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An alternative method of Bakri balloon placement for postpartum hemorrhage after vaginal delivery

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ABSTRACT

Objectives: We developed a new Bakri balloon tamponade (BBT) placement technique after vaginal delivery, which aimed to be faster without balloon slippage. This study compared the new method with standard placement of BBT in women with postpartum hemorrhage (PPH) after vaginal delivery.

Material and methods: This study was undertaken of women who underwent vaginal delivery at the obstetrics and gynecology departments of the Hospital of Chengdu University of Traditional Chinese Medicine, Sichuan Provincial Hospital for Women and Children, and Si Chuan JINXIN Women and Children Hospital between January 2014 and December 2020. Women who underwent BBT for PPH were grouped according to placement method into the old-BBT group and the new-BBT group.

Results: Of 20487 childbirths by vaginal delivery, 512 (2.50%) had PPH, 77 women underwent BBT (old-BBT n = 28, new-BBT n = 49). Background characteristics were similar except prothrombin time (PT, $p < 0.01$) and activated partial thromboplastin time (APTT, $p < 0.004$) were lower in the new-BBT group than the old-BBT group. The operation time was shorter in the new-BBT group ($p < 0.001$) with less bleeding ($p < 0.003$) and saline injection ($p < 0.001$). A balloon slippage was less likely ($p < 0.008$) and postoperative bleeding ($p < 0.01$), transfusion rate ($p < 0.03$), transfusion volume ($p < 0.002$), and hospital stay was lower in the new-BBT group ($p < 0.015$). Multivariate analysis suggested PT (OR = 0.039, 95% CI: 0.002–0.730, $p < 0.030$), international normalized ratio (OR = 8.244, 95% CI: 3.807–17.850, $p < 0.009$), and BBT method (OR = 5.200, 95% CI: 1.745-15.493, $p < 0.003$), were associated with requiring a blood transfusion.

Conclusions: This method of BBT placement reduced operation time, balloon slippage, bleeding, and hospital stay in women with PPH after vaginal delivery.

Keywords: postpartum hemorrhage; bakri balloon tamponade; vaginal delivery; retrospective study; balloon slippage

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INTRODUCTION

Despite advances in medical and surgical therapies, obstetrical hemorrhage remains the leading causes of maternal death. The most common obstetrical hemorrhage is postpartum hemorrhage (PPH) [1–5]. It is estimated that more than 125 000 women worldwide die every year because of obstetric hemorrhage [6], and 77-90% of these casualties are the result of uterine atony. Other causes of primary PPH include lacerations, retained placenta, abnormally adherent placenta, and coagulation defects [7]. A history of PPH, history of retained placenta, placental abruption, placenta previa, uterine fibroids, hydramnios, multiple pregnancies, augmentation of labor, prolonged labor, and instrumental delivery are all risk factors of PPH [8].

At present, the first-line treatments of PPH are uterine massage and conservative management with uterotonic agents. While uterine packing, external compression with uterine sutures, selective devascularization by ligation, and embolization of the uterine artery are employed as second-line treatments. Hysterectomy must be taken into

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account if conservative management has failed to stop bleeding [9, 10]. An intrauterine balloon tamponade is a timely and effective method that has been widely used in the management of PPH as a second-line treatment [11, 12].

Several types of balloon catheters have been approved by the US Food and Drug Administration (FDA) for clinical use [13]. The Bakri balloon tamponade (BBT), which was first reported in 1991, has gained the most popularity. With a number of subsequent publications, it has demonstrated efficacy and safety [14, 15]. However, in our clinical experience difficulties with placement and slippage of the balloon have not been completely overcome, especially after vaginal delivery. In related literature [16–19], improved methods, such as "holding the cervix", "placing the gauze piece transvaginally", have been discussed but those reports have not systematically and strictly regulated the procedure. Furthermore, most reports involve patients after cesarean delivery and there is an absence of recent reports on BBT after vaginal delivery.

Objectives

In this paper, we describe a new BBT placement technique after vaginal delivery, which we developed in our hospital because it took less time for placement and avoided balloon slippage.

