Original Contribution

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Clinical Usefulness of Bakri Balloon Tamponade in the Treatment of Massive Postpartum Uterine Hemorrhage

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Summary: Intrauterine globe-shaped metreurynter tamponade has been used for some time to treat massive postpartum hemorrhage (PPH). More recently, the Bakri balloon has come into use to treat PPH. It is made of silicon, possesses a drainage lumen, and has a sausage-like spindle shape. The aim of the present study was to investigate the clinical usefulness of Bakri balloon tamponade for massive PPH. Subjects in the present study comprised 5 patients with uterine atony, 3 with placenta previa, and 2 with low-lying placenta. All patients exhibited massive PPH and resistance to conventional hemostatic managements. Bakri balloon tamponade was applied to these 10 patients. The mean amounts of uterine bleeding (average ± SD) before and after Bakri insertion were 2,732 ± 1,397 mL and 380 ± 376 mL, respectively. The median (third-first quartile ranges) volume of saline inflating the balloon was 200 mL (300-150 mL). The median (third-first quartile ranges) indwelling duration of Bakri balloon was 24 hours (24-11 hrs). The overall success rate of Bakri balloon tamponade was 90% (9/10). There were no cases of slipping out or complications regarding balloon placement. Our findings suggest that Bakri balloon tamponade may be applied to the treatment of massive PPH in uterine atony and placenta previa. The Bakri balloon appears to have the following merits: (1) easy insertion into the uterine cavity and low rate of slipping out, (2) proper conformability to the hemorrhagic area due to its spindle shape, (3) ability to monitor blood loss through the drainage lumen even after insertion.

Key words Bakri balloon tamponade, massive postpartum hemorrhage, uterine atony, placenta previa

INTRODUCTION

Causes of maternal death during pregnancy include obstetrical hemorrhage, pregnancy-induced hypertension, embolism due to amniotic fluid or deep vein thrombosis, infection, and traffic accidents. However, even with medical advances, obstetrical hemorrhage is still the main cause of maternal death worldwide [1]. A prompt diagnosis and suitable treatment are very important for reducing the incidence of maternal death associated with massive PPH. Gauze-packing in the intra-uterine cavity or metreurynter tamponade have been used to treat massive postpartum hemorrhage (PPH) caused by uterine atony. Uterine artery embolization (UAE), internal iliac artery ligation (IIAL), and hysterectomy have been selected for patients who are resistant to uterotonics, gauze-packing, metreurynter tamponade and blood transfusion. Uterine gauze-packing requires skill and time, and is associated with the risk of uterine injury and endometritis [2]. Metreurynter is convenient and cheap, but the balloon can slip outside the uterus and has no drainage lumen.

Over the last decade, intrauterine Bakri balloon

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Abbreviations: DIC, disseminated intravascular coagulation; IIAL, internal iliac artery ligation; PPH, postpartum hemorrhage; UAE, uterine artery embolization

(Cook Medical Inc, Bloomington, IN, USA) tamponade has come into use to treat massive PPH. The Bakri balloon has a sausage-like spindle shape and a drainage lumen, and is made of silicon [3]. In the present study, we investigated the clinical usefulness of Bakri balloon tamponade for massive PPH in our institute.

METHODS

Ten cases of massive PPH were enrolled. All subjects were consecutively recruited between May and November 2013 at the Department of Obstetrics and Gynecology, Kagoshima University Hospital. Subjects comprised 5 patients with uterine atony, 3 with placenta previa, and 2 with low-lying placenta. In our hospital, the standard management of massive PPH such as that due to uterine atony includes massaging the uterine body, administration of uterotonics, bimanual compression of the uterus, transvaginal Bakri balloon insertion, and blood transfusion. For cases in which the standard hemostatic management described above is ineffective, we select UAE, IIAL and hysterectomy in that order. Recently, Bakri balloon placement was proposed as a treatment procedure before surgical interventions including UAE, IIAL, and hysterectomy. Therefore, we investigated the clinical usefulness of Bakri balloon tamponade for PHH in our ten cases. In the present study, PPH cases that were uncontrollable by Bakri balloon tamponade were defined as "Bakri balloon failure", and cases that achieved hemostasis without any additional surgical interventions were defined as "Bakri balloon success".

Since the Bakri balloon (total length 58 cm; tested top capacity 800 mL) is ductile, it can fit the lower part of the uterine cavity; the shaft tip has 2 holes for drainage, which allows ongoing hemorrhage to be diagnosed even after insertion of the balloon. It can be easily deflated and removed transvaginally after PPH has been controlled [4,5]. Regarding uterine tamponade, we initially infused 150 mL of saline into the Bakri balloon as a starting inflation volume. Based on blood loss following Bakri balloon insertion, the infused balloon was then adjusted with additional inflation or deflation.

