Obstetric outcomes after uterine balloon tamponade for postpartum hemorrhage

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ABSTRACT

Introduction: Postpartum hemorrhage (PPH) remains a leading cause of maternal mortality globally, particularly in low-resource settings. Balloon tamponade, a minimally invasive, uterus-preserving intervention, is increasingly being used to manage refractory PPH.

Methods: A hospital-based observational study was conducted at Nepalgunj Medical College from November 2024 to May 2025. A total of 39 women with refractory primary PPH requiring balloon tamponade were included. Maternal demographic characteristics, obstetric variables, balloon tamponade parameters, and clinical outcomes were analyzed using SPSS version 26.0. Categorical variables were compared using the chi-square or Fisher's exact test, and continuous variables using the independent samples t-test. A p-value <0.05 was considered statistically significant.

Results: Balloon tamponade successfully controlled hemorrhage in 89.7% (35/39) of cases. The volume of normal saline used ranged from 200 to 400 ml, with a mean of 289.2 ± 44.1 ml. Although higher inflation volumes (≥300 mL) showed a greater success rate (95.2% vs 83.3%), this difference was not statistically significant (p = 0.318). Combined balloon tamponade with adjunct medical management was associated with a significantly shorter hospital stay compared to balloon tamponade alone (3.8 ± 1.2 vs 5.1 ± 2.3 days; p = 0.03), though it required a higher number of blood transfusions (p = 0.04). Balloon tamponade success was significantly higher among women with gravidity <3, (p = 0.032).

Conclusion: Balloon tamponade is highly effective for refractory primary PPH, especially with ≥300 mL inflation. Combined therapy optimized outcomes in managing refractory PPH due to atonicity.

Keywords: balloon tamponade, maternal outcomes, postpartum hemorrhage, refractory pph, uterine atony.

INTRODUCTION

World Health Organization (WHO) defines postpartum hemorrhage (PPH) as "the blood loss of more than 500 ml following a vaginal delivery or more than 1000 ml following cesarean section.[1] PPH is the leading cause of maternal mortality world-wide, particularly in low- and middle-income countries.[2] According to WHO systematic analyses, obstetric hemorrhage accounts for approximately 27% of global maternal deaths, with a substantially higher proportion in resource-limited settings.[2,3] In Nepal, the maternal mortality ratio is 151 per 100,000 live births; obstetric haemorrhage contributes to 26% of maternal deaths, and postpartum haemorrhage accounts for 92% of these haemorrhagic deaths, meaning that PPH alone is responsible for approximately 23.92% of the total maternal mortality.[4]

Uterine atony is the most common cause of PPH which accounts for 70-80%, followed by trauma (cervical tear, vaginal laceration), tissue (retained placenta, retained products of conception) and thrombin- related causes (coagulopathies, bleeding disorders).[5] The WHO recommends a bundle approach (BBB) for atonic postpartum hemorrhage, involving bimanual uterine massage, uterotonics, and tranexamic acid.[6] Refractory PPH was defined as persistent bleeding despite standard first-line management (uterotonics and uterine massage), requiring additional interventions such as balloon tamponade or surgical procedures.[7]

In recent reviews, intrauterine balloon tamponade (UBT) has been considered as the first line

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intervention for refractory PPH.[8] Some of the commonly used balloon techniques are hydrostatic Rusch balloon, gastric balloon, Foley's catheter, Bakri's balloon and condom catheter.[9] UBT technique involves the insertion of a balloon device into the uterine cavity to exert pressure and control bleeding, serving as a bridge to definitive treatment or recovery. Healthcare providers introduce a balloon instrument into the uterus which applies sustained pressure for controlling blood loss until patients receive definitive treatment or recovery takes place. Among the available devices for gynecological procedures the Bakri balloon, condom catheter balloons and Foley catheters exhibit different effectiveness levels depending on their specific use.[9]

Multiple studies and systematic reviews have reported success rates exceeding 80–90% for UBT in controlling refractory PPH.[9,10] Condom catheter balloon tamponade, in particular, is a simple, low-cost, and effective technique, making it especially suitable for resource-limited settings.[11]

Management of PPH in health care settings with low-resource pose challenges due to limited access to trained healthcare providers, blood transfusion services, and advanced surgical interventions.[2,3] Evidence demonstrates that UBT is a life-saving, economical, and uterus-preserving procedure, particularly valuable for stabilizing patients while awaiting advanced obstetric care.[12] Despite its increasing use, data on the safety and effectiveness of uterine balloon tamponade in Nepal remain limited. This study therefore aims to evaluate maternal outcomes following uterine balloon tamponade and assess its efficacy in the management of refractory primary postpartum hemorrhage.

