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Original Research Article

Study to compare the effectiveness of intravaginal misoprostol alone with combined use of intravaginal misoprostol and intracervical foley's catheter for termination of mid trimester pregnancy

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ABSTRACT

Background: The main concern of obstetrician is to provide the most effective and safest regimen for mid trimester termination of pregnancy which combines the shortest expulsion interval with least side effects. The combination of intravaginal misoprostol and intracervical Foley catheter for second trimester pregnancy termination has been described in previous studies with conflicting results. Hence gap exists in literature and not adequate evidence available so this study is undertaken.

Methods: A prospective and interventional randomized comparative study was conducted in the department of obstetrics and gynecology, tertiary care centre, New Delhi. A total 60 pregnant female of 14 to 20 weeks of gestation who were admitted for termination of pregnancy due to any indication included in the study. Patients were divided into two groups (30 patients in each group). Group A (misoprostol and foleys combination group) and Group B (misoprostol group). Quantitative variables were compared with unpaired t-test/Mann-whitney test (when the data sets were not normally distributed) between the two groups and qualitative variables were compared by using chi-square test/Fisher's exact test.

Results: The mean induction to abortion interval was 18.31 ± 1.95 hours in the female where misoprostol and foleys combination was used and 21.90 ± 2.62 hours in the women where misoprostol alone used group. Authors found a significant reduction in induction to expulsion time in misoprostol and foleys combination group as compared to misoprostol alone group for mid-trimester termination of pregnancy. Total required dose of misoprostol use for termination of pregnancy was significantly less ($p 0.008$) in the women where both misoprostol and foleys was used than misoprostol alone.

Conclusions: With the use of intracervical Foley's catheter, the duration from induction to expulsion of abortus gets shortened and required dose of misoprostol is also reduced without any significant increase of side effects.

Keywords: Foleys catheter, Mid trimester, Misoprostol, Termination of pregnancy

INTRODUCTION

Termination of pregnancy is defined as elective expulsion or extraction of products of conception from uterus instead of spontaneous onset of process irrespective of duration of pregnancy. Congenital abnormality and missed abortion are the most common reason of second trimester termination of pregnancy. It is associated with

three to five times higher risk of maternal morbidity and mortality than termination of pregnancy during first trimester.¹ In intrauterine fetal death, expulsion may take several weeks.

Second trimester abortions constitute 10-15% of all induced abortions worldwide but are responsible for two-thirds of all major abortion-related complications.² There

is 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 cardiovascular and skeletal malformation.³

Ultrasonography and latest modern parental diagnostic methods are very helpful in identifying the fetal abnormalities at an early stage of pregnancy, resulting into the increased number of women who are requiring termination of pregnancy.⁴

There are several methods of termination of pregnancy in mid-trimester, which are broadly classified into two groups medical and surgical methods;

Surgical methods

- Dilatation and evacuation, hysterotomy.

Medical methods

- Prostaglandins (misoprostol, mifepriston with misoprost, gemeprost, dinoprostone, carboprost)
- High dose oxytocin
- Intrauterine instillation of hypertonic solution (0.1% ethacridine lactate, hypertonic saline 20%).⁵

Termination of second trimester pregnancy is more-risky and as surgical methods have more morbidity, therefore the medical methods of TOP seem to be better alternative to surgical methods.⁶ Prostaglandins (PGE1, PGE2) induce labour with cervical effacement and dilatation. They have collagenolytic property. Misoprostol is a synthetic analog of PGE1, has been used to induce miscarriage through its various routes of administration. One of its advantages over other drugs is that it has multiple routes of administration (oral, vaginal, buccal, rectal or sublingual).

