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Original Article

Performance of Bakri balloon tamponade in controlling postpartum hemorrhage

Ying Wang*, Chanyun Xiao*, Na Zhang, Guoqiang Sun

*Department of Obstetrics, Maternal and Child Health Hospital of Hubei Province, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430070, Hubei, P. R. China. *Equal contributors.*

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Abstract: Objective: Bakri balloon tamponade (BBT) is currently being used worldwide. This study aimed to explore the real-world performance of BBT for the treatment of postpartum hemorrhage (PPH). Methods: A total of 279 women with PPH who failed to respond to first-line conservative management and received BBT were consecutively recruited, reflecting authentic settings. The maternal baseline clinical data, PPH management, and perinatal outcome were recorded. In addition, the perinatal outcomes of women with pre-BBT blood loss <1000 mL were compared to those with ≥1000 mL. Finally, the factors related to pre-BBT blood loss ≥1000 mL were analyzed by logistic regression. Results: The mean gestational age of all recruited women was 39.03±1.98 weeks, with a primipara proportion of 68.82%, a vaginal delivery rate of 60.93%, a uterine atony rate of 74.91%, and placenta accreta rate of 53.05%. Perinatal outcomes showed a hemostasis success rate of 88.89%, a transvaginal BBT placement rate of 80.29%, and a blood transfusion rate of 65.95%. Compared to women with blood loss <1000 mL (33.33%), women with blood loss ≥1000 mL (66.67%) showed a lower proportion of gestational hypertension (P=0.026), cesarean section (P=0.024), a shorter time from delivery to insertion (P=0.037), and greater pre-BBT blood loss and blood transfusion (both P<0.001). Notably, there were no significant differences in hemostasis success rate (P=0.346) or post-BBT blood loss (P=0.907). Delivery mode and uterine atony were closely correlated with pre-BBT blood loss. Conclusions: BBT is effective in stopping PPH among women with massive blood loss in documented settings.

Keywords: Bakri balloon, postpartum hemorrhage, effectiveness, perinatal outcomes, real world evidence

Introduction

Postpartum hemorrhage (PPH) is a life-threatening complication of childbirth, defined as a loss of 500 mL or more of blood within the first 24 h after birth [1]. PPH accounts for more than 100,000 deaths annually [2, 3], and is characterized by its unpredictability and sudden onset. The condition can be induced by many factors, such as cesarean delivery, uterine atony, placenta previa, low-lying placenta, genital tract laceration, and placental abnormalities. Placenta previa is a major cause of PPH [4, 5]. Furthermore, high-income or developed countries typically present a lower prevalence of PPH compared to low-income or undeveloped countries [6, 7]. Postpartum bleeding may require surgical intervention, interventional radiology, blood transfusion for severe anemia, iron supplementation, or even a hysterectomy. Despite the advancements in medical and surgical techniques, the rate of emergency peripartum hysterectomy (0.1%-0.3%) remains on the rise in the USA [8]. The high morbidity is closely correlated with peripartum hysterectomies, which greatly increase the risk for losing fertility [9]. Therefore, finding a more effective and safer treatment strategy is essential in minimizing the risk to puerperial women.

To date, uterotonic drugs such as prostaglandin, vaginal packing, uterine massage, surgical repair of genital tract lacerations, B-lynch compression sutures, arterial ligation, uterine artery embolization (UAE), and removal of retained placental tissues are mainly used as first-line management for PPH. The first Bakri balloon tamponade (BBT) was designed by Bakri and was used for PPH due to placenta previa in 1999. Subsequently, BBT has been recom-

mended as life-saving and fertility-sparing second-line management for PPH before resorting to more invasive interventions [10]. Several uterine tamponade devices have been used in postpartum bleeding, such as Foley, condom, and tube catheters, but showed inconsistent results [11]. Compared to other uterine tamponade devices and conservative interventions, BBT requires less training time and minimal local resources, while achieving high effectiveness [12]. However, second-line management for PPH is still challenging due to a lack of evidence [13], and previous studies investigating the efficacy and safety of BBT were inconclusive [14]. Studies about the timing of balloon insertion have not been reported. Very few reports have disclosed the real-world performance of BBT in controlling bleeding and the effects of influencing factors on blood loss.

This cohort study was performed in a single tertiary center, aiming to explore the effectiveness of BBT for the treatment of PPH in real-world settings. The characteristics and perinatal outcomes of the 279 recruited subjects were collected and analyzed. The related variables associated with blood loss ≥1000 mL before using BBT were analyzed. Moreover, the impact of the timing of balloon insertion was explored.

