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CLINICAL ARTICLE

Oral misoprostol reduces vaginal bleeding following surgical evacuation for first trimester spontaneous abortion

Mahmoud Shokry, Ahmed Y. Shahin *, Mohammed M. Fathalla, Omar M. Shaaban

Department of Obstetrics and Gynecology, Women's Health Centre, Assiut University, Assiut, Egypt

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ABSTRACT

Objective: To assess the effectiveness and tolerability of misoprostol to reduce the amount and duration of vaginal bleeding following surgical evacuation for first trimester spontaneous abortion. *Methods:* A total of 160 patients who underwent surgical evacuation for first trimester spontaneous abortion between 8 and 12 weeks of pregnancy were randomized into 2 groups to receive either 200 μg of oral misoprostol immediately after evacuation followed every 6 hours for 48 hours or no misoprostol. Pain scores, duration and amount of bleeding, and endometrial thickness were assessed over 10 days. *Results:* Women who received misoprostol had significantly fewer bleeding days after evacuation (4.11 ± 2.69 vs 5.89 ± 3.06; $P<0.001$), fewer patients reported vaginal bleeding lasting 10 days or more (3.8% vs 15.0%; $P=0.014$), and endometrial thickness 10 days after evacuation was less (6.25 ± 2.38 vs 7.23 ± 1.94; $P=0.05$). Pain scores were comparable in both groups (1.54 ± 0.65 vs 1.63 ± 0.83; $P=0.40$) after 10 days. *Conclusion:* Oral misoprostol is effective in reducing the prevalence and amount of vaginal bleeding after surgical evacuation for first trimester spontaneous abortion.

1. Introduction

Fifteen percent of clinically apparent pregnancies do not develop past the first trimester. The lifetime risk of a woman experiencing at least one early pregnancy failure is estimated to be 25% [1–3].

The most common cause of persistent vaginal bleeding after surgical evacuation is incomplete abortion [4]. Clinicians treating such bleeding tend to exclude the possibility of retained products of conception. Once this has been ruled out, blood clots within the cavity or coagulation defects may be the cause of the persistent bleeding. Incomplete abortion rates in busy obstetric settings have been reported to be around 1.5% [4].

Misoprostol is a thermostable prostaglandin E1 analog that has a long shelf life, is easy to administer, and is significantly cheaper than other uterotonics [5]. It has been used successfully to prevent and treat postpartum hemorrhage [6–9] as well as to induce labor [10–12] and abortion [13,14]. The use of misoprostol to reduce vaginal bleeding after surgical evacuation has not been studied.

The aim of the present study was to assess the effectiveness and tolerability of oral misoprostol (200 μg every 6 hours for 48 hours) administered after surgical evacuation for first trimester spontaneous abortion to reduce the amount and duration of vaginal bleeding following the procedure.

2. Materials and methods

A prospective randomized controlled trial was conducted at the Women's Health Centre, Assiut University, Egypt from September, 2007 to February, 2009. The study protocol was approved by the Institutional Council of The Department of Obstetrics and Gynecology. Patients between 8 and 12 weeks of pregnancy who underwent surgical vaginal evacuation for missed abortion, anembryonic pregnancy, and inevitable or incomplete spontaneous abortion were included in the study. Patients who were hemodynamically unstable, had septic abortion, fever, bronchial asthma, or known hypersensitivity to misoprostol were excluded. All patients provided written informed consent before recruitment into the trial.

Eligible women were divided into 2 groups using a computer-generated randomization table. Both groups underwent surgical uterine evacuation and curettage under general anesthesia according to the department's protocol and standard technique.

All patients received 1 g of oral azithromycin (Zithromax; Pfizer, Egypt) at the time of the operation. Women in group 1 received the standard care treatment after evacuation (400 mg of oral ibuprofen to use on demand, iron formulation in the form of 1 capsule per day of Haemoton (GlaxoSmithKline, Egypt) containing 350 mg of ferrous fumarate) plus 200 μg of oral misoprostol (Misotac; Sigma Pharmaceuticals) taken immediately after evacuation and then every 6 hours for 48 hours. Women in group 2 (the control group) received only the standard treatment as described above, without misoprostol.

Abdominal pain was assessed immediately before evacuation, and then at 6 hours, 24 hours, and 10 days after the operation using a

* Corresponding author. Department of Obstetrics and Gynecology, Assiut University, 71116 Assiut, Egypt. Tel.: +20 1000 24322; fax: +49 1212 53 270 6248.
E-mail address: Ahmed.Shahin@web.de (A.Y. Shahin).

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visual analogue scale (VAS) consisting of a 10-cm line with verbal anchors of "no pain" at one end and "excruciating pain" at the other. The person assessing pain score was blinded to whether the participants had been allocated to the study or control group.

