Combined use of intracervical foley catheter and vaginal misoprostol for termination of second trimester pregnancy: a three-year observational study

Mohamed Rezk¹*, Mohamed Abo-Elnasr¹,² and Alaa Al-Halaby¹

¹Department of Obstetrics and Gynecology, Faculty of Medicine, Menoufia University, Menoufia, Egypt ²Department of Obstetrics and Gynecology, Faculty of Medicine, Taibah University, Madina, Saudi Arabia

Abstract

Objectives: To assess the effectiveness, safety and acceptability of intracervical foley catheter and vaginal misoprostol versus vaginal misoprostol for termination of second trimester pregnancy.

Methods: This clinical study was conducted on 200 pregnant patients intended for termination of pregnancy between 13–24 gestational weeks for any indication. Enrolled women were equally allocated into two groups:

Group I (Misoprostol group): a standard regimen of moistened misoprostol tablets (400 μg) 4 hourly inserted vaginally.

Group II (Combined group): intracervical Foley catheter inserted with a standard regimen of moistened misoprostol tablets (400 μg) 4 hourly intravaginally was used.

Procedure efficacy (defined as complete abortion performed on site), safety and acceptability were assessed.

Results: The induction to abortion interval was 8.16 ± 1.52 hours in the combined group compared to 12.76 ± 1.63 hours in the misoprostol group (P value<0.001) with success rate of 96% in the combined group and no major complications reported.

Conclusions: Combined use of intracervical foley catheter and vaginal misoprostol is a novel safe, effective and acceptable method for termination of second trimester pregnancy.

Correspondence to: Mohamed Rezk, MD, Department of Obstetrics and Gynecology, Faculty of Medicine, Menoufia University, Menoufia, Egypt, Tel: 00201006237186, E-mail: m_rezk9207@yahoo.com; Mohamed.abdallah1975@yahoo.com

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the success rate within 24 hours (P=.05, 2-sided). To compensate for possible non-evaluable data, we enrolled over 100 participants in each group.

A total of 209 (1.42%) pregnant women out of 14682 pregnant women attending the outpatient clinic and emergency room at Menoufia University Hospital, admitted for termination of pregnancy between 13-24 weeks of pregnancy for any indication were enrolled and randomly assigned into two study groups using a computerized random number generator in a sequence of sealed, numbered opaque envelopes, with a 1:1 randomization ratio. Nine patients were dropped out (5 discontinued drug intake and 4 requested removal of the catheter). A total of 200 pregnant women completed the study (Figure 1).

Enrolled patients underwent thorough history taking, clinical examination, obstetric ultrasonography to confirm gestational age, congenital malformation, and placental localization. Patients with previous cesarean or any uterine scar, multiple pregnancies, severe anemia, hypertension, diabetes or with coagulopathy were excluded from the study.

Enrolled patients were divided into two groups:

**Group I (Misoprostol group):** a standard regimen of moistened misoprostol tablets (400 μg) 4 hourly intravaginally was used until abortion.

**Group II (Combined group):** intracervical Foley catheter inserted, inflated, and placed on traction. Under aseptic conditions, with the patients lying in the lithotomy position, the cervix was assessed and Foley catheter No. 14-16 Fr Ch was inserted into the endocervical canal, beyond the internal os and the balloon was inflated with 50ml of normal saline. The catheter was strapped to the thigh and kept in place until it was expelled spontaneously. Patients received a standard regimen of moistened misoprostol tablets (400 μg) 4 hourly intravaginally was used until abortion.

The primary outcome of the study was procedure efficacy, defined as complete abortion performed on site within 24 hours with no need for any surgical intervention. Patients in whom effective uterine contractions and cervical dilatation was not obtained within 24 hours with the primary termination method were registered as failures.

Secondary outcomes included safety and acceptability. Safety was assessed by comparing the prevalence of maternal complications. Acceptability included assessment of overall discomfort, likelihood of recommending the abortion method to other women and overall satisfaction rate.

