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Spontaneous delivery or manual removal of the placenta during caesarean section: a randomised controlled trial

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Objective To compare blood loss with spontaneous delivery and manual removal of the placenta during caesarean section.

Design A randomised controlled trial.

Setting Four university hospitals between September 1999 and June 2002.

Population A total of 472 women delivering by caesarean section at term were randomised to spontaneous placental delivery ($n = 235$) or manual removal ($n = 237$).

Methods The allocation was made by opening the next available of a series of sealed opaque envelopes and derived from a computer-generated list of numbers.

Main outcome measures Significant blood loss, defined as either a drop in haemoglobin of greater than 2.5 g/dL, or the need for blood transfusion.

Results The mean interval between delivery of the newborn and the placenta was longer in the spontaneous delivery group (3.4 *vs* 1.9 minutes), but the mean duration of the operation was similar. Significant blood loss occurred in 30 women (13%) in the spontaneous delivery group and 49 women (21%) in the manual removal one (RR 0.62; 95% CI 0.41–0.94). Post-operative fever affected 6 and 5 cases, respectively, and antibiotics were used in 14 and 12 cases, respectively.

Conclusions Allowing spontaneous delivery of the placenta reduces significant blood loss without increasing operating time.

INTRODUCTION

There are two main methods for placental delivery during caesarean section. Some experts manually cleave the placenta from the decidua basalis and remove it from the uterus, while others prefer to wait for spontaneous delivery.[1] Nine trials have compared the two techniques.[2–10]

Some trials showed a reduced risk of post-operative endometritis with spontaneous delivery of the placenta,[2,5] while others did not.[3,4,7,9] Blood loss was lower with spontaneous delivery in some trials,[6,7,9] but not in others.[3,4] Feto-maternal transfusion was less frequent with spontaneous delivery of the placenta in the study that included this outcome measure.[10]

A systematic review concluded that manual removal may increase the risk of maternal bleeding, of infection and of feto-maternal transfusion.[11] However, several trials have been conducted after this review, some showing results in disagreement with its conclusions.

A recent survey in the United Kingdom showed that 73% of obstetricians reported using controlled cord traction and spontaneous delivery, but manual removal remained the standard technique in many institutions.[12]

Our primary objective was to compare the risk of significant blood loss associated with spontaneous and manual removal of the placenta during caesarean section. The secondary outcome measures were infectious morbidity, duration of the surgery and feto-maternal transfusion.

METHODS

We conducted a randomised controlled trial in the Departments of Obstetrics and Gynaecology of four tertiary care hospitals (Geneva and Vaud University Hospitals, Switzerland, and Erasme and Brugmann Hospitals, Belgium) from September 1999 to June 2002. The study was approved by the institutional ethics committee of each centre before the start of the study.

Women undergoing an elective or an emergency caesarean section were eligible for the study only when time for

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information and consent was available. The exclusion criteria were gestational age less than 34 weeks, multiple pregnancy, placenta praevia, intrapartum fever and suspected chorioamnionitis, and clotting disorders. Written informed consent was obtained from each participant before surgery.

The random allocation scheme was derived from a computer-generated list of numbers, with randomly permuted blocks of four, six and eight participants. Sealed and consecutively numbered opaque envelopes were prepared centrally. The sets of envelopes were kept in the operating theatre of the four participating centres. Consenting women were randomly allocated to one of the groups by opening the next available envelope, either just before surgery or during the initial steps of the procedure.

For women allocated to the first group, the obstetrician was instructed to wait until spontaneous delivery of the placenta. Controlled cord traction was performed, if needed, to facilitate placental delivery. To avoid excessive bleeding in the interval, clamps were placed on the uterine incision for haemostasis. If spontaneous delivery had not occurred after 10 minutes, or in case of bleeding, manual removal of the placenta was performed. After delivery, the placenta and membranes were examined and, if found complete, manual exploration of the cavity was not performed.

In the manual removal group, the surgeon introduced his hand into the uterine cavity to detach and remove the placenta as soon as possible after the delivery of the infant. The emptiness of the uterine cavity was verified manually. In both groups, oxytocin and a cephalosporin antibiotic were administered intravenously after the delivery of the infant. All uterine incisions were low transverse and all were closed without exteriorisation of the uterus.

Estimated blood loss was evaluated by the operating theatre staff, taking into account the volume of liquid suctioned during the operation, minus the estimated volume of amniotic fluid. Blood loss estimation during caesarean section is known to be inaccurate and subjective.[1] Because blinding of clinicians was not possible in this trial, this measure is prone to bias. Therefore, we pre-specified our primary outcome based on the difference in haemoglobin level or blood transfusion. Significant blood loss was defined as a fall greater than 2.5 g/dL between the last haemoglobin measurement performed before randomisation and the measurement performed on the third post-operative day. In the case of a missing value on the third day, any post-operative haemoglobin estimate was used. Women who had blood transfusion were included in this definition, irrespective of the difference in haemoglobin concentration.

