Journal of Obstetrics and Gynaecology, 2014; Early Online: 1–4

ISSN 0144-3615 print/ISSN 1364-6893 online
DOI: 10.3109/01443615.2013.844108

informa
healthcare

Does elevating the fetal head prior to delivery using a fetal pillow reduce maternal and fetal complications in a full dilatation caesarean section? A prospective study with historical controls

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A caesarean section at full dilatation (CSFD) can be technically demanding and has consistent association with increased intraoperative trauma. There is evidence that the incidence of caesarean sections at full dilation is on the rise. We report on a prospective study of 50 women undergoing CSFD using a fetal pillow (FP) to elevate the fetal head. Data were compared with historical controls of 124 women without FP use on uterine extensions, uterine incision delivery interval, blood loss, need for transfusion, operating time, length of stay, intensive care unit admission. The FP elevated the fetal head in all 50 women ($p < 0.001$). We found that patients in the FP group had a lower incidence of extensions ($p = 0.03$), shorter operating time ($p < 0.001$), uterine incision to delivery interval ($p < 0.001$) and shorter length of hospital stay ($p < 0.001$). Blood loss > 1,000 ml and admission to ICU was also lower but were not statistically significant. There were no significant differences in the fetal complications studied, APGAR scores, admission to neonatal intensive care unit, seizures, neonatal injury or death.

Keywords: Caesarean section, fetal pillow, full dilation, morbidity

Introduction

Despite the attempts at reducing caesarean section (CS) rates, there has been a gradual and steady rise in most developed countries in the last three decades. The rate of CS has also risen in India, particularly in the last decade and is likely to continue to increase, in-keeping with the upward trend in developed countries (Mukherjee 2006). The rate of caesarean section at full dilatation (CSFD) has also increased, as expected with this overall rise in CS rates, although some consider that the rise in the rate of CSFD might be disproportional (Unterscheider et al. 2011; Loudon et al. 2010). The reasons for this are unclear, but reduction in instrumental delivery rates (particularly those associated with the use of rotational forceps), increasing use of epidural analgesia, fear of litigation and changes in training have been cited (McKelvey et al. 2010). Murphy et al. (2001) in a large UK prospective study, reported an incidence of CSFD as 2% of all deliveries, the overall rate of CS being 18%. In a larger Norwegian study in 2004, the rate was 1.4% of all deliveries with a background CS rate of 15% (Häger et al. 2004). Data from our own tertiary obstetric unit shows a significantly lower rate of 0.8% particularly significant in the presence of a high background CS rate of 30% (Seal et al. 2010).

The morbidity of CSFD has been the subject of a few studies in the last decade and there is now incontrovertible evidence that CSFD carries a much higher morbidity for both the mother and the baby (Murphy et al. 2001; Sung et al. 2007; McKelvey et al. 2010). There is a higher incidence of uterine incision extensions; postpartum haemorrhage; increased operating time; need for blood transfusion; ITU admission and increased length of hospital stay for the mother. For the baby, there is a higher risk of admission to the NICU and birth injury. The reported rates of uterine incision extensions in a CS at full dilatation are between 24% and 50% (Sung et al. 2007). There is also evidence that the time spent in second stage is directly proportional to the incidence of extensions. A few studies have looked at an intraoperative blood loss of over 1,000 ml, the need for blood transfusion and admission to intensive care and they found a much higher incidence in this group (McKelvey et al. 2010; Seal et al. 2010).

Intraoperative complications account for the majority of morbidity related to CSFD (Häger et al. 2004). These often occur as a result of the increased manipulation required for delivery of the head due to reduced liquor; thin, overstretched and oedematous lower segment; excessive caput and moulding; and the often deeply engaged head. There are many techniques described in the literature to address when severe difficulty is encountered in the delivery of a deeply impacted head (Blickstein 2004). However, moderate difficulty in the delivery of the fetal head is not well reported and probably causes most of the intraoperative complications seen in CSFD. The difficulty in delivering the fetal head is unpredictable and can occur in any CSFD whether or not there has been a prior attempt at an instrumental delivery. The sentinel audit report by the RCOG recommends that a consultant should be present whenever a caesarean section is being performed at full dilation (RCOG 2001).

The use of a fetal pillow (FP) was the subject of a small study reported previously (Singh and Varma 2008). We have prospectively investigated FP use in CSFD and the outcomes were compared with a historical group of patients who had CSFD without the use of an FP (Seal et al. 2010).

Materials and methods

Device

A fetal pillow is a device designed to elevate the fetal head atraumatically prior to a CSFD. It is a soft silicone balloon that is inserted vaginally prior to performing a CSFD. After insertion, the balloon is inflated with 180 ml of sterile saline via a tube connected to a two-way tap. The balloon inflates only in an upward direction; the base plate rests on the least distensible part of pelvic

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floor, the anococcygeal ligament, and it is designed so that it does not change position during inflation.

