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CLINICAL ARTICLE

Randomized controlled trial of elevation of the fetal head with a fetal pillow during cesarean delivery at full cervical dilatation

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ABSTRACT

Objective: To evaluate whether use of the Fetal Pillow (Safe Obstetric Systems, Shenfield, UK) affects maternal and fetal morbidity in cesarean delivery at full cervical dilatation. *Methods:* A randomized controlled trial was conducted at two teaching hospitals in West Bengal, India, between April 1, 2013, and March 31, 2014. Women undergoing cesarean delivery at full dilatation were enrolled and randomly assigned with computer-generated random numbers (block size 10) to undergo delivery with or without the Fetal Pillow. Group assignment was not masked. The primary outcome was the incidence of major uterine wound extensions (grade 2–3). *Results:* Overall, 120 women were assigned to each group. Major uterine wound extensions occurred in 6 (5.0%) women in the Fetal Pillow group and 39 (32.5%) in the control group (relative risk 0.23, 95% confidence interval 0.11–0.48). *Conclusion:* Use of the Fetal Pillow in second-stage cesarean delivery significantly reduces the risk of a major extension of the uterine incision.

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1. Introduction

Despite attempts to reduce cesarean delivery rates, there has been a gradual and steady rise in the frequency of cesarean delivery in most high-income countries [1]. The rates of cesarean delivery have also risen in India, particularly in the past decade, and are likely to continue to rise, in keeping with the upward trend in high-income countries [1]. The rates of cesarean delivery at full dilatation (CDFD) have also increased with this overall rise in cesarean delivery rates, and some observers consider that the rise in CDFD has been disproportionately high [2,3]. Potential reasons for the disproportional rise in CDFD include reductions in the use of instrumental delivery (particularly in the use of rotational forceps), increases in the use of epidural analgesia, fear of litigation, and changes in training [4].

CDFD can be technically challenging even in experienced hands, with intraoperative complications accounting for the bulk of CDFD-related morbidity [5–7]. The rate of uterine incision extensions in CDFD is between 15% and 50% [7–11]. These wound extensions are associated with the manipulations required for the delivery of a deeply engaged head in the presence of reduced liquor, a thin overstretched and edematous lower segment, or excessive caput formation and molding. Consistent evidence shows that CDFD carries a much higher risk of morbidity for the mother and the child than do all cesarean deliveries combined [5–9]. For the mother, there is a higher incidence of intrapartum hemorrhage, a longer operating time, an increased need for blood transfusion, an increased risk of admission to the intensive-care unit, and an increased length of hospital stay. For the child, there are higher risks of admission to the neonatal intensive care unit (NICU) and birth injury [5,7].

Several techniques are used when there is severe difficulty with delivery of a deeply engaged head [12,13]. The two most commonly used methods are pushing the fetal head from below and reverse breech extraction. The Fetal Pillow (Safe Obstetric Systems, Shenfield, UK) is a single-use silicone balloon device that inflates in an upward direction when filled with saline (Fig. 1). Use of the Fetal Pillow in CDFD has been the subject of a few small studies [14,15], which have shown maternal benefits. The aim of the present study was to establish whether use of the Fetal Pillow in CDFD to elevate the fetal head for an easier delivery reduces maternal and fetal morbidity.

2. Materials and methods

A prospective randomized controlled trial was undertaken in two teaching hospitals in West Bengal, India (Bankura Sammilani Medical

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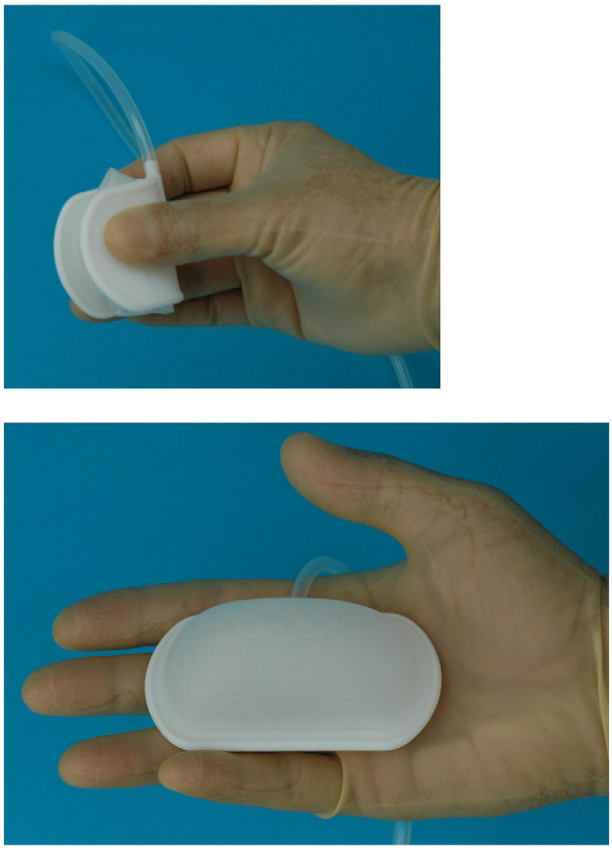

Fig. 1. Fetal Pillow (Safe Obstetric Systems, Shenfield, UK) folded for insertion (top) and inflated (bottom).

