## ORIGINAL ARTICLE

# Effectiveness of Intrauterine Bakri Balloon® Tamponade for Placenta Previa and Placenta Accreta Spectrum

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## ABSTRACT

**Objective:** To investigate the effectiveness and success rate of Bakri balloon tamponade (BBT) for postpartum haemorrhage (PPH) in patients with placenta previa and placenta accreta spectrum (PAS).

**Study Design:** Descriptive study.

**Place and Duration of Study:** Department of Obstetrics and Gynaecology, Bursa Yüksek Ihtisas Education and Research Hospital, Bursa, Turkey, from June 2016 to June 2019.

**Methodology:** Patients treated with BBT for severe PPH and uncontrollable bleeding due to treatment failure with uterotonic agents were retrospectively analysed. Exclusion criteria were age <18 years and >46 years, having multiple pregnancies, less amount of bleeding than indicated in the definition of PPH and requiring no BBT and those with hemodynamic instability before BBT requiring emergency postpartum hysterectomy, and having missing obstetric and laboratory data. The main outcome was the rate of surgical exploration and peripartum hysterectomy following the use of BBT as an adjunct treatment for refractory PPH. Secondary outcome was the need for blood transfusion. The BBT was considered to fail, if the bleeding from drainage catheter was continued and more than 100 mL during failure was 10 minutes. In case of BBT failure, C-section hysterectomy was performed.

**Results:** Of the 128 patients, 14 (10.9%) had vaginal birth and 109 (85.2%) had Cesarean section delivery. Of patients with cesarean section delivery, 84 (65.6%) had multiple repeat cesarean deliveries and 22 (17.2%) were previous cesarean cases. Ninety-one patients (71.1%) had placental site abnormality. Twenty patients (15.6%) underwent hypogastric and uterine artery ligation. Eleven patients (8.7%) with persistent uterine bleeding and hemodynamic instability underwent hysterectomy. Success rate of BBT was found to be 91.3% in PPH. No mortality was observed.

**Conclusion:** BBT is an effective tool for management of postpartum uterine atony and prevention of persistent PPH in patients with placenta previa and placenta accreta spectrum due to increased cesarean section and uterine surgeries in recent years.

**Key Words:** Placenta previa, Placenta accreta spectrum, Postpartum haemorrhage, Balloon tamponade, Bakri balloon.

## INTRODUCTION

Postpartum hemorrhage (PPH) is classically defined as the loss of more than 500 mL and 1,000 mL blood within the first 24 hours of vaginal delivery or cesarean section (C-section) delivery, respectively. Its incidence has increased up to 6% in live births in low- and middle-income countries.[1] However, in 2017, the American College of Obstetricians and Gynecologists (ACOG) redefined PPH as cumulative blood loss greater than or equal to 1,000 mL or blood loss accompanied by signs and symptoms of hypovolemia such as tachycardia, oliguria, or chest pain within 24 hours after the birth process regardless of route of delivery.[2]

It has been well documented that PPH is the leading cause of maternal mortality and morbidity worldwide and its incidence has been estimated as 25% with two– or three-fold increase in recent years, despite increased diagnostic and therapeutic efforts in obstetric-related mortality in both developed and developing countries.[3] Uterine atony is the most common cause of PPH characterised by the lost or insufficient uterine muscle contraction required to maintain hemostasis and accounts for 70% of all haemorrhage in the United States, followed by placenta previa and placenta accreta spectrum (PAS).[4,5]

The first-line treatment of PPH may include the use of uterotonic agents such as oxytocin, carbetocin, and misoprostol+oxytocin combination with bimanual uterine compression massage.[6] When these uterotonic agents are insufficient to manage PPH, surgical procedures such as uterine artery embolisation (UAE), internal iliac artery ligation (IIAL), and emergency postpartum hysterectomy, which increases maternal morbidity and mortality, are indicated. However, emergency postpartum hysterectomy can be devastating and is significantly associ-

ated with post-traumatic stress disorder. In such cases, the second-line conservative treatment is uterine packing with gauze and placement of compression sutures and intrauterine balloon.[7]

