



Comparison in Efficacy of Misoprostol and uterine- Foley- Balloon Tamponade in Postpartum Haemorrhage

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ABSTRACT

Background: Postpartum hemorrhage remains one of the leading causes of maternal morbidity and mortality, especially in low-resource settings. Misoprostol and uterine Foley balloon tamponade are widely used therapeutic approaches, but limited data exist from Azad Kashmir regarding their comparative effectiveness. **Objective:** To compare the efficacy of misoprostol versus uterine Foley balloon tamponade among pregnant women in management of post-partum haemorrhage. **Study Design:** Randomized controlled trial. **Duration and Place of Study:** This study was conducted at the Department of Obstetrics and Gynecology, CMH Rawalakot, from December 2024 to May 2025. **Methodology:** A total of 206 women aged 18–45 years presenting with primary PPH were enrolled and randomly assigned to two equal groups. Group A received 1000 µg misoprostol per rectum, while Group B was managed with uterine Foley balloon tamponade. Demographic and clinical data, including parity, gestational age, blood loss, delivery type, and neonatal weight, were recorded. Treatment was considered successful if bleeding was controlled without further complications. **Results:** The mean age of participants was 33.41±7.50 years in the misoprostol group and 30.86±7.79 years in the Foley balloon group. Misoprostol achieved efficacy in 88.3% of patients, while the Foley balloon was effective in 81.6% (p=0.173). **Conclusion:** Both misoprostol and uterine Foley balloon tamponade demonstrated comparable efficacy in controlling PPH, making them viable options in resource-constrained clinical environments.

INTRODUCTION

Postpartum hemorrhage (PPH) is among the chief causes of maternal mortality and morbidity throughout the world, particularly among low- and middle-income countries.¹ Typically, its definition is loss of over 500 milliliters following vaginal delivery or over 1000 milliliters following cesarean delivery.¹ It can rise immediately after an interval of 24 hours postnatally and results from numerous reasons such as uterine atony, retained placental tissue, genital tract trauma, or disorders of coagulopathy.² It should be recognized early because progression is associated with extensive anemia, hypovolemic shock, multi-organ dysfunction, and maternal death even.³ Preventive strategies, active monitoring throughout labor, and early treatment comprise specific factors in preventing PPH's burden.⁴

Misoprostol is a prostaglandin E1 analogue that has been a highly frequent pharmacologic therapy for postpartum hemorrhaging resulting from uterine atony.⁵ It exerts its action by causing uterine contractions to aid uterus involution and reduce blood loss.⁶ Misoprostol is favored in most scenarios because it is convenient to administer, is also stable at room temperature, and is perfect for low-resource environments where intravenous

oxytocin is usually off-target.⁶ Misoprostol has been proven to reduce significantly the volume of hemorrhage as well as supplementary interventions needed to qualify as an excellent first-line treatment.⁷ Misoprostol is also known to be associated with side effects such as fever, chills, and gastrointestinal symptoms whose monitoring should be taken seriously and appropriately managed.⁸

The uterine Foley balloon tamponade is a mechanical method used to control severe postpartum hemorrhage when pharmacological interventions are insufficient.⁹ This technique involve inserting a balloon catheter into the uterine cavity and inflating it with sterile fluid to exert pressure on the uterine walls, thereby compressing bleeding vessels and promoting hemostasis.¹⁰ It is considered a safe, minimally invasive, and cost-effective approach that can be rapidly deploy in emergency situations. The balloon tamponade is especially useful in cases where PPH persist despite the administration of uterotonics or when surgical interventions are not immediately available.¹¹ Clinical evidences indicates that it is highly effective in controlling bleeding, stabilizing patients, and potentially avoiding more invasive procedures such as hysterectomy, thus preserving fertility and improving maternal outcomes.¹¹

Leon et al. evaluated the optimal dosing and adverse effects of misoprostol in the management of postpartum hemorrhage. Their findings indicated that complications were reported in only 6.1% of cases, excluding the commonly observed side effects of fever and shivering.¹²

Doumouchtsis SK et al. investigated the use of uterine balloon tamponade (UBT) for the control of postpartum hemorrhage. Hemostasis was successfully achieved in 22 out of 27 cases (81%), while complications were noted in 5 cases (19%).¹³

Very little local information is available about effective management strategies for postpartum hemorrhage from Rawalakot, Azad Kashmir, a condition that is a principal cause of maternal mortality as well as maternal morbidity. To establish practical, accessible interventions that are also cost-effective, a comparative effectiveness analysis between uterine Foley balloon tamponade and misoprostol is needed for such a setting. Such information can be used to guide local clinical practice to improve maternal health outcomes in regionally resource-constrained health facilities.

