

# Condom-based Uterine Balloon Tamponade: An Innovation in the Management of Postpartum Hemorrhage

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Received on: 15 February 2022; Accepted on: 12 October 2022; Published on: 16 November 2022

## ABSTRACT

**Background:** Postpartum hemorrhage (PPH) remains the most common form of major obstetric hemorrhage and is also the leading cause of maternal morbidity as well as mortality. With the use of effective modalities and interventions to prevent and treat PPH, we can definitely reduce the burden of this life-threatening condition. In cases of PPH not responding to the medical line of management, second-line interventions like balloon tamponade, devascularization, compression sutures, and hysterectomy as the final resort can be thought of.

**Aims and objectives:** The aim of this study is to determine the effectiveness of ESM-uterine balloon tamponade (UBT) in cases of PPH not responding to the medical line of management.

**Materials and methods:** In this prospective case-control study, 26 cases with PPH refractory to the medical line of management in whom UBT was placed were studied. Data were collected over a period of 1 year and analyzed.

**Result:** The total number of deliveries including vaginal as well as the cesarean section was 1,359 out of which 26 patients had PPH not responding to the medical line of management, thus contributing 1.9% incidence of refractory PPH in this study. The mean age of the study population was  $28.4 \pm 2.3$  years, and the blood loss ranged from 800 to 3000 mL. The success rate of ESM-UBT alone was 85%, and if combined with additional interventions like stepwise devascularization and compression sutures, it increased to 96.15%. One patient required a peripartum hysterectomy in spite of all measures, so the failure rate was 3.85%. No maternal death was recorded in this study.

**Conclusion:** ESM-UBT is an innovative approach in the management of the PPH not responding to medical management. Our study recommends using ESM-UBT in cases of PPH with failed medical management before directly proceeding with surgical interventions.

**Clinical significance:** ESM-UBT is an inexpensive, cost-effective, easy-to-use, easily available, affordable, and effective tool to manage PPH not responding to medical management, and thus will definitely help to reduce related maternal mortality and morbidity.

**Keywords:** Balloon tamponade, Postpartum hemorrhage, Stepwise devascularization.

*Journal of South Asian Federation of Obstetrics and Gynaecology* (2022): 10.5005/jp-journals-10006-2138

## INTRODUCTION

The most prevalent type of significant obstetric bleeding, PPH is also one of the top causes of maternal mortality and morbidity worldwide.<sup>1</sup> More than 1.5 million women experience difficulties as a result of bleeding during pregnancy and the postpartum period each year.<sup>2</sup> Postpartum hemorrhage prevalence ranges from 7% to 12% in high-income countries, although it can reach 25.7% in Sub-Saharan Africa.<sup>1</sup> Despite the fact that the world has been working on reducing maternal mortality since 1990, a recent World Health Organization (WHO) assessment on improvements from 1990 to 2015 stated that PPH-related mortality in Sub-Saharan Africa remains unacceptably high. The bulk of these deaths may have been avoided if effective emergency obstetric treatment had been available sooner.

Postpartum hemorrhage is defined as vaginal bleeding of more over 500 mL within 24 hours of delivery<sup>3</sup> and is a life-threatening condition with long-term health consequences. Uterine atony, placental implantation site hemorrhage, genital tract damage, or a combination of these four are all common causes. Uterine inversion, attached placenta, and coagulation system disorders are all unusual causes.<sup>4</sup> Atonicity of the uterus is the most common cause of PPH, accounting for 80–85% of cases. Although risk indicators have been discovered, it is impossible to predict which women may develop uterine atony.<sup>5</sup>

Postpartum hemorrhage treatment involves a step-by-step deployment of pharmaceutical therapies, followed by surgical

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**How to cite this article:** Lothe SM, Bhalerao A. Condom-based Uterine Balloon Tamponade: An Innovation in the Management of Postpartum Hemorrhage. *J South Asian Feder Obst Gynae* 2022;14(5):557–562.

