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Role of Foley's Catheter as Intra-Uterine Balloon Tamponade in Controlling Primary Post-Partum Hemorrhage after Vaginal Delivery

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ABSTRACT

One of the leading causes of maternal morbidity and mortality is primary post-partum hemorrhage (PPH). The utilization of intrauterine balloon tamponade has drastically reduced this deadly complication. In low-resource areas, the balloon of a 24-French Foley catheter is used for the same purpose. **Objectives:** To determine the safety and success rate of 24 Fr Foley's catheter as intra-uterine balloon tamponade in controlling Primary Post-Partum Hemorrhage after vaginal delivery. To determine the amount of bleeding at 15 and 30 minutes after the Foleys insertion to predict failure. **Methods:** This cross-sectional study included 140 consecutive women with PPH after failed medical treatment. A 24-French Foley catheter was placed in the uterine cavity, and the balloon was filled with 100 ml of normal saline.Bleeding was observed for the next 15 and 30 minutes. **Results:** The Foley Balloon tamponade was successful in controlling hemorrhage in 125 (89.2%) patients. While 15 (9.8%) patients had failed balloon tamponade. Patients with failed balloon tamponade had a higher rate of anemia, coagulopathy, and more bleeding after delivery, after 15 minutes, and after 30 minutes of Foley balloon placement. The positive predictive value for 150 ml and 200 ml was 0.60 and 0.80, respectively. **Conclusions:** It was concluded that the 24 Fr Foley is effective in controlling primary post-partum hemorrhage. A blood loss of ≥200 ml after 15 minutes of Foley balloon placement should alert the physician to adopt a more aggressive approach to control bleeding.

INTRODUCTION

One of the most dangerous obstetric complications is postpartum hemorrhage (PPH). Globally, it is among the leading causes of maternal morbidity and mortality. It complicates up to 10% of all deliveries. It impacts 6% of cesarean deliveries and 4 % of vaginal deliveries [1]. The World Health Organization (WHO) defines it as blood loss of more than 500 milliliters following vaginal delivery or 1,000 milliliters following cesarean section. A 10% decrease in hemoglobin from the baseline or altered vital signs upon delivery are alternative definitions. Primary PPH is defined as PPH that appears within 24 hours of delivery. Up to 60% of mortality in underdeveloped nations is caused by primary PPH [2]. Uterine atony (failed uterine contraction after delivery) occurs in up to 70% of cases of primary PPH. Other causes include genital tract trauma, retained products of conception, and coagulopathy [3]. Premature or prolonged labor, excessive oxytocin use, multiple gestations, fetal macrosomia, grand multiparity,

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chorioamnionitis, and numerous other conditions are risk factors for uterine atony. In South Asia, these variables are frequently present in expectant mothers.The bulk of the population lives in rural areas, where there are disparities in the health care system, inadequate prenatal care, frequent short-spaced childbirths, lack of contraception, and unskilled birth attendants [4].The management of primary PPH includes exclusion of genital tract trauma, coagulopathy, evacuation of retained conception products, and administration of uterotonic agents. Other measures like Uterine compression, intrauterine balloon tamponade, or surgical intervention are used in primary PPH that is refractory to uterotonic agents [5]. The utility of the Foley catheter for intrauterine balloon tamponade was initially reported by Goldrath [6].The WHO, International Federation of Gynaecology and Obstetrics (FIGO), and American College of Obstetricians and Gynaecologists (ACOG) advocate that uterine balloon tamponade is useful in low-resource settings when uterotonics fail to control PPH.It can reduce bleeding and allow resuscitation before shifting the patient to the operating theatre [7].The success rate of intrauterine balloon tamponade in uterine atony is reported to be up to 87% by Suarez *et al.*, [8].For uterine tamponade, there are several different catheter options, including the Sengstaken-Blackmore tube, condom, Rusch urology catheter, and Bakri balloon.Still, the Foley catheter is less intrusive, less expensive, more widely available, and useful in low-resource environments. It functions by physically closing the orifices of the bleeding venous sinuses in the placental bed and applying mechanical pressure on them.Other processes could be the contraction of the uterine muscles and the hydrostatic pressure of the balloon, which reduces the flow of blood through the uterus. This results in blood clot formation and stops bleeding [9, 10].The primary objective of our study is to determine the safety and success rate of uterine balloon tamponade using a 24 Fr Foley catheter for treating postpartum hemorrhage in an atonic uterus.To anticipate the device's failure, it is crucial to estimate the amount of bleeding following the placement of the Foley catheter. No literature from the region has addressed this problem. The secondary objective is to determine the amount of bleeding at 15 and 30 minutes following the Foleys insertion to forecast failure.

