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CLINICAL ARTICLE

The Bakri tamponade balloon as an adjunct treatment for refractory postpartum hemorrhage

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ABSTRACT

Objective: To evaluate the Bakri tamponade balloon as an adjunct treatment for refractory postpartum hemorrhage (PPH). *Methods:* A prospective observational intervention study was conducted between January 1, 2013, and May 31, 2015, at Great Lakes Hospital and Moi Teaching and Referral Hospital in Kenya. Eligible participants were diagnosed with PPH (blood loss >500 mL after vaginal or >1000 mL after cesarean delivery, and/or hemodynamic changes suggestive of excessive blood loss) unresponsive to standard intervention and were treated using the Bakri balloon. Case report forms were completed for all participants. The primary endpoint was the frequency of surgery after use of the Bakri balloon. *Results:* Among 58 patients, postpartum bleeding was controlled without further surgical intervention in 55 (95%). Among the 55 women with uterine atony, the Bakri balloon successful controlled PPH in 52 (95%). Two of the three hysterectomies performed were for continued bleeding after placement of the Bakri tamponade balloon. Four maternal deaths occurred. *Conclusion:* The Bakri tamponade balloon proved an effective adjunct in the management of refractory PPH.

1. Introduction

Severe bleeding is reported to be the leading cause of maternal mortality worldwide [1,2]. Postpartum hemorrhage (PPH) accounts for 30.8% of all direct obstetric mortality in Africa and 33.9% of all such deaths in Asia [2]. On a global scale, these rates are equivalent to approximately 140 000 deaths annually or to one death every 4 minutes [3].

Severe or massive PPH is defined as blood loss of greater than 1000 mL [4]. Huge blood loss after delivery can be immediately life-threatening and might rapidly lead to coagulopathy, with resultant morbidity and mortality [4].

Prediction of severe PPH on the basis of risk factors is unreliable, especially in low-resource settings such as East Africa. Therefore, it is critical for all providers of obstetric care to be knowledgeable about the prevention and treatment of PPH and to be prepared for its occurrence. If conservative measures fail to stop bleeding, surgical treatment becomes necessary. However, surgical intervention and hysterectomy result in irreparable harm to reproductive function. Furthermore, these procedures are associated with a high level of subsequent morbidity and mortality.

Uterine tamponade techniques to manage PPH were first mentioned in publications in 1855 [5]. The early methods for tamponade used uterine packing with cotton gauze. Over the course of time, packing has been replaced by various balloon methods, including the condom, Foley catheter balloon inflation, Sengstaken–Blakemore gastrointestinal tube, and the Rusch or Bakri catheters [6–8].

Balloon tamponade devices have been successfully used in the delivery units of many high-resource and low-resource facilities to treat PPH and can often help to avoid the need for operative intervention such as hysterectomy [6,8,9]. The aim of the present study was to evaluate the effect of including the Bakri tamponade balloon as an adjunct treatment for refractory PPH in a standardized management algorithm to be used in a hospital setting in low-resource countries.

2. Materials and methods

A prospective observational intervention study was conducted between January 1, 2013, and May 31, 2015, at two sites in Kenya: Great Lakes Hospital in Kisumu and Moi Teaching and Referral Hospital in Eldoret. Originally, two additional centers were going to be included—New Mulago Hospital in Kampala, Uganda, and the Nairobi University Hospital in Nairobi, Kenya—but they did not receive final approval for enrollment as a result of delays in final institutional review board approval and in training. The protocol was approved by the Institutional Review Board of Duke University (Durham, NC, USA) for

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primary oversight after the participating sites had received local institutional review board approval (reference number 00029944). All participants provided informed written and/or oral consent.

Patients who experienced PPH and 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 (cesarean delivery), and/or hemodynamic changes that, in the opinion of the care team, required interventions beyond routine care (e.g. intravenous fluids or the use of ≥2 uterotonic agents). The exclusion criteria were: age younger than 18 years; arterial bleeding requiring surgical exploration or angiographic embolization; immediate need for hysterectomy; ongoing intrauterine pregnancy; 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; and signs, symptoms, or other evidence of a ruptured uterus.