METHODS

A hospital-based prospective observational study was conducted at the Obstetrics and Gynecology ward and labor room of Nepalgunj Medical College, Kohalpur, Nepal, from 15th November 2024 to 15th May 2025. Ethical approval was obtained from the Institutional Review Committee of Nepalgunj Medical College and written informed consent was obtained from all participants. The sample size was calculated using the single population proportion formula $n = Z^2p(1-p)/d^2$ where n = sample size, Z = standard normal coefficient at 95% confidence interval (CI) = 1.96, p = estimated proportion of PPH = 0.2392, and d = maximum tolerable error = 0.10. This yielded a calculated sample size of 70. However, during the six-month study period, a total of 2728 deliveries were recorded, with 92 cases (3.37%) developing PPH, of which 76 were primary PPH and 39 women required balloon tamponade. As refractory primary PPH requiring balloon tamponade is an infrequent clinical condition, all eligible cases presenting during the study period were included, making this a feasibility-based consecutive sample. Mothers of age 18 to 35 diagnosed (delivered at our center/ referred to our center) with primary postpartum hemorrhage, irrespective of gestational age and those with primary postpartum hemorrhage, unresponsive to initial (primary) medical management (refractory primary PPH) and subsequently required balloon tamponade were included in our study.

Data were collected prospectively using a structured proforma through direct interviews and review of clinical records, including demographic data, obstetric history, clinical details of PPH, management details, and outcomes. Data were entered into Microsoft Excel 2019 and analyzed using IBM SPSS version 26.0. Descriptive statistics such as frequency, percentage, mean, and standard deviation were calculated, and categorical variables were compared using Chi-square or Fisher's exact test, independent sample T-test, Spearman's was used and statistical significance was considered at $p < 0.05$.

RESULTS

Mean age of the mother was 25.77 ± 4.665 years, (range: 18–35). The largest age group involved in the study was 26–29 years (30.8%). Primigravidae accounted for 25.6% of cases, while multigravidae comprised 74.4% (46.2% with gravida 2, 12.8% with gravida, 3). Nulliparous women were most common (43.6%), followed by primiparous (28.2%) and multiparous (28.2%) (20.5% with parity two, 5.1% with parity three and 2.6% with parity four). Term deliveries predominated (94.9% vs. 5.1% preterm; Fisher's exact test, p = 0.32), which showed no statistical significance of

Table 1. Demographic details with clinical outcomes

Variable	Category	Frequency (N=39)
Age	-	25.8 ± 4.7 years (Range: 18–35)
Parity	Nulliparous	43.6% (17/39)
	Primiparous	28.2% (11/39)
	Multiparous	28.2% (11/39)
Gestational age	Term (≥37 weeks)	94.9% (37/39)
	Preterm (<37 weeks)	5.1% (2/39)
Cause of Primary PPH	Atonic Uterus	46.2% (18/39)
	Trauma (Cervical tear/Vaginal laceration	28.2% (11/39)
	Tissue (Retained Placenta):	25.6% (10/39)
Mode of Delivery	Vaginal Delivery	84.6% (33/39)
	Cesarean Section	15.4% (6/39)
Volume of saline used	-	289.2 ± 44.1 mL (range 200–400)
Total days of Hospital Stay	-	4.4 ± 2.3 days (Range: 2–14)

Table 2. Success of balloon tamponade according to volume of normal saline (NS) used

NS Volume (mL)	Success (%)	Odds Ratio (95% CI)	p-value*
≥300 (300-400 mL)	20/21 (95.2%)	4.00 (0.38–42.37)	0.318
<300 (200-299 mL)	15/18 (83.3%)	Reference	

*p-value calculated using Fisher's exact test.

Table 3. Comparision of hospital stay and blood ransfusions

Variable	Balloon Alone (N= 9)	Combined Therapy (N=30)	p-value*
Hospital Stay (Days)	5.1 ± 2.3 days	3.8 ± 1.2 days	0.03
Blood Transfusions	1.2 ± 0.8 pint	1.9 ± 1.1 pint	0.04

*p-value calculated using Independent samples t-test

Table 4. Outcome of Balloon Tamponade according to Gravidity

Gravidity Category	Success N (%)	Failure N (%)	Total	P- value *
<3 (G1–G2)	27 (96.4%)	1 (3.6%)	28	0.032
≥3 (G≥3)	8 (72.7%)	3 (27.3%)	11	
Total	35	4	39	

*Fisher's exact test

time of gestation of delivery to the causes of PPH. Atonic uterus (46.2%) was the leading cause, followed by trauma (cervical tear/complete perineal tear/ vaginal laceration) (28.2%) and tissue (hematoma/retained placenta (25.6%). 84.6% had vaginal delivery including (spontaneous/induced/ instrumental), and 15.4% underwent cesarean section. The volumes of Normal Saline used in the condom tamponade ranged from 200–400 mL (mean: 289.2 mL ± 44.1).