This study aims to provide valuable insights into the effectiveness of this intervention and potentially influence obstetric emergency protocols to improve maternal outcomes in low-resource settings where such emergencies are more prevalent. Also, it will provide evidence to intervene on time in case the Foley balloon tamponade fails.

METHODS

This cross-sectional study was conducted at the Department of Obstetrics and Gynecology, Bacha Khan Medical Complex, Swabi, from June 2023 to May 2024. Ethical clearance was taken from the institutional ethical review board (ID No:IREB/GKMCS/022411).A non-probability consecutive sampling technique was used.A sample size of 139 was calculated using a confidence interval of 90%, margin of error of 5%, and population proportion of 85% [11].The study included 140 consecutive women with primary PPH.The inclusion criteria included all patients with PPH following failed medical therapy after vaginal delivery or cesarean section, stable hemodynamic status, patients desiring for preservation of reproductive potential, patients consenting for surgery in case balloon tamponade fails. Patients with unstable hemodynamic status, suspected uterine rupture, traumatic PPH, retained placenta, bleeding tendency, and chorioamnionitis were excluded.All patients had detailed history, clinical examination, clotting profile, baseline investigations, blood grouping, and antenatal ultrasound as a routine protocol. Patients were included in the study after written informed consent and after discussing the study protocol. The patients with PPH due to uterine atony were monitored hemodynamically in labor room by recording their blood pressure, pulse, and oxygen saturation via a standard monitor. Before insertion of the Foley catheter, the blood loss was assessed visually by using suction, mops, and a collection bag. The instruments used for 24 Fr Foley catheter placement included a speculum, sponge forceps, 24 Fr Foley catheter, normal saline, a 20 milliliters syringe, gauze, urine bag. The balloon of a 24 Fr Foley catheter can withstand up to 150 mL of normal saline efficiently. The Patients were put in the lithotomy position. The cervix was examined under aseptic technique for tears. Then 24-French Foley catheter was placed in the uterine cavity with the help of sponge holding forceps. The catheter balloon was initially inflated up to 100 mL of normal saline and observed for bleeding for the next 15 minutes. When the bleeding stopped within 15 minutes or there was only a small loss <150 milliliters of blood, the procedure was deemed effective. When bleeding (>150 ml) persisted 15 minutes after the correct placement of the balloon catheter and surgical intervention was required to control the bleeding, we deemed the balloon tamponade to have failed. It was followed by resuscitation and surgical intervention in the form of compression suture, triple ligation, or hysterectomy. A roller gauze was used to pack vagina to maximize mechanical compression and prevent the expulsion of the Foley catheter. A moderate traction was applied to the catheter by tying it to the thigh with tape. The Foley catheter was connected to a urine bag for estimation of blood loss. The limit of the uterine fundus was marked with a marker. Subsequent uterine enlargement was noted from this marker line. The Bladder

