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Original Research Article

Comparative study between sequential use of Foley catheter with vaginal misoprostol versus sequential use of oral mifepristone with vaginal misoprostol for second trimester medical abortion

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ABSTRACT

Background: Abortions are one of the most commonly performed procedures in gynaecological departments worldwide. They are still a major problem in developing countries contributing to a significant percentage of maternal morbidity and mortality. The main objective of this study is to compare the efficacy, side effects and acceptability of intracervical Foley and oral Mifepristone both followed with sequential administration of vaginal misoprostol for second trimester medical abortion.
Methods: This was a prospective randomized trial of 36 healthy women opting for termination of pregnancy with ultrasound confirmed intrauterine gestation between 12 to 20 completed weeks. Intracervical Foley catheter with administration of misoprostol (200µg) vaginally was done for Group A. Mifepristone 200mg was administered on day one followed by misoprostol (200µg) vaginally, 48 hours later, to Group B. Both groups received misoprostol (200µg) vaginally at 4 hourly intervals. Completeness of abortion was assessed, and surgical evacuation was performed, if abortion was found to be incomplete.
Results: The two groups were comparable with respect to age, parity and gestational age. 83-89% of the women in both the groups had complete abortion. The mean induction abortion interval was 20.11 hours in Group A and 54.77 hours in Group B, which was statistically significant. Side effect profile was comparable in both groups however the intensity and the duration of persistence of pain was greater among patients from Group A.
Conclusions: Authors conclude that medical abortions with both methods were found to be safe, effective, inexpensive and acceptable methods. Whereas a shorter induction abortion interval was observed in the Foley induction group, induction with mifepristone was the preferred regimen in second trimester abortion because of its high efficacy, low incidence of side effects, better tolerance by the patients and due to lower dose of misoprostol required following mifepristone administration.

Keywords: Foley catheter, Induction abortion interval, Mifepristone, Misoprostol, Trimester

INTRODUCTION

Abortions are one of the most commonly performed procedures in gynaecological departments worldwide. They are still a major problem in developing countries contributing to significant maternal morbidity and mortality. WHO has reported that 53 million unplanned pregnancies result in termination each year.[1] Deaths related to these account for up to about 20% of the maternal deaths that occur each year throughout the world.[1]

Mid-trimester termination of pregnancy is one of the most controversial areas of gynecological practice.[2] It has

moral, emotional, social and technical issues. The increased incidence of second trimester medical abortions reported recently, results from an increased use of antenatal diagnostic procedures in modern day obstetrics.

Congenital abnormalities and missed abortions are amongst the common indications of second trimester termination of pregnancy.[3] The morbidity and mortality of any abortion procedure increases with the gestational age of the pregnancy.

There are several methods available for second trimester pregnancy termination like intrauterine (either the intra-amniotic cavity or the extra-amniotic space) instillation of abortifacients and administration of systemic abortifacients, dilatation and evacuation. In view of the potential side-effects and complications of dilatation and evacuation as well as instillation of intra-amniotic agents, much research has been carried out for other alternative methods.

A variety of techniques for termination of second trimester pregnancy can be used, but there is no consensus about which is the best.[4] Use of the Foley catheter for termination of pregnancy was first described by Krause in 1833.[5] In 1967, Embrey and Mollison reported a 94% successful induction rate in 100 women with Foley catheter.[6] Direct mechanical dilatation and endogenous release of Prostaglandins are the mechanisms of cervical ripening by Foley catheter and this effect is enhanced when traction is applied. The use of Foley catheter balloon alone has shown better results in achieving cervical ripening than 3mg dinoprostone vaginal pessary and it is also economical.[7]

Mifepristone, a norethindrone derivative, is a potent antiprogesterone which binds to progesterone receptors and counteracts the effect of progesterone. It also softens and dilates cervix, causes luteolysis, increases uterine contractions and enhances sensitivity to prostaglandin administration. Misoprostol, a prostaglandin E1 analogue interacts with myometrial cell receptors causing strong myometrial cell contractions leading to expulsion of embryonic tissue. It also causes cervical softening and dilatation.[8] Various routes of administration of misoprostol and various combination regimens of mifepristone and misoprostol have been investigated. Misoprostol is given either orally or vaginally, 36-48 hours after oral mifepristone. Studies have shown that combined mifepristone and misoprostol regimen is associated with shorter the induction to delivery time and decreased procedure-related pain compared to prostaglandin only regimens. The main concern of the obstetricians is to provide the most effective and safest method, which have shortest induction to expulsion time, ideally should be cost effective and with minimal side effects.