METHODOLOGY

This randomized controlled trial was carried out in the Department of Obstetrics and Gynecology at CMH Rawalakot between December 2024 and May 2025. Approval for the study was granted by the institutional ethics review committee (No: 736/Dated 09-11-2024) prior to the initiation of data collection. The sample size was determined through the WHO calculator, keeping an 80% study power and a 5% level of significance, while considering the expected proportion of complications reported with misoprostol and Foley balloon tamponade.^{12,13} A total of 206 women were included, with 103 allocated to each intervention arm. Participants were selected using a consecutive non-probability sampling technique.

Women aged 18 to 45 years presenting with primary postpartum hemorrhage following vaginal or cesarean delivery were enrolled. Those presenting late with PPH, suffering from renal or hepatic dysfunction, adrenal insufficiency, or using diuretics were excluded, as well as those who declined participation. Primary postpartum hemorrhage was defined as bleeding exceeding 500 ml after vaginal birth or more than 1000 ml following cesarean section, accompanied by clinical indicators of hypovolemia such as dizziness, palpitations, fainting, reduced urine output below 30 ml/hour, hypotension $\leq 90/60$ mmHg, tachycardia >100 beats/minute, or a relaxed uterus detected on abdominal examination.

Written informed consent was obtained from every participant prior to inclusion, with assurance of confidentiality and the right to withdraw at any stage. Baseline demographic data were recorded, including age, parity, gestational age, type of delivery, socioeconomic status, and residence. Clinical history and examination were performed to assess symptoms of hypovolemia, changes in uterine tone, and the extent of blood loss. Blood loss was measured using calibrated collection devices, graduated cylinders, or by weighing soaked pads. All patients initially received standard first-line measures including uterine massage and oxytocin administration before randomization.

Participants were then assigned into two groups. Group A received 1000 μ g misoprostol administered per rectum, while Group B was treated with a Foley catheter balloon tamponade fashioned with a condom, filled with incremental volumes of saline up to a maximum of 1000 ml. The device was maintained for a minimum of six hours and removed in stages as bleeding subsided. Prophylactic antibiotics were given to all women. Treatment was considered effective if no complications occurred, such as persistent uterine atony, excessive bleeding requiring transfusion (Hb <7 g/dl), gastrointestinal side effects (nausea, vomiting, or more than three episodes of diarrhea in a day), or expulsion of the balloon during the monitoring period.

Data were entered and analyzed using SPSS version 27. Quantitative variables were expressed as mean \pm standard deviation. Qualitative variables were presented as frequencies and percentages. Efficacy between the two interventions was compared using the chi-square test, with stratification for confounding variables. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

The study compared 206 patients with postpartum hemorrhage, equally divided between misoprostol (n=103) and uterine Foley balloon tamponade (n=103) groups. Demographic and clinical characteristics showed that patients in the misoprostol group had a mean age of 33.41 ± 7.50 years compared to 30.86 ± 7.79 years in the Foley balloon group, with gestational ages of 37.42 ± 2.47 weeks and 37.72 ± 2.46 weeks respectively. The misoprostol group had higher parity (3.13 ± 1.68 versus 2.56 ± 1.59), similar blood loss (984.11 ± 233.89 ml versus 967.31 ± 248.68 ml), and comparable duration of labor (177.78 ± 149.90 minutes versus 184.19 ± 136.98 minutes). Neonatal weights were 2558.67 ± 335.99 g in the misoprostol group and 2635.09 ± 343.20 g in the Foley balloon group. Multiple gestation occurred in 10 (9.7%) versus 8 (7.8%) patients, cesarean section rates were 71 (68.9%) versus 62 (60.2%), vaginal delivery rates were 32 (31.1%) versus 41 (39.8%), history of postpartum hemorrhage was identical at 23 (22.3%) in both groups, and immediate insertion was performed in 82 (79.6%) versus 84 (81.6%) patients respectively (as shown in Table I).

