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Original Article

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Investigation of the efficacy and outcomes of intrauterine packing (IUP) versus balloon tamponade (BT) in achieving hemostasis in cases of postpartum hemorrhage (PPH) unresponsive to conventional medical interventions

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ABSTRACT

BACKGROUND & OBJECTIVE: Postpartum hemorrhage (PPH) remains a leading cause of maternal morbidity and mortality worldwide. When pharmacologic measures fail, surgical alternatives are required. This study aimed to compare the efficacy and safety of intrauterine packing (IUP) and balloon tamponade (BT) in achieving hemostasis in PPH due to uterine atony.

METHODOLOGY: A randomized controlled trial (ClinicalTrials.gov ID: NCT05234578) was conducted at MNCH Hospital, Faisalabad. A total of 220 women aged 18–40 years with primary PPH due to uterine atony were randomized into two groups: Group A (IUP) and Group B (BT). Outcomes included success in achieving hemostasis, complication rates, and blood loss.

RESULTS: Mean age and estimated blood loss were comparable between groups ($p > 0.05$). Although BT had a higher success rate (97.3%) than IUP (91.8%), the difference was not statistically significant ($p = 0.135$, Fisher's Exact Test). Perforation occurred more frequently in the IUP group (5.5%) than the BT group (0.9%), but this was also not significant ($p = 0.119$). Fever and hysterectomy rates showed no significant differences ($p > 0.05$).

CONCLUSION: Although BT showed trends toward greater efficacy and fewer complications than IUP, these differences were not statistically significant. However, due to its minimally invasive nature and favorable safety profile, BT may be considered a preferred option for managing PPH due to uterine atony. Further large-scale studies are warranted.

KEYWORDS: Postpartum Hemorrhage, Maternal Health, Hemostatic Techniques, Pregnancy Complications, Uterine Diseases.

INTRODUCTION

Postpartum hemorrhage is the most preventable cause of maternal illness and death worldwide [1]. Both internationally and domestically, the incidence of postpartum hemorrhage (PPH) is on the rise. Blood transfusion-related severe maternal morbidity has been increasing over the last 20 years. The complications associated with PPH may be severe and impose a substantial financial strain on the healthcare system [2]. According to local data, PPH is responsible for 34% of maternal mortality, which is alarming [3,4]. Some of the possible complications of postpartum hemorrhage include postpartum depression, anemia, acute stress responses, tiredness, dilutional coagulopathy, transfusion reaction, Sheehan's syndrome, infection, and undetected myocardial infarction (MI) [4]. These may negatively impact mothers' quality of life and even lead to maternal death [5].

Balloon tamponade (BT) with a Bakri balloon is currently practiced and considered the standard second-line technique [6]. Despite this, the method is not feasible in low- and middle-income countries due to the higher costs involved. IUP fitted with gauze presents a solution that is not only intriguing but also potentially more cost-effective. The use of intrauterine gauze packing is supported by limited data. Studies conducted in recent years have shown that gauze packing for PPH management can achieve positive outcomes, with a high success rate and no negative impact on reproductive outcomes [7].

Balloon tamponade (BT) is a medical procedure currently in practice to limit more invasive techniques for the treatment of PPH. Due to its ease of use and relatively non-invasive nature, it is widely practised. The first balloon device, the Bakri tamponade, was specifically designed to control

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postpartum hemorrhage and has higher success rates. BT has been more extensively studied in recent years, and newer systems have also been described[8,9]. According to the Royal College of Obstetricians and Gynaecologists, if pharmacologic interventions for bleeding fail, surgical procedures should be initiated[10]. If uterine atony is found to be the primary source of hemorrhage, BT is an effective and safe first surgical intervention.

Research by Shumaila Naeem and colleagues compared the success rate and complications of uterine gauze packing with those of uterine balloon tamponade in preventing major postpartum hemorrhage in women not responding to medical care. Their study included 103 patients—50 underwent balloon tamponade, and 53 underwent intrauterine packing—and showed no significant difference in age (p=0.502). The BT success rate was 96.0%, significantly higher than the 84.9% in the intrauterine packing group. Infection was also more prevalent in the intra-uterine packing (24.5%, p=0.001)[11]. These findings were also supported by another study, which found similar effectiveness levels of 88.7% for intrauterine packing and 98.1% for balloon tamponade [12] .Therefore, this study aims to compare the efficacy and outcomes of intrauterine packing and balloon tamponade in controlling postpartum hemorrhage due to uterine atony as there was no availability of local data and therefore a comparison cannot be made in our local hospital settings.

