Vacuum Extractor Versus Manual Head Extraction During Cesarean Section

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Authors’ contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: For multifactorial reasons, the rate of cesarean deliveries increased clearly over a decade; decreased in vaginal births after cesarean (VBAC), multiple gestation, maternal obesity, pre-term labor, gestational diabetes or hypertension, increased number of high-risk expectant mothers and the obstetrical medico-legal environment. Delivering the fetal head at cesarean section can also be a lengthy operation and can result in maternal or fetal Complications. The vacuum extractor allows for the application of traction on the fetal head. In this study we aim to compare the safety (for mother and infant) and efficacy of delivery of the fetal head in cesarean section using vacuum extractor with the manual extraction.

Methods: This study was conducted on 60 pregnant women undergoing cesarean section. All patients were between 37 and 42 weeks of pregnancy with signs of healthy fetus and were divided into 2 groups; Group I- 30 patients subjected to vacuum extraction at the cesarean section, Group II- 30 patients subjected to the conventional cesarean method.

The result: The BMI of women in group I was 27.90 ± 0.96 and in group II was 28.0 ± 0.98. The gestational age of the babies in Group I and II were 39.0 ± 1.02 and 39.0 ± 0.98 weeks. U-D interval for Group I and Group II were 48.40 ± 17.63 and 73.87 ± 16.76 days respectively. The
estimated blood loss in group I and group II were 478.0 ± 59.62 and 464.7 ± 52.57 respectively. The birth weight of the babies delivered in Group I and Group II were 4253.33 ± 118.72 and 4246.67 ± 135.58 KG respectively. The five minutes Apgar score for Group I and Group II were 8.50 ± 0.68 and 8.57 ± 0.57.

Conclusion: The use of the vacuum extractor at cesarean section may be a safe and effective method to facilitate delivery of the large fetal head and cesarean section delivery can be simplified by this technique.

Keywords: Cesarean section; vacuum extraction; traction.

1. INTRODUCTION

The rate of cesarean deliveries (CS) has increased over a decade due to multifactorial reasons explicitly; decrease in vaginal births after cesarean (VBAC), multiple gestation, maternal obesity, pre-term labor, gestational diabetes or hypertension, increased number of high-risk expectant mothers and the obstetrical medical environment[1].

Despite public health efforts to optimize and curtail CS utilization, delivery rates by this method continue to rise unabated. The rate of CS now exceeds 55% of all deliveries in many countries [2-4]. Consequently, physicians will increasingly encounter a wider variety of clinical presentations that necessitate availability of the full range of delivery options to manage different medical scenarios and maximize outcomes. Once established as a safe and effective method of operative vaginal delivery, vacuum-assisted procedures have more recently shown clinical utility and have become widely adopted for CS [5-7].

First successful obstetric vacuum extractor (VE) was designed by James Young Simpson, professor of Obstetrics at the Edinburgh University in 1849. His device was made of a metal syringe attached to a soft rubber cup, was placed against the fetal head, the syringe was evacuated followed by application of traction at the base of the cup and the infant extracted. The device had many disadvantages; the vacuum force was limited and replenishment was impossible after the

Initial evacuation of the syringe and the device lacked a pelvic curve. Multiple innovations followed, and a metal-cup extractor was developed by Malmstrom in 1953 [8]. In 1962, Solomon used vacuum for the extraction of fetal head; he suggested that its use will reduce the

pressure on fetal head, decrease delivery time thereby decreasing fetal hypoxemia and decrease the extension of incision and vascular insult. Recently, bell-shaped and hemispheric silicone rubber cups have come into use [9]. In an elective CS, the lower uterine segment is commonly not elongated or effaced by labor, making it difficult to create an adequate incision to enable an uncomplicated delivery. In addition, at the time of an elective repeat CS, the fetal head is normally not deeply engaged in the pelvis. Procedures to facilitate delivery in this situation include fundal pressure, forceps, internal podalic version, or addition of a lateral vertical incision (“J” incision), all of which can be traumatic for both mother and fetus [10].

The advantages of using a vacuum device in this situation, to assist delivery of the fetal head, are the ability to decrease the volume of the fetal head by avoiding the use of a delivering hand or forceps blade so avoid traumatic or deliberate extension of the uterine incision, along with decrease in associated blood loss, as well the ability to decrease the amount of fundal pressure necessary for delivery, thus reducing maternal discomfort [11].

2. PATIENTS AND METHODS

This comparative prospective observational study was performed on pregnant women at Obstetrics and Gynecology Department in Tanta University Hospitals and Matrouh Maternity Hospital from 1st of November 2019 to 31st of October 2020.

Sample size: 60 Pregnant women were enrolled in this study according to inclusion and exclusion criteria.

