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ORIGINAL ARTICLE

Sublingual Misoprostol Versus Local Misoprostol with Foleys Catheter Cervical Insertion in Management of Missed Abortion

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ABSTRACT

Background: Misoprostol is a successful abortion medication when administered vaginally, orally, or sublingually, the most effective approaches would reduce the time it took to go from induction to delivery while reducing the likelihood of side effects. The present study aimed for comparing the safety in addition to the efficacy of different regimens for missed abortion termination of through using sublingual misoprostol, vaginal misoprostol alone, versus sublingual misoprostol, vaginal misoprostol with insertion of cervical Foley's catheter. **methods:** This prospective randomized controlled trial included 172 pregnant women. Group A (Sublingual group) that subdivided into 2 subgroups: I (A): 43 patients to whom misoprostol tablet was given sublingually every 4 hours up to 6 doses per day, I (B):43 patients to whom misoprostol tablet was given sublingually every four hours up to six doses per day plus Foley's catheter (18fr) insertion through cervix,Group B (Local "vaginal" group): that subdivided into two subgroups; II (A): 43 patients to whom misoprostol tablet was given vaginally every four hours up to six doses per day, II (B): 43 patients to whom misoprostol tablet was given vaginally every four hours up to six doses per day plus Foley's catheter (18Fr) insertion through cervix. **Results:** Sublingual misoprostol plus cervical Foley catheter insertion is associated with a higher success rate and least induction to abortion interval; length of hospitalization, number/total of doses of misoprostol needed for terminating the pregnancy, and need for hysterotomy.This route is also associated with the highest rate of complete expulsion of pregnancy followed by sublingual misoprostol without cervical Foley's catheter insertion then vaginal misoprostol plus cervical Foley's catheter insertion and the worst route was vaginal misoprostol without cervical Foley's catheter insertion. **Conclusions:**sublingual misoprostol plus cervical Foley catheter insertion is the best option for the management of pregnant women with missed abortions. **Keywords:** Sublingual Misoprostol; Local Misoprostol; Foleys Catheter; Cervical Insertion; Missed Abortion.

INTRODUCTION

If there are no clinical signs of expulsion and the gestational sac still contains a dead embryo or baby before the 24-week mark of gestation, it is considered a missed abortion. Miscarriage is the most common complication of early pregnancy [1]. There is a possibility for expecting a solution to a

miscarriage. Although it is cost-effective and prevents iatrogenic complications, the rate of successful abortion varies with the length of time that the patient is monitored [2].

There have been multiple strategies to manage a missed abortion during the first half of pregnancy. These include hysterotomy, injecting hyperosmolar fluid into the amniotic fluid, using prostaglandin or its analogs E1, E2, and F2α, oxytocin, anti-progesterone, methotrexate, or a mix of these approaches [3].In recent years, medical care of miscarriage has been investigated as a potential substitute for surgical management [4].

A prostaglandin E1 analog, misoprostol, outperforms its prostaglandin E2 counterparts in terms of price, half-life at room temperature, and adverse effects. Because it is available in a variety of dosage forms and administration modes (oral, vaginal, and sublingual), misoprostol is often considered the best prostaglandin. Misoprostol has been studied and used for missed abortion [5].

Misoprostol is a successful abortion medication when administered vaginally, orally, or sublingually. By comparing various doses and methods of administering misoprostol, the preferred approaches could reduce the time it took to go from induction to delivery while also reducing the likelihood of side effects [6].

Using a Foley's catheter transcervical is one example of a non-pharmacological technique. After Embrey and Mollison initially detailed the process of cervical ripening with a transcervical Foley's catheter, with evidence of the device's efficacy. The appearance of the catheter at the cervical opening has two effects: first, it mechanically dilates the cervix; second, it stimulates the endogenous production of prostaglandin [7].Mechanical cervical dilation techniques can cause localized inflammation, which in turn increases prostaglandin and/or oxytocin release [8].

An efficient, safe, cost-effective, reversible, and method with a low incidence of uterine contractile anomalies is the use of a transcervical Foley catheter in missed abortions [9].

Misoprostol in combination with mechanical methods, seems to be effective and appropriate for missed abortion. With such a short duration between induction and termination and so few side effects, both procedures are highly recommended[10].

The present work aimedfor comparing the safety in addition to the efficacy of different regimens for missed abortion termination of through using sublingual misoprostol, vaginal misoprostol alone, versus sublingual misoprostol, vaginal misoprostol with insertion of cervical Foley’s catheter.

