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Multicenter randomized controlled trial assessing the impact of a cervical traction maneuver (Amr's maneuver) on the incidence of postpartum hemorrhage

Amr Hamdy[1] | Osama Azmy[2] | Rehab Lotfy[3] | Ahmed A. Attia[3] | Moutaz M. Elsherbini[3] | Ahmed Al Sawaf[3] | Mahmoud M. Soliman[3] | Marwa F. Sharaf[3] | Ahmed Kamel[3] | Mohamed N. Abd El-Raouf[2] | Sondos Salem[2] | Mazen A. Rasheed[2] | Haitham Torky[4] | Emad R. Issak[5,*]

[1]Department of Gynecology and Obstetrics, Shoubra Hospital, Cairo, Egypt

[2]Department of Reproductive Health, National Research Centre, Giza, Egypt

[3]Department of Gynecology and Obstetrics, Faculty of Medicine, Cairo University, Cairo, Egypt

[4]Department of Gynecology and Obstetrics, Faculty of Medicine, October 6th University, Giza, Egypt

[5]ClinAmygate, Cairo, Egypt

*Correspondence
Emad R. Issak, Building 47, Becho, Zahraa Al-Maadi, Cairo, Egypt.
Email: dr.emad.r.h.issak@gmail.com

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Abstract

Objective: To assess the impact of a cervical traction maneuver (Amr's maneuver) used in conjunction with active management of the third stage of labor (AMTSL) on the incidence of postpartum hemorrhage (PPH).

Method: The present multicenter randomized controlled trial was conducted in Cairo between March 1, 2016, and June 30, 2017. Women aged at least 18 years who had singleton pregnancies and were candidates for vaginal delivery were enrolled. After block randomization, AMTSL was performed for all participants. Following placental delivery, Amr's maneuver using cervical traction for 90 seconds was carried out in the study group. The primary outcome, incidence of PPH (>500 mL blood loss) within 6 hours of delivery, was compared between the study and control groups in an intention-to-treat analysis.

Results: There were 852 patients randomized to the study (n=426) and control (n=426) groups. The incidence of PPH was significantly lower in the study group compared with the control group (6 [1.4%] vs 19 [4.5%]; *P*=0.015). Absolute risk reduction of 3.1% (95% CI 0.8–5.6), relative risk reduction of 0.32 (95% CI 0.13–0.78), and number needed to treat of 33 (95% CI 129–18) were observed in the study group.

Conclusion: Amr's maneuver was effective in decreasing the incidence of PPH.

ClinicalTrials.gov Identifier: NCT02660567

KEYWORDS

Amr's maneuver; AMTSL; Cervical traction; Postpartum blood loss; Postpartum hemorrhage; Uterine atony; Vaginal delivery

1 | INTRODUCTION

Globally, between one-quarter to one-third of maternal deaths have been reported to be caused by postpartum hemorrhage (PPH),[1–3] with prevalence rates varying widely, ranging from 7.2% in Oceania to 25.7% in Africa in a systematic review of studies from 1997–2009[2]; however, a global incidence of 2% was reported by WHO in 2012.[1] PPH is also a significant contributor to severe long-term morbidity.[4–6]

Uterine atony is the most significant cause of PPH; however, other important contributing factors include trauma (lacerations or ruptured uterus), retained placenta, and coagulation disorders. Pre-existing anemia can also aggravate the clinical consequences of PPH.[7]

One of the most prominent breakthroughs in the prevention of PPH was active management of the third stage of labor (AMTSL). AMTSL, first described in 1962, gave the three main components as prophylactic uterotonic drug administration, early cord clamping and cutting, and controlled cord traction.[8] In 2003, the International Confederation of Midwives and the International Federation of Gynecology and Obstetrics (FIGO) released their first statement on AMTSL.[9] Thereafter, AMTSL was considered the gold standard intervention for reducing the incidence of PPH.[3,10] In the last two decades, much research has been conducted to improve measures to prevent PPH, which culminated in 2012 with the addition of misoprostol to the armamentarium for its prevention.[1]

Additional interventions may help further reduce the incidence of PPH and its associated maternal mortality. In 2014, Hamdy described a new maneuver (Amr's maneuver) for the prevention of PPH, which applied sustained cervical traction after placental delivery.[11] The aim of the present multicenter randomized controlled trial was to test the hypothesis that using Amr's maneuver in conjunction with AMTSL would decrease the incidence of PPH after vaginal delivery more than that achieved by AMTSL alone, and reduce the amount of blood loss.

