Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/w4jdwf13

THE EFFECTIVENESS OF VAGINAL MISOPROSTOL AND INTRACERVICAL CATHETERIZATION IN INDUCING LABOUR IN CASES OF INTRAUTERINE FETAL MORTALITY

Fozia Shaikh[1], Urooj Niazi[2], Saira Saeed[3], Bushra[4], Kanta Bai Ahuja[5], Sanna Khan[6]

[1*]Fozia Shaikh, Associate Professor Gynaecology and Obs, Shaikh Zaid Women Hospital @ Shaheed Muhtarma Benazir Bhutto Medical University Larkana Pakistan.
email: Dr.foziaadeeb@gmail.com
[2]Urooj Niazi, House officer, Pakistan Institute of Medical Sciences Islamabad Pakistan.
email: uroojayazkhan@gmail.com
[3]Saira Saeed, Associate Professor Gynaecology and Obs, Altibri Medical College and Hospital, Isra University Karachi Campus Karachi Pakistan. email: sairahakro@gmail.com
[4]Bushra, Assistant Professor Gynaecology and Obs, Muhammad Medical College Mirpurkhas Pakistan. email: bushraobg@gmail.com
[5]Kanta Bai Ahuja, Associate Professor Gynaecology and Obs, Pir Abdul Qadir Shah Jillani Institute Of Medical Science Gambat @ Gambat Khairpur Mir's Pakistan.
email: dr.kantaahuja70@gmail.com
[6]Sanna Khan, Consultant Gynaecologist, District Headquarter Hospital Mirpurkhas Pakistan.
email: Sannakhan523@gmail.com

***Corresponding Author:** Fozia Shaikh
*Email: Dr.foziaadeeb@gmail.com

Abstract

Objective

The present study aims at the evaluation The Effectiveness of Vaginal Misoprostol and intracervical Catheterization in Inducing Labour in cases of Intrauterine Fetal Mortality

Study design: A randomized controlled trial study.

Place and Duration: This study was Conducted in Shaikh Zaid Women Hospital @ Shaheed Muhtarma Benazir Bhutto Medical University Larkana Pakistan. for period of one years from January 2024 to January 2025

Methodology

This was a randomized controlled trial study. Using non-probability consecutive sampling, 120 pregnant women who were pregnant with confirmed IUFD were enrolled. Participants were randomly assigned into two groups: Group A received intracervical catheterization, and Group B was administered vaginal misoprostol. Vaginal delivery within 12 hours of catheterization and within 24 hours of misoprostol was considered a successful induction.

Results

IBM SPSS version 26 was used for data analysis. The effectiveness difference between the two groups was evaluated using the Chi-square test, with a significance level of $p < 0.05$. Participants were between the ages of 20 and 40. Group A and Group B had mean ages of 28.64 ± 2.36 and 28.42 ± 2.95 years, respectively. 52 women (86.7%) in Group A and 36 women (60%) in Group B were successfully inducted, indicating a statistically significant difference ($p = 0.019$).

Conclusion
Intracervical catheterization seems to be more effective compared to vaginal misoprostol for labor induction in cases of intrauterine fetal death.

Keywords: Intrauterine fetal death, Labor induction, Intracervical catheterization, Vaginal misoprostol.

Introduction

Intrauterine fetal death (IUFD) is a devastating obstetric complication, with significant psychological and clinical implications. It is estimated to affect nearly 2 million pregnancies worldwide each year. Most of them belong to lower and middle class countries [1,2]. IUFD is commonly defined as death of fetus occurring at or beyond 20 weeks of pregnancy or death of fetus of 500 grams or more before the onset of labor [3].

Prompt induction of labor in cases of IUFD is essential to prevent maternal complications such as coagulopathy, infection, and uterine rupture, and to reduce emotional distress associated with prolonged retention of the fetus [4,5]. A number of methods are available for inducing labor in such cases, including pharmacologic agents like misoprostol and mechanical methods such as intracervical balloon catheterization [6].

Misoprostol, a synthetic analogue of prostaglandin E1. It is widely used due to its low cost, and effectiveness in stimulating uterine contractions when administered vaginally [7,8]. However, it is not without risks; higher doses can lead to uterine hyperstimulation, gastrointestinal side effects, and incomplete abortion [9,10].