The device is inserted by folding the base plate and it is then placed between the perineal muscles and the fetal head. The positioning of the device involves a similar technique to that used in positioning the ventouse cup for an occipito posterior position and the balloon surface should be in contact with the fetal head. The use of the device is described in detail in the instruction manual provided with the device and in an animation video (FP Instructions for use). The placement of the device remains unchanged whether the fetal head is in an occipito posterior, occipito transverse position or deflexed.

The aim of the device is to elevate the fetal head (Figure 1), to make the delivery easier with minimal manipulation and to allow the surgeon to site the uterine incision slightly higher on a wider and thicker part of the lower segment. The device is deflated as soon as the delivery is achieved, by opening the two-way tap and it is removed at the end of the procedure by gently pulling at the tubing.

Methods

We report a prospective study of FP use in 50 patients undergoing a CSFD. Ethical approval was obtained from the Bankura Sammilani Medical College ethical committee. This was a pilot study carried out during a 5-month period (October 2011 to February 2012). Bankura Sammilani Medical College is a teaching institution in West Bengal (India), where there are 19,000 deliveries per year and the overall CS rate is 30%. Inclusion criteria for the study were singleton term pregnancy at full dilation requiring a CS, including those who had a failed attempt at instrumental delivery. Patients with active genital infection, major fetal abnormalities, pregnancy induced hypertension, intrauterine growth restriction or diabetes were excluded. The unmatched historical controls were 124 patients who underwent a second stage CS from our previously reported study of second vs first stage caesarean delivery (Seal et al. 2010). All the clinicians participating in the study were instructed in the use of the device by observing a screening of the training animation video. The majority of procedures were carried out by registrars who had obtained a post-graduate degree and with at least 4 years in the speciality.

The maternal and fetal data recorded included maternal age, weight at delivery, gestational age at delivery and duration of the first and second stage of labour. The position and station of the fetal head was determined by careful vaginal examination before the device insertion. Abdominal palpation was carried out before and after the device inflation and the findings were recorded. The total operating time and uterine incision-to-delivery interval were also recorded.

The maternal morbidity outcomes studied were: extension of uterine incisions; other intraoperative complications; need for blood transfusion; intraoperative blood loss of $>1{,}000$ ml; admission to the intensive care unit; febrile morbidity; length of hospital stay and return to theatre. Uterine extensions were graded using a clinical grading system (Table I), described by Angala et al. (2012). Grade I extensions were not analysed because they do not increase operating time or lead to excessive blood loss and are, therefore, of no clinical significance (Angala et al. 2012).

The fetal outcomes studied were: a low 5-min Apgar score (≤ 3); the need for intubation; septicaemia; neonatal trauma; admission to the NICU for more than 24 h; seizures and neonatal death.

The data related to the ease of insertion, inflation, removal of FP and any expulsion during inflation were also recorded. Careful examination of maternal tissues and the fetus was carried out in order to record any trauma caused to the mother or baby by the device.

Statistical analysis

Numerical variables that were normally distributed were compared using Student's *t*-test or Mann–Whitney *U* test when the variables were not normally distributed. Categorical data were compared by χ^2-test with Yates correction when an individual cell had <4 observations. Wilcoxon sign rank test was used to see the elevation effect of the FP. Results showing $p<0.05$ were considered statistically significant. Statistica version 6 and Graph pad Prism Version 6 software (San Diego, CA) were employed for statistical analysis.

Results

There were no significant differences between the FP and the comparison group with regard to gestational age, fetal weight and maternal weight. The use of syntocinon and length of first and second stage of labour between the two groups were also similar. The main indication for CS in both groups was failure-to-progress, followed by fetal distress and a failed instrumental delivery (Table II).

Abdominal palpation prior to inflation of the FP confirmed deep fetal head engagement in all 50 patients (0/5 palpable) and vaginal examination revealed a median station of +2 cm (range +1 to +3). In the FP group, the position of the occiput was anterior in 23 (46%), posterior in 17 (34%) and transverse in 10 (20%) patients. After inflating the device using 180 ml of saline, the abdominal palpation was repeated and the findings showed a head palpation of 2/5–3/5 (median 3/5) suggesting an average elevation of 4 cm after device inflation ($p<0.001$). Therefore, elevation of the fetal head achieved in all patients was highly significant.

