



COMPARISON OF SUBLINGUAL VERSUS VAGINAL MISOPROSTOL 600 µg FOR CERVICAL RIPENING IN FIRST TRIMESTER ABORTION

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ABSTRACT

Objectives: Comparing sublingual and vaginal misoprostol 600 µg for cervical ripening in first trimester pregnancy termination. **Materials and methods:** 200 women of first trimester pregnancy for termination were randomly divided in two groups. The first group received 600 µg sublingual misoprostol and vaginal placebo and the second group received 600 µg vaginal misoprostol and sublingual placebo before evacuation. **Results:** The mean time taken for cervical ripening was less in sublingual (2.80±0.80 hrs) as compared to the vaginal (4.10±1.20 hrs) route and it was statistically significant ($P < 0.0001$). **Conclusion:** sublingual misoprostol is better than the vaginal route for cervical ripening.

KEYWORDS : Misoprostol, Sublingual, Vaginal, First Trimester Termination

Introduction

The most essential step in vacuum aspiration (VA) is Cervical dilatation. Prostaglandins (PGs) are more effective over mechanical methods in cervical dilatation [1] [2]. Although misoprostol (PGE₁) was first introduced as a gastric ulcer protective agent, it became popular for its effect on non-traumatic cervical ripening. Misoprostol is a PGE₁ analogue available in a tablet form that is stable at room temperature, inexpensive and available in different dosage forms [3]. Comparative studies of sublingual and vaginal misoprostol for cervical ripening have been carried out in different dosages [4–7]. The present study was carried out to compare the effectiveness of 600 µg of misoprostol through sublingual and vaginal routes for cervical ripening in first trimester abortion prior to VA.

Materials and methods:

This study was a randomized, prospective double blinded study. It was done at KAPV Govt medical college hospital from February 2015 to August 2015 after approval from the Medical Ethics Committee. Informed consent was obtained from the patients. All first trimester abortions including medical, threatened, incomplete and missed abortion were included. Ultrasonography confirmed the clinical diagnosis. Subjects with history of previous uterine surgery, contraindications to prostaglandins, hemoglobin < 9 g/dl were excluded.

200 Women were randomly assigned to group A and B (100 patients in each group)

Group A - received 600 µg sublingual misoprostol and vaginal placebo
Group B - received 600 µg vaginal misoprostol and sublingual placebo

the effects were noted at 1-2 h interval

The two groups were assessed for efficacy of cervical dilatation measured with Hegar's dilator. The severity of preoperative abdominal pain experienced by the subject was assessed as Score 1 - no pain, Score 2 - mild pain and Score 3 - severe pain requiring analgesics. Preoperative vaginal bleeding ranging from 0 to 3 (0 for no bleeding, 1 for minimal spotting, 2 for bleeding like menstrual flow, and 3 for severe bleeding) were noted [8]. The abortion was carried out by suction evacuation under general anesthesia. Their pulse rate, BP, temperature and other side effects associated with misoprostol were recorded.

The patients were discharged from the hospital 3-4 h after the completion of the procedure if all the parameters were normal and no complication observed.

Data are expressed as mean ± standard deviation. All outcomes were assessed using Chi-squared test and independent t-test, $P < 0.05$ was considered statistically significant. statistical analyses were done using SPSS version 16.0 statistical software.

Results:

Demographic characteristics and obstetric profile of both the groups

were comparable (Table 1).

	Group A (sublingual)	Group B (vaginal)	P value
Age(years)	28.50±4.8	27.70±6.20	>0.05
Gravida	2.20±1.20	2.50±0.70	>0.05
Parity	1.20±1.00	0.90±1.10	>0.05
Gestational Age(weeks)	9.10±2.1	8.70±2.60	>0.05

The mean time taken for Cervical ripening was significantly lower in the Sublingual group (2.80±0.80) compared to vaginal group (4.10±1.20) ($P < 0.0001$). The sublingual group had significant cervical dilatation ($P < 0.0001$) and less time duration for procedure ($P < 0.0001$) as compared to the vaginal group. (Table 2).

	Group A (sublingual)	Group B (vaginal)	P value
Time taken for Cervical ripening(h)	2.80±0.80	4.10±1.20	<0.0001
Cervical dilatation(mm)	9.10±1.20	8.40±0.70	<0.0001
Duration of procedure(min)	5.50±0.41	8.70±1.56	<0.0001

The mean Perioperative blood loss was found to be more in the vaginal group compared to sublingual group (33.80 ± 9.20 ml vs 32.70 ± 5.30 ml) but difference was not significant ($p > 0.05$). The mean perioperative abdominal pain score of the sublingual group was significantly lower ($P < 0.05$) compared to the vaginal group. The gastrointestinal adverse effects were observed in the sublingual group but the difference was not significant

No complication occurred in either of the two groups during surgery or in the post-operative period.

Discussion:

The previous studies were conducted with prostaglandins (PGs) and mifepristone in first trimester abortion for a desirable outcome. [9,10]. Mifepristone is expensive and not available in many countries. [11]. Misoprostol is the PG of choice as it is cheap and stable at room temperature and available in different dosage forms. [12].

The present study observed that the cervical dilatation achieved with misoprostol was favorable among the sublingual group compared to the vaginal group. The observed difference can be attributed to the different absorption kinetics and subsequent systemic bioavailability with the sublingual and vaginal routes. Our results were consistent with the observations by Saxena *et al.* [13] and Tang *et al.* [14]. Shagufia Parveen *et al* [4] also concluded that sublingual misoprostol is an effective and favorable cervical ripening agent for first trimester abortion as compared to vaginal and oral dosage forms.

The total duration of surgery was less in the sublingual group because of the better cervical ripening and dilatation achieved in this group. These results are consistent with Parneet Kaur *et al.* [15]

Perioperative blood loss in our study was more in the vaginal group, which could be attributed to the sustained peak plasma concentration in this route. These results are consistent with Shagufta Parveen et al [4], pain score was found to be significantly lower in the sublingual group. Saxena *et al.* [13].

The side effects such as nausea, diarrhea and vomiting are more common with the sublingual route of administration, Tang OS et al [12]

Conclusion:

This study concluded that sublingual misoprostol 600 µg is an effective and favorable cervical ripening agent for first trimester abortion as compared to vaginal misoprostol. The operative time is also decreased with sublingual route and no significant difference in side effects experienced by the subjects.

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