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EFFICACY OF INTRAUTERINE BALLOON TAMPONADE IN THE MANAGEMENT OF REFRACTORY POST-PARTUM HEMORRHAGE

Dr Hira Bilal[*1], Col Nadia Arif[2], Brig Shazia Nayyar[3], Lt Col Nusrat Noor[4] Major Murrawat Shaheen[5]

[*1,2,3,4,5] *CMH Kharian*

[*1]hirabilal414@gmail.com

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Corresponding Author: *
Hira Bilal

Abstract

Background: *Postpartum hemorrhage (PPH) is a leading cause of maternal morbidity and mortality worldwide. Refractory PPH, unresponsive to first-line medical management, requires timely and effective intervention to prevent life-threatening outcomes. Intrauterine balloon tamponade (UBT) has emerged as a minimally invasive, fertility-preserving method to control atonic bleeding.*

Objectives: *To evaluate the efficacy of intrauterine balloon tamponade in the management of refractory postpartum hemorrhage and compare outcomes based on the type of balloon used.*

Study Design & Setting: *A prospective interventional study conducted at the Department of Obstetrics and Gynecology, CMH Kharian over a period of six months.*

Methodology: *A total of 120 women with refractory PPH following vaginal or cesarean delivery were included. UBT was performed using either a 28 French Folleys Catheter or a condom catheter after failed medical management. Data on patient demographics, mode of delivery, cause of PPH, volume instilled, complications, and success rates were collected. Statistical analysis was conducted using SPSS version [insert version], and p-values < 0.05 were considered significant.*

Results: *The overall success rate of UBT was 85.0%, with 90.0% success in the 28 French Folleys Catheter group and 78.0% in the condom catheter group (p = 0.038). Vaginal deliveries had a significantly higher success rate compared to cesarean deliveries (p = 0.041). Complications were minimal, and 30.0% of patients experienced no morbidity.*

Conclusion: *Intrauterine balloon tamponade is a safe and effective intervention for refractory PPH and should be considered before surgical options.*

INTRODUCTION

Postpartum hemorrhage (PPH) remains one of the most pressing global challenges in maternal health, accounting for nearly one-quarter of all maternal deaths worldwide.[1] The World Health Organization (WHO) defines PPH as blood loss exceeding 500 mL after vaginal delivery or more than 1,000 mL after cesarean section.[2] Despite advances in obstetric care, PPH continues to pose a significant threat, particularly in low- and middle-income countries, where limited access to skilled healthcare providers and emergency interventions exacerbates maternal morbidity and mortality.[3] The condition may arise

due to uterine atony, retained placental tissue, genital tract trauma, or coagulopathies, with uterine atony being the most prevalent cause.[4]

Initial management of PPH includes uterotonic drugs, uterine massage, and fluid resuscitation. When these first-line interventions fail to control bleeding—a situation referred to as refractory PPH—more aggressive measures are warranted.[5] In the past, this often meant proceeding directly to surgical interventions such as uterine artery ligation, compression sutures (B-Lynch), or even hysterectomy. While effective, these surgical options carry substantial risks and may compromise future fertility. Consequently, there has been a growing interest in conservative, fertility-preserving approaches for managing refractory PPH.[6]

Intrauterine balloon tamponade (UBT) has emerged as a minimally invasive and effective technique in the stepwise management of refractory PPH. The principle of UBT involves inserting a sterile balloon device into the uterine cavity and inflating it with fluid to exert direct pressure on the uterine walls, thereby promoting hemostasis.[7] Devices such as the 28 French Folleys Catheter, Sengstaken-Blakemore tube, Foley catheters, and even low-cost condom catheters have been employed for this purpose.[8] Among these, the 28 French Folleys Catheter has been widely studied and endorsed by various obstetric guidelines, including those from FIGO and ACOG, particularly in cases of uterine atony or placenta previa.[9]

Numerous studies have reported high success rates of UBT in controlling hemorrhage and avoiding surgery, with effectiveness ranging from 70% to over 90% in various settings.[10-12] Moreover, UBT has demonstrated a favorable safety profile with low rates of complications such as infection, uterine rupture, or endometritis. The technique is simple, can be performed quickly at the bedside, and is especially beneficial in resource-limited settings where access to surgical facilities or blood transfusions is constrained.[13]

