



To study the efficacy of vaginal misoprostol for cervical priming in first trimester MTP

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Abstract

Background: *Induced abortion medically or surgically has been practised for thousands of years. Cervical priming prior to surgical evacuation is the most important step. Among various pharmacological agents available misoprostol PGE1 analogue is the most widely used. Various routes of administration of misoprostol has own merits and demerits. The present study will determine the role of vaginal misoprostol for cervical priming in first trimester MTP.*

Aims and Objectives: *To study the efficacy of vaginal misoprostol for cervical priming in first trimester MTP.*

Materials and Methods: *One hundred and fifty women seeking MTP between 8 to 14 weeks of gestation were recruited for the study. Among these, 75 women were randomly allocated to study group which received vaginal misoprostol 400 µg 3 – 4 hours prior to surgical evacuation and 75 women were allocated to control group which underwent surgical evacuation after mechanical dilatation. The preevacuation cervical dilatation, blood loss, operative time and any complications occurred were recorded for both the groups.*

Results: *The mean pre evacuation cervical dilatation was significantly higher in study group in comparison to control group (9.8 ± 1.90 mm; 5.45 ± 1.23 mm; $p < 0.001$). Mean blood loss and mean time taken was significantly less in study group when compared to control group.*

Conclusion: *Vaginal misoprostol when used 3-4 hours prior to suction evacuation is safe, cheap, easy to use, acceptable and effective for cervical priming before dilatation.*

Introduction

Induced abortion is the medical or surgical termination of pregnancy and has been practiced for thousands of years. Medical methods of abortion which include mifepristone followed by misoprostol or misoprostol alone are very popular

and have decreased the rate of surgical evacuation over the time. But, still medical method is not suitable for all the cases because of continued bleeding per vaginum for longer duration and non availability of emergency services 24 hours in rural area in cases of excessive bleeding per

vaginum. In addition, risk of treatment failure and incomplete abortion increases with advancing gestation. Therefore, Dilatation and evacuation and vaccum aspiration still remains the choice for many women. Insufficiently dilated cervix poses the risk of haemorrhage and cervical injury and increases the chances of incomplete abortion. Mechanical dilatation in unskilled hands has higher chances of injury to cervix.¹ Also, cervical stenosis and incompetence has been reported with mechanical dilatation in nulliparous women as late complications. Cervical priming with various drugs has been studied in past and has shown to ease the surgical abortion by reducing the operative time, blood loss and chances of incomplete abortion.^{2,3} Among various pharmacological agents misoprostol PGE1 analogue which was earlier used for gastric ulcer has shown promising results. Different routes, dose and optimal timing of misoprostol has been studied in past for its optimal efficacy.

The present study was carried out to determine the role of vaginal misoprostol for cervical priming in first trimester MTP.

Aims and Objective

To see the efficacy of vaginal misoprostol for cervical priming in first trimester MTP. Secondary outcomes were to compare the intraoperative blood loss and complication rate amongst study and control groups.

Materials and Methods

This randomized controlled study was conducted at the Department of Obstetrics and Gynaecology of Indira Gandhi Medical College, Shimla. One hundred and fifty women seeking medical termination of pregnancy between 8 to 14 weeks of gestation were included in the study. Informed written consent was obtained from all the patients. Any previous history of hypersensitivity to prostaglandin, previous uterine surgery and patients with medical conditions like organic heart disease, hypertension, epilepsy were excluded. Also, if period of gestation >14 weeks or clinical

examination revealed fever, tachycardia, jaundice or cardiac disease were excluded from the study. In cases of vaginitis or cervicitis, the procedure was postponed till ailment was treated. The patients were then randomly allocated into two groups. 75 patients were taken in study group (Group 1) in which tablet misoprostol 400 µg was kept in posterior fornix 3 to 4 hours prior to medical termination of pregnancy. Another, 75 patients were taken as controls (Group 2) in which suction evacuation was done after mechanical dilatation of the cervix.

The presence of product of conception at cervical os or in the vagina before starting suction evacuation was recorded and the degree of cervical dilatation before vaccum aspiration was measured by passing Hegar's dilator through the cervix in descending order starting with no. 12. The size of largest dilator passed into the cervical os without resistance was recorded as dilatation achieved in millimetres. Further mechanical dilatation of cervix was done depending on the size of uterus and requirement. Intraoperative blood loss was measured with the help of measuring cylinder after sieving away the products of conception. The patient was observed for 3-4 hours after suction evacuation and was discharged. Patient was advised for follow up in case of excessive bleeding per vaginum. Patients were instructed for follow up after next menstrual cycle or five weeks after the procedure whichever occur earlier. Independent t- test was applied for comparison of two groups. Proportions were compared using Chi-square of Fishers-exact test whichever was applicable.

