

Second Trimester Abortion with Vaginal Misoprostol: Is There Any Advantage with Prior Mifepristone Priming? A Comparative Study

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ABSTRACT

Objective: Second trimester medical termination of pregnancy (MTP) can be done by surgical or nonsurgical methods or by various combinations of the two. Every method has its advantages and disadvantages. An ideal method would be one which was safe, quick and 100% effective, inexpensive and without any immediate or late side-effects. However, in the absence of such, various methods in synergistic combinations have been tried to come close to an ideal method. The successes of medical method now appear to be useful in MTP even in second trimester of pregnancy. Our objective is to investigate the effectiveness of only vaginal misoprostol and compare with oral mifepristone plus vaginal misoprostol in second-trimester induction abortions (≥ 12 and ≤ 20 weeks).

Methods: The patients are selected after careful examination and necessary investigations were divided into group A (n = 62) which received 400 μg of vaginal misoprostol followed by 200 μg vaginal misoprostol 4 hourly till expulsion of fetus or a maximum dose of 2000 μg and group B (n = 60) which received 200 mg of oral mifepristone followed 48 hours later by vaginal misoprostol as in group A. Main outcomes measured were efficacy, blood loss, induction-abortion interval and complication.

Results: The present study showed that the both methods were effective in 2nd trimester MTP. Average blood loss was lesser in group B (131.66 ml) compared to group A (150 ml). Induction abortion interval was shorter in group B (6.62 hours) than in group A (12.19 hours). Ninety percent of group B and 80.7% of group A had no complications. Success rate was higher in group B.

Conclusion: Therefore, in our study, pretreatment mifepristone followed by misoprostol was found to be a very effective regimen for 2nd trimester abortion with lesser complications and higher efficacy.

Keywords: 2nd trimester, Misoprostol, Mifepristone, Induction-abortion interval.

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INTRODUCTION

According to the MTP Act, medical termination of pregnancy (MTP) in India is allowed up to 20 weeks. However, there is no ideal method for MTP between 13 and 20 weeks resulting more unsafe abortion during this period. Worldwide 42 million legal abortion¹ and 10 to 12 million clandestine abortion takes

place every year,² of which 10 to 15% is performed in second trimester. In India alone, 6.7 million induced abortions occur annually, of which late abortions constitute 10.7 to 15%.³ Though second trimester abortion accounts for a small percentage of all induced abortion, it is associated with high rate of morbidity. Two-thirds of major abortion related complications and half of abortion related mortality occur in pregnancies terminated after 13 weeks of gestation.⁴ Previously various methods, medical or surgical, either alone or in combination were used to perform MTP in second trimester with their complications. However, there is a constant search going on for an ideal method. For second trimester medical termination of pregnancy, the optimal regimen is still under development but is likely to be characterized by a short induction abortion interval (I-A-I), devoid of any serious side effect, high acceptability, easy to perform and cost-effective. Medical method in second trimester MTP is found to be effective. Our objective is to investigate the effectiveness of only vaginal misoprostol and compare with oral mifepristone plus vaginal misoprostol in second-trimester induction abortions (≥ 12 and ≤ 20 weeks).

MATERIALS AND METHODS

The study was conducted at Gynecology and Obstetrics Department of Medical College and Hospital, Kolkata, from 1st January 2010 to 31st June 2011. It was a prospective randomized study. 122 women ≥ 12 and ≤ 20 weeks of gestation with a valid legal indication for termination of pregnancy as per MTP Act were taken for the study. In all cases, written informed consent was taken and duration of pregnancy was confirmed by history, clinical and sonological examination. Women with anemia, bleeding disorders, suspected ectopic and molar pregnancy, pelvic infection and congenital malformation of uterus were excluded from the study. Cases such selected were randomly divided into two groups: Group A (n = 62) and group B (n = 60). Randomization was done using a table of random numbers. Group A received 400 μg vaginal misoprostol followed 4 hourly by 200 μg till expulsion of fetus or a maximum dose of 2000 μg . Group B received 200 mg of oral mifepristone followed 48 hours later by vaginal misoprostol as in group A (midnight doses were omitted in both groups). Vital signs were monitored every 4 hours. Fever, chest pain, breathing difficulty, vomiting and diarrhea were recorded. Blood loss was quantified by measuring cup. The parameters studied were induction abortion interval, completeness of procedure, failure of abortion, side effects, and cost per procedure. Failure of procedure was defined as failed expulsion of the fetus at 48 hours or the occurrence of systemic adverse

signs and symptoms severe enough to preclude further use of the drug. The induction abortion interval was defined as time from intake of 1st dose of misoprostol to abortion. Hemorrhage was defined as an estimated blood loss exceeding 500 ml or a need for blood transfusion. Fever was defined as a temperature of 38°C or more occurring 24 hours or more after pregnancy termination. Check curettage was done when required. Statistical analysis was carried out using Epi Info statistical software. $p < 0.05$ was considered as significant.

