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Technical report

Assisted delivery of high floating fetal head: a comparison of vacuum-assisted delivery with manual extraction

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Background: It is a well-established obstetric practice to use a vacuum device to assist in delivery of the fetal head at cesarean delivery. As a vacuum sauce, the hospital piped-vacuum supply is often used. However, no study has compared the safety and efficacy of vacuum-assisted delivery with the traditional manual extraction.
Objective: Compare the safety and efficacy of delivery of the high floating fetal head using a soft cup vacuum extractor with the traditional manual extraction.
Methods: This randomized study included 90 cases of caesarean sections with vacuum-assisted delivery using the soft cup vacuum extractor (V group) and 90 cases of caesarean sections with manual extraction of the head (M group). The hospital piped-vacuum supply was used to develop the required vacuum. Operative and post-operative maternal and neonatal data of importance were analyzed using Student t-test for continuous variables and Chi Square test for categorical variables.
Results: The U-D interval (the time of entry into the uterus until the full delivery of the fetal head) was significantly prolonged ($p < 0.001$) in M group (86.3±53.9 and 65.3±31.2 seconds, respectively). Mean blood loss in the V group was higher (576.7±182.9 mL and 504.4±204.9 mL, respectively). However, this difference was not statistically significant ($p=0.306$). There was no difference in the Apgar scores and resuscitation in the newborns of the two groups. Infants did not show evidence of any scalp remarks.
Conclusion: The extraction of the fetal head at caesarean section with vacuum extractor was a non-traumatic and rapid method that did not need the prolonged fundal compression and thus avoid unwanted consequences.

Keywords: Cesarean section, high floating fetal head, manual deliver of the head, soft cup vacuum extractor

A major technical problem of delivery by cesarean section is delivery of the fetal head through the uterine incision. Either forceps or a vacuum device is often used to assist in delivery of the fetal head at cesarean delivery when the delivery is difficult and where atraumatic manual delivery is not possible [1].

Routine vacuum use at the time of cesarean delivery has not been established in terms of benefit and safety. In fact, a few case reports do not support improved outcomes [2, 3]. Although occasional fetal injury associated with vacuum-assisted vaginal delivery is well described by Simonson et al. [4], few cases of such injuries exist [5]. It has been pointed out that the risk of neonatal depression may be increased by the prolongation of the incision to delivery-time assisted with vacuum use [3]. However, the use of a vacuum device is a well-established part of obstetric practice.

As a vacuum source, a hospital piped-vacuum supply is often used. By connecting it with a pressure reduction valve, we develop the required vacuum for ventouse delivery. However, no study has compared the safety and efficacy of vacuum-assisted delivery of the high floating fetal head at cesarean section with the traditional manual extraction.

In this study, we compared the safety (for mother and infant) and efficacy of vacuum-assisted delivery with the traditional method of manual extraction.

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Material and method

Vacuum system for ventouse delivery

We used a vacuum system for ventouse delivery illustrated in **Figure 1.** The ventouse comprised a vacuum cup communicating with a source of vacuum. We used a soft, silicone obstetric vacuum cup to evenly cover and adapt to the entire occiput and the individual fetal head contour [2].

We used the hospital piped-vacuum supply with a vacuum regulator (Precision Medical, Model Series PM3000, Precision Medical Inc, Northampton, USA) to develop the vacuum (300 mmHg) required for ventouse delivery. This vacuum pressure was much less than the vacuum pressure used for assisted vaginal delivery (550-600 mm Hg) [6]. Reading off the vacuum from the gauge on the vacuum regulator, we calibrated in "Full Vacuum (300 mmHg)", before connecting the vacuum cup to this suction line.

After the uterine incision and membranes rupture, the vacuum cup was placed over the occiput. When the previously applied clamp was removed, the suction was immediately available, and the vacuum cup becomes attached to the head. Fifteen seconds after, we applied traction concurrently with gentle fundal pressure, pulling towards the middle of the uterine incision. Holding the instrument near the base of the vacuum cup, and gentle fundal pressure was helpful for completion of the procedure. Following delivery of the head, the vacuum was discontinued, and the cup removed.

A randomized comparison

This study was conducted between June 2009 and March 2010. One hundred eighty pregnant women participated in this study. The women were scheduled for elective cesarean delivery in the Obstetric Wards, Department of Obstetrics and Gynecology, Charoenkrung Pracharuk Hospital. This study was approved by the Ethics Committee of Medical Service Department, Bangkok Metropolitan Administration. The patients counseled regarding the possible risks and benefits of this research protocol, and signed an informed consent document.