Secondary outcome measures included operating time, use of additional oxytocics (oxytocin or prostaglandins), the presence of post-operative fever or need for antibiotic administration and feto-maternal transfusion. Fever was defined as a temperature above 38.5°C on two consecutive days, excluding the first 24 hours. Feto-maternal transfusion was defined as a Kleihauer test showing more than one fetal cell among 1000 maternal cells.

Data were managed and analysed with Epi Info (CDC, Atlanta, Georgia) statistical software. All analysis were conducted on an intention-to-treat basis. We report means, with their standard deviations, for continuous variables. Statistical significance was tested using the Student's *t* test. We estimated the effect of the intervention by the relative risk (RR), the risk difference and the number needed to treat (NNT) and their 95% confidence interval (CI). The analysis was stratified using the Mantel–Haenszel method. Proportions were compared between groups with the χ^2 test.

We calculated that a sample size of 438 women had a power of 80%, with a two-tailed α of 0.05, to show a difference in the incidence of the primary outcome measure between 20% in either group and 10% in the other group.

RESULTS

A total of 472 women were randomised, 235 in the spontaneous placenta delivery group and 237 in the manual removal group. Baseline characteristics were similar between groups (Table 1). There were slightly more women with a previous caesarean and fewer primiparous women in the spontaneous delivery group.

Table 1. Characteristics of study participants. Values are expressed as *n* (%) or mean [SD].

	Spontaneous ($n = 235$)	Manual ($n = 237$)
Maternal age (years)	31 [5.0]	31 [5.2]
Gestational age (weeks)	38 [1.3]	39 [1.5]
Primiparity	99 (42)	113 (48)
Preoperative Hb level (g/dL)	12 [12]	12 [11]
Preoperative Hct level (%)	36 [3.1]	36 [3.0]
Primary indication for caesarean		
Dystocia	49 (21)	47 (20)
Fetal distress	11 (5)	15 (6)
Breech	57 (24)	64 (27)
Previous caesarean	86 (37)	77 (32)
Others	32 (14)	34 (14)
Previous caesarean (all)	102 (43)	92 (39)
Elective caesarean	154 (66)	156 (66)
Anaesthesia		
Spinal	171 (73)	172 (73)
Epidural	60 (26)	59 (25)
General	4 (2)	6 (3)
Membranes ruptured	58 (25)	53 (22)
Birthweight (g)	3300 [529]	3310 [547]

Hb = haemoglobin; Hct = haematocrit.

Table 2. Frequencies [*n* (%), *n*/*n* (%)] and relative risks (RR) with 95% confidence intervals (CI) of significant blood loss, the primary outcome measure.

	Spontaneous ($n = 235$)	Manual ($n = 237$)	RR (95% CI)
All participants			
Significant blood loss	30 (13)	49 (21)	0.62 (0.41–0.94)
Difference in Hb $\geq$ 2.5 g/dL	30 (13)	48 (20)	0.63 (0.41–0.96)
Blood transfusion	4 (2)	3 (1)	1.34 (0.30–5.9)
Stratified analysis			
Previous CS	11/102 (11)	11/92 (12)	0.90 (0.41–2.0)
Primary CS	19/133 (14)	38/145 (26)	0.55 (0.33–0.90)
Adjusted for previous CS			0.63 (0.42–0.96)
Primiparous women	17/99 (17)	31/113 (27)	0.63 (0.37–1.1)
Multiparous women	13/136 (10)	18/124 (15)	0.66 (0.34–1.3)
Adjusted for parity			0.64 (0.42–0.97)
Emergency CS	14/81 (17)	29/81 (36)	0.48 (0.28–0.84)
Elective CS	16/154 (10)	20/156 (13)	0.81 (0.44–1.5)
Adjusted for emergency CS			0.62 (0.41–0.93)

CS = caesarean section.

The results for the primary outcome for the whole sample and various subgroups are shown in Table 2, and other outcomes are presented in Table 3. The time interval between the incision and the delivery of the infant was similar between groups, but there was a slightly longer interval between the delivery of the infant and of the placenta in the spontaneous delivery group, compared with the manual removal group which did not result in a longer operating time overall.

In the spontaneous delivery group, delivery of the placenta deviated from the protocol in 31 cases (13%). In 10 cases, manual removal was performed because of a delay longer than 10 minutes and in eight cases because of excessive bleeding. In six cases, manual exploration of the uterine cavity was performed because of suspected retained membranes or placental tissue. Manual removal was performed for other reasons in seven cases. The majority of the spontaneous deliveries of the placenta occurred within 5 minutes after the delivery of the infant (93%). When the delivery of the placenta has not occurred within 5 minutes, the probability of a spontaneous delivery before 10 minutes was low (43%).

Fewer women experienced significant blood loss, the primary outcome, in the spontaneous delivery group (Table 2). The absolute estimate of the effect is a risk difference of 8% (95% CI 1–15%). Expressed as a NNT, spontaneous delivery should be performed in 13 women to avoid one additional case of significant blood loss. When adjusted for previous caesarean section, the estimate was not changed (adjusted RR 0.63; 95% CI 0.42–0.96). These results were also not modified when adjusted for other potential confounders (parity, elective or emergency, type of anaesthesia, rupture of the membranes, hospitals).