Not all women who met all other eligibility criteria were considered for Bakri balloon treatment. The two participating centers have large numbers of obstetric deliveries: Great Lakes Hospital records approximately 7000 deliveries each year and Moi Teaching and Referral Hospital records approximately 10 000–12 000 deliveries annually. Therefore, staff trained in Bakri tamponade balloon placement and prolonged medical management of mild and moderate PPH were not always available.

Before the study began, a 1-day training session in the management of PPH was held for all obstetric providers at both sites. A standardized algorithm was developed, taught, and disseminated at these training sessions (Fig. 1). All patients requiring intervention for PPH were to be initially treated according to this algorithm. The intervention was based on the 2012 WHO guidelines for PPH [4] and included uterine massage, administration of oxytocin, and bimanual uterine compression followed by surgical intervention if necessary. Minor deviations from the algorithm were allowed at each participating site to account for local variations in available staff and equipment.

For the present study, the standardized algorithm was modified to include the use of the Bakri tamponade balloon in patients who do not respond to standard management of PPH (Box 1). The Bakri tamponade balloon (Cook Medical, Bloomington, IN, USA) comprised a silicone balloon connected to a 24-French silicon catheter (length 54 cm). The collapsed balloon was generally inserted into the uterus from the vagina through the cervix and the upper segment. Once in place, the balloon was filled to the recommended maximum volume of 500 mL. The central lumen of the catheter enabled drainage and monitoring of bleeding above the balloon.

Standard case report forms were completed by a trained research nurse for all participants in the present study. The data were then transferred to an electronic case report form hosted on a website designed and maintained by the Data Coordinating Center (Cook Research, West Lafayette, IN, USA). This secure system allowed individuals with permission to access the data from any location at any time. Completed forms were reviewed, processed, and stored in electronic databases according to standard operating procedures maintained by the Data Coordinating Center.

The primary endpoint was the rate of surgical exploration and peripartum hysterectomy following use of the Bakri tamponade balloon as an adjunct treatment for refractory PPH. Secondary endpoints included the need for transfusion therapy and maternal death due to hemorrhage

