

# Effect of Bakri balloon tamponade on hemorrhage during and after cesarean section in patients with placenta previa

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**Background:** To evaluate the success rate of Bakri balloon tamponade (BBT) and the risk factors for BBT failure in the treatment of intraoperative and postpartum hemorrhage (PPH) in patients with placenta previa. **Methods:** Patients with placenta previa who underwent cesarean section and had BBT insertion for PPH were consecutively included from 2016 to 2018. Patients with placenta previa who successfully underwent routine insertion of a BBT during cesarean section and had their bleeding controlled were classified as the balloon success group. Patients who successfully underwent BBT during cesarean section but continued to have uncontrolled bleeding were classified as the balloon failure group. Multiple logistic regression was performed to examine the risk factors for BBT failure. **Results:** During the study, 270 women with placenta previa were identified. The success rate of BBT for managing PPH was 69.3%. The balloon failure group (n = 83) comprised those who had undergone BBT insertion, followed by B-lynch suture (n = 10), uterine artery ascending branch ligation (n = 32), pelvic arterial embolization (n = 21), or cesarean hysterectomy (n = 20). The intraoperative blood loss was 3098 mL (700–18,000 mL) in the balloon failure group and 1120 mL (500–4000 mL) in the balloon success group, respectively ( $p < 0.01$ ). Multiple logistic regression analysis showed that the number of weeks at pregnancy termination (odds ratio [OR] = 1.188, 95% confidence interval [CI]: 1.023–1.379), the presence of placenta accreta (OR = 2.472, 95% CI: 1.361–4.493), and placenta previa classification (OR = 4.798, 95% CI: 1.328–17.337) were positively associated with BBT failure, while preoperative albumin levels (OR = 0.788, 95% CI: 0.714–0.869) were negatively related to BBT failure. **Conclusion:** This study suggests that BBT is effective as the second-line treatment for PPH associated with placenta previa in the Chinese population. Placenta accreta and major previa are risk factors for BBT failure. However, our findings need to be confirmed in larger samples with different ethnicities.

## Keywords

Placenta previa; Bakri balloon tamponade; Cesarean section; Postpartum hemorrhage

## 1. Introduction

Placenta previa, an important risk factor for refractory intraoperative and postpartum hemorrhage (PPH), has led to an increased maternal mortality rate worldwide in the past decades [1–3]. Drugs are usually used as the first-line treat-

ment for hemostasis at the placental implantation, however, the second-line treatments, such as gauze packing, uterine arterial ligation, and pelvic artery embolization, are commonly used if the hemostasis cannot be controlled by drugs. Indeed, these second-line treatments are invasive and require specialized surgical skills [4, 5]. Therefore, other effective procedures to reduce bleeding are needed [6, 7].

In 1992, Bakri was the first to introduce intrauterine balloon tamponade to treat obstetric hemorrhage [8]. Several studies have shown the efficacy of Bakri balloon tamponade (BBT) in reducing intraoperative hemorrhage and PPH in recent years [9]. However, the efficacy of BBT in women with PPH due to placenta previa is unknown. The placental site may bleed uncontrollably owing to poor contraction of smooth muscle after the removal of the placenta, and this is a marked feature of placenta previa in the lower uterus [1, 10]. A BBT slides into the lower part of the uterus under the pressure of strong uterine contractions [11]. This pressure is increased by enlargement of the balloon, and a hemostatic effect can be obtained at the placental implantation site [12].

This study aimed to evaluate the success rate of BBT and the risk factors for BBT failure in the treatment of PPH in patients with placenta previa.

## 2. Material & methods

All women who met the inclusion criteria were recruited from Ningbo Women and Children's Hospital between January 1 2016, and December 31 2018. The maternal history and intraoperative information were collected using medical records. This retrospective study was approved by the institutional review board of Ningbo Women and Children's Hospital (approval number: 2020-ky-038). All subjects provided informed consent for inclusion before they participated in the study. The records/information of all of the women were anonymized and de-identified before analysis.

