

Efficacy of Intrauterine Balloon Tamponade by 24-French Foley Catheter in Prevention of Postpartum Hemorrhage

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ABSTRACT

Background: Postpartum hemorrhage (PPH), is one of the most common causes of maternal mortality as well as morbidity worldwide. Around 88% of maternal deaths occur in the first 4 hours of delivery. So, the majority is the consequence of events in the third stage of labor. Most cases of primary PPH are caused by atonic uterus often due to prolonged labor, pre-eclampsia, or past history of PPH.

Management of PPH involves a stepwise approach from medical to surgical management like laparotomy for systemic devascularization, uterine compression sutures, or peripartum hysterectomy.

In 1983, Goldrath published that uterine tamponade can be possible by insufflating a Foley catheter in the uterus. Commercially available catheters such as Sengstaken Blackmore tube, Rusch urological catheter, and Bakri balloon are commonly used; however, their cost is the limiting factor for the regions of less privilege. Hence, this study is planned to evaluate the efficacy of 24-French Foley catheter tamponade in atonic PPH, after the failure of medical management, which is easily available, economical, and also quantifies blood loss.

Methods: It is a prospective study. The subjects were PPH patients who failed to respond to medical management and were hemodynamically stable. Intrauterine 24-French Foley catheter was applied. The vital parameters were monitored. Monitoring for vaginal bleeding was done. The Foley catheter was kept for 24 hours.

Results: Atonic PPH was there in 961 subjects. Intrauterine balloon tamponade by 24-French Foley catheter was applied to 800 patients. The duration of the study was June 2014 to May 2020 in Gadag Institute of Medical Sciences, Gadag, Karnataka. It was effective in 766 (95.75%) subjects. Around 34 subjects were in need of surgical management. Hence this alternative simple intervention method decreased many surgical interventions and respective morbidity.

Conclusions: The intrauterine balloon tamponade by 24-French Foley catheter is the most effective, quite simple economical technique for preventing blood loss in atonic PPH.

Keywords: Atonic postpartum hemorrhage, Intrauterine balloon tamponade, 24-French Foley catheter, Foley catheter in postpartum hemorrhage.

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INTRODUCTION

Postpartum hemorrhage, which is defined as blood loss of more than 500 mL within 24 hours of delivery is one of the most common causes of maternal mortality as well as morbidity worldwide. Around 88% of maternal deaths occur in the first 4 hours of delivery. So, the majority is the consequence of events in the third stage of labor. Most cases of primary PPH are caused by atonic uterus often due to prolonged labor, preeclampsia, and a past history of PPH. Almost 25% of maternal deaths will occur due to PPH each year. The incidence is around 5% of deliveries whereas the prevalence is 6%. Mortality from PPH is 1 per 1,000 deliveries in low-resource countries whereas 1 in 100,000 deliveries in higher-resource countries.¹

The World Health Organization (WHO) defines PPH as "blood loss greater than or equal to 500 mL within 24 hours after birth" if it is greater than or equal to 1,000 mL is called severe PPH. It is one of the leading causes of maternal mortality. It accounts for nearly 35% of all maternal deaths. It is estimated that every year nearly 14 million mothers are suffering from PPH globally. Low and middle-income countries are most commonly affected with respect to maternal mortality and morbidity by PPH.²

Uterine atony is the failure of the uterus to contract after delivery of the placenta. It is the common cause of primary PPH. Genital tract trauma, retained placental tissue, uterine rupture, and maternal bleeding disorders are other causes. To prevent PPH interventions are done at various levels like prenatal, labor, delivery,

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and postnatal period. Active management of the third stage of labor (AMTSL) is a multi-step procedure. Many times, blood transfusions are needed to save mothers.³

The management of PPH can be non-medical, medical, and/or surgical interventions. The AMTSL for all vaginal births is recommended by WHO and other professional bodies. It involves a prophylactic administration of uterotonics before delivery of the placenta in addition to other non-pharmacological interventions, such as late cord clamping and controlled cord traction of the umbilical cord.⁴

Management of PPH involves a stepwise approach. The foremost step is to exclude the presence of genital trauma and any

retained products. This will be followed by uterine massage and administration of uterotonic agents like oxytocin, ergometrine, misoprostol, and prostaglandin F_{2α} (PGF_{2α}). In spite of this medical therapy PPH is not controlled, the operative therapy must be considered, including laparotomy for systemic devascularization, uterine compression sutures, or peripartum hysterectomy.

In 1983, when Goldrath⁵ through his article supported that Foley can be used for creating uterine tamponade which is also supported by Condous et al.,⁶ Doumouchtsis et al.,⁷ and Rathore et al.⁸ with a success rate of 87.5, 84, and 94%, respectively. Also, WHO also recommends it for atonic PPH when medical measures failed as the next step before surgical steps.⁹ Moreover, WHO, International Federation of Gynaecology and Obstetrics (FIGO), American College of Obstetricians and Gynecologists (ACOG), and International Confederation of Midwives (ICM) recognized that uterine tamponade will be useful in preventing intractable PPH, particularly in low-resource settings. It can be used as a temporary step while transferring the patient.¹⁰

Presently, marketed catheters such as Sengstaken Blackmore tube, Rusch urological catheter, and Bakri balloon are commonly used; however, their cost is the limiting factor for the regions of less privilege, while condom catheter is a cheap and easily available alternative which in a low resource settings; however, there is a considerable clinical drawback in using condom catheter, namely, difficulty in preparation of condom catheter and poor assessment of blood loss after condom catheter application.

