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Bakri Balloon for Treatment of Postpartum Hemorrhage: A Real-World 2016-2020 Study in 279 Women from a Single Center

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Background: Postpartum hemorrhage (PPH) may be primary or secondary and is defined as the loss of 500 ml or more of blood within the first 24 h after birth. The Bakri balloon tamponade (BBT) is an intrauterine device used as an adjunctive treatment for refractory PPH. The aim of this study was to present the real-world experience from a single center on the effectiveness of the BBT for the treatment of PPH.

Material/Methods: This cohort study of 279 women was conducted in a real-world setting. Patients' characteristics and clinical outcomes between the BBT Success group and BBT Failure group were analyzed by *t* test or chi-square test. The primary outcome was the success rate of BBT. The secondary outcomes were the perinatal outcomes.

Results: The success rate of BBT was 88.89% (248/279). A blood transfusion rate of 65.95% (184/279) was observed. After using the BBT, significant differences were observed in intervention ($P<0.001$), blood loss ($P<0.001$), in-dwelling time of BBT ($P<0.001$), and blood transfusion ($P<0.001$) between the Success group and Failure group. The Success group showed greater range of descent in blood loss (991.56.15±13.65 mL in Success group vs 816.23±7.57 mL in Failure group). Of the 31 women with BBT failure, 87.10% (27/31) received uterine artery embolization (UAE), 96.77% (30/31) received blood transfusion, and none required a hysterectomy.

Conclusions: The findings from this study from a single center in China supported those from previous studies showing that the BBT was an effective treatment to control PPH.

Keywords: Postpartum Hemorrhage • Uterine Balloon Tamponade • Postpartum Period

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Background

Postpartum hemorrhage (PPH) is still a leading cause of maternal morbidity and mortality [1], accounting for over 2.5% of maternal deaths worldwide [2]. Various risk factors were reported for PPH, such as cesarean delivery [3] and placenta accreta [4]. Uterine atony, soft-tissues injury associated with the birth canal, and placental factors such as placenta previa are considered as the most common reasons for PPH [5]. A higher prevalence of PPH is reported in undeveloped or low-income countries than in developed or high-income countries [6]. A peripartum hysterectomy may be inevitable in case of severe PPH and showed great harm to the parturient, including loss of fertility, and high morbidity was proved to be closely associated with peripartum hysterectomies [7]. Therefore, it is still essential to explore a safer and more effective method to reduce the application of hysterectomies.

To date, various conservative procedures have been developed to control PPH. The Bakri balloon tamponade (BBT) has been recommended by the American College of Obstetricians and Gynecologists (ACOG) and WHO as a second-line conservative treatment for PPH [8]. The criteria for use of uterine tamponade were: during cesarean section and after intraoperative uterine massage and use of an uterotonic such as oxytocin and carboprost tromethamine, the presence of persistent active uterine bleeding or an amount of bleeding that reached a volume of 500 mL, and the initial treatment of PPH is usually uterotonic drugs such as oxytocin and prostaglandin. Compared with other conserving interventions, such as arterial ligation, uterine artery embolization (UAE), B-lynch compression sutures, and uterine packing, BBT requires minimal local resources and does not entail extensive training or complex equipment; it showed high effectiveness and kept the mother's ability to bear additional children [9]. The balloon (a maximum volume of 500 mL) was inserted either transvaginally after vaginal delivery or transvaginally/transabdominally after cesarean delivery, and it was removed from the uterine cavity within 24 h. We sutured the uterine incision and carefully avoided puncturing the balloon. Ultrasonography was used to monitor its intrauterine position. A fluid collection bag connected to the BBT was used to monitor bleeding from the uterine cavity. The posterior fornix of the vagina can be packed with gauze to prevent the balloon from falling off. Although the efficacy and effectiveness of BBT has been intensively studied, conflicting evidence has also been reported [10]. Said Ali et al reviewed 28 articles and reported that BBT may be a less effective tool for management of PPH after vaginal or cesarean delivery [8]. The BBT proved an effective adjunct in management of refractory PPH, and postpartum bleeding was controlled without further surgical intervention in 95% of women, even those with uterine atony [11]. Moreover, knowledge about use of the BBT in the Chinese population with postpartum bleeding is limited and there is a lack of information on its effectiveness in real-world settings.

Therefore, the aim of this study was to present the real-world experience from a single center on the effectiveness of the BBT for the treatment of PPH in 279 women.