**Source of support:** Nil

**Conflict of interest:** None

**Ethical approval:** The study was approved by the Institutional Ethics Committee (IEC/NKP SIMS/4/2018) dated August 30, 2018.

operations. The administration of uterotonic medicines is the first step in the treatment of uterine atony (oxytocin, methylergometrine, carboprost, and misoprostol). If fundal massage and available oxytocic medicines fail to relieve uterine atony, further drugs such as antifibrinolytic agents can be used. If the bleeding persists, surgical procedures such as uterine tamponade, uterine compression sutures, progressive devascularization, uterine artery embolization, and even peripartum rescue hysterectomy may be required. Invasive procedures, for example, necessitate a laparotomy, expertise, and are linked with high morbidity. These

procedures may also have an impact on future fertility. Uterine artery embolization is a minimally invasive, fertility preservation procedure that necessitates specialized equipment, interventional radiologists, and a unique set-up that is not available at most institutes.

Uterine tamponade is a less invasive method that is straightforward, does not require a big operation, takes less time, and often reduces or stops bleeding right away. As a result, it may be possible to avoid laparotomy and hysterectomy, as well as blood transfusions. Even if treatment is ineffective in managing PPH, it will buy time for further interventions or for the patient to be transferred to a higher institute with all the necessary resources.<sup>6,7</sup> One of the methods indicated in the PPH's management guidelines is UBT. If uterotonics and uterine massage fail to control bleeding, the WHO, the International Federation of Gynecology and Obstetrics, and the Royal College of Obstetricians and Gynecologists all prescribe UBT.<sup>3,8,9</sup> When medicinal care of refractory PPH fails, the National rural health mission (NRHM) and DAKSHATA Guidelines for the management of PPH recommend UBT.<sup>10,11</sup> Uterine balloons from Bakri, Sengstaken–Blakemore, Rusch, Foley, ESM-UBT, and condom catheter are available on the market. Each variety of balloon has been thoroughly researched for safety and effectiveness, and each has a distinct edge over the others. We will investigate effectiveness of the condom-based ESM-UBT in cases of refractory PPH.

## MATERIALS AND METHODOLOGY

The Department of Obstetrics and Gynecology, NKPSIMS & Research Centre, and Lata Mangeshkar Hospital, Nagpur conducted a prospective observational study. In July 2019, condom-based UBT was approved for the treatment of postpartum bleeding that did not respond to medicinal treatment. From July 2019 to August 2020, prospective data on all PPH cases diagnosed or admitted to the institute were analyzed. Following approval from the Institutional Ethics Committee, the procedure and goal of the study were described to patients in their own language, and cases were included in the study after receiving written valid informed consent.

### Criteria for Inclusion and Exclusion

The study included all patients with PPH who were diagnosed, hospitalized, or referred from outside. Patients with traumatic PPH, uterine abnormalities, and uterine infections who could not be treated with balloon tamponade were excluded from the study.

All patients, diagnosed with PPH or referred from outside with PPH, who gave birth at Lata Mangeshkar Hospital were offered active care of the third stage of labor first, which includes the following:

- Uterotonic agent prophylactic administration following the delivery of the baby's anterior shoulder.
- Cord clamping is delayed.
- Cord traction that can be controlled.

In the meantime, the reason of PPH was investigated.

If traumatic PPH was discovered to be the cause, any arterial bleeding or retained placenta required immediate attention, and the case was removed from the research. Medical care of PPH cases with uterine atony as the causal component included uterotonic medicines, either alone or in combination, and uterine massage, depending on the individual case. In situations of refractory PPH



**Fig. 1:** Components of ESM-UBT. The ESM-UBT kit contents: a size 24 urinary catheter, condoms, cotton strings, Luer-lock one-way valve, illustrated checklist, and data collection card. (Source: Division of Global Health and Human Rights, Department of Emergency Medicine, Massachusetts General Hospital, Boston, MA, USA)

