balloon disimpaction device was inserted vaginally. Intraoperatively blood-stained peritoneal fluid was observed on entering the abdominal cavity. The anterior uterine wall was intact. The baby was delivered through a lower-segment transverse incision, in good condition. A vertical partial thickness posterior wall dehiscence (intact serosal layer) was noted on the uterus, which was repaired with sutures. Total estimated blood loss was 1,300 ml. The immediate and long-term recovery were uneventful. The authors noted that it is uncertain whether the posterior uterine wall ruptures were caused by an increase in intra-uterine pressure secondary to the use of the balloon disimpaction device or because of the fragility of the uterus during labour.	

Procedure technique

All studies used the Fetal Pillow (Safe Obstetrics Systems UK, now CooperSurgical) for balloon disimpaction at caesarean during the second stage of labour or at full dilation (1 study included some women who were not fully dilated; Chooi 2023).

Maternal outcomes

Uterine incision extension

Uterine incision extension or uterine angle extension was reported as an outcome in 7 studies. In the systematic review by Cornthwaite et al. (2024), the RR for uterine incision extension when balloon disimpaction was used compared with no balloon was 0.90 (95% CI 0.67 to 1.23, I^2=0%) based on 3 studies (Chooi 2023, Hanley 2020 and Sacre 2021).

The study by Hanley et al. (2020) was a retrospective cohort of 173 caesarean deliveries with or without balloon disimpaction and the primary outcome was a composite measure of 'operative complications', including uterine incision extension, need for breech extraction, use of vertical incision and bladder, ureter or bowel injury. The rates for this outcome were 17% (19/114) in the balloon disimpaction group and 25% (15/60) in the control group (OR=0.56, 95% CI 0.26 to 1.22, p=0.146; Hanley 2020).

In the cohort study of 1,703 caesareans, the rate of uterine incision extension was 25% (219/883) after the balloon disimpaction device was introduced to the maternity unit compared with 27% (84/314) before (adjusted OR=0.88, 95% CI 0.65 to 1.19; Sadler 2024). For nulliparous women, the adjusted OR was 1.13 (95% CI 0.78 to 1.62) and for nulliparous women it was 0.47 (95% CI 0.26 to 0.82). After the device had been introduced to the maternity unit, the rate of uterine incision extension was 26% (98/375) when the device was used compared with 24% (121/508) when it wasn't used (adjusted OR 1.14, 95% CI

0.83 to 1.57). The rate of uterine incision extension in the unit with availability of the balloon disimpaction device was 24% (139/574) compared with 29% (148/506) in a unit without availability of the device (adjusted OR 0.73, 95% CI 0.54 to 0.99).

In the randomised controlled trial of 60 caesarean deliveries, the rate of uterine incision extension was 20% (6/30) when a balloon disimpaction device was used and inflated compared with 43% (13/30) when the device was not inflated (p=0.05). Of the 13 extensions in the non-inflated group, 4 were into the cervix, vagina or bladder compared with none in the inflated group (Lassey 2020). In the randomised controlled trial of 50 caesareans at full dilation with a deeply engaged fetal head, the rate of uterine incision extension was 8% in the balloon disimpaction group and 24% in the modified Patwardhan technique group (p=0.001; Dutta 2019).

In the retrospective cohort study of 160 caesarean deliveries, the rate of uterine angle extension was 20% (18/91) when balloon disimpaction was used and 35% (24/69) when a hand-push technique was used (p=0.061; Safa 2016).

In the prospective non-randomised comparative study of 147 caesarean deliveries, the rate of uterine angle extension was 25% (19/75) when balloon disimpaction was used and 18% (13/72) when the Patwardhan technique was used (p=0.285; Barman 2015).

Uterine wall rupture

Three cases of uterine wall rupture were described in 2 papers (Jordan 2022, Mumtaz 2023). In 1 woman, who had had a previous caesarean, the lower segment of the uterus ruptured into the bladder before the baby was delivered. The rupture was surgically repaired and the total maternal blood loss was 3.1 litres (Jordan 2022). In the 2 other women, 1 of whom had had a previous caesarean, there was a partial or full thickness uterine posterior wall rupture

identified after the baby was delivered. These were repaired surgically and estimated blood loss was 1,000 ml and 1,300 ml respectively (Mumtaz 2023). In all 3 cases, the baby was delivered in good condition (Apgar scores 8 and above) and immediate and long-term recovery were uneventful.

