

## Original Research Article

# Efficacy of Bakri Balloon placement in early Management of Post-partum Hemorrhage

Dr. Vibhuti Thakur<sup>1</sup> (Asst. Prof.), Dr. Akanksha Thora<sup>2</sup> (Asst. Prof.),  
Dr. Richa Chouksey<sup>3</sup> (Asst. Prof.)

<sup>1,2,3</sup>Dept. of Obstetrics and Gynaecology, MGM Medical College Hospital & Research Centre, Indore, M.P.

Corresponding Author: Dr. Akanksha Thora

**ABSTRACT:**

Post-partum haemorrhage (PPH), an obstetric emergency that can complicate vaginal or caesarean deliveries & is associated with serious complications. Guidelines for the management of PPH involve a stepwise escalation of pharmacological & surgical approaches. In women who do not respond to uterotonics or medical treatment, a variety of procedures, such as uterine artery embolization, stepwise de-vascularization or obstetric hysterectomy, may be used. The Bakri balloon is an intrauterine device indicated to reduce or control PPH temporarily when conservative treatment is warranted. Here, we are presenting case series of primary atonic PPH & which were managed by Bakri Balloon Tamponade (BBT).

This case series included 91 women with PPH managed by Bakri balloon as a conservative therapeutic option. All 91 women were in age group between 19 years to 34 years. The causes of PPH were uterine atony, retained placenta & central placenta previa. The Bakri balloon was successful in controlling haemorrhage in 87 women (90.1%) who did not respond to medical management of PPH.

Bakri balloon is a simple, easy to use & effective method for conservative management of acute PPH. This device reduces bleeding, shortens the hospital stay & avoids the need for more aggressive procedures such as stepwise devascularization & obstetric hysterectomy.

**1. INTRODUCTION:**

Postpartum haemorrhage is defined as a blood loss of more than 500 ml in vaginal delivery & >1000 ml in caesarean section. PPH is accounted for to be the main source of maternal mortality overall [1]. PPH represents 30.8% of all direct obstetric mortality in Africa & 33.9% of all such passings in Asia[2].

PPH is the leading cause of maternal mortality in low-income countries, and the primary cause of nearly 25% of all maternal deaths globally [3]. Sixty percent of pregnancy related maternal deaths occur during the postpartum period. A study by Li XF et al showed 45% of these maternal death occur in first 24 hours [4].

Serious or monstrous PPH is characterized as blood loss of more prominent than 1000 mL blood misfortune after conveyance can be hazardous & may quickly prompt coagulopathy, with resultant morbidity & mortality. Risk factors for atonic PPH are overdistended uterus in cases of multiple pregnancy, polyhydramnios, induction of labor, abnormal placentation, oxytocin augmentation, prolonged labor etc. Expectation of PPH based on risk factors is

unpredictable. Therefore, all caregivers must be cautious about the anticipation & treatment of PPH.

Initial treatment of atonic PPH involves medical management, which includes uterotonic agents like oxytocin, methergin, misoprostol, and carboprost. Tranexamic acid, replacement of fluids, blood and blood products are also used. Bimanual compression of uterus is also done. If there is failure of medical management of PPH one should consider Uterine Balloon Tamponade (UBT) which is simple, less invasive and needs minimal training for insertion. Surgical methods available for atonic PPH are step wise devascularization, uterine compression sutures, internal iliac artery ligation, and hysterectomy. All these methods require expertise. The world health organization (WHO) recommends the use of UBT as a second-line treatment for PPH due to uterine atony when bimanual compression and uterotonic drugs fail. Uterine balloon tamponade is an important step to limit ongoing uterine blood loss while initiating other measures, and can be readily implemented by health care providers with minimal training. It can be a life-saving intervention, especially in low-resource settings where blood transfusion and surgical facilities availability are limited.

