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Original Research

Risk Factors of Bakri Balloon Tamponade Failure for Persistent Postpartum Hemorrhage

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Abstract

Background: The aim of this study was to identify risk factors of Bakri balloon tamponade (BBT) failure for postpartum hemorrhage (PPH) and to evaluate the efficacy of BBT for PPH caused by different etiologies. **Methods**: All women who underwent BBT for PPH at International Peace Maternity & Child Healthcare Hospital, Shanghai, China were included. Univariate analysis and logistic multivariate models were used to identify prognostic factors for BBT failure. **Results**: Of 48,511 deliveries during the study period, 487 (1.0%) women underwent BBT for persistent PPH. The overall success rate was 91.8% (447/487). The individual success rates of BBT for PPH caused by uterine atony, placenta previa, placenta accreta spectrum (PAS), and coagulopathy were 95.9%, 90.6%, 50.0%, and 25.0%, respectively. Blood loss before BBT was remarkably higher in the failure group than in the success group. In addition, estimated blood loss (EBL) before BBT insertion, disseminated intravascular coagulation (DIC) development, *in vitro* fertilization (IVF) pregnancy, and PAS were considered to be independent risk factors of BBT failure. **Conclusions**: BBT is an effective method in the management of PPH resulting from uterine atony and placenta previa. Risk factors of BBT failure primarily include the EBL before BBT insertion, DIC development, IVF pregnancy and PAS.

Keywords: Bakri balloon tamponade; postpartum hemorrhage; placenta accreta spectrum; disseminated intravascular coagulation

1. Introduction

Postpartum hemorrhage (PPH) is common and a leading cause of pregnancy-related death worldwide [1]. The factors that cause PPH are complex and mainly include uterine atony, abnormal placentation, genital tract lacerations, and retained placental product [2]. Most cases of PPH remain unpredictable; therefore, appropriate and timely management of excessive PPH is essential [3]. In recent years, guidelines for the management of PPH have involved a stepwise escalation of pharmacologic and eventual surgical approaches [4]. Primary management includes the use of uterotonic agents, fundal massage, manual exploration of the uterus, and suturing possible lacerations. If all of these techniques fail and bleeding persists, Bakri balloon tamponade (BBT) is becoming a widely suggested technique and is often regarded as a second-line procedure for the management of PPH [5,6]. The efficacy of BBT in the management of PPH has been reported. Wang *et al*. [7] reported a success rate of 91.65% using BBT in a large retrospective study in South China. Suarez *et al*. [8] reported that the overall pooled uterine balloon tamponade success rate was 85.9% in a systematic review. Kumru *et al*. [9] reported that BBT was effective in 22 (88%) of 25 patients who had severe PPH with placenta previa. Soyama *et al*. [10] revealed that in women with placenta previa, routine rapid insertion of BBT significantly reduced intra- and post-operative hemorrhage and shortened the operative time. Therefore, BBT is effective in the treatment of PPH and has the value of clinical promotion. Factors for BBT failure mainly included pre-pregnancy obesity, maternal age, caesarean delivery, estimated blood loss before BBT insertion, long operation duration, and coagulopathy [11,12]. To reduce massive hemorrhage more effectively, it is necessary to identify the risk factors of BBT failure.

In this study, we conducted a retrospective study and aimed to analyze the efficacy of BBT for the management of persistent PPH caused by different etiologies and to identify the specific risk factors related to an increased likelihood of BBT failure.

2. Materials and Methods

2.1 Study Sample and Measures

This retrospective study was conducted at International Peace Maternity & Child Health Hospital, Shanghai Jiaotong University, China. Before analysis, the information of all women were anonymized and de-identified. All women who underwent BBT for persistent PPH from January 2014 to December 2016 were reviewed. Our protocol of management of PPH was described in Fig. 1. Providers could choose B-Lynch or BBT as an initial first step in cesarean deliveries. However, BBT was the only initial step in the vaginal delivery group. BBT was used when blood