An intrauterine Bakri® balloon (Cook Medical Inc., Bloomington, IN, USA), which is a medical device in achieving hemostasis, has been widely used for temporary control and reduction of PPH.[8] A Bakri balloon is also recommended by the ACOG and World Health Organisation (WHO) as a treatment line for PPH unresponsive to uterotonics.[9,10] In addition, in 2009, the Royal College of Obstetricians and Gynaecologists recommended using the Bakri balloon in PPH secondary to uterine atony.[11] The Bakri balloon tamponade (BBT) has been widely used to reduce haemorrhage caused by placental site abnormality, placenta previa, low-lying placenta, and focally invasive or adherent placenta.[12] The advantages of BBT are being easy applicable by both vaginal and abdominal routes, more economical than other radiologic and surgical interventional techniques, fertility preserving features, and to have less morbidity and mortality as compared to hysterectomy.[12] Its effectiveness and the success rate must be determined.

The objective of the present study was to investigate the effectiveness, feasibility, and success rate of BBT in PPH secondary to uterine atony, placenta previa, and PAS and to evaluate changes in the hematological parameters in the tertiary setting.

## METHODOLOGY

A total of 128 patients with BBT for severe PPH and uncontrollable bleeding due to treatment failure with uterotonic agents, treated from June 2016 to June 2019 in the outpatient clinic of Bursa Yüksek Ihtisas Education and Research Hospital, were retrospectively analysed. Exclusion criteria were age <18 years and >46 years, having multiple pregnancies, less amount of bleeding than indicated in the definition of PPH and requiring no BBT and those with hemodynamic instability before BBT requiring emergency postpartum hysterectomy, and having missing obstetric and laboratory data. A written informed consent was obtained from each patient. The study protocol was approved by the local Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

BBT was applied to the patients with active vaginal bleeding, who were unresponsive to uterotonic agents including oxytocin, carboprosttromethamine, and ergometrine in combination with bimanual uterine compression massage. Patients were divided into three subgroups as: invasion anomaly and previa negative group (Group 1, n=37), placenta previa with no invasion (Group 2, n=70), and placenta previa with invasion (Group 3, PAS, n=21). Demographic and clinical characteristics including maternal age, gestational age, gravida, parity, abortion, previous C-section, previous PPH, comorbidities were recorded. The route of delivery (vaginal versus C-section), indications for BBT, duration of BBT *in situ*, inflation balloon volume, and the use of vaginal tamponade were also noted. Pre- and

post-procedural laboratory testing was performed including complete blood count, hematocrit, platelet count, fibrinogen, international normalised ratio (INR), prothrombin time (PT), and activated partial thromboplastin time (aPTT). The requirement for blood transfusion and the amount of blood products (red blood cell suspension, fresh frozen plasma, platelet suspension and apheresis) were examined. In case of BBT failure, the need for a second intervention such as B-Lynch suture, UAE, IIAL, and emergency postpartum hysterectomy and re-laparotomy was evaluated.

The intrauterine Bakri® balloon (Pergo MedikalveİlaçSanayi A.Ş., Izmir, Turkey) is a disposable, multiple lumen catheter in which the balloon is connected to 24 Fr, 54 cm long silicone catheter attached to an inflatable balloon system designed to provide tamponade for controlling haemorrhage from the uterus and vagina. The silicone property of the catheter provides patient comfort. Its pear-shaped design is perfectly fit for uterine anatomy and shape. It is durable and does not require any surgical operation for the removal.[13]

The main outcome was the rate of surgical exploration and peripartum hysterectomy following the use of BBT as an adjunct treatment for refractory PPH. Secondary outcome was the need for blood transfusion. The BBT was considered to fail, if the bleeding from drainage catheter was continued and more than 100 mL during failure was 10 minutes. In case of BBT failure, C-section hysterectomy was performed.

Statistical analysis was performed using the SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (IQR), or number and frequency. The Kolmogorov-Smirnov test was used to analyse normal distribution of data. One-way analysis of variance (ANOVA) or Kruskal-Wallis test was performed for three classes of placental abnormality. The significance of changes caused by surgery in the laboratory parameters was analysed using the dependent samples t-test or Wilcoxon test for normally distributed data. A p-value of <0.05 was considered statistically significant.