Uterine tamponade to forestall PPH is a well-established procedure & the main methods for uterine tamponade were loading of uterine cavity with cotton gauge . Later on these strategies were changed & uterine pressing was supplemented with many inflatable techniques like as condom catheter, foley's swell catheter, Sengstaken Blakemore GI catheter, Rusch balloon & Bakri balloon.[5,6,7,8]

Intrauterine inflatable tamponade (IUBT) has arisen as a fruitful life-saving second line treatment choice in management of PPH when uterotonic agents & bimanual compression failed to control bleeding. The presumed mechanism of action of intrauterine balloon catheters is application of inward to outward hydrostatic pressure against the uterine wall; this pressure may or may not be in excess of systemic arterial pressure. It is important to place the balloon as early as possible, it becomes ineffective once coagulopathy sets in because this procedure work by facilitating blood clotting in uterine vessels and thus reduces bleeding.[9,10]

Among all intra uterine inflatable tamponade, Bakri balloon is especially designed for control of haemorrhage in uterine atony. Bakri balloon is made up of silicon ,designed with two way catheter .Insertion is simple, can be used following vaginal delivery or caesarean section .It can be inflated with maximum 500 ml normal saline.

There is significant need for study where Bakri balloon tamponade to be used, volume of saline to be instilled to accomplish tamponade, the span of tamponade required, protocol for emptying, the utilization of adjunctive measures like vaginal packing, simultaneous oxytocin infusion & antibiotics & the elements foreseeing failure [11].

## **2. MATERIALS AND METHODS:**

A prospective study was done over a period of 18 months from December 2019 to June 2021 in MGM Medical College & M.Y. Hospital Indore, a tertiary care centre in central India with all participants provided informed written & oral consent.

Patients who experienced PPH & received treatment with the Bakri balloon were enrolled. PPH was defined as a clinically estimated blood loss of greater than 500 mL (vaginal

delivery) or greater than 1000 mL (caesarean delivery), & hemodynamic changes that, in the opinion of the care team, required interventions beyond routine care (e.g. intravenous fluids, need for blood transfusion or the use of  $\geq 2$  uterotonic agents). The exclusion criteria were: arterial bleeding requiring surgical exploration and/or immediate need for hysterectomy; cervical cancer, purulent infections of the vagina, cervix, or uterus; an untreated uterine anomaly; active disseminated intravascular coagulation; a surgical site that would prevent the Bakri tamponade balloon from effectively controlling bleeding; referral for obstructed labor & signs, symptoms, or other evidence of a ruptured uterus.

A standardized protocol was followed ;all patients requiring intervention for PPH were to be initially treated according to this protocol. This was based on the Royal College of Obstetrics & Gynaecology (RCOG) Green Top guidelines for PPH [12] & included uterine massage, administration of oxytocin, & bimanual uterine compression followed by surgical intervention if necessary. For this study some changes were made to the WHO protocol to include Bakri balloon placement in patients who does not respond to the standard conservative management.

The Bakri tamponade balloon (Cook Medical, Bloomington, IN, USA) comprises a silicone balloon connected to a 24-French silicon catheter (length 54 cm). Under all aseptic conditions after evaluating the cause of PPH (atonic); the collapsed balloon is inserted into the uterine cavity through the cervical os & placed in the upper segment. Once in place, the balloon is filled to the recommended maximum volume of 500 mL. The central lumen of the catheter enables drainage & monitoring of bleeding above the balloon in the uterine cavity.

Protocol for PPH in this study:

**MAJOR OBSTETRIC HEMORRHAGE**

Blood loss greater than 500 ml in vaginal delivery/>1000 ml in caesarean section/ continuing hemorrhage or clinical shock



