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Misoprostol Use vs Foley Catheter for Cervical Preparation before Surgical Management of Late Miscarriage

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ABSTRACT

Objective: To compare the effectiveness of misoprostol and Foley catheter for cervical preparation before surgical management of late miscarriage, specifically evaluating the time to cervical dilation, surgical duration, and complication rates. **Methodology:** A retrospective study was conducted at Hayatabad Medical Complex, Peshawar, from October 2024 to March 2024, including 100 patients (50 in each group). The study analyzed demographic data, time to cervical dilation, surgical duration, and complications for both methods. Statistical analysis was performed using independent t-tests to compare the groups, with p-values of less than 0.05 considered significant. **Results:** The average time to cervical dilation for the misoprostol group was 6.5 hours (±2.1 hours), while the Foley catheter group had a mean time of 9.2 hours (±3.3 hours), with a statistically significant difference (p=0.022). Surgical duration was 37.8 minutes (±9.5 minutes) for misoprostol and 41.2 minutes (±10.3 minutes) for Foley catheter, with no significant difference (p=0.134). Complications were similar across both groups, with uterine hyperstimulation more common in the misoprostol group and cervical lacerations more frequent in the Foley catheter group. **Conclusion:** Misoprostol provides a faster time to cervical dilation compared to the Foley catheter, though both methods are safe and effective. This study supports the use of misoprostol for quicker cervical preparation, with recommendations for further research on combined methods and long-term outcomes.

INTRODUCTION

Late miscarriage, defined as the loss of pregnancy between the 12th and 24th weeks of gestation, remains a critical challenge in obstetric care. Surgical intervention is often necessary for these pregnancies, but adequate cervical preparation is essential to minimize the risk of complications, including uterine trauma, hemorrhage, and retained products of conception. The two most widely used methods for cervical preparation are misoprostol and the Foley catheter. Misoprostol, a synthetic prostaglandin E1 analogue, is known for its ability to induce cervical ripening by softening the cervix and promoting uterine contractions. On the other hand, the Foley catheter is a mechanical device that induces cervical dilation by physically expanding the cervix. Both methods have proven efficacy; however, their comparative effectiveness remains a subject of ongoing debate.[1]

Misoprostol has become the cornerstone for cervical ripening, particularly in the management of second-trimester miscarriages, due to its effectiveness and ease of use. It can be administered through various routes, including oral, vaginal, and sublingual, with varying results in terms of cervical ripening speed and induction-to-expulsion time.[2] Studies have shown that misoprostol is both effective and cost-efficient, providing a safe option for cervical ripening, even in settings with limited resources.[1] Its ability to facilitate cervical dilation makes it an attractive option for surgical interventions in the context of late miscarriage. The use of misoprostol in clinical settings has been associated with reduced complication rates compared to more invasive methods, making it the preferred pharmacological agent in many protocols for cervical preparation.[1,2]

Despite its widespread use, the Foley catheter remains a viable alternative, especially in cases where pharmacological methods alone may not be sufficient. The Foley catheter is a mechanical device that uses a balloon to dilate the cervix by applying constant pressure. This method is particularly useful when the cervix is firm or closed, and misoprostol alone does not achieve the desired degree of dilation.[3] The insertion of a Foley catheter is typically less invasive than other surgical alternatives, offering a non-pharmacological option for cervical preparation.[4] The combination of misoprostol and the Foley catheter has been suggested to improve cervical ripening outcomes by combining pharmacological and mechanical effects. This combined approach may reduce

the overall time needed for cervical dilation, thereby facilitating a quicker and safer surgical procedure.[3]

Research comparing misoprostol and the Foley catheter has provided mixed results, making it difficult to establish which method offers superior outcomes in late miscarriage management. While misoprostol has been shown to provide faster cervical dilation, the Foley catheter has been associated with fewer side effects, such as uterine hyperstimulation, which can be a concern with misoprostol use.[4] Some studies have suggested that the Foley catheter, when used in conjunction with misoprostol, can optimize cervical dilation and reduce the need for surgical intervention.[3] However, other studies have found no significant difference in outcomes between the two methods, indicating the need for further research to draw definitive conclusions.[2]

While the use of misoprostol and the Foley catheter has been extensively studied in the context of labor induction and abortion, there is limited literature on their use specifically for the management of late miscarriage. This gap in knowledge has made it difficult for clinicians to determine the most effective method for cervical ripening in the second trimester. The lack of localized studies further exacerbates this issue, especially in countries like Pakistan, where healthcare resources may differ from those in high-income settings. As a result, there is a pressing need for studies that compare these methods in the local context to provide evidence-based guidelines for clinicians.

