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Original Research Article

A prospective, randomized, cross sectional study of manual versus vacuum extraction of mobile head in caesarean section

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ABSTRACT

Background: Considering the high rate of caesarean section, and the difficulty during delivery of the floating foetal head even by the most experienced obstetrician, the use of vacuum has been described. The present study was undertaken with the hypothesis that, vacuum assisted foetal head delivery during caesarean section is safe and effective without increasing maternal and neonatal complications. The outcomes enumerated by the limited literature available need to be evaluated before it is used routinely.
Methods: A prospective, randomized, comparative, cross sectional Hospital based study was conducted at St. Philomena's Hospital, Bangalore. Every woman randomized for the study received either conventional method or ventouse extraction of fetal head at cesarean section. 200 women were enrolled into the study with 100 in each arm. The primary outcome measures were percentage of successful extractions and I-D interval. The secondary outcome measures were, uterine incision extension, estimated blood loss, Apgar scores, neonatal hyperbilirubinemia and neonatal scalp or head injury.
Results: Successful extraction was done in 89 % and 98 % cases in manual and vacuum extraction cases. (p =0.0184). U-D interval in the manual extraction group was 66.59±4.64 seconds and in the Vacuum extraction group it was 56.06±3.46 seconds (P<0.001). The mean pre-delivery hemoglobin levels in group I was 11.6±0.73 compared to 11.36±0.49 gm% in group II. The mean post-delivery hemoglobin levels in group I was 10.29±0.79 compared to 10.21±0.53 gm% in group II (p <0.001). The uterine incision extensions were significantly higher in manual extraction group, 18 of the 100 women (18 %), whereas only 2 of the 100 women in vacuum group had uterine extensions (p=0.0002).
Conclusions: Authors conclude that the routine use of ventouse is safe and effective for mobile fetal head extraction at cesarean section.

Keywords: Blood loss, Cesarean section, Fetal head, Manual, Uterine Extension, Vacuum

INTRODUCTION

Caesarean section is the 2nd most common abdominal operation performed on women in India after tubectomy operation.[1] The caesarean section rate continued to increase.[2] 20-25% at present from 6-8% in the last 25 years. Mobile fetal head extraction during caesarean section is a major technical problem and for the extraction of fetal head through the uterine incision either forceps or a vacuum device is often used.[3,4] This surgical procedure is not without risk, one such risk is the traumatic or deliberate extension of uterine incision while attempting to deliver the fetal head.[2,5] Difficult head Extraction occur in 1-2% of all Caesarean section deliveries.[5] Techniques to effect delivery under these circumstances have included pressure on the uterus, the use of forceps blades, or additional incision on the uterus, all of which can be traumatic to both mother and fetus.[2]

The use of the vacuum to assist in delivery of the fetal head at caesarean section has been increasing in recent years, and it has been pointed out that the risk of neonatal depression may be decreased by decreasing the incision to delivery-time interval which will be achieved by vacuum use.[2] The use of a vacuum device is a well-established part of obstetric practice in recent years.[2]

The advantages of using a vacuum to assist delivery of fetal head include:

- Ability to decrease volume of fetal head by avoiding delivery by hand/manually.
- Ability to decrease/avoid traumatic or deliberate extension of uterine incision.
- Ability to decrease amount of fundal pressure thus reducing maternal discomfort.[2]

The procedure of applying vacuum made easier when the head is floating or unengaged, and when the cup was applied to vertex or posterior portion of scalp. Use of vacuum did not prolong the hospital stay of any patient.[2]

METHODS

200 women were consented to participate in the study and they were randomized into 2 groups by block randomization technique with equal block size of 3.

A detailed history of patient will be taken at the time of admission regarding age, parity, and socioeconomic status. Thorough general physical examination and systemic examination will be done. All the patients with singleton pregnancy having the mobile fetal head at term undergoing caesarean section will be included and indication for caesarean section documented.

Hb% and PCV will be sent on admission. At admission for caesarean section use of vacuum or the manual extraction will be decided by randomization. Block randomization will be used with equal block of 3. The outcome for analysis was available for 100 women in conventional/manual group and 100 women in vacuum delivery group.

Both the groups were comparable with respect to demographic data, age, parity, gestational age and clinical/physical examination.