Despite its growing use and recommendation, variability in success rates across studies raises important questions about patient selection, timing of intervention, operator experience, and the specific type of balloon device used. Hence, there remains a critical need to evaluate its true efficacy and define clear clinical guidelines for its optimal use. his study aims to evaluate the efficacy of intrauterine balloon tamponade in the management of refractory postpartum hemorrhage in a tertiary care setting. By assessing outcomes such as bleeding control, need for additional interventions, maternal morbidity, and preservation of fertility, the study will contribute valuable evidence to support clinical decision-making. Given the rising emphasis on conservative obstetric interventions, understanding the role of UBT in managing life-threatening PPH is both timely and essential for improving maternal outcomes globally.

MATERIALS AND METHODS

This prospective interventional study was conducted in the Department of Obstetrics and Gynecology at CMH Kharian over a period of six months, after obtaining ethical approval from the Institutional Review Board. A total of 120 patients who developed refractory postpartum hemorrhage (PPH) following vaginal or cesarean delivery were included in the study. Refractory PPH was defined as ongoing excessive uterine bleeding not responsive to standard initial measures such as uterine massage, administration of uterotonics (oxytocin, misoprostol, or ergometrine), and fluid resuscitation.

The sample size of 120 patients was calculated using OpenEpi software, keeping a confidence level of 95%, power of 80%, and assuming an estimated efficacy rate of intrauterine balloon tamponade of 80% based on previous studies, with a 10% margin of error.[15] Patients who were hemodynamically stable and had bleeding primarily due to uterine atony were considered eligible. Women with PPH due to retained placental tissue, genital tract trauma, coagulopathy, or uterine rupture were excluded from the study. Written informed consent was obtained from all participants or their legal guardians before enrollment. Following failure of first-line medical management, intrauterine balloon tamponade was performed using a 28 French Folleys Catheter or a condom catheter balloon, depending on device availability. Under aseptic conditions, the balloon device was inserted into the uterine cavity, and sterile saline was instilled gradually (typically 300–500 mL) until adequate pressure was achieved to control bleeding. The balloon was left in situ for 12 to 24

hours based on clinical response, after which it was deflated and removed. Patients were closely monitored for vital signs, ongoing bleeding, uterine tone, and signs of infection. Additional interventions such as uterine artery ligation, B-Lynch sutures, or hysterectomy were recorded when necessary.

Data were collected on a predesigned proforma, including demographic details, parity, mode of delivery, cause of PPH, amount of blood loss, time to intervention, volume instilled, success or failure of the procedure, and need for further surgical or medical management. The primary outcome was the success of intrauterine balloon tamponade in controlling hemorrhage without the need for further surgical intervention. Secondary outcomes included maternal morbidity (need for transfusion, febrile illness, ICU admission) and fertility preservation.

Statistical analysis was performed using SPSS version 26.0. Categorical variables such as success rate and mode of delivery were expressed as frequencies and percentages, while continuous variables such as age and amount of blood loss were presented as mean ± standard deviation. The chi-square test was used to assess associations between categorical variables, and a p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1 shows the demographic and clinical characteristics of the 120 patients included in the study. The majority of patients were between 26 and 35 years of age (48.3%), followed by those aged 18–25 years (38.3%), while only 13.4% were above 35 years. Most women were multiparous (70.8%), indicating a higher representation of women with previous childbirth experience. Vaginal delivery was the more common mode of delivery, accounting for 61.7% of the cases, while cesarean sections were performed in 38.3% of the participants. Uterine atony was the most frequent cause of postpartum hemorrhage, observed in 80.0% of cases, followed by placenta previa (10.0%) and other causes (10.0%).

As shown in Table 2, intrauterine balloon tamponade was effective in controlling bleeding in 102 out of 120 patients, resulting in a success rate of 85.0%. Only 15.0% required additional surgical interventions. The 28 French Folleys Catheter was used in 58.3% of the patients, while the remaining 41.7% were managed using a condom catheter. The volume of fluid instilled in most patients (75.0%) ranged from 300 to 500 mL, with fewer patients requiring volumes of <300 mL (10.0%) or >500 mL (15.0%).