The aim of the present study is to compare the efficacy, induction abortion interval and side effects of sequential use of Foley catheter with vaginal misoprostol verses sequential use of oral mifepristone and vaginal misoprostol for second trimester abortion.

METHODS

This study was carried out in the Department of Obstetrics and Gynaecology, Lokmanya Tilak Municipal Medical College and General Hospital between August 2017-July 2018. 36 women opting for termination of pregnancy (MTP) in the second trimester and fulfilling the inclusion criteria were included. They were randomized in to two groups of 18 patients each.

Inclusion criteria

- Women seeking MTP with ultrasound confirmed intrauterine gestation of 12 to 20 weeks and fulfilling the requirements of the MTP Act.
- Singleton pregnancy.

Exclusion criteria

- Haemoglobin <10gm%.
- Hypersensitivity to prostaglandins.
- Medical conditions like adrenal failure, liver disease, hypertension, bronchial asthma, heart disease.
- Scarred uterus
- Grand multipara
- Ruptured membranes.

Procedure: The study comprised of 36 pregnant women requesting medical termination of pregnancy from 12 to 20 weeks of gestation confirmed clinically and ultrasonographically. After an informed written consent, physical examination and baseline investigations were carried out. Indication for MTP was noted. They were allocated to one of the two groups by computer generated random number table.

Group A: Foley catheter with vaginal misoprostol

Patient was asked to empty the bladder and lithtomy position was given. Under all aseptic measures Foley catheter (18 Fr) was introduced through cervix to the extra-amniotic space beyond the internal Os and balloon was inflated with 30 ml normal saline.

Catheter was secured with due traction on the medial aspect of the patient's thigh. At the same sitting 200µg misoprostol was kept in posterior fornix and the dose was repeated every 4th hourly till the catheter got expelled out or till maximum five doses.

Group B: Mifepristone with vaginal misoprostol

Mifepristone 200mg was administered on day one followed by 200µg of misoprostol vaginally, 48 hours later, at 4 hourly intervals.

Cervical reassessment was done, and oxytocin infusion was started after 3cm dilatation in both groups. Intravenous antibiotic coverage was given to patients in both groups. Maternal vitals were monitored and side effects like nausea, vomiting, diarrhoea, fever, severe pain abdomen were observed. The two groups were assessed clinically or with Ultrasonography and evaluated for completeness of abortion. If abortion was incomplete or bleeding was excessive, surgical evacuation was performed. Effectiveness was determined by complete expulsion of fetus and placenta, need for surgical intervention (D/E, hysterotomy, hysterectomy) and rate of complications.

Parameters studied

1. Complete abortion rate
2. Induction Abortion interval
3. Need for check curettage
4. Frequency of side effects (nausea, vomiting, diarrhoea, pain)
5. Indications for termination of pregnancy.

Efficacy was determined by need for surgical intervention or non-occurrence of complete abortion within 72 hours of induction. Statistical tests like Pearson Chi Square test and Fisher Exact test (2 tailed) were used.

RESULTS

The two groups were comparable with respect to age, parity and gestational age. 77.77% of the women in group A and 83.32 % of the women in group B were in the age group of 21-30 years. Majority (88.88 %) of the women were multigravida with two or more children in both groups. Most (55.55%) of the pregnancies were terminated between 16 -20 weeks of gestation in both the groups.

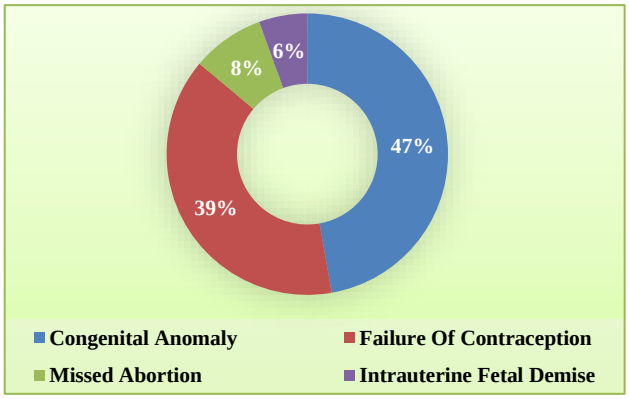

Figure 1: Indications of second trimester medical abortions.

The most common indication for termination was congenital malformation in the fetus (47.22%) followed by terminations due to failure of contraception in multiparous women (38.88%).

Medical terminations due to missed abortions (8.3%) and intrauterine fetal demise (5.5%) were among the other indications.

Table 1: Induction abortion interval.

