

A Comparative Analysis of Sublingual v/s Vaginal Misoprostol for Second Trimester Termination of Pregnancy: An Institutional Based Study

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ABSTRACT

Introduction: The term "Abortion" can be defined as a termination of pregnancy before the period of viability which usually occurs at around 20 weeks of gestation and the foetus weighing approximately 500 g. Globally, around 40-60 million abortions take place per year. Medical abortion is a safe backup option to surgical methods. In the year 1971, MTP was legalized in India. Study indicate that 46 million pregnancies are voluntarily terminated each year, 26 million happen legally and 20 million outside the legal system through loopholes. There are various medical and surgical methods of providing abortion care. Medical method is the preferred mode as it does not include late surgical complications like cervical insufficiency and complications related to anaesthesia.

Materials and Methodology: This study was a prospective comparative study which was planned to be conducted at the Department of Obstetrics & Gynaecology, Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur, Rajasthan, India. Eighty women who had fulfilled the inclusion criteria were included as the study participants. All of them had ideal indications as per MTP act. Detailed case history, physical examination, ultrasonography and blood investigations were carried out for all women who were included in the study. Informed written consent was obtained from all the participants. Eighty women were then divided in two groups, there were 40 women in each sublingual and vaginal group. Each group received 400mcg misoprostol every fourth hourly for a maximum of five doses (2000mcg). When observed, if women failed to abort after four hours of the last dose of misoprostol, oxytocin augmentation was given additionally. The number of doses of misoprostol used, the induction-abortion interval, need of instrumental evacuation were all studied.

Results: The mean age in the sublingual group and vaginal group were 26.9 and 28.9 years respectively and the mean gestational age was determined at 15.5 weeks and 14.8 weeks respectively. No statistically significant difference was found between the two groups in terms of parity and previous

abortions. the vaginal group. No statistically significant difference was observed regarding induction-abortion interval between the two groups. Most of the women in the sublingual group (71%) and vaginal group (71%) required 3-4 doses of misoprostol. The mean number of doses of misoprostol was 3.97 and 3.94 in the sublingual and vaginal group respectively. The mean dose of misoprostol in the sublingual group was 1593mcg and 1581mcg in the vaginal group. In the sublingual group, it was found 70% of women had complete abortion and 8% required instrumental evacuation. In the vaginal group 67.5% of them had complete abortion and 5% needed instrumental evacuation. Statistically no significant difference was found in the efficacy of the drug. Misoprostol was almost equally effective in both the routes followed in the study.

Conclusion: Misoprostol when administered alone either sublingually or vaginally is an effective and efficient drug for the medical termination of pregnancy during second trimester. Sublingual route is preferably better because of its high acceptability, short induction abortion interval, more efficacies with more patient comfort due to the route of administration and fewer adverse effects.


Keywords: Misoprostol, Medical Termination, Second Trimester.

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INTRODUCTION

The term "Abortion" can be defined as a termination of pregnancy before the period of viability which usually occurs at around 20 weeks of gestation and the foetus weighing approximately 500 g. Globally, around 40-60 million abortions take place per year.

Medical abortion is a safe backup option to surgical methods. In the year 1971, MTP was legalized in India.¹ Study indicate that 46 million pregnancies are voluntarily terminated each year, 26 million happen legally and 20 million outside the legal system

through loopholes.² Moreover, second trimester pregnancy loss is the most common obstetrics problem, which is a stressful event for both physicians as well as the patients.³ Appropriate management at that time can help to limit the distress caused. Earlier the protocol followed was surgical dilatation and curettage or vacuum aspiration which is effectively replaced nowadays with prostaglandins which are a widely used in the medical practice.⁴ Among the group of prostaglandins, Misoprostol (prostaglandin E1 analogue) is the drug of choice for cervical ripening, labour induction, post-partum haemorrhage as well as second trimester terminations.⁵ Stability of the drug at room temperature, low cost and ease of commercial availability make its administration simple and much more common.^{6,7}

Two most common routes of misoprostol administration are sublingual and vaginal; but each one has different pharmacokinetics and effectiveness. Sublingual misoprostol reaches its peak concentration in a short time due to rapid absorption and has higher bioavailability when compared whereas the vaginal route causes more prolonged regular uterine contractions.⁸ Moreover, the vaginal route has less adverse effects such as nausea, vomiting and diarrhoea after administration when compared to sublingual route of administration.⁹

There are various medical and surgical methods of providing abortion care. Medical method is the preferred mode as it does not include late surgical complications like cervical insufficiency and complications related to anaesthesia. Most women globally prefer the medical method due to its cost-effectiveness and the response rate to the treatment as well.^{10,11} Due to its potential complications, it is advisable that second trimester terminations

take place in a hospital care facility where blood transfusion and emergency services are available readily.¹¹

Hence, this study was undertaken to compare the efficacy of misoprostol when administered through sublingual and vaginal route for second trimester abortion. The induction-abortion interval was also studied along with.

MATERIALS AND METHODOLOGY

This study was a prospective comparative study which was planned to be conducted at the Department of Obstetrics & Gynaecology, Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur, Rajasthan, India.

Eighty women who had fulfilled the inclusion criteria were included as the study participants. All of them had ideal indications as per MTP act.

Exclusion criteria include women with a history of medical disorders and drug allergy, multiple pregnancies, those had more than one previous caesarean delivery. Detailed case history, physical examination, ultrasonography and blood investigations were carried out for all women who were included in the study. Informed written consent was obtained from all the participants. Eighty women were then divided in two groups, there were 40 women in each sublingual and vaginal group. Each group received 400mcg misoprostol every fourth hourly for a maximum of five doses (2000mcg). When observed, if women failed to abort after four hours of the last dose of misoprostol, oxytocin augmentation was given additionally. The number of doses of misoprostol used, the induction-abortion interval, need of instrumental evacuation were all studied. Statistical analysis was done using Chi-square test and Fisher's test.