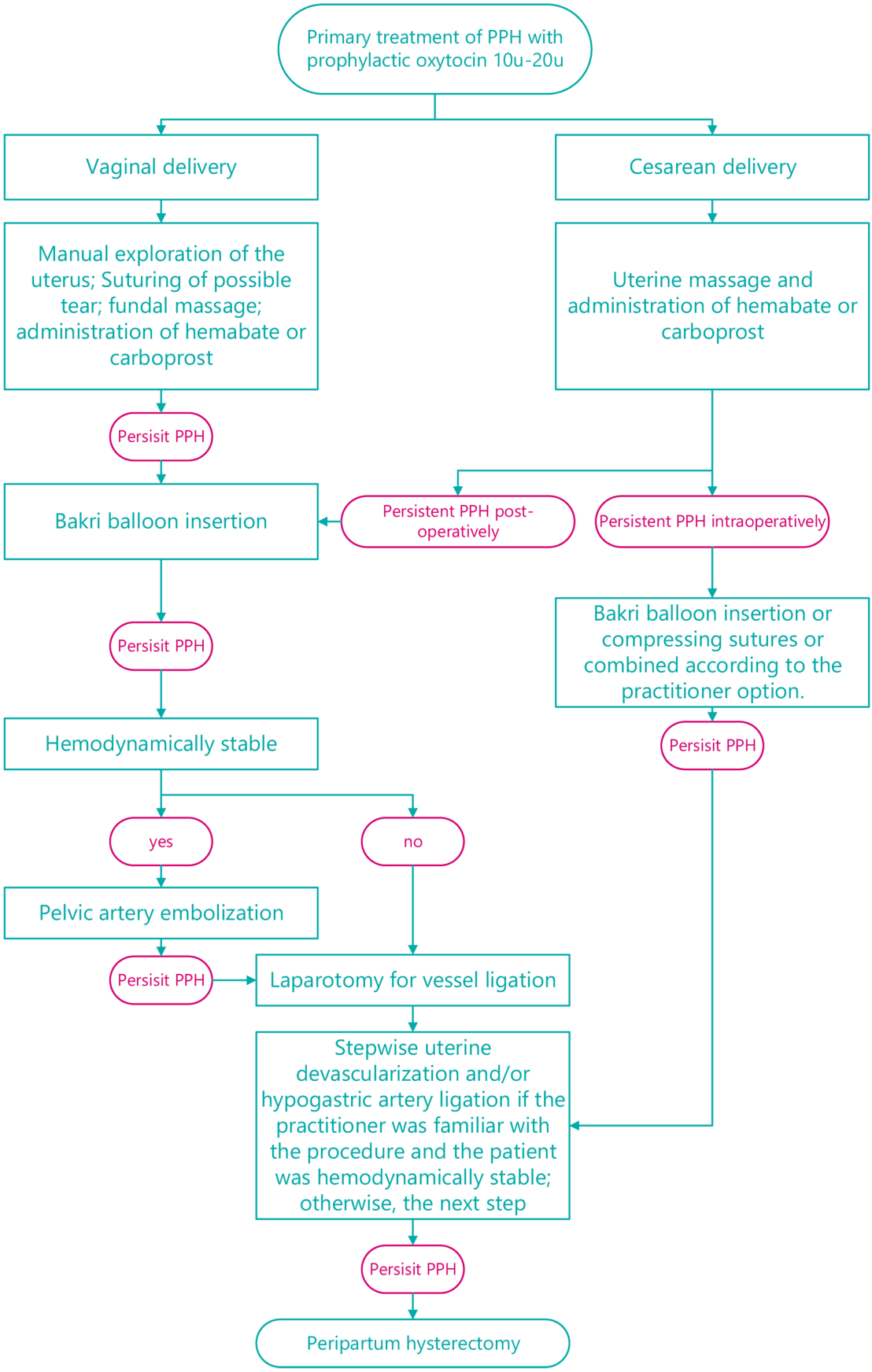

Fig. 1. Management for patients with postpartum hemorrhage.

