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A pilot randomized controlled trial of controlled cord traction to reduce postpartum blood loss

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Abstract

Objective—To evaluate whether controlled cord traction (CCT) for management of the third stage of labor reduced postpartum blood loss compared with a "hands-off" management protocol.

Methods—Women with imminent vaginal delivery were randomly assigned to either a CCT group or a hands-off group. The women received prophylactic oxytocin. The primary outcome was blood loss during the third stage of labor.

Results—In total, 103 women were allocated to the CCT group and 101 were allocated to the hands-off group. Median blood loss in the CCT group and the hands-off group was 282.0 mL and 310.2 mL, respectively. The difference in blood loss (−28.2 mL) was not significant (95% confidence interval, −92.3 to 35.9; $P = 0.126$). Blood collection in the hands-off group took 1.2 minutes longer than in the CCT group, which may have contributed to this difference.

Conclusion—CCT may reduce postpartum blood loss. The present findings support conducting a large trial to determine whether CCT can prevent postpartum hemorrhage.

Keywords

Active management of the third stage of labor; Controlled cord traction; Maternal mortality; Postpartum hemorrhage; Third stage of labor

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Conflicts of interest
The authors have no conflicts of interest.

Author contributions
FA, JMB, and PB proposed the study. FA and AA wrote the protocol; AA, GT, and GV co-ordinated the trial; LG performed the statistical analysis; FA and LG wrote the manuscript, in collaboration with AA, GT, GV, JMB, and PB. All authors read and approved the final manuscript.

Synopsis: Controlled cord traction for management of the third stage of labor may reduce postpartum hemorrhage.

1. Introduction

Postpartum hemorrhage (PPH) is a major cause of maternal mortality worldwide, accounting for approximately 100 000 maternal deaths annually [1]. International health organizations recommend active management of the third stage of labor (AMTSL), rather than the use of expectant management, to prevent PPH [2,3]. The current definition of AMTSL combines the administration of uterotonic agents, controlled cord traction (CCT), late umbilical cord clamping, and uterine massage after placental delivery [2], whereas expectant management is a "hands-off" passive physiologic approach. Active management of the third stage of labor reduces the incidence of PPH by approximately 65% compared with expectant management [4]. Despite the beneficial effects of AMTSL overall, it is important to assess the effects of its individual components in order to use the simplest, most effective, and safest intervention.

The effectiveness of uterotonic drugs used immediately after delivery in reducing PPH has been demonstrated [5]. Oxytocin is the first-choice agent, despite the trade-off between its benefits and adverse effects [5]. The use of late umbilical cord clamping is also based on strong evidence regarding beneficial effects for the neonate [6,7]. Uterine massage is recommended for immediate postpartum care (after placental delivery), with no reports of severe complications associated with this technique, although only a small pilot trial has shown promising beneficial effects [8,9]. The use of CCT is also promoted without definitive evidence of its effectiveness [10] and with uncertainty regarding its safety.

Cord traction was introduced into obstetric practice by Brandt and Andrews via the Brandt–Andrews maneuver, which consists of elevating the uterus suprapubically while maintaining steady traction on the cord [11], after the placenta is clinically separated and while the uterus is contracted. In 1962, Spencer described a modification of the technique and called it "controlled cord traction" [12]. To reduce the length of the third stage of labor, the modification entailed not waiting for clinical signs of placental separation before beginning cord traction. Since then, most studies have used this modified technique or similar ones, and the current international recommendations advocate this method [3].

A pilot randomized controlled trial was conducted to evaluate whether the management of placental delivery with CCT reduced postpartum blood loss compared with hands-off management in women having single vaginal deliveries and receiving prophylactic oxytocin for management of the third stage of labor. The feasibility of conducting such a trial under routine clinical practice conditions at public maternity hospitals in Uruguay was also evaluated.

2. Materials and methods

The present study was an individually randomized superiority trial conducted in 2 public maternity hospitals in Montevideo, Uruguay: Hospital de Clínicas (1200 deliveries annually), from December 30, 2006 to September 18, 2007; and Hospital Pereira Rossell (9000 deliveries annually), from June 29, 2007 to October 26, 2007. The trial was approved by Institutional Review Boards in the USA and Uruguay.