that had not responded to medical treatment, the ESM-UBT: Every Second Counts–UBT was used in both vaginal and cesarean deliveries. Before inserting UBT, uterovaginal canal and cervical exploration were carried out in order to rule out traumatic PPH. Normal saline (NS) (200–400 mL) was used to fill the balloon. Stepwise devascularization with balloon tamponade *in situ* was used in cases when hemorrhage was not controlled despite the use of UBT and various supplementary treatments such as compression sutures (Fig. 1). If bleeding persists despite all resuscitative efforts, a hysterectomy was performed as a last resort. The institute did not have a facility for uterine artery embolization. Blood loss was measured using a visual method in both vaginal and cesarean section deliveries. Patients were given crystalloids while blood was being arranged, and then blood and blood products were transfused based on the patient's unique needs and blood loss. Patients with UBT *in situ* had their vital parameters monitored for every 15 minutes in first 2 hours and then every hourly for next 4 hours and every 4 hours for the remaining 24 hours. Until UBT is in place, patients were provided injectable antibiotic coverage (injection cefuroxime 1.5 gm BD). Following UBT application, an oxytocin drip (10 units in 500 mL ringer lactate–20 drops/min) was sustained for 12 hours. After ensuring that the patient is vitally stable and there is no active bleeding, the uterine balloon was removed after 24–48 hours of placement. Methylergometrine was injected intramuscularly before the balloon was removed (if not contraindicated). When methylergometrine was not an option, an oxytocin drip (10 units in 500 mL ringer lactate) was started and sustained for 2 hours. By withdrawing 50 mL NS every 15 minutes, the UBT was gradually deflated. The amount of NS removed was compared to the amount placed in the clinical card of the patient. All patients were monitored for 12 hours (after the balloon was removed) by measuring their pulse, blood pressure, and active vaginal bleeding every 2 hours. Patients were followed up on and records were kept throughout their hospital stay, with thorough monitoring for any PPH consequences such as shock, sepsis, anemia, heart failure, DIC, and ICU admission. The final outcome was recorded as recovery morbidity or fatality.

## OBSERVATIONS AND RESULTS

During the study period, the total number of deliveries including vaginal as well as cesarean section was 1,359 out of which 108 (7.9%) patients suffered from PPH and 26 patients had PPH not responding to the medical line of management thus contributing 1.9% incidence of PPH in this study. The mean age of the study population was 28.4 with standard deviation of 2.3 years (Table 1). When considering parity status, 13 patients (50%) were primigravidae and remaining 50% were multigravida. Also, 17 patients (73%) were delivered vaginally while 7 (27%) were delivered by lower segment caesarian

**Table 1:** Obstetric and demographic characteristics of the patients

Clinical characteristics	Frequency (n)	%
Age distribution in years		
20–25	5	19.23%
25–30	13	50%
30–35	5	19.23%
35–40	3	11.54%
Gravida status		
Primi-	13	50%
Multi-	13	50%
Mode of delivery		
Vaginal	19	73.07%
LSCS	7	26.93%
Cause of PPH		
Uterine atony	23	88.46%
Coagulopathy	3	11.54%
Weeks of gestation in weeks		
<27.6	2	7.69%
28–36.6	5	19.23%
37–39.6	15	57.69%
>40	4	15.38%
Birth weight (kg)		
1–1.5	1	3.84%
1.5–2	4	15.38%
2–2.5	6	23.07%
2.5–3	10	38.46%
3–4	5	19.23%

LSCS, lower segment caesarian section

**Table 2:** Characteristics of four cases where ESM-UBT failed

Case no.	Age (yr)	Parity	GA weeks	Mode of delivery	Estimated blood loss	Cause of PPH	Additional measures/Comments
1	28	G <sub>3</sub> A <sub>2</sub>	36	FTND		Uterine atony	Spontaneous expulsion in 1 hour
2	32	G <sub>2</sub> P <sub>1</sub> L <sub>1</sub>	40	LSCS		Uterine atony	Rupture of the balloon with leakage
3	30	Primi-	39	FTND		Coagulopathy	Stepwise devascularization
4	35	G <sub>3</sub> P <sub>1</sub> L <sub>1</sub>	38	FTND		Uterine atony	Stepwise devascularization, compression sutures, and finally peripartum hysterectomy needed

LSCS, lower segment caesarian section

section (LSCS). The average gestational age was 35.6 weeks. The mean baby birth weight calculated was 2.6 ± 4 kg. Moreover, in 23 cases, uterine atony was the causative factor for PPH while in remaining three coagulopathy was associated with hemorrhage. The mean duration from diagnosis to balloon placement was 21.9 ± 5.3 minutes and the mean volume of inflation was 278.8 ± 13.9 mL.