Inclusion criteria were as follows: (1) a singleton pregnancy; (2) women underwent cesarean section; and (3) hemorrhage due to placenta previa was treated with insertion of a BBT during cesarean section when the bleeding volume exceeded 1000 mL. Exclusion criteria were as follows: (1) twin pregnancy; (2) intrauterine fetal death; (3)

a succenturiate lobe, *visa previa*, or eccentric cord insertion; and (4) chorioamnionitis, a retained placenta, trauma of the cervix and vagina, inherited coagulopathy, or disseminated intravascular coagulopathy. The indications for balloon placement were as follows: hemorrhage due to placenta previa with blood volume exceeding 1000 mL, thus necessitating the insertion of a BBT during cesarean section, and hemostasis thought to be achievable with insertion of a BBT. When the placenta was difficult to delivery during the operation with not much bleeding, placenta is manually removed from the uterus, otherwise surgical scissors would be used to cut out the protruding placenta tissue. If there was a heavy bleeding, we would first bind the low segment of the uterus with a cuff, and then take a further measure by placing uterine balloon to stop bleeding. However, if the bleeding cannot be stopped, ascending branch ligation, B-lynch suture or uterine artery embolization would be carried out to stop bleeding. Ultimately, hysterectomy would be performed when the above methods are invalid.

Placenta previa is a condition wherein the placenta directly covers the cervix, while a low placenta is considered when the placenta is close to the cervix [1, 13]. Placenta previa can be divided into major placenta previa, where the placenta completely or partially overlaps the endocervical membrane, and minor placenta previa, where the placenta is <20 mm away from the internal cervical membrane [13]. In this study, we used abdominal ultrasound and magnetic resonance imaging to diagnose the placenta accreta spectrum (PAS). Positive signs of the PAS include: loss of a “clear zone”, an abnormal placental lacunae, bladder wall interruption, myometrial thinning, placental bulge, and/or a focal exophytic mass by two-dimensional grayscale ultrasound; uterovesical hypervascularity, sub-placental hypervascularity, bridging vessels, and/or placental lacunae feeder vessels by two-dimensional color Doppler ultrasound; or intraplacental hypervascularity, abnormal focal uterine bulging, continuous disruption of the myometrium, and T2-weighted dark intraplacental bands by three-dimensional magnetic resonance imaging [14]. We also re-evaluated the diagnosis within 1 week before the cesarean section. Suspicion of the PAS was diagnosed at the time of the cesarean section. Finally, the PAS was confirmed when forced manual separation between the chorionic plate and myometrium was required owing to a strong placental attachment [15, 16].

General anesthesia was performed in all patients in this study. During the cesarean section, 10 IU of oxytocin uterine injection was used to treat hemorrhage, and then intravenous carbitux 100 mg or intrauterine hemagglutinate was administered. A BBT was inserted through the cesarean incision when the hemorrhage exceeded 1000 mL and a utericonstrictor was ineffective. When the balloon was placed during a cesarean section, a surgeon inserted the tamponade balloon into the uterine cavity from the cesarean section incision, while the end of the balloon was placed into the cervix. Approximately 150 to 500 mL of sterile normal

saline was injected by another surgeon through the end of the vagina. The surgeon stretched the end of the balloon to compress the bottom of the cervix and observed bleeding from the catheter drain hole. The balloon was partially inflated with 50 to 100 mL of sterile normal saline after proper placement of the catheter. The uterine incision was closed with a 1-0 absorbent suture in a double-layer manner, while avoiding the balloon being punctured. Next, 3 to 10 strips of 20 × 10 cm vaginal gauze packing was used to prevent shifting of the balloon. If the bleeding continued after the uterine incision was sutured, the balloon was further inflated up to a maximum volume of 500 mL (range: 100–500 mL), depending on the situation.

The drainage volume was checked every hour within the first 6 hours after the cesarean section, and every 4 hours thereafter when the volume was <100 mL/hour. The criteria for catheter removal included a drainage amount of <50 mL/hour and a serosanguineous drainage color. Low-dose intravenous infusion of oxytocin continued before removing the balloon. The balloon was deflated to 50% over 1 to 5 minutes and was left for 15 minutes. If no bleeding was observed, the balloon was removed by the surgeons, and a vaginal tamponade was removed. However, if there was continuous bleeding during an observation period of 15 minutes, the BBT was inflated again and removed after 24 hours. Notably, if there was heavy bleeding after the balloon was removed, necessary surgical treatment was performed, such as pelvic artery embolization and cesarean section hysterectomy. The number of gauze tapes and the volume of normal saline were checked after balloon removed by two medical personnel. The patients were examined for any sign of active bleeding within 30 minutes of catheter removal.