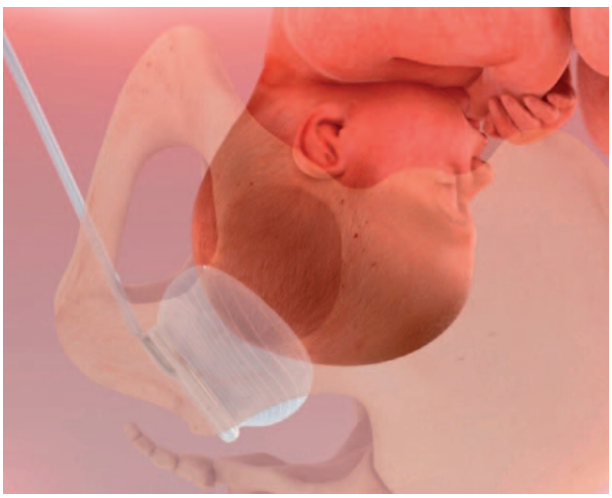

Figure 1. Inflated fetal pillow device showing an upward displacement of the fetal head.

Table I. Clinical grading system for extensions of uterine incisions during CS.

Grade I*	Extension of incision that does not increase operating time or blood loss
Grade II	Extension that increases the operating time and blood loss
Grade III	Extension the involves one or both uterine arteries, cervix, vagina or other organs

*Extensions were deemed of no clinical significance and were not analysed for the purpose of this study.

Table II. Maternal and fetal characteristics in the two groups.

Maternal and fetal characteristics	Fetal pillow group ($n = 50$)		Historical control group ($n = 124$)		p value
Maternal age (years) (mean ± SD, range)	23.1 ± 3.7	18–36	24.2 ± 3.1	18–33	0.06
Maternal weight (kg) (mean ± SD)	55.7 ± 8.7		55.6 ± 9.3		0.95
Gestational age (weeks) (mean ± SD, range)	39.1 ± 1.0	37.3–41.2	39.4 ± 0.88	38–41	0.12
Fetal weight (g) (mean ± SD, range)	2890.6 ± 32	6.3	2936.4 ± 34	2.6	0.49
Length of first stage (h) (mean ± SD)	7.7 ± 0.91		7.94 ± 1.2		0.31
Length of second stage (h) (mean ± SD, range)	2.1 ± 0.43	1.3–3.3	1.96 ± 0.53	1–3	0.10
Syntocinon use (n, %)	39	78	88	70.9	0.45
Indication for cesarean section (n, %)					0.74
1. Failure-to-progress	37	74	97	77.4	
2. Fetal distress	8	16	15	12.0	
3. Failed instrumental delivery	5	10	13	10.4	

The rate of extensions of uterine incisions observed was higher in the control group compared with the FP group ($p = 0.03$); total operating time ($p < 0.001$) and skin incision to delivery interval ($p < 0.001$) and length of hospital stay ($p < 0.001$) were all significantly shorter in the FP-assisted delivery group than in the control group. The number of patients in the FP group with haemorrhage over 1,000 ml and blood transfusion were less than the control group, but the difference was not statistically significant. There were no maternal deaths or admissions to the ICU in the FP group compared with the control group (4.03% admissions to ICU and 2% maternal deaths) but these differences did not reach statistical difference (Table III). The first maternal death was due to atonic postpartum haemorrhage, for which a hysterectomy was carried out and death was due to multiorgan failure. The second patient had severe uterine extensions leading to a blood loss of more than 2.5 litres. She required a second laparotomy for intraperitoneal haemorrhage but continued to bleed and at the third laparotomy, a hysterectomy was carried out but there was disseminated intravascular coagulation leading to death. This death was directly due to difficult delivery of the head and resulting complications.

All fetal outcomes, low Apgar score, need for intubation, admission to NICU, seizures and neonatal death were similar in both groups. There was 5% neonatal trauma in the control group compared with none in the device group, but this difference was not statistically significant (Table IV).

The insertion, inflation and removal of the device in all patients was uneventful, except in one patient where the obstetrician found it difficult to insert the device due to a very low fetal head (+3 station). This patient suffered a small 2nd degree tear during insertion; there was no other maternal or fetal trauma due to device use. There were no device expulsions or leakages.

Discussion

Caesarean section at full dilation is a technically demanding procedure, even in experienced hands. The morbidity can be significant when compared with a CS performed earlier in labour (Murphy et al. 2001; Häger et al. 2004). Most hospitals do not collect data in this group of patients. In our own unit, the increased morbidity in this group was only recognised when we specifically looked for it (Seal et al. 2010).

Encountering severe difficulty with the delivery of the fetal head due to deep impaction and excessive moulding after a prolonged labour and, particularly after a failed attempt at an instrumental delivery, occurs in around one-third of these patients and can have grave consequences for both the mother and baby. From our small experience, it seems that most of the complications in a second stage CS are in patients where there is moderate difficulty in delivering the fetal head. Therefore, even if training is provided for such a situation, it is unlikely that it will reduce most of the maternal complications we encountered.