Vacuum cup used is a small sized soft sialastic cup which will be applied to the occiput of the fetal head and then vacuum pressure is raised to 300 mm of Hg, fetal head is extracted, and the vacuum cup is released. U-D interval will be noted. The baby details will be recorded. APGAR score at 1 and 5 min will be noted. Any trauma to the neonate and need of resuscitation will be noted. Maternal details will be recorded. Uterine extensions and cervical lacerations will be noted. PCV will be measured 24 hours post caserean section. Maternal blood loss will be assessed using calculated estimated blood loss (cEBL) will be derived by multiplying the calculated maternal blood volume and the percent of blood volume lost.

Calculated maternal blood volume = 0.75 {[maternal height in inches X 50] + [maternal weight in pounds X 25]}.[6]

Percent of blood volume lost = ({predelivery HCT – postdelivery HCT}/predelivery HCT).

Baby and the mother will be followed for next three days or till the day of discharge and the condition at discharge will be recorded.

RESULTS

Present randomized control trial was conducted at St. Philomena's hospital in the Department of Obstetrics and Gynaecology, Bangalore. About 3443 number of deliveries occurred during the study period and total caesarean sections done at the institute were 1693 of which 1268 were emergency caesarean sections and 425 elective cases, out of which 283 were screened. Based on the selection criteria 51 women were excluded as they did not meet the eligibility criteria to participate in this study, 32 denied consent and remaining 200 women were enrolled. 200 gave consent for participating in the study. These 200 women were randomized into two groups of 100 each, namely group I (conventional/manual group) and group II (vacuum group) (Figure 1).

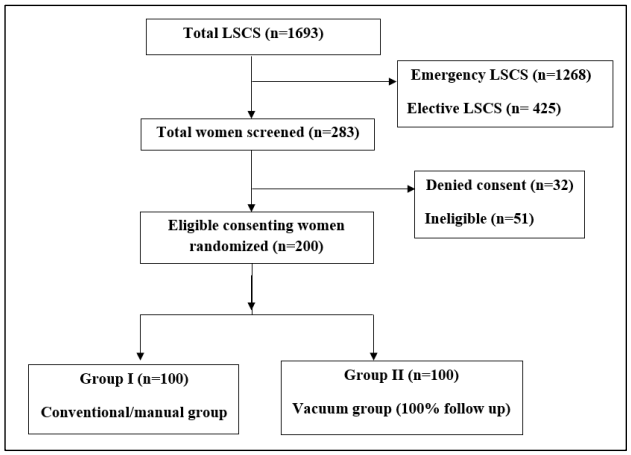

Figure 1: Flow chart of study population (consort diagram).

Overall, no significant statistical difference was noted in the parity, period of gestations and mean period of gestation, body mass index and mean body mass index ($p > 0.05$).

Table 1: Distribution of study population according to number of successful extractions.

		Group I (n=100)	%	Group II (n=100)	%	p-value
Successful extraction	Yes	89	89	98	98	0.0184, Sig
	No	11	11	2	2	

In present study, successful extraction was done in 89 % and 98 % cases in manual and vacuum extraction cases. This is statistically significant (p=0.0184) (Table 1).

Table 2: Distribution of study population according to mean±SD of I-D interval.

	Group I		Group II		p-value
	Mean	SD	Mean	SD	
I-D interval	66.59	4.64	56.06	3.46	<0.001, HS

In the present study, authors found the U-D interval in the manual extraction group is 66.59 ±4.64 seconds and in the Vacuum extraction group it was 56.06 ±3.46 seconds. There was significant (P<0.001) difference in U-D interval between Manual and Vacuum extraction groups (Table 2).

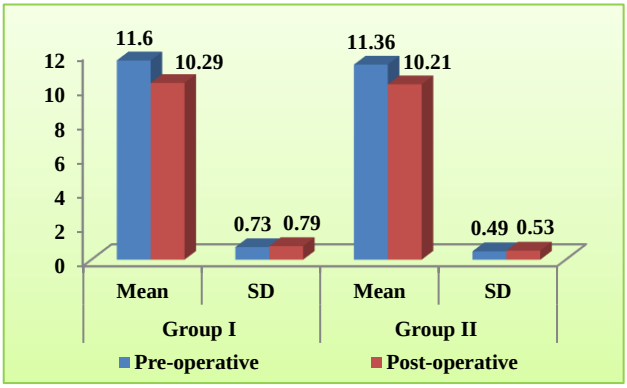

Figure 2: Distribution of study population according to mean haemoglobin: pre-operative and post-operative (ANOVA).