The amount of intraoperative bleeding was measured from the time of skin incision to the time of wound closure. The amount of PPH was defined as the total volume of blood from the end of cesarean section to 24 hours later [1, 3]. The equipment of autologous blood transfusion was prepared before surgery for all of the patients. We collected blood during the operation. This blood was then infused to the patients through Autologous Blood Reinfusion Machine, to increase the hemoglobin content if the volume of blood reached 800 mL. However, if the bleeding could not be controlled, the autologous blood did not achieve a satisfactory hemoglobin content, or the blood coagulation function was abnormal, further infusion of fresh frozen plasma or red blood cells was then required.

Patients with placenta previa who underwent insertion of a BBT during cesarean section and had their bleeding controlled were classified as the balloon success group. Patients who underwent BBT insertion during cesarean section but continued to have uncontrolled bleeding were classified as the balloon failure group. The clinical characteristics of the patients in the balloon success and balloon failure groups are shown in Fig. 1.

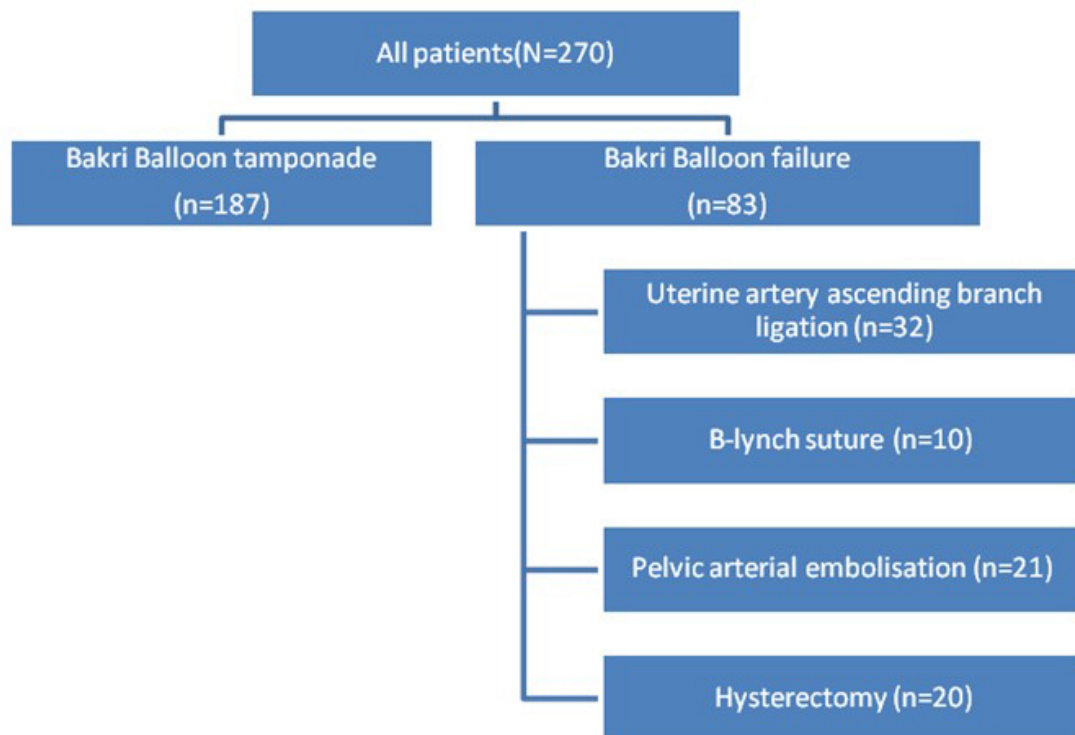


Fig. 1. Management of patients with placenta previa.