Induction abortion interval	Group A		Group B		P value
		%		%	
≤24 hours	15	83.33	0	0	$2.9x10^{-7}$ (<0.05)
>24 hours	3	16.67	18	100	
Mean induction abortion interval	20.11		54.77		

The mean induction abortion interval in group A was 20.11 hours. The mean induction abortion interval in group B was 54.77 hours. This was because Mifepristone was administered 48 hours prior to Misoprostol in Group B. The difference between the induction abortion intervals of the two groups was found to be statistically significant.

Table 2: Total dose of misoprostol.

Dose of misoprostol	Group A		Group B		P value
		%		%	
≤2	1	5.55	18	100	$4.2x10^{-9}$ (<0.05)
>2	17	94.44	0	0	
Mean dose of misoprostol	4.22		1.5		

Mean dose of misoprostol required for successful abortion after pre-treatment with mifepristone was approximately 300µg in group A. Mean dose of misoprostol required for successful abortion after Foley catheter insertion was 800 µg in group B. The difference between the two groups was found to be statistically significant.

Table 3: Need for surgical intervention.

Need for surgical intervention	Group A		Group B		P value
		%		%	
Yes	3	16.66	2	11.11	1
No	16	83.34	16	88.88	

83-89% of the women had complete abortion in both groups whereas five women required additional intervention in the form of surgical evacuation. Three patients in group A required instrumental evacuation for retained products of conception. Two patients in group B required instrumental evacuation for retained products of conception. The difference between the success rates of the two groups was not found to be statistically significant.

Complications

Pain, nausea and vomiting were more common in Foley group, present in 100%, 55.55% and 38.88% respectively in Group A. Whereas pain, nausea and vomiting were present in 100%, 22.22% and 16.66% respectively in Group B. The side effect profile and incidence were comparable in both groups and the difference was not found to be statistically significant.

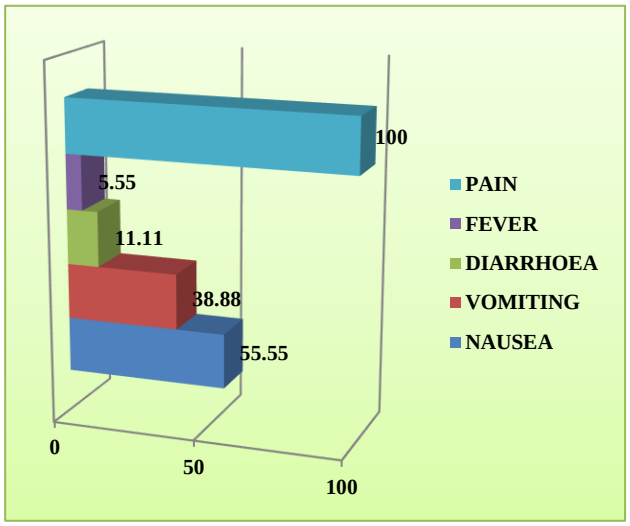

Figure 2: Complications with Foley catheter.

There was no post procedural infection or sepsis in either group. None of the women required blood transfusion or hysterotomy.

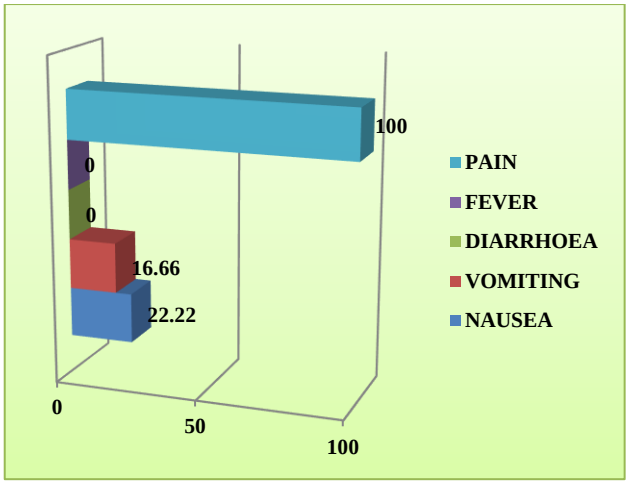

Figure 3: Complications with mifepristone.

Whereas the incidence of occurrence of pain in both groups was the same, the intensity (as assessed by the Visual Analogue Scale) and the duration of persistence of pain was more in the patients induced with Foley catheter (occurring for a mean duration of 14 hours).The pain was severe in intensity in patients induced with Foley whereas it was moderate in patients induced with Mifepristone, as assessed by visual analogue scale. The difference between the two groups was found to be statistically significant.

Table 4: Comparison of pain intensity in both groups.

Pain intensity	Group A		Group B		P value
		%		%	
Mild	0	0	1	5.55	
Moderate	3	16.66	13	72.22	0.0019
Severe	10	55.55	4	22.22	(<0.05)
Worst possible pain	5	27.77	0	0	

Mean duration of bleeding was 7 days with a range of 4-9 days in both groups. In present study 90 % of the women were counselled and adopted contraception after a successful medical abortion.