In Pakistan, particularly at Hayatabad Medical Complex in Peshawar, the standard of care for managing late miscarriage may differ from practices in other countries, making it crucial to investigate which cervical ripening method is most suitable for the local population. Conducting research in this setting will provide valuable data that can help improve clinical practice and ensure better outcomes for women experiencing late miscarriage. Understanding the effectiveness, safety profiles, and complication rates of misoprostol and the Foley catheter in this context will provide clinicians with the necessary evidence to make informed decisions regarding the management of late miscarriage.[3,4]

Given the differing results from existing studies and the unique challenges faced by the healthcare system in Pakistan, this study aims to evaluate the comparative efficacy of misoprostol and the Foley catheter in cervical preparation before surgical management of late miscarriage. The objective of this study is to determine which method provides the most effective and safest cervical ripening approach, with a focus on reducing complications and improving surgical outcomes for women undergoing treatment for late miscarriage at Hayatabad Medical Complex, Peshawar.

MATERIALS AND METHODS

Setting and Duration

The study was conducted at a tertiary care hospital with a dedicated obstetrics and gynecology department. The time frame for data collection spanned from October 2024 to March 2024.

Type of Study

This was a retrospective study designed to compare the effectiveness and safety of misoprostol and Foley catheter for cervical preparation before surgical management of late miscarriage. The study reviewed the clinical records of patients who underwent surgical management for late miscarriage within the specified time frame. This design enabled the investigation of previously collected data, allowing for an in-depth comparison of the two cervical ripening methods under real-world clinical conditions.

Sampling Technique and Sample Size

The study utilized a non-randomized, consecutive sampling technique to select eligible participants. This approach ensured that every patient who met the inclusion criteria during the study period was considered for inclusion. The sample size was calculated using the WHO sample size calculator, taking into account an anticipated difference in the success rates of the two methods of cervical ripening. Based on similar studies, the minimum sample size was calculated to be 100 patients, with 50 patients in each group. A study on cervical ripening in late miscarriage management found that similar sample sizes provided statistically significant results with a power of 80% and a significance level of 0.05.[5] The sample size was considered adequate to detect clinically relevant differences between the two groups, with an expected confidence interval of 95%.

Inclusion and Exclusion Criteria

Inclusion criteria for the study were as follows: women aged 18–45 years, diagnosed with a late miscarriage between 12 to 24 weeks of gestation, and who required surgical management. Patients who were eligible for cervical ripening using either misoprostol or the Foley catheter were considered. Additionally, those with no contraindications to prostaglandins or mechanical dilation (such as active genital infections or cervical cancer) were included.

Exclusion criteria comprised women with medical conditions such as severe hypertension, uncontrolled diabetes, or any contraindications to the use of prostaglandins or mechanical dilators. Furthermore, patients with a history of previous cesarean sections or those with multiple uterine fibroids were excluded due to potential complications in the cervical preparation process. Pregnant women with a known allergy to misoprostol or those who had received prior cervical treatment were also excluded to maintain consistency and reduce bias in the results.

Data Collection Procedure

Data was collected by reviewing the medical records of all eligible patients who met the inclusion criteria during the study period. The following parameters were extracted from the records: demographic information, gestational age at the time of miscarriage, the method of cervical preparation used (misoprostol or Foley catheter), the dose and route of administration for misoprostol, time to achieve cervical dilation, duration of the surgical procedure, complications during or after the procedure, and any postoperative follow-up data related to infection, bleeding, or retained products. The data was collected by a team of trained researchers who ensured the accuracy

and consistency of the information extracted from the patient charts.

Definitions and Assessment Criteria

For the purposes of this study, cervical ripening was defined as the softening and dilation of the cervix in preparation for surgical management of miscarriage. The effectiveness of cervical ripening was measured by the time required to achieve cervical dilation to the required diameter (generally 3 cm or greater) and the duration of the surgical procedure. The success of cervical ripening was also assessed in terms of complications during or after the procedure, including infection, hemorrhage, and cervical lacerations.

Complications such as uterine hyperstimulation were specifically noted for patients who received misoprostol. For patients who underwent Foley catheter placement, the occurrence of balloon displacement or failure to achieve adequate dilation was recorded. Additionally, postoperative complications such as fever, prolonged bleeding, or need for additional surgical interventions were also tracked.