The Mann–Whitney U test was used to examine continuous variables, and Fisher’s exact test or the chi-square test was used to examine categorical variables. Multiple logistic regression was performed to investigate the risk factors for BBT failure, with adjustment for birth weight, intraoperative blood loss, postoperative blood loss (mL), hemoglobin levels at 1 hour after surgery, albumin levels at 1 hour after surgery, autologous blood transfusion, packed red blood cells, fresh frozen plasma, weeks at pregnancy termination, presence of placenta accrete, placenta previa classification, and preoperative albumin. The odds risk (OR) and 95% confidence intervals (CI) was used as the common measure of the association between risk factors and risk of BBT failure. All statistical analyses were performed using SAS version 9.2 (SAS Institute, Inc, Cary, NC, USA). Statistical significance was defined as  $p < 0.05$ .

### 3. Results

During the study, 270 women with placenta previa were identified. The characteristics of all patients are shown in Table 1. The success rate of the BBT was 69.3%. The balloon failure group comprised patients who had BBT insertion followed by a B-lynch suture ( $n = 10$ ), uterine artery ascending branch ligation ( $n = 32$ ), pelvic arterial embolization ( $n = 21$ ), or cesarean hysterectomy ( $n = 20$ ). No significant differences in age, body mass index, gravidity, parity, abortion, history of cesarean section, the number of weeks at pregnancy termination, the location of the placenta, or the rates of an artificial reproductive technology pregnancy and combination

with uterine fibroids were observed between the balloon success and balloon failure groups. The rate of placenta accreta was significantly higher in the balloon failure group than in the balloon success group (69.9% vs 41.7%,  $p < 0.01$ ). The rate of major placenta previa was significantly higher in the balloon failure group than in the balloon success group ( $p < 0.01$ ).

We found no significant differences in hemoglobin, hematocrit, platelet, total protein, or albumin levels between the balloon success and balloon failure groups (Table 2). Additionally, no significant differences in the prothrombin time or partial thromboplastin time was found between the groups.

Clinical outcomes are shown in Table 3. Intraoperative blood loss was significantly less in the balloon success group (1120 mL, 500–4000 mL) than in the balloon failure group (3098 mL, 700–18000 mL) ( $p < 0.01$ ). Furthermore, the rates of blood transfusion, namely autologous blood transfusion, packed red blood cell transfusion, and fresh frozen plasma, were significantly lower in the balloon success group (63.6%, 8.56%, and 13.9%, respectively) than in the balloon failure group (91.6%, 54.2%, and 73.5%, respectively). Mean levels of hemoglobin and albumin were significantly lower in the balloon failure group than that in the balloon success group at 1 hour after surgery. However, the mean decrease in hemoglobin level at 24 and 48 hours after surgery was not significantly different between the two groups.

Multiple logistic regression analysis showed that the number of weeks at pregnancy termination (odds ratio [OR] =

**Table 1. Demographics and characteristics of the included patients.**

Clinical characteristics	Success group	Failure group	p
	(n = 187)	(n = 83)	
Age of mothers (years)	31.29 (17–43)	32.25 (20–45)	0.14
BMI (kg/m <sup>2</sup> )	26.40 ± 3.0	26.33 ± 2.86	0.78
Gravidity, median (range)	2 (0–9)	3 (0–9)	0.11
Parity, median (range)	1 (0–3)	1 (0–2)	0.31
Primipara, n (%)	59 (31.6)	22 (26.5)	
Multipara, n (%)	128 (68.4)	61 (73.5)	
Abortion, median (range)	1 (0–9)	2 (0–5)	0.76
History of cesarean section (yes), n (%)	82 (43.9)	42 (50.6)	0.31
Weeks at pregnancy termination (weeks)	35.81 ± 1.92	35.11 ± 2.65	0.12
Presence of placenta accreta, n (%)	78 (41.7)	58 (69.9)	<0.01
Combined with uterine fibroids (yes), n (%)	16 (8.56)	5 (6.02)	0.48
Main placental location, anterior wall (yes), n (%)	95 (50.8)	50 (60.2)	0.17
Placenta previa classification, n (%)			<0.01
Major	155 (82.9)	80 (96.4)	
Minor	32 (17.1)	3 (3.61)	
ART pregnancy, n (%)	7 (3.83)	4 (4.82)	0.68

Data are shown as n (%), mean ± standard deviation, or median (range), as appropriate. BMI, body mass index; ART, artificial reproductive technology.