Table I

Comparison of Patient Demographics and Clinical Characteristics between Misoprostol and Uterine Foley Balloon Tamponade Groups

| Demographics | Misoprostol (n=103) | Uterine Foley Balloon Tamponade (n=103) |
|---------------------------|----------------------|---|
| Age (years) | 33.41 \pm 7.50 | 30.86 \pm 7.79 |
| Gestational Age (weeks) | 37.42 \pm 2.47 | 37.72 \pm 2.46 |
| Parity | 3.13 \pm 1.68 | 2.56 \pm 1.59 |
| Blood Loss (ml) | 984.11 \pm 233.89 | 967.31 \pm 248.68 |
| Duration of Labor (min) | 177.78 \pm 149.90 | 184.19 \pm 136.98 |
| Neonatal Weight (g) | 2558.67 \pm 335.99 | 2635.09 \pm 343.20 |
| Multiple Gestation | | |
| Yes n (%) | 10 (9.7%) | 8 (7.8%) |
| No n (%) | 93 (90.3%) | 95 (92.2%) |
| Mode of Delivery | | |
| C-section n (%) | 71 (68.9%) | 62 (60.2%) |
| Vaginal Delivery n (%) | 32 (31.1%) | 41 (39.8%) |

| PPH History | | |
|-----------------|------------|------------|
| Yes n (%) | 23 (22.3%) | 23 (22.3%) |
| No n (%) | 80 (77.7%) | 80 (77.7%) |
| Insertion Time | | |
| Immediate n (%) | 82 (79.6%) | 84 (81.6%) |
| Delay n (%) | 21 (20.4%) | 19 (18.4%) |

The overall efficacy analysis revealed that misoprostol achieved success in 91 (88.3%) patients compared to 84 (81.6%) patients with Foley balloon tamponade, with failure rates of 12 (11.7%) versus 19 (18.4%) respectively, though this difference was not statistically significant ($p=0.173$) (as shown in Table II).

Table II

Comparison of Efficacy between Misoprostol and Uterine Foley Balloon Tamponade Groups (n=206)

| Efficacy | Misoprostol n=103 n (%) | Uterine Foley Balloon Tamponade n=103 n (%) | P value |
|----------|-------------------------------|---|---------|
| Yes | 91 (88.3%) | 84 (81.6%) | 0.173 |
| No | 12 (11.7%) | 19 (18.4%) | |
| Total | 103 (100%) | 103 (100%) | |

Stratified efficacy analysis by demographic variables demonstrated varying success rates across different subgroups. For age stratification, patients ≤ 30 years

showed efficacy rates of 33 (86.8%) versus 44 (80.0%) with $p=0.742$, while those >30 years had rates of 58 (89.2%) versus 40 (83.3%) with $p=0.467$. Gestational age analysis revealed that patients ≤ 36 weeks had success rates of 37 (86.0%) versus 28 (77.8%) with $p=0.392$, and those >36 weeks showed 54 (90.0%) versus 56 (83.6%) with $p=0.304$. Parity-based analysis indicated that patients with ≤ 3 previous births had efficacy rates of 59 (90.8%) versus 68 (84.0%) with $p=0.270$, while those with >3 births showed 32 (84.2%) versus 16 (72.7%) with $p=0.349$. Multiple gestation cases demonstrated 10 (100.0%) versus 6 (75.0%) success rates with $p=0.164$, while singleton pregnancies had 81 (87.1%) versus 78 (82.1%) efficacy with $p=0.385$. Mode of delivery analysis showed cesarean section cases with 63 (88.7%) versus 49 (79.0%) success rates ($p=0.140$), and vaginal delivery cases with 28 (87.5%) versus 35 (85.4%) efficacy ($p=1.000$). Patients with previous postpartum hemorrhage history had success rates of 18 (78.3%) versus 22 (95.7%) with $p=0.134$, while those without prior history showed 73 (91.3%) versus 62 (77.5%) with $p=0.021$. Finally, immediate insertion timing resulted in 72 (87.8%) versus 72 (85.7%) success rates ($p=1.000$), while delayed insertion showed 19 (90.5%) versus 12 (63.2%) efficacy with $p=0.030$ (as shown in Table III).

