

Surgical Evacuation of First Trimester Missed Miscarriage With & Without Use of Transabdominal Ultrasound: A Randomized Clinical Trial

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Abstract

Background: Surgical evacuation is one of the most popular methods of termination of pregnancy in cases of missed miscarriage. The current study aims to compare the improvement of surgical evacuation of first trimester miscarriage when done with and without transabdominal ultrasonographic guide.

Materials and methods: Setting: Women Health Hospital, Assiut University, Egypt.

Design: A randomized clinical trial conducted on 200 pregnant women with 1st trimester miscarriage who scheduled for surgical evacuation. It carried out in the period between the 1st of May 2014 and the 30th of April 2015. The women were randomly assigned to either undergone surgical evacuation blindly (group I) or under ultrasound guidance (group II). The main outcome measures were achievement of complete miscarriage, operative time and blood loss during the procedure.

Results: Two-hundred participants were recruited in the study. The mean amount of blood loss during the procedure was significantly higher in group I when compared with group II ($P = 0.002$). Also there was a statistical significant difference in the operative time between both groups, group I showed longer time than in group II ($P = 0.0001$). After surgical evacuation, 14 cases (14%) in group I and 3 cases (3%) in group II were reported to have remnants of conception. No cases of uterine perforation occurred in both groups.

Conclusion: The use of intraoperative ultrasound during surgical evacuation is associated with a significant reduction in its complications, however; the cost of using ultrasound needs further investigations.

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Introduction

The miscarriage considers the most common cause of fetal demise all over the world^[1]. The majority of cases occur in the first trimester^[2]. The termination of miscarriage may be by medical or surgical methods. However, the surgical methods represents the greater part of termination^[3]. Therefore, the safety of this procedure is a worldwide public health concern^[4]. Many clinical studies have been reported the safety of surgical evacuation in the first trimester^[5].

The suction-aspiration or vacuum aspiration is the most common surgical methods of induced miscarriage. This consists of removing the fetus, embryo, placenta, and membranes by suction using a manual syringe or electric pump. However; these technique always need cervical dilation before aspiration^[6]. The menstrual extraction does not require cervical dilation and can be used in very early pregnancy^[7].

The surgical evacuation is generally considered safe, however; short-term complications are reported due to need of dilatation of the cervix and incomplete evacuation because the surgeon is the only one who can decide the end of the operation depending on his subjective sense^[8].

However; with continuous ultrasound guidance, the process could be almost complete because the ultrasound can accurately identify the direction and size of the uterus, position of the gestational sac, observe the insertion of surgical instruments and the advancement of the operation especially when the configuration of the uterus is distorted^[9].

At present ultrasound is not considered to be an essential pre-requisite for miscarriage in all cases^[10], so our study aims to detect if complete evacuation can be achieved by ultrasonographic assistance or not. We also tried in this study to compare the operative time, amount of blood loss and the occurrence of accidental uterine perforation during the procedure with and without use of ultrasound.

Material and Methods

The current study is a clinically registered single blinded, parallel, RCT (NCT02580175) compassing the effect of ultrasound guidance during surgical evacuation of 1st trimester miscarriage. 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 the 1st of May 2014 and the 30th of April 2015. All study participants signed a written informed consent before enrollment in the study. This trial was designed and reported according to the revised recommendations of ClinicalTrials.gov for improving the quality of reporting RCTs.

Eligible participants

All study participants had a clinical history taken and general physical examination performed in the antenatal clinic. An initial ultrasound examination was performed to confirm presence of non-viable intrauterine pregnancy, to determine the gestational age, and number of gestational sacs and fetuses.

All women with confirmed non-viable first trimester intrauterine pregnancy with no contraindication to surgical evacuation under general anesthesia were included in the study. We had excluded cases with gestational age more than 13 weeks, hemodynamically unstable, or if there is suspicion of an ectopic pregnancy.

Randomization

Randomization was done using a computer-generated random table. Eligible patients who consented were randomly assigned to blind evacuation or sonographic guided evacuation. Allocation concealment was done using serially numbered closed opaque envelopes. Each envelope was labeled with a serial number and had a card showing the intervention type inside. Allocation was never changed after opening the envelopes.