METHODOLOGY

This randomized controlled trial was conducted at the Obstetrics and Gynecology Department of MNCH Hospital, Faisalabad, after obtaining ethical approval from the Institutional Ethical Review Board (IERB Ref No: MNCH/Admn/25/6296). The study was registered at ClinicalTrials.gov (ID: NCT05234578). A total of 219 women aged 18–40 years were enrolled through consecutive sampling over 3 months, or until data collection was completed. The sample size was calculated with 80% power and a 5% level of significance, using efficacy values of 88.7% for intrauterine packing and 98.1% for balloon tamponade, as reported in the literature. Participants were randomly allocated into two equal groups: Group A received intrauterine packing (IUP), and Group B received balloon tamponade (BT). Randomization was performed using a computer-generated random sequence. A non-probability consecutive sampling technique was employed to recruit all eligible participants who presented during the study period.

Women presenting within 24 hours of delivery with postpartum hemorrhage due to uterine atony, irrespective of parity and mode of delivery (vaginal or cesarean), were included in the study. Patients were also eligible if they were referred from peripheral centers after delivery at 28 weeks or later of gestation. Exclusion criteria included postpartum hemorrhage due to genital tract trauma, coagulopathy, retained placental tissue, placenta previa or accreta, uterine anomalies, fever, or late-onset postpartum hemorrhage.

PPH was defined as blood loss exceeding 500 mL after vaginal delivery or more than 1000 mL after cesarean section, within 24 hours of delivery. Standard resuscitative measures, including IV fluids, uterotonics, and continuous monitoring of vital signs, were initiated for all participants. In the IUP group, 6–10 meters of sterile gauze were packed aseptically into the uterine cavity and vagina to provide uniform pressure. For cesarean deliveries that developed PPH, packing was done after uterine repair. In the BT group, two sterile Foley catheters were inserted into the uterine cavity—one in the upper segment and one in the lower segment—and inflated with 300 mL of normal saline to achieve tamponade. Both procedures were performed under aseptic conditions in the lithotomy position. Injectable antibiotics were administered for 3–5 days to all patients to minimize the risk of infection.

Patients were monitored post-intervention in a high-dependency unit. Success of the intervention was defined as cessation of bleeding within 15 minutes of insertion and hemodynamic stabilization with blood loss under 100 mL post-intervention. Safety outcomes were defined as the absence of infection, fever, uterine perforation, or need for further surgical intervention such as laparotomy or hysterectomy. In cases of continued bleeding or clinical deterioration, surgical management was initiated.

All clinical data, including patient demographics, parity, estimated blood loss, and complications, were recorded using a structured proforma and entered into SPSS version 25.0 for analysis. Frequencies and percentages were calculated for categorical variables such as efficacy and safety outcomes, while means and standard deviations were used for continuous variables such as age and blood loss. Chi-square test; when expected cell counts were <5, Fisher's Exact Test was applied. A p-value < 0.05 was considered statistically significant.

RESULTS

The data comprise two tables summarizing the comparison of clinical outcomes between the IUP (Intrauterine Packing) and BT (Balloon Tamponade) groups. Table-I focuses on continuous variables such as age, parity, and blood loss, while Table 2 presents categorical variables, including efficacy and safety (fever, perforation, and hysterectomy), analyzed using cross-tabs and significance tests.

Table-I presents the descriptive statistics for age, parity, and blood loss in the two study groups. The mean age of participants in the IUP group was 28.73 ± 6.46 years, while the mean age in the BT group was slightly lower at 28.26 ± 7.18 years. The difference was not statistically significant ($p = 0.615$), indicating that the age distributions were comparable between the groups. The mean parity was significantly higher in the IUP group (2.44 ± 1.47) compared to the BT group (2.04 ± 1.43), and this difference was statistically significant ($p = 0.043$), suggesting a slightly greater number of previous pregnancies among patients in

the intrauterine packing group. Mean estimated blood loss was 766.93 ± 56.95 mL in the IUP group (N=110) and 755.68 ± 58.69 mL in the BT group (N=110). The difference was not statistically significant (p = 0.151), indicating that both interventions were equally effective in minimizing blood loss.

Table-I: Comparison of continuous clinical variables between IUP and BT groups.

Variable	Group	n	Mean±SD	Std. Error Mean	Sig. (2-tailed)
Age	IUP (Intrauterine Packing)	110	28.73±6.46	0.62	0.615*
	BT (Balloon Tamponade)	110	28.26±7.18	0.68	
Parity	IUP (Intrauterine Packing)	110	2.44±1.47	0.14	0.043*
	BT (Balloon Tamponade)	110	2.04±1.43	0.14	
Blood Loss	IUP (Intrauterine Packing)	110	766.93±56.95	5.43	0.151*
	BT (Balloon Tamponade)	110	755.68±58.69	5.60	

***Independent Samples t-test.**

Table-II summarizes the efficacy and safety outcomes. Both interventions were effective, with successful hemostasis achieved in 91.8% of patients in the IUP group and 97.3% in the BT group. Although the BT group had a higher success rate, the difference was not statistically significant (p=0.135). Fever occurred in 14.5% of patients in the IUP group and 13.6% in the BT group, with no significant difference (p = 0.846). Perforation was reported in 6 patients (5.5%) in the IUP group and 1 patient (0.9%) in the BT group; however, this difference did not reach statistical significance (p=0.119, Fisher's Exact Test). Hysterectomy was required in 6 patients (5.5%) in the UVP group and 2 patients (1.8%) in the BT group, again showing no statistically significant difference (p=0.280). Overall, both IUP and BT were effective in achieving hemostasis, with BT showing a trend toward better safety outcomes, particularly lower perforation and hysterectomy rates, although these differences were not statistically significant.