Mean estimated blood loss and the proportion of women with blood loss estimated to be equal or greater than 500 or 1000 mL was similar between groups (Table 3). Estimated blood loss was poorly, yet statistically significantly, correlated with decrease in haemoglobin. Among women with a decrease in haemoglobin of more than 25 g/L, 35% had an estimated blood loss during the caesarean section lesser than 500 mL. In women with a decrease lesser than 25 g/L, 28% had blood loss estimated to be equal to or greater than 500 mL.

Table 3. Other outcomes, reported as frequencies [*n* (%)] and relative risks (RR) with 95% confidence intervals (CI) or as mean [SD] and *P* values.

	Spontaneous ($n = 235$)	Manual ($n = 237$)	RR (95% CI) or *P* value
Interval between delivery of the infant and of the placenta	3.4 [2.8]	1.9 [1.2]	<0.001
Use of additional oxytocics	74 (31)	81 (34)	0.92 (0.71–1.2)
Estimated blood loss (mL)	550 [378]	546 [279]	0.90
>500 mL	78 (33)	84 (35)	0.93 (0.73–1.2)
>1000 mL	10 (4)	9 (4)	1.12 (0.46–2.7)
Total operating time in minutes	50 [15]	49 [15]	0.80
Kleihauer test ($\geq$1/1000)	6 (3)	8 (3)	0.76 (0.27–2.2)
Fever ($\geq$38.5°C on two occasions)	6 (3)	5 (2)	1.2 (0.37–3.9)
Antibiotic administration	14 (6)	12 (5)	1.2 (0.56–2.5)

We found no difference in the use of additional oxytocics, feto-maternal transfusion, post-operative fever or use of antibiotics between groups. There were no cases of endometritis during the postnatal hospital stay.

DISCUSSION

Our trial shows that allowing spontaneous delivery of the placenta during caesarean section reduces significant blood loss without increasing operative time. Some previous studies showed a difference in estimated blood loss,[3,4] while others did not.[6,7,9] We found no difference in mean estimated blood loss. Magann *et al.*[6] attempted at measuring precisely the blood loss, taking into account the weight of pads and all blood suctioned minus the volume of amniotic fluid estimated before the caesarean section using ultrasonography. Despite the great care in performing this estimation, there is no evidence that this method is reliable. Results were also reported as a mean difference in haemoglobin[4,9] or haematocrit,[2,6,7] but this approach does not identify women who had significant blood loss. We believe that a decrease in haemoglobin of more than 2.5 g/dL is more accurate than estimated blood loss and constitutes a clinically significant outcome measure.

We found no difference in post-operative fever and antibiotic administration. Some of the previous trials showed a reduction in the risk of post-operative endometritis with spontaneous delivery of the placenta,[2,5] while others trials did not.[3,4,7,9] A possible explanation is that antibiotic prophylaxis was not systematic in some trials.[2] The baseline risk of endometritis varied between the hospitals where the trials were conducted. A benefit from spontaneous delivery was demonstrated in the settings with the higher baseline risk of endometritis, while in hospitals with a lower risk, no difference was found.[4]

Feto-maternal transfusion was less frequent with spontaneous delivery of the placenta in the study that included this outcome measure.[10] We have not found such a difference between groups. Apparently, the modified Kleihauer test used in the previous trial was very sensitive, detecting a feto-maternal transfusion of as little as 0.01 mL. It is unclear how such a small transfusion can be diagnosed. Our laboratory reports the test results as negative when the test shows less than one fetal cell among 1000 maternal cells. This corresponds to a feto-maternal transfusion of less than 2 to 3 mL.

We specified in our protocol that the obstetrician must wait up to 10 minutes for a spontaneous delivery of the placenta before performing a manual removal. Waiting for such a long delay was rarely necessary and few women had a spontaneous delivery of the placenta after 5 minutes. This suggests that waiting for more than 5 minutes may not be necessary, and that proceeding to manual removal of the placenta is the best option in these cases.

Women and clinicians were not blinded to the allocated treatment, which raises the possibility of a bias in the estimation of the outcomes. We defined significant blood loss using objective measurements not prone to bias. Data collection was performed without knowing the group allocation and without prior knowledge about a possible direction of the effect of the intervention. The decision to use oxytocin in addition to the standard prophylaxis was made independently of the group allocation and a bias in this decision might operate in either direction depending on anxiety or enthusiasm for the new intervention.

Although the sample size was calculated to show a difference in the primary outcome, significant blood loss, the power of the study was, however, limited to test differences in less frequent events such as fever, use of antibiotics or blood transfusion.

CONCLUSIONS

Allowing spontaneous delivery of the placenta during caesarean section reduces significant blood loss. This intervention is highly feasible, as the increase in operating time should be minimal, especially if the waiting time is restricted to 5 minutes after the delivery of the infant.

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