loss was ≥1000 mL in all deliveries when the primary intervention failed, or ≥500 mL in women with an expected high risk of persistent PPH when the primary intervention, such as the use of uterotonic agents, fundal massage, manual exploration of the uterus, and suturing possible lacerations failed. For some parturient women with high risk factors, clinicians used BBT preventively before the expected occurrence of PPH, so that EBL of some parturient women did not reach 500 mL based on their own experience. High risk referred to high-risk factors for PPH, including twin pregnancy, preeclampsia, placenta previa, placental abruption, etc. To estimate the blood loss, we used a combination of measurements from a basin and the weight of used pads. Blood transfusions were performed in cases with clinical evidence of inadequate oxygen-carrying capacity, and fresh frozen plasma was transfused in the presence of consumption coagulopathy. The procedure for BBT insertion was similar to that originally described by the inventor [13]. For women with vaginal delivery, the BBT (Cook Medical, Bloomington, IN, USA) was placed inside the cervix of the women through the vagina. For women with cesarean section, the front and back walls of the uterus were pressed by hands and the Bakri balloon was quickly placed into the uterine cavity through the uterine incision. The balloon catheter was pulled out and the uterine incision was quickly sutured. Every woman underwent routine vaginal packing, and the distal end of the catheter was fixed to the patient's thigh, but weights were not used. A maximum of 500 mL of saline was instilled, based on the volume of the uterine cavity and the experience of the practitioners. All women were administered prophylactic antibiotics for 48 h. The BBT was removed 12–24 h after insertion.

An obstetrical chart review of each woman was done to collect data including demographic and obstetric characteristics of the study population, causative factors of PPH, mode of delivery, pretamponade treatment, amount of estimated blood loss (EBL) before insertion, timing and method of placement, amount of saline used to inflate the balloon, blood transfusion, and immediate complications. The diagnostic criteria for disseminated intravascular coagulation (DIC) were based on the International Society on Thrombosis and Hemostasis (ISTH) score and patients were diagnosed with DIC according to the diagnostic criteria of ISTH score ≥5 [14]. In addition, we encountered patients with clinical placenta accreta spectrum (PAS) disorder, which comprises placenta creta, increta, and percreta [15]; however, we did not confirm the sub-classification of PAS. Thus, to avoid complexity, we here used the terminology of PAS to express placenta creta, increta, or percreta. Moreover, BBT success was defined as an arrest of the hemorrhage after BBT insertion with no subsequent surgical procedures, regardless of the number of placement procedures. BBT failure was defined as persistent bleeding with the need for further intervention. The primary outcome was the global success rate of BBT, and other main outcomes were the predictive factors for BBT failure. Variables were compared between BBT failure and success for the management of PPH.

2.2 Statistical Analysis

SAS version 9.4 (SAS Institute, Cary, NC, USA) was used for statistical analyses. The Pearson chi-square or Fisher exact test was used to analyze the categorical variables between the groups with BBT failure and success, and the Student's or Wilcoxon test was used for the analysis of continuous variables. The mean value was used for missing data when applicable. Factors related to BBT failure with $p < 0.20$ in the univariate analysis were included in the multivariate logistic models. These models were constructed by backward stepwise regression, and adjusted odds ratios and their confidence intervals were evaluated. All hypotheses were tested at a two-tailed significance level of 0.05. Co-linearity was tested before modeling. We performed a Hosmer–Lemeshow test, a statistical test for goodness of fit, to verify the validity of our model (if $p > 0.05$, the model has a good fitting degree).

3. Results

Among the 48,511 women who delivered during the study period, 498 with persistent PPH underwent BBT. The records of 487 patients were studied and analyzed. Table 1 presents the demographic and pregnancy factors of the 487 women with BBT success and BBT failure. There was no significant difference in maternal age, body mass index, percentage of nulliparity, previous cesarean delivery, prior curettage, and birth weight between the success and failure groups. In addition, there was no remarkable difference between the two groups with regard to preeclampsia, complicated with myoma or mode of delivery. Interestingly, the percentage of pregnancies via *in vitro* fertilization (IVF) in the failure group was significantly higher than that in the success group (35.0% versus 21.0%, $p < 0.05$). The percentage of twin pregnancies was drastically higher in the failure group than that in the success group (30.0% versus 16.6%, $p < 0.05$).

The overall success rate of BBT was 91.8% (447/487), with a success rate of 91.3% and 91.8% among vaginal and cesarean deliveries, respectively. Uterine atony was the most common reason for PPH (294/487 cases, 60.4%), followed by placenta previa (171/487 cases, 35.1%). The success rate of BBT was 95.9% (282/294) for women with uterine atony and 90.6% (155/171) for women with placenta previa. In contrast, the success rate of BBT was only 50.0% (9/18) for women with PAS and 25.0% (1/4) for women with coagulopathy (Table 1).

