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Original Article

Sublingual misoprostol versus intravenous oxytocin in reducing bleeding during and after cesarean delivery: A randomized clinical trial

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ABSTRACT

Objective: This study compares the efficacy of sublingual misoprostol versus intravenous oxytocin in reducing bleeding during and after cesarean delivery.

Materials and methods: A randomized clinical trial conducted on 120 pregnant women at term (37–40 weeks) gestation scheduled for elective cesarean delivery, who were assigned to either sublingual misoprostol 400 μg or intravenous infusion of 20 units of oxytocin after delivery of the neonate. The main outcome measures were blood loss at and 2 hours after cesarean delivery, change in hematocrit value, need for any additional oxytocic drugs, and drug-related side effects.

Results: The overall mean blood loss was significantly lower in the misoprostol group compared to the oxytocin group (490.75 ± 159.90 mL vs. 601.08 ± 299.49 mL; $p = 0.025$). However, changes in hematocrit level (pre- and postpartum) was comparable between both groups. There was a need for additional oxytocic therapy in 16.7% and 23.3% after use of misoprostol and oxytocin, respectively ($p = 0.361$). Incidence of side effects such as shivering and metallic taste were significantly higher in the misoprostol group compared to the oxytocin group ($p < 0.001$).

Conclusions: Sublingual misoprostol is more effective than intravenous infusion of oxytocin in reducing blood loss during and after cesarean delivery. However, occurrence of temporary side effects such as shivering and metallic taste was more frequent with the use of misoprostol.

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Introduction

According to the World Health Organization, postpartum hemorrhage (PPH) continues to be the most significant cause of maternal morbidity and mortality worldwide [1]. Average blood loss during delivery is progressively more with the type of delivery, vaginal delivery (500 mL of blood), cesarean delivery (1000 mL), and emergency hysterectomy (3500 mL) [2].

A reduction of blood loss during cesarean delivery has a great benefit to decrease postoperative morbidity and decrease the risks associated with blood transfusions [3]. The routine use of oxytocin is associated with a significant reduction in the occurrence of PPH [4].

Although many hospitals use oxytocin as the first line to prevent uterine inertia during cesarean delivery, it may not be the ideal agent for prevention of PPH especially in compromised patients with preeclampsia, cardiac disease or prolonged labor [5]. Oxytocin increases the heart rate and has negative inotropic, antiplatelet, and antidiuretic effects [6].

Excessive blood loss is estimated by a 10% drop in the hematocrit value postdelivery or by need for blood transfusion. This occurs in approximately 4% of vaginal deliveries and 6% of cesarean deliveries [7].

Misoprostol, a PGE1 analogue, has been shown in many studies to be an effective myometrial stimulant of the pregnant uterus and selectively binds to EP-2/EP-3 prostanoid receptors [8]. Misoprostol administration, either by oral or rectal route, has been shown to be effective in preventing PPH or is considered as an effective

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alternative to other conventional oxytocic drugs especially in developing countries as it is cheap and thermostable [9]. Pharmacokinetic studies suggest that the bioavailability of misoprostol after sublingual administration is higher than after oral or vaginal administration [10].

Many management protocols for prevention of PPH have been reported and continuously improved to reduce anxiety to the patients [11]. Misoprostol, a PGE1 analogue, has been used both for prevention and management of PPH due to its strong effect on the uterus; however, there is no consensus on optimal dose or route of administration [12]. In the majority of these studies, misoprostol has been administered either orally or rectally in dosages ranging from 400 μg to 1000 μg [13].

A few studies are now available for the use of sublingual misoprostol in the prevention of blood loss following vaginal delivery and have reported its effectiveness and convenient route of administration [14].

The current study compares the efficacy of sublingual misoprostol to intravenous oxytocin in the prevention of blood loss following cesarean delivery. As recommended by Cochrane reviews, there is an urgent need for well-designed randomized trials to assess the risks and benefits of misoprostol [15].