So, there is a need for another viable alternative that is economical, readily available, and easy to use, and can also quantify blood loss. Therefore, a viable alternative with 24-French Foley catheters is being thought which has advantages of its availability, ease to use, and measure of blood loss. Hence, this study is planned to evaluate the efficacy of 24-French Foley catheter tamponade in atonic PPH after the failure of medical management.

Objective

To evaluate the efficacy of intrauterine balloon tamponade by 24-French Foley catheters in the prevention of PPH.

Purpose of The Study

To evaluate the efficacy of intrauterine balloon tamponade by 24-French Foley catheters in the prevention of PPH.

METHODS

This is an open-label, prospective observational study. It is a single-group study of 800 subjects. It was conducted in the Department of Obstetrics and Gynaecology, Gadag Institute of Medical Sciences, Gadag, Karnataka, India. The study was conducted from May 2015 to April 2021 for a 6-year duration.

Inclusion Criteria

All the PPH cases followed by either vaginal delivery or cesarean section which were not responded to medical management were notified. Patients will be informed about the protocol and written informed consent was taken. The following criteria are taken into consideration.

- Stable subjects with respect to the hemodynamic status
- Subjects with atonic PPH only
- Referred patients of atonic PPH
- Where preservation of reproductive potential is desired
- Post cesarean PPH
- Women giving consent for surgical intervention if uterine tamponade by Foley catheter fails.

Exclusion Criteria

- Hemodynamically unstable
- Suspected uterine rupture
- Traumatic PPH
- Suspected scar dehiscence or rupture of uterus
- Adherent or retained placenta
- Suspected chorioamnionitis
- Anomalous uterus



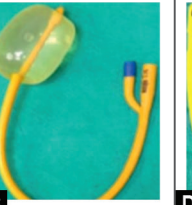
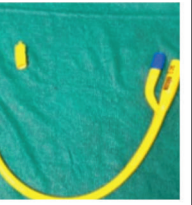
Procedure

After taking written and informed consent, the patient will be included in the study. The required materials are shown in Figure 1. Figure 2 shows the strength of 24-French Foley catheter which can withstand up to 150 mL of normal saline starting from 5 mL, withstand (Fig. 2A); 100 mL, withstand (Fig. 2B); 150 mL, withstand (Fig. 2C); and 175 mL, cannot withstand (Fig. 2D). The following steps of procedures needs to be followed:

- The blood loss due to PPH will be assessed by a visual method including the use of mops and suction apparatus before intrauterine balloon application.

Instruments	Pictures
1. Speculums	
2. Sponge forceps.	
3. French Foley catheter no. 24	
4. Normal saline	
5. 10 mL syringe	
6. Roller gauze	
7. Urobag	

Fig. 1: Instruments required for Foley catheter insertion. Speculums, sponge forceps, 24-French Foley catheter, normal saline, 10 mL syringe, roller gauze, and urobag

Volume of normal saline	75 mL	100 mL	150 mL	175 mL
Inflated balloon				
Status	Withstand	Withstand	Withstand	Cannot withstand

Figs 2A to D: Strength of 24-French Foley catheter. Volume and status of inflated balloon. (A) 75 mL, withstand; (B) 100 mL, withstand; (C) 150 mL, withstand; (D) 175 mL, cannot withstand

- Patient vital parameters such as blood pressure, pulse rate, and clinical evaluation for the stability of the patient evaluated and due precaution taken for complete setup for PPH management as per standard institutional protocol.
- Patient will be put in the lithotomy position. Parts cleaned and draped. Cervical exploration is done to exclude traumatic causes. Cervix will be held with two sponge-holding forceps.
- With aseptic precaution 24-French Foley catheter is inserted into the uterine cavity. It is done taking the help of sponge-holding forceps. The catheter will be inflated with 80–100 mL normal saline. If minor cervical and vaginal tears are sutured. A vaginal pack with roller gauze is given to provide mechanical compression and to prevent the expulsion of the Foley catheter. Then catheter will be tied to the right thigh with moderate traction. Urobag connected to the Foley catheter for assessment of blood loss which will be collected in urobag. Bladder Catheterization is done for assessment of urine output and input/output charting.
- Quantitative measurement of blood loss will be measured in urobag for analysis of the success of the method.
- Patient vitals are monitored continuously with the help of standard monitors.
- Stoppage of bleeding occurs by 5–15 minutes. Patient's vitals are monitored continuously. Any deterioration or bleeding does not stop further surgical intervention taken.
- Intrauterine balloon tamponade kept for 16–24 hours and then removed.

RESULTS

The study was done from May 2015 to April 2021. The total number of PPH cases was 1,205. Around 79.75% were atonic PPH cases and 15.93% were traumatic PPH cases whereas 4.07% were combined atonic and traumatic PPH cases.