Women aged 18 years or older with single term pregnancies who were admitted during early labor (cervical dilatation ≤6 cm), with no indication of cesarean delivery and no contraindication to prophylactic oxytocin, were invited to participate. Exclusion criteria were severe acute complications (e.g. eclampsia and hemorrhage) that were present during labor and that required emergency actions. Women who agreed to participate provided written informed consent and were randomized into one of 2 intervention groups when vaginal delivery was imminent (Figure 1). The randomization was stratified by hospital and the sequence was generated at the co-ordinating center using a computer-generated list of numbers with randomly permuted blocks of 4–6 in a 1:1 ratio. Women were allocated using sequentially numbered

opaque sealed envelopes. When delivery was imminent and the obstetrician was prepared to attend, a midwife registered the patient on the next-numbered envelope, opened the envelope, and communicated the assigned intervention to the birth attendant.

Obstetricians were instructed to manage the third stage of labor in the following way for the CCT group: (1) clamp the cord once pulsation stops or after 3 minutes in a healthy neonate; (2) stabilize the uterus by applying counterpressure during CCT; (3) during a uterine contraction, encourage the mother to push, and very gently pull downward on the cord to deliver the placenta, applying counterpressure to the uterus; (4) if the placenta does not descend during 30–40 seconds of CCT, do not continue to pull on the cord; with the next contraction, repeat CCT with counterpressure; and (5) never apply cord traction without applying countertraction on a well-contracted uterus. This technique closely followed the WHO 2007, and the International Confederation of Midwives and International Federation of Gynecology and Obstetrics 2003 recommendations [2,3].

The instructions for the hands-off group were as follows: (1) clamp the cord closed once pulsation stops or after 3 minutes in a healthy neonate; (2) do not apply CCT or fundal pressure; the placenta should be delivered physiologically and signs of placental separation should be awaited (gush of blood from the vagina, descent of the umbilical cord, and increase in height of the uterus in the abdomen as the lower segment distends); and (3) after separation, delivery of the placenta should be aided only by maternal expulsive efforts and/or gravity.

Women in both groups received 10 IU of prophylactic oxytocin intramuscularly or intravenously (slow bolus) during delivery of the anterior shoulder or within 1 minute of delivery, followed by uterine massage every 15 minutes until they were discharged from the delivery ward. If the placenta had not been delivered after 30 minutes, the intervention was terminated and hospital standard procedures for managing a retained placenta were considered. The interventions were carried out by MD residents in obstetrics who had been trained in all intervention procedures during a 3-hour competency-based workshop using anatomic models.

Because the study was designed as a feasibility and proof-of-concept trial, the primary outcome was blood loss during the third stage of labor. Secondary outcomes were rates of PPH ≥500 mL and ≥1000 mL, length of the third stage of labor, and use of additional oxytocin. The need for manual removal of the placenta, uterine curettage, or other therapeutic maneuvers was also assessed. Lost blood was collected in a plastic bag (drape) designed for this purpose [13]. The drape was placed under the mother's buttocks immediately after delivery and blood was collected for 20 minutes. If the woman was not bleeding, the drape was removed; for women with persistent bleeding, collection continued until the bleeding stopped or the women were transferred to another ward. Blood loss was measured by an independent midwife weighing the drape on an electronic scale (LEQ-5/10, Tor Rey, Monterrey, Mexico). Clinical outcome data were collected from the women's records by trained in-hospital data collectors using specially designed forms, which were completed before discharge. Data entry and validation occurred at the data center and data quality was periodically checked against the hospital records.

Based on previous studies, we assumed that women receiving prophylactic oxytocin would have a mean blood loss of 200 mL (standard deviation 60 mL) [13]. We estimated that 200 participants would be required to detect a 25-mL difference with 80% power and an α level of 0.05, accounting for a 10% loss to follow-up.

Analyses were conducted on an intention-to-treat basis. Blood loss weight in grams was converted to milliliters by dividing the figure in grams by 1.06 (blood density in grams per milliliter) [14]. Blood loss distribution was positively skewed (Figure 2); therefore, the median and its 95% confidence interval (CI) were used as summary measures of blood loss. To measure

the treatment effect, we calculated the difference in the median blood loss values between the CCT group and the hands-off group. The difference was tested with an exact Wilcoxon rank test and the 95% CI was estimated [15]. Additionally, we log transformed the blood loss values, calculated their means, and tested their difference with the *t* test. The difference-between-medians approach was used to measure the length of the third stage of labor. For dichotomous variables, we used relative risks and 95% CIs to measure treatment effects.

