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ORIGINAL ARTICLE

Transcervical Foley's Catheter Balloon with Misoprostol versus Misoprostol Alone for Cervical Ripening and Induction of Midtrimesteric Abortion in Women with Unfavorable Cervix

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ABSTRACT

Keywords: Transcervical Foley's Catheter Balloon, Misoprostol, Induction of Midtrimesteric Abortion, Unfavorable Cervix

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Background: A gradual increase in second-trimester abortion because of wide scale introduction of prenatal screening programs detecting women whose pregnancies are complicated by serious fetal abnormalities such as neural tube defects i.e.anencephaly. **Patients and Methods:** a randomized controlled trial, was conducted at Aswan university hospital, Women divided into two groups. The first group (group A) received misoprostol only; the second group (group B) received misoprostol with Foley's catheter balloon. **Results:** Success rate of inducing abortion in group (A) was 20 patients (80%) while in group (B) success rate of inducing abortion was 23 patients (92%). There were statistically significant differences between two groups P<0.001. Induction to expulsion time was ranged between 14-36 hours with mean±S.D. 22.22±7.059 in group A while in group B induction to expulsion time was ranged between 8-24 hours mean±S.D. 14.80±4.514. There was highly statistically significant difference between two groups. The use of trans-cervical Foley's catheter balloon with misoprostol vaginaly is a noval, save, effective and lower cost method for cervical ripening and induction of midtrimesteric abortion in women with unfavorable cervix. **Conclusion:** The use of transcervical Foley's catheter balloon improves the efficacy of vaginal misoprostol for termination of midtrimester pregnancy in women with unfavorable cervix with shorter induction to abortion interval with no significant increase in side effects or maternal risks.

INTRODUCTION

Termination of pregnancy (TOP) is defined as elective expulsion or extraction of products of conception from uterus instead of spontaneous onset of process irrespectable of duration of pregnancy [1]

Worldwide mid-trimester abortion constitutes 10-15% of all induced abortions but responsible for two-thirds of all major complications [2]

Despite the recent advances in prenatal diagnosis in first trimester, termination of pregnancy in second trimester due to foetal abnormalities and intrauterine foetal death still accounts for large number of abortions, and has increased the demand for rapid termination of pregnancy [3]

In intrauterine fetal death in 2nd trimester, expulsion may take several weeks. This is associated with psychological trauma, coagulopathy and intrauterine infection [4]

Among various methods of second trimester termination, evacuation and curettage induces risk of bleeding, infection, uterine perforation and cervical trauma. The introduction of misoprostol,

a synthetic prostaglandin E1 analog (PGE1) has become an important for cervical ripening and uterotonic action. It is economic, stable at room temperature and is associated with few side effects such as fever, vomiting and diarrhea. There is still debate about doses, routes and regimes of PGE1 for termination of pregnancy during 2nd trimester. Studies have demonstrated greater efficacy with vaginal misoprostol than oral misoprostol [5]

FIGO recommendation for second trimester termination with misoprostol (vaginal, sublingual or buccal) states 200µg at 4-6 hours interval for fetal death, for cervical preparation for surgical abortion: 13-19 weeks: 400µg vaginal 3-4 hours before procedure, > 19 weeks: needs to combined with other modalities [1]

Misoprostol has oxytocic action: it has combined effect of priming or ripening the cervix prior to dilatation and inducing uterine contractions. It is active orally but more effective and better tolerated when administrated vaginally and has fewer side effects. Vaginal route is preferred in first and second trimester [4]

The use of Foley's catheter has been recommended in many developing countries. The reports from different countries have mentioned excellent results with the use of Foley's catheter either alone or in combination with prostaglandins [4]

The scope of our study: is to compare the use of vaginal misoprostol alone at regular interval versus its combination with intracervical Foley's catheter balloon for pre induction cervical ripening and induction of second trimester abortion. We aim to reduce the indications for surgical methods to terminate 2nd trimester pregnancy.

METHODS:

Study Design and setting:

This study was an open randomized clinical trial. Including 50 pregnant women with midtrimesteric abortion. This study had been conducted at Aswan university hospital, department of obstetrics and gynecology, from November 2018 to November 2019.

The protocol of the study has been approved by the ethical review board of the Faculty of Medicine, Aswan University.