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Catheterization was also done for estimation of urine output. The Foley catheter was left in the uterus for 24 hours, and the vitals of patients were monitored continuously with the help of standard monitors. Coagulopathy was defined by the appearance of clinical signs (bruising, bleeding from mucosal surfaces, petechiae) coagulation profile (prolongation of apartial thromboplastin time (APTT), decrease in prothrombin time (PT) or fibrinogen, thrombocytopenia) from blood samples sent just before or at the time of 24 Fr Foley balloon placement. After 24 hours, vaginal pack was removed and the balloon was gradually deflated and removed. The patient was observed for 30 minutes. When bleeding had stopped and no further intervention was required, the balloon tamponade was deemed effective. The patients were kept on intravenous antibiotics and oxytocin infusion during the balloon tamponade. Data were collected using a proforma. All data were analyzed using SPSS version 23.0 (SPSS Inc., Chicago, Illinois, USA). Numbers and percentages were used to express categorical data. Chi-square test or Fisher's exact test was used to compare categorical data between successful and failed balloon tamponade groups. Mean and standard deviation (SD) or medians and interquartile intervals with p-value were used for quantitative data. The normality of distributions was assessed using the Shapiro-Wilk test. Quantitative variables were compared using Student's t-test or ANOVA test. A p-value ≤0.05 was considered significant. An ROC curve analysis was performed for estimated blood loss after 15 min of Foley balloon placement to determine the maximum positive predictive value for various cut-offs.

RESULTS

During the study duration, 296 patients with PPH secondary to uterine atony were managed. 140 patients had failed medical treatment and were managed with a 24 Fr Foley catheter balloon tamponade. Balloon tamponade was successful in controlling hemorrhage in 125 (89.2%) patients. While 15 (9.8%) patients had failed balloon tamponade and needed further surgical intervention, 11 patients were treated with compression suture and ligation. 4 patients needed emergency hysterectomy. Patients with successful Foley balloon tamponade and failed balloon tamponade had similar characteristics (p-value>0.05)(Table 1).

Table 1: Characteristics of enrolled Patients

Variables		Successful n (%)	Failed n (%)	p-value
Foley Catheter Balloon Tamponade		125 (89.2)	15 (9.8)	-
Maternal Age (Years)		29.1 ± 4.8	30.3 ± 6.1	0.6*
Body Mass Index (kg/m^2)		22.2 (20.0%; 26.0%)	23 (20.4%; 27.0%)	0.78*
Gestational age	≥37 Weeks	93 (74.4%)	10 (66.6%)	0.52 ǂ
	<37 Weeks	32 (25.6%)	5 (33.3%)	
Parity	Primigravida	43 (34.4%)	5 (33.3%)	1.0 ǂ
	Multigravida	82 (65.6%)	10 (66.6%)	
Mode of Delivery	Vaginal	93 (74.4%)	9 (60%)	0.47 ǂ
	Instrumental Vaginal	23 (18.4%)	4 (26.6%)	
	Cesarean Section	9 (7.2%)	2 (13.3%)	
History of PPH	Yes	13 (10.4%)	4 (26.6%)	0.8 ǂ
	No	112 (89.6%)	11 (73.3%)	
Booking Status	Booked	47 (37.6%)	2 (13.3%)	0.14 ǂ
	Un-Booked	37 (29.6%)	5 (33.3%)	
	Referral	41 (32.8%)	8 (53.3%)	
Mode of Labor	Spontaneous	103 (82.4%)	11 (73.3%)	0.48 ǂ
	Induced	22 (17.6%)	4 (26.6%)	

Means, standard deviations, or medians (1st quartile; 3rd quartile) for quantitative data. Numbers (n) and percentages (%) for qualitative data. *Student-t -t test for continuous variables. ǂ Chi-square test/Fisher's exact test for categorical variables

Results show a statistically higher rate of anemia, coagulopathy, higher volume of blood loss after delivery, shorter duration from birth to Foley balloon placement, and higher volume of blood loss after 15 minutes and 30 minutes of Foley balloon placement in the failed balloon tamponade group as compared to the successful balloon tamponade group. ICU admissions were statistically more common and hospital stay was longer in the failed Foley balloon tamponade group in comparison to successful ballon tamponade patients (Table 2).