All patients were followed-up for the first 24 hours for abdominal pain (score on VAS at 6 and 24 hours after the procedure); pulse rate; blood pressure; temperature; presence of severe vaginal bleeding defined as vaginal bleeding greater than the patient's typical menstrual amount, with or without the presence of blood clots. Severe abdominal pain was treated when necessary with a single dose of 400 mg of oral ibuprofen. Patients whose bleeding was no heavier than usual were discharged home after 24 hours. Patients experiencing heavy bleeding in the first 10 days after the operation were instructed to telephone the investigators and were booked for follow-up. These patients were examined using transvaginal ultrasound. If intrauterine contents other than blood clots were seen, uterine curettage under general anesthesia was performed. If only blood clots and/or thickened endometrium less than 15 mm was noted, oral ergometrine (Methergine; Sandoz Pharmaceuticals, Germany) was prescribed at a dose of 2 tablets per day for 3 successive days.

Patients attended a follow-up visit 10 days after the evacuation procedure where they were asked about the amount and duration of vaginal bleeding (subjective estimate, number of pads or underwear changes every day, and how soaked they were using a pictorial image of the pads and underwear), fever, pelvic pain, or passage of tissue from the vagina. Transvaginal ultrasound was performed using a Sonoline G60S imaging system (Siemens, Germany) to measure the endometrial thickness at the maximum anteroposterior diameter on the long-axis view of the uterus and to check for presence or absence of retained products of conception. Patients reporting persistent bleeding after 10 days and/or showing retained products of conception on ultrasound examination were offered uterine curettage.

The primary outcome measure was the number of days of spotting and/or vaginal bleeding after evacuation. Secondary outcomes included the proportion of patients reporting severe bleeding within and after 10 days, endometrial thickness 10 days after the procedure, and the presence of any adverse effects or major complications.

We used the study by Nguyen et al. [15] who investigated two different misoprostol doses for the management of incomplete abortion. Mean bleeding days after administration of misoprostol in their study was 4.0 ± 2.3 days. The sample size was calculated for a 1.0 day's difference in bleeding, with a standard deviation of 1.5 cm, and the power of the study set at 0.05. This gave a minimum of 47 women in each group.

Statistical analyses were performed using Microsoft Excel version 7 (Microsoft Corporation, NY, USA) and SPSS version 13 (SPSS, Chicago, IL, USA). Analysis was performed according to the intention-to-treat principle and data were described in terms of mean $\pm$ SD. Comparison of the studied groups was done using the t test. The χ^2 test was used to compare categorical variables. $P<0.05$ was considered significant.

3. Results

A total of 216 patients were assessed for eligibility to participate; of those, 18 did not meet the inclusion criteria and 38 refused to participate. The remaining 160 patients were randomized to either the misoprostol group (n = 80) or the control group (n = 80). Four (5%) patients in the misoprostol group and 6 (7.5%) patients in the control group were lost to follow-up, but were included in the analysis. Fig. 1 shows the participant flow through the study.

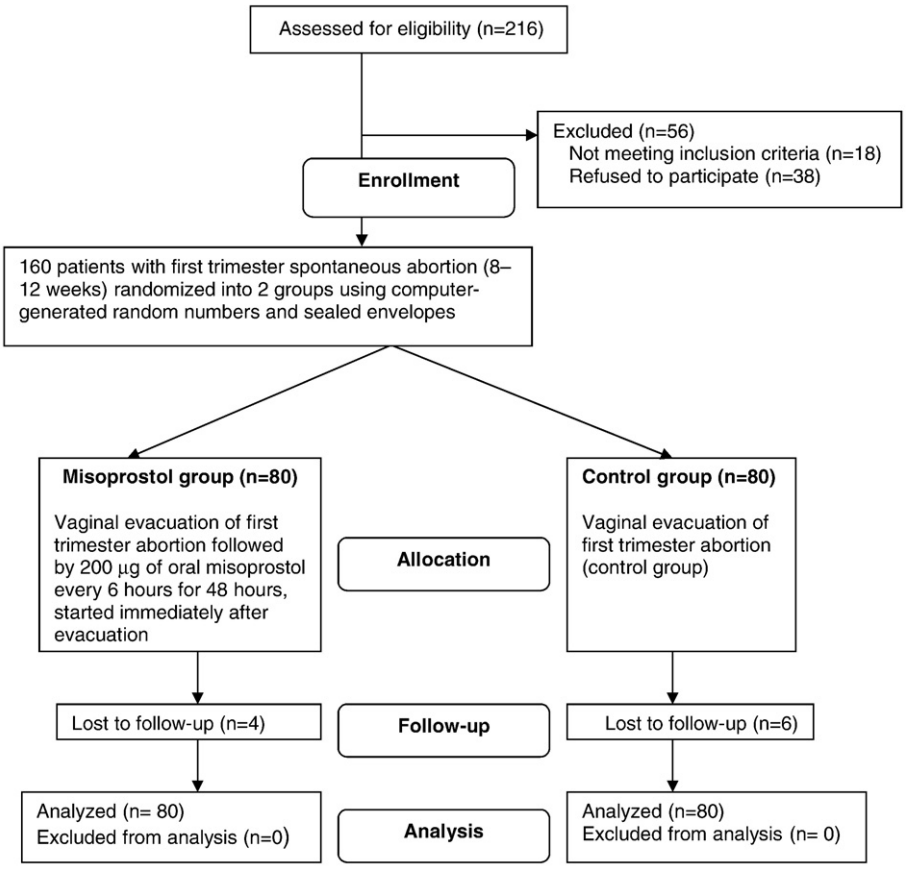

Fig. 1. Participant flow through the study.