Uterine artery tear

In the prospective non-randomised comparative study of 147 caesarean deliveries, the rate of uterine artery tear was 20% (15/75) when balloon disimpaction was used and 10% (7/72) when the Patwardhan technique was used (p=0.081; Barman 2015).

Bleeding

In the systematic review by Cornthwaite et al. (2024), the RR for postpartum haemorrhage (blood loss more than 1,000 ml) when balloon disimpaction was used compared with no balloon was 1.13 (95% CI 0.83 to 1.54, I^2=0%) based on 3 studies (Chooi 2023, Hanley 2020 and Sacre 2021).

In the randomised controlled trial of 60 caesarean deliveries, the median blood loss was 800 ml when an inflated balloon disimpaction device was used compared with 900 ml when a non-inflated device was used (mean difference=-191.7, p=0.09; Lassey 2020). In the randomised controlled trial of 50 caesareans at full dilation with a deeply engaged fetal head, the rate of blood transfusion was 0% in the balloon disimpaction group and 16% in the modified Patwardhan technique group (p=0.002; Dutta 2019).

In the retrospective cohort study of 160 caesarean deliveries, the mean estimated blood loss was 273 ml when balloon disimpaction was used and 403 ml when a hand-push technique was used (p=0.026). The rate of blood transfusion was 3% in both groups (Safa 2016).

In the prospective non-randomised comparative study of 147 caesarean deliveries, the rate of blood transfusion was 5% (4/75) when balloon disimpaction

was used and 7% (5/72) when the Patwardhan technique was used (Barman 2015).

Operative time

In the randomised controlled trial of 60 caesarean deliveries, the median time from hysterotomy to delivery was 31 seconds when an inflated balloon disimpaction device was used compared with 54 seconds when a non-inflated device was used (mean difference=-38.2 seconds, 95% CI -56.1 to -20.3, p<0.01; Lassey 2020). In the randomised controlled trial of 50 caesarean deliveries, the uterine incision to delivery time was 0 to 2 minutes in 52% of those who had balloon disimpaction and 8% of those who had modified Patwardhan technique, 2 to 4 minutes in 48% of those who had balloon disimpaction and 44% of those who had modified Patwardhan technique and 4 to 6 minutes in none of those who had balloon disimpaction and 48% of those who had modified Patwardhan technique (p=0.04; Dutta 2019).

In the prospective non-randomised comparative study of 147 caesarean deliveries, the mean baby delivery time was 180 seconds when balloon disimpaction was used and 270 seconds when the Patwardhan technique was used (p<0.0001). The mean total operative time (skin to skin) was 36.8 minutes in the balloon disimpaction group and 40.2 minutes in the Patwardhan technique group (p=0.004; Barman 2015).

Admission to high dependency unit

In the cohort study of 101 caesarean deliveries, the rate of admission to a high dependency unit was similar with or without balloon disimpaction (11% in the group with balloon disimpaction and 10% in the group without balloon disimpaction (p=0.88; Chooi 2023).

In the randomised controlled trial of 60 caesarean deliveries comparing the use of an inflated balloon disimpaction device with a non-inflated device, the authors

stated that intensive care unit admission was a rare event and not different between the groups (Lassey 2020).

Length of hospital stay

In the retrospective cohort of 173 caesarean deliveries with or without balloon disimpaction, the mean length of stay was 65.8 hours in the balloon disimpaction group and 72.6 hours in the control group (p=0.71; Hanley 2020). In the cohort study of 101 caesarean deliveries, the mean length of stay was 3.22 days in the balloon disimpaction group and 3.45 in the control group (mean difference=-0.23, 95% CI -0.75 to 0.29, p=0.39; Chooi 2023). In the retrospective cohort study of 160 caesarean deliveries, the mean length of stay was 77.9 hours when balloon disimpaction was used and 97.8 hours when a hand-push technique was used (p=0.002; Safa 2016).

Ease of delivery

In the randomised controlled trial of 60 caesarean deliveries comparing the use of an inflated balloon disimpaction device with a non-inflated device, healthcare providers described 80% (24/30) of deliveries in the inflated group as ‘easy’ or ‘very easy’ compared with 43% (13/30) in the not-inflated group. None of the deliveries in the inflated group were described as ‘difficult’ or ‘very difficult’ compared with 37% (11/30) in the not-inflated group (p<0.01). 97% (29/30) of healthcare providers in the inflated group would use the balloon elevation device again or recommend it to others compared with 77% (22/30) in the not-inflated group (p=0.03; Lassey 2020).

