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Bakri balloon tamponade in the management of postpartum haemorrhage

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Abstract
Objectives: Postpartum Hemorthage (PPH) is the largest direct cause of maternal death around the world. When the standard conservative management fails, surgical interventions including hysterectomy is required. This is not only requires surgical skills but hysterectomy results in irreversible loss of fertility. Bakri Balloon Tamponade (BBT) is a novel conservative procedure which should be considered before other surgical procedures. This study was done to know the effectiveness of this upcoming procedure as little known about the same till date.
Materials and Methods: The study was conducted in the department of Obstetrics and Gynecology, SMGS, GMC Jammu. BBT was done in 30 patients after failure of initial conservative management of PPH.
Results: Among the cases treated with BBT, uterine atony was seen in 11 (36%) patients, placenta previa/percreta in 7(23%) patients, placenta retention in 7(23%), bleeding from placental implantation site in 3(10%) patients and secondary PPH in 2(6%) cases. PPH could not be controlled and additional surgical procedures were required. Hysterectomy was required in 3 patients and uterine compressive sutures in 1 patient.
Conclusion: BBT is one of the most non-surgical interventions, due to its relative simplicity and ease of use in the management of PPH. Even if BBT failed, it may provide temporary tamponade and time to prepare for other interventions or transportation from local hospital to tertiary centre.

Keywords: bakri balloon tamponade, management, postpartum haemorrhage

Introduction
Post Partum Haemorrhage is the largest direct cause of maternal deaths with about 14 million women around the world suffering from it [1]. The causes are preventable and treatable. PPH is defined as blood loss of >500ml within 24 hrs after birth, loss of>1000 ml in the same time frame is labeled as severe PPH [2]. PPH affects 2%of all women who give birth. It is estimated that 2-4% of vaginal deliveries and 6% of LSCS suffer from PPH. Uterine atony is the most common cause of PPH but genital tract trauma, uterine rupture, RPOCS, abnormal placentation and coagulation disorders also lead to it. Though it is at declining trend, but it still remains the major cause of maternal mortality. In India, maternal deaths due to PPH is as high as 30%. The approach to the management of PPH differs depending on the etiology. Primary management for uterine atony includes well defined step wise approach with uterotonics, uterine massage, removal of retained products and early replacement of blood loss [3]. If conservative management fails, surgical intervention is required. Conventional surgical methods include ligation of uterine arteries, compressive sutures and then hysterectomy as a last resort [4]. These procedures, however require expertise surgical skills. Moreover, hysterectomy leads to irreversible loss of fertility. Therefore, other conservative measures such as Tamponade should be considered before hysterectomy. The WHO, FIGO, ACOG, RCOG recognizes balloon Tamponade as a method that could significantly improve the management of intractable PPH, especially in low resource settings. It was first used by Bakri in 2001 in 6 women and has been consequently used extensively. Currently, used specifically for PPH, it is an inflatable balloon device made up of silicone. It is 54 cm long double lumen shaft and can fill up to 800 ml but it is recommended to not exceed 500ml of saline. The Bakri Balloon has US FDA clearance for specific application to PPH. The device comes with a 60 ml syringe for filling. The balloon when filled adapts to the configuration of the uterine cavity. Bakri balloon is the only balloon designed exclusively for uterine Tamponade but only few studies have addressed to this procedure in the management of PPH.

Materials and Methods

The present study was conducted in the department of Obstetrics and Gynaecology, SMGS Jammu. The duration of the study was 6 months. This study was done to investigate the effectiveness of Bakri balloon as a conservative treatment option for PPH in women. The hospital is a tertiary facility that serves as a reference centre for obstetric pathologies. Our study was approved by the ethics committee. Informed consent was taken. Demographic and epidemiological data were recorded, as were factors associated with PPH and variables related to the appropriate use of Bakri balloon. Women were considered candidates for treatment with a bakri balloon if they had PPH that didn't respond to standard management consisting of uterine massage, volume replacement and uterotonic medical treatment and removal of retained products if any. The protocol we followed called for I/V synto, followed by I/M methergin and Miso P/R, if bleeding was not controlled.