There are several advantages of using misoprostol as it is inexpensive, stable at room temperature and does not require refrigeration for storage.⁷ It is active orally but more effective and better tolerated when administered vaginally and has fewer side effects. Vaginal route is preferred in first and second trimester.⁸

The use of foley's catheter has been recommended in many developing countries.⁹ The exact mode of action of foley's catheter is not fully understood, yet it has been postulated that catheter stimulated various unspecified regions of uterus which leads to increase its excitability and cause regular uterine contraction. Foley's catheter is economical, easily available, associated with minimal complication and thus provides a readily available and efficacious method of cervical ripening.¹⁰

The combination of intravaginal misoprostol and intracervical foley catheter for second trimester

pregnancy termination has been described in previous studies with conflicting results.¹¹

No conclusive evidence available to study the effect of misoprostol and foley catheter and conflicting reports in available studies. Hence gap exists in literature and not adequate evidence available so this study was undertaken.

METHODS

It was a prospective and interventional randomized comparative study which was conducted in the department of obstetrics and gynecology, tertiary care centre, New Delhi. All pregnant women of 14-20 weeks of pregnancy coming to hospital for termination of pregnancy were evaluated thoroughly by complete history taking, examination and routine investigations as per proforma.

Inclusion criteria

- All pregnant female between 14 to 20 weeks of gestation who will be admitted for termination of pregnancy.

Exclusion criteria

- Case of bleeding per vaginum
- Associated systemic disease like hypertension disorder, asthma
- Hypersensitivity to prostaglandin
- Scarred uterus
- Patient with infected vaginal discharge.

Population which are obtained by applying exclusion criteria over eligible population. Those fulfilling the criteria for enrolled population will be included in this study after taking a well explained consent and patients will be divided into two groups (30 patients in each group) on the basis of computer-generated randomised sequence. Allocation concealment is done by randomisation. By nature of intervention, blinding cannot be done. The following intervention will be done in two groups.

Group 1 (misoprostol group)

A standard regimen of moistened misoprostol tablet (400µg) four hourly intravaginally (max 5 doses) was given until termination.

Group 2 (misoprostol and foleys combined group)

The patients were administered 400µg misoprostol intravaginally along with inserting intracervical foley's catheter (number 16 FrCh) inflated with 50 ml normal saline. Then 400 µg misoprostol (maximum 5 doses) was repeated four hourly until termination of pregnancy.

All the women were followed up till expulsion of fetus.

Induction - abortion interval

It was measured from first dose of intravaginal misoprostol to expulsion of fetus. Any side effects (nausea, vomiting, diarrhoea, pyrexia, bronchospasm, hyperstimulation of uterus and any other complications) if occur were also recorded in both the groups.

Failure case

If the pregnancy was not terminated even after maximum doses (five doses of 400 µg) of misoprostol, considered as a failure case.

Statistical analysis

Quantitative variables were compared using unpaired t-test/Mann-Whitney test (when the data sets were not normally distributed) between the two groups. Qualitative variables were compared using chi-square test/Fisher’s exact test. A p value of <0.05 was considered as statistically significant.

RESULTS

The primary objective of this study was to compare the duration from induction to expulsion of abortus and secondary objective was to compare the safety profile of misoprostol between both groups.

The mean and the standard variation of age was 22.63±2.47 years in Group A and 23.27±2.3 years in Group B. Mean gestational age was 16.87±1.73 weeks in Group A and 17.09±1.8 weeks in Group B. There was no

significant difference of age of patient and POG in duration from induction to expulsion of abortus (Table 1).

Result of this study was statically significant (p<0.0001). The mean induction to abortion interval was 18.31±1.95 hours in the combined group (Group A) and 21.90±2.62 hours in the misoprostol group (Group B). In this study authors found a significant reduction in induction to delivery time in combined group as compared to misoprostol alone group (Table 1).

Table 1: p value of different parameters.