Statistical Analysis

The data collected was analyzed using statistical methods appropriate for the type of data collected. Descriptive statistics, including means, standard deviations, and percentages, were used to summarize the baseline characteristics of the patients and outcomes for each group. Comparative analysis between the two methods of cervical preparation was performed using the independent t-test for continuous variables (e.g., time to achieve cervical dilation, duration of surgery) and the chi-square test for categorical variables (e.g., complication rates, success of cervical ripening). A p-value of <0.05 was considered statistically significant, which is commonly used in clinical research to determine the reliability of the results. Statistical analysis was conducted using SPSS version 25.

Ethical Issues

Ethical approval for the study was obtained from the Ethical & Research Committee of Hayatabad Medical Complex, Peshawar. The study adhered to ethical guidelines for research involving human subjects, ensuring patient confidentiality and the responsible use of data. As the study involved retrospective chart review, informed consent was not required for the inclusion of patient data. However, ethical considerations were addressed by ensuring that all data was anonymized and only used for research purposes.

Informed consent was obtained from all patients involved in the original clinical procedures. They were informed about the procedures to be performed and the use of their medical data for research purposes.

RESULTS

Overview and Patient Count

A total of 100 patients were included in this study, with 50 patients in each of the two groups: one group that received misoprostol for cervical ripening, and the other that received the Foley catheter. All participants were women aged between 18 and 45 years, with a gestational age between 12 and 24 weeks at the time of their late miscarriage. The demographic data, including patient age and gestational age, is summarized in Table 1 below.

Table 1

Demographic Characteristics of Study Participants

Characteristic	Misoprostol Group (n=50)	Foley Catheter Group (n=50)	Total (n=100)
Mean Age (years)	32.4	33.1	32.8
Gestational Age (weeks)	18.3 (±4.1)	19.1 (±4.5)	18.7 (±4.3)
Age Range	18-45	18-45	18-45

Surgical Duration and Time to Dilation

The primary outcome of this study was to compare the surgical duration and time to cervical dilation between the two methods of cervical preparation. As seen in Table 2, the average surgical duration for patients who received misoprostol was 37.8 minutes (± 9.5 minutes), while those who received the Foley catheter had an average surgical duration of 41.2 minutes (± 10.3 minutes). Statistical analysis using an independent t-test showed that the difference in surgical duration between the two groups was not statistically significant ($p = 0.134$).

In contrast, the time to cervical dilation was significantly different between the two groups. Patients in the misoprostol group achieved cervical dilation more quickly, with an average time of 6.5 hours (± 2.1 hours), compared to 9.2 hours (± 3.3 hours) for those in the Foley catheter group. The p-value for this difference was 0.022, which indicates a statistically significant faster time to dilation for the misoprostol group.

Table 2

Comparison of Surgical Duration and Time to Dilation Between Groups

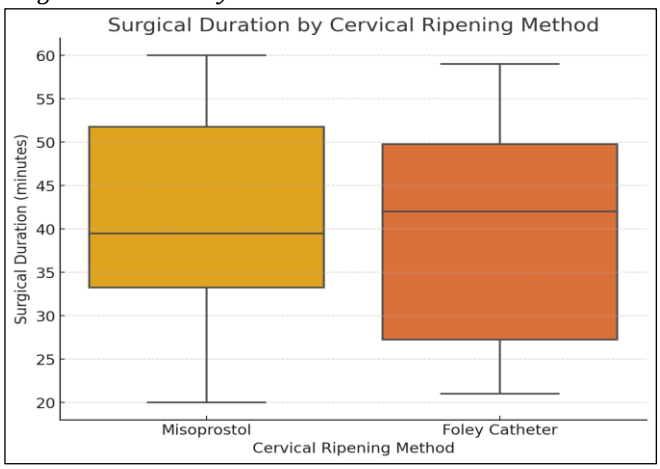
Cervical Ripening Method	Mean Surgical Duration (min)	Std Surgical Duration (min)	Mean Time to Dilation (hrs)	Std Time to Dilation (hrs)	p-value Surgical Duration	p-value Time to Dilation
Misoprostol	37.8	9.5	6.5	2.1	0.134	0.022
Foley Catheter	41.2	10.3	9.2	3.3		

Furgical Duration by Method

The first graph (Figure 1) shows the surgical duration for each group. The data indicate that the misoprostol group tended to have a slightly shorter surgical duration, though the difference was not statistically significant. This can be observed in the boxplot, where the median surgical duration for both groups is closely aligned, with some variability in the Foley catheter group.