MATERIAL AND METHODS

Patients

A retrospective study was undertaken of all deliveries in the obstetrics and gynecology departments of the Hospital of Chengdu University of Traditional Chinese Medicine, Sichuan Provincial Hospital for Women and Children, and Si Chuan JINXIN Women and Children Hospital from January 2014–December 2020. Patients were included in the study according to the following criteria 1) patients undergoing (attempted) BBT for primary PPH after vaginal delivery 2) delivery was between January 2014 and December 2020 in the obstetrics and gynecology department, Sichuan Provincial Hospital for Women and Children. The exclusion criteria were: 1) cesarean delivery, 2) secondary PPH.

Primary PPH was defined as blood loss > 500 mL after vaginal delivery or > 1,000 mL after cesarean section within 24 hours after delivery.

This study was approved by the Ethics Committee of Si Chuan Provincial Hospital for Women and Children. The use of the procedure was approved by the institutional ethics committee. All the women signed a written informed consent form before their operation.

Study design

We placed BBT with the original method between 2014 and 2016 and then used the revised method from 2017. Therefore, the women were grouped according to when they underwent BBT into the old-BBT group, for those from 2014 to 2016, and the new-BBT group, for those from 2017 to 2020. The inclusion of women in the study is shown in the flow diagram in Figure 1.

BBT placement methods

The original BBT placement method placed the balloon in the fundus of the uterus, without clamping the cervix nor placing the gauze piece. The Bakri intrauterine balloon (Cook Medical Incorporated, Bloomington, IN, USA) is a 24F, 54-cm-long silicone catheter with a balloon (a stated capacity: 500 mL). The shaft tip has two outlets for drainage, which allows an ongoing hemorrhage to be diagnosed after insertion of the balloon. It can be easily deflated and removed from the vagina once PPH has been managed. It can be placed in the uterine fundus through the vagina or abdominally (at time of cesarean section) [20–22]. The balloon is filled with sterile liquid by using the infusion port or syringe [23].

The new method placed the balloon in the lower segment of uterus in vaginal delivery, clamping the cervix and placing gauze in all cases. This process involved 7 steps: Step 1, the uterus neck was clamped at the 9 o'clock position by pincers after cervical lacerations had been examined. Step 2, the uterine balloon tamponade was placed ensuring that the lower margin was 2 centimeters away from the external cervix. Step 3, the uterus neck was clamped at the 3 o 'clock position with pincers (Fig. 2A). Step 4, sterile saline was injected into the balloon (110–300 mL) inside the uterine cavity. At the same time, ultrasound was used to view the position of the balloon. The use of sterile saline depended upon the actual situation of vaginal bleeding (Fig. 2B–E). Step 5, a piece of gauze (20 × 30 cm, four layers) was placed at the frontier and posterior fornix respectively, observing active bleeding outside the cervix by ultrasound for 10 minutes after sterile saline infusion (Fig. 2F). Step 6, the cervical pliers were removed carefully if there was no active bleeding. Step 7, vaginal bleeding and balloon catheter bleeding were monitored for 2 hours. If no active hemorrhage was observed, the catheter was reserved. The patient was moved from the delivery room to the ward. Ultrasound was used in the whole process of placing uterine balloon tamponade to determine the position of the balloon in the uterus.

Clinical data collection

Data was collected from the medical records of the women included in the study including age, body mass index (BMI), gestational weeks at delivery, birth history, fetal weight, placenta position, and whether there was placenta previa. The data collected from the procedure included