Materials and methods

Study subjects

A total of 279 women with PPH who failed to respond to first-line conservative management were recruited between January 2016 to December 2020. The study was approved by the Ethics Committee of the Maternity and Child Health Hospital of Hubei Province (IEM XM073). All procedures conformed to the 1964 Helsinki Declaration and written informed consent was obtained from every subject. All eligible subjects met the following criteria. Inclusion criteria: 1) failure of the first-line conservative treatment of PPH; 2) usage of BBT (Cook Medical, Spencer, IN, USA); 3) age ≥18 years old; 4) a gestation age ≥28 weeks. The exclusion criteria were: 1) subjects with communication disorders; 2) subjects with malignant tumors; 3) subjects with abortion; 4) subjects with pelvic infections; 5) subjects with uterine fibroids.

The participants were classified into two subgroups based on the blood loss before using BBT (women with pre-BBT blood loss <1000 mL or ≥1000 mL). The baseline maternal characteristics and perinatal outcomes were compared, and the factors related to pre-BBT blood loss ≥1000 mL were further analyzed. In addition, the influence of BBT insertion time, delivery mode, hemostasis, and pre-/post-BBT blood loss volume blood transfusion were analyzed in women subgrouped based on the time from delivery to insertion (<86.27 min or ≥86.27 min).

Maternal baseline characteristics and perinatal outcome measure collection

The maternal baseline characteristics were recorded, including weight, maternal age, gestational age, parity, vaginal/cesarean delivery mode, repeat cesarean section, number of births, gestational hypertension, gestational diabetes, abnormal coagulation, placenta accreta, placenta previa, uterine atony, and preeclampsia. The variables of perinatal outcomes were also recorded, including the time from delivery to BBT insertion, BBT placement method, uterine contractions, lower genital tract trauma, pre-/post-BBT intervention, indwelling time, infusion volume, blood loss, blood transfusion and perinatal complications.

Statistical analysis

All data were analyzed using SPSS version 23.0 (IBM Corp, Armonk, NY). Continuous variables were presented as mean ± standard deviation (SD). Categorical variables were expressed as numbers and percentages. Continuous variables were compared between women with pre-BBT blood loss <1000 mL and ≥1000 mL. Women were also grouped based on the time from delivery to BBT insertion (<86.27 min and ≥86.27 min), and women with UAE and internal iliac artery embolization (IIAE) after BBT were analyzed using the Student *t*-test (two-sided). Categorical variables between the two subgroups were compared using the Chi-square test or Fisher's exact test, as appropriate. In addition, logistic regression was used to analyze the factors associated with blood loss ≥1000 mL before using BBT. Any univariate analysis results with $P<0.1$ and variables that

Table 1. Characteristics analysis of the 279 women with postpartum hemorrhage (PPH)

Parameters	Value
Weight (Mean ± SD, kg)	70.76±10.21
Gestational age (Mean ± SD, w)	39.03±1.98
Maternal age (n, %)	
18-25 year	32 (11.50)
25-35 year	199 (71.30)
≥35 year	48 (17.20)
Parity (n, %)	
Primipara	192 (68.82)
Multipara	87 (31.18)
Delivery mode (n, %)	
Vaginal delivery	170 (60.93)
cesarean section	109 (39.07)
Birth number (n, %)	
Single births	264 (94.62)
Multiple births	15 (5.38)
Repeat cesarean section (n, %)	
No	265 (94.98)
Yes	14 (5.02)
Gestational diabetes (n, %)	
No	274 (98.21)
Yes	5 (1.79)
Gestational hypertension (n, %)	
No	270 (96.77)
Yes	9 (3.23)
Uterine atony (n, %)	
No	70 (25.09)
Yes	209 (74.91)
Placenta accreta (n, %)	
No	131 (46.95)
Yes	148 (53.05)
Abnormal coagulation (n, %)	
No	274 (98.21)
Yes	5 (1.79)
Placenta previa (n, %)	
No	269 (96.42)
Yes	10 (3.58)
Preeclampsia (n, %)	
No	271 (97.13)
Yes	8 (2.87)

PPH, Postpartum hemorrhage; SD, standard deviation.

may affect the dependent variable before using BBT were included in the logistic regression. In this study, a *P*-value of <0.05 was considered significant.

Results

Characteristics and perinatal outcome analysis of the 279 women with PPH

The baseline characteristics were analyzed, revealing the mean weight of all the recruited women was 70.76±10.21 kg, with mean gestational age of 39.03±1.98 weeks, a primipara proportion of 68.82%, a vaginal delivery rate of 60.93%, a uterine atony rate of 74.91%, and placenta accreta rate of 53.05% (**Table 1**). Perinatal outcome analysis showed a BBT hemostasis success rate of 88.89%, among which transvaginal placement was used in 80.29% of cases, and blood transfusion was performed in 65.95% of cases (**Table 2**). The mean time from delivery to insertion was 86.27±8.67 min. Pre-BBT blood loss and post-BBT blood loss were 1065.16±18.38 mL and 93.13±10.98 mL, respectively. Only 0.72% (2/92.28) of women experienced perinatal complications.

