IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 18, Issue 9 Ser.4 (September. 2019), PP 01-07
www.iosrjournals.org

A comparative study between modified Patwardhan technique and Foetal Pillow during caesarean section in full dilatation in cases of deeply engaged foetal head

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Abstract: *Objective: To evaluate whether use of the Foetal Pillow (Safe Obstetric Systems, Shenfield, UK) reduces maternal and foetal morbidity in cesarean delivery at full cervical dilatation as compared to Modified Patwardhan technique.*
Methods: A comparative prospective study was conducted in a tertiary teaching hospital, West Bengal between May 2016 to April 2017. A total of fifty women undergoing caesarean delivery at full dilatation (CSFD) were randomised into two groups i.e. Foetal Pillow (FP) and Modified Patwardhan (MP) group. Outcomes such as extension of uterine incision, operating time, uterine incision to delivery time and blood loss were measured.
Results: In FP group, only two (8%) had extension of uterine incision as compared to six patients (24%) in MP group, which was statistically significant (p 0.001). Operating time and incision-to-delivery interval was significantly shorter in FP group than MP group (p 0.02 & p 0.04 respectively). Blood loss was also significantly more in FP group than MP group (p 0.02).
Conclusion: Foetal Pillow is a quite safe obstetric device for delivery of deeply impacted foetal head during CSFD and provides better outcome compared to Modified Patwardhan technique.
Keywords: *Cesarean delivery, Full dilatation, Foetal pillow, Modified Patwardhan, Extension, Uterine incision.*

Date of Submission: 26-08-2019 Date of Acceptance: 10-09-2019

I. Introduction:

The concept of maternal reproductive health, which encompasses health of women during pregnancy, childbirth and post-partum period, has been one of the prime concerns in modern day Obstetrics and Gynaecology. The United Nations Population Fund estimated that 2, 89,000 women died of pregnancy or childbirth related causes in 2013. The increasing rates of Caesarean Section (CS) are of major clinical interest in obstetrics today [1]. Second-stage CS has been reported as a concerning increasing trend within the increasing CS rate.[2, 3]

Caesarean sections during the second stage are increasing in prevalence and are associated with significant long-term psychological and physical maternal morbidity. It is unclear how morbidity compares between operative vaginal deliveries and CS at full dilatation , but both have significant problems that require skill and knowledge to limit potential adverse events. Both are likely to remain a frequent problem for obstetricians in the foreseeable future with continuing pressures to reduce elective CS rates. There is insufficient evidence to recommend any specific technique for delivery of CS at full dilatation [3.]

To overcome this problem, various techniques have been developed namely the "Push method", "Pull method". Various studies[4,5] have compared both these methods. However, both these methods are associated with an increased rate of maternal morbidity due to a variety of causes like uterine extensions, post-partum haemorrhage, fever[6,7] etc. Patwardhan technique is another unique technique (shoulder first) which is used for delivering babies in second stage Caesarean sections[8]. Patwardhan technique is a superior and a safe technique compared to "Push" or "Pull" methods. While foetal complications are comparable in both methods, maternal morbidities are lesser in Patwardhan technique[9].

In order to further reduce the maternal and neonatal morbidity, the "Foetal Pillow" (a simple obstetric device) was introduced in the recent years, which makes the delivery of the deeply impacted foetal head easier during Caesarean sections at full dilatation (CSFD). A study has shown that the use of foetal pillow is associated

with a lower incidence of uterine extension, uterine incision – delivery interval, intra – operative blood loss, need for blood transfusion, operating time, length of hospital stays and intensive care unit admission[10].

There is no clinical study directly comparing the Patwardhan technique and Foetal pillow technique in the literature. In this context, a clinical trial was conducted in the Gynaecology and Obstetrics department of North Bengal Medical College and Hospital (NBMCH) comparing the outcomes of foetal pillow and Modified Patwardhan technique. The aim of the present study was to establish whether use of the Fetal Pillow in CSFD to elevate the fetal head for an easier delivery reduces maternal and fetal morbidity as compared to Modified Patwardhan technique.