## RESULTS

A total of 128 patients were treated with BBT and a total of 38,000 births were facilitated (0.034%). Of the patients, the mean age was 30.80 ±5.71 (19 to 46) years, the mean gravida was 3.13 ±1.41 (1 to 7) and the mean parity was 1.92 ±1.21 (0 to 6). The mean gestational age was 35.68 ±4.42 (12 to 42) weeks and the mean birth weight was 2786.89 ±833.99 (495 to 5,230) g. A total of 98 patients (76.6%) underwent BBT combined with vaginal tamponade. The mean inflation balloon volume was 254.43 ±88.72 cc saline and the mean duration of BBT *in situ* was 21.88 ±6.6 hours. The BBT was performed during C-section delivery in 112 patients and during vaginal birth in 14 patients. One patient underwent repeated BBT, while another patient received BBT during uterine curettage due to termination of scar pregnancy at week 14. The ratio of BBT to total birth number was 0.336% corresponding a success rate of 91.3%

based on the ratio of patients without hysterectomy to the total number of study population (116/127). Of the patients with C-section delivery, 84 had multiple repeat C-section deliveries and 22 were previous

C-section cases. According to the placental location, 28.9% of the patients (n=37) were in the invasion anomaly and previa negative group (Group 1), 54.7% of the patients (n=70) in the placenta previa with no invasion group (Group 2), and 16.4% of the patients (n=21) in the PAS group (Group 3). Twenty patients (15.6%) underwent hypogastric artery and uterine artery ligation. Eleven patients (8.7%) with persistent uterine bleeding and hemodynamic instability despite BBT underwent hysterectomy. Five patients (3.9%) received fertility and uterine-sparing surgery, while seven patients (5.5%) underwent re-laparotomy. During and after the procedure, the mean amount of red blood cell suspension was 1.88 U and the mean amount of fresh frozen plasma was 1.55 U. No mortality was observed.

Based on the indications, BBT was performed in 43 (33.65%) patients for uterine atony, in 80 (62.5%) patients for lower segment haemorrhage, and in 18 (3.85%) patients for placental abruption. Laboratory test results before and after the procedure are shown in Table I. Accordingly, the mean hematocrit and fibrinogen levels were significantly higher before the procedure (p<0.001). The median hemoglobin (p<0.001), platelet (p<0.001), red blood cell (Rbc) (p<0.001), lymphocyte (Lym) count (p<0.001), mean platelet volume (MPV, p=0.004), platelet distribution width (PDW) (p=0.039) and plateletcrit (Pct, p<0.001) values were significantly higher before the procedure whereas PT (p=0.018), INR (p=0.02), white blood cell (Wbc), Neutrophil (Neu), neutrophil to lymphocyte ratio (NLR) values were lower before the procedure (both p<0.001) and the p-value for platelet to lymphocyte ratio (PLR) (p=0.020) was also lower before the procedure. However, the mean PTT values were significantly lower before the procedure (p=0.020). Pre- and post-procedural biochemical measurements of all study groups are shown in Table II. The changes in laboratory parameters were not significantly different between groups.

## DISCUSSION

Postpartum haemorrhage, which is tightly related with maternal mortality and morbidity, is an obstetric emergency. Uterine atony, placental migration and invasion anomalies are the leading causes of PPH all over the world.[2,10] Placenta previa is an obstetric complication characterised by the anomalous placenta embedded in the lower uterine segment, partially or completely covering the inner cervical os and may cause severe bleeding in the last trimester, leading to preterm birth and C-section delivery.[14] In addition, PAS is a complex disorder characterised by abnormal trophoblast invasion into the myometrium of the uterine wall, resulting from placental implantation at the defective decidualisation area typically caused by preexisting damage to the endometrial-myometrial interface. It is a general term used to describe all degrees of villous invasion including accreta, increta, and percreta.[15] Currently, the main goal of peri- and post-partum hysterectomy is to prevent PAS-related mortality and to maintain control.

