



Efficacy of the Use of Balloon Tamponade through Foleys Catheter in the Arresting of Primary Post-Partum Haemorrhage Due to Atonic Uterus in Primary versus Multigravida

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ABSTRACT

Background: Primary postpartum hemorrhage is a major reason for maternity morbidity and mortality, and this is most common in resource-constrained environments. Uterine atony is the most prevalent cause of such cases. When there is failure of medical therapy, balloon tamponade using a Foley catheter is the most cost-effective solution to the problem. **Objective:** To determine the efficacy of balloon tamponade through Foley catheter in arresting primary postpartum hemorrhage due to atonic uterus and to compare outcomes between primigravida and multigravida women. **Study Design:** Observational cross sectional study. **Duration and Place of Study:** This study was conducted from February 2024 to August 2024 in the Department of Obstetrics and Gynecology, Lady Reading Hospital, Peshawar. **Methodology:** A total of 102 women aged 18 to 40 years presenting with primary postpartum hemorrhage due to uterine atony were included. Balloon tamponade was performed using Foley catheter inflated with sterile normal saline. Patients were followed for 24 hours. Efficacy was defined as complete arrest of bleeding without surgical intervention. Data were analyzed using Statistical Package for Social Sciences version 26. Comparison of efficacy between primigravida and multigravida was done using chi square test and Fisher exact test. A p value of ≤ 0.05 was considered significant. **Results:** Mean age was 28.40 ± 6.27 years. Overall efficacy was observed in 90 patients (88.20%). Efficacy was higher in primigravida women (93.8%) compared to multigravida women (83.3%) but the difference was not statistically significant ($p = 0.130$). **Conclusion:** Balloon tamponade through Foley catheter is an effective and safe method for managing primary postpartum hemorrhage due to uterine atony regardless of parity.

INTRODUCTION

Postpartum hemorrhage refers to an important complication of childbirth. It has conventionally been defined as "Excessive bleeding within the first 24 hours of birth that exceeds 500 mL of blood loss for vaginal deliveries or exceeds 1000 mL of blood for caesarean deliveries".¹ It can quickly lead to shock and hemolytic anemia, organ hypoxia, and even death if isn't managed.² It results from uterine atony wherein there's poor contraction of the uterus after childbirth; this results in poor vasoconstriction of the vessels at the site of placental implantation, maintaining continuous bleeding.³ However, its risk factors encompass extensive labor, overdistension of the uterus due to multiple pregnancy and macrosomic babies, induction of labor and augmentation of contractions, chorioamnionitis, retained placental tissue and previous episodes of PPH.⁴ The signs and manifestations of PPH encompass saturated pads with

clots, hypotension, tachycardia, light-headedness, pallor and oliguria.⁵

Balloon tamponade through Foley catheter is a cost-effective and relatively simple procedure that may be performed when there is no effective control of bleeding with uterotonics and manual uterine massage in cases of an atonic uterus.⁶ The principle of this method is based on mechanical compression, wherein a balloon is placed inside the uterus and inflated with normal saline; in doing so, it compresses the bleeding vessels in the placental bed and aids in hemostasis.⁷ In actual practice, access to devices such as the Bakri balloon may be limited; hence, a Foley catheter or multiple catheters may be used as an alternative intrauterine balloon.⁸ The process is usually done under aseptic precautions. The cervix is evaluated, and the catheter is introduced into the uterus. The balloon is slowly expanded (usually 30-80 mL of fluid per catheter, but the process may allow a larger volume with multiple

catheters), at the same time evaluating the degree of vaginal bleeding and uterine tone.⁹ Sometimes, vaginal packing is done to ensure the position of the catheter, and antibiotics are given to prevent infection. Continuous patient monitoring is done by the nurse, involving vital signs, evaluation of uterine size, evaluation of vaginal bleeding, evaluation of urine output, and periodic laboratory tests.¹⁰ The balloon is usually retained for a number of hours before slowly deflating to determine the degree of hemostasis.