METHODS

Patients:

This study was a prospective randomized controlled trial conducted on patients with missed abortions who attended to Obstetrics maternity (emergency) Hospital, Faculty of Medicine, Zagazig University in which termination of pregnancy was attempted in 172 women with missed miscarriage up to 24 weeks gestations in the duration from February to September 2023.Ultrasound imaging verified the gestational age, which was calculated from the first day of the last menstrual cycle.

Verbal and written informed consentwere obtained from all participants after an

explanation of the procedure and medical research. The research was conducted under the World Medical Association's Code of Ethics (Helsinki Declaration) for human research. This study was carried out after the approval of the Institutional Review Board (IRB) (#10636).

Cases with the following criteria were included; Pregnant females aged 18 years or above who were diagnosed by ultrasonography with missed miscarriage up to 24-week gestations, who had a single pregnancy, who had previous two or fewer uterine scars, and those who had normally situated placenta (fundal placenta).

Cases with the following characteristics were excluded; had a history or evidence of diseases that represent a contraindication to the use of misoprostol (glaucoma, sickle cell anemia, bronchial asthma)or known allergy to prostaglandins, had a history or evidence of medical disease (hypertension, cardiac disease, blood disorders, coagulative disorders, liver disease), had previous uterine scar of three or more cesarean section or uterine scars either perforation,rupture uterus or myomectomy scars, patients who had abnormal placentation.(Low lying placenta), extra uterine pregnancy or molar pregnancy, or multiple pregnancies were all excluded.

Methods

Patients included in this study were divided randomly into 2groups:

Group(I): Sublingual group: That was subdivided into two subgroups: Group I(A) included 43 patients: Misoprostol tablet was given sublingually every four hours up to six doses per day, if there was no response the regime was repeated in the next day. It was considered a failure if no response after 48 hours. Group I(B) included 43 patients: In addition to administering a sublingual dose of misoprostol every four hours for a maximum of six doses per day, the procedure involved inserting an 18-fr Foley's catheter into the cervix and inflating its balloon with 30-50 ml of normal saline. It was considereda failure if no response after 48 hours. Additional management was carried out following adherence to the program for 48 hours.

Group (II): Local(vaginal) group: Was subdivided into two subgroups: Group II(A) included 43 patients: misoprostol tablet was given vaginally every four hours up to six doses per day if there was no response occurred, and the regime was repeated in the next day. It was considered a failure if no response after 48 hours. Group II(B) included 43 patients: Every four hours, up to six doses of misoprostol were given vaginally. Additionally, a Foley's catheter (18Fr) was inserted through the cervix to the internal Os, and its balloon was inflated with 30-50ml of normal saline. It was considered a failure if no response after 48 hours.

Before inserting the misoprostol tablets into the vaginal posterior fornix, it was lubricated with a few drops of normal saline or water. With the patient in the lithotomy posture and their bladder empty, a Foley catheter (18Fr) was inserted via the cervix and inflated with 30-50 ml of normal saline under strict aseptic conditions. The catheter was advanced to the internal Os. Then, the medial side of the thigh was fastened with adhesive tape to the catheter's safeguard, which had considerable traction applied to it. To ensure traction, a plastic bag containing 200 cc of normal saline was attached to the catheter. The procedure was deemed unsuccessful if, after 48 hours of

reserving the catheter, ejection did not occur. Following adherence to the regimen for 48 hours, further management was administered.

Randomization: Patients were randomly allocated into 4 groups, papers were numbered according to sample size and placed in a draw box, odd numbers were allocated to sublingual misoprostol cases(with catheter and without catheter) ,even numbers were allocated to vaginal misoprostol cases(with catheter and without catheter) .when the patient arrived was asked to draw a paper randomly from the box, and we determine the system applied to the patient according to the number chosen. (single-blinded technique).

Misoprostol was adjusted according to gestational age accordingto FIGO[10]. Gestational age from 0-13 weeks gestations: 800 mg, Gestational age from 13-16 weeks gestations: 600 mg .and Gestational age from 16-24 weeks gestations: 400 mg.

