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Original Research Article

## Prospective study to compare the efficacy of vaginal misoprostol for first trimester MTP before six weeks and up to 9 weeks

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### ABSTRACT

**Background:** Misoprostol is prostaglandin E1 analogue that has been used for medical abortion. MTP has been legalized in India since 1971. Medical abortion refers for early pregnancy termination performed without any primary surgical interventions, usually before 9 weeks (63 days) gestational age. This prospective study was conducted to compare the efficacy of vaginal misoprostol for abortion in women at a gestational age of <6 weeks (42 days) and in woman up to 9 weeks (63 days) gestational age.

**Methods:** This is a prospective study of total 130 women seeking medical termination of pregnancy up to 9 weeks (63 days) gestational age at obstetrics and gynecology department, at a tertiary care hospital Gujarat, India, from May 2018 to May 2019.

**Results:** In result study the overall complete abortion rate was 91.54% In Group A (<6 weeks) complete abortion occurred in 93.3% women. Whereas in Group B (6 to 9 weeks) complete abortion occurred in 90% of women. The two groups did not differ significantly with respect to side effects. Overall, 91.3% women were satisfied with this method and will choose it again if required.

**Conclusions:** This study shows that vaginal misoprostol alone regimen is highly effective and well tolerated method in Indian women requiring MTP up to 63 days gestational age. However better efficacy maybe achieved at gestational age < 6 weeks (42 days).

**Keywords:** MTP, Abortion, Misoprostol

### INTRODUCTION

MTP act has been implemented in India in 1971. The term medical abortion refers to early pregnancy termination (Usually before 9 weeks gestational age (63 days)). Performed without primary surgical intervention and resulting from the use of abortion inducing medication. Some women choose medical abortion especially at a younger age or those who have not yet had their own family.<sup>1</sup> The main advantage of medical abortion is that it allows women to avoid the risk of surgery and anaesthesia. Misoprostol is a prostaglandin E1 analogue that has been initially used for the treatment

and prevention of gastric ulcer disease.<sup>2</sup> In addition misoprostol has been investigated as an agent to induce abortion by other clinicians.<sup>3-5</sup>

The administration of misoprostol along with mifepristone is highly effective for first trimester medical abortion with efficacy rates ranging from 92 to 97%.<sup>6-8</sup> Misoprostol has also been used alone for medical abortions with variable efficacy by different clinicians.<sup>6-8</sup> In December 2008 mifepristone + misoprostol (1 tablet of mifepristone 200 mg and 4 tab of Misoprostol 200 mcg each) was approved by central drugs standard control organization, directorate general of health services for the

medical termination of pregnancy (MTP) for upto 9 weeks (63 days) gestation.<sup>9</sup> As per the MTP law of India abortion pills can only be prescribed by registered medical practitioners.<sup>10</sup> We conducted this prospective study to compare the efficacy of vaginal misoprostol (upto 2 - 800 mcg doses) for MTP in women at gestational age of 42 to 63 days. Misoprostol is a synthetic prostaglandin E1 analogue and because of its uterotonic and cervical ripening actions is also widely used for various gynecological and obstetrical purposes such as cervical ripening and induction of labour, for pre-treatment of the cervix prior to surgical termination of pregnancy and in combination with mifepristone for medical abortion.<sup>11</sup>

## METHODS

From May 2018 to May 2019 130 women (Age range 18-30 years) who required MTP of < 9 weeks (63 days) were recruited for a prospective study that has been approved by institutional ethics committee.

### Inclusion criteria

Pregnant married women having age >18 years, pregnant women request for MTP, Women with live intrauterine pregnancy upto 63 days gestational age confirmed by ultrasonography (TVS), Parity <3. Prior starting of study written consent obtained from all participants with explanation about the possible risks and benefits of medical abortion with the understanding that there would be a surgical abortion if the medical abortion failed and also about the bleeding and some abdominal pain after taking the treatment. Also willingness to come for the revisit and blood tests if required.

### Exclusion criteria

Pregnant women more than 63 days gestational age, known allergy to the drug, severe anaemia (Hb <9 gm), history of cardiac, respiratory, renal, hepatic or adrenal disease, history of thrombo-embolism, hypertension, coagulopathy and diabetes mellitus.

Three clinical visits were scheduled:

*Visit 1:* At day 1, the women received 4 - 200 mcg tab (800 mcg) of Misoprostol inserted in the posterior vaginal fornix through a speculum. The Women remained recumbent for 30 minute in the clinic prior to discharge. All participants were given Prophylactic tab DCMol (Combination of Dicyclomin 20 mg + Paracetamol 500 mg) upto 3 tab per day depending on pain intensity.

*Visit 2:* On day 3 all subjects underwent examination by TVS to assess treatment success. A second dose of Misoprostol (800 mcg) was given if a gestational sac was still present or any signs of incomplete abortion.

*Visit 3:* On day 14, all subjects returned to evaluate expulsion of products conception. If expulsion was not complete subjects were offered vacuum aspiration. Efficacy rates were determined as complete abortion rate, incomplete abortion rate or no response rate observed at day 14. The participants were asked to keep a symptom log of abdominal cramping, vaginal bleeding, nausea, vomiting, diarrhoea, headache and fever.