II. Materials & Methods:

This present Hospital based comparative prospective study was conducted in the Department of Gynaecology & Obstetrics, NBMCH between May 2016 to April 2017. All Pregnant mother having single-ton pregnancy and certain of their LMP with gestational age 36 weeks or more admitted in the labour room of NBMCH with obstructed labour and meeting the inclusion and exclusion criteria were considered for this study. When women were admitted to the labour 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 with active genital infections, fetal malpresentation, non-cephalic presentation were excluded. A doctor discussed the study with eligible patients in further detail and obtained written informed consent. The institutional ethics committee of North Bengal Medical College gave ethics approval for the conduct and publication of the present study.

In the year 2014, 240 patients had undergone Caesarean Section at Full Dilatation (CSFD) in the Department of Gynaecology and Obstetrics of NBMCH, which is a tertiary level hospital. During this study period, among 9315 total deliveries, there was 3905 caesarean section (41.9%) of which sixty-two patients having CSFD. After exclusion, a total of fifty patients were considered for the study consisting of twenty-five patients in each group, i.e. twenty-five for Foetal Pillow and twenty-five for Modified Patwardhan Technique. The two techniques were applied simultaneously in the patients. The data was collected in pre-designed and pre-tested schedule. Randomization was computer generated. Treatment allocation was written on index cards and concealed in identical, sealed, opaque, sequentially numbered envelopes stored in the operating room. The proportion in Modified Patwardhan Technique was 0.45 (45%) of cases whereas the proportion in Foetal Pillow was 0.07 (7%) of cases. The expected difference was (-0.38%) 38% of cases and superiority margin was calculated to be (-0.1) 10%. The power was 80% while the α Error being 5%.

In Modified Patwardhan Technique –

In cases of occipito–transverse or occipito– anterior positions with the head deeply engaged in the pelvis, incision is made in the lower uterine segment, at the level of anterior shoulder, which is delivered out. This is followed by delivery of the posterior shoulder, axillae (by hooking method) and the trunk (by application of fundal pressure by the assistant). Finally, the foetal head, which is deeply impacted in pelvis and is still inside the uterus, is gently lifted out of the pelvis.

In Foetal Pillow –

The device (Safe Obstetric Systems, Shenfield, UK) consists of a soft silicone balloon attached to a firm base plate which can be folded to allow easy insertion and a 10 cm long tube with a two way tap at the distal end of the tube to inflate and deflate the balloon (Fig.2 & 3). The pack also contains a 60 ml syringe. The device is inserted per vaginally during the second stage of labour before Caesarean Section at Full Dilatation with balloon in contact with foetal head. To inflate the balloon, 180 cc of normal saline is pushed via the distal 2– way tap (with the help of 60 ml syringe); thereby disimpacting the foetal head from the maternal pelvis up to the level of incision. Once the baby is delivered, the balloon is deflated and the device is taken out Per Vaginally.

Primary and secondary outcomes, such as extension of uterine incision, operating time (skin to skin) in mins, uterine incision to delivery time in mins, blood loss estimated by no. of mops soaked in blood, requirement of blood transfusion and need for NICU admission and occurrence of neonatal seizures were measured.

After collecting the data, it was formulated in MS Excel Spreadsheet and summarized by routine descriptive statistics, namely mean and standard deviation for numerical variables and percentages for categorical variables in SSPS software. Relative risk was calculated where deemed relevant. Frequencies were compared between groups by Fischer's exact test or chi-square test as appropriate, while numerical variables were compared by Student's independent samples t test. Two-sided p values of less than 0.05 were considered to indicate statistical significance.

III. Results:

The present study was carried over a period of one year in the department of Gynaecology and Obstetrics with the aim to compare the outcomes between Modified Patwardhan technique and Foetal Pillow during Caesarean section at Full dilatation. All the patients who took direct admission in NBMCH or referred from other institutions with deeply engaged foetal head were included in the study. Out of total 9315 deliveries, sixty-two patients had Caesarean section at full dilatation. After exclusion, 50 patients were randomised into two groups. Twenty-five of them were studied using Foetal Pillow (FP group) and rest by Modified Patwardhan Technique (MP group).

The base – line characteristics that were age, weight, parity, augmentation of labour, duration of pregnancy, indication for caesarean, station of foetal head, birth weight were comparable in both the groups (Table-1). Table 2 showed that the data obtained from the study in relation to primary and secondary outcomes, such as extension of uterine incision, operating time (skin to skin) in mins, uterine incision to delivery time in mins, blood loss – estimated by no. of mops soaked in blood, requirement of blood transfusion and requirement of NICU admission and occurrence of neonatal seizures.