College in Bankura and R. G. Kar Medical College in Kolkata), between April 1, 2013, and March 31, 2014. In 2013, the combined annual delivery rate in the two hospitals was 42 000 deliveries, with a 30% cesarean delivery rate. When women were admitted to the labor ward, they were informed of the trial by a midwife or a doctor. Patients who were able to give informed consent when the decision was made for a CDFD were eligible for the study. Patients at fewer than 36 weeks of pregnancy and those with active genital infections were excluded. A doctor discussed the study with eligible patients in further detail and obtained written informed consent. The institutional ethics committee of Bankura Sammilani Medical College gave ethics approval for the conduct and publication of the present study.

The participants were randomized 1:1 into two parallel groups—the Fetal Pillow group (FP group) and the non-Fetal Pillow group (NFP group). The groups were allocated in blocks of 10 using computer-generated random numbers, which were placed in sealed opaque envelopes on the labor ward. Each component of a block was opened in sequence when the consent form was signed. Group assignment was not masked.

The Fetal Pillow has been in use in both hospitals since 2013 [14]. After catheterization of the bladder for CDFD, the folded Fetal Pillow silicone balloon is inserted through the vagina and placed between the fetal head and the pelvic floor [15]. The position of the Fetal Pillow is not changed, irrespective of whether the fetal head is in an occipitoposterior or occipitotransverse position, or is deflexed. When the Fetal Pillow is in position, the woman's legs are placed flat on the operating table and an assistant inflates the balloon while the woman is draped. Inflation of the Fetal Pillow produces a large bubble of fluid in the pelvic cavity that leads to a 3–4-cm upward displacement of the fetal head (Fig. 2). This is meant to facilitate the delivery with minimal manipulation. Moreover, the uterine incision can be sited higher on a

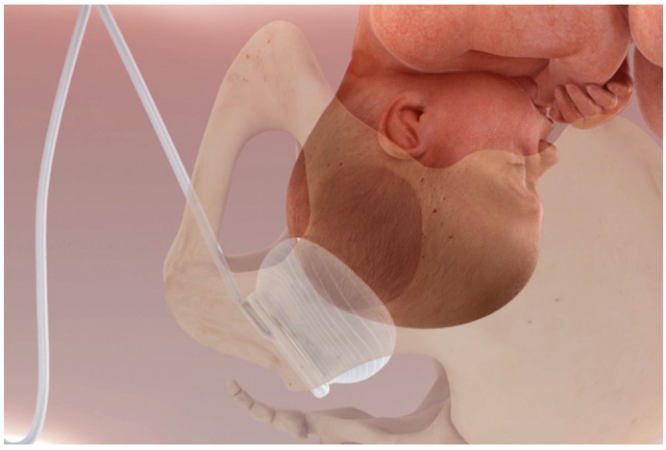

Fig. 2. Applied and inflated Fetal Pillow (Safe Obstetric Systems, Shenfield, UK).

thicker part of the lower segment. The Fetal Pillow is deflated soon after delivery of the fetal head by opening the two-way tap attached to the distal end of the filling tube. It is removed at the end of the cesarean delivery by gently pulling at the tubing.

In the NFP group, the surgeon was allowed to use an appropriate conventional method of delivery including pushing from below and reverse breech extraction [16].

All deliveries were lower-segment cesarean deliveries. Uterine extensions were clinically graded [17]. Grade 1 extensions were minor extensions that did not increase the operating time or blood loss, grade 2 extensions were those that increased the operating time and blood loss, and grade 3 extensions were those that involved one or both uterine arteries, the cervix, the vagina, or the bladder. Grade 1 extensions were not deemed to be clinically significant.

The frequency of major uterine wound extensions (grades 2–3) was the primary outcome measure. Secondary maternal outcomes were total time taken for delivery, incision-to-delivery interval, difficulty with delivery of fetal head, preoperative and postoperative hemoglobin levels, uterine extensions, blood loss of more than 1000 mL, blood transfusions, duration of hospital stay, and incidence of re-laparotomy. Secondary fetal outcomes were 5-minute Apgar score of 3 or less, admission to NICU, NICU stay of more than 24 hours, neonatal sepsis and neonatal death.