The procedure includes:

- Sims speculum inserted in the vagina.
- Anterior lip of cervix held with sponge holding forceps.
- Balloon was inserted into the uterine cavity with a sponge holding forceps.
- Balloon was inflated with appropriate volume of Normal saline (250-500) ml till bleeding was arrested. During LSCS, it was inserted through the uterine incision and distended with 10-20 cc of NS. First layer of uterine closure was done ensuring not to puncture the balloon and rest inflation done after the uterine incision was closed.
- The drainage port of the balloon was connected to a fluid collection bag to monitor haemorrhage.
- Vaginal packing was done.
- Oxytocin infusion 20 U in 500cc RL was continued in the post operative period for 4-6 hrs.
- The balloon was kept inflated for 24 hrs. with careful monitoring of haemorrhage. The balloon was then deflated gradually when adequate hemostasis was achieved and finally the vaginal packs were removed.
- During the postoperative period, proper antibiotic coverage was provided.

We reported indications for BBT, amount of haemorrhage, and use of additional procedures.

Results

Demographic and epidemiological data were recorded.

- 73% of the patients were less than 35 years of the age with 27 percent being more than 35 years.
- Majority of them were primi (43%) with only 16% being multigravida.
- History of prior curettage was seen in 13 patients while 17 patients had no history of same.
- 53% delivered vaginally while 46% underwent LSCS.

Table 1: Characteristics (n=30)

Age (in years)		Parity		H/O LSCS		H/o Prior Curettage		Gestational age (In weeks)		Mode of Delivery	
<35	22 (73%)	0	13(43%)	Yes	11 (36.6%)	Yes	13(43.33%)	<37	9(30%)	Vaginal	16 (53%)
		1-2	12 (39%)								
≥35	9 (27%)	≥3	5 (16%)	No	19 (63.3%)	no	17(56.66%)	>37	21(70%)	LSCS	14 (46%)

Table 2: Blood loss (in ml) before insertion of Bakri Balloon

Blood loss (in ml)	No. of patients
<1000	7
1000-2500	19
2500-5000	4

Majority of the patients had a blood loss between 1000 - 2500 ml with 6 patients having a blood loss <1000 ml. All these 6 patients had bleeding that did not respond to standard management and therefore were at high risk for massive PPH. Thus, Bakri Balloon was inserted before bleeding exceeded 1000 ml.

Table 3: Indications of Bakri Balloon Tamponade

Indications	Number of patients
Bleeding due to atony	11(36%)
Bleeding from placental implantation site	3(10%)
Bleeding due to placenta previa and percreta	7(23%)
Bleeding due to placental retention	7(23%)
Secondary PPH	2(6%)

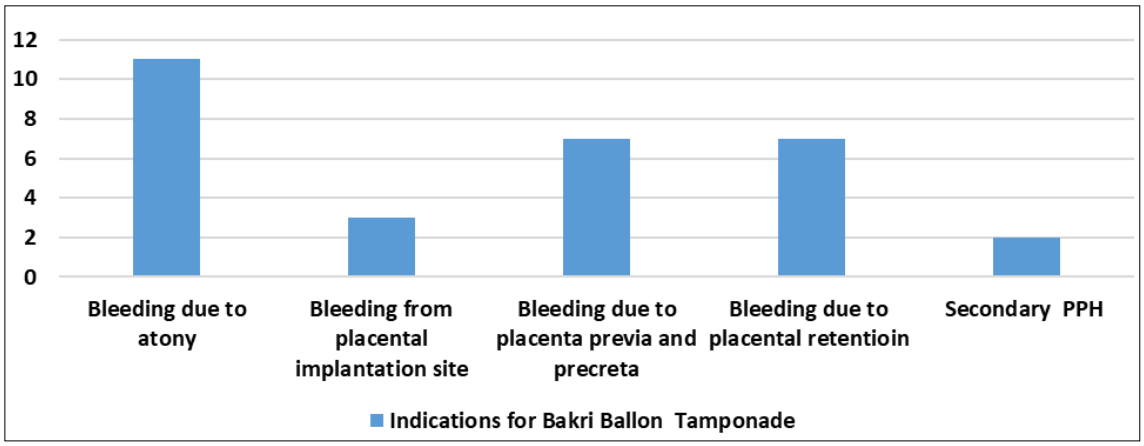

Fig 1: Indications for Bakri Ballon Tamponade

In 26 cases balloon insertion was therapeutic to control intractable hemorrhage. The primary cause of PPH in this group was atony, which accounted for 11 cases. Other causes included retained products (7 cases), placenta previa (7 cases), placental bed bleeding due to clinically suspected morbid placental adherence (3) and secondary PPH (2 cases). In cases where

retained products was the main cause of PPH, exploration of the uterus and removal of retained products of conception was carried out prior to balloon insertion.