Table 3 presents the maternal morbidity associated with intrauterine balloon tamponade. Blood transfusion was required in 53.3% of the patients. Febrile illness or postpartum fever was observed in 9.2% of cases. ICU admission was necessary for 5.0% of the patients, while endometritis occurred in 2.5%. Importantly, 30.0% of the patients experienced no complications, suggesting a generally favorable safety profile of the procedure.

Table 4 illustrates the association between mode of delivery and the success of balloon tamponade. Among women who had a vaginal delivery, the procedure was successful in 90.5% of cases and failed in only 9.5%. In contrast, among cesarean section patients, the success rate was lower at 76.1%, with a failure rate of 23.9%. This association was statistically significant ($p = 0.041$), suggesting that vaginal delivery was associated with a higher likelihood of success with intrauterine balloon tamponade.

Table 5 compares the efficacy of the two types of balloons used. The 28 French Folleys Catheter showed a higher success rate (90.0%) compared to the condom catheter (78.0%), while the failure rate was lower with the 28 French Folleys Catheter (10.0%) than with the condom catheter (22.0%). This difference was statistically significant ($p = 0.038$), indicating superior performance of the 28 French Folleys Catheter in managing refractory postpartum hemorrhage.

Table 1: Demographic and Clinical Characteristics of Study Participants (n = 120)

Variables	Category	Frequency n (%)
Age (years)	18–25	46 (38.3%)
	26–35	58 (48.3%)
	>35	16 (13.4%)
Parity	Primiparous	35 (29.2%)
	Multiparous	85 (70.8%)
Mode of Delivery	Vaginal	74 (61.7%)
	Cesarean Section	46 (38.3%)
Cause of PPH	Uterine Atony	96 (80.0%)
	Placenta Previa	12 (10.0%)
	Other	12 (10.0%)

Table 2: Management Outcomes Following Intrauterine Balloon Tamponade (n = 120)

Outcome	Frequency n (%)
Successful Control of Bleeding	102 (85.0%)
Failure (Required Surgical Intervention)	18 (15.0%)
Type of Balloon Used	
28 French Folleys Catheter	70 (58.3%)
Condom Catheter	50 (41.7%)
Volume Instilled (mL)	
<300	12 (10.0%)
300–500	90 (75.0%)
>500	18 (15.0%)

Table 3: Maternal Morbidity Associated with Balloon Tamponade (n = 120)

Complication	Frequency n (%)
Blood Transfusion Required	64 (53.3%)
Postpartum Fever	11 (9.2%)
ICU Admission	6 (5.0%)
Endometritis	3 (2.5%)
No Complications	36 (30.0%)