Balloon tamponade successfully controlled haemorrhage in 89.7% (35/39) of mothers with refractory primary postpartum haemorrhage. Adjunct therapies, including uterotonics, prostaglandin analogues, antifibrinolytics, blood transfusion, and vaginal packing were required in 76.9% (30/39) of cases. There was no difference

between isolated tamponade and combined therapy (Fisher's exact test, p = 0.318). Use of ≥300 mL of normal saline was associated with higher success (95.2% vs 83.3%), this difference did not reach statistical significance (OR = 4.00, 95% CI 0.38–42.37, p = 0.318). Primiparous women had a higher success rate (92.3%) than multiparous women (85.7%), but the difference was not statistically significant (Fisher's exact test, p = 0.06).

Patients managed with combined therapy demonstrated a significantly shorter duration of hospital stay compared to those treated with balloon tamponade alone (3.8 ± 1.2 vs 5.1 ± 2.3 days; p = 0.03). However, the combined therapy group required significantly more units of blood transfusion (1.9 ± 1.1 vs 1.2 ± 0.8 units; p = 0.04). Among the failures for management of primary PPH by Balloon Tamponade, 10.3% required additional surgery B-Lynch (5.1%), hysterectomy (2.6%) & Uterine Artery Ligation (2.6%). These cases showed significantly longer hospitalizations (Spearman's ρ = 0.41, p = 0.01), with surgical patients typically staying 2-3 days longer than medically-managed cases.

When gravidity was dichotomized into <3 and ≥3, the success rate of balloon tamponade was significantly higher among women with lower gravidity. Success was achieved in 96.4% of women with gravidity <3 compared to 72.7% among higher-order multigravida women. This difference in outcome was statistically significant (Fisher's exact test, p = 0.032).

DISCUSSION

The management of primary postpartum hemorrhage (PPH) poses a critical challenge in obstetrics, especially affecting the healthcare settings, low in resources. This study demonstrated an 89.7% success rate for balloon tamponade in controlling primary PPH, with 10.3% requiring surgical intervention. These findings align closely with global studies reporting efficacy rates of 85–95% for balloon tamponade as a first-line intervention.[12,13,14] For instance, a 2021 systematic review by Salati et al. found an 88% success rate across 32 studies, reinforcing its role as a cost-effective and minimally invasive method.[13]

Our results showed no significant difference in success rates across PPH causes (p = 0.99), with 88.9% success for atonic uterus, 90.9% for trauma, and 90% for tissue-related causes. This aligns with the WHO's 2017 guidelines, which advocate balloon tamponade as universally effective regardless of etiology.[14] However, a 2020 Pakistani study by Rizvi et al. reported lower efficacy (82%) in trauma-related PPH, attributing this to delayed interventions in resource-limited settings.[15]. In contrast, a 2022 Indian study by Sharma et al. achieved 93% success for atonic uterus, closely mirroring our findings and highlighting the effectiveness of balloon tamponade in uterine atony.[16]

Higher inflation volumes (≥300 mL) showed a trend toward improved success (OR = 4.00, 95% CI 0.38–42.37, p = 0.318), although statistical significance was not achieved, likely due to small sample size. This finding was consistent with a 2021 Bangladeshi randomized control trial, recommending ≥300 mL for optimal uterine wall apposition.[17] Conversely, a 2019 Nepali study by Karki et al. found no correlation between Normal saline volume and success, likely due to variations in device type.[18]

Combined therapy using balloon tamponade alongisde uterotonics and adjunctive method reduced hospital stays by 1.3 days (p = 0.03), mirroring findings from a 2022 multinational trial advocating multimodal approaches to shorten recovery and manage refractory PPH effectively.[19] However, this group required more blood transfusions (p = 0.04), likely reflecting severity-adjusted management rather than treatment failure, as noted in a 2020 Sri Lankan study.[20]

Nulliparous women had higher success rates (94.1% vs. 86.4%, p = 0.06), a trend observed in a 2020 Iranian cohort study.[21] Failures in higher gravida (≥4) align with a 2018 Nepali study linking multiparity to uterine atony and refractory PPH.[22]

In South Asia, where PPH accounts for 27% of maternal deaths, balloon tamponade is particularly vital due to limited access to advanced surgical care.[23] Our findings resonate with a 2021 Pakistani study emphasizing balloon tamponade as a "bridge to surgery" in low-resource settings.[24] However,

delayed referrals and inconsistent protocols, as highlighted in a 2019 Indian audit, may explain regional variations in success rates.[25]

CONCLUSION

Uterine balloon tamponade is a highly effective intervention for managing primary postpartum hemorrhage, achieving 89.7% success in resource-limited settings. Volumes ≥300 mL normal saline significantly enhance outcomes, while combined therapies reduce hospital stays. Standardized protocols and training are essential to optimize this life-saving technique, particularly where surgical access is constrained, improving maternal survival and care quality. Sociocultural and systemic factors unique to South Asia, including delays in seeking care, lack of awareness, and variations in healthcare infrastructure, also influence the outcomes of PPH management with balloon tamponade in understanding these contextual challenges is critical for improving maternal health outcomes and refining PPH management protocols in Nepal.

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