Table III

Association of Efficacy with Demographic Variables

| Demographics variables | Group | Efficacy | | P-value |
|--------------------------------|---------------|-------------|------------|---------|
| | | Yes (n, %) | No (n, %) | |
| Age (years) | | | | |
| ≤ 30 | Misoprostol | 33 (86.8%) | 5 (13.2%) | 0.742* |
| | Foley Balloon | 44 (80.0%) | 11 (20.0%) | |
| >30 | Misoprostol | 58 (89.2%) | 7 (10.8%) | 0.467 |
| | Foley Balloon | 40 (83.3%) | 8 (16.7%) | |
| Gestational Age (weeks) | | | | |
| ≤ 36 | Misoprostol | 37 (86.0%) | 6 (14.0%) | 0.392 |
| | Foley Balloon | 28 (77.8%) | 8 (22.2%) | |
| >36 | Misoprostol | 54 (90.0%) | 6 (10.0%) | 0.304 |
| | Foley Balloon | 56 (83.6%) | 11 (16.4%) | |
| Parity | | | | |
| ≤ 3 | Misoprostol | 59 (90.8%) | 6 (9.2%) | 0.270 |
| | Foley Balloon | 68 (84.0%) | 13 (16.0%) | |
| >3 | Misoprostol | 32 (84.2%) | 6 (15.8%) | 0.349 |
| | Foley Balloon | 16 (72.7%) | 6 (27.3%) | |
| Multiple Gestation | | | | |
| Yes | Misoprostol | 10 (100.0%) | 0 (0.0%) | 0.164* |
| | Foley Balloon | 6 (75.0%) | 2 (25.0%) | |
| No | Misoprostol | 81 (87.1%) | 12 (12.9%) | 0.385 |
| | Foley Balloon | 78 (82.1%) | 17 (17.9%) | |
| Mode of Delivery | | | | |
| C-section | Misoprostol | 63 (88.7%) | 8 (11.3%) | 0.140 |
| | Foley Balloon | 49 (79.0%) | 13 (21.0%) | |
| Vaginal Delivery | Misoprostol | 28 (87.5%) | 4 (12.5%) | 1.000* |
| | Foley Balloon | 35 (85.4%) | 6 (14.6%) | |
| PPH History | | | | |
| Yes | Misoprostol | 18 (78.3%) | 5 (21.7%) | 0.134* |
| | Foley Balloon | 22 (95.7%) | 1 (4.3%) | |
| No | Misoprostol | 73 (91.3%) | 7 (8.8%) | 0.021 |
| | Foley Balloon | 62 (77.5%) | 18 (22.5%) | |
| Insertion Time | | | | |
| Immediate | Misoprostol | 72 (87.8%) | 10 (12.2%) | 1.000 |
| | Foley Balloon | 72 (85.7%) | 12 (14.3%) | |
| Delay | Misoprostol | 19 (90.5%) | 2 (9.5%) | 0.030* |
| | Foley Balloon | 12 (63.2%) | 7 (36.8%) | |

*Fisher's Exact Test

DISCUSSION

The present study demonstrated comparable efficacy between misoprostol and uterine Foley balloon

tamponade in managing postpartum hemorrhage, with success rates of 88.3% and 81.6% respectively, though this difference did not reach statistical significance ($p=0.173$).

This finding suggests that both interventions represent viable first-line therapeutic options for postpartum hemorrhage control, which aligns with the physiological mechanisms underlying each treatment approach.

The slightly higher efficacy observed with misoprostol can be attributed to its dual mechanism of action as a synthetic prostaglandin E1 analog, which induces powerful uterine contractions while simultaneously promoting vasoconstriction of uterine blood vessels, thereby addressing both uterine atony and vascular bleeding sources. Conversely, the Foley balloon tamponade achieves hemostasis primarily through mechanical compression of bleeding vessels against the uterine wall and lower uterine segment, creating direct pressure that promotes clot formation and vessel closure. The 6.7% difference in efficacy may reflect the broader spectrum of action of misoprostol compared to the purely mechanical approach of balloon tamponade.

The demographic variations in treatment response reveal important clinical insights, particularly the statistically significant differences observed in patients without prior postpartum hemorrhage history ($p=0.021$) and those with delayed insertion timing ($p=0.030$). In patients without previous hemorrhage history, misoprostol showed superior efficacy (91.3% versus 77.5%), likely because these patients retain better uterine muscle responsiveness to pharmacological stimulation, whereas the Foley balloon's effectiveness depends more on anatomical factors and proper positioning rather than muscle contractility. The marked difference in delayed insertion cases (90.5% versus 63.2%) suggests that misoprostol maintains its therapeutic efficacy over time due to its systemic absorption and sustained uterine stimulation, while balloon tamponade effectiveness diminishes with delayed application as continued bleeding may alter uterine anatomy and reduce the mechanical compression efficiency.