Table 1: Patient characteristics

Parameters	Sublingual (n=40)	Vaginal (n=40)
Mean age (years)	26.9	28.9
Parity (%)		
Primi	12 (30%)	13 (32.5%)
Multi	28 (70%)	27 (67.5%)
Mean gestation (SD)	15.5	14.8
Previous abortions (%)		
Yes	10 (25%)	8 (20%)
No	30 (75%)	32 (80%)

Table 2: Efficacy of misoprostol

Parameters	Sublingual (n=40)	Vaginal (n=40)
Efficacy (%)		
Complete abortion	28 (70%)	27(67.5%)
Incomplete abortion	12(30%)	13(32.5%)
Induction-abortion Interval		
12 – 16 hrs	13(32.5%)	14(35%)
16 – 20 hrs	15(37.5%)	15(37.5%)
20 – 24 hrs	8(20%)	6(15%)
>24 hrs	4(10%)	5(12.5%)
Number of misoprostol doses		
3	13(32.5%)	14(35%)
4	16(40%)	15(37.5%)
5	11(27.5%)	11(27.5%)
Mean dose of misoprostol (mcg)	1593	1581

RESULTS

The mean age in the sublingual group and vaginal group were 26.9 and 28.9 years respectively and the mean gestational age was determined at 15.5 weeks and 14.8 weeks respectively. No statistically significant difference was found between the two groups in terms of parity and previous abortions which was given in Table 1. the vaginal group. No statistically significant difference was observed regarding induction-abortion interval between the two groups.

Most of the women in the sublingual group (71%) and vaginal group (71%) required 3-4 doses of misoprostol. The mean number of doses of misoprostol was 3.97 and 3.94 in the sublingual and vaginal group respectively. The mean dose of misoprostol in the sublingual group was 1593mcg and 1581mcg in the vaginal group. In the sublingual group, it was found 70% of women had complete abortion and 8% required instrumental evacuation. In the vaginal group 67.5% of them had complete abortion and 5% needed instrumental evacuation. Statistically no significant difference was found in the efficacy of the drug. Misoprostol was almost equally effective in both the routes followed in the study.

DISCUSSION

International Federation of Gynaecology and Obstetrics (FIGO) highly recommends the use of misoprostol alone at a dose of 400mcg at every three hours interval till the expulsion of conception products between 13 and 26 weeks of gestation.¹² By the use of misoprostol, MTP can be effectively performed and it also recommends use of misoprostol in certain pregnancy with earlier uterine scar. Most of the women included in our study were multigravidae.

*Niinimaki et al*¹³ found out that increase in the parity may reduce the induction-abortion interval. *Bhandekar et al*¹⁴ did a study comparing oral versus vaginal route of misoprostol administration in which they also used 400mcg misoprostol every fourth hourly for a maximum of five doses, like in our study. They found a significant difference in the induction-abortion interval between the two groups. Women included in the vaginal group took less time (18.574 hr) when compared to the oral group (19.59 hr). They also found that the mean number of doses of misoprostol (3.93) used was also less in the vaginal group than oral route. *Tanha et al* found no difference between sublingual and vaginal group in terms of efficacy of misoprostol and also in the mean dose of misoprostol used (1340mcg).¹⁵ Our study also shows identical results between sublingual and vaginal groups but the mean dose in our study was approx 1593mcg. *Kaur et al*¹⁶ concluded that sublingual route was more effective than vaginal route for ripening of the cervix in first trimester abortions.

*Ganguly et al*¹⁷ studied that the failure rate was highest with the oral route and least with sublingual route. In their study, they used 400mcg misoprostol every 6th hourly for a maximum of 4 doses. They compared oral, sublingual and vaginal routes of misoprostol. Induction-abortion interval was least with sublingual route. The same results were obtained in our study also which showed no significant difference in induction-abortion interval between the sublingual and vaginal groups. *Milani et al*¹⁸ found that the abortion interval was calculated shorter with the sublingual route and the patients preferred the sublingual route over the vaginal route. *Farhadifar et al*¹⁹ concluded in their double-blind control study that the efficacy of oral and vaginal misoprostol was similar.

Curettage rate was higher in the vaginal group. Based on our study, we conclude that misoprostol can be used by either sublingual or vaginal route for effective second trimester pregnancy termination. Both routes are almost equally effective and safe to be used in the second trimester MTP.

A study by *Tang et al*²⁰ where 18 cases were administered with misoprostol 200 ug, administered 3-hourly sublingually demonstrated 100% success rate with a mean induction abortion interval (12 ± 3.6 hours). Same study showed that the sublingual misoprostol in gestational age 38C in Vaginal route. *Shah et al*²¹ researched about role of vaginal misoprostol for second trimester termination. They found that it is effective and time saving drug which is very useful in second trimester abortion. 96.6% women aborted within 20 hours. Mean Induction abortion interval was 9.43 hours with very low drug related side effects. *Milani et al*¹⁸ reported similar results same as in our study. *Dickson et al*²³ studied oral, vaginal and sublingual misoprostol for second trimester abortion. They found that vaginal or sublingual misoprostol was administrated after vaginal loading dose in second trimester abortion with Mifepristone is also reported to be associated with a shorter time to pregnancy termination compared with an oral route.

CONCLUSION

Misoprostol when administered alone either sublingually or vaginally is an effective and efficient drug for the medical termination of pregnancy during second trimester. Sublingual route is preferably better because of its high acceptability, short induction abortion interval, more efficacies with more patient comfort due to the route of administration and fewer adverse effects.

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