Material and Methods

Ethics Approval

All procedures performed in the study were approved by the Ethics Committee of Maternal and Child Health hospital of Hubei Province (IEM XM073) and conformed to the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Written or orally informed consents were obtained from all patients to participate in the study.

Study Subjects

A real-world database containing electronic health record data was established. A total of 279 eligible puerpera with postpartum bleeding who failed to respond to the first-line conservative management (the routine protocol for PPH) and received BBT (Cook Medical, Spencer, IN, USA) in the cohort study were recruited from January 2016 to December 2020. All eligible women were enrolled in the study if they met the following criteria. Inclusion criteria were: 1) age ≥18 years old; 2) a gestation age of ≥28 weeks; 3) received the BBT; 4) failed first-line conservative management. Exclusion criteria were: 1) those with uterine fibroids; 2) those with malignant tumors; 3) pelvic infections; 4) those with communication disorders; 5) those with abortion; 6) data obvious exceptions in the records.

Clinical Data Collection

The maternal clinical characteristics of all pregnant women recruited were collected, including weight, gestational age, maternal age, parity, delivery mode (vaginal delivery and cesarean delivery), birth number, repeat cesarean section, gestational diabetes, gestational hypertension, uterine atony, placenta accrete, abnormal coagulation, placenta previa, preeclampsia. postpartum bleeding management and perinatal outcomes, such as balloon placement method, uterine contractions, suture method before using the BBT, lower genital tract trauma, intervention after using the BBT, infused volume, indwelling time, blood loss and transfusion, and perinatal complications. All data in the records were anonymized and de-identified before analysis.

Clinical Outcome Measures

The primary outcome was the success rate of BBT. If the postpartum bleeding was stopped utilizing only the BBT and no further surgical interventions were involved, "BBT success"

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was achieved. If the BBT failed to control the bleeding, a UAE, internal iliac artery embolization (IIAE), or hysterectomy was immediately performed.

The secondary outcomes were the perinatal outcomes between the BBT Success group and BBT Failure group, the effect of delivery methods, interventional embolization on postpartum bleeding after using the BBT on perinatal outcomes, such as blood loss, and transfusion.

Statistical Analysis

All analyses were performed using SPSS version 23.0 (IBM Corp, Armonk, NY). Categorical data were combined to obtain frequencies and percentages, while continuous data are presented as means±standard deviation (SD). Continuous data between 2 groups were analyzed for statistically significant differences using the *t* test (2-sided). Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. A *P* value of <0.05 was considered to be statistically significant.

Results

Baseline Characteristics and Primary Outcome Analysis

A total of 279 pregnant women using BBT were finally recruited in the study. Analysis of primary outcome revealed that the success rate of BBT was 88.89% (248/279, **Table 1**). Further analysis of baseline characteristics between the Failure group and Success group demonstrated no significant differences in parameters such as, weight, gestational age, maternal age, parity, delivery mode, and past medical history (all *P*>0.05).

Comparison of Perinatal Outcomes Between Failure Group and Success Group

The perinatal outcomes between the Failure group and Success group were compared (**Table 2**). The time between delivery and BBT insertion was 60.74±17.03 min in the Failure group and 89.46±9.51 min in the Success group. No significant differences were observed in time between delivery/insertion (*P*=0.300), different balloon placement method (*P*=0.670), using uterine contractions (*P*=0.367), or lower genital tract trauma (*P*=0.810). Between women with blood loss >1000 mL (n=186) and <1000 mL (n=93), BBT showed a similar effectiveness in control of bleeding (*P*=0.346). A total of 184 (65.95%) women received blood transfusion and no women required a hysterectomy. In the Failure group, the overwhelming majority (30/31; 96.77%) required blood transfusion, and there were 27 women who received UAE accounting for 87.10% (27/31) and 4 women received IIAE, accounting for 12.90% (4/31).