This prospective study included 90 cases of caesarean sections, with vacuum-assisted delivery using the soft cup vacuum extractor on the fetal scalp (diameter: 6 cm) and 90 cases of caesarean sections with usual, manual extraction of the head assisted by fundal compression. All the patients had undergone a planned caesarean section in the absence of uterine activity and preserved amniotic membranes. All mothers received spinal anesthesia. Inclusion criteria were a 38-42 week gestation, a singleton gestation, a cephalic presentation without fetopelvic engagement by vaginal examination, absence of medical and pregnancy complications, and patient willingness to be randomized to delivery technique. Exclusion criteria included fetal structural malformation, intrauterine fetal death, or evidence of high-risk fetal status.

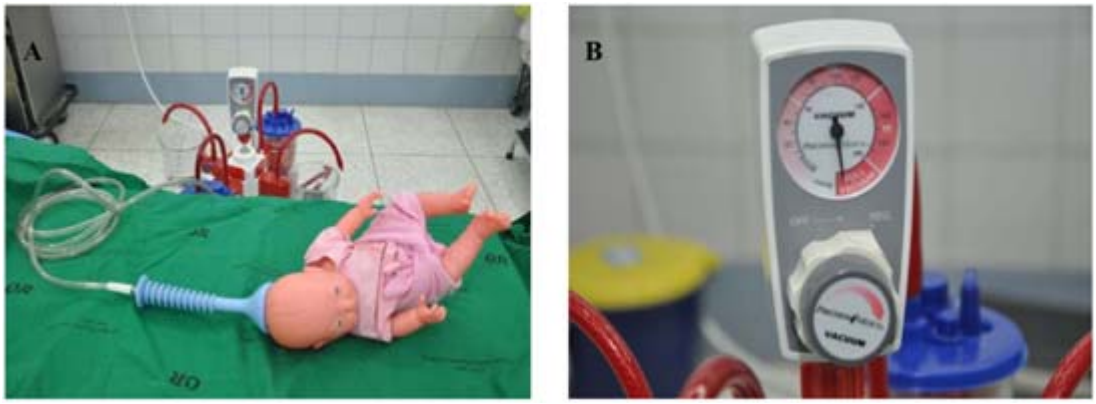

Figure 1. The vacuum system used for ventouse delivery. **A:** a vacuum cup communicated with a hospital piped-vacuum supply. It covered and adapted to the entire occiput and the fetal head contour. **B:** a vacuum regulator.

The physicians were instructed to incise the lower uterine segment and fetal membranes in the typical manner, using the scalpel blade, and by using the bandage scissors or by digital expansion. For those deliveries by means of vacuum assistance,the physicians were directed to place the cup over the occiput of the fetal head prior to application of vacuum pressure. Vacuum pressure was not to exceed 300 mmHg. Two sudden disengagements of the vacuum cup (pop-offs) mandated abandonment of the procedure, and delivery was carried out by any expeditious manner. For those deliveries by means of traditional manual extraction, if delivery was not imminent after two attempts at manual delivery, the physicians could proceed with delivery by using forceps blade/s. All deliveries were timed, using stopwatches, from the time of entry into the uterus (amniotomy or herniation of the fetal membranes through the fully transected lower uterine segment) until the full delivery of the fetal head. Using Apgar score [7], we recorded the one and five minute, while the infant general condition was assessed by the attending pediatrician. Each baby was examined thoroughly each day before discharge. Special attention was devoted to the head.

Data were collected on maternal age, body mass index (BMI), fetal head delivery technique, time interval between entry into uterus (amniotomy or herniation of the fetal membranes through the fully transected lower uterine segment) until the delivery of the fetal head, estimated blood loss for the procedure, birth weight, neonatal Apgar scores, neonatal trauma (including evidence of scalp abrasions, bruising, cephalhematoma, subgaleal or intracranial hemorrhage), and neonatal resuscitation. Operative and post-operative maternal and neonatal data of importance were recorded.

Statistical analysis

The data were analyzed using the statistical software package. Statistical analysis included Student t-test for continuous variables and Chi Square test for categorical variables. The Fisher exact test was used when the expected cell frequencies were equal to or less than five. Continuous data were analyzed and presented as mean standard deviation (SD), and categorical variables were presented as count. A p-value of <0.05 was considered statistically significant.

Results

The randomization sequence allocated 90 women in the vacuum extraction group (V group) and 90 in the manual extraction group (M group). Their demographic factors are shown in **Table 1**. We note that the mean age and the mean BMI were not statistically significant between manual and vacuum extraction groups.

Operative and post-operative data in manual and vacuum extraction groups are shown in **Table 2.** We note that there was a significant difference of the mean time U-D interval between the manual and vacuum extraction groups, but the total blood loss was not statistically significant between the groups.

Neonatal data in manual and vacuum extraction groups are shown in **Table 3.** Interestingly, the mean birth weight was not statistically between the manual and vacuum extraction groups. Our results did not show differences in the Apgar score on the first and fifth minute in the newborns of the two groups. Infants did not show evidence of any scalp remarks. There were no differences in neonatal resuscitation between the two groups.