The following procedures were done to every patient on admission: Patient counseling: The nature of the drug, administration route, side effects, health benefits, and possibilities of uterine rupture were clearly explained to each patient. Careful and detailed history was taken from the patient with special emphasis onobstetric history that included: Parity, Gravidity, Possible causes of recurrent fetal loss or recurrent intrauterine fetal death, Mode of previous deliveries or abortions, past history and surgical history for any previous uterine scars.

The general examination involved: Measurements of blood pressure, pulse and temperature**,** Presence of pallor or jaundice**,** Fundal level, and the presence of scars from prior procedures were the goals of the abdominal examination. Cervical evaluation included vaginal inspection, consistency, effacement, and positioning in addition to cervical dilatation and effacement.

The following investigations were done: Laboratory tests**:** Complete blood picture, Blood group and Rh, coagulation profile, Fasting Blood sugar, Urine examination, Viral screen, and Cross-matching of one unit of blood. Ultrasound was done to confirm the diagnosis of missed miscarriage, gestational age, and estimated fetal birth weight, excluding placenta previa and multiple pregnancies.

Each patient underwent the following procedures upon admission: Every four hours, ward staff checked in on all patients to make sure they were doing okay before dosing them again, taking their temperature, and blood pressure, and monitoring any side effects. A vaginal exam was used to determine cervical state, while an abdominal exam was used to determine uterine contraction. The patient does not need to take another dose of misoprostol if she is about to have an abortion (cervical effacement of at least 70% with a 2 cm opening). Abortion is defined as the time the fetus is evacuated (incomplete abortion), however, in certain situations, the placenta may be delivered at the same time as the induction, which is regarded to begin when the patient takes the first dose of misoprostol (complete abortion) [12].

The completion of the abortion was confirmed by an ultrasonographic test, which confirmed the effective removal of the gestational products (fetus and placenta). Achieving the evacuation of products of conception was deemed a success. The misoprostol used in this study was a

prostaglandin E_1 methyl analog (mitotic produced by Sigma Company) in tablets of 200 micrograms.

Results included the following: Induction of abortion interval, The total doses received, Side effects or complications as chest pain, hyperthermia, hypotension, the occurrence of post-abortion pyrexia or sepsis, If an abortion could not be confirmed after 48 hours of taking misoprostol, it was deemed a failure, as did the failure to fully evacuate the uterus as proven by ultrasound.

STATISTICAL ANALYSIS

Data was analyzed statistically with IIBM SPSS, version 20.0 (IBM Corporation, Armonk, New York). Quantitative data were described utilizing the mean and standard deviation, while qualitative data were expressed using the number and percentage. To compare two groups of normally distributed variables, the t-test was used. When applicable, the Chi-square test was employed to compare percentages of categorical variables. When the predicted count is less than 6 in more than 20% of cells, the association between two qualitative variables was examined using Fisher's exact test. A p-value < 0.05 is considered significant.

RESULTS

Non statistically significant differences were found between the studied groups as regards maternal characteristics, or gestational age (Table 1).

Highly statistically significant differences were revealed between the groups as regards induction to abortion interval and hospitalization (P<0.001 for each. Induction to abortion interval and hospitalization were shorter in Group I (B) followed by Group I(A) then Group II(B) and Group II(A) (Table 2).

Highly statistically significant differences were found between the groups as regards the number of doses of misoprostol and total doses of misoprostol (µg) needed for termination of pregnancy that were lower in Group I(B) followed by Group I(A) then Group II(B) and Group II(A) (P<0.001 for each) (Table 3).

Highly statistically significant differences were found between the groups as regards outcomes of induction of abortion that complete expulsion was higher, while hysterotomy and incomplete expulsion were lower in Group I(B) followed by Group I(A) then Group II(B) and Group II(A)(P<0.001 for each) (Table 4).

Statistically significant differences were found between the groups as regards incomplete expulsion was lower in Group I(B) followed by Group I(A) then Group II(B) and Group II (A), while the occurrence of hemorrhage or infection showed nonsignificant differences between groups (Table 5).

Also, highly statistically significant differences were found between the groups as regards success rates that were higher in Group I(B) followed by Group I(A) then Group II(B) and Group II(A) (P<0.001) (Table 6).

Another statistically significant differences were revealed between the groups as regards preference of the route of administration that was higher in Group I(A) followed by Group I(B) then Group II(A) and Group II(B) (P<0.001) (Table 7).