In all 26 cases, Every Second Matters ESM-UBT was placed out of which in 22 cases (85%) it was able to salvage the uterus while in 4 cases (15%) it did not meet the expectations (Table 2). In one case, it got spontaneously expelled within 1 hour of placement, and in another case rupture of the balloon with leak was noted after 2 hours. In remaining two cases, hemorrhage was not controlled even after balloon placement. So, stepwise devascularization was performed to salvage the uterus out of which in one case, in spite of all resuscitative measures including compression sutures, peripartum hysterectomy was needed. So, if combined with additional interventions like stepwise devascularization and compression sutures success rate increased to 96.15%. In remaining 22 cases (85%), balloon was *in situ* for 29.5 ± 5.3 hours and no any added surgical intervention was required. No maternal mortality was recorded in the present study, and we were able to save all 26 mothers. So, the survival rate of the present study is 100%.

During this study, the blood loss ranged from 800 to 3500 mL with mean blood loss of 1890.38 mL (Table 3). Twelve patients (46%) required >3 units of blood transfusion and remaining 14 patients (54%) required <3 units of blood transfusion. The mean units of blood transfusion were 2.28 ± 1.56 units with range from 0 to 6 L. The mean hemoglobin of the study population was 9.5 gm/dL with standard deviation of 1, and the lowest Hb recorded was 5.3 gm/dL. The duration of hospital stay of the patients ranged from 5 to 21 days. Mean duration of patient stay was 14.9 ± 4.8 days. Moreover, 5 (21%) patients needed ICU admission whereas 21 (89%) patients did not require ICU admission. Fifteen patients (57.69%) required fresh-frozen plasma (FFP) transfusion in the present study. The mean unit of FFP transfused in the study was 3.6 ± 2 units with a range from 0 to 6 units. Platelet transfusion was required in 10.21% of women. The mean unit of platelets transfused was 1.5 ± 1 units in the present study.

## DISCUSSION

Postpartum hemorrhage is traditionally described as a blood loss of <500 mL following the third stage of labor.<sup>3</sup> If the blood loss is substantial enough to damage the maternal hemodynamic system, severe maternal consequences, such as multiorgan failure or death, can occur. Postpartum hemorrhage is most commonly caused by an atonic uterus, which is also a primary cause of maternal mortality due to bleeding. Postpartum hemorrhage can be caused by genital tract injuries (such as lacerations, cervical tears, and uterine rupture),

**Table 3:** Details of hemorrhage and ESM-UBT

Characteristics	Frequency (n)	%
<b>Blood loss (in mL)</b>		
500–1000	8	30.76%
1000–2000	6	23.07%
2000–3000	8	30.76%
3000–4000	4	15.38%
<b>Volume of inflation (in mL)</b>		
200–250	6	23%
250–300	12	46%
300–350	8	31%
<b>Time required for balloon placement (min)</b>		
0–15	4	15%
15–30	20	77%
30–60	2	8%
<b>Duration of stay (days)</b>		
0–7	2	8%
7–15	15	58%
15–30	8	31%
30–40	1	4%

a retained placenta, or maternal coagulopathies. Majority of women presenting with PPH have no identifiable risk factor but prior history of PPH, grand multiparity, prolonged labor, labor dystocia, obstructed labor, placenta previa, adherent placenta, and multiple pregnancy are some of the obstetric disorders associated with an increased risk of PPH.<sup>12</sup>

The majority of women with PPH respond favorably to initial treatment (uterotonics, uterine massage, and tranexamic acid). However, between 10 and 20% of these women do not respond to these therapies. These women (the majority of whom have uterine atony) contribute to overall PPH morbidity and mortality. Additional measures such as UBT, uterine artery ligation, stepwise devascularization, compression sutures such as (B-Lynch, Hayman’s, and Cho sutures), uterine artery embolization, and, if all else fails, rescue hysterectomy can be considered. The above-mentioned second line of management necessitates laparotomy, specialized knowledge, and costly set-up and operating theatres. UBT is a low-cost, simple-to-use procedure with a short learning curve that does not necessitate a costly set-up. There are several types of balloon tamponade on the market, each with its own efficacy, benefits, and drawbacks. The effectiveness of ESM-UBT for the management of PPH was investigated in this study.

