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**Research Article**

# A Comparative Study of Sublingual Vs Oral Misoprostol for Cervical Ripening in First Trimester Termination of Pregnancy

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**Abstract:** Cervical dilatation before suction evacuation is probably the most critical step in vacuum aspiration. Misoprostol is commonly used for cervical priming. Therefore, a route which provides a faster and a higher plasma level is preferable. The aim & objective of the study was to compare efficacy and safety of misoprostol administration by sublingual and oral routes for cervical priming before surgical evacuation under anaesthesia in first trimester termination of pregnancy. This hospital based randomized comparative study was conducted on 230 patients attending the Department of Obstetrics & Gynaecology, SMS Medical College, Jaipur, for first trimester termination of pregnancy from april 2012 - august 2013 . 230 patients selected for the study were allocated into two groups of 115 each ( Group A & B ). Women in Group A were administered 400 µ of Misoprostol sublingually & in Group B orally. The mean cervical dilatation achieved preoperatively in Group-A was 8.66 ± 1.92 mm and in Group – B was 8.46± 6.15 mm (p = 0.20 , significant ). The mean duration of procedure in Group – A was 213.78 ± 58.12 sec i.e 3.56 ±0.97 min and in Group – B was 254.04 ± 64.01 sec i.e 4.23 ± 1.07 min (p< 0.05, Significant). In conclusion, Sublingual route of Misoprostol is better than oral route for cervical priming before surgical evacuation with reduction in duration of surgery in first trimester termination of pregnancy.
**Keywords:** Misoprostol, Sublingual, Oral, Cervical priming, Surgical evacuation.

## INTRODUCTION

Termination of pregnancy prior to 20th week of gestation either spontaneons or induced is defined as abortion [1]. Induction of abortion can be done by medical or surgical method.

Medical abortion obviously cannot replace surgical abortion , which is considered a ‘ gold standard ’procedure for termination of early pregnancy , but can play an important role as an alternative as well as an adjunct to surgical abortion [2].

Cervical dilatation before suction evacuation is probably the most critical step in vaccum aspiration [1]. Complication from mechanical diltation of the cervix includes cervical laceration, uterine perforation, incomplete evacuation, infection and excessive bleeding . The late complication includes infertility due to tubal blockage, cervical incompetence [1]. Measures to ripen the cervix before surgical evacuation have shown to reduce the risk of short and long term complication, amount of blood loss, pain intensity and duration and to improve operative ease for the surgeon [1]. Cervical priming can be done either by intracervical tents or by prostaglandins [3].

Misoprostol, a Prostaglandin E1analogue has several advantages over others as it is inexpensive, easily available, does not require refrigeration and has few side effects. In cases of surgical evacuation, Misoprostol is required only for cervical priming. Therefore, a route which provides a faster and a higher plasma level is preferable.

### Aim & Objective

To compare efficacy and safety of Misoprostol administration by sublingual and oral routes for cervical priming before surgical evacuation under anaesthesia in first trimester termination of pregnancy .

## MATERIALS AND METHOD

This hospital based randomized comparative study was conducted on 230 patients attending the department of Obstetrics & Gynecology, Zenana Hospital, SMS Medical College, Jaipur for first trimester termination of pregnancy from April 2012 – August 2013.

After taking a thorough history, examination , routine investigations including haemoglobin , urine analysis , ABORh , USG were carried out . After confirming the gestational age, 230 selected patients were sequentially allocated into two groups of 115 each (Group A & B). Women in Group A told to self – administer 400µ of misoprostol sublingually & in group B to self administer 400µ of misoprostol orally at 6:00 A.M at home on the scheduled surgery i.e., 3 hour prior to surgical evacuation & to report at 8.30 A.M.

Pre- operatively side effects associated with misoprostol including abdominal pain, nausea, vomiting, diarrhea, fever, shivering, headache, dizziness and bleeding per vaginum were recorded. Intra-operatively the amount of cervical dilation before performing surgical evacuation was measured using hegar dilators. Intra-operative fluid loss was measured with a graduated cylinder the volume of total uterine aspirate, after sieving away the products of conception. Duration of surgery was measured from start of dilatation until end of curettage. Any cervical or uterine injuries, injury to any other organ were noted. Post-operatively, the incidence of nausea, vomiting, diarrhoea, fever, abdominal pain, shivering, discomfort, bleeding per vaginum and overall satisfaction were noted. Follow up was done twice first after 7- 10 days and then after 30 days or the first menstrual period.

## RESULTS

The mean gestational age was 7.64 ± 1.65 weeks in Group A and 7.60 ± 1.57 weeks in Group B. Maximum of 49.57% women were of between 6-7 weeks gestational age (Table 1).