In a previous observational study [14], the incidence of major uterine wound extensions (grades 2–3) during CDFD was 15% without the Fetal Pillow and 4% when the Fetal Pillow was used. The probability of detecting a significant difference between the two groups when there is indeed a difference, with a type 1 error of 0.05 and type 2 error of 0.20, required a study with 108 patients in each group. In the present study, the aim was to randomly assign 120 patients to each group to accommodate any protocol violations and missing data.

The statistical analysis was performed using JMP Genomics 7.0 (SAS Institute, Cary, NC, USA). Continuous variables that were normally distributed were compared with the t test and reported with P values (descriptive variables) or as mean differences with 95% confidence intervals (outcome variables). Categorical variables were compared by calculating relative risks with 95% confidence intervals; when the calculation of relative risks was not appropriate, the χ^2 or Fisher exact tests were used as appropriate to compare the proportions between the groups. $P < 0.05$ was considered statistically significant.

3. Results

Between April 1, 2013, and March 31, 2014, 253 women had a CDFD, of whom 240 underwent randomization (Fig. 3). The two groups were similar in terms of the baseline characteristics (Table 1).

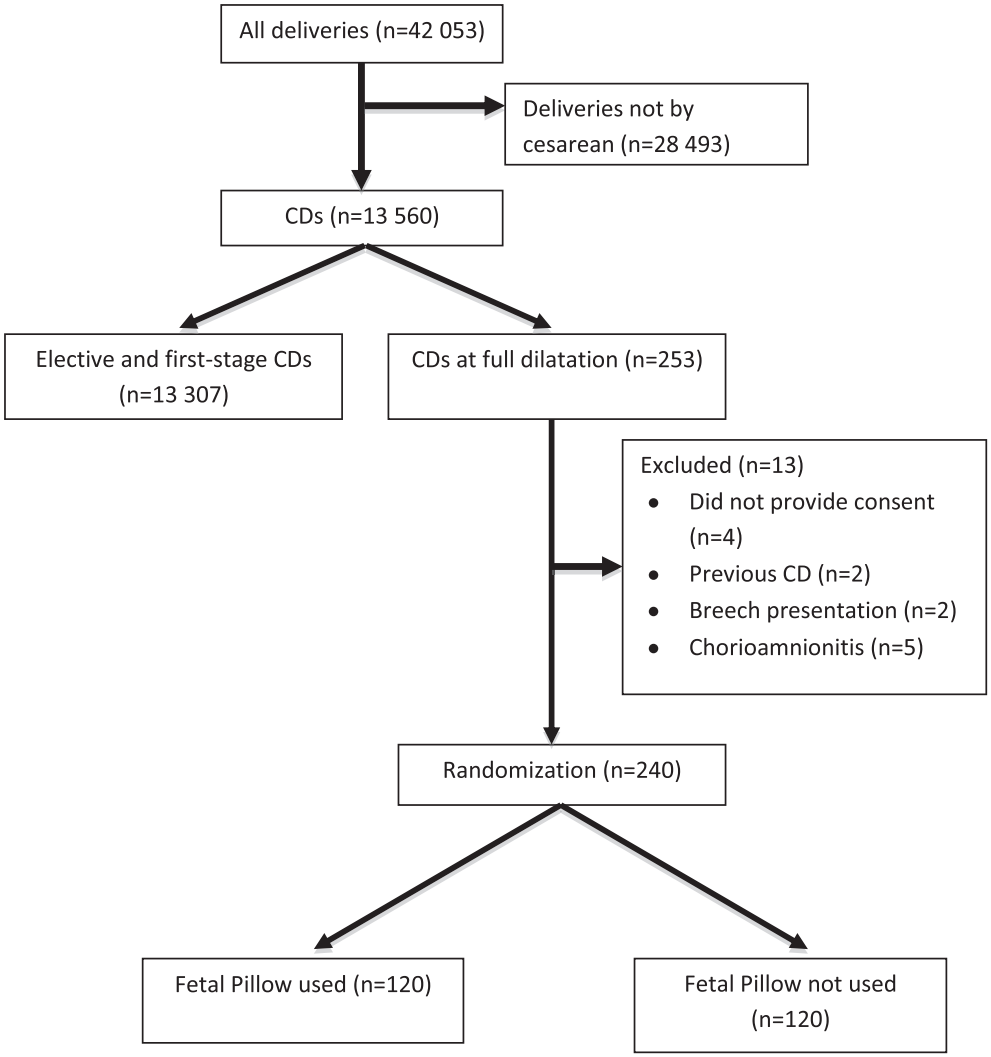

Fig. 3. Flow of patients through the study. Abbreviations: CD, cesarean delivery.

