

# Balloon Tamponade—A Novel Innovation in the Management of Refractory Postpartum Hemorrhage at Tertiary Care Center: A Study from Central India

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## ABSTRACT

**Background:** Postpartum hemorrhage (PPH) is the leading cause of maternal mortality in low-income countries and the primary cause of nearly one-quarter of all maternal deaths globally. Refractory PPH is defined as PPH failed to respond to the medical line of management and requiring second-line treatment in the form of balloon tamponade, compression sutures, stepwise devascularization, or hysterectomy.

**Aim and objective:** To assess the effectiveness of balloon tamponade in the management of refractory PPH and reduction in surgical interventions with the use of uterine balloon tamponade.

**Materials and methods:** Prospective data of all 53 women with refractory PPH who underwent balloon tamponade after failed medical management that were collected over a period of 1.5 years were analyzed.

**Results:** The study includes women from 20 to 35 years of age. The mean age of the study population was  $24.81 \pm 4.468$  years. The estimated amount of blood loss in this study ranges from 700 to 2000 mL, and the mean estimated amount of blood loss was  $1260.38 \pm 333.02$  mL. The success rate of balloon tamponade alone was 84.90%, while when combined with additional surgical intervention—compression sutures and stepwise devascularization—overall success rate increased up to 98.11% in this study, while one patient underwent rescue hysterectomy despite balloon tamponade. The failure rate was 1.89%.

**Conclusion:** UBT is novel innovation for the management of refractory PPH, and real-time blood loss assessment through Bakri balloon alerts and guides the surgeon in major decisions before proceeding to rescue hysterectomy. Our study recommends the use of balloon tamponade as a primary tool before proceeding for surgical interventions in case if uterotonics fail to manage PPH.

**Clinical significance:** Balloon tamponade is simple, easy, and cost-effective intervention, especially in low resource setting for reducing maternal morbidity and mortality due to refractory PPH.

**Keywords:** Compression sutures, Refractory PPH, Rescue hysterectomy, Stepwise devascularization, UBT, Uterotonics.

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## INTRODUCTION

Obstetrics deals with life and death situation of the mother. Time around delivery time especially is very crucial. Bleeding immediately after delivery (PPH) has to be managed very aggressively. Postpartum hemorrhage (PPH) has had an impact on the world for centuries and still continues to do so.<sup>1,3</sup> Clinically, PPH is defined as any amount of blood loss from or into the genital tract after the birth of the baby up to the end of puerperium, which adversely affects the general condition of the patient, evidenced by rise in pulse rate and falling blood pressure.<sup>2</sup>

WHO estimates of the 5,29,000 maternal deaths occurring annually, 1,36,000 or 25.7% of deaths take place in India.<sup>1,3</sup> Atonicity of the uterus is the most common cause of PPH, others being trauma to birth passage, rupture uterus, retained placental tissue, or thrombin defect.<sup>3,4</sup> The deaths of such a young population can negatively affect the nation's growth and economy. Maximum numbers of deaths are due to bleeding after delivery (PPH).

Refractory PPH is defined as PPH failed to respond to the medical line of management and requiring second-line treatment in the form of balloon tamponade, compression sutures, stepwise devascularization, or hysterectomy.<sup>5</sup>

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Exact incidence of refractory PPH is not available in the literature. Postpartum hemorrhage is a preventable entity and preventable cause of maternal mortality. Active management of the third stage of labor is considered as the gold standard for the management and prevention of PPH.

In cases of atonic PPH with failed medical management, UBT as second-line treatment has been recommended by World Health Organization (WHO).<sup>5</sup> Success rates of UBT are as high up to 97%,

thus decreasing the need for surgical intervention.<sup>6-8</sup> If bleeding continues despite the correct insertion of the UBT, definitive treatment in the form of surgical intervention must be initiated soon. Even if UBT “fails,” it gives the time needed to proceed for the next line of management as per standard treatment protocol or even for referral to facilities where surgical treatment modalities are available.<sup>9,10</sup>

NRHM and Dakshata Guidelines for the management of PPH also recommend the use of intrauterine balloon tamponade for atonic PPH or refractory PPH when medical management fails.<sup>11,12</sup>

There have to be vigilance and training drills so that the healthcare professionals are skilled enough to deal with this complication early and effectively.

The objective of this study was to assess the effectiveness of balloon tamponade in the management of refractory PPH and reduction in surgical interventions with the use of uterine balloon tamponade.