**Table 1: Distribution of cases According to period of Gestation**

| Sl. No. | Period of Gestation ( in weeks ) | Group – A | Group - B | Total |
|---|---|---|---|---|
| 1. | 6-7 weeks | 59 (51.30%) | 55 (47.83 %) | 114 (49.57%) |
| 2. | 8-9 weeks | 35 (30.44%) | 43 (37.39%) | 78 (3.91%) |
| 3. | 10-12 weeks | 21 (18.26%) | 17 (14.78%) | 38 (16.52%) |
| Total | | 115 | 115 | 230 |
| MEAN ± SD | | 7.64 ± 1.65 | 7.60 ± 1.57 | |

p> 0.05 NS

The overall mean cervical dilatation achieved preoperatively in Group – A was 8.66 ± 1.92 mm and in Group – B was 8.46 ±6.15 mm (p = 0.20, Significant). Therefore, Misoprostol is more effective by sublingual route than oral route in achieving cervical dilatation (Table 2).

**Table 2: Distribution of cases According to Cervical Dilatation Achieved**

| Dilatation Achieved ( in mm) | Group –A | Group – B | Total |
|---|---|---|---|
| ≤ 6 | 11 (9.57 %) | 21 (18.26%) | 32 (13.91%) |
| 7 - 9 | 62 (53.91%) | 69 (60.0%) | 131 (36.96%) |
| 10 – 12 | 42 (36.52%) | 25 (21.74%) | 67 (29.13%) |
| TOTAL | 115 | 115 | 230 |
| MEAN ± SD | 8.66 ± 1.92 | 8.46 ± 6.15 | |

$\chi^2$ = 7.812, d.f.= 2, p = 0.020, significant

The overall mean duration of procedure in Group – A was 213.78 ± 58.12 second i.e. 3.56 ± 0.97 minute and in Group – B was 254.04 ± 64.01 second i.e. 4.23 ± 1.07 minute (p<0.05Significant ).Therefore sublingual route is better than oral route as it takes less time for the procedure ( Table 3 ).

**Table 3: Distribution of cases According to Duration of Procedure**

| Sl. No. | Duration of Procedure ( in Second ) | Group – A | Group – B | Total |
|---|---|---|---|---|
| 1. | 120 – 180 | 43 (37.39%) | 18 ( 15.65% ) | 61 (26.52%) |
| 2. | 181 – 240 | 40 (34.78 %) | 37 (32.17 %) | 77 (33.48 %) |
| 3. | 241 – 300 | 22 (19.13 %) | 35 (30.44%) | 57 (24.78%) |
| 4. | 301 – 360 | 7 (6.09%) | 1916.52 %) | 26 (11.31 %) |
| 5. | 361 – 420 | 3 (2.61 %) | 6 (5.22 %) | 9 ( 3.91 %) |
| Total | | 115 | 115 | 230 |
| MEAN ± SD | | 213.78 ± 58.12 | 254 ± 64.01 | |

p < 0.05, Significant

The overall mean blood loss during the procedure in Group – A was 44.69 ± 13.45 ml and in Group – B was 49.78 ± 13.98 ml ( $p < 0.05$ , Significant) . Therefore sublingual route is better than oral route as the amount of blood loss was less in this group (Table 4).

**Table 4: Distribution of cases According to amount of Blood Loss**

| Sl. No. | Amount of blood loss (in ml) | Group – A | Group – B | Total |
|---|---|---|---|---|
| 1. | 10 – 20 | 2 (1.74 %) | 1 (0.87 %) | 3 (1.31%) |
| 2. | 21 – 30 | 23 (20% ) | 15 (13.04%) | 38 (16.52 % ) |
| 3. | 31 – 40 | 31 (26.96%) | 24 (20.87%) | 55 (23.91 % ) |
| 4. | 41 – 50 | 28 (24.35 %) | 27 (23.48%) | 55 (23.91% ) |
| 5. | 51 - 60 | 16 (13.91 % ) | 24 (20.87%) | 40 (17.39 % ) |
| 6. | 61 – 70 | 12 (10.43 % ) | 18 (15.65%) | 30 (13.05 %) |
| 7. | 71 – 80 | 3 (2.61 % ) | 6 (5.22%) | 9 (3.91% ) |
| Total | | 115 | 115 | 230 |
| MEAN ± SD | | 44.69 ± 13.45 | 49.78 ± 13.98 | |

$p < 0.05$, Significant

Abdominal pain was the most common side effect in Group – A in 16.52 % followed by unpleasant taste (14.78 %) and nausea (13.04%) . While in Group – B, most common side effect was nausea in 21.74 % followed by abdominal pain (19.13 % ) ($p > 0.05$ , Not Significant ). Gastro Intestinal side effects i.e. nausea, vomiting and diarrhea ($p > 0.05$) were more common in Group – B , unpleasant mouth taste found only in sublingual group ($p < 0.05$) . Fever was more common in Group – A (6.09 %) than in Group – B (4.35 %) (Table 5).