2 | MATERIALS AND METHODS

In the present prospective randomized controlled trial women aged at least 18 years with singleton pregnancies who were candidates for vaginal delivery and went on to deliver at the delivery rooms of Cairo University Hospital, Shoubra Hospital, Cairo (a general district hospital), or the National Research Centre, Giza, Egypt, during the period between March 1, 2016, and June 30, 2017. Patients who experienced prepartum hemorrhage in the index pregnancy, preterm delivery, prepartum hemoglobin level less than 8 g/dL, who had a history of hemorrhagic conditions, or who presented late in labor (with fully dilated cervix and going to deliver within minutes) were excluded. The Biomedical Research Ethics Committee of the National Research Center approved the study (registration number 15:127). The purpose of the study was explained clearly to potential participants in simple and lay Arabic and written informed consent was obtained from all participant.

Computer-generated randomization schedules were produced and placed in sequentially numbered, sealed, opaque envelopes. Block randomization with a block size of four was used with a 1:1 ratio for the study and control groups. Neither the recruiter nor the participants were aware of the group allocations. Envelopes were opened to reveal group allocations after delivery of the placenta. AMTSL was performed for all participants. After placental delivery, Amr's maneuver was conducted only among women in the study group.

In the maneuver, sustained traction downward and posteriorly was applied to the anterior and posterior lips of the cervix using ovum forceps (Muzaffar Enterprises, Sialkot, Pakistan) for approximately 90 seconds. The traction should be adequate to allow the cervix to reach approximately the level of the vaginal introitus (Fig. 1).

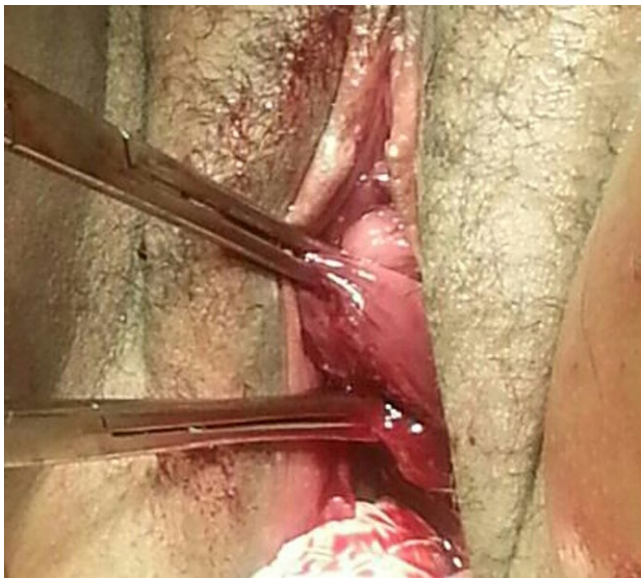

FIGURE 1 Sustained cervical traction (Amr's maneuver).

The primary outcome measure was the incidence of PPH (>500 mL blood loss) within the first 6 hours of delivery in both groups. Secondary outcome measures were amount of blood loss, need for blood transfusion, and changes in hematocrit and hemoglobin levels in both groups. Women's discomfort caused by the maneuver and evaluation of how difficult it was to learn and perform, as well as its cost, were also considered.

For each patient, amount of blood loss was first estimated using the standardized visual estimation method and then corrected using the calculated volume of blood loss. The calculated blood loss (CBL) was obtained using a modification of the Gross formula,[12] given below:

$$\text{CBL} = \text{EBV} \times \frac{\text{Preoperative hematocrit} - \text{postoperative hematocrit}}{\text{average of the preoperative and postoperative hematocrits}}$$

where EBV is estimated blood volume (mL), calculated as weight in kg ×85.

A detailed history was taken from all participants (obstetric, medical, and surgical), and general examination to exclude the presence of any disorders. Obstetric examinations were performed according to each center's protocol. Hemoglobin and hematocrit levels were taken before delivery and 6 hours after delivery in the study participants.

All women were followed-up postoperatively for 6 hours then discharged. They were informed to call the investigators should any adverse event related to labor emerge during the next 18 hours. Any discomfort caused by the intervention was assessed using a five-point Likert scale,[13] where 1 indicated extremely severe discomfort to the extent that the patient could not tolerate the procedure, and 5 meant no discomfort. At the end of the study, a questionnaire was completed by the obstetricians conducting the maneuver concerning any difficulty encountered in learning and performing it, as well as the costs involved.