In the prospective non-randomised comparative study of 147 caesareans, delivery of the fetal head was described as easy in 76% (57/75) of those in the balloon disimpaction group and 32% (23/72) of those in the Patwardhan technique group (OR=6.75, 95% CI 3.08 to 14.95; Barman 2015).

Neonatal outcomes

Neonatal trauma

Neonatal trauma (soft tissue injury, bony trauma or intracranial bleed) was reported in 30% (16/53) of babies in the balloon disimpaction group and 23% (11/47) of babies in the control group, in the cohort study of 101 caesarean deliveries (RR=1.29, 95% CI 0.67 to 2.59, p=0.45; Chooi 2023).

Apgar score at 5 minutes

In the systematic review by Cornthwaite et al. (2024), the RR for an Apgar score of less than 7 at 5 minutes when balloon disimpaction was used compared with no balloon was 1.01 (95% CI 0.84 to 1.21, I^2=0%) based on 3 studies (Chooi 2023, Hanley 2020 and Sacre 2021).

In the randomised controlled trial of 60 caesarean deliveries comparing the use of an inflated balloon disimpaction device with a non-inflated device, the median Apgar score at 5 minutes was 9 in both groups (Lassey 2020).

In the retrospective cohort study of 160 caesarean deliveries, the proportion of babies with an Apgar score below 7 at 5 minutes was 3% (3/91) when balloon disimpaction was used and 6% (4/69) hours when a hand-push technique was used (p=0.44; Safa 2016).

In the prospective non-randomised comparative study of 147 caesarean deliveries, the mean Apgar score at 5 minutes was 7.79 in the balloon disimpaction group and 5.96 in the Patwardhan technique group (p<0.0001). Two babies in the Patwardhan technique group were stillborn (Barman 2015).

Admission to special care baby unit or neonatal intensive care unit

In the randomised controlled trial of 50 caesarean deliveries, 12% of babies in the balloon disimpaction group and 60% of those in the modified Patwardhan

technique group were admitted to a special newborn care unit (p=0.04; Dutta 2019). One of the babies in the modified Patwardhan group died on day 11.

None of the retrospective non-randomised comparative studies reported a statistically significant difference in the rate of admission to a special care baby unit or neonatal intensive care. In the cohort study of 391 caesarean deliveries, the rate of admission was 9% (15/170) in the balloon disimpaction group and 12% (27/221) in the control group (RR 0.72, 95% CI 0.40 to 1.31, p=0.29; Sacre 2021). In the cohort study of 173 caesarean deliveries with or without balloon disimpaction, 33% (37/112) of babies in the balloon disimpaction group had a stay in neonatal intensive care compared with 40% (24/60) in the control group (OR=0.76, 95% CI 0.39 to 1.47, p=0.41; Hanley 2020). The mean duration of stay was 1 hour in the balloon disimpaction group and 1.5 hours in the control group (p=0.24). In the cohort study of 101 caesarean deliveries, the rate of admission was 30% (16/53) in the balloon disimpaction group and 47% (22/47) in the control group (RR=0.64, 95% CI 0.38 to 1.07, p=0.09; Chooi 2023). In the retrospective cohort study of 160 caesarean deliveries, the rate of admission was 15% (14/91) when balloon disimpaction was used and 25% (17/69) when a hand-push technique was used (p=0.14; Safa 2016).

In the prospective non-randomised comparative study of 147 caesarean deliveries, the rate of admission to a neonatal intensive care unit was 17% (13/75) in the balloon disimpaction group and 33% (24/72) in the Patwardhan technique group (p<0.0001). Two babies in the Patwardhan technique group were stillborn (p=0.025).

Umbilical cord arterial pH

In the retrospective cohort study of 391 caesarean deliveries, umbilical cord arterial pH was less than 7.1 in 7% (12/170) of babies in the balloon disimpaction group and 13% (29/221) in the control group (RR 0.54, 95% CI 0.28 to 1.02, p=0.06; Sacre 2021). In the retrospective cohort of 173 caesarean deliveries with

or without balloon disimpaction, the mean umbilical cord arterial pH was statistically significantly higher in the balloon disimpaction group (7.25) than in the control group (7.19; p=0.0001, Hanley 2020). In the cohort study of 101 caesarean deliveries, the mean cord arterial PH was similar in the 2 groups (7.25 in the balloon disimpaction group and 7.24 in the control group (p=0.92; Chooi 2023). In the retrospective cohort study of 160 caesarean deliveries, the mean cord arterial pH was statistically significant higher when balloon disimpaction was used (7.24) compared with a hand-push technique (7.19, p=0.003; Safa 2016).

