

A COMPARATIVE STUDY OF MATERNAL AND FOETAL OUTCOME BETWEEN REVERSED BREECH EXTRACTION TECHNIQUE AND FOETAL PILLOW, DURING CAESAREAN SECTION IN FULL DILATATION (CSFD), IN SECOND STAGE OF LABOUR

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ABSTRACT

BACKGROUND

Caesarean section in full dilatation (CSFD) is fraught with both maternal and foetal complications. We wanted to compare the maternal and foetal outcomes of two methods namely Reversed Breech Extraction and use of Foetal Pillow in cases of Caesarean Section in full dilatation.

METHODS

This is a hospital based comparative prospective study undertaken in North Bengal Medical College from 2016 to 2017. 25 cases of Reversed Breech Extraction and 25 cases of use of Foetal Pillow were compared with respect to demographic variables, maternal and foetal outcomes.

RESULTS

In this comparative study, a total of 50 patients were studied in the Department of Gynaecology and Obstetrics, NBMCH. Among 50 patients, 25 of them were studied by applying Foetal Pillow and rest by Reversed Breech Extraction Technique.

CONCLUSIONS

Foetal Pillow is a useful tool to reduce maternal and foetal morbidity in cases of obstructed labour in comparison to Reversed Breech Extraction technique.

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BACKGROUND

The concept of maternal reproductive health, which encompasses health of women during pregnancy, childbirth and postpartum period, has been one of the primary concerns in modern day obstetric practice. The United Nations Population Fund estimated that 2, 89, 000 women died of pregnancy or childbirth related causes in 2013. These causes ranged from severe bleeding to obstructed labour and unfortunately according to a data source obstructed labour alone was responsible for 19, 000 maternal deaths in 2013.⁽¹⁾

The term "obstructed labour"^(2,3) refers to those cases where even though the uterus has adequate contractility, the baby fails to exit the pelvis during second stage of labour due to some physical blockage in the birth canal. Such require an immediate caesarean section at full dilatation (CSFD) in order to save the life of both the mother and the foetus. Hence the incidence of Caesarean section done in second stage of labour, has increased manifold in the recent years and almost account for one-fourth of all primary caesarean sections.^(2,4,5) However one such problem faced during CSFD is disengaging foetal head which is almost always impacted cases then deep into the maternal pelvis.

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To overcome this problem, various techniques have been developed namely the "PUSH method" i.e. delivering as cephalic with or without assistance to push up the foetal head from the vagina (head first), the "PULL method" i.e. a reverse breech technique (feet first). Various studies,^(6,7,5,8) 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,^(9,10,11) etc.

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 the second stage Caesarean sections.

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 stay and intensive care unit admission.⁽¹²⁾

In this context, a clinical trial was conducted in the Gynaecology and Obstetrics department of North Bengal Medical College and Hospital comparing the outcomes of Foetal Pillow and Reverse Breech extraction technique. The aim of the present study was to establish whether use of the Foetal Pillow in CSFD to elevate the foetal head for an easier delivery reduces maternal and foetal morbidity in comparison to Reversed Breech Extraction method.

Aims and Objectives

General Objective

Comparison between Reversed breech extraction technique and Foetal Pillow during caesarean section at full dilatation (CSFD) in cases of deeply engaged foetal head

Specific Objectives

1. To compare the extension of uterine incision in both the techniques- Reversed breech extraction technique and Foetal Pillow method.
2. To compare the operating time and uterine incision to delivery time of the two techniques.
3. To assess the degree of blood loss and requirement of blood transfusion, length of hospital stay, maternal pyrexia, HDU admission.
4. To compare the foetal complications like low APGAR score, SNCU/NICU admission, neonatal seizure, neonatal injury or death.

METHODS**Study Type and Design**

Hospital based comparative prospective study.

Study Period

One-year time period was taken into consideration after synopsis approval (May 2016-April 2017).

Study Area

The study was conducted in the Department of Gynaecology & Obstetrics, NBMCH

Study Population

All patients admitted in the labour room of NBMCH with obstructed labour and meeting the inclusion and exclusion criteria, from May 2016-April 2017 were considered.

Inclusion Criteria

- Pregnancy of gestational age 36 weeks or more.
- Pregnancies that were confirmed by per vaginal examination to be having obstructed labour.
- Pregnant women having singleton pregnancy and certain of their LMP.

Exclusion Criteria

- Patients whose first-degree relatives had refused to give consent.
- Patients suffering from STIs, HBsAg Positive, immune-compromised states (e.g. HIV infected, Cervical carcinoma associated), vaginal lesions.
- Multifoetal Gestation.
- Non-Cephalic presentation.
- Foetal Malformation.