## MATERIALS AND METHODS

The study was conducted in the Department of Obstetrics and Gynecology at a tertiary care hospital in Central India. It was a prospective observational study. All the cases of refractory PPH diagnosed, referred, and admitted from October 2018–April 2020 at tertiary care center were studied. The study has been approved by the Institutional Ethics Committee (IEC 220/2018). After explaining the purpose of the study in the local language, those who agreed and consented to take part in the study were included.

### Inclusion and Exclusion Criteria

All cases of PPH are not responding to the medical line of management. All known cases of refractory PPH being admitted to tertiary care center were included. If the cause of hemorrhage was found to be arterial necessitating surgical exploration or hysterectomy or cases with untreated uterine anomaly, cervical or uterine cancer cases or with uterine sepsis needing exploration were excluded. Cases of traumatic PPH were also excluded.

All patients who delivered in the teaching institute or were referred to the teaching institute were given active management of the third stage of labor while searching for the cause of bleeding. Active management of the third stage of labor included:

- Administration of uterotonic agent after delivery of the baby
- Delayed cord clamping
- Expulsion of the placenta by controlled cord traction

The assessment of blood loss was done by visual method. For assessing blood loss after vaginal delivery, gauze of size 10 cm × 10 cm was used. For assessing blood loss during cesarean delivery, laparotomy mop of 45 cm × 45 cm was used. Cases of uterine atony leading to PPH were first given medical management in the form of uterotonics, single or in combination depending upon the blood loss. Cases in which bleeding was not controlled by medical management alone were given balloon tamponade, either Bakri balloon or ESM-UBT based on availability in both normal vaginal delivery and cesarean section. If atony persists despite balloon tamponade in refractory cases of atonic PPH, surgical intervention was done in the form of compression sutures with or without stepwise devascularization with balloon *in situ* termed as combined procedure. If bleeding still continues, hysterectomy was done as the terminal treatment modality. Patients were initially resuscitated with crystalloid and colloid;

blood and other blood products were simultaneously transfused. Slow infusion of uterotonics was continued for 24 hours, while the balloon was *in situ*. Close monitoring was done every 30 minutes for initial 4 hours with drain quantity less than 100 mL/hour and then every hourly for the next 4 hours, followed by 4 hourly till 24 hours. All patients received a single dose of cefotaxime (1 g, IV) within 30 minutes of balloon insertion. Antibiotics were continued during balloon tamponade (cefazolin, 1 g every 12 hours, IV) for 24 hours. Urethral catheterization was done in all the patients. Balloon tamponade removal was done when (1) amount of the fluid in the drain was less than 1200 mL in 24 hours; (2) color of the fluid in the drain. (3) The patient should be vitally stable. (4) No evidence of fresh bleeding. UBT was slowly deflated over 2 hours under the cover of oxytocin drip 20 IU in 500 mL ringer lactate solution. The volume of normal saline withdrawn was confirmed with the amount of fluid mentioned in patient’s clinical record at the time of insertion. Patients were examined within 30 minutes of catheter removal for any sign of active bleeding. Patients were followed up during the hospital stay and kept under close observation for any complications of PPH like shock, severe anemia, sepsis, AKI, DIC, and intensive care unit (ICU) admission. Outcome of all patients was assessed for recovery, morbidity, or mortality.

## RESULTS

The total number of deliveries during the study was 8,711 including both normal vaginal deliveries and cesarean deliveries, with a total of 53 cases suffered from refractory PPH. Thus, the incidence of refractory PPH in the present study was 0.608%. The mean age of the study population was 24.81 ± 4.468 years (Table 1). The average gestational age was 35.3 weeks. The mean baby birth weight

**Table 1:** Demographic and obstetric characteristics of the patients

Clinical characteristics	Frequency (N = 53)	Percentage
<b>Age distribution</b>		
20–25 years	35	66.04
26–30 years	10	18.87
31–35 years	8	15.09
<b>Gravida status</b>		
Primigravida	27	50.94
Multigravida	26	49.06
<b>Causes of PPH</b>		
Uterine atony	27	51
Coagulopathy	22	41.5
Retained tissue	04	7.5
<b>Gestational age in weeks</b>		
≤27 + 6	2	3.77
28–36 + 6	22	41.50
37–39 + 6	18	33.96
40–42	11	20.75
<b>Birth weight of baby in kg</b>		
<1.5	16	30.19
1.5–2	9	16.98
2–2.5	6	11.32
2.5–3	15	28.30
>3	7	13.21

reported was 2.20 kg with standard deviation 0.83 kg. Moreover, 58.49% in the study delivered through cesarean section, while 41.51% delivered vaginally. The mean duration from diagnosis of refractory PPH to placement of balloon tamponade was  $15.19 \pm 6.93$  minutes.