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Table 2: Prognostic Factors for 24 Fr Foley Balloon Failure

Variables		Successful Tamponade n=125 (%)	95% CI	Failed Tamponade n=15 (%)	95% CI	p-value
Foley Catheter Balloon Tamponade		10.2 ± 0.4	10.1-10.2	9.2 ± 0.3	9.0-9.4	<0.005*
Maternal Age (Years)	Yes	4 (3.2%)	–	9 (60%)	–	<0.005 ǂ
	No	121 (96.8%)		6 (40%)		
Blood Loss After Delivery/ C-Section to Balloon Placement (ml)		816.9 ± 112.3	797.0-836.8	906.0 ± 124.5	837-975	0.005*
Duration from Birth to Foley Balloon Placement (min)		33.4 ± 2.8	32.9-33.9	30.5 ± 2.3	29.2-31.8	<0.005*
Blood Loss at 15 min (ml)		45.4 ± 18.7	42.1-48.7	186.3 ± 33.7	167.6-205.1	<0.005*
Blood Loss at 30 min (ml)		71.2 ± 21.8	67.4-75.1	346.6 ± 46.7	320.8-372.5	<0.005*
ICU admission		25 (20%)	–	12 (80%)	–	<0.005 ǂ
Mean Hospital Stay		3.7 ± 0.7	3.6-3.9	5.9 ± 0.7	5.4-6.3	<0.005*

Numbers (n) and percentages (%) for qualitative data. ǂ Chi square or Fisher's exact test for qualitative variables. Means, standard deviations for quantitative data. *Student t-test or one-way ANOVA test for quantitative data.

Further study shows the threshold of blood loss after 15 minutes of Foley balloon placement. The positive predictive value for 150 ml and 200 ml was 0.60 and 0.80, respectively.

Table 3: Prediction of 24 Fr Foley Balloon Failure at 15 Minutes of Placement

Blood Loss at 15 minutes (ml)	Area Under Curve	Standard Error	95% CI	p-value	Sensitivity	Specificity	PPV	NPV
150	0.95	0.02	0.90-1.0	0.02	0.25	99.1	0.60	95.2
200	0.98	0.008	0.97-1.0	0.00	0.75	97.5	0.80	96.8

PPV: Positive Predictive Value, NPV: Negative Predictive Value

DISCUSSION

Previously, sterile gauze was used to pack the uterine cavity to control PPH.Recently, the use of an intrauterine balloon for PPH has streamlined this deadly complication. The Bakri Balloon is most commonly used. It is noninvasive and preserves fertility.It also provides a window to resuscitate the patient and reduce blood loss before moving to more invasive treatments like arterial embolization, internal iliac artery ligation, uterine compression sutures, and hysterectomy [12].Now it is possible to avoid multiple blood transfusions, decrease surgical interventions, and minimize related maternal morbidity and mortality.Various studies have reported success rates of Bakri balloon tamponade after vaginal delivery. A meta-analysis by Suarez *et al.*, reported a 87.1 % success rate of balloon tamponade in uterine atony [8]. A meta-analysis by Abul *et al.*, concluded that intrauterine balloon tamponade is superior to uterine gauze packing for PPH [13]. Dorkham *et al.*, reported a success rate of 90% in a retrospective study [14]. A Randomized controlled trial by Rozenberg *et al.*, compared a combination of second-line uterotonic (sulprostone) and ebb balloon tamponade with second-line uterotonic alone (sulprostone) and reported success rates of 67.2% and 74.3%, respectively [15]. However, in low-resource areas, the balloon of a Foley catheter has been used to control PPH.The uterine tamponade was successful in effectively controlling bleeding in atonic uterus in 125 (89.2%) patients in our study.This corresponds to the success rate reported by other prospective observational studies.A study by Bukhari *et al.*, reported a success rate of 98% utilizing a 16 Fr Foley catheter in the atonic uterus with PPH [16]. Similarly, a prospective study by Nipanal and Talawar, found 24 Fr Foley catheter to be 95.7% effective in controlling PPH in atonic uterus after vaginal delivery [17]. Variations in success rate are attributed to various factors like preoperative hemoglobin, history of PPH, previous cesarean section scars, placenta accreta and increta, gestational hypertension, placenta previa, and intrapartum or antepartum bleeding, timing of balloon insertion, heterogeneity of the subjects including indications and context for balloon tamponade and the inconsistency in clinical practice [18].Randomized trials that directly compare the Bakri balloon and 24 Fr Foley catheter for uterine tamponade are lacking.Similarly, angioembolization is another option for such patients in developed health care systems.A recent study compared intrauterine balloon tamponade and uterine artery embolization in PPH and found no difference in the risk of peripartum hysterectomy and/or maternal death.The small size of the sample did not allow for the determination of whether intrauterine balloon tamponade is equivalent or superior [19].However, the hemodynamic status of the patient, cost, expertise, prompt availability of an interventional radiologist, and radiology suite are limitations in low-resource healthcare.While insertion of an intrauterine 24 Fr Foley to tamponade the uterus is easier and cheaper.Our study also showed that coagulopathy increases the failure rate of intrauterine

