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Original research article

Potency and acceptability of oral misoprostol compared with vaginal misoprostol prior to first trimester abortions

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Abstract
Present study was done to assess the effectiveness and acceptability of oral misoprostol compared with vaginal misoprostol for cervical priming before termination of first trimester pregnancy. Recently, prostaglandin E_1 analogue misoprostol has caught much attention as cervical priming agent. Prostaglandins are used in different doses and different routes considering the different available results. Misoprostol was originally marketed for prevention of peptic ulcers caused by Prostaglandin synthetase inhibitor (NSAIDS) but now it has a widespread role in obstetric practice specially as a cervical priming agent. The aim of present study is to compare oral misoprostol versus vaginal misoprostol for cervical ripening and to assess its acceptability among women.

Keywords: Oral misoprostol, first trimester, pregnancy termination, cervical ripening

Introduction
According to WHO, the definition of abortion is the termination of pregnancy before 20 weeks gestation or fetus less than 500gms of weight [1]. Vacuum aspiration is the method of choice for termination of first trimester pregnancy. Cervical injury during surgical termination can be reduced by making the cervix soft and easy to dilate with the help of priming agents like prostaglandin E_1, analogue misoprostol. Prostaglandins are used in medical termination of first trimester pregnancy also [2]. Prostaglandins are a group of modified long chain fatty acids. The main prostaglandins used clinically are three (E_1, E_2 and $F_2\alpha$). Prostaglandin E_1 analogue misoprostol has been found much better alternative for cervical ripening. Surgical procedure to terminate pregnancy include dilation and curettage, vacuum aspiration which have complications like cervical rupture, perforation of uterus and even can cause injury to viscera [3]. Therefore, cervical priming with misoprostol becomes extremely important prior to termination of pregnancy.
Misoprostol tablets are available under the brand name Zytotec, Cytologue (100µgm, 200µ gm). Misoprostol (prostaglandin E_1 analogue) is administered vaginally as well as orally before surgical termination of first trimester abortion. Vaginal misoprostol is administered 4 hours prior to surgical termination of first trimester pregnancy in a dose of 400µgm. The results are effective dilatation with very less side effects [4]. Misoprostol is an effective myometrial stimulant selectively binding to EP_2 and EP_3 prostanoid receptors thus making it very effective for cervical priming. It has been found that oral route of administration has been more acceptable among women [5]. Our study compares the effectiveness, acceptability and side effects of oral misoprostol and vaginal administration of misoprostol in cervical ripening before termination of first trimester pregnancy.

Material and Methods
This study was conducted in a Govt. hospital in Jammu and Kashmir. Case under study consisted of one hundred twenty patients who are voluntarily opting for termination of pregnancy by vacuum aspiration. All patients underwent a detailed physical and obstetrical examination. Complete haemogram including haemoglobin level, blood grouping and typing was done.

Informed consent was taken from all the women willing to participate in this study. Gestational age was calculated from last menstrual period and in case the dates were not sure, ultrasonography was done to confirm the dates.

Exclusion criteria

Women who have allergy to misoprostol, previous uterine surgery and patients having medical disorders.

Pregnant women were randomly divided into oral misoprostol group and vaginal misoprostol group. The patients were given 400µgm of misoprostol either by oral route or by vaginal administration 4 hours before surgical termination of pregnancy i.e by vacuum aspiration. The data collection was done which was based on questionnaire system, vaginal bleeding and abdominal pain was noted.

Abdominal pain graded on 0-3 scale

1. No pain
2. Mild pain
3. Pain which requires no analgesies
4. Pain which requires analgesies.

Vaginal bleeding was noted on a scale of 0-3

1. No bleeding
2. Minimal bleeding
3. Bleeding like menstrual flow
4. Heavy bleeding.

Termination of pregnancy was done using Karmans Cannula of 6-10mm diameter. Cervical dilatation was measured using Hegars dilators starting from smaller dilators until a dilator entered the cervical os without resistance. The facts were entered in the statistical package for social sciences, arithmetic mean and standard deviation were calculated.

Results

In the present study, 120 women were randomized into two groups of oral misoprostol (n=52) and vaginal misoprostol (n= 70). Out of which 2 women from vaginal group were excluded because they had bleeding from administration of vaginal misoprostol. Fig.1 shows the design of study and number of patients allocated for the study. Demographic aspects of the two groups were almost similar (Table 1). The dilatation of cervix among two groups did not differ significantly (Table 2).

