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Vaginal misoprostol for cervical dilatation before operative office hysteroscopy

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Abstract

Objective To assess the efficacy of misoprostol as an adjunct for easy cervical dilatation before operative office hysteroscopy under local anaesthesia.
Design Randomized, placebo-controlled clinical trial.
Setting Tertiary centre for treatment of infertility.
Subjects Patients undergoing hysteroscopy, for simultaneous diagnostic and operative indications such as uterine septae, synechiae, submucous myomas, endometrial polyps and lost intrauterine devices, were included into the study.
Intervention 43 cases were randomized to misoprostol ($n=22$) and placebo ($n=21$) groups. The drug was administered vaginally 4 h before hysteroscopy. Hysteroscopy was performed under local anaesthesia in an examination room as an office procedure.
Main outcome measures Rapid and easy dilatation, decreased pain, decreased incidence of cervical haemorrhage, laceration and uterine perforation.
Results In the misoprostol group, a 7-mm hysteroscopic sheath passed easily without dilatation in 20 (91%) cases while it passed easily without dilatation in six (28%) of the placebo group ($P<0.001$). The average dilatation time for groups was 1.6 and 2.8 minutes respectively ($P<0.05$). Mean dilatation pain scores for the misoprostol and placebo groups were 5.1 and 9.3, respectively ($P<0.05$). Cervical bleeding was noted in two cases in the misoprostol group and laceration of the cervix was noted in three cases. In the placebo group there were eight cases each of both bleeding and laceration.
Conclusion Application of misoprostol does provide a safe, painless and effective means of cervical dilatation by chemical, rather than mechanical forces, and reduces complications such as cervical bleeding, laceration and uterine perforation.

Keywords: cervical dilatation, misoprostol, office hysteroscopy.

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Introduction

Office operative hysteroscopy offers the physician the opportunity to both diagnose and treat abnormal uterine bleeding, secondary to submucosal myomas or endometrial polyps, and to evaluate infertility and pregnancy wastage due to uterine anomalies or synechiae, and to remove lost intrauterine devices.[1]

The patients' perceptions of pain and comfort throughout the procedure and their willingness to undergo a second procedure are the most important aspects of office hysteroscopy. Saving time and money are other benefits of this procedure. Recently operative office hysteroscopy has become popular with the use of continuous flow liquid uterine distension.

Diagnostic office hysteroscopy can be done through a 5-mm hysteroscopic sheath without cervical dilatation in approximately 90% of cases.[2] For operative hysteroscopy the 7-mm operative hysteroscopic sheath should be used, so that the cervix needs to be dilated. The mechanical dilatation provided by uterine sounds may give rise to problems such as pain, laceration, bleeding of the cervix or uterine perforation. Misoprostol, a synthetic prostaglandin E_1 analogue, is an agent for the prevention of peptic ulcers. However it was reported to cause uterine contractions in very early pregnancies,[3] and later it was shown to effect cervical ripening for induction of labour.[4]

In order to assess the effect of misoprostol on cervical ripening prior to office hysteroscopy, a randomized placebo-controlled trial was designed. The trial was aimed at assessing the efficacy and acceptability of vaginal misoprostol as a means of ameliorating patient discomfort during cervical dilatation for operative hysteroscopy.

Subjects and methods

A total of 43 patients undergoing hysteroscopy as an operative office procedure were randomized to misoprostol ($n = 22$) or placebo ($n = 21$) groups. Indications for hysteroscopy were uterine septae, synechiae, submucous myomas, endometrial polyps and removal of intrauterine devices (Table 1).

In the misoprostol group, the number of patients having undergone previous delivery was nine (41%) and it was eight (38%) in the placebo group.

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group there were eight cases each of both bleeding (38%) and laceration (38%) ($P < 0.05$).

Uterine perforation was suspected when one of the patients from the placebo group experienced severe pain when the hysteroscopic sheath was first introduced. This patient was transferred to the operating room and laparoscopy was performed under general anaesthesia. Uterine perforation without any bleeding was diagnosed, and no further treatment was administered.

Discussion

Misoprostol seems to be one of the most effective agents for simultaneous cervical ripening and uterine contractions. With clinical administration for induction of labour, uterine contractions usually begin within 2–4 h. Cervical softening is a major concern with misoprostol, and for this reason we administered the drug 4 h before hysteroscopic intervention.

One of the main advantages of using misoprostol for cervical ripening seems to be that much less pain may be involved as compared with mechanical dilatation. Also it is clear that the incidence of cervical bleeding and laceration was much lowered in the study group.

In the first published study concerning its use in the induction of labour, misoprostol was administered orally.[5] Both the oral and vaginal routes have been shown to be effective for cervical ripening and uterine contractions.[4] In our study we preferred vaginal administration.