**Table 2. Preoperative laboratory findings of the patients.**

Clinical parameters	Success group	Failure group	p
	(n = 187)	(n = 83)	
Preop hemoglobin, g/dL	11.44 ± 1.28	11.54 ± 1.40	0.57
Preop hematocrit, %	34.58 ± 3.56	34.56 ± 4.21	0.97
Preop platelet, 10 <sup>3</sup> /mL	199.07 ± 54.66	192.81 ± 48.26	0.37
Preop total protein, g/L	60.55 ± 5.21	62.44 ± 5.33	0.07
Preop albumin, g/L	33.26 ± 3.33	35.44 ± 3.41	<0.01
Preop prothrombin time, s	11.82 ± 0.54	11.80 ± 0.78	0.83
Preop partial thromboplastin time, s	28.17 ± 3.10	28.39 ± 3.26	0.61

Data are shown as mean ± standard deviation. Preop, preoperative.

1.188, 95% confidence interval [CI]: 1.023–1.379), the presence of placenta accreta (OR = 2.472, 95% CI: 1.361–4.493), and placenta previa classification (major vs minor, OR = 4.798, 95% CI: 1.328–17.337) were positively associated with BBT failure. However, preoperative albumin levels (OR = 0.788, 95% CI: 0.714–0.869) were negatively related to BBT failure (Table 4).

#### 4. Discussion

This study showed that BBT was useful for major bleeding caused by placenta previa, when uterine contraction drugs and massage were not effective for PPH. The success rate of BBT was 69.3%.

Currently, the treatment of PPH caused by placenta previa is controversial in obstetrics. Several studies have shown the efficacy of BBT for placenta previa [17–23]. The success rate of BBT for PPH varies from 84% to 90% [17–21]. Mathur *et al.* [19] reported an 80% success rate of BBT in patients with placenta accreta. Soyama *et al.* [21] reported a success rate of 75% (48/64 women) of BBT in patients with

placenta previa. In our study, the success rate of BBT was 69.3% (187/270), which is lower than those in the previous studies. The median intraoperative blood loss was higher in the balloon failure group than in the balloon success group, which is in accordance with previous studies [3, 19]. This finding could be partly due to the fact that preoperative ultrasound or magnetic resonance imaging of the placenta showed no abnormalities for part of patients included in this study. The placenta was difficult to dissect during the operation because it was implanted in the myometrium, and there was more bleeding in the balloon failure group than in the balloon success group. In addition, albumin is an important substance synthesized by the human liver [24]. If the level of albumin is high in the body, which means that the level of blood volume is normal in the body, and there is a certain tolerance for bleeding [24]. In this study, the level of preoperative albumin of the failure group was lower than that of the success group, indicating that the blood volume might be at a low level before the operation, which makes it difficult to control bleeding.

**Table 3. Clinical outcomes of the patients.**

Intraoperative or postoperative parameters	Success group	Failure group	<i>p</i>
	(n = 187)	(n = 83)	
Birth weight (g)	2643 ± 352	2711 ± 402	0.76
Intraoperative blood loss (mL), median (range)	1120 (500–4000)	3098 (700–18,000)	<0.01
Postoperative blood loss (mL), median (range)	204 (50–1680)	268 (10–2800)	0.11
Hemoglobin decrease at 1 hour after surgery (g/dL)	-1.35 ± 1.20	-3.06 ± 1.85	<0.01
Hemoglobin decrease at 24 hours after surgery (g/dL)	-1.21 ± 1.32	-1.66 ± 1.66	0.47
Hemoglobin decrease at 48 hours after surgery (g/dL)	-1.32 ± 1.37	-1.62 ± 1.71	0.30
Albumin decrease at 1 hour after surgery (g/L)	-6.22 ± 3.76	-11.07 ± 5.76	<0.01
Autologous blood transfusion, n (%)	119 (63.6)	76 (91.6)	<0.01
Packed red blood cells, n (%)	16 (8.56)	45 (54.2)	<0.01
Fresh frozen plasma, n (%)	26 (13.9)	61 (73.5)	<0.01

Data are shown as n (%), mean ± standard deviation, or median (range).