Results

Both the groups had comparable demographic profile. [Table 1] Majority of the abortion seekers were in the age group between 20 to 30 years. The parity range was 0-5 in study group and 0-4 in control group. Main indication for termination of pregnancy was unwanted and unplanned pregnancy in 89 (59.4%) women and failed contraception in 61 (40.6%) women. Pre

evacuation cervical dilatation was significantly higher in study group as compared to control group. Mean blood loss was significantly less in study group in comparison to control group. Mean operative time was also significantly less in study group. [Table 2] No cervical laceration or tear was reported in study group as compared to 5 (6.67%) cervical laceration in control group and the difference was statistically significant. ($p < 0.001$) In study group, mild vaginal bleeding was present before the procedure in 14 women (18.6%), abdominal pain in 12 women (16%) and product of conception at os or vagina was seen in 8 (10.6%) patients. These side effects were mild and required no specific treatment. [Table 3]

Table 1 Demographic variables

Characteristics	Study group (n=75)	Control group (n=75)	p value
Age	28.08 ± 6.6	28.06 ± 4.7	> 0.05
Parity	2.30 ± 0.85	2.17 ± 0.70	>0.05
Gestation (in weeks)	9.55 ± 1.53	9.43 ± 1.38	>0.05

Table 2 Intraoperative findings

Characteristics	Study group (n=75)	Control group (n=75)	p value
Pre evacuation cervical dilatation	9.18 ± 1.90	5.45 ± 1.23	<0.001*
operative time (min)	5.79 ± 1.85	7.65 ± 2.33	<0.01*
Intraoperative blood loss	56.10 ± 19.40	75.00 ± 16.00	<0.01*

*P value significant

Table 3 Incidence of Complications

Characteristics	Study group (n=75)	Control group (n=75)	p value
Cervical Laceration	Nil (0%)	5 (6.67%)	<0.001*
Nausea and Vomiting	1(1.3%)	Nil	
Diarrhoea	1(1.3%)	Nil	
Lower abdominal pain	12(16%)	Nil	
Vaginal Bleeding	14(18.67%)	Nil	

*P value significant

Discussion

Various studies in past has proven the role of misoprostol as an effective cervical priming agent prior to surgical evacuation.^{4,5} The various routes

of misoprostol administration have been studied with respect to efficacy and side effect profile in the past. The studies comparing oral and vaginal misoprostol in the past has shown vaginal route to be more effective for pre evacuation cervical dilatation.^{4,5,6} In contrast, a study on pharmacokinetics of misoprostol quote sublingual route to be a better alternative because of rapid bioavailability and highest peak concentration achieved with this route.⁷ Oral or sublingual misoprostol is easy to administer and avoids the discomfort which happens during vaginal insertion of tablet. Still, vaginal route remains the preferred choice for many because it avoids the systemic side effects and slow consistent absorption from the vaginal mucosa improves the rates of cervical priming. Our study further adds to the fact that vaginal route of misoprostol is effective for cervical ripening prior to surgical abortion.

In present study, mean cervical dilatation was 9.18 ± 1.90 mm in study group with range from 6 to 12 mm and in control group it was 5.45 ± 1.23 mm with range from 4 to 8 mm, which was statistically highly significant. ($p < 0.001$) The findings were consistent with study done by Gupta et al⁸ which observed mean cervical dilatation of 9.26 ± 1.72 mm in study group and 4.28 ± 1.3 mm in control group. The mean blood loss in the study group was 56 ± 19.40 ml versus control group which observed mean blood loss to be 75 ± 16 ml. The difference was significant statistically. ($p < 0.01$) Fong et al⁹ reported 97.5 ± 19.2 ml blood loss, Singh et al⁴ had mean blood loss of 88.5 ± 3.5 ml and Ngai et al¹⁰ reported mean blood loss of 57 ml in their study group which was comparable with our study. Kaur et al¹¹ reported blood loss of 54.07 ml which was similar to our study. The mean time taken for procedure in our study group was 5.79 ± 1.85 minutes as compared to 7.65 ± 2.33 minutes in control group which was statistically significant. ($p < 0.01$) Ngai et al¹⁰ found no significant difference in time taken for procedure in their study group (4.9 ± 1.9 minute) as compared to control group (4.9 ± 2.1 minute).

Our results are comparable to those of Gupta et al⁸ who reported significant difference in time taken for the procedure in their study group (4.61 ± 0.31 minutes) as compared to control group (5.96 ± 0.61 minutes) with $p < 0.001$.

No cervical injury was observed in the study group while there was 6.6% cases of cervical injury due to forceful dilatation in control group and the difference was statistically significant ($p < 0.001$). Similar results were observed by Gupta et al⁸ where 4% uterine perforation and 4% cervical injury were reported in control group with none in study group. In study group, mild vaginal bleeding was present before the procedure in 14 women (18.6%), abdominal pain in 12 (16%) women and products of conception at os or vagina seen in 8 (10.6%) patients. Diarrhoea and nausea was observed in one woman each. These side effects were mild and required no specific treatment. The side effect profile reported was similar to study conducted by Gupta et al⁸, Singh et al⁴ and Kaur et al¹¹. Sixty (80%) of patients in study group and 56 (76%) of patients in control group who came for follow up had no complications.

Conclusion

The results of the present study suggest that use of 400 µg misoprostol intravaginally, 3-4 hours prior to suction evacuation is safe, cheap, easy to use and effective for cervical priming before dilatation. It reduces the duration of procedure, blood loss and also the risk of cervical or uterine injury.

Conflict of Interest: The authors report no conflict of interest.

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