Table 1. Demographic factors in manual and vacuum extraction groups

Demographic factors	M group (N=90)	V group (N=90)	P-value
Maternal age (years) (mean±SD)	30.7±5.8	30.2±5.1	0.194
BMI (kg/m^2) (mean±SD)	28.4±3.9	27.9±4.1	0.864

M: manual delivery of fetal head, V: use of a vacuum device to assist in delivery of the fetal head at cesarean delivery, BMI: body mass index, SD: standard deviation. N: number of case.

Table 2. Operative and post-operative data in manual and vacuum extraction groups

Operative and post-operative data	M group (N=90)	V group (N=90)	P-value
U-D Interval (second) (mean±SD)	86.3±53.9	65.3±31.2	<0.001*
Estimated blood loss (mL) (mean±SD)	504.4±204.9	576.7±182.9	0.306

U-D Interval: the time of entry into the uterus (amniotomy or herniation of the fetal membranes through the fully transected lower uterine segment) until the full delivery of the fetal head, SD: standard deviation. N: number of case. *statistically significant (p <0.05)

Table 3. Neonatal data in manual and vacuum extraction groups

Neonatal data	M group (N=90)	V group (N=90)	P-value
Birth weight (g) (mean±SD)	3,165.7±414.5	3,247.8±354.9	0.357
Apgar scores at one minute			
4-7	1	1	
>7	89	89	1.000
Apgar scores at five minutes			
4 -7	0	0	-
>7	90	90	-
Neonatal resuscitation (number)			
Nil required	17	14	0.554
Suction+oxygen	73	76	-

SD: standard deviation, N: number of case

Discussion

Delivery of the fetal head through the uterine incision is often the major technical problem during elective low transverse cesarean section, when the presenting part is unengaged. Techniques to affect delivery under these circumstances have included pressure on the uterus, the use of forceps blade/s, or additional incisions in the uterus. All of these factors are traumatic to both mother and fetus. In an effort to deliver an unengaged fetal vertex through a thick lower uterine segment, the surgeon and the assistant exerted the fundal pressure, which is often perceived as uncomfortable and painful by the patient. According to Kim and Ryu [8], systolic aortic blood flow, cardiac output, heart rate, and arterial blood pressure all decrease significantly during the period when fundal pressure was applied compared with values recorded after uterine incision.

The use of forceps blade/s can be traumatic to both mother and fetus. According to Wylie [9], during a forceps delivery, approximately 75 lb (33.75 kg) of force could be applied to the infant's head, while the majority of successful vacuum deliveries require 25 lb (11.25 kg) or less [10].

Delivery of the fetal head at cesarean section may be sometimes extremely arduous, and serious maternal and fetal complications may compound the difficult delivery. Some practitioners use vacuum extraction to assist delivery of the fetal head during a cesarean [2, 11, 12]. This practice may decrease the risk of extension of the uterine incision and may be particularly helpful in the presence of high floating head. However, Arads et al. [3] demonstrated a prolongation of the U-D interval (the interval between the final uterine incision and complete delivery) in cases of vacuum extraction at a cesarean section. This prolongation was due to the time required for application of the vacuum cup and build up of negative pressure. Prolongation of the U-D interval may have an undesirable effect on the fetus. To decrease these required time duration, we usually use the hospital piped-vacuum supply, and develop the required vacuum (300 mmHg) for ventouse delivery by connecting it with a suitable pressure reduction valve.

The continuous vacuum regulator with the vacuum cup allows the pressure to be built up and held. After making the uterine incision and rupturing the membranes, the surgeon places the vacuum cup over the occiput, and the previously applied clamp is removed, the suction is immediately available, and the vacuum cup becomes attached to the head. Then, the waiting period for the development of an adequate vacuum is minimal. Therefore, traction may be applied in a matter of seconds. Additionally, no cup detachments ('pop-offs') occurred. Lim et al. [13] and Svenningsen et al. [14] found that there was no difference in maternal and neonatal outcomes between procedures with rapid versus slow induction of vacuum. The present results demonstrated that the U-D interval was significantly prolonged in M group compared with V group (86.3±53.9 seconds vs. 65.3±31.2 seconds, $p < 0.001$).

Previous studies reported that use of the vacuum extractor at the time of elective cesarean delivery allow for delivery with less blood loss [2, 15]. However, in our study, mean blood loss in the vacuum extraction group was higher than the mean blood loss in the manual group (576.7±182.9 mL *vs.* 504.4±204.9 mL) although this difference was not statistically significant ($p=0.306$).

The Apgar scores of the two groups were not significantly different. Infants did not show evidence of any scalp remarks because delivery had been produced more quickly, less traction applied, and the cup had been attached to the scalp for only a short period. There were no differences in neonatal resuscitation between the two groups.

In conclusion, the use of the vacuum extractor communicating with the hospital piped-vacuum supply at cesarean section may be a safe and effective method to affect delivery of the fetal head. Cesarean section delivery can be simplified by this technique.

The authors have no conflict of interest to report.

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