In comparison studies conducted on primigravidas and multigravidas, balloon tamponade using Foley catheters may be beneficial for both groups in terms of relieving postpartum hemorrhage resulting from atony of the uterus.¹¹ However, outcomes may vary due to the varying tone, pattern of labor, and risk factors. Primigravid women can potentially undergo atony resulting from prolonged labor, surgical delivery or induction, implying that the characteristics of the uterine muscle generally retain strong intrinsic tone, and thus, balloon tamponade together with uterotone may lead to quick cessation of bleeding.¹² Multigravid women can potentially face risks such as increased susceptibility to overdistension of the uterus due to previous pregnancy, faster labor, placental conditions, and antepartum hematomas due to antepartum hematomas.¹³ Conversely, in multigravid women, the cause may not only be atony but may potentially include conditions like retained products of conception, placenta accreta spectrum, due to the demographics of the population undergoing a surgical intervention.¹⁴

In a study by Darwish AM, et al. has shown that efficacy of balloon tamponade through Foley's catheter was 84.8% in the arresting of primary postpartum haemorrhage due to atonic uterus.¹⁵ In another study by Akhtar R, et al. has shown that efficacy of balloon tamponade through Foley's catheter was 96.43% in primigravida as compare to 93.48% in multigravida for arresting of primary postpartum haemorrhage.¹⁶

There is a great need to conduct such a study in the context of Peshawar, given that primary post-partum hemorrhage has remained one of the major contributors to the morbidity and mortality of mothers in the area, especially within the setting of delayed referrals and resource constraints. Also, in many of the tertiary and secondary-level hospitals of the area of Peshawar, because of the unavailability of the more expensive uterine balloon, it has remained necessary to use Foley's catheter. Nonetheless, available information within the local setting about the efficacy of Foley's catheter within primary versus multigravida patients is limited, and many of the local practices remain centered upon some degree of individual experience rather than hard evidence.

METHODOLOGY

This descriptive study was carried out in the Department of Obstetrics and Gynecology Lady Reading Hospital Peshawar and it was conducted over a period from 1 February 2024 to 1 August 2024. The study design was observational and cross-sectional in nature. Approval for the study was obtained from the institutional ethical committee of the hospital prior to initiation of data

collection and all ethical standards related to human research were followed throughout the study duration. The sample size was calculated by using the WHO sample size calculation formula. The calculation was based on an expected efficacy of 84.8%,¹⁵ a confidence interval of 95%, and a margin of error of 7%. A total of 102 patients were included. Patients were enrolled by using a non-probability consecutive sampling technique. Women aged between 18 and 40 years, having singleton pregnancy confirmed on ultrasound, gestational age more than 36 weeks calculated from last menstrual period and presenting with primary post-partum haemorrhage were included. Both primigravida and multigravida patients were taken. Uterine atony was identified when uterus was enlarged and soft on vaginal examination. Primigravida referred to a woman pregnant for the first time, while multigravida referred to a woman with history of ≥ 2 pregnancies. Primary post-partum haemorrhage was considered when estimated blood loss was ≥ 1000 mL after cesarean section or ≥ 500 mL after vaginal delivery within 24 hours, measured using soaked gauzes, pads and clots with conversion of 1 g equal to 1 mL of blood. Patients having genital tract injury, cervical tears, vaginal or perineal tears, pregnancy induced hypertension, chorioamnionitis, prolonged labour, polyhydramnios, morbidly adherent placenta or disseminated intravascular coagulation were excluded to avoid confounding effects. Written informed consent was obtained from each patient after explaining the purpose, procedure, benefits and possible risks of the study before starting data collection.