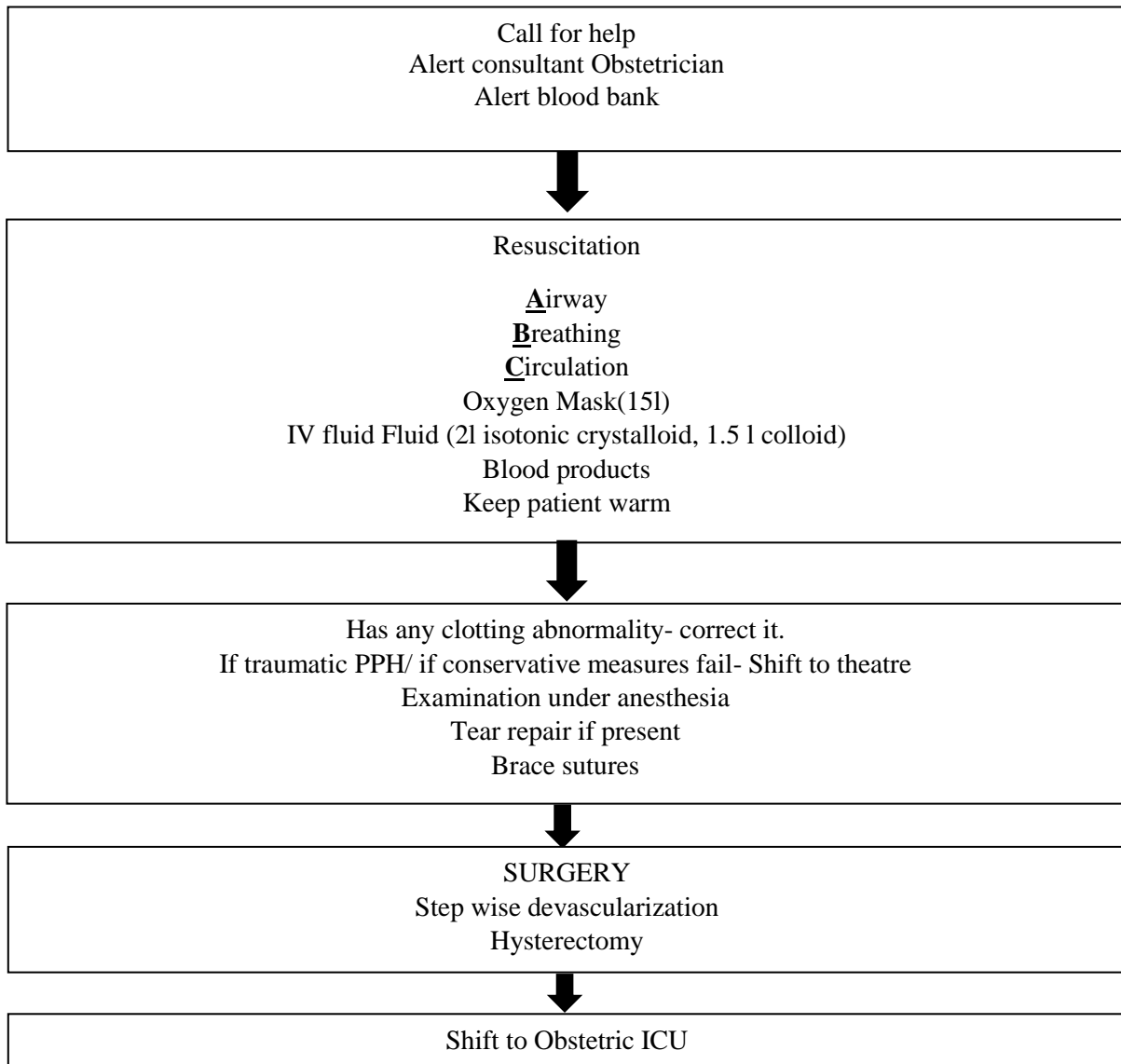


Fig 1: Protocol for the management of primary postpartum hemorrhage. The flow chart was based on the RCOG green top guidelines

**PROTOCOL FOR PLACEMENT OF BAKRI BALLOON IN THIS STUDY**

1. Patient experience major obstetric hemorrhage
2. Cause of PPH assessed
3. In case of atonic PPH, medical management of PPH done as per protocol
4. When usual measures fail, the Bakri tamponade balloon is considered for patients who fulfilling the inclusion criteria
5. The operating theatre is arranged to receive the patient as per the usual protocol.
6. The patient or family is explained of all risk and standard informed consent for treatment and surgery is taken.
7. The Bakri tamponade balloon is placed following all aseptic precautions
8. Patients is assessed for evidence of ongoing blood loss and hemodynamic stability
9. Either:
  - a. Proceed with surgical intervention if bleeding is not controlled or patient is hemodynamically unstable.
  - b. Measure vital signs approximately every 15 minutes for 2 hours
10. Assess patient for ongoing blood loss every hour for 6 hours, then every 4 hours for ≤24 hours after delivery.
11. Remove balloon per protocol, assessing bleeding and hemodynamic stability.
12. Complete data collection? form immediately after removal of Bakri balloon.
13. The data was analysed using appropriate software. All tests were done with a significance level of 0.05.