Comparison of characteristics and perinatal outcomes in women with pre-BBT blood loss <1000 mL or ≥1000 mL

The recruited women were subgrouped based on pre-BBT blood loss, including a blood loss <1000 mL (n=93) group and a blood loss ≥1000 mL (n=186) group. The baseline characteristics between the two groups were compared (**Table 3**). A higher proportion of vaginal deliveries (χ^2=5.089, *P*=0.024) and a lower proportion of gestational diabetes (χ^2=4.989, *P*=0.026) were observed in women with pre-BBT blood loss ≥1000 mL. However, no significant difference was observed in weight, gestational age, parity, maternal age, past medical history, uterine atony, placenta accreta, abnormal coagulation, placenta previa or preeclampsia (all *P*>0.05).

The perinatal outcomes were further compared (**Table 4**). Significant differences were observed in time from delivery to insertion (χ^2=2.096, *P*=0.037), blood loss before using the Bakri balloon (χ^2=-16.167, *P*<0.001), blood transfusion rate (χ^2=49.807, *P*<0.001), and blood transfusion volume, including red blood cells (*t*=-6.671, *P*<0.001), cryoprecipitate (*t*=-4.995, *P*<0.001), plasma (*t*=-5.245, *P*<0.001). Notably, there were no significant differences

Table 2. Perioperative outcome analysis in patients of the 279 women with PPH

Parameter	Value
Time between delivery/insertion (Mean ± SD, min)	86.27±8.67
Pre-BBT blood loss (Mean ± SD, mL)	1065.16±18.38
BBT placement method (n, %)	
Transvaginally	224 (80.29)
Transabdominally	55 (19.71)
Hysterotonics (n, %)	
No	259 (92.83)
Yes	20 (7.17)
Hemostasis (n, %)	
No	31 (11.11)
Yes	248 (88.89)
Intervention before using BBT (n, %)	
None	223 (79.93)
UAE	15 (5.38)
"8" suture	16 (5.73)
Other	25 (12.53)
Lower genital tract trauma (n, %)	
No	258 (92.47)
Yes	21 (7.53)
Intervention after using BBT (n, %)	
None	248 (88.89)
UAE	27 (9.68)
IIAE	4 (1.43)
Post-BBT blood loss (Mean ± SD, ml)	93.13±10.98
Infused volume (Mean ± SD, ml)	414.72±3.81
Indwelling time (Mean ± SD, min)	985.57±26.71
Blood transfusion (n, %)	
No	95 (34.05)
Yes	184 (65.95)
Red blood cell, RBC (Mean ± SD, U)	2.37±0.14
Cryoprecipitate (Mean ± SD, U)	1.755±0.14
Plasma (Mean ± SD, mL)	186.56±14.56
Perinatal complications (n, %)	
No	277 (92.28)
Yes	2 (0.72)

PPH, Postpartum hemorrhage; BBT, Bakri balloon tamponade; UAE, uterine artery embolization; IIAE, internal iliac artery embolization; SD, standard deviation.

in hemostasis success rate (χ^2=-0.889, P=0.346), and post-BBT blood loss (t=-0.117, P=0.907).

Influential factors for blood loss ≥1000 mL before using BBT

Binary logistic regression was used to analyze the influential factors for pre-BBT blood loss ≥1000 mL (**Table 5**). The univariate analysis results with P<0.1 and variables that may affect blood loss before using BBT were further analyzed. The variables included maternal age, weight, gestational age, parity, delivery mode, number of births, repeat cesarean section, gestational diabetes, gestational hypertension, uterine atony, abnormal coagulation, placenta accreta, placenta previa, preeclampsia, lower genital tract trauma and suture before using BBT. A vaginal delivery (OR=0.318, 95% CI: 0.155-0.652, P=0.002) and uterine atony (OR=2.211, 95% CI: 1.068-4.578, P=0.033) were independent influential factors for pre-BBT blood loss ≥1000 mL.

Influence of early BBT usage

The influence of early BBT usage was further analyzed. As shown in **Figure 1**, all women were subgrouped based on the time from delivery to insertion (86.27 min). There were no significant differences in the rate of women with pre-BBT blood loss <1000 mL or ≥1000 mL (χ^2=0.897, P=0.344) or the rate of hemostasis success (χ^2=2.296, P=0.130) between women with time from delivery to insertion <86.27 min and ≥86.27 min. Pre-BBT blood loss volume (t=0.580, P=0.561) and post-BBT blood loss volume (t=1.760, P=0.080) also showed no significant difference. Interestingly, a higher rate of cesarean section (49.35%) was observed in the <86.27 min group than the ≥86.27 min group (35.15%) (χ^2=4.724, P=0.030). Furthermore, a higher rate of blood transfusion was observed in the <86.27 min group (71.78%) compared to the ≥86.27 min group (50.65%) (χ^2=11.087, P=0.001).

