How can methods of placental delivery in cesarean section affect perioperative blood loss? A randomized controlled trial of controlled cord traction versus manual removal of placenta

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Abstract

Aim: Of the different described methods of placental delivery during cesarean section (CS), manual removal and cord traction are the most commonly used techniques. The ideal method of placental delivery during CS is still a conflicting issue as the data derived from the previous studies are widely heterogeneous and inconsistent. This study has investigated the effect of two different methods of placental delivery, controlled cord traction and manual removal, on perioperative blood loss.

Methods: This randomized controlled trial recruited 345 pregnant women scheduled for elective cesarean delivery at term. Eligible participants were randomly assigned to have their placentae delivered either by manual removal or cord traction. Perioperative blood loss was the study primary outcome measure.

Results: A total of 300 women were included in the final analysis. The longer placental delivery time in the cord traction group (n = 150) (60 s. [45–61.25] versus 45 s. [35–60] in the manual placental delivery group, P < 0.001) was associated with a statistically significant but clinically insignificant higher visually estimated blood loss (500 mL [interquartile range, 500–700] versus 500 mL [interquartile range, 400–500] in the manual removal group, P < 0.001). Although there were statistically significant differences in the hemoglobin levels, postoperatively, these differences were clinically insignificant and were not reflected in the corresponding deficits and percentages of deficit at 12- and 48-h postoperative intervals.

Conclusions: Of the studied placental delivery techniques, there were no clinically significant differences in terms of the considered intraoperative and postoperative outcomes; hence, the practice of placental delivery can be left up to obstetrician’s discretion and intraoperative scenario.

Key words: blood loss, cesarean section, cord traction, manual placental removal, placental delivery.

Introduction

The rate of cesarean section (CS) has increased over the last few decades.¹ It is potentially associated with morbidities: bleeding, postoperative fever and endometritis, venous thromboembolism and abnormal placentation in the subsequent pregnancies.²,³ The risk of hemorrhage is higher for women undergoing cesarean delivery compared to vaginal delivery.⁴ Different surgical techniques have been studied...
at each step of CS to minimize bleeding, including in situ versus exteriorization during uterine closure, finger splitting versus scissor cutting while performing the uterine incision and the multiple methods of placental delivery. 5–7

Of the different described methods of placental delivery during CS, cord traction and manual removal are the most commonly used techniques. The ideal mode of placental delivery during CS is still a conflicting issue. Previously, it has been claimed that the manual removal of the placenta is associated with increased risks of post-partum hemorrhage, postpartum endometritis and abnormal placentation in subsequent pregnancies. 1,8,9 However, until now, the choice between these two techniques has largely been dependent on the surgeon’s preference 10 as the data derived from the previous studies are widely heterogeneous and inconsistent, and there is no clear high-quality recommendation regarding this issue. This randomized controlled clinical trial (RCT) investigated the effect of controlled cord traction compared with manual removal of the placenta on perioperative blood loss. A two-tailed hypothesis (nondirectional hypothesis) has been adopted: one placental delivery method would be superior to the other with regard to the intraoperative blood loss. Cord traction can be associated with longer placental delivery time and subsequently more bleeding; similarly, manual removal is more likely to induce local trauma that can lead to excessive blood loss.

**Methods**

This RCT was conducted at the Obstetrics and Gynecology department, Armed Forces Hospital Southern Region, Khamis Mushait, Saudi Arabia (annual number of deliveries is ±8000, with a CS rate of 25%) in the period between April 1, 2015 and June 31, 2016, after receiving approval from the local hospital research and ethics committee and being prospectively registered at ClinicalTrials.gov (NCT02405663).

The study recruited young women (20–35 years) with singleton uncomplicated pregnancies who attended the outpatient antenatal clinic and were scheduled for elective delivery by CS at term. Emergency CS, multifetal gestations, preterm deliveries, maternal anemia (HB < 10 gm/dl), hypertensive disorders, rupture of fetal membranes, chorioamnionitis, placental abruption, placenta previa, placenta accreta, coagulopathy and significant medical disease and/or any other risk factor that would affect the risk of bleeding during CS were considered preoperative exclusion criteria of the study. The study was explained to all eligible women, and a written signed informed consent form was obtained from each participant before the beginning of the trial.

Eligible consenting women were then randomized according to the mode of placental delivery into two groups, group (A) and group (B), and had their placentae removed by cord traction and manual extraction, correspondingly. Block randomization was performed using a computer-based randomly generated sequence. The randomization/allocation process was concealed using sequentially sealed opaque envelopes. Each envelope was labeled with a serial number and had a card mentioning the type of intervention. Once allocation has been completed, it could not be changed. A ratio of 1:1 was considered during allocation.