Large bore IV cannula in both hands  
 Send all routine investigation  
 Cross match  
 Insert foleys catheter  
 Hb analysis  
 Maintain vital charting

Find cause of PPH if **atonic** then:  
 Uterine massage  
 Oxytocin 5IU slow IV (repeat if necessary)  
 Oxytocin infusion 40IU in 500 ml  
 Carboprost 0.25mg IM every 15 minutes (upto 8 times)  
 Misoprostol 800 mcg sublingually  
 Tranexamic acid 1 gm  
 Balloon tamponade

**3. RESULTS:****Table No. 01: Age Distribution**

S. No.	Age	No.	Percentage
1	19-24	26	28.7
2	25-30	48	52.7
3	More than 31 Years	17	18.6

**Table No. 02: Parity**

S. No.		No.	Percentage
1	Primigravida	27	29.6
2	Multigravida	64	70.4

**Table No. 03: Booking Status**

S. No.	Booking Status	No.	Percentage
1	Booked	23	25.2
2	Unbooked	68	74.8

**Table No. 04: Pre Delivery Anaemia**

S. No.	Pre Delivery Anaemia	No.	Percentage
1	Mild	19	20.8
2	Moderate	42	46.3
3	Severe	30	32.9

**Table No. 05: Mode of delivery**

S. No.	Mode of delivery	No.	Percentage
1	Vaginal	39	42.8
2	Caesarean	52	57.2

**Table No. 06: Route Balloon Placement**

S. No.	Route Balloon Placement	No.	Percentage
1	Vaginal	54	59.3
2	Uterine	37	40.7

**Table No. 07: Successful Balloon Placement**

S. No.	Successful Balloon Placement	No.	Percentage
1	Successful	82	90.1
2	Unsuccessful	09	09.9

**Table No. 08: Patient Outcome**

S. No.	Patient Outcome	No.	Percentage
1	Survived	87	95.6
2	Expired	04	04.4

**Table No. 9: Need for blood transfusion**

S. No.	Need for blood transfusion	No.	Percentage
1	PRBC	30	32.9
2	PRBC & other blood components (FFP, PRP or platelet concentrates.	61	67.1

#### 4. DISCUSSION:

The utility of a UBT in cases of uterine atony, especially when medical methods of management of PPH fails or conditions preclude the use of uterotonics, or when excessive haemorrhage is observed should be kept in mind. In our study 91 cases were studied in whom Bakri balloon was inserted after initial PPH protocol failed to arrest bleeding. Majority of women were in the age group of 25-30 years (52.7%). 28.7% women were in the age group of 19-24 years.

18.6 % women were of age above 31 years. There were 27 primigravida (29.6%) & 64 Multigravida (70.4%). Among these 91 cases, 23 women (25.2%) were booked in our hospital & 68 were unbooked (74.8), referred during emergency hours. All 91 women were anemic. 19 women (20.8%) were mildly anemic, 42 were moderately anaemic (46.3%) & 30 were severely anaemic (32.9%). In these 91 cases, 39 women were delivered vaginally (42.8%) & remaining 52 were delivered by caesarean section (57.2). Bakri balloon placement can be done by trans-vaginal route or uterine route. Out of 52 cases who delivered by caesarean section, 37 cases had intrauterine placement of Bakri balloon & 15 had intravaginal placement. All 39 cases who delivered vaginally had transvaginal placement of Bakri balloon. Success rate of Bakri placement was 90.1% in our study. In 9 cases, BBT failed to control haemorrhage & obstetric hysterectomy was done. A study by Alouini et al Bakri balloon tamponade for severe post-partum haemorrhage: efficiency & fertility outcomes showed PPH was stopped in 88% of cases. [14] A study by Vitthala et al in a series of 15 cases, use of Bakri balloon in post-partum haemorrhage showed Bakri balloon was effective in 80% of cases. [13] A systematic review and meta-analysis by Suarez et al uterine balloon tamponade for the treatment of postpartum haemorrhage showed overall pooled success rate was 85.9% for uterine balloon tamponade [15]. In our study Bakri balloon tamponade was

successful in controlling haemorrhage in 90.1% (82 cases). In Remaining 9 cases tamponade alone was failed to control haemorrhage & surgical management (Obstetric hysterectomy) was done. 4 cases of massive post-partum haemorrhage were complicated by DIC & could not be saved. All women receive blood transfusion. In 61 cases (67.1) received blood & blood components (like RBC, PRP, FFP, Cryoprecipitate) & 30 cases (32.9) were managed only by PRBC.