Composite outcome

The cohort study of 1,703 caesareans used a composite neonatal outcome, which included perinatal death, hypoxic ischaemic encephalopathy, seizure, birth trauma, acidosis (cord pH less than 7.10) or neonatal intensive care unit admission for at least 48 hours. The rate for this outcome was 4% both before and after the balloon disimpaction device was introduced to the maternity unit. After the device was introduced to the maternity unit, the rate was 5% (18/375) when the device was used compared with 4% (20/508) when it wasn't used (adjusted OR 1.01, 95% CI 0.51 to 1.99). When comparing 2 different maternity units, the composite neonatal outcome was 5% (27/574) in the unit with availability of the balloon disimpaction device and 7% (33/506) in the unit without availability of the device (adjusted OR 0.73, 95% CI 0.39 to 1.36; Sadler 2024).

Seizures or jitters

In the randomised controlled trial of 50 caesarean deliveries, neonatal seizure was reported in none of the babies in the balloon disimpaction group and 4% of those in the modified Patwardhan technique group (p=0.03; Dutta 2019). Seizure or jitters was reported in none of the babies in the balloon disimpaction group and 9% (4/47) of babies in the control group, in the cohort study of 101 caesarean deliveries (p=0.045; Chooi 2023).

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They listed the following anecdotal adverse events:

- Neonatal sepsis
- Time to insert
- Failure

Three professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

Validity and generalisability

- The published evidence includes data from the UK.
- One study included some women whose cervix was less than fully dilated (7 cm or above; Chooi 2023). The other studies stated that the caesarean deliveries were done when the cervix was fully dilated or during the second stage of labour.
- Of the 2 randomised controlled trials included in the systematic review by Cornthwaite et al. (2024), 1 was assessed as low risk of bias (Lassey 2020) and 1 was at high risk of bias (Dutta 2019). All 5 non-randomised studies included in the review were at serious or critical risk of bias. The certainty of evidence was low or very low, using GRADE criteria. One of the studies was identified as being at risk of retraction and has since been retracted. Another

study was published in a journal that was described in the review as 'potentially predatory' (Dutta 2019).

- The authors of the systematic review noted that there was a lack of standardisation in the measuring and reporting of outcomes associated with caesarean birth.
- One small randomised controlled trial, included in the systematic review, compared an inflated device with an uninflated device. The primary outcome for this trial was the time between hysterotomy and delivery, and it was underpowered to detect significant differences in other outcomes (Lassey 2020).
- In the cohort study by Sadler et al. (2023), there were statistically significant differences in demographic and clinical characteristics between comparison groups.
- The primary outcome differed between studies.
- The fetal head station was not reported in all studies and this is likely to be associated with the degree of difficulty encountered in the delivery.
- None of the studies reported the time between the decision to do an emergency caesarean and delivery, or the time taken to insert the balloon disimpaction device.
- Most of the studies were underpowered to detect clinically relevant differences in rarer outcomes.
- Most of the non-randomised comparative studies were retrospective, so there is a risk of bias in patient selection and definitions of maternal and neonatal outcomes.
- Ease of delivery is a subjective outcome and prone to bias.
- In the studies by Lassey et al. (2020) and Dutta et al. (2019), balloon disimpaction devices were donated by Safe Obstetric Systems, UK. None of the other studies declared any potential conflicts of interest.

Related NICE guidance

NICE guidelines

Caesarean birth (2021, last updated: 30 January 2024) NICE guideline 192.

Professional societies

- Royal College of Obstetricians and Gynaecologists
- The Royal College of Midwives
- Royal College of Paediatrics and Child Health (neonatology)
- British Maternal & Fetal Medicine Society.

Evidence from people who have had the procedure and patient organisations

NICE received 1 submission from a patient organisation about balloon disimpaction of fetal head at emergency caesarean delivery.

Company engagement

NICE asked 1 company who manufactures a device potentially relevant to this procedure for information on it. NICE received 1 completed submission. This was considered by the interventional procedures technical team and any relevant points have been taken into consideration when preparing this overview.