The trial Data and Safety Monitoring Committee met after the first 100 women were recruited and, after an interim analysis, advised that the study should continue without change. The Committee also verified the main outcome analysis at the end of the trial. The trial was registered at clinicaltrials.gov (NCT00781066).

3. Results

Of the 240 eligible women in early labor who were invited to participate, 36 were excluded and 204 were randomized; 103 and 101 women were randomly allocated to the CCT group and the hands-off group, respectively. Of the 204 study participants, 134 were recruited at Hospital de Clínicas and 70 were recruited at Hospital Pereira Rossell. During the study period, 274 and 579 vaginal deliveries occurred at these hospitals, respectively. Baseline characteristics and prognostic factors of primary outcomes were similar between the groups (Table 1). In total, 101 women in the CCT group and 98 in the hands-off group were analyzed. The reasons for pre- and post-randomization exclusions are shown in Figure 1.

Management of the third stage of labor in both groups was conducted according to the protocol. All but one of the enrolled women received prophylactic oxytocin, and late umbilical cord clamping was used in 77.0% of deliveries in the CCT group and in 70.4% in the hands-off group. Controlled cord traction was used in 99.0% of deliveries allocated to the CCT group and in 5.2% of those in the hands-off group (Table 2). Compliance with uterine massage was not measured. Lost blood was collected for 20 minutes from at least 95% of the women in both groups. The mean time of collection was 1.2 minutes longer in the hands-off group; this difference was statistically significant ($P = 0.021$) (Table 2).

Median blood loss was 28.2 mL lower in the CCT group than in the hands-off group, although this difference was not statistically significant (Table 3). The difference between the blood loss log means was marginally statistically significant ($P = 0.077$). The incidence of PPH ≥500 mL and PPH ≥1000 mL was 26% and 42% lower, respectively, in the CCT group, although this reduction was not statistically significant (Table 3). The use of additional oxytocin was similar between the groups. Blood loss distribution was asymmetric, positively skewed, and similar between the groups (Figure 2). The third stage of labor was significantly shorter in the CCT group than in the hands-off group (median length 4.0 minutes [range, 3.0–5.0 minutes] and 22.0 minutes [range, 19.0–23.0 minutes], respectively; $P<0.001$). However, it should be noted that the time in the hands-off group included the time taken for placental expulsion or extraction from the vagina rather than the time taken for placental detachment. Incidences of membrane retention, manual extraction of the placenta, or examination under general anesthetic occurred in 3 women and were similar between the groups. No uterine inversions were observed.

4. Discussion

The present study showed that CCT for AMTSL may reduce postpartum blood loss compared with a hands-off protocol. Although the observed beneficial effect on blood loss and PPH can be explained by chance, it seems likely that CCT actually reduces blood loss. The study also showed that a large trial comparing these management alternatives—to resolve the issue with

rigorous methods and adequate precision—is feasible in the maternity hospitals of low-income countries.

The present findings are supported by several strengths of the trial. The allocation concealment via sealed opaque envelopes administered by a third person was successful and the 2 trial arms were similar in terms of baseline factors. Adherence to the assigned intervention protocols was excellent, even under routine conditions at public maternity hospitals and working with birth attendants who had limited experience, such as residents. Blood loss was measured in a standardized way; the use of special drapes enabled the complete collection of lost blood, and a third person weighing the blood on an electronic scale ensured an objective, accurate, and precise measurement. Because the interventions could not be blinded, these procedures were important for ensuring that ascertainment bias was an unlikely explanation of the results.

