

Vaginal Misoprostol as an Alternative to Mechanical Dilatation of Cervix for Suction Evacuation in First Trimester Pregnancy Termination

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OBJECTIVE - To compare the effectiveness of misoprostol with its non-use before voluntary termination of pregnancy by suction evacuation. **METHODS** - One hundred women requesting termination of pregnancy and fulfilling the inclusion and exclusion criteria were taken up for the study. Fifty of them had insertion of 400 µg of misoprostol in the posterior fornix 3 hours prior to dilatation and evacuation procedure while the remaining 50 formed the control group. Ease of dilatation, the time taken for the procedure, blood loss and side effects were studied. **RESULTS** - The mean cervical dilatation in subjects was 8.37 mm after 3 hours of vaginal insertion of 400 µg misoprostol. Dilatation was easy in 96% of subjects whereas it was moderately difficult in 84% of controls. The time taken for the evacuation procedure and blood loss were significantly less in subjects as compared to those in the controls. **CONCLUSION** - Insertion of 400 µg of misoprostol in the posterior fornix three hours prior to vacuum aspiration reduces the force needed to dilate the cervix, the blood loss and time taken for the procedure. Vaginal misoprostol is effective and safe for cervical ripening and dilatation before suction evacuation.

Key words : misoprostol, vaginal misoprostol, dilatation for suction evacuation, voluntary termination of pregnancy

Introduction

In surgical methods of termination of first trimester pregnancy, there is a likelihood of early complications like hemorrhage and shock due to trauma, incomplete abortion, uterine perforation and cervical laceration and the late complications like infertility due to tubal blockage cervical incompetence and ruptured uterus. Most of these complications are caused by traumatic handling of the cervix¹. Trauma from mechanical dilatation can be reduced by the use of prostaglandin E₁ analogues which are inexpensive and stable at room temperature. Vaginal route is preferred over oral as there is better delivery of the drug at the local site, faster onset of action and least incidence of side effects. For better patient management and to reduce the incidence of iatrogenic complications, an easier, economical and safe method of managing first trimester abortions has to be evolved. Of the choices available PG E₁ analogue, misoprostol, is easily available and cheap.

This effectiveness of pre-operative use of misoprostol on cervical dilatation, the ease of dilatation, the time taken for the procedure and the blood loss were studied in the subjects and compared with those in the controls.

Material and Methods

One hundred pregnant women requesting termination of pregnancy were taken up for this study from January 2002 to December 2002. Inclusion criteria were gravidity one to four, gestational age five to twelve weeks, previous difficult cervical dilatation during pregnancy termination, any age and any socioeconomic status. Exclusion criteria were gestational age <12 weeks, gravidity five and more, cardiorespiratory disorders, Hb < 6.5G%, previous scar on the uterus, epilepsy, ulcerative colitis, cervicitis, vaginitis and pelvic inflammatory disease. Gestational age was estimated by LMP and bimanual pelvic examination and confirmed by sonography (USG). A detailed history was taken and routine examination and basic investigations were carried out. Written informed voluntary consent was taken.

Women were allocated randomly into two groups - study group and control group. In the study group, two tablets, 200 µg of misoprostol each were inserted in the posterior vaginal fornix 3 hours prior to suction evacuation. In the control group, no drug was inserted in the vagina. No premedication was given to any woman in both the groups. Subjects were informed of the possibility of pain in lower abdomen, nausea, vomiting, fever and bleeding. Vacuum aspiration was performed under general anesthesia three hours after insertion of 400 µg of misoprostol.

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Observations

1. The degree of cervical dilatation before vacuum aspiration: This was measured by passing Hegar's dilator in descending order starting with Hegar's no.12 dilator. The size of the largest Hegar dilator that could be passed through the internal os of the cervix without resistance was recorded as the cervical dilatation achieved.
2. Ease of dilatation was noted as: Easy – no resistance encountered, slightly difficult – same number of dilators had to be inserted twice, moderately difficult – one smaller number of dilators needed to be inserted again.
3. Time taken for the procedure: The time spent for the operation from the initiation of cervical dilatation to the end of suction evacuation was considered as the time taken for the procedure.
4. Blood Loss: Intraoperative blood loss was taken as the volume of the total uterine aspiration after sieving away the products of conception as measured with a measuring cylinder.
5. Adverse effects: Side effects like pain in abdomen, fever, nausea, vomiting, diarrhea and vaginal bleeding were assessed in each woman.
6. Complications: Any other complication, if it occurred, was treated and recorded.

The statistical analysis was done by 'Z' test.

Results

Age ranged from 15-45 years in both the groups with mean age of 29.9 years and of 28.9 years in subjects and control group respectively. The mean gestational age in both the groups was 8.4 weeks. Both the groups were comparable with respect to age, gestational age and hemoglobin percentage. Table I shows the degree of cervical dilatation at the beginning of the surgical procedure in the two groups. In the control group the mean cervical dilatation was 3.5 mm; in the study group it was 8.37 mm. The difference was statistically significant ($p < 0.01$).