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**Follow up & Analysis**

| 14,682 pregnant women attending the outpatient clinic and emergency room |
|---|
| 225 women were seen over 3 years |
| 6 women declined to participate |
| 10 women were excluded from the study |
| 209 women were recruited |
| Misoprostol group (n=105) | Combined group (n=104) |
| Follow up & Analysis |
| 5 women dropped out (declined to complete the drug). |
| 4 women dropped out (requested removal of the catheter). |
| Misoprostol group (n=100) | Combined group (n=100) |

*Figure 1. Flow diagram of recruitment and retention of participants in the study.*
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The cases were closely monitored for side effects, the onset of contraction, induction to abortion interval. All incomplete abortions were surgically evacuated, the decision to perform surgical evacuation was made on clinical basis, i.e. in cases of heavy bleeding or retained placenta. Routine sonographic evaluation was performed following abortion to confirm the absence of retained products of conception by the obstetrician on duty.

All patients received prophylactic antibiotics, which included a combination of doxycyclin 100 mg and metronidazole 500 mg twice daily for 7 days. Rh antibody was given to all the Rh negative cases at the end of the procedure. All patients were followed up for a period of 4 weeks.

Statistical analysis

Data were collected, tabulated, statistically analyzed by computer using SPSS version 16 (SPSS Inc, Chicago, IL, USA), two types of statistics were done:

1- Descriptive statistics:
Quantitative data are expressed to measure the central tendency of data and diversion around the mean, mean (x) and standard deviation (SD).

2- Analytic statistics:
Chi-square (x2) and t-test were used to compare two groups.
All these tests were used as tests of significance at
- P value > 0.05 was considered statistically non significant.
- P value ≤ 0.05 was considered statistically significant.
- P value ≤ 0.001 was considered statistically highly significant.

Results

Table 1 reveals maternal characteristics of the two groups.

Table 2 shows indications of termination of pregnancy & induction to abortion interval. There was a highly significant difference between the two groups regarding induction to abortion interval (p<0.001) with IAI of 8.16 ± 1.52 hours in the combined group in comparison to 12.76 ± 1.63 hours in the misoprostol group.

Table 3 reveals the maternal complications. There was no significant difference between the two groups regarding the frequency of maternal uterine rupture, cervical lacerations, fever, method failure, nausea & vomiting, blood transfusion and venous thromboembolism.

Table 4 shows maternal acceptability. There was no significant difference between the two groups regarding the overall discomfort.
There was a significant difference between the two groups regarding the likelihood of recommending the abortion method to other women and overall satisfaction rate which was higher in the combined group.

Discussion

Misoprostol is now widely used for second trimester terminations. However, there is still a need to find out the best route and dose with minimum IAI along with minimal side effects and complications [10].

In low resource settings like our country mifepristone is non-affordable and non-available. In order to shorten the induction to abortion interval and to minimize the side effects of repeated doses of misoprostol, we used intracervical foley catheter in combination with vaginal misoprostol.

In this study, the induction to abortion interval was 8.16 ± 1.52 hours in the combined group which is significantly shorter than using misoprostol alone or when combined with mifepristone that take about 10-15 hours [11,12].

The rate of surgical evacuation in the present study was 8% in the misoprostol group which is consistent with the 3–9% rate described in earlier studies [3,6]. The success rate in our study was 96% in the combined group which is comparable to mifepristone-misoprostol combination regimen with lower cost and no additional maternal risks.