Preoperatively, all women had a thorough obstetric assessment; routine preoperative workup, including measuring hemoglobin (HB) values, was performed, and the baseline demographic data were registered.

All CS were performed by the same team (i.e. four senior obstetricians with ≥15 years of experience in operative obstetrics), and a consistent operative procedure was used for all women. Intravenous antibiotic prophylaxis (first-generation cephalosporin) was given preskin incision. All procedures were performed through a Pfannenstiel incision: the fascia was incised transversely, followed by separation of the two recti muscles and opening of the parietal peritoneum by finger dissection. After careful dissection of the urinary bladder, the lower uterine segment was incised transversely, and the incision was the extended in a cephalad-caudal direction by a blunt finger dissection. The baby’s delivery was assisted by gentle external fundal pressure followed by complete delivery of the placenta and fetal membranes, either manually or by cord traction according to the patient’s allocation. In group A, placental delivery was aided by external massage of the uterine fundus combined with gentle umbilical cord traction, while in group B, manual removal of the placenta was performed by introducing the obstetrician’s hand into the uterine cavity to cleave the placenta from the decidua basalis. After the placental delivery, 10 units of oxytocin (Syntocinon Inj. 5iu/ml. Novartis Pharma) were placed in 500 cc of ringer lactate and infused over 4 h. The uterus was then repaired in situ by double-layer continuous suturing using a polyglycolic acid.
synthetic absorbable suture material (Vicryl Ethicon, Inc., Somerville, NJ).

Intraoperative exclusion criteria included intraperitoneal adhesions, upper segment CS and/or surgical complications that could increase bleeding and/or necessitate intraoperative or postoperative blood transfusion.

The postoperative management plan was also similar for all women, including: early ambulation, intravenous fluids, measurement of vital data, thromboprophylaxis, oral intake and repeat complete blood count (CBC) at 12 and 24 h.

Postoperative exclusion criteria included incomplete follow up and any postoperative complication that could affect the studied outcomes and that was not related to the mode of placental delivery. These complications included internal hemorrhage, reexploration, hemolysis, fever, sepsis and/or hematoma.

The primary outcome measure of the study was the amount of the perioperative blood loss, which was assessed via the following parameters: visually estimated blood loss (VEBL) and postoperative HB values as well as their deficits and percentages of deficit at 12 and 24 postoperative hours.

Blood loss estimation was started from the time of onset of placental delivery up to 24 h postdelivery. Blood loss estimation was performed by the same experienced obstetricians who were trained in estimating the blood loss. VEBL was conducted according to the pictorial guidelines of Bose et al. and the amount of blood collected in the suction container after placental delivery was measured. According to Bose et al.’s pictorial guidelines, the maximum saturated capacity of the small (10 × 10 cm), medium (30 × 30 cm) and large (45 × 45 cm) swab is 60 mL, 140 mL, and 350 mL, respectively. One kilogram of soaked swabs accommodate 1000 mL of blood; a 50 cm diameter floor spill is 500 mL, 75 cm diameter floor spill is 1000 mL, and 100 cm diameter floor spill is 1500 mL. Postoperative blood loss was measured using the same described gravimetric technique.

To optimize the quantification of VEBL, the following precautions were followed up: first, all amniotic fluid was sucked and discarded before starting placental delivery, and second, no irrigation was allowed at the surgical site except after full uterine closure and finally counting the blood-soaked drapes and accurately documenting the VEBL.

The secondary outcomes measures included the placental delivery time (calculated from time of completed delivery of the new born till the time of completed delivery of the placenta), operative duration (calculated from the time of skin incision to the time of last stitch), need of extra ecbolics (type and dose of used ecbolics, including oxytocin, methylergometrine and misoprostol, were documented), need of blood transfusion (indication and type and amount of blood product given were documented), excessive blood loss (defined as VEBL ≥ 1000 mL) and postoperative endometritis and puerperal pyrexia.

The surgeon was not involved in any later aspect of data collection. Participants, postoperative care providers and, whenever possible, outcome assessors were kept blinded to the intervention. In addition, data analysts and the persons in charge of reporting the results of the trial were kept unaware of the identity of the study groups.

The study sample size was computed using G*Power version 3.1.9.2 (Franz Faul, Kiel university, Germany) based on a two-tailed t-test to detect the difference between the mean estimated operative blood loss in the study groups. It has been hypothesized that an effect size of 200 mL would be clinically significant. In a previous study, the mean estimated blood loss during CS was 935.4 ± 201.2 mL; thus, a total sample size of 96 women was needed to achieve 95% power (1-β) at a 0.05 significance level.