	F+M	M	p value
Age (years)			
Mean±SD	22.63±2.47	23.27±2.3	0.309
POG			
Mean±SD	16.87±1.73	17.09±1.8	0.635
Duration from induction to expulsion of abortus (hours)			
Mean±SD	18.31±1.95	21.9±2.62	<0.0001
Total dose of Miso			
Mean±SD	4±0.59	4.43±0.68	0.008

Total 10/58 (17.24%) cases abort within 14-17 hours, among them 8/29 (27.59) cases from Group A, 2/29 (6.90%) cases from Group B. Total 28/58 (48.28%) cases abort within 18-21 hours, among them 19/29 (65.52%) cases from Group A, 9/29 (31.03%) cases from Group B. Total 20/58 (34.48%) cases abort within 22-26 hours, among them 2/29 (6.90%) cases from Group A, 18/29 (62.07%) cases from Group B. Mean duration from induction to expulsion of abortus was 18.31±1.95 hours in Group A and 21.9±2.62 hours in Group B (Table 2).

Table 2: Distribution according to duration from induction to expulsion of abortus.

		Groups		Total	p value
		A (n=30)	B (n=30)		
Duration from induction to expulsion of abortus (hours)	14-17	8 (27.59%)	2 (6.90%)	10 (17.24%)	<0.0001
	18-21	19 (65.52%)	9 (31.03%)	28 (48.28%)	
	22-26	2 (6.90%)	18 (62.07%)	20 (34.48%)	
Total		29 (100.00%)	29 (100.00%)	58 (100.00%)	

Table 3: Distribution according to total dose of misoprostol.

		Groups		Total	p value
		A (n=30)	B (n=30)		
Total dose of misoprostol	3.00	5 (16.67%)	3 (10.00%)	8 (13.33%)	0.012
	4.00	20 (66.67%)	11 (36.67%)	31 (51.67%)	
	5.00	5 (16.67%)	16 (53.33%)	21 (35.00%)	
Total		30 (100.00%)	30 (100.00%)	60 (100.00%)	

Total required dose of misoprostol use for TOP was significantly less (p 0.008) in combined group (Group A)

than misoprostol group (Group B). No significant effect of age of pregnant patient, POG, parity and gravida on

total duration from induction to expulsion and total dose of misoprostol required for TOP (Table 1). In total 8/60 (13.33%) cases abortion occurred in 3 doses of tab Miso, among them 5/30 (16.67%) cases from Group A, 3/30 (10%) cases from Group B. In total 31/60 (51.67%) cases abortion occurred in 4 doses of tablet Miso, among them 20/30 (66.67%) cases from Group A, 11/30 (36.67%) cases from Group B.

In total 21/60 (35%) cases abortion occurred in 5 doses of tab Miso, among them 5/30 (16.67%) cases from Group A, 11/30 (53.33%) cases from Group B. Median of total dose was 4 in Group A and 5 in Group B (Table 3). Out of 60 cases, 58 cases had successfully TOP and only two cases were included in failure category (one from each group) as they had to be taken up for surgery.

DISCUSSION

Misoprostol is widely used in combination with mifepristone for second trimester terminations. Since

mifepristone is comparatively costly so in low resource settings like our country to reduce the cost, to shorten the induction to abortion interval and to minimize the side effects of repeated doses of misoprostol, authors used intra cervical foley catheter in combination with vaginal misoprostol for mid trimester TOP.

Different studies have discussed various methods for induction of abortion in the second trimester, but there is still no agreement on the which is the most effective and safest way to induce abortion in mid-trimester cases having an unripe cervix.

TOP in second trimester despite being costly procedure and associated with higher risk as compared to first trimester abortion, is a necessity in today's time as due to advances in antenatal diagnosis, the decision to terminate gets delayed. There are the many methods, two popular methods used by modern obstetricians are vaginal misoprostol alone or use of cervical foley's catheter combined with misoprostol.

Table 4: Comparison between different studies.