Inclusion criteria: 37 - 42 weeks gestation (average sized head and large head).

Singleton gestation: Cephalic presentation to allow vacuum application (all cases).
Exclusion criteria: Deeply engaged head and obstructed labour.
Intra uterine fetal death due to loss of fetal circulation which is essential to produce caput that help in head extraction by vacuum.
Intra uterine growth restriction to avoid fetal injury.
Fetal structure malformation as anencephaly.
Fetal distress.
General anesthesia to avoid effect of anesthesia on fetus.

2.1 Methods:
The 60 Pregnant women were divided into 2 groups:

- Group I ((V group)): cesarean sections with vacuum-assisted delivery and included 30 women.
- Group II ((M group)): cesarean sections with manual extraction of the head and included 30 women.

Both groups included cases of average baby size (average sized head) and macrosomic feti (large head), so:

- Group I ((V group))
  - Group IA: included 15 women with average size feti
  - Group IB: included 15 women with macrosomic feti
- Group II ((M group)):
  - Group IIA: included 15 women with average size feti
  - Group IIB: included 15 women with macrosomic feti

All patients in this study were subjected to the following:

1-History taking:
- Personal history
- Obstetric and Gynecological history
- Menstrual history (last menstrual period)
- Medical history and Drug intake
- Surgical history

2-Examination:
- General look, weight, height
- Vital signs
- Head and Neck examination
- Chest examination
- Lower limbs examination

b) Local abdominal examination:
- Inspection
- Palpation: Fundal level, Fundal grip, Lateral grip, 1st & 2nd pelvic grip.
- Percussion
- Auscultation

3-Investigational studies:

a) Transabdominal ultrasound examination
Ultrasound examination was performed to detect gestational age, fetal presentation and position, fetal size.

b) Laboratory investigation:
ABO-Rh grouping, CBC, coagulation profile, liver and kidney function.

Procedure and Intervention: All included women after informed consent were undergone a planned cesarean section in the absence of uterine activity and preserved amniotic membranes (elective cesarean section).

In V. group a kiwi vacuum system was used to deliver head. The lower uterine segment and fetal membranes were incised in the typical manner. After the uterine incision and membranes rupture, the vacuum cup was placed over the flexion point, ~3 cm anterior to the posterior fontanelle along the sagittal suture. After the cup was put on the head, we checked the edges of the cup to ensure that no maternal, placental, or other tissues have been drawn underneath the cup. We raised vacuum level to 100 mmHg (yellow zone) and rechecked the cup edges again the raised vacuum to 450-600 mm Hg (green zone). We draw fetal head upward gently through incision. When fetal head was delivered, we released vacuum with release valve button and removed cup before delivery of shoulders and body.

In M. group the head was delivered by routine manual method.

Data were collected on maternal age, body mass index (BMI), fetal head delivery technique, time interval between entry into uterus until the delivery of the fetal head (U-D interval),
estimated blood loss for the procedure, birth weight, neonatal Apgar scores, neonatal trauma and neonatal resuscitation.

2.2 Statistical Analysis

The sample size was calculated using Epi-Info software statistical package created by World Health organization and center for Disease Control and Prevention, Atlanta, Georgia, USA version 2002. The criteria used for sample size calculation (n>33) were 95% confidence limit, 80% power of the study, expected outcome in treatment group 90% compared to 60% for control groups.

Analysis of data were performed by SPSS v25 (SPSS Inc., Chicago, IL, USA). Quantitative parametric variables (e.g. age) were presented as mean and standard deviation (SD). They were compared between the two groups by unpaired student’s t-test and within the same group by paired T test. Quantitative non-parametric variables (e.g. VAS) were presented as median and range and compared between the two groups by Mann Whitney (U) test and within the same group by Wilcoxon test. P value < 0.05 was considered significant.

3. RESULTS

This study was conducted on 60 cases divided into two groups group I vacuum-assisted delivery and group II with manual method.

4. DISCUSSION

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 the routine atraumatic manual delivery is not possible [12].

Routine vacuum use at the time of cesarean delivery has not been established in terms of benefit and safety [13].