A major extension of the uterine wound (grade 2–3 extension) was less common in the FP group than in the NFP group, and the overall frequency of uterine extensions was also reduced in the FP group (Table 2).

The incision-to-delivery interval was significantly shorter in the FP group, as was the total time taken for cesarean delivery (Table 2). Delivery of the head was significantly easier in the FP group than in the NFP group ($P < 0.001$) (Table 2).

The preoperative hemoglobin concentration was similar in the two groups (Table 2). However, blood loss of more than 1000 mL and the need for blood transfusion were significantly less common in the FP group, and the postoperative hemoglobin concentration in the FP group was significantly higher than that in the NFP group (Table 2).

The length of hospital stay was significantly shorter in the FP group (Table 2). Four patients required a further laparotomy in the NFP group compared with no patient in the FP group ($P = 0.12$). There were no fetal or maternal injuries attributable to Fetal Pillow use.

With regard to the neonatal outcomes, newborns in the FP group were less likely to have a 5-minute Apgar score of 3 or less, be admitted to the NICU, or stay in the NICU for more than 24 hours, than were newborns in the NFP group (Table 3).

4. Discussion

The present study showed that there are significant benefits in using the Fetal Pillow among women who require a CDFD. The maternal benefits include a lower risk of major uterine wound extension, reduced blood loss, and importantly a reduced need for blood transfusion. The present study also showed that there was a significant shift from the expected difficulty in delivering the fetal head to an actual ease of delivery when the Fetal Pillow was used.

With regard to the neonate, use of the Fetal Pillow during CDFD was associated with a 74% reduction in the incidence of NICU admission and a 38% reduction in the incidence of staying in the NICU for longer than 24 hours. These reductions were not statistically significant, perhaps because these events are uncommon in CDFD and will therefore require larger samples to clarify the benefits to the neonate.

Because maternal mortality continues to fall in high-income and low-income countries, maternal morbidity has become an important indicator for the quality of obstetric care. Many studies [5–9] have recorded an increase in maternal morbidity in association with CDFD. An audit in Scotland [18] showed that CDFD was an important contributor (25%) to the occurrence of massive obstetric hemorrhage. This is now such an important concern that the Royal College of Obstetricians and Gynaecologists in the UK has recommended that a consultant should be present at the time of a CDFD [19]. The present study shows that more than one in five (21.7%) CDFDs were associated with blood loss of more than 1000 mL and more than one in six (18.3%) CDFDs were associated with blood transfusion when the Fetal Pillow was not used. The

Table 1
Baseline characteristics.[a]

Variable	FP group (n = 120)	NFP group (n = 120)	*P* value
Maternal age, y	22.1 ± 2.6 (18–28)	22.8 ± 2.0 (18–33)	0.06
Maternal weight, kg	55.6 ± 4.6	54.8 ± 4.9	0.15
Parity			0.40
0	82 (68.3)	84 (70.0)	
1	33 (27.5)	27 (22.5)	
2	5 (4.2)	7 (5.8)	
3	0	2 (1.7)	
First stage of labor, h[b]	7.8 ± 0.7	7.6 ± 0.6	0.07
Augmentation of labor	79 (65.8)	80 (66.7)	0.89
Second stage of labor, h[c]	1.9 ± 0.3	1.9 ± 0.3	0.86
Pregnancy duration, wk	38.9 ± 1.0	39.0 ± 1.0	0.40
Indication for cesarean			0.58
Failed progress	88 (73.3)	82 (68.3)	
Failed instrumental delivery	20 (16.7)	21 (17.5)	
Fetal distress	12 (10.0)	17 (14.2)	
Station of head			0.87
0	2 (1.7)	2 (1.7)	
1	46 (38.3)	50 (41.7)	
2	72 (60.0)	68 (56.7)	
Position of the head			0.30
Occipitoanterior	48 (40.0)	60 (50.0)	
Occipitotransverse	33 (27.5)	27 (22.5)	
Occipitoposterior	39 (32.5)	33 (27.5)	
Birth weight, kg	2.85 ± 0.26	2.87 ± 0.31	

Abbreviations: FP, Fetal Pillow; NFP, no Fetal Pillow.
[a] Values are given as mean ± SD (range), mean ± SD, or number (percentage), unless indicated otherwise.
[b] Data available for 89 patients in the FP group and 92 in the NFP group because some were transferred from other hospitals while already in labor.
[c] Data available for 90 patients in the FP group and 95 in the NFP group because some were transferred from other hospitals while already in labor.

routine use of the Fetal Pillow during CDFD reduced the incidence of blood loss of more than 1000 mL to one in 24 (4.2%) and that of blood transfusion to one in 30 (3.3%).

