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## Efficacy of vaginal misoprostol with mifepristone and misoprostol alone in the termination of pregnancy during second trimester

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### Abstract

**Background:** Abortions in second trimester is a major obstetric challenge and is considered to be less safe than first trimester abortions. Vaginal misoprostol with Mifepristone is an efficient modality in the second trimester abortions. This study was designed to assess the efficacy of misoprostol with mifepristone and misoprostol alone in the termination of pregnancy during second trimester.

**Materials and methods:** A total of 120 cases requesting abortion in their second trimester with gestation age 14-20 weeks were recruited. The study participants were randomly divided into two groups. Group 1 administered with vaginal misoprostol with mifepristone and group 2 administered with vaginal misoprostol alone.

**Results:** The mean interval between induction and abortion in group 1 was 8.74 hours and in group 2 was 11.98 hours. In group 1, complete abortion was seen in group 2, 65% showed complete abortion. Post-operative symptom like nausea, postoperative pain and vomiting were more common in group 2 than group 1. 100% cases where as in % success rate was seen in vaginal misoprostol with mifepristone group.

**Conclusion:** Mifepristone with misoprostol is showing dominant outcome than misoprostol alone in related to induction abortion interval, success rate and in the complete abortion rate.

**Keywords:** misoprostol, mifepristone, second trimester pregnancy, abortion, induction and abortion interval

### Introduction

Pregnancy termination during mid-trimester is controvertible and associated with more morbidity and mortality than when it is performed during the first trimester <sup>[1]</sup>. Methods available to terminate the pregnancy during second trimester are undergoing critical appraisal and scrutiny is still continuing for the safest, cost effective, optimal and easiest method <sup>[2]</sup>. Methods of MTP has gained attention and use of prostaglandin analogues is the trending scenario <sup>[3, 4]</sup>. Misoprostol, an inexpensive, stable analogue of prostaglandin E1 and is powerful in uterine contraction by binding to myometrial cells. It was extensively used during pregnancy termination at second trimester <sup>[5, 6]</sup>. Mifepristone, an anti-progestin which reduces the induction abortion interval <sup>[7]</sup>. Various drugs have been used either alone or in combination to terminate the pregnancy. This study was designed to assess the regimen composed of vaginal induced misoprostol with mifepristone and misoprostol alone in the termination of pregnancy during second trimester.

### Materials and Methods

The present prospective randomized comparative study was conducted in Department of Obstetrics and Gynaecology, MNR Medical College and Hospital and Government Medical College, Nizamabad during April 2018 to August 2019. A total of 120 cases requesting abortion in their second trimester were recruited. Cases with gestation age 14-20 weeks, with single foetus, full filling the MTP indicators and willing to undergo the procedure were included. Cases with contraindications to study drugs, intra uterine foetal death and undergoing the procedure along with other were excluded from the study. Informed consent was obtained from all the study participants and study protocol was approved by institutional ethics committee. Based on the drug administered, the study participants were randomly divided into two groups. Group 1 administered with vaginal misoprostol with mifepristone and group 2 administered with vaginal

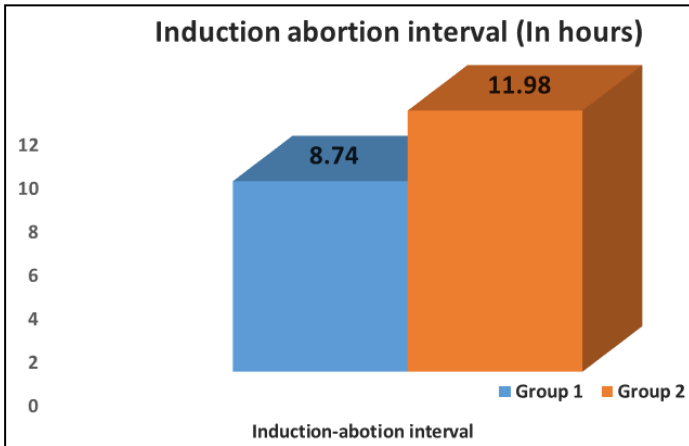
Misoprostol alone. In group 1, cases medicated with 200mg Mifepristone, followed by 800mcg misoprostol vaginally after 36 hours. After 3 hours, 400mcg vaginal misoprostol and continued for every 3 hours interval till delivery. In group 2, cases administered with 800mcg misoprostol vaginally followed by 400mcg vaginal misoprostol and continued for every 3 hours interval till delivery. Parameters like Induction abortion interval, success rate, outcome of abortion, postoperative side effects and details of misoprostol usage were studied. Outcome data was noted in Microsoft Excel and was analysed by using SPSS statistical tool version 20.0.

**Result**

The mean age of cases in group 1 was 25.2±3.38 and in group 2 was 25.7±3.62. Majority of the cases were belongs to age group 21-30 years.