Study population:

Pregnant women attending ANC clinic with midtrimesteric pregnancy at obstetrics and gynecology department Aswan university hospital were considered for enrollment in the study period, 50 eligible women were selected and randomized into groups of pregnant women: Group A: 25 women who received misoprostol alone, Group B: 25 women who received misoprostol with transcervical Foley's catheter balloon.

Inclusion Criteria:

- Women aged between 18 - 40 years of age.
- Gestational age between 14 and 26 weeks (based on menstrual history was confirmed by ultrasound examination when possible).
- Singleton pregnancies.
- Previous one CS and non prev.CS pregnant women.
- There is legal indication for termination of pregnancy: missed abortion, lethal congenital anomaly.

Exclusion Criteria:

- Previous 2 CS or more.
- Medical contraindications for prostaglandin therapy (allergy to prostaglandins, glaucoma or severe asthma).

- Associated Systemic disease (Hypertensive Disorder, Diabetes).
- Severe anaemia.
- Women with excessive vaginal discharge or rupture of membrane.
- Women having any complication of miscarriage like bleeding, chorioamnoiitis, disseminated intravascular coagulopathy etc.
- Women having any complication in previous cesarean like endometritis, re opening, scar dehiscence etc.
- Active genital infection e. g. active genital Herpes simplex infection.

Study method:

1- Study groups:

Group A: Misoprostol alone **Group B:** Misoprostol with Foley's catheter balloon

2- Screening and baseline assessment:

Screening was done at Obstetrics and Gynecology department Aswan university hospital, the baseline assessment included: history taking, examination, investigations and ultrasound evaluation.

Complete history taking:

1. Personal history, Obstetric history, Present history and Past history
2. The indication for termination (fetal death or fetal anomaly)

Examination:

A. General examination: Evaluation of vital signs and measurement weight, height (BMI).

B. Abdominal and local clinical examination:

* To assess fundal level and gestational age. * Scar of previous operation.

C. PV Examination

D. Investigations: all included patients were subjected to:

1- Laboratory investigation:

A) Routine laboratory investigations

B) To detect complications: e.g: coagulation profile.

2- Ultrasound for: diagnosis of intrauterine fetal demise or lethal congenital anomaly, Gest. age - AF – placenta.

Study Outcomes:

- Primary outcome: Difference in success rate of cervical ripening and inducing abortion when the 2 methods are compared (at 24 hours).
- Secondary outcomes: Difference in the incidence of side effects, induction-to-expulsion period, the rate of manual removal of placenta, the rate of postabortive bleeding (defined as estimated blood loss > 500 ml after expulsion), use of analegesic or pain reliefer and its doses.

Statistical analysis

Data collected throughout history, basic clinical examination, laboratory investigations and outcome measures coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis. P value was set at <0.05 for significant results & <0.001 for high significant result.

RESULTS

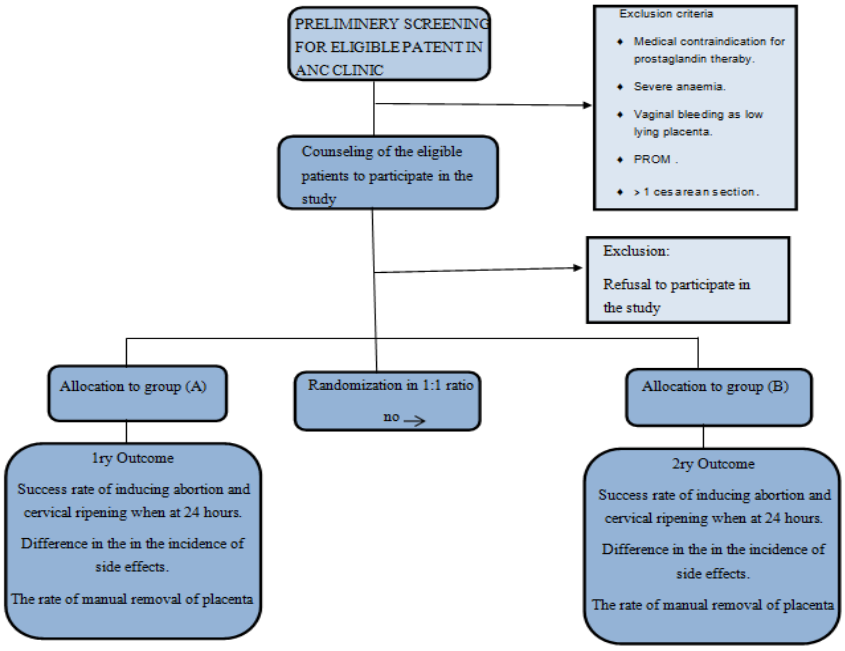

Table (1): Maternal demographic data of two groups:

	Group (A) (n=25)	Group (B) (n=25)	P Value
Maternal age			0.112
Mean± S.D	30.45±3.734	27.95±5.763	
Residency			
Rural	13 (52%)	8 (32%)	0.341
Urban	12 (48%)	17 (68%)	
Occupation			
House wife	14 (56%)	13(52%)	0.578
Working	11 (44%)	12 (48%)	
Educational Level			
Illiterate and 1ry school	13 (52%)	12 (48%)	0.596
2ry and high school	12 (48%)	13 (52%)	

No statistically significant differences were found between the two groups on regard age, residency, occupation, education as shown in **table (1).**

Table (2): Obstetrics data of two groups:

	Group (A) (n=25)		Group (B) (n=25)		P Value
Parity					
Nullipara	5	20%	7	28%	0.811
Multipara	20	80%	18	72%	
Previous C.S					
Previous 1 CS	11	44%	8	32%	0.731
Fundal Level					
Mean ± S.D	22.67±2.338		22.00±1.700		0.519
Gestational Age					
Min.-Max.	13-26		14-26		0.060
Mean± S.D	20.70±4.330		23.15±3.646		

No statistically significant differences were found between the two groups as regard parity, previous C.S or not, fundal level and gestational age as shown in **Table (2)**.

Table (3): The dose of oxytocin used in two groups:

The use of oxytocin by i.u.	Group (A) (n=25)	Group (B) (n=25)	P Value
Dose of oxytocin (Mean± S.D)	23.00±9.787	18.25±4.375	0.055

Table (3) shows the use of oxytocin in group (A) with mean value of 23.00±9.787i.u., while in group (B) with mean value of 18.25±4.375i.u.. No statistically significant differences between two groups where P=0.055.

Table (4): Induction to expulsion time in two groups:

The difference of induction to expulsion time	Group (A) (n=25)		Group (B) (n=25)		P Value
	No.	%	No.	%	
<6 hours	0	0	0	0	0.010*
6 - <12 hours	0	0	5	20	
12 - <18 hours	9	36	13	52	
≥ 18 hours	16	64	7	28	
Min.-Max.	14-36		8-24		<0.001*
Mean± S.D	22.22±7.059		14.80±4.514		

Induction to expulsion time in Group (A) was ranged between 14-36 hours with mean±S.D. 22.22±7.059 hours while in Group (B) was ranged between 8-24 hours with mean±S.D. 14.80±4.514 hours. There were highly statistically significant differences between two groups. **Table (4).**

Table (5): Comparison between two groups as regard to patient‘s number of doses of misoprostol needed:

Number of doses needed	Group (A) (n=25)		Group (B) (n=25)		P Value
	No.	%	No.	%	
One	2	8	16	64	<0.001*
Twos	8	32	7	28	
Three	7	28	2	8	
Four	8	32	0	0	
Total	25	100	25	100	

Number of doses needed in Group (A) show that 2(8%) need one dose, 8(32%) need two doses, 7(28%) need three doses and 8(32%) need four doses while in Group (B) 16(64%) need one dose, 7(28%) need two doses and 2(8%) need three doses. There were statistically significant differences between two groups where P<0.001. **Table (5).**

Table (6): Responce to induction of abortion in two groups:

	Group (A) (n=25)		Group (B) (n=25)		P-Value
	No.	%	No.	%	
Success rate	20	80	23	92	<0.001

In group (A): Success rate of inducing abortion was 80% while in group (B) success rate of inducing abortion was 92%. There was statistically significant difference between two groups where P<0.001. **Table (6).**

Table (7): Comparison between two groups as regard to patient‘s need for blood transfusion:

Blood transfusion	Group (A) (n=25)		Group (B) (n=25)		P Value
	No.	%	No.	%	
No	18	72	25	100	0.001
One Unit	4	16	0	0	
Two Units	2	8	0	0	

Three Units	1	4	0	0	
Total	25	100	25	100	

Table (7) shows blood transfusion in Group (A): 4 women (16%) need one unit, 2 women (8%) need two units and one woman (4%) need 3 units while in Group (B) no woman need blood transfusion. There were statistically significant differences between two groups where P=0.001.