The majority of patients with multiple high risks in our study were already in the early or severe stages of coagulopathy when they were admitted to the tertiary facility. Early referral to a higher center is recommended in high-risk pregnancies.<sup>13–15</sup> Furthermore, out of 26 patients in our study, 22 were successfully managed with balloon tamponade (ESM-UBT), with additional interventions required in four cases. The success rate of ESM-UBT alone is 85%, but when combined with additional surgical intervention such as compression sutures and stepwise devascularization, the overall success rate increased to 96.15% in this study (Table 4). However,

**Table 4:** Comparison with other studies of balloon tamponade

Author	Success rate (%)	Estimated blood loss (mL)	Volume of inflation (mL)	Blood and blood product transfusion	Hysterectomy required	ICU stay	Additional intervention	Maternal mortality
Nelson et al. <sup>21</sup>	100	2500 [median (2000–3000 mL)]	100 [median (60–250)]	2 units median (2–5 units)	–	–	B-lymph suture in all five cases	None
Sharma et al. <sup>20</sup>	84.62%	1260 ± 333 [mean (700–2000 mL)]	357.9 ± 34.33 [mean (300–450 mL)]	2.18 ± 1.78 (mean)	1 (1.89%)	32.08%	Stepwise devascularization in six cases; a combined procedure in two cases (one each of B-lymph and Cho sutures)	2
Alkış et al. <sup>17</sup>	91.4%	2100 [median (700–7600 mL)]	246 mL [mean (80–500 mL)]	2.4 units [median (0–22 units)]	4	–	Four failed cases required hysterectomy	None
Kong et al. <sup>18</sup>	79%	2000 [median (1500–6320 mL)]	–	–	2	100%	Four patient required additional intervention 2-UAE 2-hysterectomy	None
Present study	85%	800–3500 mL	278.8 ± 13.9 [mean (200–350 mL)]	2.28 ± 1.56 [mean (0–6 units)]	1	21%	Two cases: failure with expulsion and rupture 1st case: stepwise devascularization 2nd case: stepwise devascularization f/b hysterectomy	None



one patient underwent rescue hysterectomy despite balloon tamponade, resulting in a 3.85% failure rate. As there was no fatality documented in this trial, the survival rate is 100%.

The success rate of UBT in managing refractory PPH has been reported to range from 80 to 100%,<sup>16</sup> and it was 85% in our trial. In literature, the necessity for additional surgical intervention in the form of compression sutures, bilateral internal iliac artery ligation, or uterine artery embolization ranges from 8.6% in the study by Alkış et al.<sup>17</sup> to over 21.05% in the study by Kong et al.<sup>18</sup> The need for additional intervention with balloon tamponade for successful management of refractory PPH was found to be 15.38% in this investigation, which was close to the findings of Alouini et al.<sup>19</sup> by 14.63%. Furthermore, ICU admission data ranges from 32.08% in the study by Sharma et al.<sup>20</sup> to 100% in the study by Kong et al.<sup>18</sup> Women requiring ICU admission accounted for 21% of the women in this study.

The maternal survival rate refers to the number of women who have survived refractory PPH after undergoing balloon tamponade or any other surgical intervention, if necessary. In most studies, the maternal survival rate approaches 100%. The survival rate in the investigations by Nelson et al.,<sup>21</sup> Alkış et al.,<sup>17</sup> and Kong et al.<sup>18</sup> is 100%, which matches the current study's survival rate of 100%. Similar results were reported by Garg et al.,<sup>22</sup> and Garg and Yadav.<sup>23</sup>

## CONCLUSION AND CLINICAL SIGNIFICANCE

The use of ESM-UBT is a novel treatment for refractory PPH. Additional interventions, such as major artery ligation, gradual devascularization, or compression sutures, may be required in a few situations. The overall effectiveness and success rate of the balloon tamponade are improved by these additional interventions. According to the findings, ESM-UBT should be considered as the primary intervention in tertiary care centers and low-resource settings before other invasive procedures. Its ease of usage and short learning curve provide an added benefit of being able to conduct it in a low-resource environment. It can also be utilized when referring the patient to higher center or while making preparations for a procedure to prevent blood loss.

Balloon tamponade is a straightforward, practical, cost-effective, and easy-to-use technique for lowering maternal morbidity and mortality owing to refractory PPH in cases where medical therapy is unsuccessful or surgery is not available, particularly in low-resource settings. In the event that medical care fails, we highly advise using balloon tamponade as a first line of defense before resorting to surgical intervention.

## ACKNOWLEDGMENTS

Authors would like to thank Dr Thomas F Burke, Chief of the Division of Global Health and Human Rights, for providing us ESM-UBT. Authors would also like to thank all the consultants and nursing staff for active teamwork, data and record keeping, which helped in the study.

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