**Table 5: Distribution of cases According to Side Effects**

| Sl. No. | Side Effects | Group – A | Group - B | Total | p Value |
|---|---|---|---|---|---|
| 1. | Nausea | 15 ( 13.04% ) | 25 ( 21.74% ) | 40 ( 17.39% ) | >0.05 NS |
| 2. | Vomiting | 3 (2.61 % ) | 9 ( 7.83 % ) | 12 (5.22 % ) | >0.05 NS |
| 3. | Diarrhoea | 1 (0.87 % ) | 4 ( 3.48 % ) | 5 ( 2.17 % ) | >0.05 NS |
| 4. | Abdominal Pain | 19 (16.52 % ) | 22 ( 19.13 % ) | 41 ( 17.83 %) | >0.05NS |
| 5. | Shivering | 6 ( 5.22 % ) | 4 ( 3.48 % ) | 10 ( 4.35 % ) | >0.05NS |
| 6. | Dizziness | 2 (1.74 % ) | 3 ( 2.61 % ) | 5 ( 2.18 % ) | >0.05NS |
| 7. | Unpleasant Taste | 17 ( 14.78 % ) | 0 | 17 ( 7.39 % ) | < 0.05 S |
| 8. | Fever | 7 ( 6.09 % ) | 5 ( 4.35 % ) | 12 ( 5.22 % ) | >0.05NS |
| | Total | 70 ( 60.87 % ) | 72 ( 62.62 % ) | 142 (61.75 % ) | |

## DISCUSSION

Misoprostol is a synthetic Prostaglandin E1 analogue that is widely used for a variety of indications including medical abortions, medical management of miscarriage, induction of labour cervical ripening before surgical procedures and postpartum haemorrhage [1]. Misoprostol effects are dose dependent and include cervical softening and dilatation, uterine contractions, nausea, vomiting, diarrhea, fever and chills [1].

Routes of misoprostol administration include oral, vaginal, sublingual,buccal, or rectal. The sublingual

route of administration has more rapid absorption and higher peak levels than either vaginal or oral administration [4].

Nevertheless, the sublingual route also causes uterine contractions at a rate equivalent to vaginal administration and has less variation in absorption [5]. Misoprostol is a proven cervical ripening agent prior to first-trimester surgical abortion [6]. Studies have shown that the optimal dose in terms of balancing effectiveness and side effects is 400 µg [7]. There are data evaluating oral, vaginal, and sublingual routes of administration. Effective regimens are 400 µg of misoprostol vaginally 3 to 4 hours, 400 µg orally 8 to 12 hours, or 400 µg sublingually 2 to 4 hours prior to suction curettage [8]. In our study the mean cervical dilatation achieved preoperatively in Group – A was 8.66 ± 1.92 mm and in Group – B was 8.46 ± 6.15 mm ($p = 0.20$, Significant ). The mean duration of procedure in Group – A was 213.78 ± 58.12 sec i.e 3.56 ± 0.97 min and in Group – B was 254.04 ± 64.01 sec i.e 4.23 ± 1.07 min ($p< 0.05$, Significant). Therefore, sublingual Misoprostol is preferable to other routes as it has quicker onset of action with better cervical ripening and reduction in duration of surgery as also concluded by Saxena P *et al*. [9], Sharma M *et al*. [10], Parveen S *et al*. [11]. Because of a high systemic concentration due to avoidance of first pass metabolism in the liver and as it bypasses gastrointestinal absorption , so less Gastro Intestinal effects as compared to when administered orally [6, 7].

Cervical dilatation before suction and evacuation is the most critical step in vacuum aspiration. Cervical ripening before surgical evacuation have shown to reduce the risk of cervical injury and uterine perforation and to achieve additional beneficial effects such as a reduction in the short and long term complication, amount of blood loss, pain intensity, duration of surgery and to improve operative ease for the surgeon [1, 2].

Misoprostol is a safe, inexpensive, easily available, lacks need for refrigeration and highly effective drug that can be used for cervical priming preoperatively to avoid complications caused by mechanical dilatation [9-11].

## CONCLUSION

Cervical ripening before surgical evacuation has shown to reduce the risk of cervical injury and uterine perforation and to achieve additional beneficial effects. Misoprostol is a highly efficacious drug for cervical priming. As far as efficacy (for cervical dilatation) is concerned sublingual route of Misoprostol is more effective than oral route. The total duration required for completing the procedure, amount of blood loss and side effects were comparatively less in sublingual route than oral route. The overall success rate and satisfaction was more in sublingual route as compared to oral route. Therefore, sublingual route of Misoprostol is better than oral route for cervical priming before surgical evacuation in first trimester termination of pregnancy.

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