Table 3. Clinical features in patients with pre-BBT blood loss <1000 mL and ≥1000 mL

	<1000 mL (n=93)	≥1000 mL (n=186)	t/χ^2	*P*
Weight (Mean ± SD, kg)	70.69±9.42	72.30±10.56	-1.248	0.213
Gestational age (Mean ± SD, w)	38.85±2.15	39.13±1.96	-1.114	0.266
Maternal age (n, %)				
18-25 year	11 (11.83)	21 (11.29)		
25-35 year	65 (69.89)	134 (72.04)	0.150	0.928
≥35 year	17 (18.28)	31 (16.67)		
Parity (n, %)				
Primipara	60 (64.52)	132 (70.97)		
Multipara	33 (35.48)	54 (29.03)	1.203	0.273
Delivery mode (n, %)				
Vaginal delivery	48 (51.61)	122 (65.59)		
cesarean section	45 (48.39)	64 (34.41)	5.089	0.024
Birth number (n, %)				
Single births	88 (94.62)	176 (94.62)		
Multiple births	5 (5.38)	10 (5.38)	0.000	1.000
Repeat cesarean section (n, %)				
No	85 (91.40)	180 (96.77)		
Yes	8 (8.60)	6 (3.23)	3.760	0.052
Gestational Diabetes (n, %)				
No	89 (95.70)	185 (99.46)		
Yes	4 (4.30)	1 (0.54)	4.989	0.026
Gestational hypertension (n, %)				
No	89 (95.70)	181 (97.31)		
Yes	4 (4.30)	5 (2.69)	0.517	0.472
Uterine atony (n, %)				
No	30 (32.26)	40 (21.51)		
Yes	63 (67.74)	146 (78.49)	3.814	0.051
Placenta accreta (n, %)				
No	42 (45.16)	89 (47.85)		
Yes	1951	97 (52.15)	0.180	0.671
Abnormal coagulation (n, %)				
No	90 (96.77)	184 (98.92)		
Yes	3 (3.23)	2 (1.08)	1.629	0.202
Placenta previa (n, %)				
No	88 (94.62)	181 (97.31)		
Yes	5 (5.38)	5 (2.69)	1.296	0.255
Preeclampsia (n, %)				
No	89 (95.70)	182 (97.85)		
Yes	4 (4.30)	4 (2.15)	1.030	0.310

BBT, Bakri balloon tamponade; SD, standard deviation.

Effects of interventional embolization after BBT in women with hemostasis failure

The effects of different interventional embolization after BBT were further explored in women with hemostasis failure (**Table 6**). No significant differences were observed in timing of BBT insertion, delivery mode, pre-BBT blood loss or pre-BBT blood loss between women received UAE and women received IIAE (all *P*>0.05). However, there were significant differences in infused volume (*t*= 2.134, *P*=0.041), indwelling time (*t*=-3.181, *P*= 0.003) and the proportion of blood transfusion (χ^2= 6.975, *P*=0.008).

Discussion

Bakri postpartum balloon (BBT) is commonly used to control PPH in clinical practice, especially in cases with uterotonics, placenta previa, and placenta accreta and increta. This study included 279 women, demonstrating that BBT is effective in stopping PPH among women with massive blood loss in real-world settings. Analysis of perinatal outcomes revealed a hemostasis success rate of 88.89% in the general population, and 91.40% in women with pre-BBT blood loss <1000 mL and 87.63% in women with pre-BBT blood loss ≥1000 mL. None of the recruited women required a postpartum hysterectomy. Vaginal delivery (*P*=0.002, OR= 0.318) and uterine atony (*P*=0.033, OR=2.211) were independent influential factors for pre-BBT blood loss ≥1000 mL. Early usage of BBT was closely correlated with delivery mode and blood transfusion.

The baseline characteristics and perioperative outcomes among the 279 women with PPH

Table 4. Perioperative outcome analysis in patients with pre-BBT blood loss <1000 mL and ≥1000 mL