**Table 1:** Details of parity and gestational age of study participants.

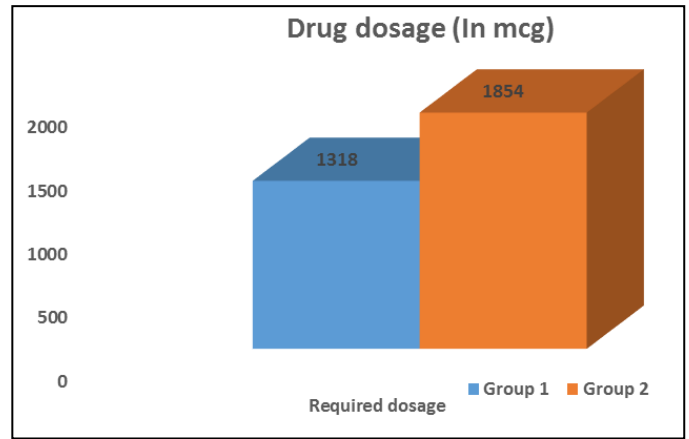
Parameters	Group 1 (n=60)		Group 2 (n=60)	
	Number	Percentage	Number	Percentage
<b>Gravida</b>				
Gravida 1	22	36.7%	18	30%
Gravida 2	16	26.7%	15	25%
Gravid 3 & above	22	36.6%	27	45%
<b>Gestational age (In weeks)</b>				
14-16	10	16.7%	08	13.3%
17-18	35	58.3%	38	63.3%
19-20	15	25%	14	23.3%



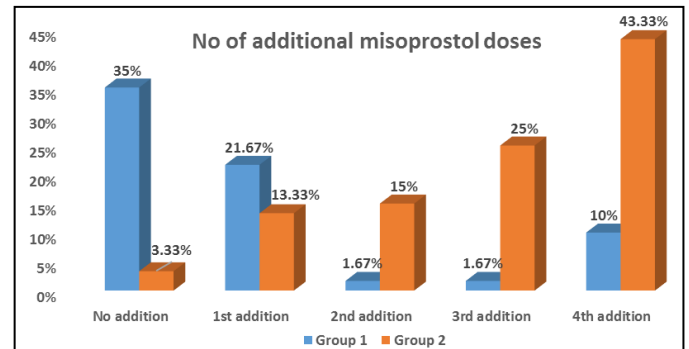
**Fig 1:** Duration between Induction and abortion (In hours)

**Table 2:** Duration of induction and abortion related to Parity, gestational age.

Parity	Group 1 (In hrs.)	Group 2 (In hrs.)
Gravida 1	10.56	13.58
Gravida 2	9.4	13.2
Gravida 3	7.02	11.7
Gravida 4	5.56	10.08
Gravida 5	5.2	8.55
p-value	0.0224	0.671
<b>Gestational age (In weeks)</b>		
14-16	10.64	12.31
17-18	8.26	12.65
19-20	8.04	13.28
p-value	0.324	0.712



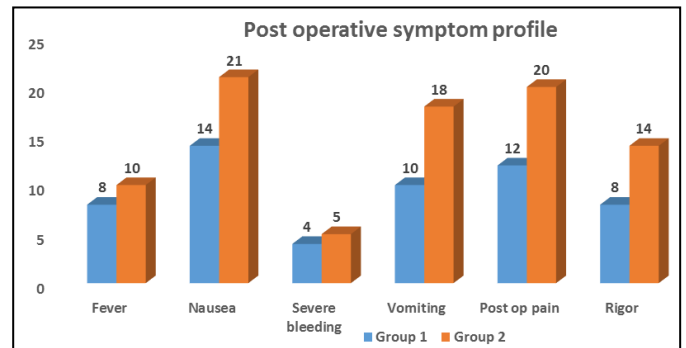
**Fig 2:** Details of amount of drug dosage required



**Fig 3:** Total number of misoprostol doses required for abortion

**Table 3:** Details of study outcome and success rates in both study groups

	Group 1	Group 2
<b>Study outcome</b>		
Full termination	52 (86.67%)	39 (65%)
Partial termination	08 (13.3%)	18 (30%)
Failed in termination	NIL	03 (5%)
<b>Study success rate</b>		
Within 12 hours	52 (86.67%)	21 (60%)
12-24 hours	08 (13.3%)	35 (58.3%)
>24 hours	NIL	01 (1.67%)
Failed in termination	NIL	03 (5%)



