

## Original Article

## A Cross Sectional Comparative Study of Two Different Methods: Intrauterine Bakri Balloon Tamponade Versus Intrauterine Gauze Packing in The Management of Postpartum Haemorrhage in A Tertiary Care Hospital in Gwalior, Madhya Pradesh

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### Abstract

**Background:** Obstetric haemorrhage is one of the most serious complication during delivery. It accounts for one quarter of major direct causes of maternal deaths globally; while it rises up to nearly one third in Africa and Asia. Postpartum haemorrhage the most common type of obstetric haemorrhage. If there is persistent atonic PPH despite treatment with first line conventional basic measurement such as uterotonic drugs and other conservative interventions, second line intervention should be used without further delay. Uterine Balloon Tamponade has been added to the treatment modalities of PPH. Uterine gauze packing which is another conservative procedure, although it is readily available and inexpensive measure for the management of PPH, it is questioned and civilized because of the potential risk of post partum infection, uterine trauma and ineffective packing, concealed haemorrhage. **Method:** In this cross sectional comparative study we reviewed 50 cases of PPH who were managed with intrauterine gauze packing and 19 cases who were managed with intrauterine Bakri balloon insertion. A comparative study was done between the two methods in controlling PPH. The study was conducted in the department of obstetrics and gynaecology, G.R. Medical College, Gwalior, M.P. **Results:** The commonest method for using both the methods i.e. intrauterine gauze packing and bakri balloon is atonic PPH. Both method has success rate of 90 % in Bakri balloon method and 94 % in intrauterine gauze packing method. Intrauterine gauze packing method is associated with febrile morbidity, wound sepsis and difficulty in removal. **Conclusion:** Intrauterine bakri balloon insertion and intrauterine gauze packing both methods are safe, quick and effective conservative procedures for controlling postpartum haemorrhage, which avoids the need for more aggressive procedure to save life of mother.

**Keywords:** Postpartum haemorrhage (PPH), bakri balloon, intrauterine gauze packing

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### Introduction

Postpartum haemorrhage (PPH) is commonly defined as a blood loss of 500 ml or more within 24 hours after birth. It affects approximately 2 % of all women who give birth. It is associated not only with nearly one quarter of all maternal deaths globally but is also the leading cause of maternal mortality in most low-income countries[1].

PPH is a significant contributor to severe maternal morbidity and long-term disability as well as to a number of other severe maternal conditions generally associated with more substantial blood loss, including shock and organ dysfunction[1].

The most common cause of early PPH is uterine atony in 80-85 % cases. If uterine atony is unresponsive to fundal massage and the available oxytocic drugs, surgical techniques including uterine tamponade, uterine compression sutures, major vessel ligation and embolisation, and even hysterectomy will have to be considered[2].

The invasive procedures involve laparotomy, requires 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.

Uterine tamponade is a less invasive procedure which is simple, does not require major surgery, can be done within minutes, and will often immediately reduce or stop the bleeding. Thus, it may avoid the need for laparotomy and hysterectomy as well as need of blood transfusion with its inherent risk. Uterine tamponade requires developing intrauterine pressure to stop bleeding. This can be accomplished by insertion of a balloon that distends in the uterine cavity or by insertion of a uterine pack consisting of a gauze roll[3].

At present WHO, RCOG and FIGO recommend the use of uterine balloon tamponade for refractory bleeding or if uterotonics are unavailable, after the exclusion of retained products and genital tract trauma[4,5]. There are several reports in the literature describing success using hydrostatic balloon tamponade either alone or in combination with additional surgical methods. In such studies successful balloon tamponade outcomes have been reported in the range of 80-100 % [6].

The possibilities of trauma, infection and ineffective packing resulting in concealed bleeding together with the increasing effective pharmacological agents to treat uterine atony resulted in a gradual reluctance in the use of intrauterine packing. Despite the declining popularity, there are reports in the literature describing success with uterine packing in cases of intractable hemorrhage[7].