The pre-labour hemoglobin level of the success group was higher than that of the failure group (median, 115.0 g/L versus 110.5 g/L, $p < 0.05$). The median amount of red blood cell (RBC) transfusion in the failure group was 6 (4.0–9.5) units, which was remarkably higher than that in

Table 1. Selected baseline and pregnancy-associated characteristics of women with successful and failed Bakri balloon tamponade.

Characteristics	Success (N = 447)	Failure (N = 40)	*p*
Maternal characteristics			
Age, years, median	32 (29.0–35.0)	33 (31.5–36.0)	0.07
Previous uterine surgery, n (%)			0.67
Previous cesarean section	101 (22.6)	9 (22.5)	
Previous myomectomy	13 (2.9)	2 (5.0)	
Others	16 (3.6)	2 (5.0)	
Body mass index at first prenatal visit, kg/m^2, median	22.4 (20.6–24.7)	22.45 (20.6–24.4)	0.75
Complicated with myoma, n (%)	42 (9.4)	5 (12.5)	0.57
Pre-labour HB (g/L), median	115.0 (108.0–123.0)	110.5 (106.0–115.0)	0.02
Peripartum HB (g/L), mean $\pm$ SD	101.3 $\pm$ 15.8	79.8 $\pm$ 14.6	0.00
Nulliparity, n (%)	304 (68.0)	26 (65.0)	0.70
History of prior curettage, n (%)			0.70
0	257 (57.5)	22 (55.0)	
1	123 (27.5)	10 (25.0)	
$\geq$2	67 (15.0)	8 (20.0)	
Obstetric characteristics			
Twin pregnancy, n (%)	74 (16.6)	12 (30.0)	0.03
Pre-eclampsia, n (%)	37 (8.3)	7 (17.5)	0.08
IVF pregnancy, n (%)	94 (21.0)	14 (35.0)	0.04
Gestational age (wks), median	37.6 (37.0–39.0)	36.6 (35.3–38.0)	0.00
Birth weight (g), median	3445.0 (3080.0–3900.0)	3485.0 (3022.5–4075.0)	0.94
Mode of delivery, n (%)			0.78
Cesarean	405 (90.6)	36 (90.0)	
Vaginal delivery	42 (9.4)	4 (10.0)	
DIC development, n (%)	6 (1.3)	23 (57.5)	0.00
ICU admission, n (%)	188 (42.1)	37 (92.5)	0.00
PPH characteristics			
Causes of PPH, n (%)			0.00
Uterine atony	282 (63.1)	12 (30.0)	
Placenta previa	155 (34.7)	16 (40.0)	
PAS	9 (2.0)	9 (22.5)	
Coagulopathy	1 (0.2)	3 (7.5)	
Blood loss before insertion of Bakri balloon (mL), median	500 (200.0–2000.0)	1612.5 (600.0–5500.0)	0.00
EBL $<$1000 mL, n (%)	390 (87.2)	5 (12.5)	
EBL 1000 mL–2000 mL, n (%)	57 (12.8)	20 (50.0)	
EBL $>$2000 mL, n (%)	0 (0)	15 (37.5)	
Red blood cell units transfused (units), median	0 (0.0–0.0)	6 (4.0–9.5)	0.00

Data are presented as n (%), mean $\pm$ SD, or median [range]. *p*-values are presented for comparison between the BBT success group and the BBT failure group. BBT, Bakri balloon tamponade; HB, hemoglobin; PPH, postpartum hemorrhage; IVF, *in vitro* fertilization; DIC, disseminated intravascular coagulation; ICU, intensive care unit; EBL, estimated blood loss; PAS, placenta accreta spectrum.

the success group (0 units, $p < 0.05$). In addition, the development of DIC during labor was significantly decreased in the success group compared with the failure group (1.3% versus 57.5%, $p < 0.05$). Consistently, women in the success group had a lower rate of intensive care unit (ICU) admission than those in the failure group (42.1% versus 92.5%, $p < 0.05$; Table 1).

