

TO COMPARE THE EFFECTIVENESS & TOLERABILITY OF MISOPROSTOL AS A CERVICAL RIPENING AGENT IN FIRST TRIMESTER ABORTION THROUGH SUBLINGUAL & VAGINAL ROUTES OF ADMINISTRATION

Jayati Nath¹, Snehal Shah², Rina Sharma³.

1. Assistant Professor, Department of Obstetrics & Gynaecology, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh.
2. Senior Resident, Department of Obstetrics & Gynaecology, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh.
3. Professor, Department of Obstetrics & Gynaecology, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh.

CORRESPONDING AUTHOR

Dr. Jayati Nath,
Assistant Professor,
Obstetrics & Gynaecology Department,
TMMCRC, TMU Campus, Delhi Road,
Moradabad, Uttar Pradesh.
Email- jayati.nath@yahoo.com

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ABSTRACT:-OBJECTIVE: To compare the effectiveness and tolerability of misoprostol as a cervical ripening agent in first trimester abortion through sublingual and vaginal routes of administration.

MATERIAL AND METHODS: This study was carried out in the department of Obst. & Gynae TMMC & RC. A total of 120 patients were included in the study. They were divided in two groups

GROUP A – 60 patients – sublingual

GROUP B – 60 patients – vaginal

The drug was administered 3-4 hours before suction and evacuation by sublingual and vaginal routes.

Efficacy was assessed on the basis of time taken for ripening, dilatation achieved, duration of the procedure, intraoperative blood loss and pain. The patient's tolerability was noted on the basis of side effects.

RESULTS: The mean time taken for cervical ripening was more in the sublingual group as compared to the vaginal ($P < 0.001$). The duration of suction and evacuation was less as compared to the vaginal route. The mean intraoperative blood loss was more in sublingual as compared to the vaginal group. The intraoperative pain score was comparatively lower ($P < 0.05$) as compared to the vaginal. Side effects like loose motions, nausea vomiting were more with sublingual group.

KEY WORDS: misoprostol, 1st trimester abortion, sublingual, vaginal route

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INTRODUCTION: Prostaglandins have revolutionized the treatment of abortion¹. Mechanical dilatation of cervix before surgical abortion carries a risk of cervical injury and uterine perforation more so in the nulliparous and in previous caesarean patients². Comparative studies of Sublingual oral vaginal misoprostol for cervical priming have been carried out in different parts of the world³⁻⁷.

The aim of this study was to determine the efficacy of 400 µg of misoprostol through Sublingual versus vaginal routes for cervical ripening in the first trimester abortions before suction and evacuation. This study also evaluates tolerability, operative ease and blood loss with misoprostol by two routes.

MATERIAL AND METHODS: The present study was conducted in the department of obstetrics and gynaecology from July 2011 to June 2012 in TMMCRC. A total of 120 patients were included in the study, presenting with complaints of amenorrhoea of less than 12 wks of duration with a provisional diagnosis of either missed abortion or incomplete abortion. Informed consent of patients were taken and study was approved by institutional ethics committee.

INCLUSION CRITERIA:

- Having single intrauterine pregnancy less than 10 wks by USG.
- Patients giving informed consent.
- Hb ≥9 gm %.

EXCLUSION CRITERIA:

- Patients with threatened or inevitable abortion.
- Cardiovascular disease.
- Known coagulopathy or blood dyscrasias.
- Any uterine anomaly.
- Any infection.

STUDY DESIGN AND CONDUCT: It was a prospective randomized study carried over a period of 1 year. The patients were divided into two groups of 60 each Group A sublingual and Group B vaginal. The patients were explained about the procedure and informed consent was obtained. Detailed clinical history including medical and surgical history with drug allergy was taken into account along with detailed clinical examination. Baseline investigations like Haemoglobin, Blood group, Bleeding time, Clotting time, renal function test, Liver function test, Urine routine analysis, Blood sugar were done. Misoprostol dose was decided from the previous studies (3, 8, 9).

GROUP A:- n = 60 (from 1-60) These patients were given sublingual 400µg of Misoprostol and examined after 3-4 hours.

GROUP B:- n = 60 (from 61-120) These patients were given sublingual 400µg of Misoprostol inserted in the posterior fornix and examined after 3-4 hours.