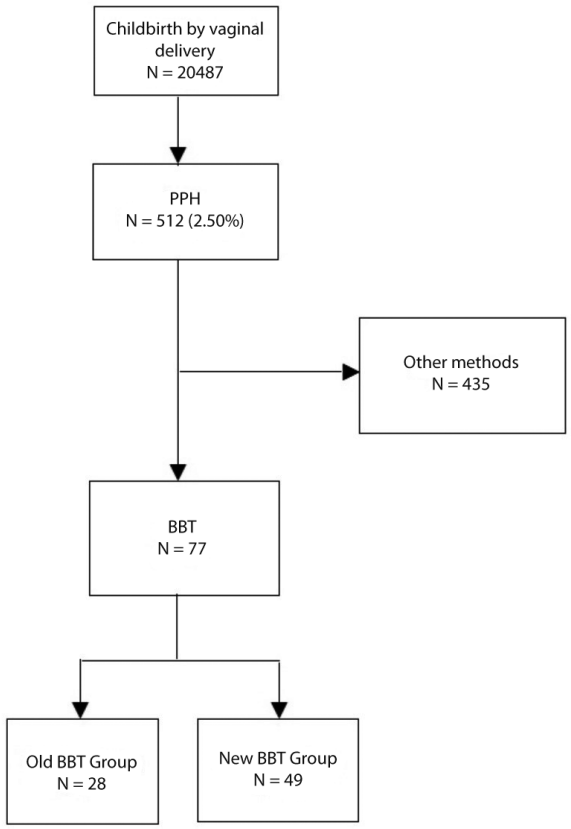

Figure 1. Flow diagram showing the inclusion of women in the study. Women who underwent Bakri balloon tamponade (BBT) for postpartum hemorrhage (PPH) were grouped into the old-BBT group, for the standard placement method, and the new-BBT group, for the new method

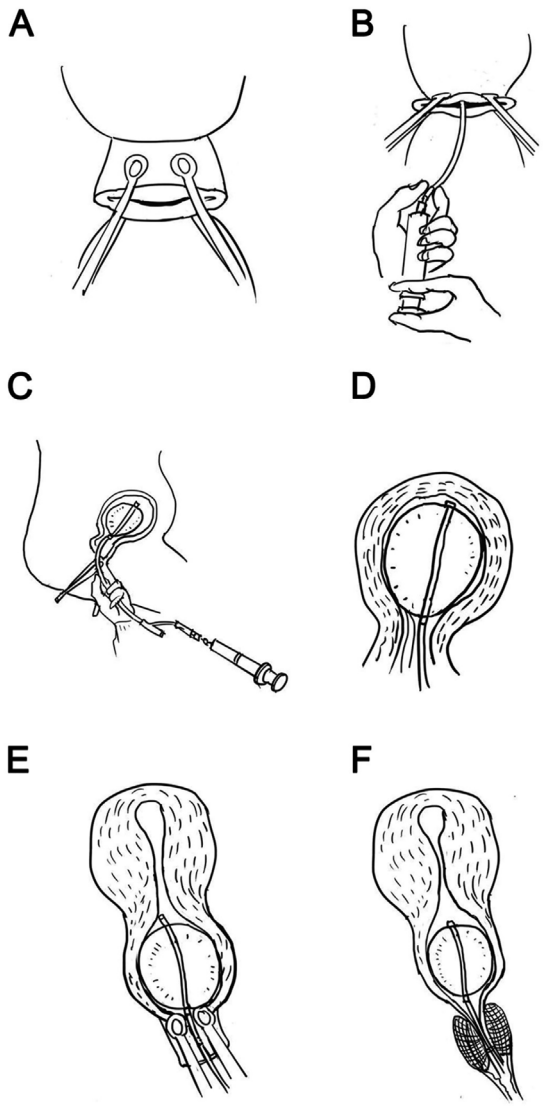

Figure 2. The new method of Bakri balloon placement in the lower segment of the uterus. The uterus neck was clamped at the 9 o'clock position by pincers after cervical lacerations had been examined. The uterine balloon tamponade was placed ensuring that the lower margin was 2 centimeters away from the external cervix. The uterus neck was clamped at the 3 o 'clock position with pincers (**A**). Sterile saline was injected into the balloon inside the uterine cavity. At the same time, ultrasound was used to view the position of the balloon. The use of sterile saline depended upon the actual situation of vaginal bleeding (**B**–**E**). A piece of gauze was placed at the frontier and posterior fornix respectively, observing active bleeding outside the cervix by ultrasound for 10 minutes after sterile saline infusion (**F**). The cervical pliers were removed carefully if there was no active bleeding. Vaginal bleeding and balloon catheter bleeding were monitored for 2 hours

operation time, bleeding volume, balloon placement time, balloon saline injection time, and whether the patient was transferred to the intensive care unit (ICU). The outcome was also recorded including whether it was a live birth, whether there were postoperative complications, whether the balloon slipped, postoperative bleeding volume, whether a postoperative transfusion was given, and the length of hospital stay.