Commercially available catheters like Bakri balloon has a prohibitory high cost. Condom catheter is a cheap and easily available alternative in low resource settings, but it is an improvised device that relies on the availability of the various components at the time of the PPH and the confidence of the health care provider in assembling and using the device. Uterine packing may be a reasonable alternative to further surgical intervention in patients with intractable obstetrical hemorrhage. So, the aim of this study was to compare and evaluate

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the effectiveness of the uterine tamponade by Bakri balloon and intrauterine packing in treatment of non traumatic postpartum hemorrhage.

### Aims and Objectives

To compare the efficacy of two different methods i.e. bakri balloon and intrauterine gauze packing to arrest PPH.

### Method

This cross sectional comparative study was carried out at Department of Obstetrics and Gynaecology, Kamla Raja Hospital, Gwalior (M.P.) during a period of 1 year 2019 to 2020. The present study is to compare the efficacy of two different methods to control postpartum haemorrhage.

We reviewed 50 cases of PPH who were managed with intrauterine gauze packing and 19 cases of PPH who were managed with introduction of intrauterine bakri balloon. All women with traumatic PPH were excluded. Case records were reviewed and parameters were collected and analysed with regards to material sociodemographic characteristics, obstetric history, gestational age, laboratory test parameters, presence of risk factors, mode of delivery, indication of caesarean section and cause of PPH. Time duration for which both method was kept was noted. Main outcome including success rate, need for additional procedure, amount of blood transfusion, febrile morbidity, pain during removal, duration of hospital stay, need for higher antibiotics, were also analysed.

Each of delivery was conducted with active management of third stage of labour. A step wise approach in the management of PPH was followed according to hospital protocol and as soon as atonic PPH was diagnosed. After emptying of bladder, uterine massage started and uterotonic agents, namely injection oxytocin, injection carboprost and tab misoprostol per rectally was used. Maternal resuscitation was started while these procedures are being administered. In cases refractory to uterotonic drugs in group A intrauterine bakri balloon was inserted. We used Bakri postpartum balloon (Cook medical, Spenur IN), which was only device designed to control PPH. We use to get this balloon through Jeev Daya Foundation. The bakri balloon tamponade was inserted through cesarean section incision or transvaginally according to cervical opening. After proper placement of the catheter, balloon was inflated with around 250 ml upto 500 ml of sterile normal saline. It comes with a 50 cc syringe to inflate quickly. While introducing balloon tamponade via cervix we use to catch upper and low lip of cervix with two sponge holders and with help of uterine packing forcep or a long artery we used inserted the balloon tamponade. In case of

vaginal delivery, after inflation of balloon upto required amount vaginal packing was placed used a tape gauze measuring 20x10 cm prevent expulsion of Bakri balloon. In cases of cesarean section Bakri balloon was partially inflated with 50-100 ml of sterile normal saline. Uterine incision was closed in double layer using No. 1 vicryl carefully to avoid puncturing the balloon. Then vaginal packing done same as mention earlier. Before packing balloon was inflated with sterile normal saline 250-500 cc as required. Then we kept on checking amount of blood draining through catheter upto 1 hr every 15 min and then ½ hrly till 6 hours if < 100 ml/hr every 4 hr thereafter. The total amount of tape gauge used for vaginal packing and total volume of normal saline used to inflate the balloon was recorded.

All patients were given injection tramadol for analgesia for 48 hours to manage post procedure pain. All patients received Inj. Oxytocin 20 unit in following 2 days. The decision to remove the catheter was made following day or in few cases according got blood loss. Criteria used for catheter removal.

1. Drainage amount < 50 ml/hr, 2. Serosanguineous drainage color. After removing vaginal packing, the balloon was gradually deflated around 50 cc in every 15 min till 100 % deflated (We follow this protocol in our institute).

The number of tape gauge retrieved and volume of normal saline withdrawn were cross checked pain while removing were assessed by VAS (Visual Analogue Scale). Patients were examined and were under observation for 30 min after catheter removal for any sign of active bleeding. All patients received antibiotics. All patients and Foley's catheter inserted into bladder for absolute bed rest.

We acknowledge the limitation of this study.

Firstly our study design was a non-randomized retrospective study from a single center. The diagnosis of PPH be very subjective as accurate measurement as blood shed is impossible. We have only limited number of cases of Bakri balloon as it is not freely available in our institute. It is mainly available in routine time not in emergency hours.