Out of 25 cases studied by FP group, only two (8%) had extension of uterine incision whereas in MP group, six (24%) had extension of uterine incision which was statistically significant (p 0.001) (Table-2). Operating time was significantly shorter in FP group than MP group (p 0.02). It is probably because of more time required in manipulation in the later technique. The incision-to-delivery interval was significantly shorter (p 0.04) in the FP group, than MP group (Table-2).

In the FP group, eighteen cases (72%) could be performed by using 2 mops soaked in blood, and four cases (16%) required more than two mops. But for MP group, twenty cases (80%) required 2 mops soaked in blood and five cases (20%) had more than two mops soaked in blood. The calculated p value is 0.02, which indicates that the study is statistically significant. None of the patients required blood transfusion in FP group but for MP group, four patients (16%) required blood transfusion indicating increased incidence of blood loss during operative procedure which was statistically significant(p 0.002) (Table 2).

Three babies (12%) had to be admitted in SNCU in the FP group where as in MP group, fifteen babies (60%) required SNCU admission. Out of these fifteen babies, one baby had bruises over back and abdomen and expired on day 11 (early neonatal death). The result was statistically significant (p 0.04) (Table 2). In the FP group, none of the delivered babies had neonatal seizures, but in MP group, one baby had an episode of neonatal seizure on day 5 which was statistically significant (p 0.03) (Table 2).

IV. Discussion:

The comparative study revealed that patients studied with Foetal pillow had far better outcome in terms of maternal and fetal morbidity compared to the patients studied with Modified Patwardhan technique. There was much lesser incidence of extension of uterine incision, increased volume of blood loss, requirement of blood transfusion. The operating time (skin to skin) in mins and uterine incision to delivery time in mins were also lesser in Fetal Pillow group. Requirement of SNCU admission and incidence of neonatal seizure were also comparatively less in Foetal Pillow group.

The Royal College of Obstetricians and Gynaecologists (RCOG) reports that approximately 6% of caesarean sections for singleton pregnancies occur at full dilatation.[11] In half of these deliveries, there was no attempt at an instrumental delivery.[11]. The international literature also [12,3,13] suggests that within a rising CS rate, there is an increasing trend to CS at full cervical dilatation. This trend appears to be multifactorial with an increasing perceived safety of CS coupled with a decrease in the experience of junior trainees with reluctance to attempt anticipated difficult instrumental deliveries. The strong medicolegal mindset in current obstetrics and concerns over neonatal and maternal morbidity associated with difficult or failed instrumental delivery may contribute to this trend [1]. However, our rates of CS at full cervical dilatation are lower than other published cohorts[2, 14].

Caesarean section in the second stage of labour is a challenging operation with distortion of pelvic anatomy and a fetal head that is often deeply impacted in the maternal pelvis. Women delivered by CS at full dilation have a higher risk of postpartum haemorrhage, operative morbidity with visceral injury, sepsis and prolonged hospital stay[7, 15]. In our study, in MP group, there was significantly increased incidence of major blood loss that requiring sixteen percentages more incidence of blood transfusion than FP group suggesting Fetal pillow is better alternative than Modified Patwardhan technique. A recent study performed by Dr. S L Seal et.al[10], has also shown reduced maternal morbidity with lesser operative time, and lesser incidence of blood transfusion with the use of Foetal Pillow to elevate deeply engaged foetal head during CSFD. Strength of our present study was comparable baseline similarity between two groups which has sufficient power to study the primary outcomes in terms of maternal and neonatal morbidity. However, limitation of our study was small sample size.

In conclusion, it is evident from the study that Foetal Pillow is a quite safe obstetric device for delivery of deeply impacted foetal head during CSFD and provides better outcome compared to Modified Patwardhan technique in terms of maternal and neonatal morbidity and mortality.

Acknowledgement:

We are thankful to the Principal, North Bengal Medical College for allowing us to carry out the study and Safe Obstetric Systems (Shenfield, UK) provided the devices.

Conflict of interest:

The authors have no conflicts of interest.