	<1000 mL (n=93)	≥1000 mL (n=186)	t/χ^2	*P*
Time between delivery/insertion (Mean ± SD, min)	111.82±22.79	73.50±6.135	2.096	0.037
Pre-BBT blood loss (Mean ± SD, mL)	928.20±43.67	1014.25±33.47	-16.167	0.000
BBT placement method (n, %)				
Transvaginally	71 (76.34)	153 (82.26)		
Transabdominally	22 (23.66)	33 (17.74)	1.370	0.242
Hysterotonics (n, %)				
No	88 (94.62)	171 (91.94)		
Yes	5 (5.38)	15 (8.06)	0.673	0.412
Hemostasis (n, %)				
No	8 (8.60)	23 (12.37)	0.889	0.346
Yes	85 (91.40)	163 (87.63)		
Intervention before using BBT (n, %)				
None	78 (83.87)	145 (77.96)		
UAE	4 (4.30)	11 (5.91)		
“8” suture	8 (8.60)	8 (4.30)		
Other	3 (3.23)	22 (11.83)	7.691	0.053
Lower genital tract trauma (n, %)				
No	85 (91.40)	173 (93.01)		
Yes	8 (8.60)	13 (6.99)	0.232	0.630
Intervention after using BBT (n, %)				
None	85 (91.40)	163 (87.63)		
UAE	7 (7.53)	20 (10.75)		
IIAE	1 (1.08)	3 (1.61)	0.890	0.641
Post-BBT blood loss (Mean ± SD, mL)	91.31±15.21	94.04±14.64	-0.117	0.907
Infused volume (Mean ± SD, mL)	409.01±65.89	417.58±4.58	-1.061	0.290
Indwelling time (Mean ± SD, min)	924.65±63.48	1071.94±23.88	-1.523	0.129
Blood transfusion (n, %)				
No	58 (62.37)	37 (19.89)		
Yes	35 (37.63)	149 (80.11)	49.807	<0.001
Red blood cell (Mean ± SD, U)	1.16±0.18	2.98±017	-6.671	<0.001
Cryoprecipitate (Mean ± SD, U)	0.80±0.18	2.23±0.18	-4.995	<0.001
Plasma (Mean ± SD, mL)	83.33±17.42	238.17±18.96	-5.245	<0.001
Perinatal complications (n, %)				
No	93 (100.00)	184 (98.92)		
Yes	0 (0.00)	2 (1.08)	1.007	0.316

BBT, Bakri balloon tamponade; UAE, uterine artery embolization; IIAE, internal iliac artery embolization; SD, standard deviation.

were analyzed. The women in this study had a mean weight of 70.76±10.21 kg, a mean gestational age of 39.03±1.98 weeks, a mean pre-BBT blood loss of 1065.16±18.38 mL, a mean indwelling time of 985.57±26.71 min, a primipara proportion of 68.82%, a vaginal delivery rate of 60.93%, a uterine atony rate of 74.91%, a placenta accrete rate of 53.05%, BBT transvaginal placement in 80.29% of cases, and blood transfusion in 65.95% of cases. Unlike in previous studies, the women who received cesarean section only accounted for 39.07%, which was lower than the 76% reported in Liu's study [15] and 67% in “real world experience” by Richelle *et al.* [16]. Severe PPH is defined as a blood loss of ≥1000 ml within 24 h following delivery [17]. Considering the blood loss, most subjects in our study were women with severe PPH, and vaginal delivery was associated with more blood loss. This may be correlated with

Table 5. Related factors analysis for pre-BBT blood loss ≥1000 mL by logistic regression

Variables	β	S.E.	Wald	df	*P* value	OR	95% CI	
							Lower	Upper
Maternal age			3.09	2	0.214			
25-35 year	0.38	0.44	0.78	1	0.378	1.470	0.625	3.457
≥35 year	1.03	0.60	2.92	1	0.088	2.802	0.859	9.139
Weight	0.03	0.02	3.36	1	0.067	1.028	0.998	1.060
Gestational age	0.03	0.08	0.12	1	0.727	1.030	0.872	1.216
Parity	-0.16	0.34	0.23	1	0.632	0.848	0.432	1.664
Delivery mode	-1.15	0.37	9.77	1	0.002	0.318	0.155	0.652
Birth number	0.31	0.69	0.20	1	0.651	1.366	0.353	5.275
Repeat cesarean section	-0.29	0.73	0.16	1	0.687	0.746	0.180	3.101
Gestational Diabetes	-2.50	1.50	2.79	1	0.095	0.082	0.004	1.541
Gestational hypertension	-0.13	0.82	0.02	1	0.876	0.880	0.177	4.386
Uterine atony	0.79	0.37	4.57	1	0.033	2.211	1.068	4.578
Placenta accreta	-0.02	0.33	0.00	1	0.947	0.978	0.513	1.866
Abnormal coagulation	-1.74	1.01	2.96	1	0.085	0.175	0.024	1.275
Lower genital tract trauma	-0.50	0.52	0.91	1	0.339	0.605	0.216	1.694
Placenta previa	-0.74	0.94	0.63	1	0.428	0.475	0.076	2.989
Preeclampsia	-0.27	0.83	0.11	1	0.746	0.765	0.151	3.874
Suture before using BBT			11.70	3	0.008			
UAE	0.41	0.63	0.43	1	0.513	1.513	0.438	5.226
"8" suture	0.03	0.61	0.00	1	0.958	1.033	0.314	3.402
Other	2.58	0.78	11.03	1	0.001	13.162	2.876	60.241
Constant	-3.01	3.66	0.68	1	0.410	0.049		

BBT, Bakri balloon tamponade; UAE, uterine artery embolization.