Intervention

Eligible participants were randomly assigned to one of two groups: group I (blinded evacuation); which ring evacuation was performed in the conventional way without use of ultrasound followed by sharp gentle curettage until complete evacuation. Group II (evacuation under ultrasound guidance); which ring evacuation was performed under ultrasound guidance using real-time ultrasound by 3.5 MHz convex transabdominal probe (Mindray-6600, China) followed by sharp gentle curettage until

complete evacuation. The probe was placed longitudinally on the patient's abdomen and the uterus scanned longitudinally from the cervix to the fundus. The surgery was considered complete when the endometrial cavity appeared as a regular echogenic line. The operation was performed as a day case under general anesthesia.

Study outcomes

The primary outcome was to detect if complete evacuation was achieved by ultrasound guidance or not. Secondary outcomes included the operative time, amount of blood loss and the occurrence of accidental uterine perforation during the procedure.

Follow-up schedule

All study participants were followed at the end of the operation. We evaluated the blood loss: by subtracting the dry weight of absorbing materials (pads, sponges, etc) from the weight of blood containing materials (using sensitive balance) and using the conversion 1 gm weight = 1 mL to quantify the blood volume contained in the materials (the weight of the pad used is 50 gram) then added this with the amount of blood loss in graduated container. We also assessed the hemoglobin level for all patients before and after evacuation. In addition to operative time which calculated from introduction of the ring till the end of the procedure. As regard the assessment of the retained parts of conception; transvaginal ultrasound was done for all cases 4hours after evacuation, presence of thick endometrium more than 15 mm is indicative of presence of retained parts of conception^[7].

Sample size calculation

Sample size was calculated using Epi Info software version7. A sample of 200 women attending Women's health Hospital (100 cases in each arm) was needed to detect an effect size of 0.3 between the two group regarding the efficacy of ultrasound guidance during uterine surgical evacuation, with a p value < 0.05 and 95% power.

Data collection and analysis

The data were collected and entered on Microsoft access database to be analyzed using the Statistical Package for Social Science (SPSS Inc., Chicago, version 18). Comparisons between the groups were done using Student's t-test to compare the mean values between groups in scale variables. However, χ^2 test was used to compare the dichotomous and ordinal variables in the groups. For analysis P-Value < 0.05 was considered significant.

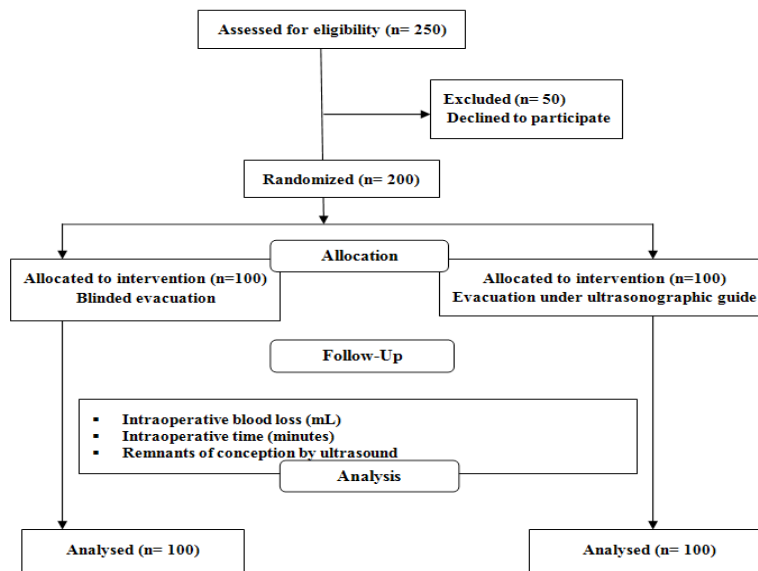
Results

Two-hundred participants with proven first trimester miscarriage were approached to participate in this study (study flow chart, Figure 1). Table 1 shows the demographic characteristics of the study participants. No significant differences were found between the two study groups as regards patients' age, parity, gestational age and number of previous miscarriages or cesarean deliveries.