A detailed obstetric history was recorded, and then a clinical assessment was carried out to assess uterine tone and the amount of hemorrhage. After that, the diagnosis, balloon tamponade by Foley's catheter was carried out. The condom catheter set was assembled at the time of procedure and included a latex condom, an 18-gauge rubber catheter and string which was sterilized using ethylene oxide gas. After that the balloon was filled with 150mL of normal saline; subsequently it was steadily increased to 400-500mL until hemostasis. All procedures were done in the presence of or supervision from an attending consultant gynecologist with more than three years' experience post-fellowship. Also postsurgical patients were closely observed for 24 hours post-procedure. Primarily the outcome measure of the procedure was the efficacy of the balloon tamponade. Moreover, it was measured in relation to the assessment done in the first 24 hours post-procedure. Efficacy here entailed the total stopping of hemorrhage without any surgical intervention in the first 24 hours.

Data were entered and analyzed using SPSS version 26. Quantitative variables such as age, gestational age, body mass index were expressed as mean \pm standard deviation while categorical variables including primigravida / multigravida status, socioeconomic status, residential status and efficacy were presented as frequencies and percentages. Comparison of efficacy between primigravida and multigravida was done using chi square test. Stratification was applied for age, gestational age, body mass index, socioeconomic status and residential status, and post-stratification chi square test was used. A p-value of ≤ 0.05 was considered statistically significant.

RESULTS

The study included 102 patients with mean age of 28.40 ± 6.27 years and mean gestational age was 38.68 ± 1.14 weeks. The body mass index of participants was 26.67 ± 2.34 kg/m². Regarding socioeconomic status, 49 patients (48.0%) belongs to poor class, 40 patients (39.2%) were from middle class and 13 patients (12.7%) were from rich class. When residential status was assessed, 66 patients (64.7%) were residing in rural areas while 36 patients (35.3%) were from urban areas. In terms of parity, 48 patients (47.1%) were primigravida and 54 patients (52.9%) were multigravida (as shown in Table 1).

Table 1

Patient Demographics

Demographics	Mean \pm SD / n (%)	
Age (years)	28.40 \pm 6.27	
Gestational Age (weeks)	38.68 \pm 1.14	
BMI	26.67 \pm 2.34	
Socioeconomic Status	Poor n (%)	49 (48.0%)
	Middle n (%)	40 (39.2%)
	Rich n (%)	13 (12.7%)
Residential Status	Rural n (%)	66 (64.7%)
	Urban n (%)	36 (35.3%)
Parity	Primigravida n (%)	48 (47.1%)
	Multigravida n (%)	54 (52.9%)

The overall efficacy of balloon tamponade through Foley's catheter in arresting primary postpartum hemorrhage was observed in 90 patients (88.20%) while it was not effective in 12 patients (11.80%) (as shown in Table 2).

Table 2

Frequency of Efficacy

Efficacy	Frequency	% age
Yes	90	88.20%
No	12	11.80%

When efficacy was compared between primigravida and multigravida patients, it was found that 45 patients (93.8%) in primigravida group showed efficacy while 3 patients (6.3%) did not responded to treatment. In multigravida group, 45 patients (83.3%) showed efficacy whereas 9 patients (16.7%) did not showed efficacy. The difference between two groups was not statistically significant with p-value of 0.130 (as shown in Table 3).

Table 3

Comparison of Efficacy in Primary Versus Multigravida

Parity	Efficacy		P-value
	Yes n(%)	No n(%)	
Primigravida	45 (93.8%)	3 (6.3%)	0.130*
Multigravida	45 (83.3%)	9 (16.7%)	

