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Original Article

Comparative Study between Oral Misoprostol Alone versus Weighted Intrauterine Foley's Catheter Plus Oral Misoprostol in Termination of Mid-Trimester Abortion

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ABSTRACT

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Background: Second-trimester termination of pregnancy [13-28 weeks of gestation] remains a medical challenge, as it accounts for 10-15% of all induced abortions. In recent years, medical induction has replaced surgical methods; however, this issue continues to be a matter of debate.

Aim of the work: This study aimed to investigate the value of inserting a weighted, fluid-filled intrauterine Foley catheter on the outcomes of termination of pregnancy induced by oral misoprostol.

Patients and methods: This study included 50 women indicated for second-trimester termination at the Obstetrics and Gynecology Department of Al-Azhar University Hospital. Women were randomized into one of two groups [each consisting of 25 women]. The first group received oral misoprostol [200 micrograms, six times a day]. The second group received the same dose of oral misoprostol as the first group, in addition to the placement of a Foley catheter with fixed weight traction at the distal end. Clinical, radiological, and laboratory evaluations were performed. Cervical dilatation and effacement, hemodynamics, and expulsion of the fetus were assessed every four hours and continued for 12 hours' post-expulsion. Any complications were recorded.

Results: There was no significant difference between the groups regarding demographic or clinical data. Additionally, no significant difference was observed in the need for surgical removal of the placenta [12% vs. 4%], post-expulsion bleeding [12% vs. 4%], or blood transfusion requirements [4% vs. 0%]. However, the time from induction to expulsion of the fetus was significantly reduced in the Foley catheter group [Group II] compared to the misoprostol alone group [19.36 ± 4.72 hours vs. 36.32 ± 13.35 hours, respectively].

Conclusion: The use of a weighted trans-cervical Foley catheter filled with 30-50 mL of saline improves the effectiveness of 200 µg oral misoprostol in terminating mid-trimester pregnancies.

Keywords: Misoprostol; Urinary Catheterization; Induced Abortion; Pregnancy.



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INTRODUCTION

Second-trimester abortion is defined as the termination of pregnancy between 13 and 28 weeks of gestation. It is categorized into early and late termination, the early termination assigned for abortion at 13 to 22, while late abortion was assigned for cases from 23 to 28 weeks of gestation [1-3].

In developing countries, about one third of pregnancies are unwanted. About 20% of them ends by termination. This termination was considered unsafe and responsible for 13% of maternal mortality all over the world. Up to 15% of abortions are reported in the second trimester. This accounts for more than 65% of major maternal abortion-related complications [4-6].

Factors lead to second trimester abortions are diverse and include, but not limited to, maternal factors [e.g., uterine malformations, uterus occupying growths like fibroids, or cervical conditions]. However, not all pregnancies in the presence of these factors end in abortion, some ends by premature birth. The genetic abnormalities are responsible for majority of first trimester abortions, but these abnormalities or chromosomal aberrations are responsible for about one third of second trimester abortions [7-9].

Termination of pregnancy in the second trimester is associated with more risk than during the first trimester. Thus, the termination using drugs seems to be a reasonable alternative to surgical evacuation [10,11].

Many drugs are used to terminate the second master pregnancy. Misoprostol is one of the most widely used drug in different concentrations [200 to 800 µg] at different intervals [3 to 12 hours]. However, the use of higher doses at short intervals is associated with high rate of side effects. In addition, it was used as a sole drug or in combination with drugs [12-14].

Misoprostol is a prostaglandin E1 analog used for cervical ripening. It is widely used for abortion induction in the first and the second trimesters. It has many advantages, being available, cheap and easily storage. In addition, it can be used by different routes [oral, vaginal, sublingual or in combination] [12, 15-17].

On the other side, many studies from lower and higher income countries, have described the use Foley's catheter for ripening of the uterine cervix. It is able to increase the Bishop's score in women with unripe cervix. In addition, its efficacy being comparable to misoprostol for pre-induction ripening of the uterine cervix. It is a safe, inexpensive and has low incidence of complications. Studies comparing catheter to misoprostol are present in previous literature. However, the results are heterogeneous [18-21].