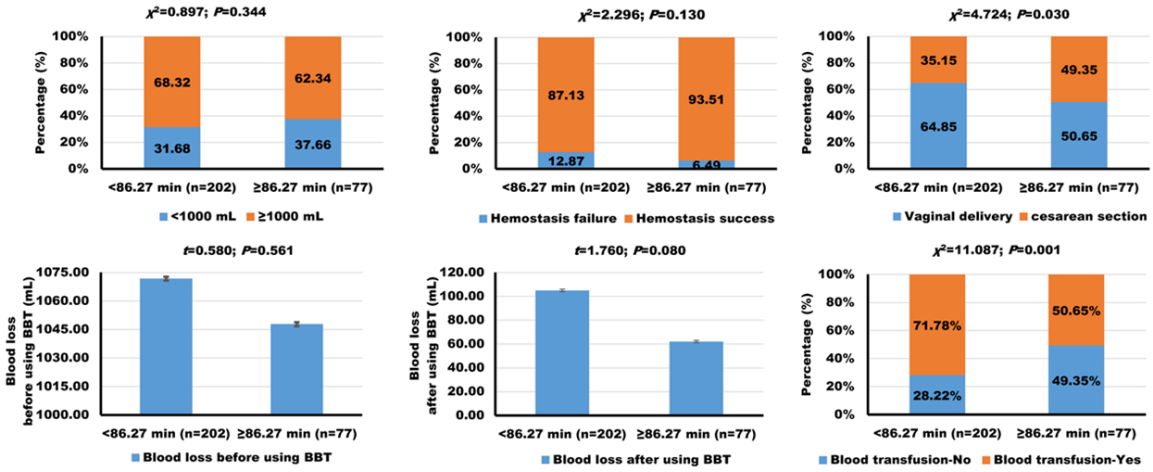

Figure 1. Influence of early usage of BBT.

the encouraged vaginal delivery policy in our hospital. The women with pre-BBT blood loss ≥1000 mL accounted for 66.67% (186/279), mostly underwent vaginal delivery (*P*=0.024), and had a higher rate of gestational hypertension (*P*=0.026) compared to women with pre-BBT blood loss <1000 mL. Notably, no significant difference was observed in uterine atony between the women with pre-BBT blood loss <1000 mL and ≥1000 mL (*P*=0.051). The main

Table 6. Analysis of the effect of interventional embolization after BBT in women with hemostasis failure

	UAE (n=27)	IIAE (n=4)	t/χ^2	*P*
Timing of BBT insertion (n, %)				
<86.27 min	22 (81.48)	4 (100)		
≥86.27 min	5 (18.52)	0 (0.00)	0.883	0.347
Delivery mode (n, %)				
Vaginal delivery	19 (70.37)	2 (50.00)		
cesarean section	8 (29.63)	2 (50.00)	0.662	0.416
Pre-BBT blood loss (Mean ± SD, mL)	1260.37±84.21	1050.00±95.74	0.937	0.356
Pre-BBT Blood loss (n, %)				
<1000 mL	7 (25.93)	1 (25.00)		
≥1000 mL	20 (74.07)	0 (75.00)	0.002	0.968
Post-BBT blood loss (Mean ± SD, mL)	425.93±81.66	357.5±189.23	0.304	0.763
Infused volume (Mean ± SD, mL)	439.63±8.89	385±29.86	2.134	0.041
Indwelling time (Mean ± SD, min)	226.59±34.97	754.00±399.97	-3.181	0.003
Blood transfusion (n, %)				
No	0 (0.00)	1 (25.00)	6.975	0.008
Yes	27 (100.00)	3 (75.00)		
Red blood cell (Mean ± SD, U)	5.83±0.63	3.13±1.05	1.599	0.121
Cryoprecipitate (Mean ± SD, U)	5.12±0.57	3.06±1.02	1.329	0.194
Plasma (Mean ± SD, mL)	516.67±65.99	337.50±117.92	1.003	0.324

BBT, Bakri balloon tamponade; UAE, uterine artery embolization; IIAE, internal iliac artery embolization; SD, standard deviation.

risk factors for PPH include uterine atony [18] and placenta accreta [19, 20], which support our findings. A previous study reported that 75-90% of PPH resulted from uterine atony [18], which may be caused by various etiologies, such as prolonged labor, uterine distension, prolonged use of oxytocin, exhaustion of the myometrium, placenta previa, and intrapartum or antepartum bleeding [21]. The placenta is often located across the lower uterine segment and the cervix, where hemorrhage commonly occurs [19, 20]. Variables from the univariate analysis with $P<0.1$ and variables that may affect blood loss before using BBT were analyzed in the logistic regression model. Our findings demonstrated that the delivery mode ($P=0.002$, OR=0.318) and uterine atony ($P=0.033$, OR=2.211) were independently associated with pre-BBT blood loss ≥1000 mL. In Ruiz Labarta's study, maternal age, history of cesarean section, cesarean delivery, anteriorly located placenta, placenta accreta, pre-pregnancy obesity, blood loss, transfusion of ≥7 red blood cell units and curettage before using BBT, long operation duration, and coagulopathy were independent factors for BBT failure [22]. Similarly, Liu *et al.* reported that multiple gestations, blood loss, and placenta accreta spectrum were independent risk factors for BBT failure [15]. Our results suggested that delivery mode and uterine atony may be the main causes of PPH in the present study, while some women may have multiple causes. The potential risk factors for PPH may not be confounding factors for the efficiency of BBT.