Table 1: Characteristics of the study participants

	GROUP I (Blind evacuation) n = 100	GROUP II (Ultrasound guided evacuation) n = 100	P-value
Age (years) mean \pm SD	25.70 \pm 4.94	25.21 \pm 5.25	0.498
Parity mean \pm SD	2.5 \pm 0.98	2.3 \pm 0.77	0.26
Gestational age (weeks) mean \pm SD	9.49 \pm 1.67	9.48 \pm 1.55	0.965
Previous miscarriage, n	51	46	0.392
Previous cesarean, n	46	39	0.317

SD standard deviation

**Figure 1:** Flow Chart of the study participants

The mean amount of blood loss during the procedure was significantly higher in group I when compared with group II ($P = 0.002$), but no statistically significant difference between both groups as regard the hemoglobin level before and after evacuation. Also there was a statistical significant difference in the operative time between both groups, group I showed longer time than in group II ($P = 0.0001$) (Table 2).

Table 2: Comparison of the study outcomes between the two groups

Characteristics	GROUP I (blind evacuation) n = 100	GROUP II (Ultrasound guided evacuation) n = 100	P-value
Blood loss (ml) mean \pm SD	58.70 \pm 18.57	51.00 \pm 16.65	0.002*
Preoperative hemoglobin (gm/dl) mean \pm SD	10.23 \pm 1.11	10.30 \pm 0.91	0.593
Postoperative hemoglobin (gm/dl) mean \pm SD	9.42 \pm 1.16	9.49 \pm 0.95	0.623
Operative time (minutes) mean \pm SD	5.23 \pm 1.05	4.08 \pm 1.09	0.0001*
Presence of remnants, n (%)	14 (14)	3 (3)	0.0001*

SD standard deviation

(*) statistical significant difference

After surgical evacuation, the failure rate in the ultrasound guided group was 3 cases (3%) compared to 14 cases (14%) of the group without ultrasound guidance with statistical significant difference ($P = 0.0001$) (Table 2). No cases of uterine perforation occurred in both groups.

Discussion

In the current RCT we had compared the outcome of surgical evacuation in first trimester missed miscarriage with and without ultrasound guidance. Ultrasound guided evacuation had a significant beneficial effect in reducing blood loss, operative time of the procedure with the advantage of complete evacuation.

Our study was in agreed with Say et al who compared seven randomized trials in a Cochrane review and concluded that the rate of incomplete evacuation is more in medical methods compared to vacuum aspiration and the duration of bleeding was more in

medical method than vacuum aspiration^[11].

Another randomized study conducted by Fait et al. who compared the results between the suction evacuation with or without ultrasonographic guidance as we did. However; they reported no significant difference between both groups in the amount of blood loss, operative time which differs from our results. But they reported 7 cases with retained parts of conception without need for re-evacuation^[12].

Acharya conducted another randomized controlled trial comparing the surgical evacuation of missed miscarriage cases with or without ultrasound and we found that the operative time is shorter and blood loss is fewer during the evacuation when ultrasound was used. However; no retained products of conception while were reported when using the ultrasound^[13].

The most recent randomized study was done by Elsayed in 2013. He supported our results and concluded that surgical evacuation under ultrasonographic guidance is beneficial because there are significant cases with missed miscarriage which can be incompletely evacuated without the use of the ultrasound guidance^[14].

We found that the presence of retained products of conception post evacuation was more common in blind evacuation group (14 cases) than ultrasound guidance group (3 cases) with shorter operative time. Although; the blood loss was less with ultrasound guidance, there was no significant difference between both groups as regard the hemoglobin level.

Our explanation to these results may be due to; firstly the ultrasound allows the surgeon to see the uterine cavity and its contents well and to be targeted directly on product of conception which he wants to evacuate. Secondly, the surgeon can decide at which time to end the evacuation therefore less operative time and less the amount of blood loss is associated with ultrasound use. Thirdly, he can see the uterine cavity well so the presence of remnants is rare with relatively low incidence of perforation.

The explanation of that hemoglobin level before and after evacuation as indicator of blood loss between the two groups is not significant may be attributed to that the amount of blood loss between the cases before reaching the emergency unit was different and the amount of blood loss intraoperative is small (measured in ml) in a way that not affect the hemoglobin level significantly.

Conclusion

The study concluded that the use of intraoperative ultrasound during surgical evacuation is associated with a significant reduction in its complications, however; the cost of using real time ultrasound guidance during evacuation needs further research.

Conflict of Interest: We have no conflict of interest to declare.

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