DISCUSSION

Various regimens of second trimester medical abortion are available today. Regimens for medical abortion continue to evolve and are modified so as to provide best and safe options for the women seeking termination of pregnancy. The success of medical abortion depends on various factors like the regimen used, dosage schedule, route of administration, gestational age.

In present study mean age of the patients in both the groups was 27 years. Multigravida accounted for 89% of the total patients enrolled in both groups. The mean gestational age was 17 weeks in both groups, majority were between 16-20 weeks.

In this prospective study patients in both groups were comparable with respect to age, parity and gestational age. In the present study in both group A and B, efficacy was determined by need for surgical intervention or non-occurrence of complete abortion within 72 hours of induction. In the present study, success rate was 83.3% in Group A, while in Group B it was 88.8 % and it was not significantly different in Group A compared to Group B (p>0.0001). Bhathena, Allhabadia found success rates 92% and 98% respectively.[9,10] The cut-off point for a failed case in these studies was 72 hours, Bebbington et al found 87% success rate with 400 mcg misoprostol every 4 hours with induction abortion interval of 19.6 hours.[11] Agarwal S reported 97% success rate with 200mcg misoprostol every 4 hours.

Table 5: Success rate in various studies with Foley catheter.

This study	Bhathena et al[9]	Bebbington et al[11]	Prachasilpchai et al[16]
83.3%	92%	76%	75%

The mean induction abortion interval in Group A was 20.11 hours. Present results about induction abortion interval in Group A are comparable with the results obtained by Bhathena et al, Prachasilpchai et al. In Group B the mean induction abortion interval was 54.77 hours which were comparable with the results obtained by Allahbadia, Agarwal et al.

Table 6: Success rate in various studies with Mifepristone Misoprostol combination.

This study	Allahabadia et al[10]	Agarwal et al[17]	Dikinson et al[18]	Bebbington et al[11]
88.88%	98%	97%	76%	87%

Table 7: Induction abortion interval (in hours) in studies with Foley catheter.

This study	Bhathena et al[9]	Bebbington et al[11]	Prachasilpchai et al[16]
20.11	28	33	18

Mean dose of misoprostol required for successful abortion after pre-treatment with mifepristone was 200 to 400µg in group A. Mean dose of misoprostol required for successful abortion after Foley catheter insertion was 800 µg in group B. These were comparable to values obtained by Prachasilpchai et al.

Table 8: Induction abortion interval (in hours) in studies with Mifepristone Misoprostol.

This study	Allahabadia et al[10]	Agarwal et al[17]
54.77	35	59

83-89 % of the women had complete abortion in both groups whereas five women required additional intervention in the form of surgical evacuation (13.88%). According to Elsheikh A et al in his study retained products required surgical evacuation in in 9.2%.[12] According to Bugahlo A et al complete uterine evacuation has occurred in 76% cases, manual evacuation in 24.12% and conventional curettage in 3.07%.[13]

Table 9: Misoprostol dose (in µg) required after Foley induction.

Present study	Prachasilpchai et al[16]
800	600

Pain, nausea and vomiting were more common in Foley group, present in 100%, 55.55% and 38.88% respectively in Group A. Pain, nausea and vomiting were present in 100%, 22.22% and 16.66% respectively in Group B. Whereas the incidence of occurrence of pain in both groups was the same, the intensity (as assessed by the Visual Analogue Scale) and the duration of persistence of pain was more in the patients induced with Foley catheter (occurring for a mean duration of 14 hours). Their occurrence in both groups was comparable and not found to be statistically significant. Side effects observed by Jain and Mishell using misoprostol are Fever (11%), vomiting (4%), diarrhea (4%) and by Herabutya et al are fever (41%), vomiting (15%), diarrhea (20%).[14,15] Side effects observations made by Allhabadia et al by using ethacridine lactate alone are fever (6%), vomiting (2%), rigors (5%), haemorrhage (2%).

Table 10: Misoprostol dose (in µg) required after pre-treatment with Mifepristone.

Present study	Patel et al[19]
300	600

CONCLUSION

Authors conclude that medical abortions with sequential use of mifepristone with misoprostol as well as sequential Foley with misoprostol were found to be safe, effective, inexpensive and acceptable methods. Whereas a shorter induction abortion interval was observed in the Foley induction group, induction with mifepristone was the preferred regimen in second trimester abortion because of its high efficacy, low incidence of side effects, better

tolerance by the patients, also due to lower dose of misoprostol required following mifepristone administration.

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