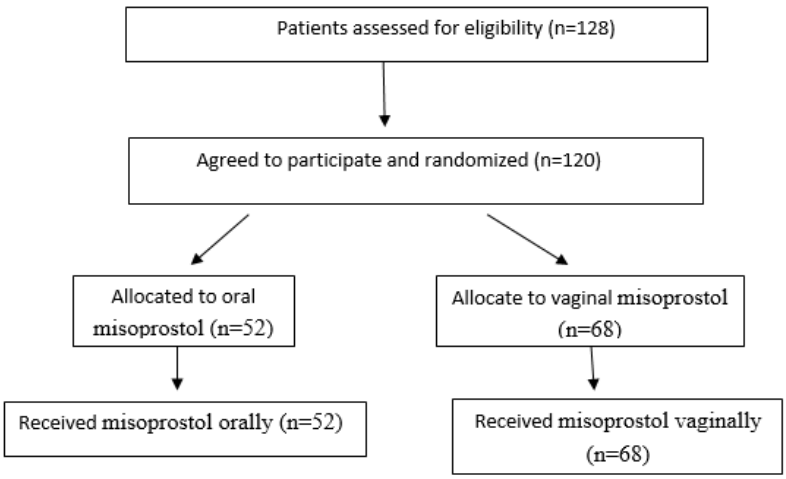

Fig 1: Number of women selected for study and study design.

Table 1: Characteristics of patients undergoing cervical priming using oral and vaginal misoprostol.

Characteristics	Oral (n=52)	Vaginal (n=68)	P Value
AGE (YEARS)	26.76± 6.37	27.62± 5.0	0.322
Parity	2.59± 1.30	3.01 ±0.98	0.078
Gestational Period (DAYS)	58.86 ±12.64	59.96± 7.18	0.586
BMI	22.21 ±2.96	22.34 ±3.30	0.834

Table 2: Outcome in both the groups.

Outcome	Oral (n=52	Vaginal (n=68)	P Value
Women Acceptability (Satisfied)	46	50	0.055
Cervical Dilatation	5.63	5.43	0.748

Table 3: Side effects

Side effects	Oral (n=52)	Vaginal (n=68)	P Value
Vomiting	5%	2.5%	0.574
Abdominal pain	5%	16%	0.922
Preorerative vaginal bleeding	24%	42%	0.55

There was no significant differences in oral and vaginal misoprostol as far as cervical dilatation is concerned (5.63mm versus 5.43mm). A total of 89% patients in oral misoprostol group expressed their satisfaction whereas a total number of 75% patients in vaginal misoprostol group were satisfied. The women in vaginal group experienced more bleeding 42% versus 24% in oral group. Questionnaire responses showed that incidence of side effects like nausea, vomiting, diarrhea were not

significantly different among the two groups. The number of patients having pain and fever were also almost similar in both the groups. No major side effects such as excessive vaginal bleeding or uterine perforation were seen in both the groups. The duration of bleeding after termination of pregnancy was similar in both groups with median of 5 days in oral misoprostol group and 6 days in vaginal misoprostol group.

Discussion

Misoprostol is a stable and synthetic prostaglandin E1 analogue [6] and is presently known for its highest consumption in obstetrics and gynaecology. The drug absorption rate varies depending on the method of administration and dose. Prostaglandins are extensively used for cervical ripening before vacuum aspiration for first trimester pregnancy. Studies have shown that misoprostol is far more effective than placebo [7, 8]. and as effective as gameprostone and dinoprostone [9, 10] in relation to basal cervical dilatation before termination of first trimester pregnancy.

Our study showed that a higher percentage of women in oral misoprostol group showed satisfaction as compared to vaginal misoprostol group. The study also suggests that oral administration of misoprostol is an effective alternate measure to vaginal administration. The percentage of side effects was also same in both the groups. Sublingual route has also been evaluated as an alternative to vaginal and oral misoprostol. Studies [11] have shown the pharmacokinetics of different routes of administration in Asian women. Women given sublingual misoprostol showed peak serum levels as compared to women of vaginal and oral route. Similar results have also been evaluated [12] in which peak serum levels were achieved more in sublingual group as compared to oral group. So sublingual administration becomes an extra choice in women who wish to avoid vaginal administration. As far as side effects are concerned, they are more in sublingual groups as compared to vaginal group [13]. Present study showed that oral misoprostol achieves similar cervical dilatation when compared with vaginal misoprostol. The side effects in both the groups are almost similar which is comparable with other studies [14].

Conclusion

This study suggests that the effectiveness of oral misoprostol is similar to vaginal misoprostol for preinduction cervical ripening but since women are more satisfied in oral misoprostol group than vaginal group. It reflects that oral misoprostol becomes an alternative for vaginal administration.

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