Statistical analysis

Statistical analysis was performed using SPSS software (SPS Inc., USA). The Mann–Whitney U test was used to examine continuous variables and Fisher's exact test, or Chi-square test was used to examine categorical variables. Statistical significance was defined as values of $p < 0.05$.

RESULTS

Baseline characteristics

From January 2014 to December 2020, there were a total of 20487 childbirths by vaginal delivery in our hospital, 512 (2.50%) of them had PPH. Only 77 women underwent BBT during the 7 years of the study, 28 in the old-BBT group and 49 in the new-BBT group.

The patient characteristics are shown in Table 1, the background characteristics were not different between the two groups. However,prothrombin time (PT) and activated partial thromboplastin time (APTT) were lower in the new-BBT group than in the old-BBT group (13.09 ± 0.59 vs

Table 1. Baseline characteristics of the maternal study population

	Old-BBT group (n = 28)	New-BBT group (n = 49)	p value
Age [y]	26.82 ± 4.33	28.02 ± 2.98	0.155
BMI	26.90 ± 1.91	26.34 ± 2.72	0.447
Gestational weeks at delivery	38.18 ± 4.34	38.10 ± 4.98	0.946
Birth history gravida	2.71 ± 1.47	2.90 ± 1.60	0.447
Birth history parity 0 1	 21 (75.00) 7 (25.00)	 27 (55.10) 22 (44.90)	0.067
IVF Yes No	 0 28	 0 49	-
Fetal weight	3195.22 ± 779.53	3286.47 ± 379.95	0.339
Placenta position Anterior Posterior	 21 (75.00) 7 (25.00)	 37 (75.51) 12 (24.49)	0.584
Placenta previa Yes No	 0 22	 0 18	
PT	13.09 ± 0.59	10.89 ± 1.01	< 0.01
APTT	35.62 ± 4.50	32.10 ± 5.20	0.004
INR	1.05 ± 0.11	1.02 ± 0.11	0.438

BBT — Bakri balloon tamponade; BMI — body mass index; IVF — *in vitro* fertilization; PT — prothrombin time; APTT — activated partial thromboplastin time; INR — international normalized ratio

Table 2. Information collected during the Bakri balloon tamponade (BBT) procedure

	Old-BBT group (n = 28)	New-BBT group (n = 49)	p value
Operation time [min]	15.36 ± 4.84	10.16 ± 4.25	< 0.001
Bleeding volume [mL]	1290.00 ± 449.04	998.47 ± 370.52	0.003
Balloon placement time [min]	22.66 ± 3.15	24 .06 ± 0.43	0.381
Balloon saline injection volume [mL]	291.79 ± 57.16	235.41 ± 75.73	< 0.001
ICU after operation Yes No	 1 (3.57) 27 (96.43)	 0 (0) 49 (100)	0.364

ICU — intensive care unit

10.89 ± 1.01, p < 0.001; 35.62 ± 4.50 ± 4.47 vs 32.10 ± 5.20, p < 0.004, respectively).

Comparison of the two procedures

Table 2 shows the clinical details during BBT placement. The operation time was shorter in the new-BBT group (15.36 ± 4.84 vs 10.16 ± 4.25, p < 0.001). The bleeding volume was less in the new-BBT group (1290.00 ± 449.04 vs 998.47 ± 370.52, p < 0.003). The balloon saline injection volume was less in the new-BBT group (291.79 ± 57.16 vs 235.41 ± 75.73, p < 0.001).