Table (1): Maternal characteristics and distribution of the studied groups according to gestational age at time of termination (weeks)

	Group(I) (n=86)	Group(II) (n=86)	t-test	P-value
Maternal age (years) (mean±SD)	26.50 ± 3.45	27.49 ± 3.72	1.7	0.07
Parity(mean± SD)	2.37±1.06	2.11±1.18	1.5	0.13
Body mass index (kg/m^2) **(mean±SD)**	28.02 ± 4.45	29.28 ± 4.77	1.79	0.075

Gestational age (weeks)	**Group I (n=86)**				**GroupII (n=86)**				**P -value**
	GroupI(A) (n=43)		**Group I(B) (n=43)**		**GroupII(A) (n=43)**		**GroupII(B) (n=43)**		
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	
From 0-13	25	58.1%	25	58.1%	23	53.4%	22	51.1%	0.88
From 13-	12	27.8%	14	32.5%	14	32.5%	16	37.2%	0.86
From 16-	6	13.9%	4	9.3%	6	13.9%	5	11.6%	0.75
Total	43	100%	43	100%	43	100%	43	100%	

Table (2): Clinical features of processes of termination of pregnancy in studied groups

	Group I (n=86)		**GroupII (n=86)**		**P -value**
	GroupI(A) (n=43)	**Group I(B) (n=43)**	**GroupII(A) (n=43)**	**GroupII(B) (n=43)**	
Induction to abortion interval (hours) (Mean ±SD)	31.07±23.84	25.20±31.28	45.07±23.84	41.20±31.28	<0.001**
Hospitalization (days) (Mean ±SD)	3.11±1.02	2.371±1.98	4.11±1.02	3.171±1.98	<0.001**

Table (3): Number of doses and total doses of misoprostol (µg) needed for termination of pregnancy in studied groupsaccording to Gestational age (weeks)

Gestational age (weeks)	Group I (n=86) (Mean ±SD)		GroupII (n=86) (Mean ±SD)		P -value
	GroupI(A) (n=43)	Group I(B) (n=43)	GroupII(A) (n=43)	GroupII(B) (n=43)	
From 0-13	5.72±0.56	4.35±0.32	6.11±0.12	7.17±0.18	<0.001**
From 13-	7.72±0.84	5.35±0.29	10.11±0.82	10.97±0.92	<0.001**
From 16-	8.72±0.54	6.35±0.22	11.11±0.02	10.17±0.98	<0.001**

Total doses of misoprostol (µg)needed for termination of pregnancy in studied groups according to Gestational age (weeks)					
Gestational age (weeks)	Group I (n=86) (Mean ±SD)		GroupII (n=86) (Mean ±SD)		P -value
	GroupI(A) (n=43)	Group I(B) (n=43)	GroupII(A) (n=43)	GroupII(B) (n=43)	
From 0-13	1120.72±156.2	8635.33±132.4	1211±112.66	1117.7±118.66	<0.001**
From 13-16	1560.72±184.4	1135±129.6	1311±182.8	1297.54±192.7	<0.001**
From 16-24	1872±0132.7	12335±122.7	1980.43±123.7	2017±198.55	<0.001**

Table (4): Outcomes of induction of abortion in studied groups

Gestational age (weeks)	Group I (n=86)				GroupII (n=86)				P -value
	GroupI(A) (n=43)		Group I(B) (n=43)		GroupII(A) (n=43)		GroupII(B) (n=43)		
	N	%	N	%	N	%	N	%	
Complete expulsion	36	83.7%	37	86%	27	62.8%	24	55.8%	0.001**
Incomplete expulsion	5	11.6%	5	11.6%	11	25.6%	15	34.9%	0.001**
Hysterotomy	2	4.7%	1	2.3%	5	11.6%	4	9.4%	0.31
Total	43	100%	43	100%	43	100%	43	100%	

Table (5): Complications in studied groups

	Group I (n=86)				Group II (n=86)				P –value
	Group I(A) (n=43)		Group I(B) (n=43)		Group II(A) (n=43)		Group II(B) (n=43)		
Complications effects	N	%	N	%	N	%	N	%	
Incomplete expulsion	5	11.6%	5	11.6%	11	25.6%	15	34.9%	0.011**
Haemorrhage	5	11.6%	4	9.3%	7	16.2%	8	18.6%	0.58
Rupture uterus	0	0%	0	0%	1	2.3%	2	4.6%	0.29
Infection	3	6.9%	5	11.6%	7	16.2%	9	20.9%	0.27