However, we cannot exclude the possibility that the longer period of blood collection in the hands-off group was caused by the intervention instructions to that group (e.g. not touching the cord or aiding the expulsion of the placenta for at least 20 minutes) rather than the clinical conditions of the mothers. A longer collection period could have contributed to greater blood loss in that group. This potential bias should be prevented in future trials by defining a specific time period in which blood loss should be measured, irrespective of maternal clinical conditions or management. The period should be long enough to cover both detachment and expulsion of the placenta from the vagina in normal deliveries (60 or 120 minutes, if possible). For the present pilot study, 20 minutes was chosen following agreement with the birth attendants that this length of time would be sufficient for detecting a potential CCT effect and would not complicate the routine immediate postpartum care procedures of the hospitals. Under routine conditions in busy maternity hospitals, it was a challenge to keep all women in the labor ward during the immediate postpartum period to measure blood loss. The recruitment rate was significantly lower at the larger hospital; during the study period, approximately 12% of women having vaginal deliveries were included in the trial at Hospital Pereira Rossell, compared with 49% at Hospital de Clínicas. The need for sufficient time and personnel to conduct the trial activities appropriately at each included delivery was identified by the birth attendants as a major determinant of the low recruitment rate at Hospital Pereira Rossell.

No implications for practice can be concluded from the present trial, but several recommendations for research can be made. The findings support conducting a large trial to determine adequately whether CCT reduces blood loss and prevents PPH in women giving birth at maternity hospitals and receiving prophylactic oxytocin for management of the third stage of labor.

Simple, short, competency-based training can educate birth attendants in the intervention protocol and can lead to good adherence to the assigned interventions. This should be complemented with an observer to monitor adherence at each delivery and to be in charge of the randomization procedures and blood loss measurements. Lost blood should be collected accurately and measured precisely and objectively. The use of special drapes for blood collection and of electronic scales to weigh the blood is recommended. Moreover, highly precise electronic scales would make the measurements extremely accurate, enabling small differences in blood loss to be detected. It is likely that, if it exists, the reduction in blood loss produced by CCT is small. Primary measurements of blood loss should be performed at predefined time periods, irrespective of the clinical management or condition of the mother.

Conducting such a trial would probably be easier at middle-sized hospitals in which the organization of delivery and postpartum care could be adapted to comply with the procedures mentioned. Maintaining these standards in busy large hospitals may result in lower recruitment rates.

Most of these issues have been considered in the large trial that the WHO is currently conducting to evaluate the effectiveness of CCT [16].

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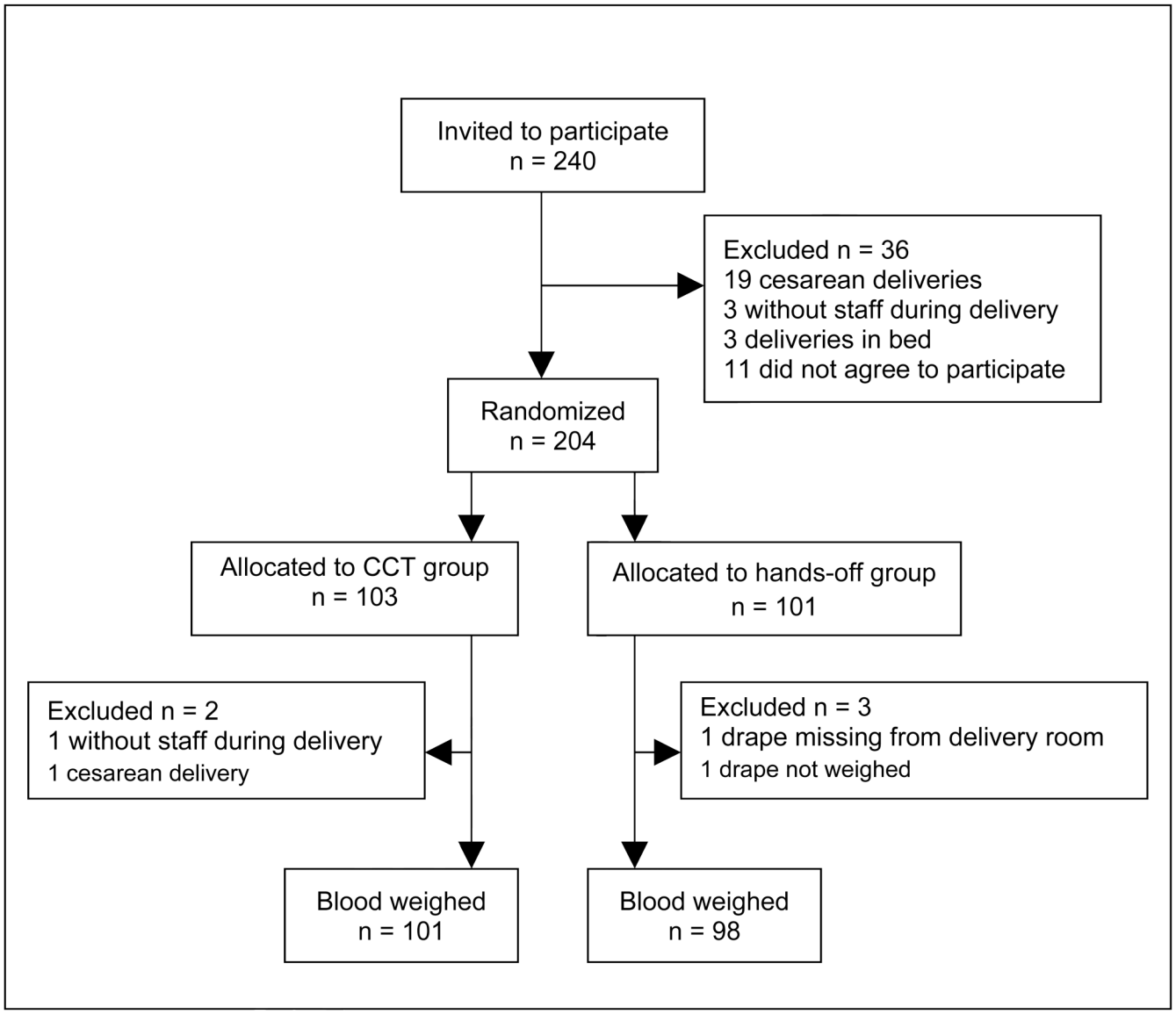