Among 1,205 PPH cases, we have included atonic PPH in 961 cases among which 161 cases excluded reason being not giving consent with exclusion criteria. Hence, a total of 800 cases were studied. Around 57.75% of cases were in the age group of 20–25 years. The mean age of the patient was 24.8 years. In our study, 42.75% of them primipara and 39.12% are multiparas.

Out of 800 cases of PPH, 509 (63.63%) cases were vaginal deliveries. Lower segment caesarian section cases were 240 (30%). Instrumental delivery occurred in 51 (6.38%) patients. So, a major portion of cases was of vaginal delivery only.

Out of 961 total atonic PPH patients, intrauterine balloon tamponade was inserted in 800 eligible patients which accounts

Table 1: Outcome of the study

Outcome	Number of subjects	%
Success of Foley catheter	766	95.75
Needed further surgical methods	34	4.25
Death	0	0

for 83.25%. Surgical and medical line of treatment was given in 161 cases. In those patients who are not subjected to intrauterine Foley catheter but were taken for surgical management directly, B Lynch sutures were done in 63.98%, and internal iliac artery ligation was done in 16. Among 15% patients, a subtotal hysterectomy was done in 18.63% of patients.

In the total of 800 study subjects, intrauterine Foley catheters were successful in 766 (95.75%) patients. Surgical management was required in 34 (4.25%) patients. There was no death case (Table 1).

Out of 34 subjects of failed intrauterine balloon tamponade, 12 (1.5%) had uterine compression sutures, uterine artery ligation was done in 8 (1%) subjects, and 10 (1.25%) underwent internal iliac artery ligation. Four subjects underwent a subtotal hysterectomy.

In 800 subjects 728 (91%), Foley catheter was inserted within 4 hours of delivery and for the rest 72 (9%) subjects required 5–24 hours intervals.

The associated complications in our study population which clearly mention anemia was a major complication 59.5% followed by pre-eclampsia 32.5%.

After the application of the Foley catheter, bleeding was stopped in 766 (95.75%) subjects within 10–15 minutes and was followed up for 24–48 hours. The Foley catheter was removed after 24 hours. On average, 0.87 units of blood (range 0–4 units) were needed to produce hemodynamic stability of the patients. All the patients were put on prophylactic antibiotics.

DISCUSSION

Postpartum hemorrhage accounts for 50 times increased risk of maternal morbidity.¹¹ Hence, intrauterine insertion of Foley catheter to create tamponade is a very simple, effective, and economical, as well as minimally invasive technique. It can avoid excessive blood loss.⁴ It avoids unnecessary hysterectomy and coagulation disorders like disseminated intravascular coagulopathy if timely intervention is taken by Foley catheter. So, it will help in preserving reproductive potential. It will be useful in all types of settings. It can become therapeutic as well as a prophylactic measure too.

Table 2: Comparative studies of success rates with intrauterine balloon tamponade

Study	Number of subjects	Success	%
Knight ¹⁵	–	–	25
Nahar et al. ¹⁶	53	52	98
Tirumuru et al. ¹⁷	43	41	87.2
This study	800	766	95.75

It does not need any special training. It is one of the easy-to-use, accessible, and inexpensive materials. It will be the most effective measure for periphery working staff to shift the patient for further management to a higher center.

In the total 800 study subjects, intrauterine Foley catheters were successful in 766 (95.75%) patients. Surgical management was required in 34 (4.25%) patients. The mean age of our study patients (24.8 years) is comparable with other studies of Gai et al. (29.71 ± 4.18 years), and Al-Zirqi et al. (25 years).^{12,13} Even Bhavana et al. study conducted in Deccan College of Medical Sciences, Hyderabad, Telangana, India also has similar results.¹⁴

Our study resulted in higher success rates of 95.75% than a study which is national cohort study conducted by Knight,¹⁵ in National Perinatal Epidemiology Unit, University of Oxford, Old Road Campus, and Oxford, UK. The success of the study by Nahar et al.¹⁶ conducted in a tertiary care center in Bangladesh accounts for 98% whereas the study by Tirumuru et al.,¹⁷ in Russells Hall Hospital, Dudley Hospitals NHS Foundation Trust, Dudley, UK showed effectiveness up to 87.2% (Table 2). Similar results have been reported by Garg et al., and Garg and Yadav.^{18,19}

Many studies reported the success rate of internal iliac ligation from 40% to 100%. Many other studies have quoted that internal iliac artery ligation can avoid hysterectomy in only up to 50% of cases.

CONCLUSION

Hemorrhage is the leading cause of admissions to the intensive care unit and the most preventable cause of maternal mortality. In this study, among 800 subjects, intrauterine Foley catheters were successful in 766 (95.75%) patients. Hence, it is effective in nearly 96% of stable atonic PPH patients. Therefore, intrauterine insertion of a Foley catheter to create tamponade is a very simple, effective, and economical, as well as minimally invasive technique. Foley catheter is one of the easy-to-use, accessible, and inexpensive materials. It can significantly reduce the need for surgical interventions in managing the PPH.

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