Table 1. Comparison between the two studied groups according to different parameters

<table>
<thead>
<tr>
<th></th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>Test of</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. – Max.</td>
<td>23.0 – 33.0</td>
<td>23.0 – 33.0</td>
<td>t=</td>
<td>0.964</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>27.10 ± 2.78</td>
<td>27.07 ± 2.94</td>
<td>0.045</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>26.50(25.0 – 29.0)</td>
<td>26.0(25.0 – 29.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. – Max.</td>
<td>1.0 – 3.0</td>
<td>1.0 – 3.0</td>
<td>U=</td>
<td>0.576</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>1.90 ± 0.71</td>
<td>2.0 ± 0.69</td>
<td>415.50</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>2.0(1.0 – 2.0)</td>
<td>2.0(2.0 – 2.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. – Max.</td>
<td>26.0 – 29.0</td>
<td>26.0 – 29.0</td>
<td>t=</td>
<td>0.691</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>27.90 ± 0.96</td>
<td>28.0 ± 0.98</td>
<td>0.399</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>28.0(27.0 – 29.0)</td>
<td>28.0(27.0 – 29.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous caesarean section</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>9</td>
<td>9</td>
<td>$\chi^2$=</td>
<td>0.946</td>
</tr>
<tr>
<td>1</td>
<td>15</td>
<td>14</td>
<td>0.111</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This table shows that there were insignificant differences between two groups as regard age, parity, BMI and previous caesarean section

Table 2. Comparison between the two studied groups according to delivery gestational age

<table>
<thead>
<tr>
<th>Delivery gestational age</th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. – Max.</td>
<td>38.0 – 41.0</td>
<td>38.0 – 41.0</td>
<td>0.00</td>
<td>1.000</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>39.0 ± 1.02</td>
<td>39.0 ± 0.98</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>39.0(38.0 – 40.0)</td>
<td>39.0(38.0 – 40.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This table shows that there was insignificant difference between two groups as regard Delivery gestational age

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Table 3. Comparison between the two studied groups according to U-D interval\(\text{second}\) (time interval between entry into Uterus until the Delivery of the fetal head)

<table>
<thead>
<tr>
<th>U-D interval(\text{second})</th>
<th>Group IA (n = 15)</th>
<th>Group IIA (n = 15)</th>
<th>Group IB (n = 15)</th>
<th>Group IIB (n = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. – Max.</td>
<td>20.0 – 70.0</td>
<td>15.0 – 65.0</td>
<td>30.0 – 80.0</td>
<td>45.0 – 110.0</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>44.07 ± 16.24</td>
<td>41.53 ± 16.19</td>
<td>48.40 ± 17.63</td>
<td>73.87 ± 16.76</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>45.0 (31.50 – 56.0)</td>
<td>42.0 (29.0 – 54.0)</td>
<td>38.0 (35.0 – 62.5)</td>
<td>75.0 (62.50 – 86.0)</td>
</tr>
<tr>
<td>U</td>
<td>102.0</td>
<td>35.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>0.683</td>
<td></td>
<td></td>
<td>0.001</td>
</tr>
</tbody>
</table>

Group IA: vacuum method with average size feti, Group IIA: manual method with average size feti, Group IB: vacuum method with macrosomic feti, Group IIB: manual method with macrosomic feti

This table shows that there was insignificant difference in U-D interval\(\text{second}\) between vacuum and manual method as regard average size feti but there was significant decrease in U-D interval\(\text{second}\) in group used vacuum versus manual group as regard macrosomic feti.

Table 4. Comparison between the two studied groups according to estimated blood loss (ml)

<table>
<thead>
<tr>
<th>Estimated blood loss (ml)</th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. – Max.</td>
<td>400.0 – 600.0</td>
<td>350.0 – 600.0</td>
<td>0.919</td>
<td>0.362</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>478.0 ± 59.62</td>
<td>464.7 ± 52.57</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>465.0 (430.0 – 500.0)</td>
<td>450.0 (430.0 – 500.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This table shows that there was insignificant difference between two groups as regard estimated blood loss (ml).

Table 5. Comparison between the two studied groups according to maternal operative complications

<table>
<thead>
<tr>
<th>Maternal operative complications</th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>(\chi^2)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>30.0 100.0</td>
<td>30.0 100.0</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Extension of uterine incision</td>
<td>0.0   0.0</td>
<td>0.0   0.0</td>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>

This table shows that there were no maternal operative complications in two groups.

Fig. 1. Comparison between the two studied groups according to U-D interval\(\text{second}\) that shows that there was significant decrease in U-D interval\(\text{second}\) in group used vaccum (group I) versus manual group (group II) as regard macrosomic feti.
In the current study we aimed to compare the safety (for mother and infant) and efficacy of delivery of the fetal head in cesarean section using vacuum extractor versus routine manual extraction. Sixty cases divided into two groups, group I vacuum-assisted delivery and group II with routine manual delivery.

In the current study we found that there were insignificant differences between two groups as regard age, parity, BMI and previous cesarean section.