No patients died during the study. Among all patients, 18 women in the success group developed puerperal fever with no specific infection detected. All patients experienced resolution and recovered well after antibiotic treatment. Five patients developed endometritis in the success group and were treated with antibiotics. They all recovered favorably as well. Three patients in the success group suffered from incision infection or dehiscence, which required re-suturing. In addition, BBT failed to control bleeding in 40 women. Among them, one woman had central placenta previa with placenta implantation. The woman had a history of cesarean section twice, and the blood loss was 3900 mL. One woman had central placenta previa and was pre-

mature with 1450 mL of bleeding. One woman had central placenta previa with 5500 mL of bleeding. These three women ultimately required peripartum hysterectomy after all conservative interventions. A total of 35 pelvic arterial embolizations were attempted and succeeded. Laparotomy was performed in only one woman who had pelvic inflammation. The balloon was then removed, and B-Lynch sutures were applied. One woman was managed by massive blood transfusion plus clotting factors after BBT failure.

Finally, we constructed the multivariate logistic model on those variables with $p < 0.20$ in the univariable analysis (Table 2). Four variables were considered as independent risk factors of BBT insertion failure: EBL before insertion (EBL <1000 mL was used as the reference; odds ratio (OR), 13.25; 95% confidence interval (CI), 3.89–45.18), DIC development (OR, 8.59; 95% CI, 2.33–31.72), IVF pregnancy (OR, 3.77, 95% CI 1.08–13.19), and PAS (OR, 10.29; 95% CI, 1.73–61.35). In contrast, pre-labor hemoglobin of the patient was a favorable predictive for the success of BBT (OR, 0.96; 95% CI, 0.93–1.00). The Hosmer–Lemeshow test with its *p*-value of 0.962 validated the model's goodness of fit.

Table 2. Multivariate logistic model of prognostic factors for BBT failure.

Variable	β	*S.E*	*Wald* x^2	*p*	*OR (95% CI)*
Pre-labor HB	–0.04	0.02	4.50	0.03	0.96 (0.93–1.00)
EBL before insertion					
≥1000 mL	2.58	0.63	17.05	0.00	13.25 (3.89–45.18)
<1000 mL					1
IVF	1.33	0.64	4.30	0.04	3.77 (1.08–13.19)
DIC	2.15	0.67	10.40	0.00	8.59 (2.33–31.72)
PAS	2.33	0.91	6.55	0.01	10.29 (1.73–61.35)
Placenta previa	1.40	0.61	5.21	0.02	4.04 (1.22–13.40)

BBT, Bakri balloon tamponade; HB, hemoglobin; OR, odds ratio; CI, confidence interval; IVF, *in vitro* fertilization; DIC, disseminated intravascular coagulation; PAS, placenta accreta spectrum.

4. Discussion

Our large retrospective study of 487 patients who underwent BBT for persistent PPH at our tertiary center demonstrated two key findings: (1) the risk factors of BBT failure included EBL before insertion, DIC development, IVF pregnancy and PAS. (2) BBT was an effective method in the management of PPH resulting from uterine atony and placenta previa, with success rates of 95.9% and 90.6%, respectively.

BBT was first reported in 2001 for the management of persistent bleeding from the lower uterine placental site [13]. The mechanism of BBT had been possibly attributed to the intrauterine pressure, which is greater than the systemic arterial pressure, created by the balloon. BBT has become a popular management method because it is simple to use and has a success rate of 80%–100%. Alkıs *et al*. [2] found that BBT was effective in 14 (87.5%) patients with PPH caused by placenta previa. Similarly, the success rate of BBT was 90.6% (155/171) for persistent PPH caused by placenta previa in this study. In addition, uterine atony is also a main cause of PPH. Previous studies have reported that BBT was effective in cases of PPH caused by uterine atony [16,17]. In the present study, 60.4% (294/487) of patients were complicated with persistent PPH caused by uterine atony, and the success rate of BBT was 95.9%. These results indicate that BBT is effective in the management of PPH caused by placenta previa and uterine atony.

Our findings indicated that the risk factors of BBT failure included EBL before insertion, DIC development, IVF pregnancy and PAS. In agreement with our results, Wang *et al*. [7] also reported that DIC development is one of the risk factors in the BBT failure. Ruiz Labarta *et al*. [11] found that EBL before insertion was associated with BBT failure. In addition, PAS is associated with life-threatening maternal PPH. In a systematic review and meta-analysis, Suarez *et al*. [8] examined the efficacy of uterine balloon tamponade and discovered that the success rate for PAS was 66.7%. Mathur *et al*. [18] reported that the failure rate of BBT reached 50% in PPH caused by placenta increta. In Grönvall's cases series of 50 patients, BBT failure was noted in two of five cases of placenta accreta/increta, both of which required hysterectomy [19]. Similarly, in our study, there were 18 cases of PPH caused by PAS, with nine failures (success rate: 50.0%). Interestingly, we found in the study that patients of IVF pregnancy would have higher risk of BBT failure, which was not identified in previous studies. This may be due to the high rate of twin pregnancy with IVF pregnancy. Furthermore, patients of IVF pregnancy may have some potential hormonal disorders, which may lead to unresponsiveness to medication and severe bleeding before further intervention deployed.