Table 3
Neonatal outcomes.[a]

Variable	FP group (n = 120)	NFP group (n = 120)	RR (95% CI) or *P* value
5-minute Apgar score ≤3	1 (0.8)	8 (6.7)	0.22 (0.03–1.37)
Admission to NICU	13 (10.8)	21 (17.5)	0.74 (0.47–1.15)
Duration of NICU stay >24 h	3 (23.1)	12 (57.1)	0.38 (0.12–1.13)
Neonatal sepsis	0	4 (3.3)	0.12[b]
Neonatal death	0	3 (2.5)	0.25[b]

Abbreviations: FP, Fetal Pillow; NFP, no Fetal Pillow; RR, relative risk; CI, confidence interval; NICU, neonatal intensive care unit.
[a] Values are given as number (percentage) unless indicated otherwise.
[b] Fisher exact test.

The strengths of the present randomized study include the similarity between the groups at baseline, the fact that the study had sufficient power to assess the primary endpoint (incidence of clinically significant uterine extensions), and the availability of complete data. The main weakness is a weakness common to all randomized studies—namely, that the findings cannot be easily generalized to the whole population. However, the present findings can be generalized to women aged 18–33 years in their first labor at term who require a CDFD because of failed progress in labor, failed instrumental delivery, or fetal distress, irrespective of the fetal station and the position of the head.

In conclusion, CDFD will continue to be an important cause of excessive morbidity in all settings and the presence of experienced doctors is required to manage this unpredictable emergency. With the routine use of the Fetal Pillow, this unpredictable and serious clinical situation can be managed by all grades of staff, and without the excesses of prolonged theatre time and blood transfusion. When the Fetal Pillow is readily available in the labor ward and is used during CDFD, this has benefits for women in this emergency, for doctors who have to manage them, and for hospitals that have to cope with the emergency. The present study did not show significant benefits to the neonate, but a study with a larger sample size might be able to show any small significant benefits on fetal morbidity that might be present.

Table 2
Maternal outcomes.[a]

Variable	FP group (n = 120)	NFP group (n = 120)	MD, RR, or *P* value[b]
Total time taken for LSCD, min	32.7 ± 4.3	53.9 ± 10.3	−21.1 (−19.1 to −23.1)[c]
Incision-to-delivery interval, s	176.5 ± 14.0	297.2 ± 27.1	−102.7 (−97.2 to −108.2)[c]
Difficulty with delivery of fetal head			<0.001[d]
Very difficult	2 (1.7)	26 (21.7)	
Difficult	5 (4.2)	21 (17.5)	
Moderately easy	11 (9.2)	3 (2.5)	
Easy	57 (47.5)	31 (25.8)	
Very easy	45 (37.5)	39 (32.5)	
Preoperative hemoglobin, g/L	103 ± 6	103 ± 5	0.01 (−0.13 to 0.14)[c]
Postoperative hemoglobin, g/L	96 ± 5	90 ± 8	0.60 (0.43 to 0.76)[c]
Uterine extensions	12 (10.0)	43 (35.8)	0.37 (0.22 to 0.63)[e]
Grade of uterine extension			0.004[d]
1	6 (50.0)	4 (9.3)	
2	3 (25.0)	12 (27.9)	
3	3 (25.0)	27 (62.8)	
Major uterine extension (Grades 2–3)	6 (5.0)	39 (32.5)	0.23 (0.11 to 0.48)[e]
Blood loss >1000 mL	5 (4.2)	26 (21.7)	0.29 (0.13 to 0.66)[e]
Blood transfusion	4 (3.3)	22 (18.3)	0.28 (0.11 to 0.70)[e]
Duration of hospital stay, d	3.9 ± 0.8	5.0 ± 1.2	−1.1 (−1.34 to −0.82)[c]
Re-laparotomy	0	4 (3.3)	0.12[f]

Abbreviations: FP, Fetal Pillow; NFP, no Fetal Pillow; MD, mean difference, RR, relative risk; LSCD, lower-segment cesarean delivery.
[a] Values are given as mean ± SD or number (percentage).
[b] Values in parentheses are 95% confidence intervals.
[c] MD.
[d] χ^2 test.
[e] RR.
[f] Fisher exact test.

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Conflict of interest

The authors have no conflicts of interest.

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