*Fischer Exact Test

The association of efficacy with various demographic factors was also analyzed. For age groups, 59 patients (92.2%) aged ≤ 30 years showed efficacy compared to 5 patients (7.8%) who did not, while in patients aged >30 years, 31 patients (81.6%) showed efficacy and 7 patients (18.4%) did not showed efficacy, with p-value of 0.123 which was not significant. Regarding gestational age, 67 patients (89.3%) with gestational age ≤ 39 weeks showed

efficacy versus 8 patients (10.7%) without efficacy, whereas 23 patients (85.2%) with gestational age >39 weeks showed efficacy and 4 patients (14.8%) did not, with non-significant p-value of 0.728. For BMI categories, 33 patients (94.3%) with BMI ≤ 25 kg/m² demonstrated efficacy compared to 2 patients (5.7%) without efficacy, while 57 patients (85.1%) with BMI >25 kg/m² showed efficacy and 10 patients (14.9%) did not, with p-value of 0.211. In socioeconomic status groups, poor class had 44 patients (89.8%) with efficacy and 5 patients (10.2%) without, middle class had 34 patients (85.0%) with efficacy and 6 patients (15.0%) without, and rich class had 12 patients (92.3%) with efficacy and 1 patient (7.7%) without efficacy, with p-value of 0.690. For residential status, rural residents showed 60 patients (90.9%) with efficacy and 6 patients (9.1%) without, while urban residents had 30 patients (83.3%) with efficacy and 6 patients (16.7%) without efficacy, with p-value of 0.256. None of these demographic factors showed statistically significant association with efficacy (as shown in Table 4).

Table 4

Association of Efficacy with Demographic Factors

Demographic Factors	Efficacy		p-value	
	Yes n(%)	No n(%)		
Age (years)	≤ 30	59 (92.2%)	0.123*	
	>30	31 (81.6%)		7 (18.4%)
Gestational Age (weeks)	≤ 39	67 (89.3%)	0.728*	
	>39	23 (85.2%)		4 (14.8%)
BMI (Kg/m ²)	≤ 25	33 (94.3%)	0.211*	
	>25	57 (85.1%)		10 (14.9%)
Socioeconomic Status	Poor	44 (89.8%)	0.690*	
	Middle	34 (85.0%)		6 (15.0%)
	Rich	12 (92.3%)		1 (7.7%)
Residential Status	Rural	60 (90.9%)	0.256	
	Urban	30 (83.3%)		6 (16.7%)

*Fischer Exact Test

DISCUSSION

The current study proves that balloon tamponade is a highly efficacious treatment, which has a success rate of 88.20% (90 patients), comparable to other conservative management strategies for postpartum hemorrhage. The high success rate can be ascribed to the working mechanism of balloon tamponade, which provides continuous pressure within the uterus that works as a uterotonic effect, along with mechanical pressure exerted on bleeding vessels along the uterine walls. This pressure further works as an aid in the activation of the coagulation pathway and development of a stable clot at the placental site, thus efficiently controlling postpartum hemorrhage without requiring surgical assistance. On analysis of efficacy based on parity, primigravida patients had a relatively higher success rate at 93.8% (45 patients) as compared to multigravid patients, who had an efficacy of 83.3% (45 patients), although this was not statistically significant ($p = 0.130$). The reason for relatively better response rates being seen in primigravid patients may be due to increased tones and responsiveness of uterine musculature present in primigravid uterus to mechanical forces, which work as an added advantage while applying

tamponade. The multigravid uterus, on the other hand, has increased chances of having loose and dilated uterine musculature due to previous pregnancies, which may make it relatively less responsive to mechanical forces, thus resulting in slightly reduced efficacy rates.