References

1. Cornthwaite K, van der Scheer JW, Kelly S et al. (2024) Management of impacted fetal head at cesarean birth: A systematic review and meta-analysis. Acta Obstetricia et Gynecologica Scandinavica DOI: 10.1111/aogs.14873
2. Sadler LC, Thompson JMD, Alsweiler JM et al. (2024) Maternal and neonatal morbidity associated with Fetal Pillow use at full dilatation

caesarean: A retrospective cohort. BJOG: An International Journal of Obstetrics and Gynaecology 131:1240–48

3. Lassey SC, Little SE, Saadeh M et al. (2020) Cephalic elevation device for second-stage cesarean delivery: a randomized controlled trial. Obstetrics and Gynecology 135: 879–84
4. Dutta S, Bhattacharyya SK, Adhikary S et al. (2019) A comparative study between modified Patwardhan technique and Foetal Pillow during caesarean section in full dilatation in cases of deeply engaged foetal head. IOSR Journal of Dental and Medical Sciences18: 1–7
5. Sacre H, Bird A, Clement-Jones M et al. (2021) Effectiveness of the fetal pillow to prevent adverse maternal and fetal outcomes at full dilatation cesarean section in routine practice. Acta Obstetricia et Gynecologica Scandinavica 100: 949–54
6. Hanley I, Sivanesan K, Veerasingham M et al. (2020) Comparison of outcomes at full-dilation cesarean section with and without the use of a fetal pillow device. International Journal of Gynecology and Obstetrics 150: 228–33
7. Chooi KYL, Deussen AR, Louise J et al. (2023) Maternal and neonatal outcomes following the introduction of the Fetal Pillow at a tertiary maternity hospital: A retrospective cohort study. Australian and New Zealand Journal of Obstetrics and Gynaecology 63: 360–64
8. Safa H and Beckmann M (2016) Comparison of maternal and neonatal outcomes from full-dilatation cesarean deliveries using the Fetal Pillow or hand-push method. International Journal of Gynecology & Obstetrics 135: 281–84
9. Barman SC, Chakraborty B, Saha S et al. (2015). Use of fetal pillow during cesarean section in deeply engaged head: A comparative study with Patwardhan's technique. Indian Journal of Clinical Practice 26: 375–80 https://issuu.com/ijcp/docs/ijcp_sep_2015
10. Jordan A, Herbert N, Rundle-Thiele D et al. (2022) Foetal Pillow associated uterine and bladder rupture. Journal of Obstetrics and Gynaecology 42: 1551–52
11. Mumtaz H, Magro M, Kunal Rathod K (2023) Two cases of posterior uterine rupture after Foetal Pillow use; do we need to think twice about using the Foetal Pillow? Journal of Gynecology, Clinical Obstetrics, and Reproductive Medicine 1: 90–5

Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour from the medical literature. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

Search strategy design and peer review

This search report is informed by the Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension (PRISMA-S).

A NICE information specialist ran the literature searches on 24/06/2024. See the search strategy history for the full search strategy for each database.

The principal search strategy was developed in MEDLINE ALL (Ovid interface). It was adapted for use in each of the databases listed in table 4a, taking into account the database's size, search functionality and subject coverage. The MEDLINE ALL strategy was quality assured by a NICE senior information specialist. All translated search strategies were peer reviewed to ensure their accuracy. The quality assurance and peer review procedures were adapted from the Peer Review of Electronic Search Strategies (PRESS) 2015 evidence-based checklist.

Review management

The search results were managed in EPPI-Reviewer version 5 (EPPI-R5). Duplicates were removed in EPPI-R5 using a 2-step process. First, automated deduplication was done using a high-value algorithm. Second, manual deduplication was used to assess low-probability matches. All decisions about inclusion, exclusion and deduplication were recorded and stored.

Limits and restrictions

The CENTRAL database search removed trial registry records and conference material. The Embase search excluded conference material.

English language limits were applied to the search when possible in the database. This is standard NICE practice for review topics.

The search wasn't limited by date. Any records already identified by previous searches for this topic were found and removed through the de-duplication process in EPPI-R5.

The limit to remove animal studies in the searches is standard NICE practice, which has been adapted from Dickersin K, Scherer R, Lefebvre C (1994) Systematic Reviews: Identifying relevant studies for systematic reviews. BMJ 309(6964): 1286.

