ORIGINAL ARTICLE

Comparative Efficacy of Sublingual Misoprostol for Uterine Ripening 2, 6, and 12 Hours before Hysteroscopy in Postmenopausal Women

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Abstract

Introduction: Misoprostol is a therapeutic method for uterine ripening in postmenopausal women under hysteroscopy, and determination of best dosage and time of administration is important to attain the best outcomes.

Objectives: This study was performed to determine and compare efficacy of sublingual misoprostol for uterine ripening 2, 6, and 12 hours before hysteroscopy in postmenopausal women.

Materials and methods: In this randomized clinical trial, 103 postmenopausal women attending to Akbarabadi and Rasool Hospitals in 2017 and 2018 for hysteroscopy were enrolled and randomly assigned to receive sublingual misoprostol for uterine ripening either 2 or 6 hours or and 12 hours before hysteroscopy. The outcomes and adverse effects were determined and compared.

Results: In this study, the frequency rate of complications and also the external and internal os diameters were alike across the three study groups (p value > 0.05).

Conclusion: It may be concluded that efficacy of sublingual misoprostol for uterine ripening 2, 6, and 12 hours before hysteroscopy in postmenopausal women is same, and for this matter, use at 2 hours before hysteroscopy is recommended for further supervision and more convenience.

Keywords: Hysteroscopy, Menopause, Ripening.

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Introduction

Menopause is an important period in life of women which is usually accompanied with different important somatic and mental health alterations.[1,2] These subsequent manifestations include uterine changes that may result in periodical monitoring for precancerous and malignant lesions.[3,4] Hysteroscopy is a routine procedure for diagnosis and treatment of uterine disorders with different efficiencies according to the ripening level.[5] It is useful for assessment of the cause of abnormal uterine bleeding, polyps, fibroma, uterine adhesions, and increased endometrial thickness and sometime for initial assessment before main surgeries.[6]

Uterine ripening is important for better assessment and lower pain during hysteroscopy. Use of prostaglandin analogs such as misoprostol is good method for better ripening.[7] It is among the routine therapeutic methods for cervical ripening before hysteroscopy.[8,9] However the dosage and the time interval between prescriptions are important factors affecting the final outcome.[10–12]

Objectives

Hence, this study was performed to determine the comparative efficacy of sublingual misoprostol for uterine ripening 2, 6, and 12 hours before hysteroscopy in postmenopausal women.

Materials and Methods

In this single-blind randomized clinical trial, 103 consecutive postmenopausal women attending to Akbarabadi and Rasool Hospitals, Tehran, Iran, in 2017 and 2018 for hysteroscopy were enrolled and randomly assigned to receive sublingual misoprostol for uterine ripening either 2 or 6 hours or and 12 hours before hysteroscopy.

The study was approved by local ethical committee. The Helsinki Declaration was respected across the study. The outcomes and adverse effects of the procedure of hysteroscopy were determined and compared across the three study groups.

Statistical Analysis

After data collection for 103 patients, statistical analysis was done by SPSS version 25.0 software. The utilized tests were analysis of variance and Chi-square, and p values <0.05 were considered statistically significant.

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Results

The background variables are shown in Table 1 and were alike across the groups (p values > 0.05). Also, 58.8%, 61.8%, and 57.1% in groups 2 hours, 6 hours, and 12 hours were overweight/obese, respectively. As demonstrated in Figure 1, there was no significant difference between groups for adverse effects (p values > 0.05).

The indications of hysteroscopy in three understudy groups were alike (p values > 0.05). Resectoscope was used in 32.4%, 32.4%, and 28.6% in groups of 2, 6, and 12 hours, respectively (p values > 0.05). The cervix was soft in 44.1%, 52.9%, and 28.6%, respectively (Fig. 2). The uterine was in neutral position in 47.1%, 44.1%, and 40.0% in groups of 2, 6, and 12 hours, respectively (p values > 0.05). Among all patients, only two complications were seen including bleeding and rupture that were both in higher drug dose. As shown in Figure 3, the hysteroscopic findings were same across the groups (p values > 0.05).

Discussion

In this study, same misoprostol dose was used at different time intervals, including, 2, 6, and 12 hours before hysteroscopy. There was no significant difference between groups for outcomes and complications. Tanha et al.[13] assessed 100 patients attending for cervical ripening and reported dose of 400 mg at 6 hours before hysteroscopy. But we found no difference between the times. The study by Mathlouthi and colleagues[14] showed that among 108 cases under hysteroscopy in two groups of sublingual misoprostol and placebo, and there was no significant difference between the groups. However, we had no placebo group but different administration timed had same results.

Table 1: Background factors across the groups

Group	*Age*	*Parity*	*NVD count*	*Cesarean count*	*Years passed from last delivery*
2 hours	52 ± 6	2.2 ± 1.7	1 ± 1.5	1.1 ± 1.1	14.4 ± 5.2
6 hours	54.6 ± 7.2	2.5 ± 1.7	1.5 ± 1.9	0.9 ± 0.9	18.5 ± 8.5
12 hours	52.1 ± 5.8	2.3 ± 1.8	1.4 ± 1.8	0.6 ± 0.9	16.1 ± 8.1