**Study Design:** Cross Sectional Comparative Study.

### Statistical Analysis

Statistical analysis was performed with SAS version 9.3 data were expressed for percentage for categorical variable comparisons between two groups were made by Chi – square test or Fisher's exact test when appropriate. All statistical tests were 2 sided which statistical significance defined as  $p < 0.05$ .

### Results

**Table 1: Distribution of Patients According to Age**

Age	Group A N=19	Group A (%)	Group B N=50	Group B (%)	Chi square, p value
20-25	9	47.36	19	38	2.825, 0.243
26-30	6	31.57	26	52	
31-35	4	21.05	5	10	

Table No. 1: The above table shows that maximum number of patients in age group A is between 20-25 years and maximum number of patients in group B is between 26-30 years. No statistical difference has been seen between them.

**Table 2: Distribution of patients according to parity**

Parity	Group A N=19	Group A (%)	Group BN=50	Group B (%)	Chi square, p value
P1	7	36.84	16	32	0.1453, 0.703
≥P2	12	63.16	34	68	

Table No. 2: The above table show distribution of patients in both groups according to their parity. In both groups maximum number of patients were having parity 2 or more than 2.

**Table 3: Distribution of Patients According to Mode of Delivery**

Parity	Group A N=19	Group A (%)	Group B N=50	Group B (%)	Chi Square, P Value
Caesarean section	11	57.89	42	84	5.2678, 0.022*
Vaginal delivery	8	42.11	8	16	

Table No. 3: In above mentioned table no. 3 shows that in group B maximum number of patients which was 84 % delivery by caesarean section in whom intrauterine packing has been done. The difference is statistically significant. Both procedures can be used irrespective of mode of delivery. Uterine packing more effective following caesarean section.

**Table 4: Distribution of Patients According to Indication**

Indication	Group A N=19	Group A (%)	Group B N=50	Group B (%)	Chi square (Fisher exact), p value
Atonic PPH	13	68.42	33	66	17.450, 0.001*
Secondary PPH	2	10.52	0	0	
Intractable PPH	1	5.3	0	0	
Adherent placenta	1	5.3	0	0	
Prophylactic	2	5.3	1	2	
DIC	0	5.3	3	6	
Bleeding from placental bed	0	0	13	26	

Table No. 4: This table is showing distribution of patients according to indication of using either bakri balloon or intrauterine packing according for the management of PPH and according to this atonic PPH is commonest cause for these management. 2 patients had secondary PPH, 1 patients had intractable PPH and in two patient prophylactic bakri balloon was used. Only in 1 patient prophylactic intrauterine packing was used. There were 3 patients with DIC and 13 patients with placental site bleeding where intrauterine packing were used. The statistically significance was seen.

**Table 5: Table Showing Time of Insertion of Bakri Balloon and Intrauterine Packing**

Time	Group A N=19	Group A (%)	Group B N=50	Group B (%)	Fishers exact P Value
Routine 8:00 am to 3:00 pm	18	94.73	15	30	23.124,
Emergency 3:00 pm to 8:00 am	1	5.2	35	70	<0.001

Table No. 5: This table shows that at what time either routine or emergency hours bakri balloon and intrauterine packing has been used. As bakri balloon has been supplied to us by Jeev Daya foundation and they were limited and available only for routine hours. So in group A 94.73 % patient had undergone bakri balloon method during routine hours i.e. between 8:00 am to 3:00 pm. In group B 70 % cases were of emergency time. The value is statistically significant.

We kept bakri balloon for maximum upto 72 hours only in 5 cases. Intrauterine packing was kept in situ for upto 48 hours in 14 cases (28 %) and in maximum patients pack was removed in 24 hours (68 %).

**Table 6. Outcome of Procedure**

Outcome	Group A N=19	Group A (%)	Group B N=50	Group B (%)	Fishers exact P Value
Success	17	90	47	94	0.420,
Failure	2	10	3	6	0.611

Table No. 6: This table shows that in both methods has good success rate. In bakri balloon success in 90 % and failure is 10 %. In group B which is intrauterine packing success is 94 % and failure is 6 %. No significant difference has been seen in outcome of procedure.