Figure 1.
Flow chart of the study procedures.

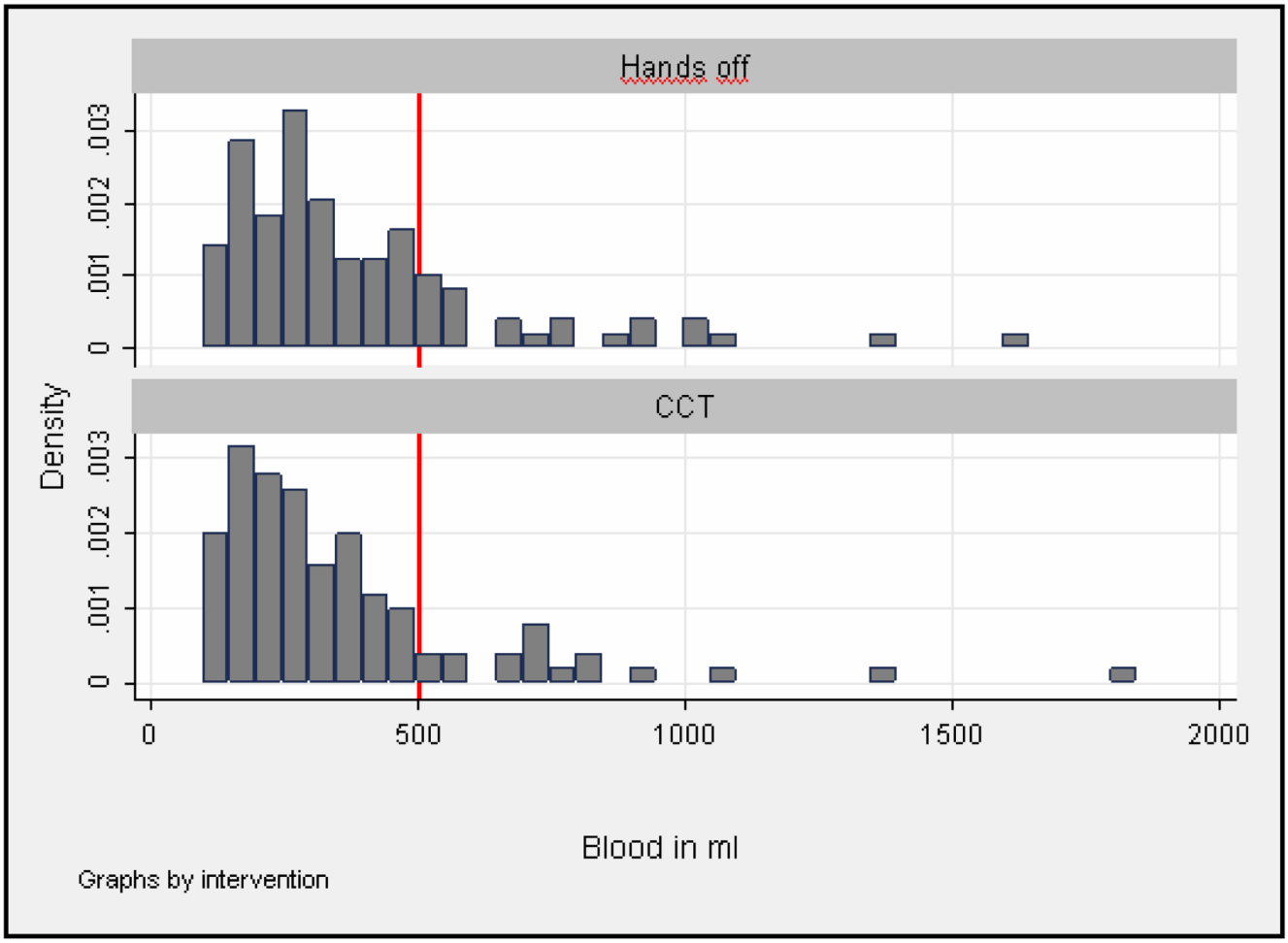

Figure 2.
Histogram of blood loss distribution.

Table 1

Baseline variables [a]

Variable	CCT group (n = 103)	Hands-off group (n = 101)
Nulliparous women [b]	37 (37.0)	36 (36.4)
Gestational age, weeks	39.0 ± 1.5	39.0 ± 1.2
Maternal age, years	25.8 ± 6.1	25.3 ± 6.4
Birth weight, g	3293.7 ± 541.2	3267.5 ± 539.5
Episiotomy or vaginal tears [c]	70 (69.3)	61 (63.5)

Abbreviation: CCT, controlled cord traction.

[a] Values are given as mean ± SD or number (percentage).

[b] Available data: 100 participants in CCT group and 99 in hands-off group.

[c] Available data: 101 participants in CCT group and 96 in hands-off group.

Table 2

Adherence to the assigned intervention and blood loss measurement [a]

All randomized women	CCT group	Hands-off group
Administration of 10 UI of prophylactic oxytocin im or iv immediately after delivery	100/101 (99.0)	98/98 (100.0)
Cord clamping when pulsations finish or 3 minutes maximum after delivery	77/100 (77.0)	69/98 (70.4)