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balloon tamponade.The time for Foley balloon insertion in the failure group was shorter, but the volume of blood loss was higher.Although serum fibrinogen <2 g/L can serve as a predictor for progression to severe PPH, it does not help clinicians during the management of PPH due to the delay of blood results [20].In addition, some patients may have more than one cause of PPH, and uterine atony may be secondary to abnormalities of the placenta.However, the risk of coagulopathy increases with larger blood loss and leads to more bleeding as reported in the literature.Liu *et al.*, reported that multiple gestations, blood loss, and placenta accreta spectrum were independent risk factors for Bakri balloon tamponade failure [21].Also, Intrauterine balloon tamponade was only 54.8% successful in cases with previa abnormalities.A retrospective cohort study found that higher antenatal hemoglobin values were negatively correlated with the incidence of transfusion, uterine artery embolization, or hysterectomy.Similarly, uterine balloon tamponade performed in the placental site bleeding group was more likely to have adverse PPH outcomes compared to the uterine atony group [22]. Antenatal anemia was common in our patients with PPH. Antenatal anemia needs to be investigated and treated in such patients. More than half of our patients with PPH were unbooked,referred cases,or multigravidas with no antenatal screening at all.Low or lower limit of normal hemoglobin in such patients is not uncommon.A lower prenatal hemoglobin value means that the mother has a lower reserve capacity for blood loss, which is an important parameter in managing PPH.Our study showed that failure of an intrauterine Foley balloon can be predicted within 15 minutes, thus avoiding delay in further surgical interventions.Our results showed that 200 ml blood loss has a positive predictive value of 0.97 for Foley balloon tamponade failure. In a retrospective cohort study by Leleu et al., the predictive positive value of 250 ml blood loss was 0.94 at 10 minutes [23].Current results also match these findings. One may suspect that balloon tamponade may delay surgical intervention in case of failure.However, this is merely an assumption.Intrauterine Balloon tamponade's utilization improves the hemodynamic status of patients undergoing interventional angioembolization.No complications were found in our patients, although intrauterine balloon tamponade may cause fever, endometritis, uterine necrosis, cervical tears, scar dehiscence, or uterine perforation [24].The strengths of our study are utilizing a cheap alternative for uterine balloon tamponade, highlighting the need for early intrauterine placement of a 24Fr Foley in PPH and early recognition of failure of balloon tamponade after 15 minutes with estimated blood loss of 200 ml.This finding can help trigger more invasive treatment and reduce blood loss.

CONCLUSIONS

It was concluded that the placement of a 24 Fr Foley catheter in the uterine cavity effectively controls PPH in low-resource settings. A blood loss of ≥200 ml after 15 minutes of Foley balloon placement should alert the clinician to adopt a more aggressive approach to control bleeding. However, the results should be interpreted with caution due to the observational nature of the study. Multicenter, larger-sized randomized control trials in the future will address the limitations and biases inherent to this study.

Authors Contribution

Conceptualization: AK[1]
Methodology: B, AR, SAR
Formal analysis: AK[1]
Writing review and editing: NK, AK[2], MFH

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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