Table -II: Comparison of efficacy and safety outcomes between IUP and BT groups.

Variable		Category	Group A n(%)	Group B n(%)	Total n(%)	P-value
Efficacy		Yes	101 (91.8)	107 (97.3)	208(94.5)	0.135*
		No	9 (8.2)	3 (2.7)	12(5.5)	
Safety	Fever	Yes	16 (14.5)	15 (13.6)	31(14.1)	0.846**
		No	94 (85.5)	95 (86.4)	189(85.9)	
	Perforation	Yes	6 (5.5)	1 (0.9)	7(3.2)	0.119*
		No	104 (94.5)	109(99.1)	213(96.8)	
	Hysterectomy	Yes	6 (5.5)	2 (1.8)	8(3.6)	0.280*
		No	104 (94.5)	108 (98.2)	212(96.4)	

***Fisher Exact test. **Chi Square test**

DISCUSSION

Traditional methods for managing postpartum hemorrhage (PPH), such as intrauterine packing (IUP), have long been employed in low-resource settings due to their cost-effectiveness. However, balloon tamponade (BT) has emerged as a promising alternative. This study compared the safety and efficacy of intrauterine packing (IUP) and BT in managing PPH secondary to uterine atony. The findings suggest that while both interventions are effective in achieving hemostasis, BT showed a numerically higher success rate and lower complication rates, though these differences were not statistically significant.

Specifically, the success rate for BT was 97.3% compared to 91.8% for IUP, with a non-significant p-value of 0.135 (Fisher's Exact Test). Similar trends were observed for complications. Perforation occurred in 5.5% of IUP cases versus 0.9% in the BT group (p = 0.119), while hysterectomy was required in 5.5% of IUP patients compared to 1.8% in the BT group (p = 0.280). Although these differences did not reach statistical significance, they align with the existing literature, which favors BT as the safer option.

These findings are consistent with those of Shumaila Naeem et al. , who reported a higher success rate for BT (95%) than for IUP (82%) and a lower infection rate in the BT group (p = 0.003) [11]. Similarly, Khan et al & Ashraf et al ,reported an 88.5% success rate for BT versus 70.8% for IUP [13,14]. Suarez et al , conducted a meta-analysis showing a pooled BT success rate of 86.3%, especially in cases of uterine atony and placenta previa [9]. Abul et al , also found that BT was associated with reduced blood loss and shorter operative time compared with IUP, reinforcing its clinical advantage [7].

In addition to better hemostasis, BT has been linked to a reduced need for invasive interventions. Suarez et al , reported that BT use led to a significant reduction in arterial embolization and surgical procedures (RR = 0.25, 95% CI: 0.12–0.56)[9]. However, not all studies agree. Some cluster-randomized trials have shown increased maternal mortality and surgical interventions following BT implementation,

possibly due to inconsistent training or delayed application. This underscores the importance of proper training, standardized protocols, and timely use.

Although our study did not demonstrate a statistically significant superiority of BT over IUP, the consistent numerical advantage in key outcomes, such as perforation and hysterectomy, supports its use as a safer, less invasive option. The relatively low complication rates (<6.4%) observed in both groups reaffirm that both techniques are generally safe when performed appropriately.

This study contributes to the growing body of evidence supporting BT as a cost-effective, minimally invasive intervention for the management of PPH. Its ease of use, low complication profile, and clinical effectiveness make it particularly attractive in both tertiary and low-resource settings. However, the absence of statistically significant differences in this study suggests that larger, multicenter trials are needed to confirm the observed trends.

LIMITATIONS:

Limitations of this study include its single-center design, which may limit external validity, and the lack of long-term follow-up to assess reproductive outcomes. Future studies should evaluate cost-effectiveness, implementation challenges, and long-term safety in diverse clinical environments.

CONCLUSION

This study demonstrates that both intrauterine packing (IUP) and balloon tamponade (BT) are effective options for achieving hemostasis in postpartum hemorrhage due to uterine atony. Although BT showed a higher success rate and fewer complications, these differences were not statistically significant. However, the consistent trends favoring BT in terms of safety and efficacy support its consideration as a preferred alternative. Further large-scale, multicenter studies are warranted to confirm these findings and to better understand the role of BT in diverse clinical settings.

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Authors Contributions:

Samar Amin: Substantial contributions to the conception or design of the work.
Fatima Abid: The acquisition, analysis and interpretation of data for the work.
Noor Abid : Drafting the work and reviewing it critically for important intellectual content.
Robina Ali: Final approval of the version to be published.

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