Study	Duration from induction to expulsion of abortus in combined group (hours)	Duration from induction to expulsion of abortus in misoprostol group (hours)	Effectiveness
Ayman ²²	15.6±4.9	21.9±5.4	Significant result (p<0.05)
Toptas ¹⁹	9.50-15.33	11.33-17.25	Non-significant result (p 0.14)
Rezk ³¹	8.16±1.52	12.76±1.63	Significant result (p<0.001)
Farzana ³³	9.340±0.605	10.645±0.622	Non Significant result (p>0.05)
Present study	18.31±1.95	21.90±2.62	Significant result (p<0.0001)

This study was conducted on 60 pregnant cases in whom TOP was done between 14-20th weeks of gestation, they were divided into two groups (n=30, in each group). Allocation of cases into group was done on the basis of computer-generated randomized sequence. Allocation concealment was done by randomization. The purpose of this study was to compare the effectiveness of misoprostol alone and in combination with intracervical foley's catheter for medical termination of second trimester pregnancy. Duration from induction to expulsion of abortus, total dose of misoprostol and associated complication were noted.

In present study, total 60 pregnant women with indication for mid-trimester TOP were included. The mean and the standard variation of age was 22.63±2.47 years in Group A and 23.27±2.3 years in Group B, this result was comparable to the study of Subha et al (mean age 23.4±4.1 years).¹²

Mean gestational age in this study was 16.87±1.73 weeks in combined Group A and 17.09±1.8 weeks in misoprostol Group B which was comparable to the study

of Deepti et al.¹³ (mean gestational age was 17+7 weeks in misoprostol group and 17.8+6.2 weeks in combined group).

In this study 48.33% women were nulliparous, 41.67% women were primiparous and 10% of women were multiparous. This result of this study was similar to the study done by Afsheen et al (nulliparous 44.3%, primiparous 32.2% and multiparous 23.5%).¹⁴

In this study the indications observed for termination of pregnancy were missed abortion (51.67%), anencephaly (13.33%), other congenital abnormalities (26.67%) and contraception failure (8.33%). Indications of midtrimester TOP in the study conducted by Subha et al, were fetal demise in 64%, gross congenital anomaly in 32% and maternal indication in 4% women.¹²

Indication for TOP in another study of Afsheen et al, were intrauterine uterine death in 52.2% women, missed abortion in 36.5% and congenital abnormality of the fetus in 11.3% women.¹⁴

In present study effectiveness of combined group was statically significant ($p < 0.0001$). The duration from induction to abortion was 18.31 ± 1.95 hours in the combined group (Group A), 21.90 ± 2.62 hours in the misoprostol group (Group B).

This result was comparable to the study of Ayman et al, (duration induction to termination interval in combined group 15.6 ± 4.9 hours in combined group versus 21.9 ± 5.4 hours in misoprostol alone group; $p < 0.05$) and the study of Rezk et al, (duration from induction to abortion was 8.16 ± 1.52 hours in the combined group versus 12.76 ± 1.63 hours in the misoprostol group; p value < 0.001).^{15,16}

In some studies result was statically nonsignificant. These studies were Toptas et al, (induction to abortion interval was 11.33-17.25 hours in misoprostol alone group versus 9.50-15.33 hours in combined group; $p = 0.14$) and Farzana et al, (mean induction to expulsion interval was 9.340 ± 0.605 hours in combined group while it was 10.645 ± 0.622 hours in group of misoprostol alone; $p > 0.05$) (Table 4).^{17,18}

In this study success rate of TOP was 96.67% in each group and no major complications reported. In 88.33% cases no complication occurred with misoprostol and in 11.67% cases mild complications occurred (diarrhea in 71.43% women and fever in 28.57% women). Outcome of this study was comparable to the study of Rezk et al, in which success rate was 96% and no major complications reported.¹⁶

From the results obtained in this study, the combined use of intracervical foley's catheter and vaginal misoprostol is a safe, effective and acceptable method for termination of second trimester pregnancy. The use of foley's catheter with misoprostol for termination of pregnancy was cheaper and very convenient methodology for both patients and obstetricians. This study supports the use of misoprostol combine with foley's catheter.

CONCLUSION

Following conclusion are drawn from this study

- With the combined use of intravaginal misoprostol and intra cervical foleys catheter, there was significant reduction in the duration of abortion (induction to expulsion of abortus) than intravaginal misoprostol alone.
- Total required dose of misoprostol for termination of pregnancy was less with foleys and misoprostol combination than misoprostol alone.

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