Data analysis was performed on a personal computer using IBM SPSS Statistics version 21 (IBM Corp., Armonk, NY). The Kolmogorov–Smirnov goodness of fit test was used to test the normality of numerical data distribution. Normally distributed numerical data were presented as mean ± SD, and in-between groups differences were tested using independent samples student t test, while the skewed data were presented as median and interquartile range (IQR), and in-between groups differences were tested non-parametrically using the Mann–Whitney U test. Categorical data were presented as number and percentage, and in-between group differences were tested using the Chi-square test or Fisher’s exact test, as appropriate. Parameter correlations were calculated using Spearman’s coefficient of rank correlation (rho). All P values were two-tailed, and P < 0.05 was considered statistically significant.

Results

A total of 300 women were included in the final statistical analysis of the study (Figure 1).
Preoperatively, there were no statistically significant differences between the two groups regarding baseline demographic criteria, preoperative HB values and presence of relevant medical or surgical history (Table 1).

Intraoperatively, there were no statistically significant differences between the two groups regarding mode of anesthesia, type of CS, CS duration and neonatal birth weight. However, it has been indicated that group (A) had a statistically significant rise in the VEBL (Figure 2), and group (B) had significantly shorter placental delivery time (Table 2). There were no cases of a failed cord traction mode that necessitated manual removal of the placenta.

Postoperatively, there were three cases with blood loss ≥1000 mL, but their clinical condition did not require any blood transfusion. Two of these were included in group (A) and one in group (B). None of the studied women developed fever ≥38°C either during the initial hospital stay or during the follow-up in
the postnatal clinic. Moreover, no cases of postoperative endometritis, wound infection or dehiscence were recorded.

Although there were statistically significant lower postoperative HB levels in group (A), the corresponding deficits and percentages of deficit did not confirm this significance (Figure 3). There were no significant differences between women of both groups in terms of the duration of hospital stay. However, there was a statistically significant higher need for using extra ecbolics in group (A) (Table 3).

**Discussion**

In this RCT, the effect of two different placental delivery methods on perioperative blood loss during elective CS has been investigated. The authors do believe that the mode of placental delivery does not significantly affect the actual perioperative blood loss. Most probably, it is the longer duration of placental delivery in the cord traction group that affected the blood loss rather than the technique itself. The shorter placental delivery time in the manual placental delivery group was associated with a statistically significant, but clinically insignificant, lower VEBL and higher postoperative HB values. Moreover, this was not reflected on the deficits or the deficits percentages of HB at postoperative intervals of 12 and 24 h.

**Table 1** Preoperative data†

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A Cord traction</th>
<th>Group B Manual extraction</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age, years</td>
<td>29 ± 5</td>
<td>30 ± 5</td>
<td>0.62</td>
</tr>
<tr>
<td>BMI ‡</td>
<td>27.0 ± 5</td>
<td>27 ± 5</td>
<td>0.70</td>
</tr>
<tr>
<td>Gestational age at delivery, weeks</td>
<td>39 ± 1</td>
<td>39 ± 1</td>
<td>0.60</td>
</tr>
<tr>
<td>Number of deliveries</td>
<td>2 (1–4)</td>
<td>2 (1–4)</td>
<td>0.57</td>
</tr>
<tr>
<td>Number of prior CSs</td>
<td>1 (0–1)</td>
<td>1 (0–2)</td>
<td>0.29</td>
</tr>
<tr>
<td>Preoperative HB, gm/dl</td>
<td>11.3 ± 1.2</td>
<td>11.5 ± 1.2</td>
<td>0.10</td>
</tr>
<tr>
<td>Relevant medical history§</td>
<td>14 (9.3%)</td>
<td>14 (9.3%)</td>
<td>1.00</td>
</tr>
<tr>
<td>History of laparotomy</td>
<td>3 (2.0%)</td>
<td>2 (1.3%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

†Values are given as mean ± standard deviation, number (percentage) or median (interquartile range), as appropriate.; ‡Calculated as weight in kilograms divided by the square of height in meters.; §Abnormal health status prior to the delivery, including prior major illnesses and/or any current ongoing illness, for example, diabetes, hypertension. BMI, body mass index; CS, cesarean section; HB, hemoglobin.