Table (5): Success rate in studied groups

	Group I (n=86)		GroupII (n=86)		P -value
	GroupI(A) (n=43)	Group I(B) (n=43)	GroupII(A) (n=43)	GroupII(B) (n=43)	
Success rate	83.7%	86%	62.8%	55.8%	<0.001**
Failure rate	16.3%	14%	37.2%	44.2%	<0.001**

Table (7): Preference of the route of administration in studied groups

	Group I (n=86)				Group II (n=86)				P –value
	Group I(A) (n=43)		Group I(B) (n=43)		Group II(A) (n=43)		Group II(B) (n=43)		
	N	%	N	%	N	%	N	%	
Preferred the route	40	93%	33	76.7%	34	79%	24	55.8%	<0.001
Did not prefer	3	7%	10	13.3%	9	31%	19	44.2%	<0.001

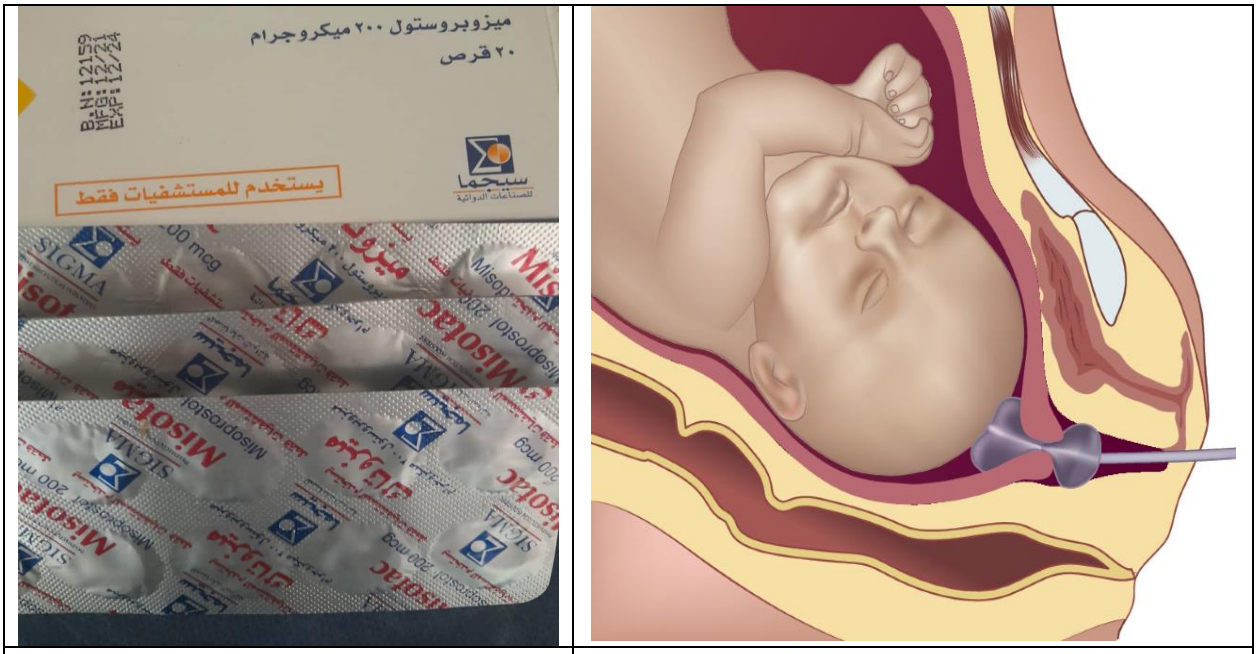

Figure 1: (A) Misoprostol used for sublingual and Local Cervical, (B): Local Misoprostol With Foleys Catheter Cervical Insertion Method in Management of Missed Abortion

DISCUSSION

DISCUSSION

Due to the low rate of maternal morbidity, medical abortion is best performed in the late second trimester [13].The benefits of misoprostol include its low cost, stability at room temperature, and the variety of modes of administration. An affordable, safe, and successful way to end a pregnancy is with a Foley catheter [14].When it comes to women who have had multiple cesarean sections, heavy doses of misoprostol are not safe, despite its effectiveness in terminating pregnancies in the second trimester[15].

Most of the studies that disagreed with our results were due to several causes as different study methodologies, outcomes, sample size, and different medical conditions and gestational age of studied cases at the time of enrollment.