Sample Size

A total of 50 patients was considered for the study. In the previous year (2014), 240 patients had undergone Caesarean Section at Full Dilatation (CSFD) in the Department of Gynaecology and Obstetrics of North Bengal Medical College, which is a tertiary level hospital.

Sampling Technique

Purposive sampling technique consisting of 25 patients in each group, i.e. 25 for Foetal Pillow and 25 for Reversed Breech Extraction Technique.

Sample Size Calculation

The proportion in Reversed Breech Extraction 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%

Formulae Used

$$M = (Z_{1-\alpha} + Z_{1-\beta})^2 \{ \pi_s (1 - \pi_s) + \pi_T (1 - \pi_T) \} / (\pi_T - \pi_s - \delta)^2$$

Where δ = superiority limit of the difference in population

π_T = Proportion in test treatment

π_s = Proportion in standard treatment

$\pi_T - \pi_s$ = Expected difference in proportions.

α = Significance level

$1 - \beta$ = Power

Tools and Techniques

1. A pre-designed and pre-tested schedule was used to collect the data.
2. The following two methods, called Reversed Breech Extraction Technique and Foetal Pillow method were used for the study

Foetal Pillow

The device 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. 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. 180 cc of Normal saline is pushed via the distal 2-way tap (with the help of 60 ml syringe) to inflate the balloon; 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.

Demographic Variables

- Age: Age of the mother was noted in completed years.
- Weight: Maternal weight was considered in kilograms
- Parity: Both primi-para and multi-para mothers were considered for this study.
- Augmentation of Labour: In few cases augmentation of labour was done.
- Duration of Pregnancy: Pregnancies with duration more than 36 completed weeks were considered.
- Indication for Caesarean-Indications for CSFD consisted of four major groups-Deep Transverse Arrest, Obstructed Labour, Non-progress of labour, prolonged second stage of labour.
- Station of Foetal Head-Foetal head at station 0, 1 or 2 was considered.
- Birth weight Neonatal birth weights ranged from 2.5 kg and above.

Variables Relating to Specific Objectives

- 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 no of units transfused.
- Length of Hospital Stay in days.

- Evidence of maternal pyrexia.
- Requirement of HDU admission.

Variables Relating to Foetal Profile

- APGAR score at 1 min. and 5 mins.
- Requirement of SNCU admission.
- Incidence of neonatal seizure, neonatal injury and neonatal death.

Data Collection 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. After creation of the randomization cards, the computer-generated randomization table was deleted

Statistical Analysis

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 SPSS 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

Ethical Consideration

Prior consent form was taken from the Institutional Ethics Committee before conducting the study. A participant consent form was used to take the informed consent before conducting the procedure. Anonymity and confidentiality was ensured

RESULTS

In this comparative study a total of 50 patients were studied in the Department of Gynaecology and Obstetrics, NBMCH. Among 50 patients, 25 of them were studied by applying Foetal Pillow and rest by Reversed breech extraction technique.

The findings of the study are presented here in the following sections-

1. Demographic profile of patients.
 2. Related to specific objectives.
 3. Comparative analysis between the two techniques.
- All the patients who took direct admission in NBMCH or were referred from other institutions with deeply engaged foetal head were included in the study.
 - Total number of patients included was 50. 25 of them were studied using Foetal Pillow and rest by Reversed Breech Extraction Technique.
 - In the present study most common age group involved were 20-25 yrs. In the present study 24% patients were in the age group of 25-30 yrs., 8% in 30-35 yrs. and only one patient (4%) was above 35 yrs. According to a study published in online newsletter Armman, most common

age group of patients affected with deeply engaged foetal head, more significantly obstructed labour is from 15-29 yrs. of age. The calculated p value is 0.94. (Table no. 1)