Moreover, 66.04% were managed by ESM-UBT, while 33.96% were managed by Bakri balloon tamponade. The mean volume of inflation of balloon tamponade was  $357.92 \pm 34.33$  mL. Inflation volume ranges from 300 to 450 mL.

Balloon tamponade was done in all 53 cases, out of which in one case it failed within 1 hour of tamponade (Bakri balloon). One patient died within 1 hour after tamponade, while another patient died 3 hours after the balloon tamponade; in rest, all other patients' balloon tamponade was done for 24 hours duration. Out of 53 women, 51 women survived (Table 2). Spontaneous balloon expulsion was noted in two cases of balloon tamponade (ESM-UBT). The mean duration of balloon tamponade was  $23.17 \pm 4.24$  hours in the present study.

Moreover, 15.38% underwent surgical intervention along with balloon tamponade placement for the management of refractory PPH, whereas 84.62% did not require any surgical intervention. Out of all eight patients who underwent surgical management, stepwise uterine devascularization was performed for six (75%) patients to control intractable postpartum hemorrhage, whereas two patients underwent both compression sutures (one each of B-Lynch and Cho sutures) and stepwise uterine devascularization with balloon tamponade. Out of six cases that underwent stepwise devascularization, one case underwent rescue hysterectomy as bleeding continued despite the stepwise devascularization and balloon tamponade placement.

The duration of hospital stay ranges from 1–32 days. The mean duration of patient stay was  $6.32 \pm 4.34$  days. Moreover, 32.08%

required ICU admission with balloon tamponade as in-patient care, and 67.92% were managed uneventfully indoors without the need for ICU admission. The mean hemoglobin (Hb) reported was 8.20 g/dL with 2.22 g/dL standard deviation. The minimum Hb was 3.4 g/dL and maximum was 12.0 g/dL reported among all the 53 patients. The mean blood transfused to the patients was  $2.18 \pm 1.78$  units with a range from 0 to 8 units. Thirty-eight women (71.7%) required fresh frozen plasma (FFP) transfusion in the present study. The mean unit of FFP transfused in the study was  $4.96 \pm 5.01$  units with a range from 0 to 20 units. Platelet transfusion was required in 13.21% of women. The mean unit of platelets transfused was  $0.75 \pm 2.29$  units in the present study with a range from 0 to 8 units.

## DISCUSSION

Second-line management of refractory PPH not responding to medical line of management includes balloon tamponade, compression sutures like B-Lynch or Cho sutures or Hayman sutures, stepwise devascularization, and in resistant cases emergency subtotal or total hysterectomy as last resort. Varieties of balloon tamponade options are available across the world, which have been improvised and evolved over a period of time as per effectiveness, local needs, cost, availability, accessibility, and usefulness.<sup>8,13–16</sup>

Available literature states placental pathology such as retained placenta, morbidly adherent placenta, or placenta previa as high-risk factors related to severe life-threatening PPH.<sup>10,17,18</sup>

Moreover, 60.78% of mothers reported disseminated intravascular coagulation (DIC) as the major risk factor contributing to atonic PPH in the present study due to majority of the patients are referred from periphery and the time duration required for transportation was more from periphery to tertiary care facility so

**Table 2:** Comparison with different studies of balloon tamponade

Author	Success rate (%)	Estimated blood loss (in mL)	Vol. of balloon inflation (in mL)	Blood and blood products transfused	Rescue hysterectomy, n (%)	ICU admission	Additional interventions	Maternal deaths
Yoong et al. <sup>31</sup>	100	1500 (median)	300 (median) [150–350 mL]	2 units (median)	None	None	100% (all cases—11) B-Lynch sutures in two patients and Hayman's modification in nine patients	None
Alouini et al. <sup>25</sup>	88	1600 (mean) [1200–2250 mL]	350 (mean) [205–450 mL]	—	—	—	In six cases, the BB was inefficient and uterine embolization or a surgical procedure was performed to stop PPH.	—
Nelson et al. <sup>32</sup>	100	2500 (median) [2000–3000 mL]	100 (median) [60–250 mL]	2 units (median) [2–5 units]	—	—	Placement of a B-Lynch suture in all five cases.	None
Meliza et al. <sup>28</sup>	89.47	2000 (median) [1500–6320 mL]	—	3 units (median) [1–10]	2 (10.53%)	100% [1–4 days]	Placement of a B-Lynch suture in one case; uterine artery embolization in two cases	None
Present study	84.62	$1260 \pm 333$ (mean) [700–2000 mL]	$357.9 \pm 34.33$ (mean) [300–450 mL]	$2.18 \pm 1.78$ (mean)	1 (1.89%)	32.08% [1–14 days]	Stepwise devascularization in six cases; <sup>a</sup> combined procedure in two cases (one each of B-Lynch and Cho sutures)	2