Significant differences were observed in blood loss before using the BBT, different suture method before using the BBT, intervention after using the BBT, blood loss after using the BBT, and indwelling time of BBT, blood transfusion (red blood cell, cryoprecipitate, plasma) between the Failure group and Success group (all *P*<0.01) The indwelling time of the balloon was significantly shorter in the Failure group than in the Success group (294.65±63.48 min vs 1071.94±23.88 min; *P*<0.01). Compared with the Failure group, the blood loss volumes were significantly lower in the Success group whether before using the BBT (1233.23±75.08 mL vs 1044.15±18.06 mL, *P*<0.01) or after using the BBT (417.10±74.25 mL vs 52.64±3.03 mL, *P*<0.01). Although the blood loss before and after using the BBT in the Failure group was greater than in the Success group, the Success group showed greater range of decrease in blood loss (991.56.15±13.65 mL in Success group vs 816.23±7.57 mL in Failure group). As expected, the proportion of patients receiving a blood transfusion was higher in the Failure group (30/31, 96.77%) than in the Success group (154/248, 62.10%) (*P*<0.01). The transfusion volumes of red blood cells, cryoprecipitate, and plasma were all higher in the Failure group than in the Success group (5.48±0.58 U vs 1.98±012 U, *P*<0.01; 4.85±0.53 U vs 1.37±0.12 U, *P*<0.01; 493.55±59.87 mL vs 148.19±12.67 mL, *P*<0.01), respectively.

Comparison of Perinatal Complications Between Failure Group and Success Group

Analysis of perinatal complications showed postoperative fever in 1 patient in each group (**Table 2**). The difference showed no significance (*P*=0.079).

Discussion

Currently, PPH is still the leading cause of maternal mortality and morbidity worldwide. In our study, we present the real-world experience from a single center on the effectiveness of the BBT for the treatment of PPH. BBT showed a success rate of 88.89% (248/279) and a failure rate of 11.11% (31/279). A total blood transfusion rate of 65.95% (184/279) was observed, accounting for 62.10% (154/248) in the Success group and 96.77% (30/31) in the Failure group. After using the BBT, significant differences were observed in intervention (*P*<0.001), blood loss (*P*<0.001), indwelling time of BBT (*P*<0.001), and blood transfusion (*P*<0.001) between the Success group and Failure group. The Success group showed greater range of decrease in blood loss (991.56.15±13.65 mL in Success group vs 816.23±7.57 mL in Failure group). Of the 31 women with BBT failure, 87.10% (27/31) received UAE, 96.77% (30/31) of women received blood transfusion, and no women required a hysterectomy.

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Table 1. Comparison of patients' characteristics between Failure group and Success group.

	Failure group (n=31)	Success group (n=248)	t/χ^2	*P*
Weight (mean±SD, kg)	70.15±1.57	71.97±0.66	-0.937	0.350
Gestational age (mean±SD, w)	39.08±0.51	39.03±0.12	0.147	0.883
Maternal age (n, %)				
18-25 year	3 (9.68)	29 (11.69)	3.085	0.080
25-35 year	25 (80.64)	174 (70.16)		
≥35 year	3 (9.68)	45 (18.15)		
Parity (n, %)				
Primipara	24 (77.42)	168 (67.74)	1.203	0.273
Multipara	7 (22.58)	80 (32.26)		
Delivery mode (n, %)				
Vaginal delivery	21 (67.74)	149 (60.08)	0.679	0.410
Cesarean section	10 (32.26)	99 (39.92)		
Birth number (n, %)				
Single births	29 (93.55)	235 (94.76)	0.079	0.778
Multiple births	2 (6.45)	13 (5.24)		
Repeat cesarean section (n, %)				
No	31 (1)	234 (94.35)	1.842	0.175
Yes	0 (0.00)	14 (5.65)		
Gestational diabetes (n, %)				
No	31 (1)	243 (97.98)	0.636	0.425
Yes	0 (0.00)	5 (2.02)		
Gestational hypertension (n, %)				
No	29 (93.55)	241 (97.18)	1.163	0.281
Yes	2 (6.45)	7 (2.82)		
Uterine atony (n, %)				
No	7 (22.58)	63 (25.40)	0.117	0.733
Yes	24 (77.42)	185 (74.60)		
Placenta accreta (n, %)				
No	12 (38.71)	119 (47.98)	0.952	0.329
Yes	19 (61.29)	129 (52.02)		
Abnormal coagulation (n, %)				
No	30 (96.77)	244 (98.39)	0.407	0.523
Yes	1 (3.23)	4 (1.61)		
Placenta previa (n, %)				
No	31 (1)	238 (95.97)	1.296	0.255
Yes	0 (0.00)	10 (4.03)		

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Table 1 continued. Comparison of patients' characteristics between Failure group and Success group.