The clinical outcomes of the two groups are shown in Table 3. Balloon slippage was less likely to occur in patients in the new-BBT group (21.43% vs 2.04%, p < 0.008). The postoperative blood transfusion rate was less in the new-BBT group (46.43% vs 14.29%, p < 0.003) with less bleeding volume [88.50 (0–1490) mL vs 57.50 (0–250) mL, p < 0.01], and less blood transfused [0 (0–700) mL vs 0 (0–500) mL, p < 0.002]. The length of hospital stay was shorter in the new-BBT group (4.75 ± 0.97 days vs 4.27 ± 0.73 days, p < 0.015). There was no statistically significant difference in other factors.

Follow-up

For all the women, a follow-up was performed 7 days after hospital discharge. In addition, we carried out an examination on the 42nd day after delivery. One case of induced delivery in which placental tissue residues were found, was treated with hysteroscope surgery, and no infection or lochia was found in any of the cases at the 42-day postpartum examination.

Table 3. Patient outcomes

	Old BBT-group (n = 27)	New-BBT group (n = 49)	p value
Death	0	0	
Live birth Yes No	 25 (89.29%) 3 (10.71)	 47 (95.92%) 2 (4.08%)	0.251
Postoperative complications	0	0	
Balloon slippage	6 (21.43%)	1 (2.04)	0.008
Postoperative bleeding volume median (range) [min]	88.50 (0–1490)	57.50 (0–250)	0.01
Postoperative blood transfusion rate	13 (46.43)	7 (14.29)	0.003
Postoperative blood transfusion median (range) [min]	0 (0–700)	0 (0–500)	0.002
Hospital stay [days]	4.75 ± 0.97	4.27 ± 0.73	0.015

BBT — Bakri balloon tamponade

Table 4. Multivariate analysis of factors related to whether or not blood transfusion was required after surgery

	Multivariate analysis	
Variables	**OR (95% CI)**	**p value**
Treatment method	5.200 (1.745–15.493)	0.003
Age [year]	1.602 (0.921–1.226)	0.407
Gestational weeks	0.930 (0.843–1.025)	0.145
PT	0.039 (0.002–0.730)	0.030
APTT	1.121 (0.893–1.409)	0.340
INR	8.244 (3.807–17.850)	0.009
Operation time	1.053 (0.946–1.172)	0.342

OR — odds ratio; CI — confidence interval; PT — prothrombin time; APTT — activated partial thromboplastin time; INR — international normalized ratio

Factors related to the need for a blood transfusion

Table 4 shows the analysis for factors related to the requirement for a blood transfusion in the complete population of women who underwent the BBT procedure. Multivariate analysis suggested that treatment method (OR = 5.200, 95% CI: 1.745–15.493, $p < 0.003$), PT (OR = 0.039, 95% CI: 0.002–0.730, $p < 0.030$), and the international normalized ratio (INR) (OR = 8.244, 95% CI: 3.807–17.850, $p < 0.009$) were associated with the need for a blood transfusion.

DISCUSSION

The present study shows that the BBT procedure was shorter in the new-BBT group and balloon prolapse was less likely. The bleeding volume, balloon saline injection volume, and postoperative blood transfusion rate were all lower in the new-BBT group. Hospital stay was shorter in the new-BBT group. However, PT and APTT were higher in the old-BBT group than in the new-BBT group. Investigation of factors related to the requirement for a blood transfusion identified PT, INR, and placement method as independent factors.

This study supports the view that BBT is a safe and effective method of treating PPH [14, 15]. However, we found that when we used BBT in our clinic sometimes the balloon placement was difficult and time consuming, and that sometimes the balloon slipped after placement. This is shown in this study by the longer time taken to undertake the procedure in the old-BBT compared to the new-BBT group and that while slippage occurred in 21.43% of cases in the old-BBT group, only one case occurs balloon slippage occurred after we used the new method. Implementation of the new method decreased the blood loss in the women treated by BBT and the rate for a blood transfusion, so it can be considered more effective than the standard placement procedure. This view is supported by the BBT placement method being identified by the multivariate analysis in this study as an independent factor related to the requirement for a blood transfusion, alongside PT and INR.