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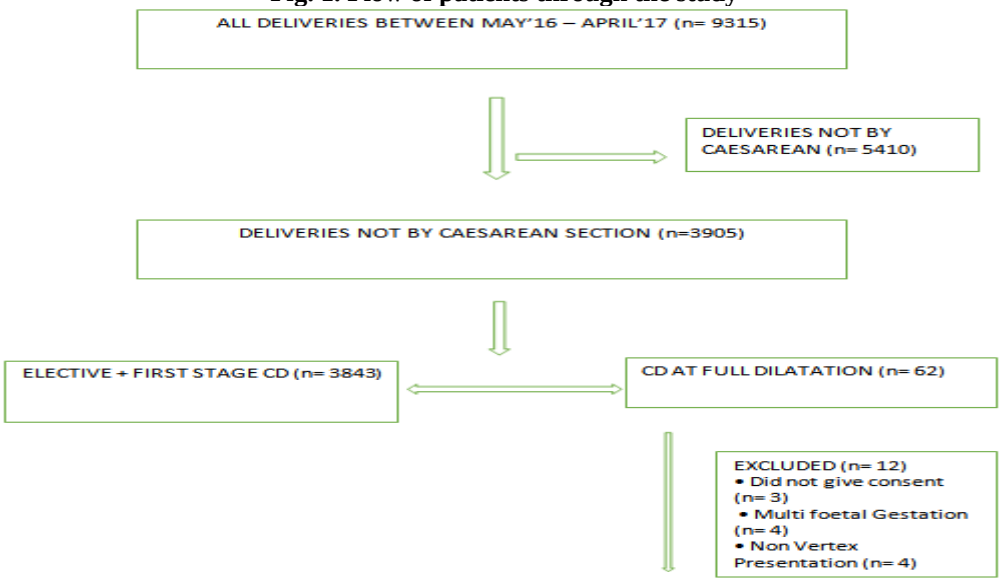
Fig. 1. Flow of patients through the study



Abbreviations: CD = caesarean delivery

Fig. 2: Foetal Pillow (Safe Obstetric Systems, Shenfield, UK)

Fig. 3: Inflated Foetal Pillow (Safe Obstetric Systems, Shenfield, UK)

Table 1. Base line characteristics :

Variable	FP Group (n=25)	MP Group (n=25)	p value
Maternal Age	24.92 ±3.74	25.04±4.75	0.94
Maternal Weight	55.64±7.04	56 ±9.05	0.41
Parity			0.38
a. 0 b. 1 c. 2 d. 3	16(32%) 6(12%) 3(6%) 0	14(28%) 6(12%) 3(6%) 2(4%)	
Augmentation of Labour	16(32%)	12 (24%)	0.89
Pregnancy Duration (wks)	38.04±0.93	38.96±1.33	0.98
Indication for Caesarean			0.07
a. DTA	10 (20%	5(10%)	
b. Obstructed Labour	9 (18%)	4 (8%)	
c. NPL	4 (8%)	10 (20%)	
d. Prolonged 2nd Stage of labour	2(4%)	6 (12%)	
Station of Foetal Head a. 0	7 (14%)	5 (10%)	0.53
b. 1 c. 2	7 (14%) 11 (22%)	8 (16%) 12 (24%)	
Birth Weight, Kg	3.25±0.50	3.32±0.48	0.76

Table-2. Maternal and Foetal outcomes.

Variable	FP Group (n=25)	MP Group (n=25)	p value
1. MATERNAL OUTCOMES			
A. Extension of incision			0.001
1. Yes	8%	24%	
2. No	92%	76%	
B. Operating Time (skin to skin) in mins			0.02
1. 30 – 40 mins	80%	64%	
2. 40-50 mins	12%	28%	
3. 50-60 mins	8%	4%	
4. >1 h	0%	4%	
C. Uterine incision to delivery time (in mins.)			0.04
1. 0-2 mins	52%	8%	
2. 2-4 mins	48%	44%	
3. 4-6mins	0%	48%	
D. No. of mops soaked in blood			0.02
1. One(1)	12%	0%	
2. Two(2)	72%	80%	
3. >Two(>2)	16%	20%	
E. Requirement of Blood Transfusion			0.002
1. Yes	0%	16%	
2. No	100%	84%	
2. FOETAL OUTCOMES			
A. SNCU admission			0.04
1. Yes	12%	60%	
2. No	88%	40%	
B. OCCURANCE OF NEONATAL SEIZURE			0.03
1. Yes	0%	4%	
2. No	100%	96%	

Dr Subir Kumar Bhattacharyya" 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 Sciences (IOSR-JDMS), vol. 18, no. 9, 2019, pp 01-07.