Our findings of 88.3% efficacy for misoprostol and 81.6% for uterine Foley balloon tamponade align closely with several contemporary studies examining similar interventions for postpartum hemorrhage management. The balloon tamponade success rates in our study are consistent with Chandrakar et al.¹⁴ who reported 88% efficacy for Foley's condom balloon tamponade, and Akhtar et al.¹⁵ who demonstrated 93.98% success with Foley's catheter balloon tamponade. Similarly, Nipanal et al.¹⁶ achieved 95.75% hemostasis using 24-French Foley catheter in 800 women with atonic PPH, while Agrawal et al.¹⁷ reported 98.1% efficacy with balloon tamponade compared to 88.7% with uterovaginal packing. These consistently high success rates across different populations and settings reinforce the reliability of balloon tamponade as a mechanical intervention, with variations likely attributable to differences in patient selection criteria, timing of intervention, and specific balloon techniques employed.

The demographic characteristics in our study, including mean ages of 33.41 ± 7.50 years for misoprostol and 30.86 ± 7.79 years for Foley balloon groups, are comparable to other investigations. Agrawal et al.¹⁷ reported similar ages of 28.25 ± 4.67 and 28.30 ± 4.61 years, while Akhtar et al.¹⁵ documented a mean age of 27.90 ± 4.96 years, suggesting that postpartum

hemorrhage predominantly affects women in their late twenties to early thirties across different geographical regions. The comparable blood loss volumes in our study (984.11 ± 233.89 ml versus 967.31 ± 248.68 ml) mirror the findings of Agrawal et al.¹⁷ who reported 600.28 ± 25.34 ml versus 699.21 ± 70.18 ml, though their absolute values were lower, possibly due to earlier intervention or different measurement protocols.

Interestingly, our non-significant difference between misoprostol and balloon tamponade ($p=0.173$) contrasts with the findings of Dumont et al.¹⁸ who investigated uterine balloon tamponade with condom-catheter as an adjunct to misoprostol versus misoprostol alone in 116 women. Their study revealed that adding balloon tamponade to misoprostol did not provide significant benefit and actually showed higher rates of invasive surgery or death (16% versus 7%, $p=0.238$) and increased blood loss >1000 ml (80% versus 52%, $p=0.01$). This divergence may be explained by the different study designs, as Dumont et al. used combination therapy rather than comparing the interventions as monotherapy, and their urban low-resource setting with immediate surgical access may have influenced treatment algorithms and patient outcomes differently than our study population.

The timing aspects observed in our study, where delayed insertion showed significantly better outcomes with misoprostol compared to balloon tamponade (90.5% versus 63.2%, $p=0.030$), find partial support in the literature regarding intervention timing. Akhtar et al.¹⁵ reported mean hemostasis time of 12.69 minutes with Foley's catheter, while Chandrakar et al.¹⁴ documented mean time to stop bleeding of 7.08 ± 2.14 minutes for Foley's balloon and 6.91 ± 1.45 minutes for JH balloon, suggesting that mechanical interventions may be more time-sensitive than pharmacological approaches. This temporal sensitivity likely reflects the progressive nature of postpartum hemorrhage, where continued bleeding may compromise the mechanical effectiveness of balloon tamponade through altered uterine geometry and reduced tissue responsiveness to compression.

The safety profiles observed in our study align with the broader literature, as Shetty et al.¹⁹ conducted a comprehensive narrative review of 33 studies comparing different balloon tamponade devices and found no significant differences in safety or complications between various approaches. Their reported effectiveness rates of 92.3% for condom-UBT, 84.3% for Bakri-UBT, and 97.3% for ESM-UBT bracket our findings and support the conclusion that multiple balloon tamponade techniques can achieve comparable efficacy. The absence of long-term complications reported by Chandrakar et al.¹⁴ and the low perforation rates documented by Agrawal et al.¹⁷ (0.9% versus 8.5% compared to uterovaginal packing) further substantiate the safety profile of these interventions when properly implemented.

The present study has several limitations that should be acknowledged when interpreting the findings. As a single-center study conducted at one institution, the generalizability of our results to other healthcare settings with different patient populations, resource availability, and clinical protocols may be limited. The study design did not include long-term follow-up assessment beyond the immediate postpartum period, which restricts our ability

to evaluate potential delayed complications or long-term reproductive outcomes associated with either intervention. Additionally, the non-blinded nature of the study may have introduced observer bias in outcome assessment, particularly regarding subjective measures of treatment success.

CONCLUSION

Our study has concluded that both misoprostol and uterine Foley balloon tamponade demonstrate comparable efficacy as first-line interventions for managing

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