	Failure group (n=31)	Success group (n=248)	t/χ^2	P
Preeclampsia (n, %)				
No	29 (93.55)	242 (97.58)	1.609	0.205
Yes	2 (6.45)	6 (2.42)		

SD – standard deviation.

Table 2. Comparison of perinatal outcomes between Failure group and Success group.

	Failure group (n=31)	Success group (n=248)	t/χ^2	P
Time between delivery/insertion (mean±SD, min)	60.74±17.03	89.46±9.51	-1.041	0.299
Blood loss before using the Bakri balloon (mean±SD, ml)	1233.23±75.08	1044.15±18.06	3.289	0.001
Control bleeding (n, %)				
<1000 mL	8 (8.60)	85 (91.40)	0.889	0.346
>1000 mL	23 (12.37)	163 (87.63)		
Balloon placement method (n, %)				
Transvaginally	24 (77.42)	200 (80.65)	0.181	0.670
Transabdominally	7 (22.58)	48 (19.35)		
Uterine contractions (n, %)				
No	30 (96.77)	229 (92.34)	0.815	0.367
Yes	1 (3.23)	19 (7.66)		
Suture method before using the Bakri balloon (n, %)				
No	16 (51.6)	207 (83.47)	110.061	0.000
UAE	14 (45.16)	1 (0.40)		
"8" suture	0 (0.00)	16 (6.45)		
Arterial ligation	1 (3.23)	9 (3.63)		
"8" suture + arterial ligation	0 (0.00)	7 (2.82)		
Other	0 (0.00)	8 (3.23)		
Lower genital tract trauma (n, %)				
No	29 (93.55)	229 (92.34)	0.058	0.810
Yes	2 (6.45)	19 (7.66)		
Intervention after using the Bakri balloon (n, %)				
No	0 (0.00)	248 (100.00)	279.000	0.000
UAE	27 (87.10)	0 (0.00)		
IIAE	4 (12.90)	0 (0.00)		
Blood loss after using the Bakri balloon (mean±SD, ml)	417.10±74.25	52.64±3.03	13.348	0.000

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Table 2 continued. Comparison of perinatal outcomes between Failure group and Success group.

	Failure group (n=31)	Success group (n=248)	t/χ^2	*P*
Infused volume (mean±SD, ml)	432.58±9.08	412.49±4.12	1.667	0.000
Indwelling time (mean±SD, min)	294.65±63.48	1071.94±23.88	-10.923	0.000
Blood transfusion (n, %)				
No	1 (3.23)	94 (37.90)	14.756	0.000
Yes	30 (96.77)	154 (62.10)		
Red blood cell, RBC (mean±SD, U)	5.48±0.58	1.98±012	8.999	0.000
Cryoprecipitate (mean±SD, U)	4.85±0.53	1.37±0.12	8.818	0.000
Plasma (mean±SD, ml)	493.55±59.87	148.19±12.67	8.316	0.000
Perinatal complications (n, %)				
No	30 (96.77)	247 (99.60)	3.085	0.079
Yes	1 (3.23)	1 (0.40)		

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

So far, the available data on BBT in controlling PPH are inconclusive. Our results support those from previous studies, showing that the BBT was an effective treatment to control PPH from a single center in China.

In Olsen's study [12], BBT effectiveness for PPH with a "real-world experience" was explored in 35 women, and the success rate of the BBT at their institutions was 67.57% (25/37). BBT failure was associated with cesarean section (67% vs 16%, *P*=0.031) and predelivery Pitocin (67% vs 28%, *P*=0.003), and had more ICU admissions (58% vs 4%, *P*=0.0003), transfusions (5.4 red blood cell units vs 1.6, *P*=0.007) and hospital days (5.65 vs 3.75, *P*=0.011). In the Failure patients, the maximum balloon capacity did not stop continued bleeding in 50% cases, including 16% with a balloon out of the uterus and 34% with unclear cause of failure. The most common problems related to BBT failure are continued atony, extrusion of the balloon, and continued bleeding after BBT (suggesting inadequate filling of the uterine cavity).