Bakri balloon is a therapeutic tool which was firstly introduced for the management of PPH due to placenta previa in 2001. It is known to be an effective and easily applicable treatment option. Bakri balloon was designed to lead a decrement in persistent capillary and venous bleeding from uterus layers by enforcing pressure against the uterine wall.[8] In the present study, we examined the effectiveness, feasibility, and success rate of BBT in PPH secondary to uterine atony, placenta previa, and PAS and evaluated changes in the laboratory parameters in the tertiary setting.

This study results showed that BBT was effective for avoiding hysterectomy and maintaining fertility with an overall success rate of 91.3% in severe PPH.

In a systematic review and meta-analysis, Suarez et al. included 91 studies consisting of 4,279 women with PPH and examined the efficacy and safety of uterine balloon tamponade.[16] The overall success rate was found to be 85.9% with the highest success rate for uterine atony (87.1%) and placenta previa (86.8%) and the lowest success rate for PAS (66.7%) and retained products of conception (76.8%). In this study, BBT was performed in 33.6% patients for PPH secondary to uterine atony, in 62.5% patients for lower segment haemorrhage, and in 14.1% patients for placental abruption. A total of 57% patients with multiple repeat C-section deliveries underwent elective C-section. In addition, only 10.9% patients had vaginal delivery, while 85.2% had C-section delivery in our study. Among them, 17.2% were previous C-section cases, while 65.6% had multiple (≥3) repeat C-section deliveries. In a review including 28 articles, Said Ali et al. found that the primary indication for the use of BBT was PPH and uterine atony was the underlying cause of PPH in 21 studies (75%).[17]

In addition, BBT was performed after vaginal delivery in most of the studies. Hysterectomy was necessary in 2% of the patients requiring BBT (95% CI: 0-8%). Similarly, Alkis et al. evaluated the success rate of BBT for the management of PPH as a fertility-sparing intervention and found that BBT was effective for avoiding hysterectomy and maintaining fertility in 91.4% of patients with severe PPH intractable to conservative medical treatment.[18] The procedure failed in only four patients, and the overall success rate was 91.4%, consistent with our study findings. In another study, Guo et al. examined the effect of BBT and vaginal tamponade combined with abdominal compression for the management of PPH and found a clinical efficacy of 93.26%.[19] In this study, BBT was applied with vaginal tamponade in 98 (76.6%) patients and this approach yielded successful outcomes applying an adequate pressure on the uterine cavity and the main vessels by the BBT and preventing balloon prolapse. Several studies have reported a mean inflation volume of balloon of 367 mL ranging from 30 to 500 mL. In another study, Kaya et al. reported that the inflation volume of the Bakri balloon was adjusted according to the type of PPH, and that a volume exceeding 500 mL might be necessary for the successful treatment of uterine atony.[20]

**Table I: Laboratory test results before and after the procedure.**

| Variables | Pre-procedural | Post-procedural | p |
|---|---|---|---|
| Hb (g/dL) | 11.10 [9.9 - 11.8] | 9.55 [8.6 - 10.6] | <0.001[b] |
| Hct (%) | 32.098 ±4.157 | 28.705 ±4.676 | <0.001[a] |
| Plt (10³µL) | 220.65 ±65.95 | 202.75 ±70.28 | <0.001[a] |
| Fibrinogen (g/L) | 387.48 ±108.951 | 344.02 ±123.239 | <0.001[a] |
| aPTT (sec) | 28.597 ±4.173 | 29.31 ±3.665 | 0.020[a] |
| PT (sec) | 13.3 [12.4 - 14.2] | 13.7 [12.4 - 14.3] | 0.018[b] |
| INR | 1.01 [0.97 - 1.05] | 1.02 [0.98 - 1.08] | 0.002[b] |
| Rbc (10³µL) | 3.91 [3.52 - 4.19] | 3.5 [3.03 - 3.84] | <0.001[b] |
| Wbc (10³µL) | 12.97 [10.60 - 16.20] | 15.12 [12.45 - 18.65] | <0.001[b] |
| Neu (10³µL) | 10.69 [8.61 - 13.14] | 13.04 [10.42 - 16.02] | <0.001[b] |
| Lym (10³µL) | 1.68 [1.30 - 2.04] | 1.33 [1.01 - 1.70] | <0.001[b] |
| NLR | 5.89 [4.26 - 9.26] | 9.47 [7.78 - 13.75] | <0.001[b] |
| PLR | 130.00 [97.31 - 170.86] | 145.06 [100.91 - 212.61] | 0.020[b] |
| Mpv (fl) | 9.3 [8.45 - 10.40] | 9.1 [8.2 - 10.0] | 0.004[b] |
| Pdw (kU/L) | 16.6 [16.2 - 17.0] | 16.6 [16.1 - 17.3] | 0.039[b] |
| Pct (µg/L) | 0.2 [0.16 - 0.23] | 0.18 [0.15 - 0.21] | <0.001[b] |