Material and methods

The current study is a clinically registered open, parallel, randomized clinical trial (NCT02562300) comparing the effect of sublingual misoprostol to intravenous oxytocin in the prevention of blood loss following cesarean delivery. The ethical review board of the Faculty of Medicine of the Assiut University approved the study. The participants were recruited from the Outpatient Obstetrics Clinic of the Assiut Women's Health Hospital. It was carried out in the period between January 1, 2015 and April 1, 2015. This trial was designed and reported according to the revised recommendations of ClinicalTrials.gov for improving the quality of reporting randomized clinical trials.

Eligible participants

There were 120 pregnant women at term (37–40 weeks) gestation scheduled for elective low segment cesarean delivery under spinal anesthesia enrolled in this study (Figure 1).

Women with anemia (hemoglobin < 8 g), multiple gestation, placental abnormality (e.g. placenta previa, placenta abruption), polyhydramnious, two or more previous cesarean deliveries, current or previous history of heart disease, liver, renal disorders or known coagulopathy were excluded from the study.

Randomization

Randomization was done using a computer-generated random table. Eligible patients who consented were randomly assigned to receive either sublingual misoprostol or intravenous oxytocin after delivery of the fetus. Allocation concealment was done using serially numbered closed opaque envelopes. Each envelope was labeled with a serial number and had a card noting the intervention type inside. Allocation was never changed after opening the envelopes.

Intervention

Eligible participants were allocated to one of two groups. The sublingual misoprostol group received 400 μg of sublingual misoprostol, immediately after delivery of the neonate. The oxytocin group received 20 IU oxytocin dissolved in 1 L of lactated Ringer's or saline solution and infused at the rate of 125 mL/h, immediately after delivery of the neonate. Additional oxytocic therapy was given if the uterine tone was inadequate. The volume of blood loss during cesarean delivery and 2 hours postoperatively was assessed. Total blood loss during cesarean delivery was measured by adding the volume of the suction bottle with the blood soaked sponges (know dry weight). Blood loss 2 hours after cesarean delivery was measured by using blood collection drape. The whole blood loss was estimated by adding the blood in the suction bottle, blood soaked sponges and blood collection drape.

Hematocrit values were determined before surgery and 24 hours following surgery. Vital signs were observed continuously intraoperative and every 30 minutes after that.

Study outcomes

The primary outcome of this study was estimation of blood loss during and after cesarean delivery following administration of sublingual misoprostol or intravenous oxytocin.

The secondary outcome measures included the need for any additional oxytocic drugs, changes in hematocrit value after delivery, and incidence of side effects.

Sample size

Sample size was calculated based on the primary outcome (blood loss in women after cesarean delivery), taking mean blood loss with the use of oxytocin as 974 mL with a standard deviation of 285 mL [16]. Assuming that sublingual misoprostol is more effective than oxytocin in reducing blood loss by 155 mL, 60 participants in each group will have > 80% power at 5% significance to detect such a difference (Epi-info: Centers for Disease Control and Prevention, Atlanta, GA, USA).

Statistical analysis

The data were collected and entered into a Microsoft Access database and analyzed using SPSS version 21 (SPSS Inc., Chicago, IL, USA). The demographic and baseline data were compared between the groups. The outcome variables were calculated using a paired t test to compare continuous variables before and after treatment and using an unpaired t test between groups. For dichotomous variables, Chi-square was used to estimate the significance value. For analysis, $p < 0.05$ was considered significant.

Results

This study included 120 women. All recruited women had an elective cesarean delivery. None of the patients required conversion to general anesthesia during the surgery. The demographic data of the two groups are shown in Table 1. There were no significant statistical differences between both groups with regard to the demographic data.

The misoprostol group reported a larger reduction in intraoperative blood loss compared with the oxytocin group (160.75 ± 85 mL, 376.08 ± 75 mL, $p = 0.025$). Although the misoprostol group also reported a higher reduction in blood loss postoperatively in comparison with the oxytocin group, this difference did not reach statistical significance ($p = 0.067$).

Finally, the overall estimated mean blood loss was significantly lower in the misoprostol group (490.75 ± 159.90 mL) compared to the oxytocin group (601.08 ± 299.49 mL, $p = 0.025$; Table 2).

There was no statistical significant difference between both groups as regard to pre- and postpartum hematocrit values ($p = 0.453$ and 0.432, respectively). The mean reduction of hematocrit was 3.61% in the misoprostol group and 3.63% in oxytocin

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