**Fig 4:** Post-operative symptom profile among two study groups

**Discussion**

Methods available to terminate the pregnancy during second trimester are undergoing critical appraisal worldwide [8]. This study was designed to assess the efficacy of misoprostol with mifepristone and misoprostol alone in the termination of pregnancy during second trimester. The mean age of cases in group 1 was 25.2±3.38 and in group 2 was 25.7±3.62. Study by Arunadevi and Geetha observed that the mean age

in mifepristone with misoprostol group was 24.9 years with 16-35 years range and in misoprostol alone group the mean age was 25.1 years with a range of 18-36 years<sup>[9]</sup>. Sreeja G R *et al.*, observed that the mean age 24.5 years. In mifepristone with misoprostol group majority cases were in between 25-30 years, whereas in misoprostol group more cases were in between 18-24 years<sup>[10]</sup>. In this study, case distribution based on gravidity showed that there was equal distribution of cases in gravida 1 (36.6%) and gravida 3 & above (36.6%). In group 2, 45% cases were gravida 3 & above followed by Gravida 1 (30%) and gravida 2 (25%) (Table 1). Cases distribution as per gestational age showed that in group 1, majority cases were between 17-18 weeks (58.3%) followed by 19-20 weeks (25%) and 14-16 weeks (16.7%). In group 2, 63.3% cases were in between 17-18 weeks of gestation followed by 23.3% cases between 19-20 weeks and 13.3% cases between 14-16 weeks. Study by Arunadevi and Geetha found that the mean gestation age in mifepristone with misoprostol group was 18.08 weeks and in only misoprostol group was 18.44 weeks<sup>[8]</sup>. Study by Sreeja G R *et al.*, observed that the mean maternal age in mifepristone with misoprostol group was 26.1 and in misoprostol group was 24.7<sup>[10]</sup>. Study by Dickinson E Jan *et al.*, found that the mean gestation age in mifepristone with misoprostol group was 19.1 weeks and in only misoprostol group was 19.6 weeks<sup>[11]</sup>. Study by Mrudula Karri *et al.*, found that the mean gestation age in mifepristone with misoprostol group was 17.14 weeks and in only misoprostol group was 17.86 weeks<sup>[12]</sup>. Study by Burman SK *et al.*, observed that the 40% cases between gestation age 8-10 weeks followed by 30% in 6-8 weeks and 30% in 10-12 weeks of gestation<sup>[13]</sup>. The mean duration between induction and abortion in group 1 was 8.74 hours and in group 2 was 11.98 hours (Figure 1). Study by Arunadevi and Geetha found that the mean induction abortion interval in mifepristone with misoprostol group was 8.2 hours and in misoprostol group was 12.8 hours<sup>[9]</sup>. Study by Jan E Dickinson found the mean induction abortion interval in group 1 was 8.6 hours and in group 2 was 15.5 hours<sup>[11]</sup>. Study by Mrudula Karri *et al.*, found mean induction abortion interval in group 1 was 9.08 hours and in group 2 was 17.86 hours<sup>[12]</sup>. Study by Meetali Mukund Khairnar *et al.*, found that the mean induction abortion interval in group A was 6.2±2.1 hours whereas in Group B it was 10.8±2.5 hours<sup>[14]</sup>. Study by Akkenapally PL found that the mean induction abortion interval in group A was 8-13 hours 28 minutes whereas in Group B it was 4.15 to 7.40 hours<sup>[15]</sup>. Study by Nigeria Tripti and Sirmor Namrata found that the mean induction abortion interval in group A was 2-13 hours and in group B was 5-21 hours<sup>[16]</sup>. Study by Premila W. Ashok and Templeton A found that the mean induction abortion interval in group A was 6.08 hours and in group B was 8.67 hours<sup>[17]</sup>. Study by Ngoc *et al.*, found that the mean induction abortion interval was shorter in mifepristone with misoprostol group (8.1 hours) than misoprostol group (10.6 hours)<sup>[18]</sup>. Study by Rasha *et al.*, found that the mean induction abortion interval in group A was 10.46 hours and in group B was 20.6 hours<sup>[19]</sup>. The total amount of drug dosage required in group 1 was 1318 mcg, whereas in group 2 was 1854 mcg (Figure 2). The number of additional dosage of misoprostol require in group 2 was more when compared to group 1 (Figure 3). Study outcome in group 1 showed that complete abortion was seen in 86.67% cases and partial termination in 13.3% cases, but none of the case had failure in the termination of pregnancy. In group 2, complete termination was seen in 65% cases, partial termination in 30% cases and in 5% cases abortion procedure was failed. Study by Sreeja G R *et al.*, observed complete abortion in 94% cases of group A and 86% cases in group B. Incomplete abortion was seen in 6% cases of group A and 8% cases in group B. No failure in group A but 6% cases had failure in the abortion<sup>[3]</sup>. Nausea<sup>[14]</sup>, postoperative pain<sup>[12]</sup> and vomiting<sup>[10]</sup> was common post-operative clinical symptoms in group 1. Similar symptoms was commonly seen in group B. But Post-operative complication was more common in group 2 than group 1.

### Conclusion

Mifepristone with misoprostol group is showing dominant outcome than misoprostol alone group in related to induction abortion interval. The success rate in group 1 was 100%, complete abortion rate was more in group 1, post-operative side effects were less in group 1 than group 2 and success rate was taken less duration (<12 hours) in group 1 than

group 2. Above finding concluding that Mifepristone with vaginal misoprostol group is efficient in termination of pregnancy during second trimester than misoprostol alone.

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