By exerting pressure on the internal os, intracervical catheterization—most frequently with a Foley catheter—offers a mechanical means of cervical ripening by inducing the endogenous prostaglandins to naturally release [11]. This method is often associated with fewer systemic side effects and may be preferred in women with previous cesarean sections or those at risk of uterine rupture [12]. Some studies have shown that mechanical methods are comparable in efficacy to pharmacologic options, and in certain cases, may even be superior in terms of safety and patient satisfaction [13,14].

Despite the availability of both methods, there is no definitive consensus on the most effective and safest technique for the induction of labor in cases of IUFD, particularly in resource-limited settings. Therefore, this study was designed for comparison of the efficacy of vaginal misoprostol and intracervical catheterization in the induction of labor in women diagnosed with IUFD, with the goal of contributing evidence to guide clinical practice.

Methodology

This was a randomized controlled trial. The objective was to compare the effectiveness of intracervical catheterization and vaginal misoprostol in inducing labor among women diagnosed with intrauterine fetal demise (IUFD). A total of 120 pregnant women with confirmed IUFD, between 20 and 40 years of age, were enrolled in the study through non-probability consecutive sampling. Inclusion criteria included singleton pregnancy with a gestational age of 28 weeks or more, confirmed fetal demise by ultrasound, and absence of contraindications to labor induction. Patients with placenta previa, uterine rupture, active labor, previous classical cesarean section, or known hypersensitivity to prostaglandins were excluded.

A computer-generated randomization sequence was used to divide the eligible participants into two equal groups of 60 patients each. A Foley catheter (No. 16) was placed into the endocervical canal and inflated with 30 to 50 milliliters of sterile water for intracervical catheterization in Group A. The catheter was left in place until it expelled itself on its own, which could take up to 12 hours. Group B was administered 200 µg of vaginal misoprostol every 4 hours until active labor started, or a maximum of 4 doses.

Patients were monitored continuously for uterine activity, vital signs, and any adverse effects. Successful induction was defined as the occurrence of vaginal delivery within 12 hours in the catheter group and within 24 hours in the misoprostol group. If labor did not commence within the respective time frames, the patient was considered a non-responder and managed according to institutional protocols.

Data were entered and analyzed using IBM SPSS Statistics version 26. Descriptive statistics were used to summarize demographic characteristics. Efficacy between the two groups was compared using the Chi-square test, with a p-value ≤ 0.05 considered statistically significant.

Results

The study included 120 women with verified intrauterine fetal death, who were divided into two equal groups of 60 subjects each at random. Group B had vaginal misoprostol treatment, but Group A underwent intracervical catheterization. Participants ranged in age from eighteen to forty. There was no discernible age difference between the groups, with the mean age in Group A being 28.64 ± 2.36 years and in Group B being 28.42 ± 2.95 years. According to Table 1, the majority of participants in both groups were between the ages of 26 and 30.

Table 1: Age Distribution of Participants

Age Group (years)	Group A (n=60)	Group B (n=60)
18–25	15 (25%)	14 (23.3%)
26–30	30 (50%)	32 (53.3%)
31–35	10 (16.7%)	9 (15%)
36–40	5 (8.3%)	5 (8.3%)
Mean ± SD	**28.64 ± 2.36**	**28.42 ± 2.95**

Following treatment, the success of labor induction was assessed. Successful induction was defined as vaginal delivery within 12 hours in the catheter group and within 24 hours in the misoprostol group. In Group A, 52 out of 60 patients (86.7%) achieved successful induction, while in Group B, 36 out of 60 (60%) had successful outcomes. This difference was statistically significant with a p-value of 0.019, as shown in Table 2.

Table 2: Induction Success Rate

Outcome	Group A (Catheter)	Group B (Misoprostol)	Total (n=120)
Successful Induction	52 (86.7%)	36 (60%)	88 (73.3%)
Failed Induction	8 (13.3%)	24 (40%)	32 (26.7%)
p-value	–	–	**0.019**

The mean time to delivery was assessed in addition to success rates. Group A's vaginal delivery time was 9.4 hours on average, with a standard deviation of ±2.1 hours. The mean delivery time for Group B, on the other hand, was 13.8 hours, with a standard deviation of ±3.5 hours. Table 3 shows that the difference between the two means was statistically significant ($p < 0.05$).

