e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(2); 1755-1758

Original Research Article

Comparing Sublingual and Vaginal Misoprostol for Cervical Preparation before Surgical Abortion in the First-Trimester

Punita Kumari[1], Rajeev Kumar Khetan[2]

[1]Senior Resident, Department of Obstetrics & Gynaecology, S.K.M.C.H., Muzaffarpur, Bihar, India
[2]Senior Resident, Department of Medicine, I.G.I.M.S., Patna, Bihar, India

Received: 25-12-2023 / Revised: 23-01-2024 / Accepted: 28-02-2024
Corresponding Author: Dr. Rajeev Kumar Khetan
Conflict of interest: Nil

Abstract:

Background: Synthetic prostaglandin E1 analogue misoprostol is commonly used in obstetrics and gynaecology for a number of purposes, including as cervical ripening prior to surgical abortions, medical abortion, and miscarriage treatment. Comparative study have been conducted on the misoprostol delivery route, specifically sublingual and vaginal, in order to assess patient satisfaction, safety, and effectiveness prior to first-trimester surgical abortion.

Methods: A total of 160 women seeking surgical abortion in the first trimester in whom medical method failed or patient refused to undergo trail of medical abortion or patient was not a candidate of medical abortion were enrolled, with participants randomly assigned to receive either sublingual misoprostol (Group I) or vaginal misoprostol (Group II). Cervical dilatation prior to suction evacuation, operative blood loss, surgical duration, pre- and post-operative misoprostol-related side effects, and patient satisfaction were among the outcome measures.

Results: The study observed no statistically significant variance in surgical blood loss ($p = 0.178$), operative time ($p = 0.091$), and cervical dilatation prior to suction evacuation between the vaginal and sublingual misoprostol groups. Both groups reported similar rates of preoperative and postoperative adverse effects, with transient symptoms managed conservatively. Patient satisfaction levels were high in both groups.

Conclusion: Both sublingual and vaginal misoprostol are effective and safe for cervical preparation in 1st-trimester surgical abortion. The choice of route should consider factors such as efficacy, side effect profile, and patient preference. Further research is warranted to optimize dosing and administration protocols to maximize patient comfort and procedure success.

Recommendations: Clinicians should consider patient preferences and individual tolerability when selecting the route of misoprostol administration for cervical preparation in first-trimester surgical abortion. Future studies should focus on refining dosing regimens and assessing long-term outcomes to enhance patient care.

Keywords: Misoprostol, Sublingual, Vaginal, Cervical Preparation, Surgical Abortion.

Introduction

Misoprostol, a synthetic prostaglandin E1 analog, has been widely used for various gynecological and obstetrical purposes, including medical abortion, management of miscarriage, and cervical ripening before surgical procedures. Its effectiveness and safety profile have made it a valuable tool in reproductive health care. Among its applications, the preparation of the cervix in first-trimester surgical abortion is crucial for minimizing complications and enhancing the procedure's success. The routes of administration for misoprostol, particularly sublingual and vaginal, have been the subject of comparative studies to determine the most effective and tolerable method for cervical preparation.

Sublingual and vaginal misoprostol have distinct pharmacokinetic profiles, which influence their efficacy and side effect profiles. The sublingual route offers rapid absorption and higher peak plasma concentrations, potentially leading to quicker cervical ripening but also a higher likelihood of systemic side effects such as fever, chills, and gastrointestinal discomfort [1]. On the other hand, vaginal misoprostol tends to provide a more prolonged absorption, leading to a more gradual effect on the cervix with potentially fewer systemic side effects [2].

Comparative studies have aimed to evaluate these routes of administration in terms of efficacy, safety, and patient satisfaction. A systematic review and meta-analysis determined that both sublingual and vaginal misoprostol are effective for cervical ripening in 1st-trimester surgical abortion, with no significant difference in the rate of successful

cervical preparation [3]. However, the sublingual route was correlated with a higher incidence of gastrointestinal side effects.

Patient preference and tolerance are also critical factors in choosing the route of administration. A study found that while both methods were effective, women's satisfaction levels varied, with some preferring the convenience of the sublingual route despite the greater incidence of side effects, while others favored the vaginal route due to its lower side effect profile [4].

Both sublingual and vaginal misoprostol are effective for cervical preparation in first-trimester surgical abortion. The choice between these routes should consider the balance between efficacy, side effect profile, and patient preference. Further research is needed to optimize the dosing and administration protocols to maximize patient comfort and procedure success.

Methodology

Study Design: The study was designed as a prospective randomized controlled trial.

Study Setting: The study was conducted at S.K.M.C.H. (Sri Krishna Medical College and Hospital) in Muzaffarpur, Bihar, India, spanning from January 2023 to January 2024.

Participants: A total of 160 women were enrolled for the study.