Conversely, a randomized controlled trial (RCT) by Dumont et al [13] included 116 women from 7 healthcare facilities and showed that BBT may be harmful due to increased risk of blood loss more than 1000 mL and increased case fatality rate. The proportion of women with invasive surgery or who died before hospital discharge did not differ significantly between the BBT arm (16%; 9/57) and the standard second-line treatment arm (7%; 4/59): relative risk 2.33 (95% CI 0.76 to 7.14, *P*=0.238). A significantly increased proportion of women with BBT and misoprostol versus misoprostol alone had total blood loss more than 1000 mL: relative risk 1.52 (95% CI 1.15 to 2.00, *P*=0.01). Case fatality rate was higher in the BBT group (10%; 6/57) than in the control group (2%; 1/59) (*P*=0.059).

In a systematic review by Said Ali et al [8], the safety and effectiveness of BBT in the management of PPH were assessed. Twenty-eight articles for RCTs and observational studies from 2001 to 2018 were included. The study found BBT seemed to be a less effective tool for management of PPH either after vaginal or cesarean delivery. Only 67.9% (19/28) quantified the estimate blood loss necessary to use the BBT. Most of the studies on BBT are followed by vaginal birth (3/4). BBT displacement from the uterine cavity was reported by 5 publications, with the overall rate being 9% (95% CI: 5-15%). Hysterectomy was necessary for 1% (95% CI: 0-8%) of the women who required the BBT.

In a systematic review and meta-analysis by Suarez S et al [10], 91 studies that included 4,729 women met the required inclusion criteria. These studies included 6 randomized trials, one randomized cluster trial, 15 non-randomized clinical studies, and 69 clinical case series [10]. The findings demonstrated that BBT has a high success rate for treating severe PPH and appears to be safe. The overall pooled BBT success rate was 85.9% (95% confidence interval, 83.9-87.9%). The success rates corresponded to uterine atony (87.1%) and placenta previa (86.8%), and to placenta accreta spectrum (66.7%) and retained products of conception (76.8%), respectively. The BBT success rate was lower in cesarean deliveries (81.7%) than in vaginal deliveries (87.0%). However, in contrast with observational studies, the evidence on BBT efficacy and effectiveness

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from randomized and nonrandomized studies is conflicting, with experimental studies suggesting no beneficial effect.

In the current single-center study in China, our findings demonstrated that BBT effectively stops bleeding, and the effectiveness is comparable to the results of previous studies cited above and may be achieved by local compression pressure induced by BBT on the vasculature of the placental bed [14]. Similarly, in most studies, BBT showed beneficial effects in women with PPH, which may reduce the need for surgical interventions and arterial embolization after vaginal delivery [15,16]. The success rate of BBT has been reported to vary greatly, ranging from 67.57% to 93.26%. An 86% global success rate of BBT was reported by Laas [17] and another study reported 70.8% [18]. In earlier studies, few patients (2-18 patients) were included and BBT has been advocated for management of obstetric hemorrhage, with its effectiveness at 80-90% [19-21]. In women with placenta accreta and increta, the success rate of the BBT was 84.21% [22]. In our hospital, the use of BBT is more active and BBT showed an overall efficacy rate of 88.89% (248/279).

The efficacy of BBT is controversial [8,10], and there are only 3 reports in the Chinese population, which are consistent with our conclusion that BBT is an effective treatment to control PPH.

In a retrospective study by Guo Y et al [23], 305 cases with PPH from the International Peace Maternal and Child Health Hospital of China Welfare Institution in Shanghai, China were recruited. BBT showed an overall success rate of 93.26%, and the BBT alone was 87.3% (124/142). BBT combined with vaginal tamponade and abdominal compression is more effective in the treatment of PPH compared with BBT alone. None of the cases resulted in a hysterectomy.

In Hong Kong, a retrospective case series by Kong [24] included 19 cases with severe PPH. An overall success rate of 79% (15/19) was reported. Hysterectomy was avoided in 2 patients who received UAE and 2 patients with BBT failure underwent hysterectomy.

In a large prospective observational multicenter cohort study conducted in Guangdong, China, by Wang et al [25], BBT showed a clinical efficacy rate of 91.65% (373/407 women). The finding demonstrated that early use of the BBT is more effective for the management of PPH. The blood loss before and after BBT were significantly higher in the BBT Failure group (1700±1429.88 mL before and 1209.58±1139.72 mL after using the balloon) than those in the BBT Success group [918±493.92 mL before (P=0.002) and 266.57±361.60 mL after using the balloon (P=0.001)].