Our study revealed that sublingual misoprostol + cervical Foley's catheter insertion is associated with higher success rate and least induction to abortion interval; length of hospitalization, number/total of doses of misoprostol needed for terminatingthe pregnancy and need for hysterotomy. This route is also associated with the highest rate of complete expulsion of pregnancy followed by sublingual misoprostol without cervical Foley's catheter insertion then vaginal misoprostol + cervical Foley's catheter insertion and the worst route was vaginal misoprostol without cervical Foley's catheter insertion.

The present study results agreed with those of Saleh et al. [7] since theyfound that a safe, effective, and cost-effective method for terminating a pregnancy in the third trimester when there is a history of uterine scars involves placing a Foley's catheter through the cervix and taking misoprostol sublingually. One hundred forty patients made it thus far in the trial by using either Foley's catheter in conjunction with vaginal misoprostol Group 2 G or sublingual

misoprostol Group 1 (GI) to induce abortion (GI) (II). In GI, the mean (SD) of the time it took from induction to abortion was significantly longer (51.07±23.84 vs. 45.20±31.28 hours) compared to G II (P-value 0.021). With a p-value of 0.001, the total misoprostol dose (1100.72±23.54) was greater in G II (645.35± 322) than in GI. G I had a significantly longer admission-termination hospitalization (days) (4.11±1.02) compared to G II (2.371±1.98), with a p-value of 0. 004..

Our study agreed also with the study of Barakat et al. [16] asthey examined the same type of patients but, unlike our two-patient groups, theirs consisted of three.Their goal was to detail the various techniques employed at a tertiary care centre to end a second trimester pregnancy in women who had experienced a uterine scar and to compare the safety and effectiveness of these techniques. The 105 pregnant women who were in good health and between 14 and 28 weeks along in their pregnancies were split into three equal groups. One group, GI, received 400 µg of misoprostol every 6 hours through the vaginal or sublingual routes to end the pregnancy. The second group, G (II), had a Foley's catheter inserted under strict aseptic conditions. The third group, GIII, consisted of women who received 200 µg of misoprostol in addition to the intracervical catheter. If the fetus is born prematurely, any of the preceding methods must be continued for another 24 hours.They demonstrated that a combination of misoprostol and Foley's catheter is more effective than using either method alone to terminate a pregnancy in the middle of the third trimester when there is a history of uterine scars. This method also has fewer non-serious complications and side effects, and a shorter duration.

There was a substantial difference among the three groups when it came to IAI, with the shortest in GIII at 11.6 ±2.6, the longest in GII at 17.3 ±3.4, and in between for GI at 15.9 ±3.4 (P< 0.001), when data was analyzed after treatment began and postoperative problems were noted (100 percent for GIII, 91.4 percent for GI and 85.7 percent for GII, p 0.02).

Ayati et al. [17] conducted a study comparing the use of a Foley catheter and sublingual misoprostol to induce labour and ripen the cervical spine in women suffering from preeclampsia or gestational hypertension. Like us, they demonstrated that sublingual misoprostol can shorten the cervical ripening period and other factors associated with the length of a vaginal birth when compared to the Foley catheter. Minimal adverse effects on the mother were observed with this misoprostol treatment.

Sharma et al. [18] investigated the effectiveness of inducing of labor (IOL) with sublingual misoprostol alone against a combination of sublingual misoprostol plus a transcervical Foley catheter in women with pre-eclampsia between weeks 28 and 34 of pregnancy. In pre-eclampsia cases occurring between 28 and 34 weeks of pregnancy, they concurred with our findings and reported that a combination of a transcervical Foley catheter and sublingual misoprostol was superior to sublingual misoprostol for IOL in facilitating a vaginal birth within 24 hours. The amount of misoprostol dosages or the time between induction and delivery did not vary, though.

Ait-Allah et al. [19] administered misoprostol to one group of patients at the Aswan University Hospital in a randomised controlled experiment. The other group received misoprostol in addition to Foley's

catheter balloon. Their correspondence with us revealed that there was no discernible rise in maternal risks or side effects when transcervical Foley's catheter balloon was used to enhance the effectiveness of vaginal misoprostol in terminating midtrimester pregnancies in women with an unfavourable cervix. The procedure also resulted in a shorter interval between induction and abortion.