Perinatal outcomes in our study revealed that BBT showed high efficiency in stopping bleeding, with significant differences in pre-BBT blood loss ($P<0.001$) and no significant differences in post-BBT blood loss ($P=0.907$) between women with pre-BBT blood loss ≥1000 mL and <1000 mL. Blood transfusion was performed in 65.95% of cases, and significant differences were observed in women with blood loss ≥1000 mL and <1000 mL (80.11% *vs.* 37.63%; $P<0.001$). In contrast, Soltan *et al.* demonstrated that BBT was associated with significant reductions in blood transfusions, higher hemoglobin levels, duration in the intensive care unit, and hematocrit at discharge [23]. The high blood transfusion rate in our hospital may be due to the physical attributes of pregnant women and risk factors such as uterine atony. A blood transfusion may correlate

with massive hemostatic volume. The blood transfusion also improved the prognosis of the mother. As a vital procedure, interventional embolization treatment plays an important role in women with hemostasis failure [2]. In our further analysis, the majority of women with hemostasis failure (87.09%, 27/31) received UAE. Furthermore, 81.48% (22/27) of women had a time to BBT insertion of <86.27 min; and 74.07% (20/27) of cases had pre-BBT blood loss of ≥1000 mL. Our results indicated that massive bleeding mainly occurred in the early phase before using BBT, and hemodynamic instability emergencies may be due to hemostatic impairment. More women with UAE required blood transfusion. In addition, the infused volume was negatively correlated with indwelling time. A higher infusion volume and a shorter indwelling time were observed in UAE compared to IIAE, but no significant differences were observed compared to women without interventional embolization. The women who underwent IIAE had a 3 times longer indwelling time than those who underwent UAE (12.57 h *vs.* 3.78 h), with an average indwelling time of 4.91 h. Similarly, Dorkham *et al.* reported that all failures (6.08%, 18/296) occurred within 6 h of balloon insertion [24], which was consistent with our study. Therefore, BBT prolapse may lead to hemostasis failure. Usage of BBT improves hemodynamic stability in women with PPH and to undergo interventional embolization, which could successfully stop bleeding and reduce the need for a hysterectomy. The early usage of BBT in PPH could be effective in minimizing bleeding.

Despite the extensive usage of BBT around the world, controversial evidence has been reported concerning its efficacy [10, 14]. Notably, our findings supported that BBT was effective in controlling PPH. Similarly, D'Alton et al. demonstrated that BBT was a new rapid and effective treatment option for PPH or abnormal postpartum uterine bleeding, potentially preventing severe maternal morbidity and mortality [25]. This study was undertaken at 12 centers in the USA and showed a success rate of hemorrhage control in 94% (100/106, 95% CI 88-98%) of these participants. Most investigators would recommend BBT (97%) and reported it as easy to use (98%). In Gauchotte *et al.*'s study, the success rate of BBT was 92.1%, and BBT significantly reduced the need for interventional radiology or surgery for PPH [3]. The population-based retrospective cohort study performed by Revert *et al.* in France [26] included a total of 72,529 women from 19 maternity units. The use of BBT was associated with a significantly lower rate of invasive procedures for hemorrhage control among women undergoing vaginal delivery in routine clinical practice. In contrast, a randomized controlled trial (RCT) recruited 116 women from 7 healthcare facilities in France and revealed that BBT might be a harmful option for PPH due to increased case fatality rate (BBT group 10% *vs.* control group 2%; *P*=0.059) and increased risk of blood loss ≥1000 mL (relative risk 1.52, 95% CI 1.15-2.00, *P*=0.01) [27]. Moreover, a systematic review including 28 RCTs and observational studies from 2001 to 2018, proved BBT to be a less effective treatment for PPH after vaginal or cesarean delivery, and 1% (95% CI: 0-8%) of women who received BBT still had to undergo hysterectomy [10]. However, in a systematic review by Suarez *et al.*, conflicting evidence on BBT efficacy and effectiveness was observed across randomized and nonrandomized studies [14]. A cluster randomized trial reported that the frequency of PPH-related invasive procedures or maternal death was significantly higher after BBT introduction than before BBT introduction (11.6/10000 *vs.* 6.7/10000; *P*= 0.04). Conversely, a nonrandomized cluster study reported that the use of invasive procedures was significantly lower during the perinatal period with BBT compared to without BBT (3.0/1000 *vs.* 5.1/1000; *P*<0.01). The current study explored the effectiveness of BBT for PPH in 279 women in real-world settings, yielding a success rate of 88.89%. None required a postpartum hysterectomy. Our study was consistent with previous research, showing the beneficial effect of BBT on women with PPH, which may reduce surgical intervention.