Table (8): Comparison between two groups as regard to patient‘s manual or surgical removal of placenta:

Manual or surgical removal of placenta	Group (A) (n=25)		Group (B) (n=25)		P Value
	No.	%	No.	%	
No	8	32	19	76	
Yes	17	68	6	24	0.004*
Total	25	100	25	100	

Manual or surgical removal of placenta in Group (A): 17 women (68%) with manual or surgical removal while in Group (B): 6 women (24%) with manual or surgical removal. There were statistically significant differences between two groups where P=0.004. **Table (8).**

Table (9): The incidence of postabortive bleeding in two groups of patients:

Postabortive bleeding	Group (A) (n=25)		Group (B) (n=25)		P Value
	No.	%	No.	%	
No	15	60	22	88	
Yes	10	40	3	12	0.001*
Total	25	100	25	100	

The incidence of postabortive bleeding in Group (A) was 40%, while in Group (B) was 12%. There were statistically significant differences between two groups where P=0.001. **Table (9).**

Table (10): Comparison between two groups as regard to patient‘s use of pain relief and number of doses of.

Use and number of doses of pain relief	Group (A) (n=25)		Group (B) (n=25)		P Value
	No.	%	No.	%	
Zero	1	4	2	8	
One dose	4	16	10	40	0.001*
Two doses	15	60	11	44	
Three doses	5	20	2	8	

Table (10) shows number of doses of pain relief: in group (A) one woman (4%) not used pain relief, 4 women (16%) need one dose, 15 women (60%) need two doses, 5 women (20%) need three doses. While in group (B) 2 women (8%) not used pain relief, 10 women (40%) need one dose, 11 women (44%) need two doses, 2 women (8%) need three doses.

There were statistically significant differences between two groups regard to patient’s use of pain relief where P=0.001**. Table (10).**

DISCUSSION

Second trimesters abortions constitute 10–15% of all induced abortions worldwide but are responsible for two-thirds of all major abortion-related complications **[6].**

This study was basically a comparative effectiveness research compare two methods in pregnant women with 2nd trimester abortion. This study was RCT compare two methods for termination of pregnancy in 2nd trimester the two methods were: induction by vaginal misoprostol alone, induction by vaginal misoprostol with tanscervical Foley’s catheter balloon without traction.

Mid-trimester abortion is an inpatient procedure, so it should be quick, employ an easily followed protocol, cheap, without additional infrastructure, without compromising safety, both short

time and long time. Prostaglandins are known to cause cervical tears both vertical and bucket handle type. Cervical ripening can prevent the immediate and late complications of cervical injury [7]

Although the World Health Organization recommends a combination of mifepristone and misoprostol, mifepristone is not available in some countries, including Egypt, because of its high cost [8]. In addition, it is free from the complications especially in scared uterus [9].

The use of Foley's catheter has been recommended in many developing countries. The reports from Turkey, Egypt, Ethiopia, India, Nigeria have mentioned excellent results with the use of Foley's catheter either alone or in combination [10]

With the misoprostol alone regimen, 80–90% of women will abort within 24 h. Induction of abortion by the condom-Foley's catheter method in pregnant women with intra-uterine fetal death at 20–28 weeks was reported within 24 h, with a 100% success rate when compared with oxytocin infusion alone [11]

Many studies have evaluated the efficacy of using a combination of a mechanical and pharmacological method simultaneously to achieve cervical ripening hypothesizing that the two methods together may have a synergistic effect in achieving cervical ripening and preinduction of abortion. Studies as ***Shabana et al. (2012)[12], Afsheen et al. (2014)[4], Rezk et al. (2015)[10] and Subha et al. (2016)[13]*** evaluated the combination of Foley's plus misoprostol together versus misoprostol alone with similarly conflicting results of demonstrating shorter time to induction of abortion with the combination of Foley's and misoprostol together in some studies and not in others.

In the present study: the most common indications for TOP. In Group (A): missed abortion 14 women (56%) , Hydrops Fetalis 3 women (12%) and lethal Congenital anomaly 8 women (32%), while in Group (B) missed abortion 13 women (52%) and lethal Congenital anomaly 12 women (48%). With ***Rezk et al. (2015)[11],*** which their indications of TOP were IUFD, congenital anomalies and PROM.

The success rate of inducing abortion in the present study: in group (A) was 80%, while in group (B) success rate of inducing abortion was 92%. There were statistically significant differences between two groups where P<0.001. In addition to in this study which was the comparative assessment of induction interval. Induction to expulsion time in Group (A) was ranged between 14-36 hours with mean±S.D. 22.22±7.059 hours while in Group (B) was ranged between 8-24 hours with mean±S.D. 14.80±4.514 hours. There were highly statistically significant differences between two groups.