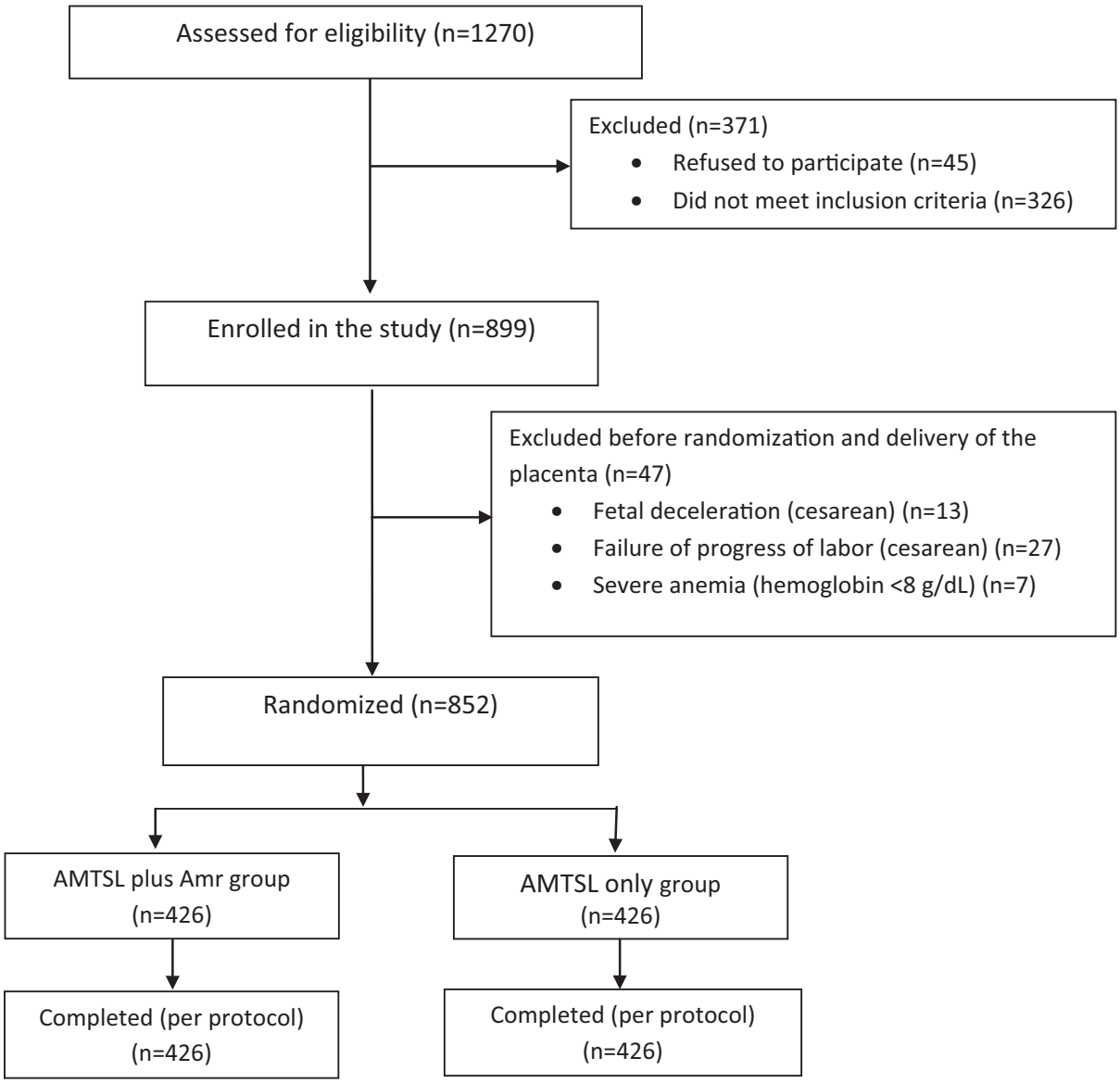

FIGURE 2 Flow diagram of study participants.

With reference to Begley et al.,[10] the rate of PPH with AMTSL is 5%. We expected that the rate of PPH would be 1.5% with the addition of Amr's maneuver to AMTSL. Therefore, with a significance level of α=0.05 and equal sample size from two proportions, the rates of PPH in both arms were considered sufficiently different to warrant rejecting the hypothesis of no difference. The required sample size to achieve 80% power (β=0.2) was determined to be 402 women in each arm. Therefore, the sample size needed was 804, rounded to 850 participants to allow for loss to follow-up or exclusions.