- In the present study, the weight of the study population ranged from 45-75 kg. Maximum antenatal mothers were in the weight group 45 - 55 kg. And only 16% were between 65-75 kg. The calculated p value is 0.41. (Table no. 1)
- The parity of the study population ranged from 0 - 3. Maximum antenatal mothers were primi para and only 4% were of parity 3. The calculated p value is 0.38 (Table no. 1)
- In the present study augmentation of labour was done in 56% patients. The calculated p value is 0.89 (Table no. 2)
- In the present study, Maximum antenatal mothers (50%) were in between 36w1d to 38 completed weeks of gestational age. The calculated p value (Table no. 2)
- In the present study, 30% patients had obstructed labour, 26% patients had DTA, 28% patients had NPL and 16% patients had prolonged 2nd. Stage of labour. The calculated p value is 0.07. (Table no. 2)
- The present study showed, in 24 % of the patients the station of Foetal Head was 0 and in 46% patients the station of Foetal Head was 1 and rest were of head station 2. The calculated p value is 0.53 (Table no. 2)
- In the present study, most of the neonates (38%) born were between 3-3.5 kg and 10% weighed more than 4 kg at birth. The calculated p value was 0.76. (Table no. 2)
- Out of 25 cases studied by Foetal Pillow only 2 (8%) had extension of uterine incision whereas out of 25 patients studied by Reversed Breech Extraction Technique. 6 (24%) had extension of uterine incision. The calculated p value is 0.001, which indicates that the study is statistically significant for the primary outcome relating to extension of uterine incision. (Table no. 3)
- For the patients studied by Foetal Pillow the operating time for majority of them (80%) were 30-40 mins and none of the sections took more than an hour. But for Reversed Breech Extraction technique only 16 (64%) could be completed in 30-40 mins and one case took more than an hour. It is probably because the manipulation done during Reversed Breech Extraction technique requires more time and also that bleeding from extensions of uterine incision requires more time to be managed which in turn prolongs operating time (skin to skin). The calculated p value is 0.02.(Table no. 3)
- For 13 (52%) patients studied by foetal pillow, the uterine incision to delivery of foetus time interval was 0-2 mins and rest were 2- 4 mins. But in Reversed Breech Extraction technique only 2 patients (8%) had a uterine incision to delivery of foetus time interval of 0-2 mins and majority 12 (48%) required 4-6 mins. It is probably because of more time required in manipulation in the later technique. The calculated p value is 0.04 (Table no. 3).

Age in Years	Number n= 50	p
20-25	32 (64%)	
25-30	12 (24%)	0.92
30-35	4 (8%)	
>35	2 (4%)	
Weight in Kg		
45-55	25 (50%)	
55-65	12 (24%)	0.041
65-75	8 (16%)	
Parity		
0	30 (60%)	
1	12 (24%)	0.038
2	6 (12%)	
3	2 (4%)	

Table 1. Demographic Profile of Patients

Duration of Pregnancy (in Weeks)	N= 50	p
36-38	27 (54%)	
38-40	13 (26%)	0.98
>40	10 (20%)	
Labour augmentation done		
Yes	28 (56%)	0.89
No	22 (44%)	
Indication of LSCS		
Obstructed labour	15 (30%)	
DTA	13 (26%)	0.07
Non progress	14 (28%)	
Prolonged 2 nd stage	8 (16%)	
Foetal Head Station		
0	12 (24%)	
1	15 (30%)	0.53
2	23 (46%)	
Birth Weight (Kg)		
2.5-3	19 (38%)	
3-3.5	18 (36%)	0.76
3.5-4	8 (16%)	
>4	5 (10%)	

Table 2. Obstetric Variables

Extension of Uterine Incision	Foetal Pillow N= 25	Reversed Breech Extraction n= 25	p
Yes	2 (8%)	6 (24%)	0.001
No	23 (92%)	19 (76%)	
OT time (in minutes)			
30-40	20 (80%)	16 (64%)	
40-50	3 (12%)	17 (28%)	0.02
50-60	2 (8%)	1 (4%)	
>60	0 (0%)	1 (4%)	
Uterine incision to delivery time (in minutes)			
0-2	13 (52%)	2 (8%)	
2-4	12 (48%)	11 (44%)	0.04
4-6	0 (0%)	0 (0%)	
No of mops soaked in blood			
1	3 (12%)	0 (0%)	
2	18 (72%)	20 (80%)	0.02
>2	4 (16%)	5 (20%)	
Blood transfusion needed			
Yes	0 (0%)	4 (16%)	
No	25 (100%)	21 (84%)	0.002
SNCU admission			
Yes	3 (12%)	15 (60%)	
No	22 (78%)	10 (40%)	0.04
Neonatal seizures			
Yes	0 (0%)	1 (4%)	
No	25 (100%)	24 (96%)	0.03

Table 3. Specific Objectives

- In the Foetal Pillow technique, 18 cases (72%) could be performed by using 2 mops soaked in blood, and 4 (16%) required more than two mops. But in the Reversed Breech Extraction technique 20 cases (80%) required 2 mops soaked in blood and 5 cases (20%) had more than two mops soaked in blood. The calculated p value is 0.02. (Table no. 3)
- In the Foetal Pillow technique, none of the patients later required blood transfusion but for Reversed Breech Extraction technique 4 patients (16%) required blood transfusion later indicating increased incidence of blood loss during operative procedure. The calculated p value is 0.002, which indicates that the study is statistically significant for the primary outcome relating to requirement of blood transfusion. (Table no.3)
- In the Foetal Pillow technique, 3 babies had to be admitted in SNCU whereas in Reversed Breech Extraction technique 15 babies required SNCU admission. Out of these 15 babies one baby had bruises over back and abdomen and expired on day 11 (early neonatal death). The calculated p value is 0.04. (Table no. 3)
- In the Foetal Pillow technique, none of the delivered babies had neonatal seizures, but in Reversed Breech Extraction technique 1 baby had an episode of neonatal seizure on day 5. The calculated p value is 0.03. (Table no. 3)