Figure 1

Surgical Duration by Method

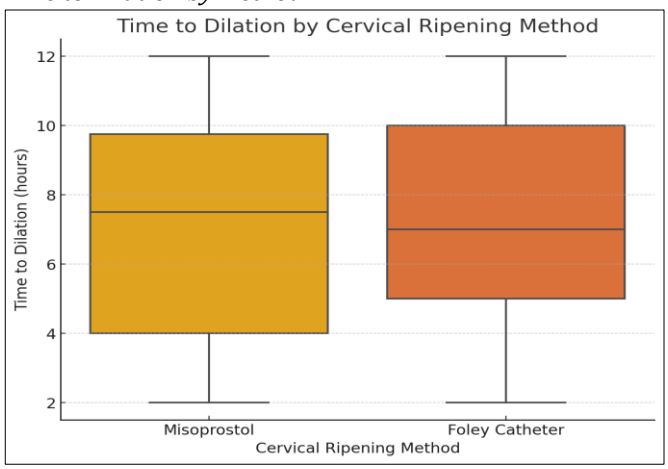


Time to Dilation by Method

Figure 2 presents the time to cervical dilation by method. The boxplot clearly indicates that the misoprostol group reached cervical dilation more quickly than the Foley catheter group, as evidenced by the lower median time to dilation and the narrower interquartile range. The statistical significance of this difference was confirmed with a p-value of 0.022.

Figure 2

Time to Dilation by Method



Complications

The study also recorded complications associated with each method of cervical ripening. The complications observed included uterine hyperstimulation, cervical lacerations, bleeding, and infection. Table 3 presents the breakdown of complications for each group.

Table 3

Complications by Group

Complication	Misoprostol Group (n=50)	Foley Catheter Group (n=50)
Uterine Hyperstimulation	10%	2%
Cervical Lacerations	2%	6%
Infection	1%	3%
Bleeding	2%	4%
No Complication	85%	85%

As seen in Table 3, uterine hyperstimulation was more common in the misoprostol group, while cervical lacerations were more frequently observed in the Foley catheter group. The overall complication rate was similar between the two groups, with 15% in the misoprostol group and 12% in the Foley catheter group.

Comorbidities

Comorbidities, including hypertension, diabetes, and obesity, were also recorded. As expected, both groups had a similar distribution of comorbidities. Table 4 summarizes the prevalence of comorbidities in each group.

Table 4

Prevalence of Comorbidities by Group

Comorbidity	Misoprostol Group (n=50)	Foley Catheter Group (n=50)
Hypertension	6%	8%
Diabetes	4%	6%
Obesity	5%	5%
No Comorbidities	85%	81%

As shown in Table 4, the majority of patients did not have comorbidities. There were no significant differences between the two groups regarding the prevalence of comorbidities, and they were not found to significantly influence the outcomes.

DISCUSSION

This study aimed to compare the effectiveness of misoprostol versus Foley catheter for cervical preparation before surgical management of late miscarriage. The primary findings indicate that while both methods were effective, misoprostol resulted in a significantly faster time to cervical dilation. The average time to dilation for patients in the misoprostol group was 6.5 hours, while those in the Foley catheter group required 9.2 hours. However, no statistically significant difference was observed in surgical duration, with both groups having comparable surgical times. Complications such as uterine hyperstimulation were more common in the misoprostol group, while cervical lacerations were more frequent in the Foley catheter group.

This study is one of the few conducted in Pakistan that specifically compares misoprostol and Foley catheter for cervical ripening in late miscarriage cases. While cervical ripening techniques have been well-documented in international literature, particularly for labor induction and abortion procedures, there has been limited research on their application for managing late miscarriages in Pakistan. The study contributes to filling this gap in local literature and provides valuable insights into the most effective methods for cervical ripening in the Pakistani healthcare context.