Kadu et al.[20] reported that an intracervical Foley catheter with 25 µg of misoprostol was more effective for induction of labor than 25 µg of intravaginal misoprostol alone every six hours for a maximum of four doses in terms of induction to delivery interval, meconium-stained amniotic fluid, mode of delivery, intrapartum complications, and puerperal infection.

The present study demonstrated that no differences were noted between study groups as regard maternal age, parity, body mass index and gestational age at time of termination.

The present study agreed with Saleh et al. [7] who reported that no significant difference was found in the demographic criteria of both groups (P-value>0.05).

The present study agreed with Barakat et al. [16] who stated that with a p-value greater than 0.05, there was no statistically significant difference between the three groups when it came to the patients' age, weight, gravidity, parity, length of pregnancy, and number of prior scars.

On the other hand, sublingual misoprostol with/without cervical Foley's catheter insertion was associated with higher rate of adverse effects as nausea, vomiting and diarrhea, however no differences were noted between study groups regarding the incidence of fever, hemorrhage, intrauterine infection and rupture uterus. Also, sublingual misoprostol without cervical Foley's catheter insertion was associated with better women's compliance and preference.

The present study disagreed with Saleh et al. [7] who reported that There was no statistically significant difference in the frequency of side effects between the two groups, except fever, which occurred 17.1% in G I and 5.7% in G II (P = 0.01).

Fathalla et al. [21] reported that 39 individuals (26.5% of the total) experienced retained placental components as a complication, with surgical evacuation following closely after. In three instances, the perforation was unintentional and repaired without hysterectomy using laparotomy after an unplanned uterine perforation during evacuation. There were three cases of infection (1.7 percent). In four instances, a hysterotomy was necessary due to severe hemorrhage.

The current study agreed with Barakat et al. [16] who reported that GII had the fewest cases of diarrhea (no cases), GI had the most (five occurrences), and GIII had the fewest (one case) (P0.024). The misoprostol group had a greater incidence of post-induction nausea, vomiting, and fever.

In this study, the total dose of misoprostol (in µg) was significantly lower in the GII group (645.35±322) compared to the GI group (1100.72± 23.54), with a p-value of 0.001. The total number of days spent in the hospital, from admission to the start of induction to the abortion and discharge, was significantly longer in the GI group (4.11±1.02) compared to the GII group (2.371±1.98), with a p-value of 0.004. This was in line with what Barakat et al. [16] found.

In G I, complications comparable to incomplete expulsion were more common

than in GII (P = 0.04), but in G II, bleeding was more common than in GI (P = 0.03). There were no documented instances of infection, and there were no statistically significant variations in the frequency of uterine rupture between the two groups. This contradicted the results of the study by Barakat et al. [16], which indicated that there were no statistically significant variations in terms of bleeding between the two groups.

While comparing patients who had previously undergone a cesarean section with those who had not, several studies discovered no statistically significant difference in the risk of hemorrhage or uterine rupture when using misoprostol to induce a mid-trimester abortion [22].

The strength points of this study include that it was a prospective randomized controlled trialdesign and had no patients who were lost during the study period. It was the first study in Zagazig University Hospitals to compare the safety and efficacy of different treatments for terminating the missed abortion either by using sublingual misoprostol or vaginal misoprostol alone, versus sublingual or vaginal misoprostol with cervical Foley's catheter insertion. We took great care to record all relevant data, and we used only comprehensive records in our analyses.This study's clinical evaluation, delivery, and outcome evaluation were all carried out by the same group of individuals.

The limitations of the study include that it was a hospital-based study, this study did not represent any particular community, had a small sample size compared to the number of cases, and was not multicentric, all of which increased the likelihood of publication bias.

CONCLUSIONS

From our study we can conclude that sublingual misoprostol + cervical Foley's catheter insertion is the best option for the management of pregnant women with missed abortion. This rout is associated with higher success rate and least induction to abortion interval; length of hospitalization, number/total of doses of misoprostol needed to terminate the pregnancy and need for hysterotomy. This route is also associated with the highest rate of complete expulsion of pregnancy followed by sublingual misoprostol without cervical Foley's catheter insertion then vaginal misoprostol + cervical Foley's catheter insertion and the worst route was vaginal misoprostol without cervical Foley's catheter insertion.sublingual misoprostol with/without cervical Foley's catheter insertion was associated with higher rate of adverse effects as nausea, vomiting and diarrhea. Also, sublingual misoprostol without cervical Foley's catheter insertion was associated with better women's compliance and preference.

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