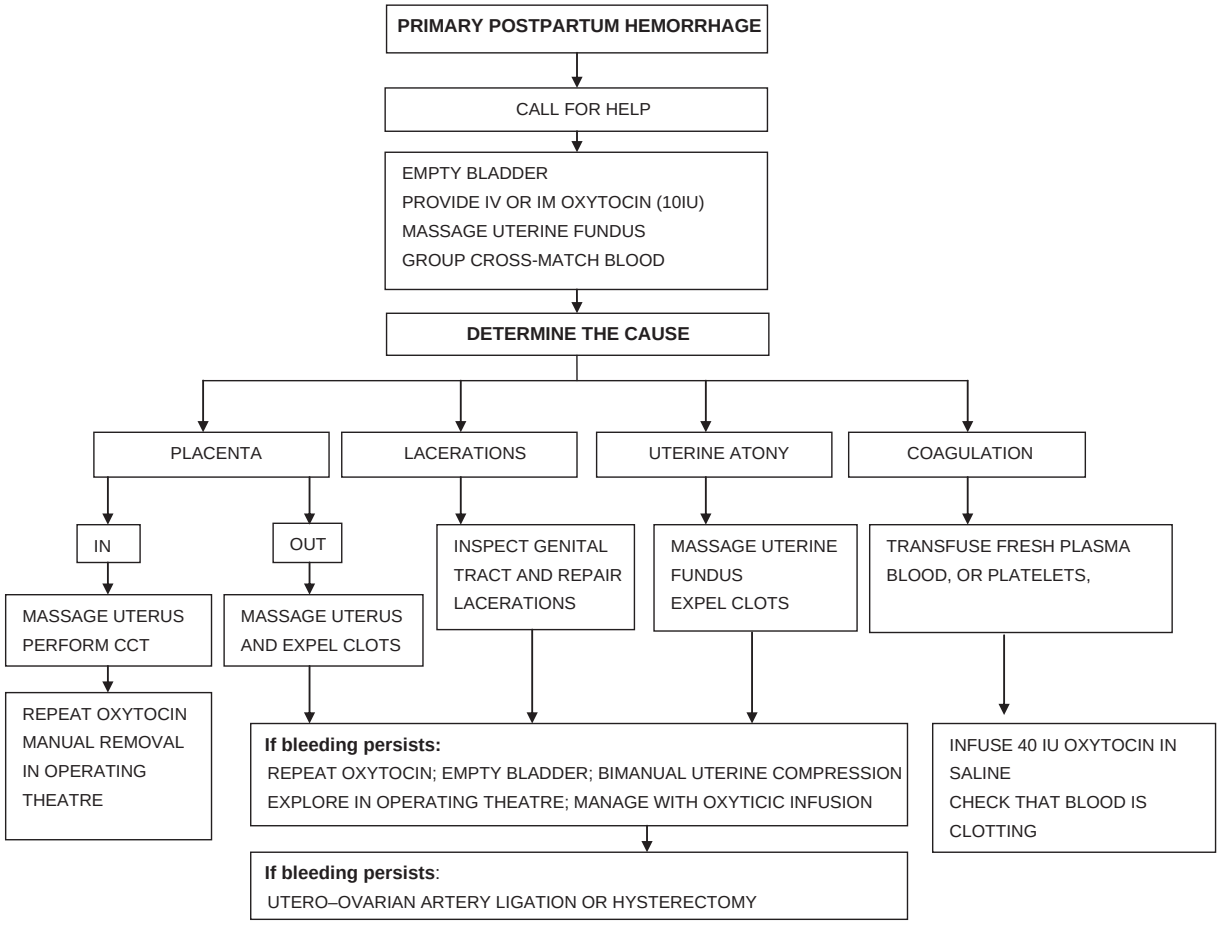

Fig. 1. Protocol for the management of primary postpartum hemorrhage. The flow chart was based on the 2012 WHO guidelines [4]. Abbreviations: IM, intramuscular; IV, intravenous; CCT, controlled cord traction.

Box 1
Algorithm for placement of the Bakri tamponade balloon.

1. Patient experiences PPH
2. Provider performs usual interventions for management of PPH
3. If usual measures fail, the Bakri tamponade balloon will be considered for patients who meet the inclusion criteria
4. The operating theatre will be made ready to receive the patient as per the usual protocol for each institution
5. The patient or family will provide the standard informed consent for treatment and surgery
6. The Bakri tamponade balloon will be placed by an obstetrics provider who has been trained in the procedure
7. Patient transferred to the operating theatre or the preoperative holding area per the usual protocol for a patient undergoing operative intervention
8. Patients treated by Bakri tamponade balloon 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

Abbreviation: PPH, postpartum hemorrhage.

from all causes. Between-site heterogeneity in the efficacy of the device to influence primary and secondary endpoints was also explored.

The data were analyzed using Enterprise Guide version 4.3 (SAS Institute, Cary, NC, USA). For categorical data, a χ^2 test was used to assess the difference between the two participating sites. For continuous data, the two-sample *t* test was used to compare differences. All tests were done with a significance level of 0.05.

3. Results

Overall, 58 women underwent adjunct treatment for refractory PPH with the Bakri tamponade balloon at the study centers (31 from Great Lakes Hospital, 27 from Moi Teaching and Referral Hospital) and were enrolled in the present study. The Bakri tamponade balloon was in place for longer at Moi Teaching and Referral Hospital than at Great Lakes Hospital ($P<0.001$) (Table 1). Additionally, more women from Moi Teaching and Referral Hospital than from Great Lakes Hospital had undergone induction of labor ($P=0.033$), and the length of the first stage of labor was shorter at Moi Teaching and Referral Hospital ($P<0.001$) (Table 1).

The mean total blood loss before balloon placement was 1447.0 ± 689.0 mL at Moi Teaching and Referral Hospital and 1323.0 ± 648.0 mL at Great Lakes Hospital ($P=0.04$). The most common primary cause of PPH was uterine atony (Table 2). No difference in the cause of PPH was detected between the two participating sites (data not shown). Fundal massage was the most frequent intervention, followed by manual uterine exploration and bimanual uterine massage (Table 2).

The Bakri tamponade balloon successfully controlled bleeding among 52 (95%) of the 55 women with uterine atony as the primary cause of PPH. Bleeding was controlled without further surgical intervention among 55 (95%) of all 58 women with refractory PPH.