In our previous study, the main method of delivery when there was severe difficulty encountered was by pushing from below in half of the patients and a reverse breech extraction technique in the others. In our experience, pushing from below increased the risk of maternal injury and febrile morbidity, while the reverse breech extraction technique appeared to increase the risk of fetal injury (Seal et al. 2010). The paper from Murphy et al. (2001) did not specify the technique used in this group of patients but showed a significantly higher fetal trauma rate and admission to the neonatal intensive care unit. Various methods described in the literature to deal with this problem require expertise and experience that is not always readily available on most labour wards around the clock.

Table III. Maternal outcomes in the two groups.

Maternal outcomes (SD)	Fetal pillow group ($n = 50$)		Historical control group ($n = 124$)		p value
	n	(%)	n	(%)	
Uterine incision to delivery time (min) (mean ± SD)	2.79 ± 0.4		8.43 ± 1.7		< 0.001
Total caesarean time (min) (mean ± SD, range)	31.8 ± 4.6	24–50	52.1 ± 10.7	35–90	< 0.001
Length of hospital stay (days)	4.1		6.4		< 0.001
Extension of uterine incisions (Grade II and III)	2	4	19	15.2	0.03
Blood loss > 1,000 ml	1	2	10	8	0.18
Blood transfusion	1	2	6	4.8	0.36
Admission to intensive care unit	0		5	4.0	0.18
Maternal death	0		2	1.6	0.51

Table IV. Neonatal outcomes in the two groups.

Neonatal outcomes	Fetal pillow group ($n = 50$)		Historical control group ($n = 124$)		p value
	n	(%)	n	(%)	
Apgar score <3 at 5 min	2	4	4	3.2	0.55
NICU admission >24 h	3	6	12	9.6	0.33
Intubation	0		5	4.0	0.18
Neonatal injury	0		6	4.8	0.12
Infection	0		7	5.6	0.09
Neonatal seizure	1	2	3	2.4	0.68
Neonatal death	0		2	1.6	0.51

In India, maternal mortality has halved in the last 10 years but still continues to be unacceptably high (Bhatt and Hazara 2001). This is due to the high number of home births in rural areas, but even when the births are in hospitals the supporting services such as availability of blood products and intensive care are often inadequate (Kumar et al. 1989). In developed countries, severe maternal morbidity is now considered to be a more sensitive indicator of health system quality and performance than maternal mortality. The Royal College of Obstetricians and Gynaecologists (UK) has suggested a trigger list for incident reporting in maternity units that includes unsuccessful forceps or ventouse, blood loss $>1{,}500$ ml, return to theatre, hysterectomy, ICU admission and readmission (RCOG 2005). A caesarean section in the second stage of labour is more likely to be associated with most of these complications. In a more recent Scottish Audit of Severe Maternal Morbidity, emergency CS was the most common cause of massive obstetric haemorrhage ($>2{,}500$ ml) and 25% of these were as a result of a CSFD (NHS 2009).

The incidence of second stage caesarean section in our setting is lower than in the developed world. The reasons for this are unclear, as the use of rotational forceps in our unit has declined in the last few years, in-keeping with the changes in the developed countries. Lack of epidural use might have a role to play, as this may reduce the risk of failure-to-progress at full dilation. It may also be true that when this failure occurs in the absence of an epidural, the impaction in the pelvis is much greater and the resulting complications more severe. Our experience from the use of FP suggests that the least traumatic delivery of the head at a CS is achieved when the fetal head is 2/5–3/5 palpable abdominally and the FP achieves this level of elevation when filled with 180 ml of saline.

It is unlikely that CS rates will fall significantly in the near future, therefore, we need to explore other ways of reducing the morbidity related to these procedures to acceptably low levels. Improving training in vaginal instrumental delivery might help to reduce CSFD. Other options may be emerging that might help to predict the success of an instrumental delivery. A recent study of translabial ultrasounds use in the second stage of labour indicates that it might be a better predictor of a failed instrumental delivery than clinical assessment (Ghi et al. 2009). The use of FP is likely to appeal to the obstetricians because of its simplicity of use. The strength of this study is that it is a prospective study but the weakness is that the controls were historical. Adoption of new medical technology requires careful evaluation in prospective trials and in some instances, randomised clinical trials.

A prospective randomised study of FP use in the second stage of CS is presently in progress in our unit. In our study, the FP, when used in CSFD in our setting, seems to be very effective in elevating the fetal head consistently and reducing maternal morbidity while not increasing fetal/neonatal morbidity.

Acknowledgements

We would like to thank all clinicians including the midwives at Bankura Sammilani Medical College who were involved in caring for these women on the labour ward. Safe Obstetric Systems Ltd provided the devices for this study.

Contribution to authorship

SS designed the study along with preparing some of the manuscript. Data collection was carried out by all those who were involved in the study. AD, SCB, GK, JM were all involved in clinical management of some of the patients in the trial and data collection. JM provided help with the analysis and improving the manuscript. All authors saw and approved the final version of the article. SS is the corresponding author and has the final responsibility.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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