The amount of saline instilled to inflate the balloon ranged widely from 80 to 1300 ml (mean 408 ml) depending on the size and capacity of the uterus and according to the perception of resistance on inflation and amount of insufflation required to achieve haemostasis.

Table 4: Additional procedure used with Bakri Balloon Tamponade Failure (n=4)

Causes of PPH	Risk Factors of PPH	Additional Procedure required	Number of cases
Uterine Atony	Multiple Pregnancy	Uterine compressive sutures	1
Placental retention/ accrete	2 Prior curettage	TAH	3
Total			4

Table 5: Distribution of cases according to results of Balloon Tamponade

Result	Number	Percentage
Successful	26	86.7%
Unsuccessful	4	13.3%
Total	30	100%

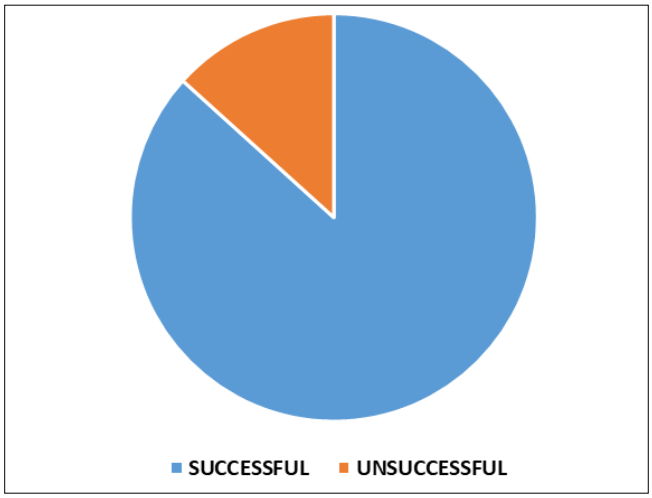

Fig 2: Result of balloon tamponade

As is shown in the pie chart, Bakri Balloon Tamponade was successful in most of the patients in controlling PPH [26(86.7%)], while in 4(13.3%) patients, PPH could not be controlled and they required additional procedures.

Discussion

Bakri *et al*. [5] first proposed a specifically designed I/V Balloon catheter, which he did in a series of 5 women with haemorrhage from low lying placenta. Subsequently, various types of Balloon catheters, including the Foley's catheter [6], Sengstaken – Blakemore [7], Rusch have been adopted for similar scenario. At present the Bakri Balloon remains the only balloon specifically designed for the control of PPH.

The overall success rate of intrauterine Balloon Tamponade in our series was consistent with rates in other previous small studies which have ranged from 60 to 94 percent. A study by Vithalla and colleagues [8] included 15 women and Bakri Balloon was effective in 80 percent cases. Georgiou study [9] 106 cases of PPH which were treated with different types of intrauterine Balloon with an overall success rate of 91.5%. Another series of 20 cases was published recently, in which the Bakri Balloon was used as the treatment of first choice in 20 cases [10]. Of these, 12 were successfully managed with the Balloon alone but 6 warranted the Balloon and B-lynch sutures, while 2 finally had a hysterectomy. The Scottish Confidential Audit of Severe Maternal Morbidity (2009) identified 57 cases where balloon tamponade was used for the management of major PPH; hysterectomy was averted in 50 (88%) women [11].

Surgical options for major PPH include uterine compression sutures, vessel ligation and hysterectomy [12]. These procedures are invasive, involve laparotomy, require specialist expertise, may be associated with significant morbidity and may compromise future fertility. Interventional radiology offers a minimally invasive, fertility-preserving alternative but requires special equipment, trained interventional radiologists and is not readily available in most obstetric units.

Recently, balloon tamponade has been widely used in the management of PPH unresponsive to standard management. It is likely that, in the UK, a number of women with PPH are successfully managed with uterotonics and intrauterine tamponade alone. According to the UKOSS study, 25% of women had intrauterine tamponade before the use of another second-line therapy.

Balloon tamponade in our study was effective in 26 of 30 cases (86.7%) of PPH from different causes such as uterine atony, placenta previa, and placental bed bleeding without further intervention.

Conclusion

In conclusion our series confirms that balloon tamponade is an effective means of controlling severe PPH with success rates of approximately 86.7%. This treatment is also cost effective as it may avoid the need for hysterectomy and also hospital stay and convalescence are likely to be shorter compared to other invasive surgical procedures.

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