A previous single center observational study was conducted in a total of 91 pregnancies. Women who met the termination of pregnancy criteria due to feto-maternal indications between 13 to 26 gestational weeks were included into the study. Study participants received intravaginal misoprostol in combination with Foley catheter (n=46) or intravaginal misoprostol alone (n=45). The authors concluded that combination of intravaginal misoprostol and extraamniotic Foley catheter for second trimester pregnancy termination does not provide additional efficacy with one case experienced uterine rupture in the catheter group [8].
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More recently, we conducted comparative study including 90 pregnant women intended for termination of pregnancy between 13 and 24 gestational weeks for any indication. Enrolled women were equally allocated into three groups the first received vaginal misoprostol (n=30), the second received intracervical Foley catheter alone (n=30) and the third received both (n=30). The induction to abortion interval was 7.5 ± 1.25 h in the combined group, compared to 11.76 ± 1.63 h and the third received intracervical Foley catheter alone (n=30) equally allocated into three groups the first received vaginal misoprostol and 24 gestational weeks for any indication. Enrolled women were pregnant women intended for termination of pregnancy between 13 and 24 gestational weeks for any indication. Enrolled women were equally allocated into three groups the first received vaginal misoprostol (n=30), the second received intracervical Foley catheter alone (n=30) and the third received both (n=30). The induction to abortion interval was 7.5 ± 1.25 h in the combined group, compared to 11.76 ± 1.63 h in the misoprostol group and 19.76 ± 1.52 h in the catheter group (p value<0.001) with a success rate of 100% and no major complications reported [9].

A recent randomized clinical trial to evaluate the efficacy of two routes of administration of misoprostol (sublingual and vaginal) for medical termination of second trimester pregnancies over 48 hours. The success rate was 61.2% (n=41) in the vaginal group versus 70.1% (n=47) in the sublingual group (p=0.3). Twenty-six patients (38.8%) in the vaginal group underwent D&C due to retained tissue, compared with 20 patients (29.8%) in the sublingual group [13].

The use of intracervical Foley catheter may act in addition to its mechanical effect by increasing the release of prostaglandin and/or oxytocin release secondary to localized inflammation [14].

In our study, the frequency of fever was higher in the combined group but still insignificant in comparison to misoprostol group as the use of intracervical Foley catheter is associated with a significant increase in intracervical pathogenic organisms despite undertaking routine aseptic measures as proved in a previous study [15].

Inability to conduct a double blind multi-center study and to include women with previous uterine scar were the main limitation of our study.

From the results obtained in this observational study, the combined use of intracervical Foley catheter and vaginal misoprostol is a novel safe, effective and acceptable method for termination of second trimester pregnancy which is comparable to mifepristone-misoprostol combination regimen with lower cost and no additional maternal risks.

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Disclosure

We certify that no actual or potential conflicts of interest in relation to this article exist.

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Table 3. Maternal complications.

|                      | Misoprostol group (n=100) | Combined group (n=100) | Chi-square test | P-value | Odd’s ratio(CI 95%) |
|----------------------|---------------------------|------------------------|-----------------|---------|--------------------|
| Uterine rupture      | 0                         | 0                      | -               | -       | -                  |
| Cervical lacerations | 4                         | 6                      | 0.421           | > 0.05  | 2 (-5.03; 9.03)    |
| Fever                | 7                         | 13                     | 2.00            | > 0.05  | 6 (-3.2; 15.2)     |
| Method failure       | 8                         | 4                      | 1.418           | > 0.05  | 4 (-3.5; 11.5)     |
| Nausea & vomiting    | 6                         | 8                      | 0.307           | > 0.05  | 2 (-6; 10)         |
| Blood transfusion    | 5                         | 9                      | 1.229           | > 0.05  | 4 (-4.05; 12)      |
| Venous Thromboembolism| 0                        | 0                      | -               | -       | -                  |

CI 95% = Confidence interval 95%.

Table 4. The acceptability of methods of termination of pregnancy.

| Overall discomfort with abortion: | Misoprostol group (n=100) | Combined group (n=100) | Chi square | P-value |
|-----------------------------------|---------------------------|------------------------|------------|---------|
| -Moderate/High/Extreme            | 14                        | 10                     | 0.757      | >0.05   |
| -None or slight                   | 86                        | 90                     |            |         |
| Overall Satisfaction with abortion:|                          |                        |            |         |
| -Very or somewhat satisfied       | 82                        | 94                     | 2.39       | <0.05   |
| -Neutral or somewhat not satisfied| 18                        | 6                      |            |         |
| Would recommend the abortion method to other women: | | | | |
| -Highly or somewhat agree         | 80                        | 92                     | 2.24       | <0.05   |
| -Neutral or somewhat disagree     | 20                        | 8                      |            |         |
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