**Table 4. Multiple logistic regression analysis of general characteristics and laboratory measurements between the balloon success and balloon failure groups.**

Variables	OR	95% CI	<i>p</i>
Weeks at pregnancy termination	1.188	1.023–1.379	0.02
Presence of placenta accreta	2.472	1.361–4.493	<0.01
Placenta previa classification (major vs minor)	4.798	1.328–17.337	0.02
Preoperative albumin	0.788	0.714–0.869	<0.01

OR, odds ratio; CI, confidence interval.

A univariate analysis revealed that the incidence of placenta accreta was significantly lower in the balloon success group than that in the balloon failure group. Multiple logistic regression showed that the number of weeks at pregnancy termination and the presence of placenta accreta were positively associated with BBT failure. Previous studies have shown that the incidence of placenta accreta is substantially increasing in many Western countries [25–27]. Placenta previa with accreta is often the leading indication for peripartum hysterectomy [1, 4, 6]. Grönvall *et al.* [13] observed placenta accreta in 26/127 women with placenta previa, and 15 of these women underwent peripartum hysterectomy at the time of delivery. Therefore, when the diagnosis of the PAS is confirmed before delivery, other procedures should be prepared in advance.

Major placenta previa was a significant risk factor for BBT failure in our study. Soyama *et al.* [10] reported that balloon prolapse was the major cause of BBT failure for PPH in nine patients with placenta previa. However, there were only a few patients in their study. In the current study, 83 patients had BBT failure, and major previa and the PAS were identified as risk factors. This finding is in accordance with that of a study by Maher *et al.* [19], who showed that balloon success was associated with the absence of placenta accreta. The presence of major placenta previa increases the risk of severe PPH and the requirement for emergency peripartum hysterectomy [28]. In placenta previa, a weaker contractile force in the lower uterine segment, such as the placental separation site, causes difficulty in controlling the closure of blood vessels [2, 28]. When using BBT, with expansion of the

balloon, the pressure gradually increases, which causes blood vessels to close and stop bleeding [2, 20].

This study also suggested that BBT treatment should be defined as failure if hemoglobin and albumin levels are significantly reduced at 1 hour after cesarean section. If the BBT treatment not successful, the next step (B-lynch suture or pelvic arterial embolization) should be initiated immediately. Hemostasis was achieved in women in whom BBT was combined with the B-lynch suture, which is called a “uterine sandwich” [29, 30].

We found that autologous blood transfusions, placenta accreta, and fresh frozen plasma administration occurred more frequently in the balloon failure group than in the balloon success group. Therefore, if preoperative placenta test indicated that there was a placenta previa with placenta accrete, autotransfusion equipment should be prepared before cesarean section [1, 31]. Notably, intraoperative reinfusion is considered as a safe intervention [31]. This treatment might help patients who refuse blood transfusions and could quickly restore their hemoglobin levels.

There are several limitations to this study. First, this study was retrospective with small number of cases in a single center. Second, compared with other surgical treatments, the efficacy of intrauterine balloon tamponade is still inconclusive. Further randomized, controlled trials and multicenter studies are required in the future. Third, all patients in this study were recruited from a Chinese population. Further studies from other populations are required to confirm our findings. Finally, data on several confounding factors, such as tobacco smoking, alcohol consumption, nutritional status, and socio-

economic conditions, were not available in this study, which might have led to overestimation of the effect size. Therefore, our results should be interpreted with caution.

## 5. Conclusions

Our study adds to the limited evidence that BBT is effective as a second-line treatment for massive hemorrhage due to placenta previa in the Chinese population. PAS and major previa are risk factors for BBT failure. However, our findings need to be confirmed in larger samples with different ethnicities.

## Author contributions

DML—Project Development, Data Collection, Manuscript Writing; XBH—Data Collection, Data Analysis; HRC—Data Collection, Manuscript Writing; JJZ—Project Development, Manuscript Editing.

## Ethics approval and consent to participate

All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Ningbo Women and Children's Hospital (approval number: 2020-ky-038).

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## Conflict of interest

The authors declare no conflict of interest.

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