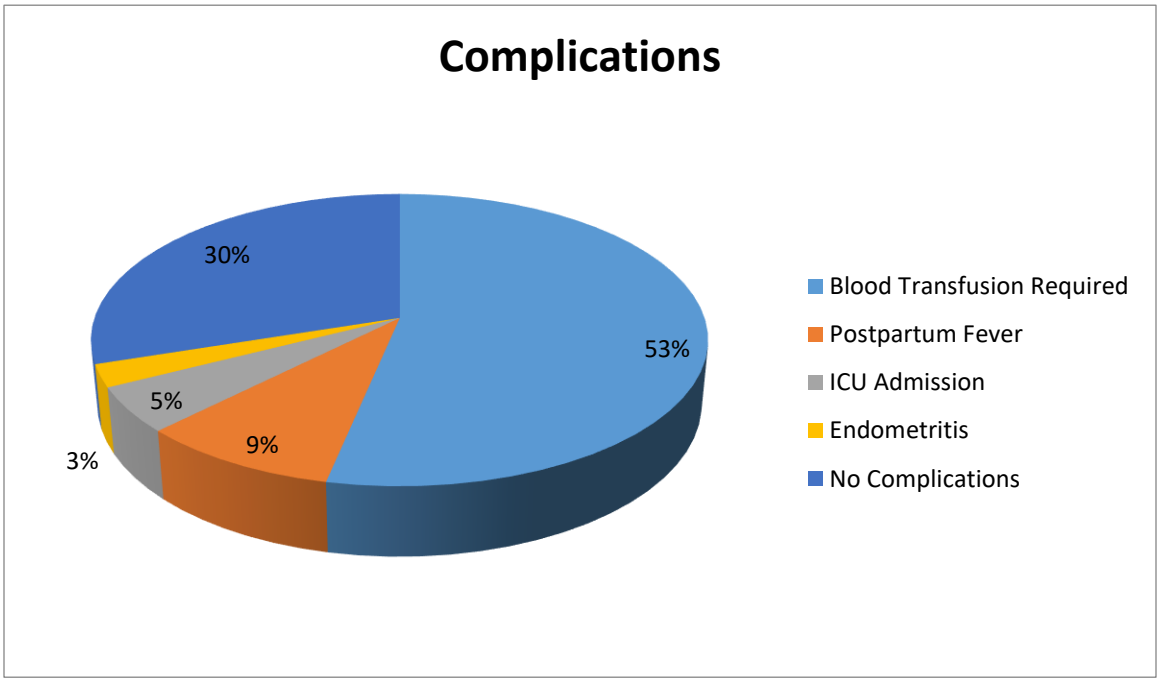

Figure 1: Maternal Complications Associated with Balloon Tamponade

Table 4: Association of Mode of Delivery with Balloon Tamponade Success (n = 120)

Mode of Delivery	Success n (%)	Failure n (%)	Total n (%)	p-value
Vaginal	67 (90.5%)	7 (9.5%)	74 (61.7%)	0.041*
Cesarean Section	35 (76.1%)	11 (23.9%)	46 (38.3%)	

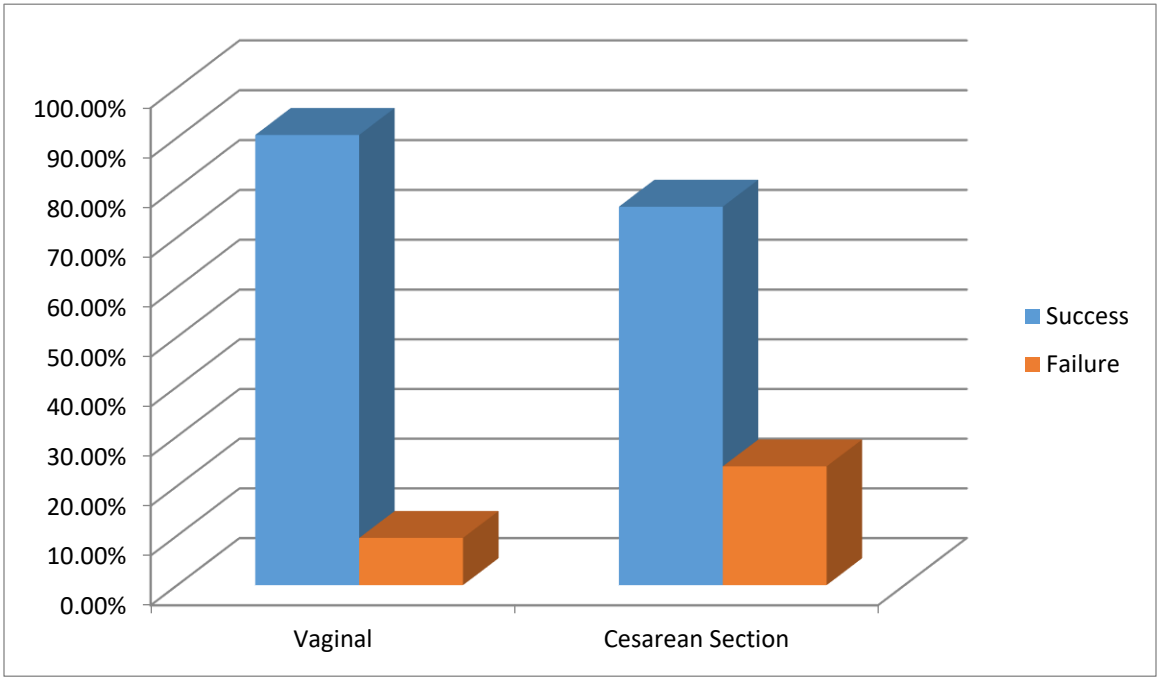

Figure 2: Mode of Delivery with Balloon Tamponade Success

Table 5: Association Between Type of Balloon Used and Outcome (n = 120)

Type of Balloon	Success n (%)	Failure n (%)	Total n (%)	p-value
28 French Folleys Catheter	63 (90.0%)	7 (10.0%)	70 (58.3%)	0.038*
Condom Catheter	39 (78.0%)	11 (22.0%)	50 (41.7%)	