The study of ***Rezk et al. (2015)[10],*** that 90 women were included in the study. There was a high statistical difference between the three groups regarding the induction to abortion interval (IAI) with the shortest interval in the combined group (7.5±1.25 h) compared to 11.76±1.63 h in the misoprostol group and 19.76±1.52 h in the catheter group.

The study of ***Subha et al. (2016)[13]***, the induction of abortion interval was 13.84±5.37 hours in the combined group compared to 22.68±4.82 hours in the misoprostol group (P value<0.001) with success rate of 90% in the combined group and no major complications reported. with the study of ***Greenberg and Khalifeh (2015)[14]***, they concluded that Intracervical Foley's balloon catheters are a relatively safe and effective way to ripen the cervix compared to other cervical ripening agents. Due to their low cost and lower rates of uterine hyperstimulation.

In contrast to study to ***Toptas et al. (2014)***[15], that reported the combination of intravaginal misoprostol and Foley's catheter insertion does not provide additional efficacy over intravaginal misoprostol alone in the termination of second-trimester pregnancies.

The study of ***Kusumam et al. (2018)[16]***, concluded that the induction abortion intervals in group 1 (mifepristone misoprotol) 14.64h and group 2 (mifepristone Foley's) 18.4h p value.02.

The study showed that side effects of the drugs were fever, chills, headache, vomiting and diarrhea. There were no statistically significant differences between two groups.

The study of ***Rezk et al. (2015)***[10], that had reported the frequency fever as a side effect had been high in the combined group but still insignificant in comparison to misoprostol group as the use of intracervical Foley's catheter is associated with a significant increase in intracervical pathogenic organisms despite undertaking routine aseptic measures as proved in a previous study.

Regarding to manual or surgical removal of placenta and membranes in this study : in Group (A) was done with 17 women (68%), while in Group (B) was done for 6 women (24%). There were statistically significant differences between two groups where P=0.004.

The study of ***Subha et al. (2016)***[13], surgical evacuation was needed in (10%) of cases in combined group as compared to 18% in the misoprostol group.

The study by ***Toptas et al. (2014)***[15], two patients had placental retention. Both of those patients had a uterine scar; one in misoprostol group and one received misoprostol Foley's combination. Vaginal bleeding was moderate (<2pads/day) in the majority of patients. Intense vaginal bleeding (≥5 pads/day) was observed in only four patients. Two of them needed blood transfusions, in one of those, manual placental extraction was performed due to the total placental retention. The other one underwent laparotomy due to the uterine rupture.

The incidence of postabortive bleeding in the present study: Group (A): 10 patients (40%) had postabortive bleeding while in Group (B): 3 patients (12%) had postabortive bleeding. There was statistically significant difference between two groups where P=0.001.

The study of ***Subha et al. (2015)***[13], that concluded postabortive bleeding in group (A) 8 patients (16%), while in group (B) 5 patients (10%) with postabortive bleeding. There was statistically significant difference between groups where P=0.001.

According to blood transfusion in this study in Group (A): 4 patients (16%) needed one unit, 2 patients (8%) needed two units and 1 patient (4%) needed 3 units which had been due to major intraoperative bleeding and postabortive bleeding after CS, while in Group (B): no patients needed blood transfusion. There were no statistically significant differences between two groups where P=0.001.

The study of ***Rezk et al. (2015)***[11], recorded the blood transfusion in group A (misoprostol) was 5 patients (5%) while in group B (combined group) the blood transfusion was 9 patients (9%) with(P value >0.05).

From the results obtained in the present study, the use of trans-cervical Foley's catheter balloon with misoprostol vaginaly is a noval, save, effective and lower cost method for cervical ripening and induction of midtrimesteric abortion in women with unfavorable cervix. As reflected by a shorter induction to abortion interval with no significant increase in the incidence of side effects and no additional maternal risks.

CONCLUSION

In conclusion, the use of vaginal Misoprostol was safe and effective for ripening and induction of midtrimestric abortion in women with unfavorable cervix.

However the use of transcervical Foley's catheter balloon in combination with vaginal misoprostol improve the efficiency for termination of medtrimester pregnancy with shorter induction to delivery interval with no significant increase in side effects and it was a non-invasive method in second trimester pregnancy termination.

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