OBSERVATIONS

A total of 122 patients were divided into group A ($n = 62$) who received vaginal misoprostal and group B ($n = 60$) which received oral mifepristone plus oral misoprostal. Both the groups had similar parity and gestational age distribution (Table 1). Mean requirement of misoprostol in group B was 613.33 μg whereas in group A was 870.96 μg (Table 2). So requirement of misoprostol was much less in group A and this was statistically significant ($p\text{-value} = 0.004$). Induction abortion interval (Table 3) was also significantly less in group B compared to group A (6.61 hours vs 12.19 hours). Average blood loss was 150 ml in group A whereas it was 131.66 ml in group B (Table 4). Group B had lesser complications and adverse effects than group A. Ninety percent of group B and 80.70% of group A had no complications (Table 5). There was

Table 1: Comparison of gestational age and parity

	Gestational age (days)		Parity	
	Mean	SD	Mean	SD
Group A	113.3548	16.6564	2.5161	1.2061
Group B	111.5333	15.0991	2.4000	1.3025

Table 2: Comparison of total dose of misoprostol (μg) required

Determinants	Group A ($n = 62$)	Group B ($n = 60$)
Mean	870.9677	613.333
SD	250.5907	156.9831

Table 3: Comparison of induction abortion interval (hours)

Determinants	Group A ($n = 62$)	Group B ($n = 60$)
Mean	12.1917	6.6167
SD	3.9614	2.3413

Table 4: Comparison of blood loss (ml)

Determinants	Group A ($n = 62$)	Group B ($n = 60$)
Mean	150	131.6667
SD	105.0451	62.2610

Table 5: Comparison of complications (%)

Adverse effects	Nil	Fever and vomiting	Diarrhea	Fever	Vomiting	Rupture
Group A	80.7	3.2	3.2	9.7	3.2	0
Group B	90	0	0	3.3	6.7	0

Table 6: Comparison of success and failure rates

	Group A ($n = 62$)	Group B ($n = 60$)
No. of failure cases	1	0
Failure rate	3.23%	0%
No. of successful cases	61	60
Success rate	96.77%	100%

nine cases (14.51%) incomplete abortion in group A and 6 (10%) cases in group B, surgical evacuation done in these cases. It is to be noted that the success rate of group B was 100% and that of group A was 96.77% (Table 6).

DISCUSSION

Abortion is defined as termination of pregnancy by any means before the fetus is viable. In our study, a total of 122 patients of gestation ≥ 12 and ≤ 20 weeks were taken and divided into two groups—group A ($n = 62$) received vaginal misoprostol only whereas group B ($n = 60$) received oral mifepristone followed by vaginal misoprostol.

In our study, the success rate of group A was 96.77% which is comparable to the findings of Tang et al, 2004⁵ and Bhattacharya et al, 2006.⁶

Success rate in group B was 100% which is similar to the findings of Mittal et al 2009⁷ who reported a success rate of 99.3%.

The present study showed that total amount of misoprostol required was significantly less in group B ($613.33 \pm 156.98 \mu\text{g}$) compared to group A ($870.96 \pm 250.59 \mu\text{g}$).

Similar findings were reported by Bartly et al, 2002;⁸ Ashok et al, 2004⁹ and Tang et al, 2005.¹⁰

In our study induction abortion interval was shorter in group A is 12.19 ± 3.96 hours in comparison to group B 6.61 ± 2.34 hours. Tang et al¹⁰ also found the median duration 8.7 hours of treatment in the mifepristone/misoprostol group.

Average blood loss was also lesser in group B (131.66 ± 62.26 ml) compared to group A (150 ± 105.04 ml). Ninety percent of group B and 80.7% of group A patients had no complications. There were no cases of rupture uterus in either group.

The cost of therapy was higher in group B ($\text{₹ } 890.40$) compared to group A ($\text{₹ } 390.65$).

In our study, it is evident that group B-mifepristone and misoprostol regimen had shorter induction interval, lesser complications and higher success rate.

CONCLUSION

Medical abortion in the second trimester using the combination of mifepristone and misoprostol appeared to have the highest efficacy and shortest abortion time interval.¹¹ Our study also has the same opinion that the combination of 200 mg

mifepristone and vaginally administered misoprostol is a safe, effective and noninvasive regimen for termination of pregnancy between 12 and 20 weeks. More stress should be given on efficacy and one should not compromise efficacy for the cost.

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