Table II shows the ease of cervical dilatation in the two groups. In the control group in 8 (16%) women, there was a slight difficulty and in 42 (84%), moderate difficulty while dilating the cervix. In 48 (96%) women in the study group, there was a slight difficulty. Table III shows the time taken for the dilatation and vacuum aspiration procedure. The mean time taken for the procedure was 17.3 minutes and 8.1 minutes in the control group and study group respectively. The difference was statistically significant ($p < 0.01$). Table IV shows the amount of blood loss. The mean amount of blood loss was 80.1 ml and 46.5 ml in the control group and study group respectively. The difference was statistically significant ($p < 0.01$). In the study group, two (4%) women had diarrhea, four (8%) had mild lower abdominal pain, six (12%) had pre-operative vaginal bleeding out of which two (4%) had incomplete abortion and had to be taken up for emergency suction evacuation and 40 women (80%) had no side effects.

Table I: Degree of Cervical Dilatation at the Beginning of the Surgical Procedure

| Dilatation (mm) | Controls n=50 | Subjects n=50 |
|-----------------|------------------|------------------|
| 0-2.5 | 2 | 0 |
| 2.5-5.0 | 48 | 0 |
| 5.0-7.5 | | |
| >7.5 | 0 | 0 |
| Mean | 3.5 mm | 8.37 mm |

Table II : Ease of Dilatation

| Ease of dilatation | Controls n=50 | Subjects n=50 |
|----------------------|------------------|------------------|
| Easy | 0 | 48 |
| Slightly difficult | 8 | 2 |
| Moderately difficult | 42 | 0 |

Table III : Time taken for the Procedure

| Time taken for the procedure in minutes | Controls n=50 | Study group n=50 |
|---|------------------|---------------------|
| 5-10 | 0 | 44 |
| 10-15 | 2 | 6 |
| 15 | 48 | 0 |

Table IV : Blood Loss

| Blood loss (ml) | Controls n=50 | Study group n=50 |
|-----------------|------------------|---------------------|
| 30-45 | 4 | 26 |
| 45-60 | 2 | 18 |
| 60-75 | 4 | 6 |
| 75-90 | 28 | 0 |
| 90-105 | 12 | 0 |

Discussion

Misoprostol is a prostaglandin E₁ analogue that has been approved by the Food and Drug Administration (FDA) to be taken orally for the prevention and treatment of gastric ulcers associated with the use of NSAIDs². It has also become an important drug in obstetric practice because of its uterotonic and cervical ripening actions.

Zieman et al³ compared the pharmacokinetics of vaginal and oral administration of PGE₁ analogue misoprostol in 20 women receiving 400µg doses either orally or as tablets placed in the vagina. Assuming that the pharmacological effect of misoprostol is related to its concentration in the plasma, their observation of prolonged serum concentration in the vaginal group suggested that vaginal administration could be dosed at longer intervals than oral. Danielsson and Marions⁴ observed that the uterine contractility was higher after vaginal administration. Lawrie et al⁵ compared the effectiveness and acceptability of oral misoprostol 400µg 12 hours prior to suction evacuation with that of 800µg misoprostol vaginally 2 to 4 hours prior in 60 women. The mean cervical dilatation in oral and vaginal group was 6.91 mm and 6.99 mm respectively. Two women in the oral group experienced incomplete abortion at home and one woman required early admission because of heavy bleeding. Because of the unpredictability of action of oral misoprostol, the oral route could not be recommended. Gonzalez et al⁶ reported that seven Brazilian children whose mothers attempted to abort using misoprostol in the first trimester of gestation

without success presented with limb defects and in four of them, a diagnosis of Mobius' sequence was made. Kuldip Singh et al⁷ used vaginal misoprostol for pre-abortion cervical priming in 60 pregnant women between 6 to 12 weeks gestation. They concluded that 3 hours after vaginal insertion of misoprostol is the optimal time for evacuation procedure and 400µg misoprostol is optimal. Fong et al⁸ concluded that 400µg of misoprostol used vaginally is the optimal dose for pre-operative cervical dilatation before vacuum aspiration in the first trimester of pregnancy.

In the present study, the mean cervical dilatation prior to the surgical procedure was 3.5 mm and 8.37 mm in the control group and the study group respectively ($p < 0.01$). In the control group, dilatation was difficult in 84 % of women while in the study group, it was difficult in only 4%. In the misoprostol group, the time taken for the procedure was significantly ($p < 0.01$) less than that in the control group. The mean amount of blood loss in the misoprostol group and in the control group was 46.5 ml and 80.1 ml ($p < 0.01$) respectively.

Abortion is the common cause of maternal morbidity and mortality in India. WHO warrants that services for voluntary termination of pregnancy (MTP) should be an integral part of maternity and family health services. With the insertion of 400 µg misoprostol in the posterior fornix, the time needed for suction evacuation, the force used to dilate the cervix, the blood loss and the complications of suction evacuation are all reduced.

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