All statistical analyses were performed using the intention-to-treat analysis method. Statistical tests used a significance level of 95%. SPSS software version 20.0 (IBM, Armonk, NY) was used for statistical analysis. Data were expressed as mean ± SD or median (range) for continuous variables and as frequency and percentage for categorical variables. The χ^2 test was used for comparison between groups for categorical variables and the independent *t* test or Mann-Whitney test was used for continuous variables. For the analysis of the primary outcome variable, we calculated relative risk (RR) with 95% confidence interval, absolute risk reduction, relative risk reduction, and the number needed to treat.

3 | RESULTS

A total of 1270 singleton pregnant women at term were assessed for eligibility to participate in the study. Forty-five women refused to participate, and 326 did not meet the eligibility criteria, leaving 899 eligible patients. Before delivery of the placenta, 47 women were excluded (as described in Fig. 2) leaving a total of 852 women who were then randomized into the study group (426) and the control group (426). No women were excluded from the study after randomization (Fig. 2).

TABLE 1 Characteristics of the participants.[a]

Characteristic	Study group (n=426)	Control group (n=426)	*P* value
Age, y	26.38 ± 4.31	26.56 ± 3.83	0.186
BMI	28.6 ± 3.42	28.57 ± 3.12	0.987
Parity			0.339
Primiparous	65 (15.3)	74 (17.4)	
Multiparous	361 (84.7)	352 (82.6)	
Induction of labor	106 (24.9)	128 (30.0)	0.462
Episiotomy	123 (28.9)	128 (30.0)	0.674

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters).
[a]Values are given as mean ± SD or number percentage, unless indicated otherwise.

Baseline characteristics in both groups were comparable. There was no significant difference between the two groups concerning maternal age (*P*=0.186), body mass index (BMI) (*P*=0.987), parity (*P*=0.339), and baseline hemoglobin level (*P*=0.129) (Table 1). Episiotomy was performed in 123 (28.9%) women from the study group and 128 (30.0%) from the control group (*P*=0.674). Induction of labor was initiated in 106 (24.9%) women from the study group and 128 (30%) from the control group (*P*=0.462).

A total of 25 women had postpartum blood loss of more than 500 mL. The incidence of PPH was significantly lower in the study group (*P*=0.015), where 6 (1.4%) women had PPH compared with 19 (4.5%) women in control group (Table 2). The different causes of PPH encountered are shown in Table 2. None of the patients with PPH needed a blood transfusion. Retained placenta was encountered in 6 (1.4%) women from the study group and 5 (1.2%) from the control group (*P*=0.993). All patients with PPH were managed using the standard protocol for PPH in each center. During the 18 hours after discharge, none of the patients called to report any adverse events such as excessive vaginal bleeding, pain, urinary symptoms, or syncope.

TABLE 2 Incidence of postpartum hemorrhage.[a]

Variable	Study group (n=426)	Control group (n=426)	*P* value
PPH	6 (1.4)	19 (4.5)	0.015
Cause of PPH			
Atonic	2 (0.5)	11 (2.6)	
Traumatic	3 (0.7)	6 (1.4)	
Mixed	1 (0.2)	2 (0.5)	
Emergent complications			
Blood transfusion	0	0	
Retained placenta	6 (1.4)	5 (1.2)	0.993

Abbreviation: PPH, postpartum hemorrhage.
[a]Values are given as number (percentage) unless indicated otherwise.

The absolute risk reduction was 3.1% (95% CI, 0.8–5.6), with relative risk reduction of 0.32 (95% CI, 0.13–0.78) and number needed to treat of 33 (95% CI, 129–18).

Median calculated blood loss was significantly lower in the study group compared with the control group (148 vs 323 mL; *P*<0.001) (Table 3). Prepartum hemoglobin and hematocrit levels were comparable between the groups (*P*>0.05). However, median postpartum hemoglobin level was significantly higher in the study group compared with the control group (10.6 vs 10.2 g/dL; *P*=0.015), and the median reduction in hemoglobin level was significantly lower in the study group compared with the control group (0.018 vs 0.05; *P*<0.001). Moreover, median postpartum hematocrit level was significantly higher in the study group compared with the control group (31.65 vs 29.4; *P*=0.027). This was reflected in the median reduction in hematocrit level, which was significantly lower in the study group compared with the control group (0 vs 0.37; *P*<0.001) (Table 3).

Discomfort caused by the maneuver was assessed using a five-point Likert scale. Mean discomfort score for the study group was 3.09 ± 0.22, whereas it was 3.22 ± 0.34 for the control group (*P*=0.084). All the patients tolerated the procedure.