Main search

Table 4a Main search results

Database	Date searched	Database platform	Database segment or version	Number of results downloaded
Cochrane Central Register of Controlled Trials (CENTRAL)	24/06/2024	Wiley	Issue 5 of 12, May 2024	57
Cochrane Database of Systematic Reviews (CDSR)	24/06/2024	Wiley	Issue 6 of 12, June 2024	1
Embase	24/06/2024	Ovid	1974 to 2024 June 21	365
INAHTA International HTA Database	24/06/2024	https://database.inahta.org/	n/a	5
MEDLINE ALL	24/06/2024	Ovid	1946 to 2024 June 21	238

Search strategy history

MEDLINE ALL search strategy

1. (balloon* adj4 (dilat* or expand* or inflat* or device*)).tw. 20797
2. (cephalic adj4 elevat*).tw. 37
3. ((elevat* or (disimpact* or dis-impact*)) adj4 (foetal or fetal or fetus or foetus)).tw. 1249
4. ((foetal or fetal or fetus or foetus) adj4 (pillow* or balloon* or cushion*)).tw. 125
5. or/1-4 22175
6. cesarean section/ 54154
7. (caesarian or cesarian or caesarean or cesarean).tw. 76659

8. c-section.tw. 1872
9. (reverse breech adj4 (method* or technique* or extract* or deliver*)).tw. 30
10. or/6-9 90732
11. cephalopelvic disproportion/ or dystocia/ 4070
12. ((cephalopelvi* adj4 disproport*) or dystocia).tw. 5152
13. (cord adj4 prolapse).tw. 576
14. Fetal Distress/ 3546
15. Labor Presentation/ 4547
16. ((foetal or fetal or fetus or foetus) adj4 (distress* or non-reassuring or malpresentation*)).tw. 6387
17. or/11-16 19076
18. Labor Stage, Second/ 1649
19. ((engage* or impact* or fix*) adj4 (foetal or fetal or fetus or foetus) adj4 head*).tw. 175
20. ((obstruct* or second-stage or advanced) adj4 labo?r).tw. 4146
21. (full* adj4 dilat*).tw. 763
22. or/18-21 5508
23. 10 or 17 or 22 105876
24. 5 and 23 270
25. Fetal Pillow.tw. 18
26. Fetal Disimpacting System.tw. 0
27. 25 or 26 18
28. 24 or 27 271
29. animals/ not humans/ 5199241
30. 28 not 29 255
31. limit 30 to English language 238

Embase search strategy

1. balloon dilatation/ 24552
2. (balloon* adj4 (dilat* or expand* or inflat* or device*)).tw. 36065
3. (cephalic adj4 elevat*).tw. 39
4. Fetal head elevator/ 35
5. ((elevat* or (disimpact* or dis-impact*)) adj4 (foetal or fetal or fetus or foetus)).tw. 1797
6. ((foetal or fetal or fetus or foetus) adj4 (pillow* or balloon* or cushion*)).tw. 224
7. or/1-6 49535
8. cesarean section/ 131355
9. (caesarian or cesarian or caesarean or cesarean).tw. 112027
10. c-section.tw. 5008
11. (reverse breech adj4 (method* or technique* or extract* or deliver*)).tw. 48
12. or/8-11 154807
13. cephalopelvic disproportion/ or dystocia/ 6482
14. ((cephalopelvi* adj4 disproport*) or dystocia).tw. 6828
15. umbilical cord prolapse/ 517
16. (cord adj4 prolapse).tw. 730
17. Fetus Distress/ 10356
18. malpresentation/ 1592

19. ((foetal or fetal or fetus or foetus) adj4 (distress* or non-reassuring or malpresentation*)).tw. 9351
20. or/13-19 25008
21. ((engage* or impact* or fix*) adj4 (foetal or fetal or fetus or foetus) adj4 head*).tw. 258
22. Obstructed labor/ or Labor stage 2/ 3307
23. ((obstruct* or second-stage or advanced) adj4 labo?r).tw. 5579
24. (full* adj4 dilat*).tw. 1294
25. or/21-24 7933
26. 12 or 20 or 25 171382
27. 7 and 26 694
28. Fetal Pillow.tw. 52
29. Fetal Disimpacting System.tw. 2
30. 28 or 29 54
31. 27 or 30 695
32. Nonhuman/ not Human/ 5467922
33. 31 not 32 678
34. (conference abstract or conference paper or conference proceeding or "conference review").pt. 5976910
35. 33 not 34 410
36. limit 35 to English language 364