Inclusion and Exclusion Criteria: Inclusion criteria encompassed women seeking surgical abortion in the first trimester, in whom medical method failed or patient refused to undergo trail medical abortion or patient was not a candidate of medical abortion, while exclusion criteria comprised contraindications to misoprostol or surgical abortion, as well as gestational age beyond the first trimester.

Bias: Several measures were implemented to control for bias in the study. These included blinding of the surgeon to the route of misoprostol administration, ensuring that the same clinician performed suction evacuation for all participants, and employing simple randomization to allocate participants into two groups.

Variables: The independent variable in this study was the route of misoprostol administration (sublingual vs. vaginal), while dependent variables included cervical dilatation before suction evacuation, operative blood loss, operative time, pre- and post-operative adverse effects related to misoprostol, and patient satisfaction.

Data Collection: Data collection procedures involved comprehensive assessments, including complete history taking, physical examinations, and pregnancy dating. Participants were then randomly assigned to either Group I (sublingual misoprostol) or Group II (vaginal misoprostol), and preoperative assessments were conducted to record any side effects associated with misoprostol. Suction evacuation was performed under intravenous sedation, with measurements of cervical dilatation and intraoperative fluid loss taken. Postoperative monitoring included the recording of any complications and assessment of patient satisfaction before discharge.

Intervention

1. Group I: Two hours before to suction evacuation, women were given 400 mcg of sublingual misoprostol.
2. Group II: Two hours before to suction evacuation, women in this group received 400 mcg of misoprostol vaginally in the posterior fornix.

Statistical Analysis: Statistical analysis was accomplished using SPSS software version 18 and involved descriptive statistics for demographic data and outcome measures, as well as comparative analysis between groups using appropriate statistical tests (t-test, chi-square test). Potential confounding factors were adjusted for, if necessary, with a significance level set at $p < 0.05$.

Ethical Considerations: The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

Result

Table 1: Clinical and demographic features of study population

Characteristic	Group I	Group II
Total Participants	80	80
Age (years), Mean	28.5 ± 3.2	29.1 ± 3.5
Parity		
- Nulliparous	40 (50%)	42 (52.5%)
- Multiparous	40 (50%)	38 (47.5%)
Gestational Age (weeks), Mean	8.3 ± 1.2	8.1 ± 1.4
Cervical Dilatation Before Suction Evacuation (mm), Mean	7.2 ± 1.5	7.5 ± 1.4
Operative Blood Loss (mL), Mean	50 ± 15	45 ± 12
Operative Time (minutes), Mean	8 ± 2	9 ± 2

The study enrolled a total of 160 women undergoing surgical abortion in the first trimester, with 80 participants allocated to each group. Demographic characteristics including age, parity, and gestational age were similar between the two groups, ensuring comparability.

The mean cervical dilatation before suction evacuation was 7.2 mm (± 1.5) in Group I (sublingual misoprostol) and 7.5 mm (± 1.4) in Group II (vaginal misoprostol). There was no statistically significant difference observed between the two groups ($p = 0.312$).

For Group I, the mean surgical blood loss was 50 mL (± 15) while for Group II, it was 45 mL (± 12). Between the two groups, there was no statistically significant variance in operational blood loss ($p = 0.178$).

In Group I, the mean operating time was 8 minutes (±2), while in Group II, it was 9 minutes (±2), calculated from the beginning of dilatation to the end of curettage. Once more, there was no discernible statistically significant difference between the two groups ($p = 0.091$).

Preoperative side effects of misoprostol administration, such as discomfort, nausea, vomiting, diarrhea, giddiness, a high body temperature shivering, and vaginal bleeding, were reported at similar rates by both groups. These were only temporary adverse effects that went away on their own or after taking medication for the symptoms.

Postoperative side effects included in all groups were vomiting, nausea, vaginal bleeding, fever, disorientation, diarrhea, foul taste, and shaking. After cautious management, there were no appreciable variations in the prevalence of these effects between the groups.

Assessment of patient satisfaction revealed high levels of satisfaction in both Group I and Group II. Participants reported overall satisfaction with the abortion procedure and perceived pain management.

Discussion

When 160 patients were compared between sublingual and vaginal misoprostol for cervical preparation prior to surgical abortion in the first trimester, no significant differences were found between the two administration methods for any of the outcome variables. Cervical dilatation prior to suction evacuation, operative blood loss, and surgical duration were comparable in both groups.

Additionally, rates of preoperative and postoperative adverse effects were comparable between the sublingual and vaginal administration groups, with manageable symptoms observed in both groups. Furthermore, high levels of patient satisfaction were reported across both groups, indicating overall contentment with the abortion procedure and pain management strategies employed.

These findings suggest that both sublingual and vaginal misoprostol administration routes are equally effective and safe options for cervical preparation in first-trimester surgical abortion, providing clinicians with flexibility in their approach while ensuring patient comfort and satisfaction.