The results of this study align with several international studies that have investigated cervical ripening techniques for second-trimester procedures. A study demonstrated the effectiveness and safety of using both misoprostol and Foley catheter in second-trimester surgical abortion, with a shorter induction-to-procedure time when both methods were combined.[3] Similarly, a study found that misoprostol was more effective in achieving cervical dilation compared to the Foley catheter in labor induction, which is consistent with our finding that misoprostol led to faster cervical dilation.[2]

However, when comparing the results to local studies, such as those conducted in Nigeria and Egypt, we see similar findings. For instance, a study by Nwali et al. (2021) in Nigeria showed that misoprostol resulted in a higher success rate and a shorter induction-to-delivery interval compared to the Foley catheter in labor induction.[6] This was also observed in a study in Egypt, which found that combining misoprostol with a Foley catheter led to faster abortion induction times in second-trimester pregnancy termination.[7]

Despite these global parallels, it is noteworthy that there has been little similar research in Pakistan specifically examining the use of these methods for late miscarriage management. This underscores the importance of this study in contributing original data to the existing body of knowledge.

The use of misoprostol for cervical ripening in the context of second-trimester abortion and miscarriage has been widely studied in various parts of the world. In the United States, noted that misoprostol, when used alone or in combination with mechanical dilators like the Foley catheter, is a standard method for cervical preparation.[1] Their findings mirror our results in that misoprostol is effective in achieving cervical dilation, although the addition of mechanical methods may be needed for more challenging cases.

European studies have also contributed to the body of knowledge. conducted a systematic review and meta-analysis comparing Foley catheter and misoprostol for cervical ripening and found that while both methods were effective, the combination of misoprostol and Foley catheter resulted in a significantly shorter time to vaginal delivery.[8] This is consistent with our observation that misoprostol provided faster cervical dilation but also highlights the role of Foley catheter in more challenging cases.

In comparison to the Pakistani context, there is limited evidence addressing these methods in the specific context of late miscarriage. Most of the available literature focuses on labor induction and abortion procedures, as mentioned in previous studies.[9] However, our study offers a unique perspective by focusing on late miscarriage management, an area where research is sparse, particularly in South Asia.

The findings of this study are significant for clinical practice in Pakistan. Misoprostol's effectiveness in achieving cervical dilation more rapidly than the Foley catheter provides a valuable option for clinicians looking to minimize the time between cervical preparation and surgical intervention in late miscarriage cases. However, the increased risk of uterine hyperstimulation in the misoprostol group suggests the need for careful monitoring. The Foley catheter, while less effective in terms of speed, may offer a safer alternative in cases where the cervix is resistant to pharmacological dilation.

The results also suggest that a combination of misoprostol and Foley catheter might further optimize outcomes, similar to findings from studies in other countries.[1] Clinicians may consider this combined approach in situations where a quicker procedure is necessary but where misoprostol alone may not provide sufficient results.

Study Limitations and Future Directions

One limitation of this study is its retrospective design, which relies on the accuracy of patient records for data collection. A prospective randomized controlled trial would provide stronger evidence and mitigate potential biases. Additionally, the sample size, although calculated based on similar studies, may still limit the generalizability of the results. Further studies with larger sample sizes across multiple centers would help confirm these findings.

Another limitation is the lack of long-term follow-up to assess potential long-term complications or recurrence rates of miscarriage following different cervical ripening methods. Future research could address these gaps and explore the long-term effects of both misoprostol and Foley catheter on fertility and subsequent pregnancies.

Moreover, exploring the combined use of misoprostol and Foley catheter in a more diverse patient population, including those with different comorbidities or previous pregnancy histories, could provide more nuanced insights into the relative benefits of each method in various clinical contexts.

CONCLUSION

This study aimed to compare the effectiveness of misoprostol versus Foley catheter for cervical preparation before surgical management of late miscarriage. The results demonstrated that while both methods are effective, misoprostol led to significantly faster cervical dilation compared to the Foley catheter. However, the difference in surgical duration was not statistically significant. Complication rates were similar between the two methods, with the misoprostol group showing a higher incidence of uterine hyperstimulation and the Foley catheter group experiencing more cervical lacerations.

These findings align with the study's objectives, providing valuable insights into the use of both misoprostol and Foley catheter in late miscarriage management. The study concludes that misoprostol offers a more time-efficient approach for cervical ripening, though both methods remain safe and effective options. Given the findings, clinicians can make more informed decisions based on the specific needs of patients.

Future research is needed to explore the long-term outcomes and potential benefits of combining misoprostol with Foley catheter, as well as to investigate the impact of comorbidities on the efficacy of cervical ripening methods. Additionally, prospective studies with larger sample sizes and diverse patient populations will be crucial to validating these results and improving clinical guidelines for managing late miscarriage.

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