**Table 2** Operative data†

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A Cord traction</th>
<th>Group B Manual extraction</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of CS</td>
<td>Primary</td>
<td>45 (30.0%)</td>
<td>51 (34.0%)</td>
</tr>
<tr>
<td></td>
<td>Repeat</td>
<td>105 (70.0%)</td>
<td>99 (66.0%)</td>
</tr>
<tr>
<td>Mode of anesthesia</td>
<td>Spinal</td>
<td>37 (24.7%)</td>
<td>52 (34.7%)</td>
</tr>
<tr>
<td></td>
<td>General</td>
<td>113 (75.3%)</td>
<td>98 (65.3%)</td>
</tr>
<tr>
<td>Visually estimated blood loss, ml</td>
<td>500 (500–700)</td>
<td>500 (400–500)</td>
<td>0.00*</td>
</tr>
<tr>
<td>Duration of placental delivery, seconds</td>
<td>60 (45–61.25)</td>
<td>45 (35–60)</td>
<td>0.00*</td>
</tr>
<tr>
<td>Duration of cesarean section, minutes</td>
<td>50 (45–65)</td>
<td>55 (45–60)</td>
<td>0.79</td>
</tr>
<tr>
<td>Neonatal birth weight, gm</td>
<td>3070.0 ± 480.3</td>
<td>3025.0 ± 487.0</td>
<td>0.42</td>
</tr>
</tbody>
</table>

*Indicates statistical significance (P < 0.05); †Values are given as mean ± standard deviation, number (percentage) or median (interquartile range), as appropriate. CS, cesarean section.
To the extent of our knowledge, this is one of the relatively large RCT to study the effect of placental delivery methods during elective transverse lower segment CS at term. Another potential point of strength in the current study is the use of strict exclusion criteria. All women went through elective CS and were randomly assigned to the mode of placental delivery. The technique of CS, measuring VEBL and assessing study outcomes and the postoperative care plan was standardized and consistent for all the conducted CS. The previous studies’ data were largely heterogeneous and inconsistent. Few authors\textsuperscript{9,13} used only elective CS data, while almost all other studies\textsuperscript{14} had mixed data from both elective and emergency CS. Some authors included women with term pregnancies,\textsuperscript{14} and others\textsuperscript{13,15,16} included women with a gestational age of 34 weeks and above. The CS type itself was different between trials, where some used data of lower transverse CS only,\textsuperscript{8,13,17,18} while others used classic CS and vertical skin incisions data.\textsuperscript{10,12,15,19}

It is well known that the perioperative blood loss at CS delivery is difficult to estimate, and different techniques, including serial change in HB levels, visual estimation and the gravimetric method, have been described.\textsuperscript{20,21}

The methods used to estimate the amount of blood loss intraoperatively and postoperatively were also variously different. Some authors calculated blood loss with the amniotic fluid with the rationale that it will be the same in most of cases.\textsuperscript{8} Others tried subtraction of the estimated antenatal amniotic fluid amount\textsuperscript{12,16} or complete drainage\textsuperscript{17} in order to decrease the number of soaked towels. Considering most of the described methods, it seems that there is no 100% agreement on the accuracy, reliability and superiority of one method above another. Anorlu \textit{et al.}\textsuperscript{14} recorded significant heterogeneity ($I^2 = 91\%$) among the included studies in their systematic review. Schorn \textit{et al.}\textsuperscript{21} concluded that a combination of direct measurement, by directly collecting blood into plastic bags or bedpans, and gravimetric methods is the most practical method. In this trial, the visual estimation of blood loss was used with a direct observation method depending on the pictorial guidelines by Bose \textit{et al.}\textsuperscript{11}

Accurate estimation of blood loss facilitates timely resuscitation and minimizes the risks of disseminated

Table 3: Postoperative data and outcomes\textsuperscript{5}

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cord traction</td>
<td>Manual extraction</td>
<td></td>
</tr>
<tr>
<td>Postoperative 12 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB, gm/dl</td>
<td>$10.3 \pm 1.4$</td>
<td>$10.7 \pm 1.3$</td>
<td>0.02*</td>
</tr>
<tr>
<td>HB deficit, gm/dl</td>
<td>$1.0 \pm 0.9$</td>
<td>$0.8 \pm 0.8$</td>
<td>0.22</td>
</tr>
<tr>
<td>HB deficit percentage</td>
<td>$0.1 \pm 0.1$</td>
<td>$0.1 \pm 0.1$</td>
<td>0.15</td>
</tr>
<tr>
<td>Postoperative 24 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB, gm/dl</td>
<td>$10.1 \pm 1.5$</td>
<td>$10.4 \pm 1.4$</td>
<td>0.10</td>
</tr>
<tr>
<td>HB deficit, gm/dl</td>
<td>$1.2 \pm 0.9$</td>
<td>$1.1 \pm 0.9$</td>
<td>0.60</td>
</tr>
<tr>
<td>HB deficit percentage</td>
<td>$0.1 \pm 0.1$</td>
<td>$0.1 \pm 0.1$</td>
<td>0.40</td>
</tr>
<tr>
<td>Use of extra ecbolics</td>
<td>44 (29.3%)</td>
<td>7 (4.7%)</td>
<td>&lt;0.00*</td>
</tr>
<tr>
<td>Duration of hospital stay, days</td>
<td>3 (3–4)</td>
<td>3 (3–4)</td>
<td>0.14</td>
</tr>
</tbody>
</table>