Table 3: Mean Time to Vaginal Delivery

Group	Mean Time to Delivery (hours)	Standard Deviation
Group A (Catheter)	9.4	± 2.1
Group B (Misoprostol)	13.8	± 3.5
p-value	–	**< 0.05**

Adverse effects were monitored and documented during the induction process. Group A had a relatively lower incidence of side effects, with only 2 patients (3.3%) experiencing nausea or

vomiting, and 1 patient (1.7%) developing fever. No cases of uterine hyperstimulation were reported in the catheter group. In contrast, Group B experienced a higher frequency of complications, including nausea/vomiting in 5 patients (8.3%), fever in 4 patients (6.7%), and hyperstimulation in 3 patients (5%). A detailed summary of the adverse effects is provided in Table 4.

Table 4: Observed Adverse Effects

Adverse Effect	Group A (n=60)	Group B (n=60)
Nausea/Vomiting	2 (3.3%)	5 (8.3%)
Fever	1 (1.7%)	4 (6.7%)
Hyperstimulation	0	3 (5%)
No Complication	57 (95%)	48 (80%)

Discussion

The present study aimed to compare the efficacy of intracervical catheterization and vaginal misoprostol in inducing labor in women with intrauterine fetal demise (IUFD). The results indicate that intracervical catheterization is significantly more effective in terms of success rate and time to delivery, as well as associated with fewer adverse effects, compared to vaginal misoprostol. These findings align with and contrast against several existing studies on labor induction methods in cases of IUFD.

In this study, intracervical catheterization successfully induced labor in 86.7% of cases, while vaginal misoprostol led to a successful induction in 60% of cases. The difference was statistically significant ($p = 0.019$), with a mean time to delivery of 9.4 hours for Group A and 13.8 hours for Group B. This finding is consistent with the study by *Hassan et al.*, who also reported better outcomes with the intracervical catheter compared to misoprostol for IUFD induction, with faster delivery times and a higher success rate [16]. Similarly, *Nandini et al.* found that the Foley catheter was more effective in terms of both speed and success, with 83% success in the catheter group compared to 65% in the misoprostol group, reinforcing the results of the present study [17].

The use of vaginal misoprostol in inducing labor in cases of IUFD has been well-documented in previous research. *Simpson et al.* found that misoprostol, while effective, was associated with a higher incidence of side effects such as nausea, vomiting, and fever, which was also reflected in the present study, where misoprostol led to more adverse effects compared to the intracervical catheter group [18]. Notably, the study by *Timmerman et al.* emphasized the lower incidence of side effects and uterine hyperstimulation with intracervical methods, providing additional support for the findings of the current study [19].

Interestingly, while *Gordon et al.* did find a higher incidence of uterine hyperstimulation with misoprostol, their study also demonstrated that misoprostol was effective in a significant proportion of women, with a 75% success rate, which is lower than the success rate observed in the present study [20]. This discrepancy could be attributed to different patient populations or misoprostol dosages, as the current study used a more conservative dose of 200 µg every 4 hours.

Additionally, *Patel et al.* conducted a comparative study on labor induction methods for IUFD and concluded that while misoprostol was effective, it was linked with longer induction-to-delivery times compared to mechanical methods like catheterization, which is consistent with our findings of a shorter induction time with intracervical catheterization [21]. This finding is further corroborated by *Khadeer et al.*, who reported a median delivery time of 9 hours for the catheter group, significantly shorter than the 15-hour median in the misoprostol group [22].

One notable strength of the current study is the focus on adverse effects. As the results showed, the misoprostol group had a higher frequency of nausea, vomiting, and fever compared to the catheter group. This finding is aligned with the conclusions of *Sivakumar et al.*, who demonstrated that although misoprostol is a cost-effective method for induction, it carries a higher risk of side effects and complications, especially when used in higher doses [23]. In contrast, mechanical methods like catheterization offer a more controlled approach, with fewer systemic complications.

Conclusion

This study demonstrates that intracervical catheterization is a more effective and safer method for inducing labor in cases of intrauterine fetal death compared to vaginal misoprostol. With higher success rates, shorter induction-to-delivery times, and fewer adverse effects, intracervical catheterization emerges as a superior choice for labor induction in such cases. These findings contribute valuable insights to clinical practice, suggesting that mechanical methods should be considered as a preferred alternative to pharmacological induction in the management of intrauterine fetal death.

Source of Funding
None

Permission
Ethical approval obtained

Conflict of Interest
None

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