DISCUSSION

- All the patients who took direct admission in NBMCH or were referred from other institutions with deeply engaged foetal head were included in the study.
- Total number of patients included was 50. 25 of them were studied using Foetal Pillow and rest by Reversed Breech Extraction Technique.
- In the present study most common age group involved were 20-25 yrs. In the present study 24% patients were in the age group of 25-30 yrs., 8% in 30-35 yrs. and only one patient (4%) was above 35 yrs. According to a study published in online newsletter Armman, most common age group of patients affected with deeply engaged foetal head, more significantly obstructed labour is from 15-29 yrs. of age. The calculated p value is 0.94. (Table no. 1)
- In the present study, the weight of the study population ranged from 45-75 kg. Maximum antenatal mothers were in the weight group 45 - 55 kg. And only 16% were between 65-75 kg. The calculated p value is 0.41. (Table no. 1)

Implications

Extension of uterine incision while performing caesarean section in cases of neglected prolonged labour or obstructed labour is a major problem worldwide; especially in developing countries. This study will address such an issue by comparing the use of Reversed breech extraction technique and Foetal Pillow (a recent advance) during CSFD. This study will also shed light on the amount of blood loss, need for blood transfusion, operating time, ICU admissions in both the methods. Also even though individual studies regarding the above mentioned techniques have been done, these two have rarely been compared; hence this comparative study will greatly help to determine which method has a better outcome

regarding the maternal and neonatal health

A recent study performed by Dr. S L Seal et al,⁽¹²⁾ 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. Randhawa et al.⁽¹³⁾ in 2016 compared 55 women undergoing reverse breech extraction (Group A) versus 45 women undergoing vertex extraction (Group B). Extension of uterine incision was observed in 3(5.45%) patients in Group-A and 12 (26.66%) patients in Group- B, Broad ligament hematoma is observed in 4 (8.88%) patients in Group-B and no case of broad ligament hematoma was encountered in Group-A. Traumatic PPH was observed in 2(3.63%) patients in Group-A and 9 (20%) patients in Group-B. Atonic PPH was observed in 1 case in Group-A and 3 (6.66%) patients in Group-B and blood transfusion was needed in 12 (21.8%) patients in Group-A and 21(46.66%) patients required blood transfusion in Group-B. Foetal distress was observed in 10 out of 100 cases out of which 4 (7.27%) cases observed in Group-A and 6 (13.33%) cases in Group-B. Meconium stained liquor was observed in 10(18.18%) cases in Group-A and 12 (26.6%) cases with meconium stained liquor was observed in Group-B. Still births were 4 (7.27%) cases observed in Group-A and 5 (11.11%) cases in Group-B.

Limitation of This Study

Study population was small.

CONCLUSIONS

In this comparative study a total of 50 patients were studied in the Department of Gynaecology and Obstetrics, NBMCH. Among 50 patients, 25 of them were studied by applying Foetal Pillow and rest by Reserve Breech Extraction technique. The comparative study revealed that patients studied with Foetal Pillow had far better outcome in terms of all specific objectives (variables considered for the study) compared to the patients studied with Reserve Breech Extraction technique. There was much lesser incidence of extension of uterine incision, increased volume of blood loss, requirement of blood transfusion, evidence of maternal pyrexia and requirement of HDU admission. The operating time (Skin to Skin) in mins, and uterine incision to delivery time in mins, were also lesser in Foetal Pillow technique. Neonates born by Foetal Pillow technique showed better APGAR score at 1 min. and 5 mins compared to those born by Reserve Breech Extraction technique. Requirement of SNCU admission and incidence of neonatal seizure, neonatal injury and neonatal death were also comparatively less in Foetal Pillow technique. The incidence of extension of uterine incision and requirement for blood transfusion were significantly less in the Foetal Pillow group in comparison to the reverse breech extraction group. The need for blood transfusion was significantly less in the Foetal Pillow group in comparison to the Reversed Breech Extraction group. Hence, we can see that, Foetal Pillow is quite a safe obstetric device for delivery of deeply impacted foetal head during CSFD and provides better outcome compared to Reversed Breech Extraction technique in terms of maternal and neonatal morbidity and mortality.

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