*Indicates statistical significance ($P < 0.05$); †Values are given as mean ± standard deviation, number (percentage) or median (interquartile range), as appropriate.; $\Delta$Deficit = (preoperative value – postoperative value); $\Delta$Deficit percentage = ([Preoperative value – Postoperative value] / Preoperative value × 100). HB, hemoglobin.
intravascular coagulation and hemorrhagic shock. VEBL is quick and easy; however, it is not 100% accurate as it is vulnerable to high rates of error because of its subjectivity. Relying on the VEBL can result in the underestimation of blood loss by 33–50%. In this study, postoperative HB was measured and correlated with the VEBL to decrease the potential margin of error in the blood loss estimation. On the other hand, quantitative blood loss (QBL) is laborious and time consuming but has a lower rate of error. Due to its accuracy, the use of QBL has been encouraged by the California Maternal Quality Care Collaborative (CMQCC) and the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN). This point should be considered in future studies.

This is the first study to measure the placental delivery time, which was significantly shorter in the manual placental delivery group and significantly correlated with VEBL.

Some authors reported a statistically significantly longer hospital stay with manual delivery of the placenta. However, all of them included emergency CS data, and two studies used data of classic CS and vertical abdominal incision, which might require a longer hospital stay.

Morales et al. and Cernadas et al. did not show any statistically significant difference in the rate of puerperal pyrexia between women who had manual placental removal and those who had cord traction. The different methodology of most of the trials in literature made judgment on the incidence of puerperal pyrexia and endometritis unrealistic. Trials including emergency CS with prolonged labor or prolonged rupture of the membranes should not be compared with elective CS. There was also no agreement about using perioperative antibiotic prophylaxis in the current study, antibiotic prophylaxis has been used for all women, and no single case of puerperal pyrexia, endometritis, wound infection or dehiscence have been reported.

The current study is limited by not being a double-blinded study as the surgical team was aware of the technique used to deliver the placenta. Moreover, the findings of this study are only applicable to low-risk women undergoing elective cesarean delivery. It is unclear whether similar results would be seen for higher-risk women or women undergoing cesarean delivery after a trial of labor, and further studies are needed. The very high rate of general anesthesia in each group is another demerit of this study as this practice is not consistent with obstetric anesthesia practices in Western Europe or North America, where rates of neuraxial anesthesia are substantially higher for elective CS. The use of intraoperative and postoperative exclusion criteria raises concerns about selection bias and nonutilization of intention-to-treat analysis; these criteria were used to avoid the inclusion of women with increased perioperative blood loss, which is not related to the mode of placental delivery. Finally, as the in-between group difference in estimated blood loss (EBL) was small, it can be speculated that the study may have been underpowered to show a statistically significance. Performing a larger RCT may have detected a statistically significant difference; however, the clinical relevance of confirming such a small difference may be questionable.

To sum up, in the current study, placental delivery time was longer in the cord traction group, and this was associated with a statistically significant but clinically insignificant higher VEBL. The statistically significant differences in the postoperative hemoglobin levels were also clinically insignificant and were not reflected in the corresponding deficits and percentages of deficit at postoperative intervals of 12 and 48 h. The practice of placental delivery can be left up to obstetrician’s discretion and intraoperative scenario because there were no clinically significant differences in terms of the considered intraoperative and postoperative outcomes. Apart from few studies, including the current study, the major bulk of available evidence still supports the use of controlled cord traction as a placental delivery method in CS. Unfortunately, the most important systematic review supporting the use of controlled cord traction as a method of placental delivery in CS is limited by a significant heterogeneity. It seems that the perfect placental delivery mode will stay controversial as long as the study designs, enrollment criteria, intervention types, methods of VEBL, antibiotic prophylaxis and postoperative care stays different between trials. A large-scale multicenter study with strict recruitment criteria and standard technique is needed to make a decision regarding the superior placental delivery mode, if any.

It can be concluded that both the manual placental delivery and controlled cord traction techniques have comparable blood loss as the shorter placental delivery time associated with the manual placental delivery technique, in this study, led to clinically insignificant lower VEBL.

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