**Table 7: Maternal Morbidity and Mortality**

Complication	Group A N=19	Group A (%)	Group B N=50	Group B (%)	Fishers exact P Value
Febrile morbidity	0	0	3	6	1.192, 0.556
Wound sepsis	0	0	3	6	1.192, 0.556
Difficulty in removal	0	0	4	8	1.614, 0.204
Maternal mortality	1	5.3	0	0	2.670, 0.102

Table No. 7: This table shows maternal morbidity and mortality in both groups. In group A there were no febrile morbidity, wound sepsis or difficulty in removal was seen. One mortality was there in group A. Patient was morbidly obese with DM with preeclampsia has undergone elective LSCS followed by PPH for which bakri balloon was inserted postoperatively. But she had intractable PPH. Cesarean hysterectomy was performed but she went into sudden cardiac arrest and not survived. In group B, 3 patients had febrile morbidity, 3 were having wound sepsis. In 4 cases there were difficulty in removal was seen. We have remove in steps like cutting some part and leaving behind the remaining and after few days again tried to removed them and got success. No mortality was there in group B.

#### Discussion

Postpartum haemorrhage is an obstetric emergency. It is associated not only with nearly one quarter of all maternal deaths globally but is also the leading cause of maternal mortality in most low income countries[1]. In this retrospective study, we evaluated 69 women with PPH and who had undergone either Bakri balloon tamponade or

intrauterine packing for management of PPH. In both the groups there was no difference in the rate of successful haemostasis. It is also reported in the study by Jingwei et al[8]. For maternal complication compared with women with bakri balloon and women with intrauterine packing febrile morbidity, wound sepsis, difficulty in removal was found in group B only. It is comparable with study done by Jing Wei et al and Javed et al[8,9]. In our study one patient died due to intractable PPH followed by haemorrhagic shock. Patient was morbidly obese (125 kg, elderly primigravida with GDM with preeclampsia she conceived after IVF. She was taken for elective LSCS at 37 weeks. She had atonic PPH in postoperative period. Immediately bakri balloon was inserted. But within 15 min blood loss was > 1000 ml in balloon catheter. So immediately cesarean hysterectomy was performed. But patient couldn't be survived. A recent study found that severe blood loss before balloon tamponade increases the risk of procedure failure or treatment failure[10].

Intrauterine gauze packing is an older method used to control bleeding. Previous studies have shown that both Bakri balloon and

intrauterine gauze packing are effective in prevention and treatment of postpartum haemorrhage in patients with placenta previa[11,12]. In present study most common indication of both the procedures was PPH due to atonic uterus. In study by HSU et al, uterine atony unresponsive to oxytocics was the common indication for uterine packing[13].

Three cases of failure were observed in group B. First was the case of atonic PPH, following caesarean section, done for obstructed labour not managed by uterotonic drugs, so intrauterine packing was done. But bleeding was not controlled, so subtotal hysterectomy was performed to save the life. In other 2 cases of previous section with placenta previa placenta found adhered to the lower uterine segment. On manual removal of placenta, placenta bed started bleeding profusely. Firstly intrauterine packing was done, but bleeding continued. So total hysterectomy was performed to save the life of mother. In both the cases post recovery period was uneventful and both were discharged and healthy.

Interval for removal of intrauterine packing and balloon tamponade has to be individualized according to clinical findings. Before removing either of them oxytocin infusion was started 20 min prior to removal and tab. Misoprostol 800 µg was kept per rectally in all the cases.

In present study time of insertion of bakri balloon and intrauterine packing was compared and found to statistically significance. This is because bakri balloon is not readily available all the time. Intrauterine gauze packing is easily available throughout emergency hours also. In our institute we get bakri balloon from Jeeva Daya foundation that too in limited number.

Both the procedure has good success rate in controlling postpartum haemorrhage.

### Conclusions

Intrauterine gauze packing is more traditional method of controlling postpartum haemorrhage but associated with more morbidity as compared to bakri balloon tamponade. Intrauterine packing is simple, last and cost effective procedure and a reasonable alternative to further surgical intervention in the treatment of postpartum haemorrhage, especially when other options are unavailable. If bakri balloon will be made less costly, easily available or may be in future supplied by government it will become the first choice for managing the postpartum haemorrhage.

**Conflict of Interest: Nil**

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