The new method of BBT placement was based on a simple flexible, timesaving, and stable method, and can be used easily in clinical practice. Besides, this method can be applied not only to the pregnant women with uterine atony, but also to hemorrhage caused by placental factors or coagulation dysfunction, especially for hemorrhage caused by low placental position, which advocates the placement as soon as possible after determining the cause of hemorrhage and excluding placental factors. Some previous studies have also presented methods to improve BBT placement [16–19]. However, although the practice is common in clinic, there have been no reports addressing this issue, nor the standard operating procedure. By observing and practicing for a long time, we have improved this method, and achieved a good result, therefore, it has become a standard procedure in our department.

According to the manufacturers, original positioning of the balloon is located at the uterine fundus, but sometimes due to an irregular uterine cavity, placement is difficult, time-consuming, and blood loss is increased. The new meth-

od presented here with the BBT located at the lower segment of the uterus, is simple and practicable. The cervix is firmly sealed by two pincers, the balloon will not slip, and time is saved, hemostasis is quick. After being placed in the lower uterine segment, gauze was used to compress hemostasia and prevent slippage**.** The gauze piece was placed on the frontier and posterior fornix of the vagina dome respectively. There are two main functions, one is providing pressure from the frontier and posterior fornix, closing the vaginal orifice of the cervix to prevent the balloon slipping; the other is that the vaginal portion of the cervix is usually longer after delivery, it can even reach 4–5 cm. By filling with the gauze piece, local compression and hemostasis can be provided. The gauze can have a tail piece hanging out, which makes it easy to remove. Therefore, these modifications make this method effective, especially with lower uterine atony after vaginal delivery in which other hemostasis are sufficient .After placement of the balloon and package of the gauze, we moved the clamps because slippage of BBT was prevented and this also prevented suffering of patients and ischemic necrosis of the cervix leading from compression of ovary forceps on the cervix, this was not mentioned in other articles [16].

The uterus is composed of a unique interlacing network of muscle fibers, the 'myometrium' [24]. The blood vessels that supply the placental bed pass through this latticework of uterine muscle [24, 25]. Myometrial contraction is the main driving force for both placental separation and hemostasis, through constriction of these blood vessels [24]. Therefore, the conventional wisdom is that balloon tamponade works primarily by applying pressure directly on the placental bed/myometrial vessels, thus mimicking normal physiology. The success of surgical compression techniques has added validity to this theory [26, 27]. Similarly, the generally accepted rationale for the mechanism of action of the balloon catheter is that of hemostasis through the direct pressure applied to the myometrium and placental bed [28, 29], provided the uterus is able to contract down on the balloon. The shape of the Bakri balloon is easily conformable to the hemorrhagic areas of the uterine cavity by inflating or deflating the balloon [3, 18, 30], so when placed in the lower uterine segment with transabdominal ultrasound examination, the BBT expanded rapidly into the uterine cavity with infusion of sterile saline, applying pressure to stop bleeding (Fig. 2D). The balloon was inflated until it conformed to the contour of the uterus to provide a symmetric tamponade effect.

This study also has some limitations. The sample of women who received BBT placement was quite small over the study period. Multiple centers will treat a large number of women with second line therapies for PPH, so a larger study in multiple centers would improve the value of these results. As a retrospective study that evaluated patients during different time periods there is likely to be some bias in the patient selection. A randomized trial might show more obvious differences between the groups.

CONCLUSIONS

In the treatment of PPH after vaginal delivery, BBT is a timely and effective method. The new method of placement presented here for women with PPH after vaginal delivery took less time, reduced the chance of balloon slippage, and reduced blood loss. Making it less likely that a blood transfusion was required. Therefore, we suggest that this method be considered by other clinics treating women for PPH after vaginal delivery.

Article information and declarations

Data availability statement

All data generated or analysed during this study are included in this published article.

Author contributions

Xiaoyin Wang and Mei Yan carried out the studies and drafted the manuscript. Xiaoyin Wang and Mei Yan performed the statistical analysis and critically for important intellectual content. Xiaoyin Wang and Mei Yan participated in acquisition, analysis, or interpretation of data and drafted the manuscript. All authors participated in collecting data. All authors read and approved.

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Conflict of interest

None.

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