Patient satisfaction was evaluated by questioning the women on whether they feel this procedure unsatisfactory, satisfactory or very satisfactory and also whether they would choose this method again.

## RESULTS

The characteristics of the 130 subjects are presented in Table 1. Total subjects divided in two groups A and B. In Group A patient with <6 weeks (42 days) included. In Group B patient with <9 weeks (63 days) included. In Group A complete abortion occurred in 93.3% cases whereas in Group B complete abortion occurred in 90% cases. Significant differences in abortion rates were observed after first and second dose of misoprostol. In Group A 36 Women received one dose of Misoprostol (60%) and 24 Women received two doses of Misoprostol (40%). In Group B 30 Women received one dose (43.2%) and 40 Women received two dose (66.8%).

**Table 1: Patient characteristics.**

	Group A (n=60), Gestation <42 days	Group B (n=70), Gestation <63 days
<b>Age (in years)</b>		
18-20	15	20
20-25	32	35
25-30	13	15
<b>Parity</b>		
0	11	14
1	33	40
2	16	16
Mean gestational age (days)	36	55

**Table 2: Complete abortion rate after each dose of misoprostol and failure rate.**

	Group A	Group B	Total (%)
<b>After 1st dose</b>	36	30	50.76%
<b>After 2nd dose</b>	24	40	49.23%
<b>Failure rate</b>	4	7	8.46%

Suction curettage was arranged for 4 women (6.7%) in Group A and 7 women in Group B (10%). Medical abortion failure cases for each group are listed in table 3. The main indication for suction curettage was incomplete abortion. The incidences of all reported side effects are shown in table 4. The two groups did not differ significantly with respect to side effects. Overall, most of the women were satisfied with the method and would choose it again if required as avoiding the risk of surgery and anesthesia seemed attractive. However, the duration of the protocol and the serial examinations remained a problem.

**Table 3: Causes of medical abortion failure.**

	Group A	Group B
<b>Number of Failure</b>	4	7
<b>Causes of Failure</b>		
<b>No Effect</b>	0	1
<b>Incomplete abortion</b>	4	5
<b>Excessive Bleeding</b>	0	1

**Table 4:**

Side Effects	Group A	Group B	Total
<b>Abdominal pain</b>	56	61	90%
<b>Vaginal bleeding</b>	49	62	85%
<b>Nausea / vomiting</b>	20	23	32%
<b>Headache / fever</b>	15	17	25%
<b>Sleeplessness</b>	2	4	5%
<b>Loss of appetite</b>	5	8	10%

## DISCUSSION

For first trimester medical abortion misoprostol along with mifepristone or methotrexate used extensively.<sup>6-8</sup> In India drug controller general of India approved the use of mifepristone in April 2002 and misoprostol in December 2006. For termination of pregnancy upto 49 days gestational period and in 2008 they extended use of this combination upto 63 days.<sup>12</sup>

In India as per the guidelines medical abortion is offered only to those patients who are ready for minimum 3 follow up visits, can understand the instruction, ready for surgical procedure if failure or excessive bleeding, good family support and easy access to appropriate health care facility.<sup>13</sup> The main advantage of medical abortion is that it allows women to avoid the risks of surgery and anesthesia. In this prospective study we found that doing MTP using vaginal misoprostol alone has 95% efficacy in women with gestational age <6 weeks (42 days) and 87% efficacy in women with gestational age of 42 - 63 days. It

has been reported that the efficacy of vaginal misoprostol decreases as pregnancy advanced.<sup>7</sup> In contrast to our findings previous studies have shown that the efficacy of the vaginal misoprostol is not affected by the duration of pregnancy.<sup>8,11,14</sup> The discrepancy in our findings may be due to our patient selection as we have excluded patient having history of prior elective abortion and parity of >3. In addition we also offer them surgical intervention after 14 days of waiting but abortion might have occurred later.<sup>15-17</sup> The two groups did not differ significantly with respect to side effects. One woman received blood transfusion and three women received emergency curettage because of heavy bleeding in Group B. Various studies shows these complications are uncommon.<sup>18</sup> One study also shows that 1% of patient undergoing medical abortion will need emergency curettage because of heavy bleeding.<sup>19-20</sup> In both group abdominal pain and nausea, vomiting like complaints was well tolerated by medication like paracetamol and metaclopramide.<sup>11</sup> Sleeplessness and loss of appetite could be due to disturbed mental health of women undergoing abortion.

## CONCLUSION

The Vaginal Misoprostol alone regimen is highly effective and cheap remedy for women seeking medical abortion of pregnancies <63 days which also avoids surgical and anaesthesia related complications. Misoprostol related gastrointestinal side effects were minimal and well treated by medication. In rural India where illiteracy and unacceptability about contraception is prevalent, this method of medical abortion gives excellent results. This method should be used as early as possible of diagnoses of pregnancy as our study shows better efficacy after this method at a gestational age of <42 days.

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