The current work was designed to investigate the value of the insertion of a weighted fluid filled intrauterine Foley's catheter with or without oral misoprostol for termination of the mid-trimester termination of pregnancy. The main question was "Is the use of Foley's catheter further improve the effectiveness of oral misoprostol in termination of pregnancy?"

PATIENTS AND METHODS

This prospective, interventional, comparative study included 50 women with an indication for the second trimester termination of pregnancy. They were selected from the Department of Obstetrics and Gynecology [Al-Azhar University Hospitals, Egypt]. The methods were explained to every woman and each signed an informed consent to participate in the study. Then, woman was randomized for one of the equal [each 25 women] two groups of the study by the closed enveloped method.

The first group for oral misoprostol only [200 micrograms, 6 times a

day; with a total dose of 1200 microgram per day]. **The second group** included women who were assigned to oral misoprostol in a dose similar to the first group, plus Foley's catheter inserted till the passage of the internal cervical os and then the balloon was inflated by 30 -50 ml of saline along with fixed weight traction [500 ml saline bottle] to the distal end of the catheter.

The inclusion and exclusion criteria: The study included women with age range from 20 to 35 and gestational age between 14-26 weeks with pregnancies diagnosed with ultrasound with absent fetal pulsation. On the other side, the exclusion criteria were contraindication to misoprostol [e.g., bronchial asthma, coronary heart disease, renal failure, low placenta, congenital uterine malformations, uterine infections, marked vaginal bleeding and multiple gestations].

Each woman participated in the study was submitted to full clinical evaluation by detailed review of the medical, menstrual and obstetric history, clinical examination [general and local vaginal examination], laboratory investigations [CBC, ESR, CRP, coagulation profile, blood glucose, liver and renal function tests] and radiological investigations [ultrasound]. The obstetric ultrasound was used to confirm pregnancy, determine the expected date, confirm fetal viability, number of fetuses, check for congenital abnormalities, and check fetal movements].

In the second group, the termination was induced by inserting an 18F Foley's catheter inside the uterus of the patient in the lithotomy position, the cervix was visualized using a Cusco's speculum and then was cleaned with povidone Iodine. The anterior lip of the cervix was grasped with a ring forceps and another ring forceps was used to push the catheter through the cervix under direct visualization. The balloon was inflated with [30-50ml] saline and the catheter was pulled against the internal OS. A fixed weighted traction [500 ml normal saline bottle] was applied to the distal end of the catheter to provide moderate traction plus A 200 microgram misoprostol oral dose "one tablet" was swallowed every 4 hours as in group [I].

Re-assessment of the dilatation and effacement of the cervix, hemodynamics, expulsion of fetus, and any complications was performed every 4 hours. After expulsion of the fetus, each woman received 20 IU of intravenous oxytocin. The separation of placenta was expected within 30 minutes after oxytocin administration. If this was not the case, the woman was anesthetized and manual separation of the placenta or surgical evacuation was performed. The observation of side effects or complications was extended for the first 12 hours after termination beside the whole duration of the process.

Ethical Aspects

The study protocol was evaluated and approved the local research and ethics committee of the faculty of Medicine [DFM, Damietta, Egypt]. The confidentiality and privacy of patients were guaranteed. In addition, an informed consent was signed by the woman and her husband. The collected data were used only for the purpose of research.

Methods of Data management

Data were collected and submitted to statistical analysis in a coded format to assure patient privacy. All analyses were performed electronically by the statistical package for social science [SPSS, version 22]. Qualitative data were represented as frequencies and percentages. Chi square test [χ^2] and Fisher exact were used to calculate associations between qualitative variables as indicated. Quantitative data were expressed as arithmetic means, and standard deviations [SD] for parametric, median and interquartile range for non-parametric data.

Independent student and Mann Whitney tests were used to calculate difference between quantitative variables in two groups for parametric and non-parametric variables respectively. All statistical comparisons were two tailed with significance level at P-value ≤ 0.05 .