The world health organization (WHO) recommends the use of Bakri balloon tamponade as a second line treatment for PPH due to uterine atony when uterotonic agents & bimanual compression fails. Early insertion of BBT is useful way of limiting ongoing blood loss while initiating other measures & it can be readily implemented by providers with minimal training. It can be a life saving intervention especially in low resource setting where blood transfusion & surgical facilities are not available. Patients can be successfully referred to higher centre after tamponade & thus helps in reduction of maternal mortality

## 5. CONCLUSION:

Postpartum haemorrhage is a potentially life-threatening event. Given that the technology is simple to deploy and with minimal adverse effects, a balloon tamponade method should become a familiar component of existing guidelines for the management of PPH, although not as an isolated form of therapy. Balloon tamponade was the least invasive and most rapidly implemented, and that it seemed logical to use it in suitable cases.

## 6. REFERENCES:

- [ 1]. Carroli G, Cuesta C, Abalos E, Gülmezoglu AM. Epidemiology of postpartum 296 haemorrhage: a systematic review. *Best Pract Res Clin ObstetGynaecol* 2008; 22(6):999–1012.
- [ 2]. Khan KS,Wojdyla D, Say L, Gülmezoglu AM, Van Look PF.WHO analysis of causes of maternal death: a systematic review. *Lancet* 2006;367(9516):1066–74.
- [ 3]. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller AB, Daniels J, et al. Global causes of maternal death: a WHO systematic analysis. *Lancet Glob Health*. 2014;2(6):e323-33
- [ 4]. Li XF, Fortney JA, Kotelchuck M, Glover LH. The postpartum period: the key to maternal mortality. *Int J Gynaecol Obstet*. 1996;54(1):1-10.
- [ 5]. Majumdar A, Saleh S, Davis M, Hassan I, Thompson PJ. Use of balloon catheter tamponade for massive postpartum haemorrhage. *J Obstet Gynaecol* 2010;30:586-93.
- [ 6]. Ramsbotham FH. *The principles and practice of obstetric medicine and surgery: in reference to the process of parturition*. Philadelphia, PA: Blanchard and Lea; 1855.
- [ 7]. Georgiou C. 2014. A review of current practice in using Balloon Tamponade Technology in the management of postpartum haemorrhage. *Hypertension Research in Pregnancy* 2:1–10.
- [ 8]. Akhter S, Begum MR, Kabir Z, Rashid M, Laila TR, Zabeen F. Use of a condom to control massive postpartum hemorrhage. *MedGenMed* 2003;5:38-43.
- [ 9]. Diemert A, Ortmeyer G, Hollwitz B, Lotz M, Somville T, Glosemeyer P, et al. 2012. The combination of intrauterine balloon tamponade and the B-Lynch procedure for the treatment of severe postpartum hemorrhage. *American Journal of Obstetrics and Gynecology*206:65.e1–65.e4.



- [ 10]. Dabelea V, Schultze P, Mcduffie RS. 2007. Intrauterine balloon tamponade in the management of postpartum hemorrhage. *American Journal of Perinatology* 24:359–364.
- [ 11]. Grönvall M1, Tikkanen M, Tallberg E, Paavonen J, Stefanovic V. Use of Bakri balloon tamponade in the treatment of postpartum hemorrhage: a series of 50 cases from a tertiary teaching hospital. *Acta Obstet Gynecol Scand* 2013;92:433-8.
- [ 12]. Mavrides E, Allard S, Chandrabaran E, Collins P, Green L, Hunt BJ, Riris S, Thomson AJ on behalf of the Royal College of Obstetricians and Gynaecologists. Prevention and management of postpartum haemorrhage. *BJOG* 2016;124:e106–e149.
- [ 13]. Vitthala S, Tsoumpou I, Anjum ZK, Aziz NA. Use of Bakri balloon in post-partum haemorrhage: a series of 15 cases. *Aust N Z J Obstet Gynaecol.* 2009;49:191–4.
- [ 14]. Alouini S, Bedouet L, Ramos A, Ceccaldi C, Evrard ML, Khadre K. Bakri balloon tamponade for severe post-partum haemorrhage: efficiency and fertility outcomes. *J Gynecol Obstet Biol Reprod.* 2014;45: 52-9.
- [ 15]. Suarez S, Conde-Agudelo A, Borovac-Pinheiro A. Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review and meta-analysis. *Am J Obstet Gynecol.* 2020;222:e1- 52.