[ ] denotes range; <sup>a</sup>Combined procedure: uterine balloon tamponade + stepwise devascularization + compression sutures (B-Lynch/Cho suture); BB, bakri balloon

the patient most often lands up in either early or advanced stage of DIC due to delays at various levels. Most patients with multiple high risks were already in either the initial or advanced stage of coagulopathy at the time of admission to the tertiary center. For improving the outcomes in high-risk pregnancy, higher center referral has been recommended.<sup>19–21</sup>

Out of 53 cases, 52 were managed successfully with balloon tamponade (Bakri balloon or ESM-UBT balloon) with additional surgical intervention needed in eight cases. The success rate of balloon tamponade alone is 84.90%, while when combined with additional surgical intervention—compression sutures and stepwise devascularization—overall success rate increased up to 98.11% in this study, while one patient underwent rescue hysterectomy despite balloon tamponade; thus, the failure rate in this study was 1.89%.

The need for additional surgical intervention in the form of either compression sutures, stepwise devascularization/bilateral internal iliac artery ligation, or uterine artery embolization in the literature varies from 8.6% in the study done by Alkış et al.<sup>22</sup> to as high as around 30% in the study done by Cekmez et al.<sup>23</sup>

The findings in the present study of the need for additional intervention with balloon tamponade for successful management of refractory PPH were similar to findings by PınarKumru et al.<sup>24</sup> 12% and Alouini et al.<sup>25</sup> 14.63%, respectively.

Moreover, 31% required ICU admission in the study by Vintejoux et al.<sup>26</sup> corresponding to 32.08% of women requiring ICU admission with balloon tamponade in the present study. ICU admission in another study by Cho et al.<sup>27</sup> and Kong et al.<sup>28</sup> ranges from 17 to 100%. Moreover, 64.7% require less than 4 days ICU stay in the present study.

Maternal survival rate refers to the number of women who survived refractory PPH after undergoing either balloon tamponade or with additional surgical intervention if needed. Maternal survival rate in most studies approaches 100%. In the studies by Burke et al.<sup>29</sup> and Ramanathan et al.,<sup>30</sup> it approximates to 94–95% survival rate, which corresponds to the survival rate of 96.3% in the present study.

In the study by Ramanathan et al.,<sup>30</sup> nine maternal deaths were reported due to hemorrhagic shock, two died from sepsis—the symptoms of sepsis were present prior to delivery in both cases—and one died of possible pulmonary embolism. On the contrary, two maternal deaths were observed in the present study. The death in the first case was due to sepsis with multiple organ dysfunctions present since the time of admission, while in the other case, pulmonary embolism was the cause of death.<sup>31,32</sup>

The present study has few limitations: (1) Small sample size. (2) Being observational study, it lacks comparison group; refractory PPH being life-threatening entity with impending mortality and mortality designing randomized control trial for the same is difficult. (3) Blood loss estimation was done by visual method, which is having its own drawbacks. (4) Study duration was short; thus, results could be affected due to increased use of balloon tamponade with the study progression.

## CONCLUSION AND CLINICAL SIGNIFICANCE

Balloon tamponade for the management of refractory PPH is novel innovation. Real-time blood loss assessment through Bakri balloon not only alerts but also guides the surgeon in decision-making before proceeding to the last resort of treatment. In few cases, surgical intervention in the form of compression sutures

or stepwise devascularization may be needed. The additional interventions have an add-on effect on improving the overall effectiveness and success rate of the balloon tamponade. It should be considered first intervention in the institute level and the periphery with minimal resources prior to other invasive procedures. Healthcare professionals in low resource setup can easily perform the balloon tamponade due to its ease of use and can effectively apply it due to the steep learning curve. It can be used during referral or while preparing for a surgical procedure to reduce blood loss. Balloon tamponade is simple, easy, and cost-effective intervention, especially in low resource setting for reducing maternal morbidity and mortality due to refractory PPH. We strongly recommend the use of balloon tamponade as a primary tool before proceeding for surgical interventions in case if uterotonics fail to manage PPH.

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## Ethical Approval

The study was approved by the Institutional Ethics Committee (IEC-220/2018).

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