Table 3 provides demographic data for the participants who required surgical intervention and hysterectomy (n = 3) and/or died (n = 4). Three (10%) women at Moi Teaching and Referral Hospital died, as did 1 (4%) at Great Lakes Hospital. The Bakri tamponade balloon was placed in all these women for presumed uterine atony, although this was not the etiology of PPH for three patients. Therefore, only one of the maternal deaths should be considered a potential failure of the device. This death was ultimately due to coagulopathy before surgical intervention was initiated. Three of the four deaths were related to advanced coagulopathy that was not apparent before balloon placement. In one death that occurred at Moi Teaching and Referral Hospital, the balloon was in place for 12 minutes before the patient was taken to surgery for hysterectomy for unrecognized cervical lacerations, uterine rupture, and uncontrollable hemorrhage. Two maternal deaths were related to unrecognized uterine rupture and one to undiagnosed cervical and vaginal lacerations. Two of the three women who had undergone secondary hysterectomy survived; the third woman died due to coagulopathy after 2 days in the intensive care unit. As such, the rate of secondary hysterectomy for women who received adjunct treatment was 5.2%. Two of the hysterectomies were for uterine atony refractory to all treatments, including the Bakri tamponade balloon. Both these procedures occurred after cesarean delivery and both women survived.

4. Discussion

In the present study, use of the Bakri tamponade balloon was successful as an adjunct after other conservative measures to treat PPH, including uterine massage and uterotonic agents, had failed to control bleeding among women with uterine atony as the underlying cause. Training of obstetrics providers in the correct placement of the device was readily achieved during a 1-day course.

Two of the reported failures of the device among the subgroup of women with uterine atony occurred following cesarean delivery (one of which was elective); both of these women survived after surgical

Table 1
Characteristics and obstetric management of patients with postpartum hemorrhage (n = 58).[a]

Variable	Moi Teaching and Referral Hospital (n = 27)	Great Lakes Hospital (n = 31)	*P* value
Maternal age, y	24.7 + 6.0	27.6 + 5.6	0.06
Labor induction	1 (4)	7 (23)	0.033
Duration of stage 1 labor, h	12.3 ± 5.5	6.8 ± 3.5	<0.001
Total duration of labor, h	12.9 ± 5.5	9.4 ± 3.4	0.11
Stage 3 of labor actively managed	27 (100)	28 (90)	0.17
Duration that the Bakri tamponade balloon was in place, h	5.3 ± 3.6	14.2 ± 9.4	<0.001

[a] Values given as mean ± standard deviation or number (percentage), unless indicated otherwise.

Table 2
Etiology and treatment of patients with PPH (n = 58).

Variable	No. (%)
Etiology of PPH	
Uterine atony	55 (95)
Genital tract trauma (lacerations)	1 (2)
Unrecognized uterine rupture	2 (3)
Retained tissue	5 (9)
Coagulopathy	7 (12)
Treatment of PPH [a]	
Fundal massage	55 (95)
Bimanual uterine massage	19 (33)
Manual uterine exploration	20 (34)
Gauze packing	5 (9)
Compression suture with balloon	1 (2)
Blood products transfused	12 (21)

Abbreviation: PPH, postpartum hemorrhage.
[a] Before placement of the Bakri tamponade balloon.

Table 3
Adverse events experienced by patients with postpartum hemorrhage.

Patient	Age, y	Parity	Mode of delivery	Hysterectomy	Duration of Bakri tamponade balloon placement, h	Volume of Bakri tamponade balloon, mL	Etiology of PPH	Coagulopathy	Admission to ICU	Death
1	30	1	Vaginal	Yes	0.2	500	Uterine rupture	Yes	Yes	Yes
2	28	6	Vaginal	No	11	500	Uterine rupture	Yes	No	Yes
3	36	2	Cesarean	Yes	3	500	Uterine atony	No	No	No
4	33	0	Vaginal	No	2	480	Vaginal laceration	No	No	Yes
5	38	3	Cesarean	Yes	5	300	Uterine atony	No	Yes	No
6	22	2	Vaginal	No	3	399	Uterine atony	Yes	Yes	Yes

Abbreviations: PPH, postpartum hemorrhage; ICU, intensive care unit.

intervention with hysterectomy. However, the Bakri tamponade balloon was in place for just 3 hours and 5 hours, respectively.

Four maternal deaths occurred in the present study but none was related to the use of the Bakri tamponade balloon. Of these deaths, three were related to coagulopathy from excessive bleeding owing to undiagnosed uterine rupture and cervical vaginal lacerations. Two maternal deaths occurred at Moi Teaching and Referral Hospital, despite the fact that these women had received aggressive medical and surgical management, including hysterectomy. In one case, the device was in place for only 12 minutes because the cause of PPH was determined to be uterine rupture rather than uterine atony.