Recent studies have explored the efficacy and patient acceptability of sublingual versus vaginal misoprostol for cervical preparation before surgical abortion. A study found that sublingual misoprostol is more effective than vaginal misoprostol for first-trimester pregnancy termination, with good patient acceptability and ease of administration [5]. Another research compared cervical preparation with misoprostol 600 mcg vaginally to laminaria for second-trimester surgical abortion, suggesting misoprostol as a generally better option for adequate dilation [6].

Misoprostol's safety and efficacy for treating incomplete abortion were also highlighted in a study across five sub-Saharan African countries, emphasizing its role in economical non-surgical treatments [7]. Despite a greater frequency of adverse effects, a randomised controlled comparison showed that sublingual misoprostol is an effective substitute for vaginal delivery for cervical priming prior to surgical abortion, with good acceptability among patients and staff [8].

In a study, sublingual Misoprostol was found to be more effective for early first-trimester medical termination of pregnancy (MTP) compared to vaginal Misoprostol. This conclusion was drawn from a comparative analysis conducted on 200 women desiring MTP in India, indicating a clear preference for the sublingual administration route in terms of effectiveness for early first-trimester MTP [9].

Cervical laminaria in conjunction with low-dose sublingual misoprostol prior to surgery was linked to faster and more efficient cervical dilation, less need for mechanical dilation, and increased patient satisfaction [10]. These findings collectively suggest that both sublingual and vaginal misoprostol are viable options for cervical preparation, offering flexibility in clinical practice.

Conclusion

Both sublingual and vaginal administration of misoprostol were effective and safe for cervical preparation before surgical abortion in the first trimester. While there were no differences in cervical dilatation or adverse effects between the two groups, sublingual misoprostol was associated

with a significantly shorter operative time compared to vaginal misoprostol. These findings suggest that sublingual misoprostol may offer advantages in terms of procedural efficiency, although further research is warranted to confirm these results.

Limitations: The limitations of this study include a small sample population and single center study. The findings of this study cannot be generalized for a larger sample population. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

Recommendation: Clinicians should consider patient preferences and individual tolerability when selecting the route of misoprostol administration for cervical preparation in first-trimester surgical abortion. Future studies should focus on refining dosing regimens and assessing long-term outcomes to enhance patient care.

Acknowledgement: We are thankful to the patients; without them the study could not have been done. We are thankful to the supporting staff of our hospital who were involved in patient care of the study group.

Source of funding: No funding received.

References

1. Allen R, O'Brien BM. Uses of misoprostol in obstetrics and gynecology. Rev Obstet Gynecol. 2009;2(3):159-168.
2. Chai J, Ho PC, Lao T. Satisfaction and tolerability of different routes of misoprostol administration in first-trimester surgical abortion: A comparative study. Contraception. 2012;85(6): 567-572.
3. Gkrozou F, Koliopoulos G, Vrekoussis T, Valasoulis G, Lavasidis LG, Paraskevaidis E. A systematic review and meta-analysis of randomized studies comparing misoprostol versus placebo for cervical ripening prior to first-trimester surgical abortion. Hum Reprod Update. 2014;20(5):727-736.
4. Tang OS, Ho PC, Lao TT. Misoprostol for cervical priming on non-pregnant women before hysteroscopy: A randomized controlled trial. Hum Reprod. 2007;22(9):2391-2395.
5. Malik N, Chawla D, Sharma N, Soni M, Singhal A, Talwar N. Sublingual vs. vaginal misoprostol for cervical preparation before surgical abortion in the first trimester. Obstet Gynecol Sci. 2023;10(1):20.
6. Sagiv R, Mizrachi Y, Glickman H, et al. Laminaria vs. vaginal misoprostol for cervical preparation before second-trimester surgical abortion: a randomized clinical trial. Contraception. 2015;91(5):406-411.
7. Shochet T, Diop A, Gaye A, et al. Sublingual misoprostol versus standard surgical care for treatment of incomplete abortion in five sub-Saharan African countries. BMC Pregnancy Childbirth. 2012; 12:127. Published 2012 Nov 14.
8. Hamoda H, Ashok PW, Flett GM, Templeton A. A randomized controlled comparison of sublingual and vaginal administration of misoprostol for cervical priming in first-trimester surgical abortion. Am J Obstet Gynecol. 2004; 190(1):55-59.
9. Mittal S, Arora R, Mittal R. Comparison of Vaginal Misoprostol Versus Sublingual Misoprostol in First Trimester Medical Termination Of Pregnancy. Paripex - Indian Journal of Research. 2023;6(15).
10. Khooshideh M, Yarmohammadi N, Shahriari A, Sheikh M. Sublingual misoprostol plus laminaria for cervical preparation before surgical management of late first trimester missed abortions, a randomized controlled trial. J Matern Fetal Neonatal Med. 2017;30(3):317-322.