RESULTS

The majority of included women were in their third decade of life and mostly were obese. The mean gestational age at inclusion was 17.08 ± 3.33 and 16.92 ± 3.23 weeks in the first and second groups respectively. In addition, 28% and 16% of groups I and II respectively were primigravidae. Finally, no significant differences were found between the groups I and II, regarding women age, weight, body mass index, gestational age, gravidity,

mode of last delivery, and associated comorbid conditions [Table 1]. In addition, the laboratory investigations showed non-significant differences between groups I and II respectively [Table 2].

Regarding outcome, no significant difference was recorded between groups I and II regarding the surgical removal of placenta [12% vs 4%], post-expulsion bleeding [12% vs 4%] or the need for blood transfusion [4% vs 0.0%]. However, the time from induction to expulsion of fetus was statistically reduced in by Foley's catheter [group II] than the first group [19.36 ± 4.72 vs 36.32 ± 13.35] hours, respectively [table 3]. The percentage of time reduction was more than 45% [46.70%] [Table 3].

Table [1]: Demographic characteristics and clinical data among the study groups

Variables and measurements		Group I [n=25]	Group II [n=25]	Test	P
Age [years] [mean±SD]		29.12 ± 7.46	30.76 ± 6.61	1.25	0.107
Weight [kg] [Mean ± SD]		94.55 ± 13.74	93.4 ± 10.82	0.331	0.743
BMI [kg/m ²] [Mean ± SD]		33.45 ± 5.39	32.23 ± 5.17	0.804	0.426
GA [weeks] [Mean ± SD]		17.08 ± 3.33	16.92 ± 3.23	0.173	0.864
Gravidity [n,%]	Primigravida	7 [28%]	4 [16%]	1.05	0.306
	Multigravida	18 [72%]	21 [84%]		
Mode of delivery [n,%]	No	9 [36%]	8 [32%]	2.52	0.284
	Cesarean section	9 [36%]	5 [20%]		
	Vaginal delivery	7 [28%]	12 [48%]		
Associated comorbid chronic diseases [n,%]	Hypertension	4 [16%]	2 [8%]	0.758	0.384
	DM	2 [8%]	1 [4%]	0.355	0.552
Family history of DM and HTN [n,%]		4 [16%]	6 [24%]	0.500	0.480

Table [2]: Laboratory parameters of the two studied groups.

Variable	Group I [n=25]	Group II [n=25]	t	P
Hb [g/dL]	10.45 ± 0.536	10.35 ± 0.502	0.650	0.519
PT	12.99 ± 0.022	12.99 ± 0.037	0.182	0.856
Bleeding time	4.15 ± 0.988	4.23 ± 0.898	0.309	0.759
Clotting time	0.861 ± 0.127	0.913 ± 0.122	1.49	0.144
RBS [mg/dL]	91.05 ± 5.29	88.6 ± 4.43	1.77	0.083
ALT [U/L]	27.51 ± 15.78	24.38 ± 4.69	0.499	0.618
AST [U/L]	32.55 ± 16.37	30.63 ± 7.03	0.810	0.418

Table [3]: Outcome among study groups

		Group I [n=25]	Group II [n=25]	MW	P
Time from induction to expulsion [hrs] [Mean ± SD]		36.32±13.35	19.36±4.72	66	<0.001*
Complications [n, %]	Surgical removal	3 [12%]	1 [4%]	1.08	0.299
	Post-expulsion bleeding	3 [12%]	1 [4%]	1.08	0.299
	Blood transfusion	1 [4%]	0	1.02	0.315

DISCUSSION

The results of the current work showed that, the main advantage of the combined use of misoprostol and Foley's catheter with weight traction was the significant reduction of the termination time. The use of Foley's catheter produced more than 45% reduction of time than the use of misoprostol alone. This accomplishes one aim of the obstetrician pregnancy termination management goals. The second goal was the use of safe procedures. The results showed that, no significant differences were recorded as regard peri-procedural complications. In addition, and to remove the effect of any confounding factor [that may affect the final outcome], we enrolled two well-matched groups in baseline data. Thus, there was no statistically significant differences between the study groups as regard age, GA, gravidity, mode of delivery, weight, BMI, comorbid conditions. Additionally, laboratory data were comparable between the two groups.