Another problem with the administration of misoprostol concerns dosage. In our study, we used 400 μg (2 tablets). In one randomized trial for labour induction, 50–600 μg misoprostol was used, in an increasing mode.[6] In another study of labour induction, 1600 μg misoprostol was used in 48 h. For the pregnant uterus, 50 μg misoprostol seems effective in inducing labour with cervical ripening, but we did not experiment with this dosage.

Prostaglandins have side-effects such as diarrhoea, nausea, vomiting and fever. We did not encounter side-effects such as these, except for chills. Similar findings, even at high dosage, have been reported in the literature concerning misoprostol.[6,7]

In one recent study, misoprostol, at 200 μg, was shown to provide cervical ripening to the extent of a no. 8 Hegar uterine sound, before cervical dilatation, to facilitate first trimester pregnancy interruption.[8] However, in our study, even with patients who had previously delivered, we noted cervical ripening to no. 6 sound with nonpregnant uteri.

In conclusion, application of misoprostol provides a safe, painless and effective way of cervical dilatation by chemical, rather than mechanical means, and reduces the incidence of complications such as cervical bleeding, laceration and uterine perforation.

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Table 1 Patient characteristics and indications for hysteroscopy

	Misoprostol group $n = 22$	Placebo group $n = 21$
Age, median (range), years	26.2 (17–36)	27.1 (18–38)
Number of patients with previous delivery	9 (41%)	8 (38%)
Number of patients with previous cervical dilatation (for hysteroscopy or D&C)	12 (54%)	10 (47%)
Indications		
Endometrial polyps	4	4
Submucous myomas	4	2
Uterine septae	6	7
Uterine synechiae	3	4
Lost intrauterine device	5	4

The numbers of patients having previously undergone cervical dilatation for hysteroscopy or dilatation and curettage were 12 (54%) and 10 (47%) respectively.

Misoprostol (Cytotec, Searle Pharmaceuticals–Ali Raif İlaç Sanayi, Istanbul, Turkey), 400 μg (2 tablets), was administered to the posterior fornix 4 h before hysteroscopic intervention. The same protocol was performed for the placebo (control) group.

The patient, in the lithotomy position, was infused with 0.9% NaCl solution with 50 mg Meperidine, and paracervical block was obtained with bupivacaine (0.5%, 10 ml) and Citanest (2%, 10 ml), at the 5 and 7 o'clock positions of the cervix. The patients received a combination of intravenous analgesia and local anaesthesia to the cervix, in order to maintain systemic analgesia.

A speculum was placed within the vagina and the cervix grasped anteriorly with the tenaculum. Following this, the 7-mm hysteroscope sheath was inserted into the cervix. If this was not possible, a no. 6 Hegar dilator was tried and dilatation was continued to no. 8 Hegar dilator. Dilatation time, pain score, cervical bleeding and laceration were noted. Laparoscopy was performed for one patient who experienced severe pain while the hysteroscopic sheath was introduced, and uterine perforation was diagnosed.

The hysteroscope employed for all diagnostic procedures was a 30° 4-mm rigid Storz (Tuttlingen, Germany) telescope and the Hamou 7-mm resectoscope (Storz) was used for performing intrauterine operations.

A pain score was provided by using a comparison with the patient's worst menstrual pain. The patient was asked to score the pain of dilatation, having noted that the worst menstrual pain was scored as 10, moderate pain as 5, and no pain as zero.

Student's *t*-test was used for statistical analysis, and $P < 0.05$ was judged as significant.

Results

A 7-mm hysteroscope sheath was inserted into the cervix, but if this was not possible, a no. 6 Hegar dilator was tried and dilatation continued to a no. 8 Hegar dilator for all patients. With the misoprostol group, the 7-mm hysteroscope sheath passed easily without dilatation in 20 cases (91%); in the placebo group it passed easily without dilatation in six cases (28%) and this difference was found to be statistically significant ($P < 0.001$).

The average time for dilatation for the misoprostol group was 1.6 min (range, 1–2), while it was 2.8 min (1–4) for the placebo group ($P < 0.05$).

The mean score for dilatation pain compared with menstrual pain was 5.1 (4–10) in the misoprostol group, and 9.3 (6–10) for the placebo group ($P < 0.05$).

Cervical bleeding was noted in two cases (9%) in the misoprostol group and laceration of the cervix was noted in three cases (13.6%). In the placebo

Table 2 Main outcome variables

	Misoprostol $n = 22$	Placebo $n = 21$	*P*
Number of patients with adequate cervical ripening, (7-mm hysteroscopic sheath or 6-mm Hegar fits)	20 (91%)	6 (28%)	<0.001
Dilatation time, min	1.6 (1–2)	2.8 (1–4)	<0.05
Dilatation pain score (in comparison with menstrual pain)	5.1 (4–10)	9.3 (6–10)	<0.05
Cervical bleeding	2 (9%)	8 (38%)	<0.05
Cervical laceration	3 (13.6%)	8 (38%)	<0.05
Uterine perforation (while introducing hysteroscopic sheath)	0	1	>0.05