ORIGINAL ARTICLE

A randomized trial of vaginal misoprostol for cervical priming before hysteroscopy in postmenopausal women

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ABSTRACT

Objective: To perform hysteroscopy the cervix needs to be dilated and in nullipara and postmenopausal women this is sometimes difficult. Well-known, entry-related complications during hysteroscopy include cervical tear, creation of false tract, bleeding, uterine perforation, scarring, and subsequent anatomical stenosis.
Materials and Methods: This study was done to investigate the priming effect of vaginal misoprostol on cervical dilatation in postmenopausal women, before hysteroscopy, to prevent such complications. Two hundred micrograms of misoprostol was inserted into the vagina at least 12 hours before the procedure and the control group did not receive any cervical priming agent. Pre-procedural dilatation, additional dilatation required, and time taken for dilatation was noted in each case.
Observations: The study showed a significant difference between the study group (7.7 ± 1.7 mm) and the control group (4.5 ± 1.8 mm) in terms of pre-procedural cervical width and the number of women requiring a dditional dilatation (7 / 25 versus 22 / 25), and hence, the time required for dilatation (4.7 ± 8 seconds versus 20.6 ± 9.3 seconds).
Conclusion: The pre-procedural cervical width was significantly more in the study group as compared to that in the control group. We found significant differences between the study and control groups with respect to the number of women who required cervical dilatation. To conclude, this study helps derive a conclusion that vaginal misoprostol as a cervical priming agent in postmenopausal women appears to be safe, effective, and inexpensive, with mild side effects.

Key Words: Cervical priming, hysteroscopy, misoprostol

INTRODUCTION

Hysteroscopy is an important tool used for observing, diagnosing, and treating pathological conditions of the uterine cavity.

To perform hysteroscopy the cervix needs to be dilated and in nullipara and postmenopausal women this is sometimes difficult. Well-known, entry-related complications include cervical tear, creation of false tract, bleeding, uterine perforation, scarring, and subsequent anatomical stenosis.

Misoprostol is a stable synthetic prostaglandin E1 analog. Although its obstetrical uses have been studied by different researchers, the use of misoprostol for gynecological indications has received less attention.[1-6]

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Misoprostol use has been recently studied in cervical priming prior to hysteroscopy, artificial insemination, endometrial biopsy, and dilation and curettage (D and C). The cervical priming effect of misoprostol in non-pregnant women, especially after menopause, is not well-established.

This study was carried out to investigate the priming effect of vaginal misoprostol for cervical dilatation in postmenopausal women, before hysteroscopy.

MATERIALS AND METHODS

A prospective randomized case control study was

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conducted at the Asian Institute of Medical Sciences, Faridabad. This is a tertiary care center catering to a wide area of Haryana and NCR, comprising of a mixed urban, suburban, and rural population.

Fifty postmenopausal women, who underwent hysteroscopy, between March 2010 and January 2011, were included in this study. The women requiring hysteroscopy were randomized into two groups: the pretreatment with misoprostol group (study group) and no pretreatment group (control group). A full medical, obstetrical, and gynecological history was taken followed by a physical examination. The study group was given 200 micrograms of misoprostol to be inserted in the vagina at least 12 hours before the procedure and the control group did not receive any cervical priming agent. All hysteroscopies were carried out under general anesthesia. Before hysteroscopy the dilatation of cervix was assessed with the number of Hegar's dilator passed without resistance (pre-procedural dilatation). If sufficient cervical dilatation did not occur then dilatation was done using successively larger Hegar's dilators. Using a stop watch, the length of time required to dilate the cervix to 8 mm was noted.

After hysteroscopy, the women were observed for six hours before being sent home. The data collected was analyzed using student's *t* test and Chi square test.

Indication for hysteroscopy in all women was postmenopausal bleeding.

RESULTS

There were 25 women in the study group and 25 in the control group. Both the groups were comparable with respect to age and parity. The mean age of the study group was 53.6 ± 6.8yrs and that in control group was 53.1 ± 5.7yrs which was comparable. The study showed a significant difference between the study group (7.7 ± 1.7 mm) and the control group (4.5 ± 1.8 mm) in terms of pre-procedural cervical width, number of women requiring additional dilatation (7/25 versus 22/25), and also the time required for dilatation (4.7 ± 8 seconds versus 20.6 ± 9.3 seconds) [Table1].

Table 1: Important findings in study group versus control group

	Study group	Control group	*P* value
Number	25	25	NA
Age	53.6 ± 6.8	53.1 ± 5.7	0.77NS/*t* test
Cervical width	7.7 ± 1.7	4.5 ± 1.8	3.24928E – 06 S/*t* test
Additional dilatation required	7	22	0.001824104 S/Chi test
Time for dilatation	4.7 ± 8	20.6 ± 9.3	3.24928E-06 S/*t* test

Thus the pre-procedural cervical width was significantly more in the study group as compared to that in the control group.

No cervical tear or perforation was noted in either group. Although nausea was higher in the study group as compared to the control group it was not statistically significant.

DISCUSSION

The research to date using misoprostol clearly demonstrates its effectiveness in cervical priming on a well estrogenized cervix in pregnant women, both in early and late pregnancies (R). H Rusen *et al.*, in their study on postmenopausal women studied the priming effect of misoprostol on an estrogen pretreated cervix. They found that the mean baseline cervical widths for the estrogen and placebo groups were 4.4 ± 0.7 mm and 3.7 ± 0.7 mm, respectively. This difference was statistically significant ($P < 0.05$).[7]

Rusen *et al.*,[7] in their study on postmenopausal women, for evaluating the priming effect of misoprostol on an estrogen pretreated cervix, found a significant reduction in the time required to dilate the cervix up to Hegar's dilator number 9, in the study, as compared to the control group. The time required by the study group was 44.5 ± 16.2 seconds as compared to 61.4 ± 18.3 seconds, this was significantly less ($P = 0.010$). They speculated that a favorable effect of PGE2 on cervical remodeling had not been observed as estrogen was deficient in postmenopausal women. Assuming this hypothesis Rusen *et al.*, in their study, compared the priming effect of misoprostol on estrogen pretreated cervix in postmenopausal women. They concluded that misoprostol was an effective drug for cervical ripening in pregnant and premenopausal women, but its efficacy was limited in the postmenopausal period.

Ngai *et al.*,[8] reported in a study on postmenopausal women that 400 micrograms, 12 hours before hysteroscopy, was ineffective. Similar to our study and contrary to the above-mentioned reports Bancaite *et al.*,[9] reported that vaginal misoprostol applied before hysteroscopy reduced cervical resistance and the need for cervical dilatation in peri- and postmenopausal women, with only mild adverse effects. Thomas *et al.*,[10] compared the effectiveness of placebo and 400 micrograms of oral misoprostol given 24 hours, and again 12 hours before hysteroscopy, to women who were premenopausal, perimenopausal, postmenopausal or pretreated with a GnRH agonist,

and found increased ease of cervical dilatation after administration of misoprostol in both estrogenized and hypoestrogenic women and in women who received estrogen. Similar to our study, they found significant differences between the study and control groups, with respect to the number of women who required cervical dilatation. They also observed that this benefit might be due to the extended dosing regimen.

To conclude, this study helps derive a conclusion that vaginal misoprostol as a cervical priming agent in postmenopausal women appears to be safe, effective, and inexpensive with mild side effects.

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