In agreement with our result Sritippayawan et al showed that the mean age and the mean BMI...
Fig. 3. Comparison between the two studied groups that shows that there were insignificant differences between two groups as regard neonatal resuscitation and NICU admissions

Table 8. Comparison between the two studied groups according to maternal post-operative complications

<table>
<thead>
<tr>
<th>Maternal post-operative complications</th>
<th>Group I (n = 30)</th>
<th>Group II (n = 30)</th>
<th>χ²</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>27</td>
<td>28</td>
<td>0.218</td>
<td>1.000</td>
</tr>
<tr>
<td>Wound infection</td>
<td>3</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This table shows that there was insignificant difference between two groups as regard maternal post-operative complications.

were not statistically significant between manual and vacuum extraction groups [14].

Swain S et al showed that The Maternal age in the manual extraction group was 25.78±3.27 years, in the forceps extraction group it was 25.53±2.99 years and in the vacuum extraction group it was 25.68±3.01 years. The BMI in the manual extraction group was 28.39±2.04 Kg/m², in the forceps extraction group was 26.87±0.64 Kg/m² and in the vacuum extraction group it was 27.27±0.58 Kg/m² with insignificant differences [15]. In the current study we found that there was insignificant difference between two groups as regard Delivery gestational age.

In agreement with our result Swain S et al showed that the gestational age in the manual extraction group was 39.04±0.51 weeks, in the forceps extraction group was 38.84±0.50 weeks and in the vacuum extraction group it was 38.63±0.43 weeks with insignificant differences [16].

Study done by Arad I et al and Banu F et al showed that there was no significant difference in gestational age between the two groups [17-18].

In the current study we found that there was insignificant difference in U-D interval second between vacuum and manual method as regard average size feti but there was significant decrease in U-D interval second in group used vacuum versus manual group as regard macrosomic feti.

This goes with Sritippayawan S et al as showed that there was a significant difference of the mean time U-D interval between the manual and vacuum extraction groups. The U-D interval was significantly Prolonged in M group (86.3±53.9 and 65.3±31.2 seconds, respectively) [19].
However, Arads et al. demonstrated a prolongation of the U-D interval in cases of vacuum extraction at a cesarean section [20]. 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.

The U-D interval in the manual and vacuum extraction group was 43.5±8.6 seconds and 75.6±9.02 seconds respectively, in the study done by Banu F et al. [21].

Swain S et al found that the U-D interval in the manual extraction group was 90.56±4.91 seconds, in the forceps extraction group was 70.2±5.02 seconds and in the Vacuum extraction group it was 62.3±2.03 seconds. The difference in U-D interval was significant between manual extraction and forceps extraction groups. There was significant difference in U-D interval between Manual and Vacuum extraction groups [22].

In the current study we found that there was insignificant difference between two groups as regard estimated blood loss (ml).

This is consistent with Sritippayawan S et al as showed that the total blood loss was not statistically significant between the groups [23].

However previous studies reported that use of the vacuum extractor at the time of elective cesarean delivery allow for delivery with less blood loss [24].

Swain S et al showed that there was a significant difference in the estimated blood loss between the manual and forceps extraction group and between the forceps and vacuum extraction group. The difference in estimated blood loss between the manual and vacuum extraction groups was not significant [25].

In the current study we found that there was insignificant difference in fetal birth weight between vacuum and manual group as regard average size feti and there was insignificant difference in fetal birth weight between vacuum and manual group as regard macrosomic feti.

This agrees with Sritippayawan S et al as showed that the mean birth weight was not statistically significant between the manual and vacuum extraction groups [25].

In the current study we found that there was insignificant difference between two groups as regard Apgar scores.

Sritippayawan S et al agree with our result as showed that results did not show differences in the Apgar score on the first and fifth minute in the newborns of the two groups [25].

Another study agrees with our result by Swain S et al showed that there was no significant difference in APGAR scores at 1 min between the manual and forceps extraction groups, between the forceps and vacuum extraction groups and between the manual and vacuum extraction groups, the difference in the APGAR score at 5 min was not significant between the manual and vacuum extraction groups [25].

In the current study we found that there were insignificant differences between two groups as regard to neonatal resuscitation and NICU admissions.

In agreement with our result Sritippayawan S et al showed that there were no differences in neonatal resuscitation between the two groups [25].

In the current study we found that there were insignificant differences between two groups as regard to maternal operative or post-operative complications.

Banu F et al found that maternal operative complications like spreading of uterine incision was lower in vacuum assisted group [26].

5. CONCLUSIONS

As regard macrosomic feti, there was significant decrease in the U-D interval between vacuum group and manual group respectively but as regard average size feti, there were no differences between both groups. So, the use of the vacuum extractor at cesarean section may be a safe and effective method to facilitate delivery of the large fetal head and cesarean section delivery can be simplified by this technique.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not
intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the authors.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES


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