Nine (90%) of the 10 participating obstetricians reported that the procedure had no extra cost and 1 (10%) stated that it cost less than US$ 5.67. The maneuver was easy to learn (all reported just watching it once and were then able to repeat it) and none needed hands-on training. Moreover, all of the participating obstetricians found it easy to perform.

4 | DISCUSSION

This multicenter randomized controlled trial was conducted to test the hypothesis that the addition of Amr's maneuver to AMTSL would reduce the incidence of PPH as well as decrease the amount of blood loss compared with using AMTSL alone at vaginal delivery. Additional measures were to assess the tolerability of the maneuver and evaluate ease of use and cost involved in this nonpharmacologic procedure.

Adding Arm's maneuver to AMTSL reduced the incidence of PPH. This resulted in significantly improved hematological parameters, with less blood loss and better postpartum hematocrit level in the study group compared with the control group. Furthermore, the reduction in hemoglobin level was lower in the study group than in the control group after delivery. The maneuver was also found to be tolerable as shown by the measurement of patient discomfort.

Three studies have reported on the use of Amr's maneuver: a case-series study by the maneuver's creator,[11] a nonrandomized comparative study with a sample size of 200 women,[14] and a randomized controlled study that recruited 500 women.[15] Both comparative studies used the blood collecting drape method to estimate blood loss. The results of these two studies showed a significant reduction in the amount of blood loss without a significant reduction in the incidence of PPH.[14,15]

The results of the present study are substantiated by the results of the two comparative studies. However, the incidence of PPH in the

TABLE 3 Changes in hematological parameters.

Variable	Study group (n=426)		Control group (n=426)		*P* value
	Mean ± SD	Median (range)	Mean ± SD	Median (range)	
Prepartum hemoglobin, g/dL	10.8 ± 0.69	11 (3)	10.99 ± 0.72	11 (3)	0.129
Postpartum hemoglobin, g/dL	10.63 ± 0.67	10.6 (2.1)	10.6 ± 0.58	10.2 (3.7)	0.015
Reduction in hemoglobin level	0.015 ± 0.032	0.018 (0.15)	0.034 ± 0.030	0.05 (0.43)	<0.001
Prepartum hematocrit, %	32.24 ± 1.74	31.8 (12.3)	32.45 ± 1.42	31.7 (6)	0.447
Postpartum hematocrit, %	31.72 ± 1.69	31.65 (13.6)	30.13 ± 3.39	29.4 (14.2)	0.027
Reduction in hematocrit level	0.85 ± 0.03	0 (1.05)	1.33 ± 0.09	0.37 (4.07)	<0.001
Calculated blood loss, mL	153.35 ± 88.37	148 (710)	331.79 ± 112.51	323 (733)	<0.001

present study was significantly lower in the study group than in the control group. Severe PPH was not encountered in either of the two comparative studies or the present study.

The present study used calculated blood loss as it is more suitable and practical than the drape or gravimetric methods.

The exact mechanism by which the maneuver reduces blood loss is outside the scope of this study. However, the Ferguson reflex may explain it.[15] Another suggestion is that the kinked uterine arteries result in reduced blood flow, and are more suitable for the process of thrombin formation and clotting.[16,17] In the present study, it was observed that traction of the cervix led to reflex uterine contraction.

The maneuver is applicable in both low- and high-resource settings as it can reduce the use of medications, blood transfusion, and invasive exploration. The current study is reasonably robust to prove the efficacy of the maneuver. Therefore, we believe that its use would help reduce the impact of PPH.

Although the study did not employ long-term follow-up for possible adverse events, we do not believe that the maneuver would lead to maternal pelvic organ prolapse. The traction exerted during the maneuver is no different from that done while suturing a cervical tear; moreover, it may be of shorter duration. Furthermore, organ prolapse caused by traction of the cervix while suturing a cervical tear has not been reported.

Studying the hemodynamic effects of the maneuver on the uterine artery as well as its impact on oxytocin is recommended.

In conclusion, Amr's maneuver when added to AMTSL for vaginal delivery effectively decreased the incidence of PPH and postpartum blood loss. It was tolerable, easy to learn, easy to perform, and had no adverse effects.

AUTHOR CONTRIBUTIONS

AH, OA, SS, and MAR contributed to designing the study and revising the manuscript. RL contributed to designing the study, patient recruitment, data collection, and writing the manuscript. AAA, MME, AAS, MS, MFS, AK, MNAE-R, and HT contributed to patient recruitment, data collection, and revising the manuscript. ERI contributed to designing the study, data analysis, and writing and revising the manuscript.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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