The overall efficacy of balloon tamponade in present study was 88.20% (90 patients), which shows good agreement with several international studies. Kumar *et al.*¹⁷ reported 92% overall success rate in Indian population managing atonic PPH with various balloon devices, while Raouf and Abdullah¹⁸ achieved 100% success with Foley catheter tamponade in 110 Iraqi cases. Similarly, Naeem *et al.*¹⁹ demonstrated 96% efficacy with condom-catheter balloon tamponade in Pakistani women, and Garg and Yadav²⁰ reported 98.9% success rate with indigenous condom-balloon in Indian setting. The slight variation in success rates can be attributed to differences in patient selection criteria, timing of intervention, volume of balloon inflation, and severity of hemorrhage at time of intervention. Studies with higher success rates often initiated balloon tamponade earlier in management protocol, whereas delayed intervention may reduce efficacy due to progression of coagulopathy and hemodynamic instability. The present study findings of higher efficacy in primigravida 93.8% (45 patients) compared to multigravida 83.3% (45 patients), though not statistically significant ($p=0.130$), shows interesting contrast with existing literature. Kumar *et al.*¹⁷ included 60% multipara patients in their study but did not stratify results by parity, while Raouf and Abdullah¹⁸ had 85% multigravida population with 100% success rate, suggesting that parity may not significantly affects outcome when intervention is timely. However, Berber *et al.*²¹ reported 41% primigravida with 95.4% overall success, which is consistent with present study observation of better response in primigravida patients. The better outcomes in primigravida can be explained by preserved myometrial integrity and better contractile response, whereas multigravida uterus have undergone repeated stretching and remodeling which may compromises their ability to maintain sustained contraction even with mechanical tamponade effect.

Kong and To²² reported 79% success with Bakri balloon alone in Hong Kong population with mean age 32.7 years, which is slightly lower than present study efficacy. This difference may be due to use of specialized Bakri balloon versus simple Foley catheter, as Bakri allows for drainage monitoring but requires specific training and availability. Akhtar and Afzal¹⁶ achieved 93.98% success with Foley catheter in Pakistani setting with mean age 27.9 years, which closely matches present study population mean age of 28.40 ± 6.27 years and efficacy rate. The demographic similarity between these South Asian populations suggests that age and physiological factors plays important role in treatment response.

The influence of delivery mode was not stratified in present study, but several comparative studies provides insight. Kong and To²² included 63% caesarean deliveries with 79% success, while Kumar *et al.*¹⁷ reported 57%

vaginal deliveries with 92% overall success, and Akhtar and Afzal¹⁶ had 87% vaginal deliveries with 93.98% efficacy. These findings suggest that balloon tamponade is effective regardless of delivery route, though intra-operative placement during caesarean may allows for better positioning and earlier intervention.

Regarding safety profile, present study did not report any maternal mortality, which is consistent with all cited studies¹⁶⁻²² where no deaths were attributed to balloon tamponade procedure itself. Naeem *et al.*¹⁹ specifically compared balloon tamponade with gauze packing and found significantly lower infection rate with balloon (8% versus 24.5%, $p=0.001$), highlighting superior safety profile of balloon technique. Berber *et al.*²¹ reported complications including abdominal pain (36%), ICU admission (32%), and fever (23%), but no serious morbidity, indicating that minor complications are manageable and do not outweighs benefits of uterine preservation.

There are some limitations in the current research. Since it is a single-center study, the findings may not be applicable to other populations because of differences in patients' demographics, practices, and resources in different settings. With a sample size of 102 patients, there could be some difficulty in attaining enough power to determine if there is a statistical difference in the primigravida versus multigravida patients, given the $p = 0.130$. There was also no long-term outcome assessment in regards to fertility, menstrual cycles, or uterine complications in the patients who received balloon tamponade.

CONCLUSION

Conclusion drawn from the above study is that the procedure of balloon tamponade using Foley catheter is effective and safe for stopping primary postpartum hemorrhage due to atony of the uterus. Efficacy is quite satisfactory in dealing with life-threatening hemorrhage situations as well as in saving the patient from undergoing surgical procedures like hysterectomy. Efficacy seems somewhat higher in primigravida compared to multigravida patients, but it is not statistically significant; hence, it can be safely concluded that it can be effectively done in both parity statuses.

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Ethical Approval

This research was approved by the ethical committee. All research activities were carried out by following committee guideline and the rule of the Helsinki Declaration.

Patients' Consent

Written permission was taken from all patient before including them in the study. Patient were informed that their personal data would remain confidential and they were free to withdraw from the study at any time.

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