CCT	95/96 (99.0)	5/97 (5.2)
Mean time of blood collection, min	20.8 ± 2.8	22.0 ± 4.1
Blood collection for at least 20 minutes	96/101 (95.0)	93/97 (95.9)

Abbreviations: CCT, controlled cord traction; im, intramuscularly; iv, intravenously.

[a] Values are given as number (percentage) or mean ± SD.

Table 3

Main outcomes [a]

Outcome	CCT group	Hands-off group	RR (95% CI)	
Blood loss, mL	282.0 [191.8; 423.0]	310.2 [228.9; 487.4]	−28.2 (−92.3 to 35.9) [b]	0.126
PPH ≥500 mL	17/101 (16.8)	22/98 (22.5)	0.74 (0.42–1.32)	0.318
PPH ≥1000 mL	3/101 (3.0)	5/98 (5.1)	0.58 (0.14–2.37)	0.444
Additional oxytocin required	13/96 (13.5)	13/94 (13.8)	0.98 (0.48–2.00)	0.954

Abbreviations: CCT, controlled cord traction; RR, relative risk; CI, confidence interval; PPH, postpartum hemorrhage.

[a] Values are given as number (percentage) or median [incidence rate] unless otherwise indicated.

[b] Median CCT group – median hands-off group (95% CI) (exact Wilcoxon rank test).