Table 3: Distribution of study population according to number of angle extensions.

		Group I (n=100)	%	Group II (n=100)	%	p-value
Angle extensions	Yes	18	18	2	2	0.0002, HS
	No	82	82	98	98	

The mean pre-delivery haemoglobin levels in group I was 11.6±0.73 compared to 11.36±0.49 gm% in group II. The mean post-delivery haemoglobin levels in group I was 10.29±0.79 gm% compared to 10.21±0.53 gm% in group II. This is statistically highly significant with p value <0.001 (Figure 2).

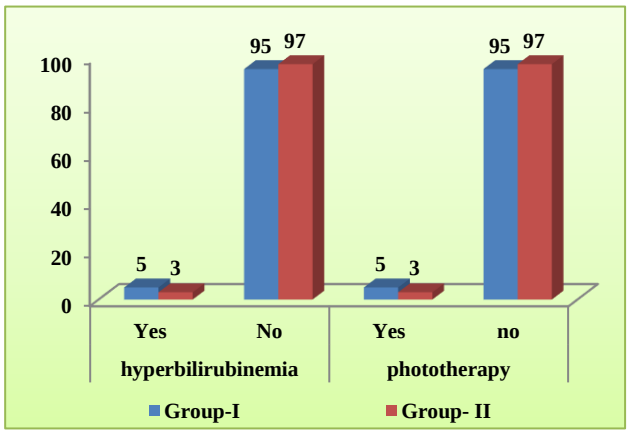

Figure 3: Distribution of study population according to foetal complications.

In present study, the uterine incision extensions in present study, was significantly higher in manual extraction group, 18 of the 100 women (18%), whereas only 2 of the 100 women in vacuum group had uterine extensions. This was statistically significant (p=0.0002) (Table 3).

In present study hyper bilirubinaemia was seen in 3% babies in vacuum group compared to 5% of babies in conventional extraction group requiring phototherapy which was not statistically significant (p=1.0) (Figure 3).

DISCUSSION

Earlier studies found no difference in the rate of uterine extensions or traumatic PPH; change in haemoglobin from pre- operative to post-operative level; and no increased maternal or neonatal morbidity with the use of vacuum delivery of mobile foetal head at caesarean section in comparison to conventional manual method.[3]

Effectiveness of vacuum at delivering a foetal head

Successful extraction was done in 89% of babies in conventional /manual extraction group compared to 98%

babies in vacuum extraction group (p=0.0184). This is comparable to the extraction rate reported by another study.[7]The failure of vacuum delivery was attributed to failure to generate sufficient pressure. In the manual delivery group, in case of difficult extraction, vacuum was used to deliver the foetal head. This suggests that vacuum is an effective measure to deliver a foetal head during caesarean section.

In the study done by Arad I et al the U-D interval in the manual extraction group was 40.9±9.8 seconds and in the Vacuum extraction group it was 79.4±10.2 seconds.[8]

In the present study, authors found the U-D interval in the manual extraction group is 66.59±4.64 seconds and in the Vacuum extraction group it is 56.06±3.46 seconds. There was significant (P<0.001) difference in U-D interval between Manual and Vacuum extraction groups.

Sritippayawan S et al found the U-D interval in the manual extraction and vacuum extraction group to be 86.3±53.9 seconds and 65.3±31.2 seconds respectively.[3] In the study done by Banu F et al the U-D interval in the manual and vacuum extraction group was 43.5±8.6 seconds and 75.6±9.02 seconds respectively.[9] The difference in U-D interval was found to be significant in the studies done by Arad I et al (P<0.01), Sritippayawan, S et al (P<0.001) and Banu F et al (P≤0.0001).