[a]Paired samples t-test, [b]Wilcoxon test. Hb, hemoglobin; Hct, hematocrit; Plt, platelet; aPTT, activated partial thromboplastin time; PT, prothrombin time; INR, international normalized ratio; Rbc: red blood cell; Wbc, white blood cell; Neu, neutrophil; Lym, lymphocyte; NLR, Neutrophil-lymphocyteratio; PLR, Platelet-lymphocyte ratio; MPV, mean platelet volume; Pdw, platelet distribution width; Pct, Platelecrit.

**Table II: Pre- and post-procedural biological measurements according to anomaly groups.**

| Variables | Group 1 (Invasive anomaly (-) (n=37) | Group 2 (Pl. previatotalis+Pl. marginalis (n=70) | Group 3 PAS (Pl.percreta+Pl.accreta) (n=21) | p |
|---|---|---|---|---|
| Hbchange (g/dL) | 1.178 ±1.036 | 1.117 ±1.389 | 1.157 ±1.099 | 0.971[a] |
| Hct change (%) | 3.03 ±3.336 | 3.375 ±4.347 | 4.152 ±4.098 | 0.599[a] |
| RBC change (10³µL) | 0.373 ±0.374 | 0.34 ±0.558 | 0.33 ±0.495 | 0.935[a] |
| Platelet change (10³µL) | 7 [-1.50 -23.50] | 21 [3-36] | 23 [0.75-56.5] | 0.117[b] |
| WBC change (10³µL) | -0.574 ±6.997 | -2.493 ±5.247 | -2.980 ±6.487 | 0.222[a] |
| Neutrophil change (10³µL) | -1.016 ±6.729 | -2.739 ±5.2 | -3.816 ±6.124 | 0.187[a] |
| Lymphocyte change (10³µL) | 0.275 [-0.23 -0.66] | 0.3 [-0.13 -0.86] | 0.31 [0.12-0.68] | 0.880[b] |
| NLR change | -3.06 ±6.607 | -3.43 ±5.558 | -5.132 ±4.768 | 0.413[a] |
| PLR change | -33.840 ±73.536 | -10.788 ±76.675 | -16.513 ±1.666 | 0.343[a] |
| MPV change (fL) | 0.2 [-0.2 -0.6] | 0.1 [-0.2 -0.7] | 0.1 [-0.2 -0.95] | 0.940[b] |
| PDW change (kU/L) | -0.1 [-0.5 -0.1] | 0 [-0.3 -0.2] | -0.1 [-0.43 -0.2] | 0.556[b] |
| PCTchange (%) | 0.01 [-0.01 - 0.03] | 0.01 [ 0 -0.06] | 0 [-0.01 -0.02] | 0.119[b] |
| Fibrinojen change (g/L) | 54.5 [18.75 -93.75] | 27.5 [0 -53.75] | 43.5 [15.5-80.0] | 0.100[b] |
| aPTT change (sn) | 0 [-1.38 -2.28] | -0.2 [-2.13 -0.58] | -2.5 [-3.95 -0] | 0.480[b] |
| PT change (sn) | 0.05 [-0.7 -0.56] | -0.1 [-0.6 -0.3] | -0.2 [-1.4 -0] | 0.456[b] |
| INR change | 0.01 [-0.05 -0.02] | -0.02 [-0.06 -0.01] | -0.01 [-0.08 -.01] | 0.599[b] |

[a]ANOVA, [b]Kruskal-Wallis test. Hb, hemoglobin; Hct, hematocrit; RBC, red blood cells; WBC, white blood cells; NLR, neutrophil/lymphocyte ratio; PLR, platelet/lymphocyte ratio; MPV, mean platelet volume; PDW, platelet distribution width; PCT, plateletcrit; PTT, activated partial thromboplastin time, PT, prothrombin time; INR, international normalized ratio.