Meanwhile, 15 of the 40 failed cases had a blood loss of >2000 mL before the insertion of the BBT. The risk for BBT failure when EBL ≥1000 mL before insertion would be more than 13 fold of that when EBL <1000 mL before insertion. It is plausible to deduce that most of these women had experienced secondary consumption coagulopathy DIC as a result of massive PPH. Accordingly, the rates of DIC development and ICU admission were remarkably higher in the failure group than in the success group, and the risk for BBT failure increased. The early insertion of BBT might prevent further blood loss before the presentation of coagulopathy and could improve the efficacy in PPH. In addition, we found that women with a higher prelabor hemoglobin level had a lower risk of BBT failure. The higher the prelabor hemoglobin value, the lower the risk for the development of DIC with blood loss and the lower the requirement for RBC transfusion to correct coagulopathy. Similarly, Vintejoux *et al*. [20] also found that the success rate of

Bakri balloon was 100% for women with bleeding <1000 mL, indicating that the early use of BBT was more effective for the management of PPH. Wang *et al*. [7] also discovered that the usage of BBT is more effective for the treatment of PPH in a timely manner. Howard and Grobman [21] demonstrated that women receiving intrauterine balloon tamponade at lower EBL quartiles had higher nadir hemoglobin levels, fewer transfusions of RBCs, fewer ICU admissions, and fewer hysterectomies. These findings suggest that BBT should be deployed earlier in the PPH treatment protocol.

This study has several strengths. First, it is one of the largest studies to address the issue of the success and failure rates of BBT. The large number of included patients also makes the results more convincing. Second, participants from our single medical center had the same diagnostic criteria and underwent similar management for PPH, which resulted in the limitation of potential confounders. Third, the overall success rate of BBT was 91.8%, which was consistent with that reported in previous studies [22,23]. In addition, this study has several limitation. First, the sample size of the outcomes of interest was small (n = 40, with only four PPH cases caused by coagulopathy), this series might not have the ability to detect some other predictive factors. Second, we could choose either B-Lynch or BBT as the initial first step in cesarean deliveries, which was not standardized and might have caused bias. However, BBT was the only initial step in the vaginal delivery group, and the success rate of BBT was similar to that of cesarean deliveries. This suggests that randomness in cesarean deliveries is unlikely to have a significant effect on the main results we were concerned about. Third, our study lacked a control group, which may have resulted in overestimation of the efficacy of BBT. Only a randomized study could assess the true efficacy of BBT.

Our results regarding the risk factors of BBT failure have important clinical significance because they may assist caregivers in optimizing the management of PPH. Notably, although BBT is not effective in some situations with risk factors of failure, it may be used as a temporary tamponade, which permits practitioners to prepare for the next intervention or patient transfer. For example, at our tertiary center, BBT in combination with pelvic artery embolization can enhance the treatment effectiveness of BBT failure and lower the risk of peripartum hysterectomy. In addition, other treatment options instead of Bakri and embolization such as ligation of the ampulla tubae uterinae or the application of a Celox tamponade can be used for PPH.

5. Conclusions

We demonstrated that BBT is an effective treatment method for PPH caused by uterine atony and placenta previa. The risk factors of BBT failure primarily include EBL before insertion, development of DIC, IVF pregnancy and PAS. In addition, timely intervention of BBT for patients at high risk of PPH may result in a high success rate.

Author Contributions

XL designed the study. YC and WC contributed to experiment and methodology. EM collected and analyzed the data. TT wrote the manuscript. All authors read and approved the final manuscript.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of International Peace Maternity & Child Health Hospital, Shanghai Jiaotong University. The ethical approval number is GKLW2017-113. Informed consent was obtained from all subjects involved in the study.

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Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/j.ceog4911255.

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