Both the groups were assessed for efficacy on the basis of various parameters like cervical ripening, time taken for cervical ripening, cervical dilation, intraoperative blood loss and duration of procedure. Cervical dilation was measured with at least No. 8 or more size Hegars dilator passed though the cervical or without any resistance. Intraoperative blood loss was measured after sieving away the products and then subtracting the amount of liquor for the gestational age from the total aspirate. Associated complications were also taken into account. Before surgical evacuation⁽⁹⁾

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patients were asked about the side effects like nausea, vomiting, shivering, vaginal bleeding ranging from 0-3

- 0 for no bleeding
- 1 for minimal bleeding
- 2 for bleeding like menstrual flow
- 3 for severe bleeding

In all the two groups suction and evacuation was done with intra venous sedation i.e fortwin and phenargan and patients were discharged after 3 hours of the procedure if all the parameters were normal and no complications were observed.

STATISTICAL ANALYSIS: The data were recorded in mean \pm SD. ANOVA followed by a multiple comparison test (Kruskal Wallis) was applied. F. value, degree of freedom and $P < 0.05$ were considered statistically significant.

The chi square test was applied wherever applicable.

OBSERVATION AND RESULT: The age and the obstetrical profile of the study population was comparable.

TABLE 1

Parameters	Sublingual Route n= 60	Vaginal Route n=60	Result
Age	36.0833 \pm 3.30	26.25 \pm 3.8	F = 0.66 P = 0.798
Gravida	2.35 \pm 0.87	2.45 \pm 0.88	F = 1.79 P = 0.18
Parity	1.15 \pm 0.75	1.35 \pm 0.75	F = 2.104 P = 0.15
Amenorrhoea (weeks)	8.3 \pm 1.34	8.37 \pm 1.36	F = 0.363 P = 0.548

The values are expressed as mean \pm SD

Table 1 – Epidemiological and obstetric profile of study patients.

Majority of the patients were between 20 – 30 year of age group and P_{1+0}

TABLE 2: shows the comparison of different parameters in patients administered 400 μ g of Misoprostol.

Parameters	Sublingual Route n= 60	Vaginal Route n=60	Result
Cervical ripening %	74.5	70.25	F = 51.722
Time taken for Cervical ripening (hour)	3.54 \pm 0.30	4.39 \pm 0.77	F = 62.361
Cervical dilation (mm)	7.76 \pm 1.35	6.9 \pm 0.796	F = 18.195
Intraoperative blood loss (ml)	24.07 \pm 2.02	24.87 \pm 3.04	F = 2.886
Duration of procedure (min)	7.36 \pm 1.60	9.65 \pm 1.2	F = 74.624

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The values are expressed as mean \pm SD (standard deviation) ANOVA test was used for statistical analysis.

DISCUSSION: Dilation and vacuum aspiration still remains the most widely accepted method for first trimester pregnancy termination.

Several studies have assumed the efficacy of PGs with or without mifepriston^{10, 11}. Mifepristone is expensive and it is highly desirable to develop a regimen without it.¹² Misoprostol is the PG of choice as it is cheap and stable at room temperature and available in different dosage forms.¹³

The study shows that (fig 1, table 2) observes that the cervical ripening effect and the mean time taken by misoprostol by SUB LINGUAL route was better than the vaginal route. The observed differences can be attributed to the different absorption kinetics and more systemic bioavailability with the SUBLINGUAL route than the vaginal.

Our results were consistent with the ref 14, 3, 44, observation of Tangetal 154 and Saxena et al 8. The mean intraoperative blood loss was more in the vaginal group and it was compared to the SUB LINGUAL group as it was comparable to the observations made by Shagufta et al.¹⁵

The total duration of surgery was less in the SUB LINGUAL group which was due to better cervical ripening and dilation achieved in this group. These results are different with the studies of Saxena et al.⁸

The observed side effects like abdominal pain, loose motions, vaginal bleeding and nausea and vomiting were quite different from the earlier studies of Tang et al¹⁵ it could become of multiple doses used in this study.

Vaginal bleeding was more in the vaginal group; this observation was also reported by study done by Shagufta et al¹⁵. This could be attributed to sustained peak plasma concentration in this route.

Many clinical studies have shown that the vaginal route is superior to oral misoprostol in termination of pregnancy N jai et al ¹⁶. However administration of oral drug with water 3hr before operation may cause problems especially if the patient requires GA.

Sublingual Misoprostol in medical termination of pregnancy has been studied ¹⁷. The buccal mucosa being very vascular and misoprostol tablet being soluble in water dissolves within 10 min. of administration¹⁴. This route is convenient to use avoid vaginal administration.

The present study has few shortcomings as it was not a placebo controlled trial. The No. of patients was relatively less, repeat dose, single dose and pharmacokinetic parameters while comparing these routes were not studied for the comparative results of the study.

CONCLUSION: Sublingual Misoprostol is an effective and favourable cervical ripening agent for 1st trimester abortions.

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