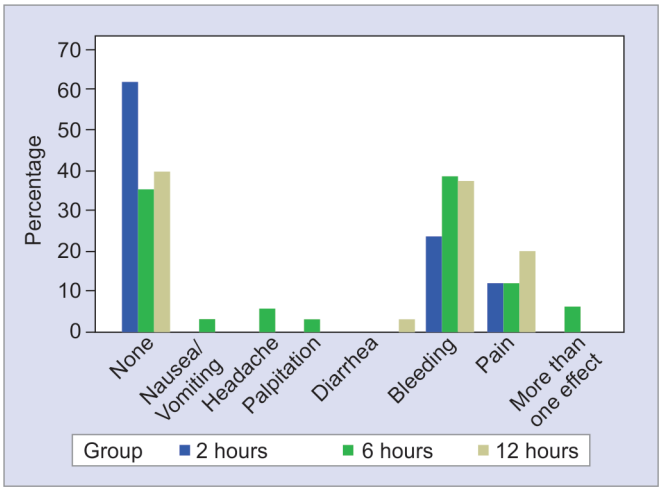

Fig. 1: Frequency distribution of adverse effects across the groups

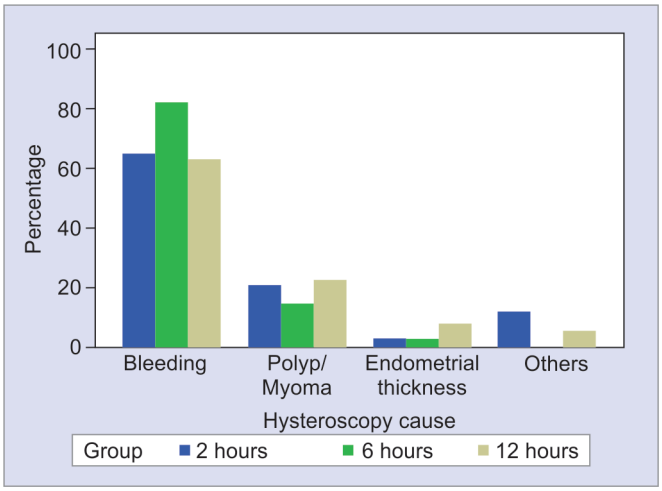

Fig. 2: Indications for hysteroscopy in patients

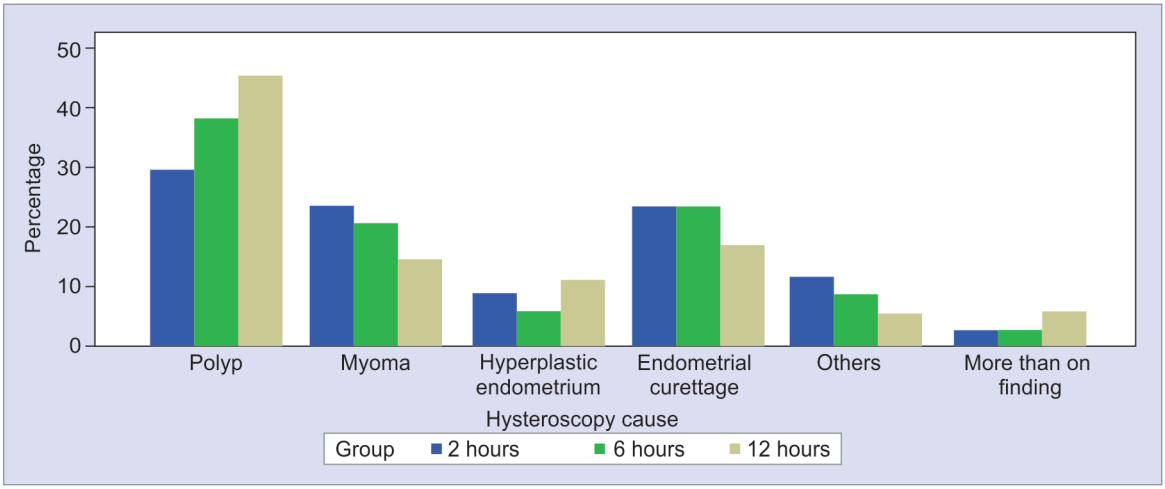

Fig. 3: Hysteroscopy in finding patients

Bisharah et al.[15] assessed two groups of women under hysteroscopy allocated in two groups of sublingual misoprostol with the dose administered 12 hours before procedure and placebo group and found that there was no significant difference between softening, outcomes, adverse effects, and dilatation across the groups. In our study, safety profile was good and the groups were not different. Hwang et al.[16] compared different doses of misoprostol administered in different times and reported highest efficacy for dose of 200 mg at 8 hours before procedure. In our study, dose of 200 mg had good efficacy that did not differ between times.

Hua et al.[17] reported no significant difference between various administration times of misoprostol, but the best doses with highest efficacy and lowest adverse effects were 200 and 400 mg as shown in our study. The review study by Arena et al.[18] showed that misoprostol is nonexpensive, safe, and effective for ripening in hysteroscopy cases as shown in our study. The study by Allen et al.[19] showed that misoprostol dose of 200 mg without consideration of the administration time is beneficial for cervical ripening. Similarly. all groups in our study had same effect. Also Kale et al.[20] revealed that optimal misoprostol dose is 400 mg administered 12 hours before procedure. But the times of prescription had least effect on the outcomes in current study.

Conclusion

Hence, it may be concluded that efficacy of sublingual misoprostol for uterine ripening 2, 6, and 12 hours before hysteroscopy in postmenopausal women is same, and for this matter, use at 2 hours before hysteroscopy is recommended for further supervision and more convenience. However, further studies with larger sample size and multicenter samplings are required to attain more definite results, especially with consideration of administration route in patients.

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