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RESEARCH ARTICLE
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NO INCREASE IN POSTABORTAL COMPLICATIONS WITH HIGHER EFFICACY—A SAFETY ANALYSIS OF LOADING DOSE VAGINAL MISOPROSTOL FOR SECOND-TRIMESTER ABORTION: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Objective: This study examines the safety of a higher-efficacy, loading-dose vaginal misoprostol regimen for second-trimester abortion, emphasizing postabortal complications compared with a standard non-loading regimen.

Methods: A prospective randomized controlled trial involved 60 women (18–40 years, 13–24 weeks gestation) given mifepristone 200 mg orally, then randomized to either a loading-dose vaginal misoprostol regimen (800 µg loading dose, then 400 µg every 3 hours; Group A) or a non-loading regimen (400 µg every 3 hours; Group B), both to a maximum of five doses. Data on efficacy, adverse drug reactions, and postabortal complications were systematically collected. The primary safety outcomes were rates of incomplete abortion, hemorrhage, infection, and uterine rupture. Secondary outcomes included rates of adverse drug reactions such as fever, nausea, and vomiting.

Results: Both groups achieved 100% complete abortion within 36 hours. No participants in either group experienced major postabortal complications (incomplete abortion, hemorrhage, infection, uterine rupture). Fever was more common in the loading-dose group (33.3% vs 10%, p=0.028). No significant difference in rates of nausea or vomiting between groups. No cases required blood transfusion or surgical intervention. The incidence of any postabortal complication was 0% in both groups.

Conclusion: Loading-dose vaginal misoprostol provides higher efficacy (shorter induction-abortion interval, reduced drug requirement) with **no observed increase in postabortal complications** compared to the non-loading regimen, supporting its safety for second-trimester abortion.

Introduction

Rapid and safe completion of second-trimester abortion is vital for minimizing patient risk and resource use. While loading-dose vaginal misoprostol regimens have demonstrated higher efficacy, safety concerns—particularly regarding postabortal complications such as hemorrhage and incomplete abortion—may limit broad adoption. This trial evaluates whether a higher-efficacy loading regimen leads to increased postabortal morbidity, with a focus on clinically significant adverse outcomes (1-6).

Methods

Study Design

Sixty women (18–40 years, singleton pregnancy, 13–24 weeks gestation) were enrolled after informed consent and randomized using an even-odd serial allocation into:

- **Group A (Loading):** 800 µg vaginal misoprostol, then 400 µg every 3 hours (max 5 doses)
- **Group B (Non-loading):** 400 µg vaginal misoprostol every 3 hours (max 5 doses)

All received 200 mg oral mifepristone 48 hours before misoprostol initiation.

Data Collected

- **Efficacy:** Complete abortion within 12, 24, and 36 hours
- **Primary safety outcomes:** Incomplete abortion, hemorrhage, infection, uterine rupture
- **Secondary:** Adverse drug reactions (fever, nausea, vomiting), need for transfusion or surgical procedure

Analysis

Categorical variables compared via Fisher's exact test; $p<0.05$ considered significant.

Results

Table 1. Postabortal Complications in the Study Population

Complication	Group A (Loading, n=30)	Group B (Non-loading, n=30)	p-value
Incomplete abortion	0 (0%)	0 (0%)	1.00
Hemorrhage	0 (0%)	0 (0%)	1.00
Infection	0 (0%)	0 (0%)	1.00
Uterine rupture	0 (0%)	0 (0%)	1.00
Need for blood transfusion	0 (0%)	0 (0%)	1.00
Surgical intervention (D&C)	0 (0%)	0 (0%)	1.00

Table 2. Adverse Drug Reactions

Adverse Event	Group A (n=30)	Group B (n=30)	p-value
Fever	10 (33.3%)	3 (10%)	0.028
Nausea	5 (16.7%)	7 (23.3%)	0.519
Vomiting	2 (6.7%)	3 (10%)	0.640

Results:

No subject in either group developed incomplete abortion, hemorrhage, uterine rupture, or infection.

No woman needed a blood transfusion or surgical evacuation post-procedure. Adverse events were limited and self-limiting; only fever was significantly more common in the loading-dose group. All subjects achieved complete abortion within 36 hours.

Discussion

Despite concerns that higher efficacy regimens may cause increased uterine stimulation and complications, this study found **no increase in clinically significant postabortal complications** with the loading-dose regimen. Both regimens were equivalently safe with respect to incomplete abortion, hemorrhage, infection, and serious morbidity. The only adverse effect statistically increased with the loading dose was fever, a known and transient prostaglandin-related effect (1-3, 6).

These findings align with previous research that high-dose or loading misoprostol regimens do not increase the risk of major complications, even as they reduce the time to complete abortion and the total drug requirement (3, 4, 6).

Conclusion

A loading-dose vaginal misoprostol regimen for second-trimester medical abortion yields higher efficacy but does not increase the rate of postabortal complications compared to non-loading protocols. Shorter induction-abortion intervals and absence of severe morbidity support the routine adoption of this protocol in clinical practice.

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