*Chi-square test applied; *p < 0.05 considered statistically significant

DISCUSSION

Postpartum hemorrhage (PPH) is a major cause of maternal morbidity and mortality, especially in developing countries. It is defined as blood loss of more than 500 mL after vaginal delivery or more than 1,000 mL after cesarean section. Refractory PPH refers to bleeding that does not respond to first-line medical interventions.[12,13] Intrauterine balloon tamponade (UBT) has emerged as an effective, fertility-preserving method to control such bleeding. Devices like the 28 French Folleys Catheter or condom catheter are used to apply pressure within the uterine cavity.[14] This study aims to evaluate the efficacy and outcomes of UBT in women with refractory PPH.

In this study, intrauterine balloon tamponade (UBT) was found to be an effective intervention in managing refractory postpartum hemorrhage (PPH), with an overall success rate of 85.0%, aligning well with global data. When compared with Wang et al. (2023), who reported a hemostasis success rate of 88.9%, our findings are consistent and support the effectiveness of balloon tamponade in high-volume obstetric settings.[16] Similarly, Afzal (2021) demonstrated a success rate of 86% in a smaller cohort, which closely mirrors our outcome and

reinforces the value of UBT as a reliable, conservative approach for PPH due to uterine atony. In our study, success was significantly higher among patients who delivered vaginally (90.5%) compared to those who underwent cesarean section (76.1%, p = 0.041).[21] This trend was also noted by Rozenberg et al. (2023), where although there was no significant difference in primary outcomes between intervention and control groups, cesarean delivery was associated with higher composite complications and more blood loss.[17] Similarly, in the study by Yousaf et al. (2023), 55.6% of patients delivered vaginally, and the tamponade success rate was 81%, which falls slightly below our result but still confirms the general efficacy of the method in spontaneous vaginal deliveries.[18]

Pingray et al. (2021) presented a meta-analysis showing wide variability and generally low-certainty evidence, with one randomized trial showing a relative risk (RR) of 2.33 (95% CI: 0.76–7.14) for the composite outcome when comparing condom-catheter balloon with standard care. In contrast, our study showed a statistically significant difference in success rates between the 28 French Folleys Catheter (90.0%) and the condom catheter (78.0%, p = 0.038), thus supporting the preferential use of the 28 French Folleys Catheter over improvised alternatives where available.[15] Khan et al. (2023) conducted a comparative study which found UBT to be significantly more effective (89.3%) than uterine gauze packing (72.6%, p = 0.006), further validating our results and reinforcing that balloon tamponade is superior to traditional methods in controlling PPH caused by uterine atony.[19] Likewise, Ozgen et al. (2020) reported a BBT success rate of 91.3% in a high-risk population, which again supports the robustness of balloon tamponade in severe PPH, even in cases with complicated obstetric history such as multiple cesarean deliveries or placental site abnormalities.[20]

Maternal morbidity in our study was limited, with 53.3% requiring blood transfusion, 9.2% experiencing febrile illness, and only 2.5% developing endometritis. Rozenberg et al. (2023) observed a similar complication profile with 2.7% endometritis cases in the intervention group and none in controls (p = 0.06), indicating that infection risk remains low with proper technique and aseptic precautions.[17] Overall, our findings not only reinforce the established role of UBT in the stepwise management of refractory PPH but also demonstrate outcomes comparable to both local and international studies. The higher success rate with 28 French Folleys Catheter, better outcomes in vaginal deliveries, and minimal complication rates highlight the clinical utility and safety of UBT as a first-line conservative option before progressing to surgical interventions.

A major strength of this study is its prospective design and inclusion of a well-defined sample size. Use of standardized protocols for balloon tamponade ensured consistency. The study provides comparative data on different balloon types. However, it was conducted in a single center, which may limit generalizability. Long-term outcomes such as fertility preservation were not assessed. Additionally, the study excluded non-atonic causes of PPH, narrowing the scope.

CONCLUSION

Intrauterine balloon tamponade was found to be highly effective in managing refractory postpartum hemorrhage. The 28 French Folleys Catheter showed superior success compared to the condom catheter. UBT should be considered a valuable conservative option before proceeding to surgical interventions.

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