Cochrane Library (CDSR and CENTRAL) search strategy

1. (balloon* near/4 (dilat* or expand* or inflat* or device*)):ti,ab,kw 2613
2. (cephalic near/4 elevat*):ti,ab,kw 3
3. ((elevat* or (disimpact* or dis-impact*)) near/4 (foetal or fetal or fetus or foetus)):ti,ab,kw 38
4. ((foetal or fetal or fetus or foetus) near/4 (pillow* or balloon* or cushion*)):ti,ab,kw 52
5. #1 or #2 or #3 or #4 2693
6. MeSH descriptor: [Cesarean Section] this term only 4504
7. (caesarian or cesarian or caesarean or cesarean):ti,ab,kw 17871
8. (c-section):ti,ab,kw 433
9. (reverse breech near/4 (method* or technique* or extract* or deliver*)):ti,ab,kw 11
10. #6 or #7 or #8 or #9 18014
11. MeSH descriptor: [Cephalopelvic Disproportion] this term only 1
12. MeSH descriptor: [Dystocia] this term only 148
13. (cephalopelvi* near/4 disproport* or dystocia):ti,ab,kw 673
14. (cord near/4 prolapse):ti,ab,kw 80
15. MeSH descriptor: [Fetal Distress] this term only 199
16. MeSH descriptor: [Labor Presentation] this term only 105
17. ((foetal or fetal or fetus or foetus) near/4 (distress* or non-reassuring or malpresentation*)):ti,ab,kw 1132
18. #11 or #12 or #13 or #14 or #15 or #16 or #17 1864
19. MeSH descriptor: [Labor Stage, Second] explode all trees 255

20. ((engage* or impact* or fix*) near/4 (foetal or fetal or fetus or foetus) near/4 head):ti,ab,kw 35
21. ((obstruct* or second-stage or advanced) near/4 labo?r):ti,ab,kw 1191
22. (full* near/4 dilat*):ti,ab,kw 272
23. #19 or #20 or #21 or #22 1434
24. #10 or #18 or #23 19652
25. #5 and #24 123
26. (Fetal Pillow):ti,ab,kw 22
27. (Fetal Disimpacting System):ti,ab,kw 0
28. #26 or #27 22
29. #25 or #28 136
30. "conference":pt or (clinicaltrials or trialsearch):so 750874
31. #29 not #30 58

INAHTA HTA Database search strategy

1. (balloon* AND (dilat* or expand* or inflat* or device*)
2. (cephalic elevat*)
3. (foetal or fetal or fetus or foetus) AND (elevat* or disimpact* or dis-impact)
4. (foetal or fetal or fetus or foetus) AND (balloon or pillow or cushion)
5. #1 OR #2 OR #3 OR #4
6. "Cesarean Section"[mh]
7. (caesarian or cesarian or caesarean or cesarean)
8. (c-section)
9. (reverse breech AND (method* or technique* or extract* or deliver*))
10. "Cephalopelvic Disproportion"[mh]
11. "Dystocia"[mh]
12. ((cephalopelvi* AND disproport*) or dystocia)
13. (cord AND prolapse)
14. "Fetal Distress"[mh]
15. "Labor Presentation"[mh]
16. ((foetal or fetal or fetus or foetus) AND (distress* or non-reassuring or malpresentation*))
17. "Labor Stage, Second"[mh]
18. ((engage* or impact* or fix*) AND (foetal or fetal or fetus or foetus) adj4 head*)
19. ((obstruct* or second-stage or advanced) AND (labor or labour)
20. (full* AND dilat*)
21. #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20
22. ("fetal pillow" or "fetal disimpacting system")
23. #5 AND #21
24. #22 OR #23

Inclusion criteria

The following inclusion criteria were applied to the abstracts identified by the literature search.

Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events not available in the published literature.

People having an emergency caesarean during the second stage of labour, with an impacted fetal head.

Intervention or test: balloon disimpaction.

Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in Appendix B: Other relevant studies.

Find out more about how NICE selects the evidence for the committee.

Appendix B: Other relevant studies

Other potentially relevant studies that were not included in the main evidence summary (tables 2 and 3) are listed in table 5 below.