Further, we analyzed the characteristics between the Success and the Failure group women. As previously reported, uterine atony and placenta accrete were still the main causes of hemorrhage. The first BBT was designed by Bakri for PPH treatment due to low-lying placenta and placenta previa [19]. In women with placenta accreta, the placenta is often located across the cervix and lower uterine segment, where the bleeding most commonly occurs [26,27]. A review by Wright revealed that uterine atony was specified as the underlying etiology of postpartum hemorrhage in 75% (9/12) of publications [28]. In our study, the women with uterine atony or placenta accrete accounted for 77.42% (24/31), 61.29% (19/31) in the Failure group and 74.60% (185/248), 52.02% (129/248) in the Success group, respectively. Few women with placenta previa were recruited. Notable findings showed no significant differences in parameters such as gestational diabetes, gestational hypertension, uterine atony, placenta accrete, abnormal coagulation, placenta previa, or preeclampsia between the Failure group and Success group. The results suggest the potential risk factors for PPH may not be the confounding factors for the efficacy of BBT.

Analysis of perinatal outcomes before using the BBT revealed that blood loss and UAE rate in the Failure group were significantly higher than in the Success group. After using the BBT, more blood loss, more blood transfusion, and shorter indwelling time were observed in the Failure group. The results suggested that urgent hemodynamic instability was more common in the Failure group than in the Success group, and balloon prolapse was untenable for BBT failure. The massive bleeding occurring in the early phase after birth may be due to hemostatic impairment before balloon insertion, thus leading to the more blood loss and hemostasis achievement after balloon insertion. Increasing infusion volume of the balloon may not be effective in stopping bleeding. Interestingly, our findings above were consistent with the prospective, observational multicenter clinical study in South China cited above [14]. In addition, an increase in the rate of UAE and a decrease in the rate of "8" suture/arterial ligation were also observed in patients of the Failure group. A total of 45.16% (14/29) women received UAE before Bakri insertion and 87.10% (14/29) after Bakri insertion; 64.29% (9/14) of women with placenta accrete immediately received UAE, and no case required postpartum hysterectomy. It was also noted that women with IIAE had longer indwelling time (3.33 times) and received less red blood cells (53.68%) than women with UAE. Our findings suggest that the temporizing measure may reduce unnecessary surgical interventions, such as hysterectomy. BBT makes it possible to empower enough hemodynamic stability to undergo UAE in women with PPH. An alternative explain may be due to the placental retention resulting in more blood loss, making UAE inevitable. Thus, it is important to simulate the real situation in advance in order to start the rapid plan (rapid BBT insertion or an additional hemostatic procedure) to minimize bleeding.

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Use of BBT was associated with a significant decrease in mean blood loss. In our study, the blood loss before and after balloon insertion in the Failure group were both significantly more than those in the BBT success group. The opposite result was observed in indwelling time in the 2 groups; similar result showed in women with different interventional embolization, suggesting that the indwelling time and blood loss are potential factors in evaluating the efficiency. More studies are needed. Hemostatic volume in the Success group was greater than in the Failure group. Further analysis showed that hemostatic volume in women with blood loss >1000 mL was greater than in women with the blood loss ≤1000 mL, and hemostatic volume in women with vaginal delivery was greater than in women with cesarean delivery. Soltan showed that BBT was associated with significant reductions in blood transfusions and intensive care unit length of stay, and increased hemoglobin and hematocrit at discharge [29]. In our study, a blood transfusion rate of 65.95% was observed, including the Failure group (30/31, 96.77%) and Success group (154/248, 62.10%). The high blood transfusion may be due to physical fitness and risk factors such as uterine atony and placenta accrete. Blood transfusion may correlate with the massive hemostatic volume and have nothing to do with delivery mode. A systematic review demonstrated BBT is a less effective tool for management of postpartum hemorrhage after vaginal or cesarean delivery [8], which supports our conclusions. Our findings show that the BBT has great advantages in stopping bleeding among women with massive blood loss.

Limitations

There are several limits in our study. The subjects are all from our single center, and the sample size was relatively small for a cohort study. BBT has been authorized for use in PPH management in China since 2012, and was introduced in our hospital in 2016. However, we believe that our study shows the real-world use status of BBT in women with postpartum bleeding in China. Further research is needed to assess correlations of the efficacy with independent predictors for BBT failure and different delivery modes.

Conclusions

The findings from this study from a single center in China supported those from previous studies, which showed that the BBT was an effective treatment to control PPH. The current research expands the knowledge about women with postpartum bleeding to better guide the clinical use of BBT in real-world settings.

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