The efficacy of BBT in treating PPH also varied greatly. Most early research works were case studies or case series studies, including only a few patients (2-18 patients). Since then, BBT has been advocated for postpartum bleeding management, with an effectiveness of 80-90% [28-30]. With the advances in science and technology, BBT usage is being increasingly widespread. In Richelle Olsen's study, the effec-

tiveness of BBT for PPH between 2008 and 2010 was 67.57% (25/37) [16]. In Laas's study in 2012, BBT was described as an attractive adjunctive strategy for the prevention of invasive procedures and to achieve hemostasis in intractable hemorrhages. The results indicated a global success rate of 86% (37/43) [31]. In 2020, a meta-analysis by Suarez *et al.* included 4,729 women from 91 studies (7 RCTs, 14 non-randomized studies and 70 case series) and showed a BBT efficiency of 85.9% (95% CI, 83.9-87.9%) [14]. In women with placenta accreta and increta, the success rate of the BBT was reported as 84.21% [32]. The studies investigating BBT efficiency in the Chinese population were searched, identifying a retrospective case series, two retrospective cohort studies, and a prospective multicenter cohort study. In Hong Kong, a retrospective case series in 2013 reported a success rate of 79% (15/19) [33]. Another retrospective study recruited 305 cases of PPH from the International Peace Maternal and Child Health Hospital of China Welfare Institution in Shanghai, China [34]. BBT showed an overall success rate of 93.26%, with the Bakri balloon alone being 87.3% (124 of 142). The other retrospective cohort study included 106 women with severe PPH from 14 representative hospitals across 10 provinces in China, and BBT revealed an overall success rate of 70.8% (75/106) [15]. In addition, a large prospective multicenter cohort study in Guangdong, China, was conducted, in which the Bakri balloon showed a clinical efficacy rate of 91.65% (373/407 women) [35]. In our hospital, a protocol for controlling postpartum bleeding using BBT has been established since its introduction, and the use of BBT has been standardized. As expected, the efficacy was comparable to the results of previous studies, which can be attributed to local compression pressure induced by BBT on the vasculature of the placental bed [36]. The disparity in the results may be due to the heterogeneity of the subjects, such as indications and context for BBT and the inconsistency in clinical practice. Thus, more studies are required to strengthen the evidence.

The time to BBT insertion may greatly influence the perinatal outcomes. Furthermore, we preliminarily explored the influence of early usage of BBT on the delivery mode, hemostasis, pre/post-BBT blood loss volume, and blood transfusion. All subjects were divided based on the timing of balloon insertion into the <86.27 min group (n=202) and the ≥86.27 min group (n=77). Interesting results were observed. Significant differences were observed in the delivery mode and blood transfusion between the two subgroups. The women who received balloon insertion before 86.27 min presented a lower rate of cesarean section (35.15%) and a higher rate of blood transfusion (71.87%). Therefore, women with more severe symptoms may benefit from early BBT to avoid a cesarean section. However, the blood loss volume in vaginal delivery was not necessarily less than in cesarean section. 64.85% (131/202) of the women who had a vaginal delivery received balloon insertion before 86.27 min, and 74.05% (97/131) had blood loss ≥1000 mL. Early BBT usage may improve the hemostasis success rate. The two subgroups revealed a similar rate of hemostasis. Similarly, Gao *et al.* reported that early BBT usage combined with a rapid diagnosis of PPH showed higher effectiveness [35], which supported our conclusion.

Nevertheless, the limitations of this study should be acknowledged. The women were all recruited from a single center in China and the sample size is relatively small. Large multicenter prospective cohort studies are required to confirm the results. Although BBT has been authorized for using PPH management in China since 2012, our hospital works as a top tier specialty hospital, and have formulated a delicate and practical scheme for postpartum bleeding since the introduction of BBT in 2016. We believe that our findings represent the real-world use of BBT and provide additional evidence for its application in controlling PPH. However, further studies are required to investigate the correlations between the efficiency and independent predictors, such as different delivery modes, Bakri failure, the timing of balloon insertion, and severe PPH.

In summary, BBT is an effective and safe treatment method for PPH, especially in women with more blood loss before using BBT. Early BBT usage should be considered in those with severe maternal conditions. The current research investigated the real-world performance of BBT in women with PPH, highlighting its application in clinical practice.

Disclosure of conflict of interest

None.

Address correspondence to: Na Zhang, Department of Obstetric, Maternal and Child Health Hospital of Hubei Province, Tongji Medical College, Huazhong University of Science and Technology, No. 745, Wu Luo Road, Hongshan District, Wuhan 430070, Hubei, P. R. China. Tel: +86-18162670563; Fax: +86-027-87882324; E-mail: zn20180126kk@163.com

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