Table 5 additional studies identified

Study	Number of people and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Cornthwaite K, Hewitt P, Van Der Scheer JW et al. (2024) Definition, management, and training in impacted fetal head at cesarean birth: a national survey of maternity professionals. Obstetrical and Gynecological Survey 79: 135–37	Survey of 419 maternity professionals in the UK	More than 70% found that a change of operator, manual cephalic extraction, tocolysis, operating changing hand, reserve breech extraction, Fetal Pillow, head-down tilt, and vaginal disimpaction were safe and effective techniques and adjunctive measures for managing impacted fetal head at caesarean delivery. The use of Fetal Pillow was positively accepted by 71 participants.	Survey of the management of impacted fetal head at caesarean birth in UK.
Cornthwaite KR, Bahl R, Lattey K et al. (2024) Management of impacted fetal head at cesarean delivery. American Journal of Obstetrics and Gynecology 230: 980–87	Expert review	There is currently no consensus on how best to manage impacted fetal head at caesarean delivery, resulting in a lack of confidence among maternity staff, variable practice, and potentially avoidable harm in some circumstances. Evidence for improved	Review of overall management of impacted fetal head at caesarean delivery.

		outcomes with balloon disimpaction is conflicting and no published study reported the decision to-delivery interval. Well-designed randomised controlled trials, in which the inclusion criteria are clearly defined and clinicians are appropriately trained, are urgently required to further investigate the management of impacted fetal head at caesarean delivery.	
Di Girolamo R, Galliani C, Buca D et al. (2021) Outcomes of second stage cesarean section following the use of a fetal head elevation device: A systematic review and meta-analysis. European Journal of Obstetrics, Gynecology, and Reproductive Biology 262: 1–6	Systematic review n=1,326 (10 studies)	Application of a fetal head elevation device at full dilatation caesarean section seems to be associated with improvement in some maternal and neonatal outcomes.	One of the included randomised controlled trials has been retracted since the review was published. A more recent systematic review is included, which excludes the retracted trial.
Jeve YB, Navti OB, Konje JC (2016) Comparison of techniques used to deliver a deeply impacted fetal head at full dilation: a systematic review and meta-analysis. BJOG 123: 337–45	Systematic review n=12 studies	Meta-analysis showed that the risks of uterine incision extension, infection, mean blood loss, and operative time were statistically significantly higher with the push technique compared with the reverse breech extraction. The evidence to support the Patwardhan method and fetal pillow was inadequate.	Review included only 1 study on balloon disimpaction, which has been retracted. A more recent systematic review is included.

Sadler L, Cronin R, Browne E et al. (2024) Obstetrician views on Fetal Pillow device use and research in Aotearoa New Zealand: A cross-sectional survey. The Australian & New Zealand Journal of Obstetrics & Gynaecology doi.org/10.1111/ajo.13824	Review	The Fetal Pillow is available in most maternity units in Aotearoa New Zealand. Most obstetric clinicians believe it reduces maternal morbidity, while acknowledging the lack of scientific evidence. Most would support a randomised trial.	Survey of obstetrician views on balloon disimpaction device.
Walker KF, Mitchell EJ, Ayers S, J et al. (2023) Feasibility of a RCT of techniques for managing an impacted fetal head during emergency caesarean section: the MIDAS scoping study. Health Technol Assess 27(6)	Scoping study	A trial was proposed to compare the fetal pillow with a long-established procedure, the vaginal push technique. Such a trial would be widely supported by health-care professionals. To be powered to test an effect on important short term maternal and baby outcomes it would need 754 participants per group. This would be feasible within the UK.	Study assessing the feasibility of a trial.
Wyn Jones N, Mitchell EJ, Wakefield N et al. (2022) Impacted fetal head during second stage Caesarean birth: A prospective observational study. European Journal of Obstetrics, Gynecology, and Reproductive Biology 272: 77–81	Prospective observational study n=3,518 second stage caesareans (564 with disimpaction technique)	The most common disimpaction techniques used were manual elevation of the head by an assistant through the vagina (n=235) and a fetal "pillow" (n=176). Thirteen babies (2%) died or sustained severe injury. Four babies died (2 directly attributable to the impacted fetal head). Fetal pillow was the most popular preventative strategy. Some units reported	Survey of obstetricians practice in the UK.

		mandating use of the pillow in all caesareans following unsuccessful instrumental birth. The pillow was also used as treatment but less commonly than the push technique.	