Time from induction to expulsion was significantly shorter among combined misoprostol plus Foley's catheter group than the misoprostol only group [19.36 ± 4.72 versus 36.32 ± 13.35 hours, respectively, $p < 0.001$]. These results are in line with the previous literature. For example, **Agarwal et al.**^[7] reported that, the mean time of induction to delivery in misoprostol alone group was 17.53 ± 5.39 hours, which was significantly longer than the combined Foleys plus misoprostol group [12.66 ± 4.89 hours] [$p < 0.0001$]. However, their results are much shorter than the current work in both studies.

This can be explained by the additional use of mifepristone plus misoprostol in their study. In addition, **Ait-Allah et al.**^[22] from Egypt, showed that, the induction to expulsion time ranged between 14-36 hours and it was significantly shorter in the combined than the misoprostol alone group [14.80 ± 4.51 vs 22.22 ± 7.059 respectively].

Other studies by **Mizrachi et al.**^[23], **Edwards et al.**^[24] and **Barda et al.**^[25] reported that, the time between induction and expulsion of the fetus was significantly shorter in the Foley catheter group than prostaglandins groups [either dinoprostone or misoprostol groups].

In agreement with the results of the current work, **Desouky et al.**^[26] reported that, the use of a weighted trans-cervical Foley's catheter improves the effectiveness of 400 µg misoprostol in termination of the mid trimester pregnancies. This was reflected by a shorter induction to delivery interval [18.47 ± 7.34 vs 23.17 ± 6.19 hours] with no significant increase in the incidence of side effects

On the extreme side, **Henry et al.**^[27] and **Jozwiak et al.**^[28] stated a reverse results than the current study, where the time between induction and expulsion of the fetus was faster with the usage of PGE2. This can be explained by the two facts, the first they use prostaglandin as vaginal gel versus Foley's Catheter alone [they compared medical to mechanical induction], and they use them at term delivery, not for termination of midtrimestric pregnancy. However, when the comparison was performed between Foley catheter and prostaglandins versus Foley's catheter or prostaglandin alone, the induction-to-delivery time was significantly shorter with the combination than the single use as reported in above studies.

In addition, **Chowdhary et al.**^[29] reported significant shortening of time in combined than the use of Foley's catheter alone [16 hours and 16 minutes vs. 20 hours 44 minutes, $p = 0.002$]. This was significant especially with the lower rate of side effects or complications and similar rate of cesarean delivery.

However, in contrast to the current study, **Fathalla et al.**^[30] showed that there was a significant difference between the time intervals taken by each group to complete termination. The time interval in the group which

used misoprostol [12.45 ± 7.12] is shorter than that in the other groups, and the difference is significant. But there is no significant difference between the group which used Foley's catheter alone, and the combined group. The group of patients who received misoprostol after Foley's catheter expelled has the longest time interval [31.53 ± 13.46] with a significant difference between it and other groups. The contrast with our results may be due to the difference in sample size and indication of abortion. The difference in the induction-to-expulsion time between studies may be attributed to the differences in misoprostol administration route, dose, number of doses and timing [as the study used patients who received misoprostol after Foley's catheter was expelled].

In line with current results, **El Sharkwy et al.**^[18] revealed that the incomplete abortion rate that needs surgical evacuation was significantly lower in the combined than the misoprostol only group [2.6% versus 15% respectively, $p = 0.03$]. However, in the current work, the results did not reach statistical significance. It may be due to the lower rate [12% vs 4%] and small sample size.

In addition, **Desouky et al.**^[26] showed that there was no significant difference in the need for post abortive manual separation of the placenta. However, they reported higher rate of need for manual separation in the combined than misoprostol alone group [39% vs 24% respectively]. The contrast to our results may be attributed to the differences in misoprostol administration route, dose, number and timing of doses.

Conclusion: The use of a weighted trans-cervical Foley's catheter filled with [30-50 saline] improves the effectiveness of 200 µg oral misoprostol in the termination of mid trimester pregnancies as reflected by a shorter induction to delivery interval with no significant increase in the incidence of side effects. We advocate the use of combined approach to manage future abortions in the mid of the second trimester of pregnancy. However, due limitation of the current work by the small sample size, this conclusion and recommendation needs further validation in future, large scale studies.

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