Most of the blood loss in cases of PPH owing to uterine atony arises from contractile dysfunction in the upper contractile segment and/or at the lower segment at the placental implantation site [10]. The mechanism of action for the intrauterine balloon is the application of hydrostatic pressure against the uterine wall [11–13]. Additionally, compression of blood vessels at the level of the uterine artery insertion into the lower segment reduces blood flow and allows time for clotting to occur. The end result is reduced persistent capillary and venous bleeding from the endometrium, placenta bed, and myometrium.

The findings of the present study are in line with those of Gao et al. [14]. These researchers reviewed the efficacy and safety of the Bakri tamponade balloon in an analysis of 109 cases of PPH recorded at 13 Chinese hospitals. Successful hemostasis was achieved in 102 (93.6%) cases; the success rates after cesarean and vaginal delivery were 94.0% and 90.0%, respectively. Hysterectomy was required among six of the seven cases in which balloon intervention did not control bleeding.

The Bakri balloon, the BT-Cath (Utah Medical Products, West Midvale, UT, USA), and the Ebb two-balloon system (Glenveigh Medical, Chattanooga, TN, USA) have been referred to as uterine-specific tamponade balloons [7]. Head-to-head comparisons of the Sengstaken-Blakemore tube and the Bakri balloon found them to be equally effective in controlling PPH [15,16]. However, a suggested advantage of the Bakri tamponade balloon is the conformation to the intrauterine cavity once inflated [7].

Predicting which patients are at risk of severe bleeding is difficult because approximately two-thirds of all women with PPH have no risk factors [17–19]. A systematic review by Prendiville et al. [20] demonstrated that active management of the third stage of labor helped to prevent or reduce PPH after vaginal delivery among women at low risk of PPH. Such intervention includes the use of uterotonics, clamping of the umbilical cord, and controlled traction of the cord immediately after delivery of the fetus. In 2004, a joint statement by the International Confederation of Midwives and the International Federation of Gynecology and Obstetrics endorsed this practice for all deliveries [21].

Advantages of the present study were that the obstetrics providers were trained in the use of the device and that the criteria for using the balloon followed a standardized protocol after conservative measures to treat PPH had failed. Limitations of the present study included the small sample size (n = 58) and the fact that not all the women who met the inclusion criteria were enrolled. Selection of the participants was not random; consequently, the potential for selection bias could not be discounted. The two participating sites were referral hospitals and so might be expected to have greater capability to use the Bakri tamponade balloon than other facilities. Another limitation was that these sites were tertiary care teaching centers with a high obstetric volume and trained delivery attendants; therefore, they were probably better resourced than other sites where deliveries occur in low-income countries. As such, use of the Bakri tamponade balloon might be limited by both financial costs and lack of trained personnel. In such environments, a condom or Foley balloon might offer a viable option for intrauterine tamponade until affected individuals can be transferred to a facility capable of performing life-saving surgical management if the bleeding has not been controlled.

In summary, the Bakri tamponade balloon proved to be a valuable adjunct in the management of PPH caused by uterine atony. When surgical intervention might be the only other option to control hemorrhage, the use of the balloon could serve as a temporizing measure, potentially preventing the need for surgical intervention and hysterectomy to control blood loss. The hysterectomies performed for uncontrolled PPH in the present study were due to uterine rupture and cervical lacerations. Hence, it is important to exclude genital tract trauma, lacerations, and retained products as the etiology of PPH before initiating treatment with the Bakri tamponade balloon. The device should also be used before the development of coagulopathy because three of the four maternal deaths recorded in the present study were due to this condition. Therefore, management of PPH is best addressed with a systematic approach that rapidly recognizes the underlying cause and initiates treatment before the onset of excessive bleeding, severe morbidity, or maternal death from cardiovascular collapse.

Author contributions

H.L.B. and J.W. contributed to protocol development. S.O., H.M., and J.W. contributed to training. S.O. and H.M. were site principal investigators and contributed to patient recruitment. S.O., H.M., and J.S. collected data. H.L.B. and J.S. analyzed data. H.L.B. was principal investigators and prepared the manuscript.

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Conflict of interest

The authors have no conflicts of interest.

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