In our study, the mean volume of the infused saline for Bakri balloon was 253.83 mL and a higher volume was needed to prevent balloon failure or balloon prolapse or migration and one patient received BBT and vaginal tamponade simultaneously. These findings indicate that the inflation volume mostly depends on the severity of uterine atony or placenta previa, as well as the size of the uterus and the presence or absence of multiple pregnancies.

Furthermore, in a previous study, the mean duration of Bakri® balloon in situ was 12.7 hours ranging from one to 28 hours.[20] In this study, the mean duration of the balloon left in situ was 21.88 ±6.6 hours and its duration in the uterine cavity was longer in cases in whom the placental parts were present. Furthermore, in the current study, the mean preoperative hematocrit ratio slightly decreased from 32.10 ±4.16% to 28.69 ±4.70% in the postoperative period.

In our study, the mean amount of red blood cell suspension was1.88 ±1.66U and the mean amount of platelet was 1.55 ±1.515 U in patients undergoing BBT before hemodynamic instability occurred. In another study Pala *et al*. Compared the results of BBT and C-section hysterectomy in the management of placenta accreta and increta and found that the mean amount of packed red blood cell suspension was 2.7 U and 5.7 U in the BBT group and hysterectomy group, respectively, indicating a significantly lower amount in the BBT group.[21] Similarly, in this study, BBT significantly reduced the massive blood transfusion.

Although BBT is effective in PPH, there are other invasive methods to stop and manage PPH. In a previous study, Madhubala *et al*. evaluated the utility and outcome of emergency bilateral IIAL in 31 patients with severe PPH and found that it was as a life-saving procedure and should be done before deciding hysterectomy in intractable PPH, saving fertility and menstrual function.[22] Similarly, Mathur *et al*. assessed the effect of BBT in conservative management of PPH and reported that they applied B-lynch suturation in 12.5% of the patients, uterine artery ligation in 2.5% and arterial embolisation in 5% of the study group.[23] Lo *et al*. assessed the effect of BBT on the rate of postpartum hysterectomy secondary to uterine atony and BBT was applied to 43 patients.[24] Hysterectomy was needed for PPH in 21 patients, of which 14 were before and seven were after the insertion of the BBT. Similarly, 20 patients underwent hypogastric artery and uterine artery ligation in our study, while 11 patients with persistent uterine bleeding and hemodynamic instability despite BBT underwent hysterectomy. Furthermore, 21 patients (16.4%) had PAS (placenta accreta n=13 and placenta percreta n=8), and seven patients (5.5%) required re-laparotomy. In 8.7% of the patients, PPH was managed with peripartum hysterectomy.

Nonetheless, there are some limitations to this study. The retrospective design is the main limitation. In addition, the sample size is small, as PAS is a potentially life-threatening complication with severe morbidity and mortality and emergency postpartum hysterectomy is performed without delay in the vast majority of cases.

## CONCLUSION

BBT is an effective tool with high overall success rates for the management of PPH secondary to placenta previa and PAS, which has potentially catastrophic maternal outcomes, in patients unresponsive to first-line treatment with uterotonic agents. High overall success rate of BBT is also associated with a marked reduction in the rate of PPH-related invasive procedures such as artery ligation, uterine compression sutures, hysterectomy, and UAE. In addition, it is a life-saving, time effective and less invasive procedure with minimal complications.

**ETHICAL APPROVAL:**
The study was approved by the Institutional Ethics Committee (No.2011-KAEK-25 2019/08-13).

**PATIENTS' CONSENT:**
A written informed consent was obtained from each patient.

**CONFLICT OF INTEREST:**
The authors declared no conflict of interest.

**AUTHORS' CONTRIBUTION:**
GO: Conception, design, analysis and interpretation of data for the work and drafting.
GAA: Conception, design, analysis drafting and final approval.

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