Maternal outcome

Overall, no significant statistical difference was noted in the parity, period of gestations and mean period of gestation, body mass index and mean body mass index (p >0.05). It is Comparable to the study done by Sritippayawan S et al where no significant difference was found with respect to similar variables between the two groups.[3]

In the present study, there was significant fall in mean haemoglobin levels in conventional / manual group post operatively (12.02±1.33 to 9.65±1.56) in comparison to vacuum group (12.41±1.37 to 10.39±1.59) (p<0.001). This was comparable to another study where the estimated blood loss was less in caesarean section with vacuum delivery of the foetal head (680.9 cc versus 810.0 cc; p <0.04).[2]

Estimation of haemoglobin change is now the accepted as a measure of blood loss during surgical procedure. By definition, post-partum haemorrhage is defined as blood loss of more than 1000 ml following caesarean birth i.e. more than 20% fall in haemoglobin percentage.

The mean pre-delivery haemoglobin levels in group I was 11.6±0.73 compared to 11.36±0.49 gm% in group II and The mean post-delivery haemoglobin levels in group I was 10.29±0.79 compared to 10.21±0.53 gm% in group II. This is statistically highly significant with p value <0.001 which is comparable to earlier studies.[3]

The extensions of uterine incision in present study was significantly higher in conventional group, 18 of the 100 women (18 %), whereas only 2 of the 100 women in vacuum group had uterine extensions which is comparable to a study which documented 4 of 25 women had uterine extensions in conventional group.[3] Although this is statistically highly significant (p-0.0002), the extensions in both the groups could have resulted from relative inexperience of the residents to deliver an unengaged/ floating head. The cases enrolled were either elective or first stage caesareans, where lower uterine segment are not well formed, thus increasing the chances of extension by making extraction difficult. However, since the extensions were fewer in the vacuum group, it only signifies that it is a relatively easier procedure to perform.

A total of 8 cases of post-partum haemorrhage occurred including 3 in vacuum group, they could be contributed to traumatic PPH although atonic PPH was noted in 2 cases. In the cases where extensions occurred, PPH was prevented by identifying the extension edges and were immediately clamped and haemostasis secured. The probability of occurrence of atonic PPH is same in both the groups.

Neonatal outcome

In the present study, it was observed that, significantly higher number of babies had Apgar score of >7 in both manual extraction (98 %) and vacuum group (97%) at 1 minute. Transient apnea secondary to the stress caused by the delay/manipulation in extraction of foetal head may have led to lower Apgar score at 1 minute in both the groups. Also, Apgar score was comparable in both the groups at 5 min which was similar to earlier studies.[3,5,10] Contrary to the belief, the incidence of hyper bilirubinemia within first 48 hours of birth in neonates was observed to be less in vacuum group. Hyper bilirubinemia was seen in 3 % babies in vacuum group compared to 5 % of babies in conventional extraction group which was not statistically significant (p=1.00). However, this finding suggests that the vacuum is a safe measure to deliver the foetal head without increasing cephalohaematoma or intracranial haemorrhage incidence. In the present study no cases of scalp abrasions, bruising or lacerations, were observed with the use of vacuum for delivery of foetal head at caesarean section. This is in contrary to the case reported.[5] Even larger babies can be effectively and safely delivered by use of vacuum at caesarean section (birth weight range 1915-4200gms)**.** Although the previous publications reported that use of vacuum during caesarean section permits delivery through a smaller uterine incision. In the present study, the actual length of uterine incision was not measured post-delivery of foetal head. The findings of this study are consistent with another RCT reported by Mc Quivery et al in 2005, which has concluded with 25 cases in each arm; that vacuum delivery of foetal head is safe and effective.[2]

The strengths of the present study are randomization method by block randomization which eliminated the selection bias of the patient by the investigator; multiple operating surgeons including residents were involved in the study; blood loss estimation was done by using formula for calculated blood loss from pre-delivery and post-delivery Hb % and PCV; uterine incision to delivery time was calculated.

The limitations of the present study are sample size considered is small; the findings of the present study can to be confirmed by a larger sample size, multi-centre, randomized controlled trial.

CONCLUSION

The use of vacuum extractor is an easy, non-traumatic and rapid method which abates the need of rough and prolonged fundal compression and significantly fewer maternal and foetal complications. Vacuum extraction is becoming increasingly popular; it is important that obstetric care providers are aware of the risks associated with manual extraction and alternatives available to aid in a safe and expedient delivery.

From this study it is evident that vacuum delivery of foetal head during caesarean section is not only effective but also safe, without increasing maternal or neonatal morbidity. The added advantages are less incision to delivery interval, less blood loss and lesser extensions of uterine incision. The findings of the same can be confirmed by larger multicentre trial.

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