RESULTS

Table 1 shows the clinical profiles and outcomes of Bakri balloon tamponade in patients with PPH. The mean amounts of uterine hemorrhage (average ± SD) before and after Bakri insertion were 2,732 ± 1,397 mL and 380 ± 376 mL, respectively. The volume of amniotic fluid was not included in these amounts. Of the five patients with uterine atony (cases No. 3, 6, 7, 8, and 9), who suffered massive PPH ranging from 1,790

TABLE 1.
Clinical profiles and outcomes of Bakri balloon tamponade

Case	Age	Gravidity Parity	Diagnosis	Mode of Delivery	Blood loss(mL)*		Finally infused volume(mL)	Indwelling time(hr)
					before	after		
1	34	G0P0	partial placenta previa (Twin pregnancy)	C/S	2,880	40	200	24
2	35	G0P0	Low-lying placenta (PIH)	C/S	2,900	85	150	16
3	31	G0P0	atonic bleeding (placental retention)	TV	2,600	800	300	6
4	36	G1P1	total placenta previa	C/S	2,090	57	150	24
5	27	G0P0	total placenta previa	C/S	720	50	150	24
6	29	G0P0	atonic bleeding	C/S	3,100	400	200	24
7	36	G2P0	atonic bleeding (uterine leiomyoma)	C/S	3,289	1,182 (UAE)	150	3
8	36	G1P0	atonic bleeding	C/S	1,790	362	450	11
9	40	G1P0	atonic bleeding	C/S	6,050	540	500	28
10	20	G1P1	Low-lying placenta	C/S	1,900	286	300	25

PIH: pregnancy-induced hypertension, C/S: cesarean section, TV: transvaginal,
UAE: uterine artery embolization,
*Blood loss excluding amniotic fluid was measured before and after Bakri balloon insertion.
Success rate = 90% (only case No.7 was uncontrollable by Bakri balloon tamponade)

to 6,050 mL, blood loss in 4 cases was reduced to 362-800 mL after Bakri balloon insertion. However, atonic bleeding in case No.7, who had a large uterine leiomyoma measuring 10 cm in diameter, could not be controlled by Bakri tamponade. In this case, hemorrhage was stopped by 150 ml of Bakri balloon tamponade during cesarean section, but recurred after 3 hours in the recovery room (1,182 mL in blood loss even after tamponade). Additional UAE was performed and PPH was stopped. PPH in the patient with uterine atony complicated by placental retention after transvaginal delivery (case No. 3) stopped after Bakri balloon insertion. Five patients with placenta previa (cases No. 1, 4, and 5) and low-lying placenta (cases No. 2 and 10) showed uterine hemorrhage (720 to 2,900 mL) during cesarean section; however, blood loss was effectively decreased to 40-286 mL after Bakri tamponade.

There was no case of hysterectomy or IIAL. Thus, the overall success rate of Bakri balloon tamponade was 90% (9/10). The median (third-first quartile range) volume of the infused saline for Bakri balloon was 200 mL (300-150 mL). The median (third-first quartile range) indwelling duration of Bakri balloon was 24 hours (24-11 hours). There were no cases of the balloon slipping outside the uterus or complications regarding Bakri balloon placement.

DISCUSSION

In the present study, we found that the overall success rate of Bakri balloon tamponade was 90% in the treatment of massive PPH. This result was consistent with previous findings by Gronvall et al. [6], who reported an overall success rate of 86% (43/50). Our success rate was superior to that of Kaya et al. [7], in which hemostasis was achieved in 34 out of 45 patients (75.5%). In general, our result was similar to those in previous studies [8-12].

The type of obstetrical hemorrhage that is a suitable indication for using the Bakri balloon needs to be considered. In the present study, Bakri balloon was effective in all 5 patients with placenta previa, including low-lying placenta. In the study by Gronvall et al. [6], the success rate of the Bakri balloon for placenta previa was 100% (9/9). Kumru et al. [13] reported that Bakri balloon tamponade was successful in 22 of 25 cases (88%) with placenta previa. In the original study conducted by Bakri et al. [3], 3 out of 5 cases with placenta previa or low-lying placenta were successfully treated by the Bakri balloon alone, whereas the remaining 2 patients were not. These 2 patients were treated by IIAL. For uterine atony, the success rate of the Bakri balloon was 80% (4/5) in our study. One patient with a large uterine leiomyoma was additionally treated by UAE. Although the hemorrhage was successfully stopped by 150 mL of Bakri balloon tamponade at the end of cesarean section, massive hemorrhage recurred 3 hours later. The large myoma may have been responsible for this "Bakri balloon failure". Gronvall et al. [6] reported that the Bakri balloon was effective in 5 (62.5%) out of 8 patients with atonic bleeding. Dabelea et al. [12] showed that the balloon was effective in 100% of cases of hemorrhagic uterine atony. Thus, Bakri balloon tamponade may be applied to the treatment of placenta previa and uterine atony in cases that cannot be controlled by conventional hemostatic management. Even if Bakri balloon tamponade is unsuccessful, it may provide temporary hemostasis and time to prepare for other interventions or transportation from a local hospital to a higher level medical center [6].

Our study does have some limitations, including the small number of enrolled subjects. We encountered only cases of uterine atony and placenta previa during the study period. Therefore, it remains unclear whether Bakri balloon tamponade is effective for placental retention alone or placental abruption. Regarding placental retention, a previous study demonstrated that the Bakri balloon was effective in 12 (80%) out of 15 patients [6]. We also experienced a "successful" case of Bakri tamponade for a patient with placental retention accompanied by atonic bleeding. As for disseminated intravascular coagulation (DIC) due to placental abruption, the efficacy of Bakri balloon tamponade has not yet been established to the best of our knowledge. Anti-DIC therapy and blood transfusion are the best treatment for bleeding due to placental abruption. However, temporary Bakri balloon tamponade may provide enough time to prepare other hemostatic interventions. Bakri balloon seems to be contraindicated in cases of (latent) uterine rupture, because one of the mechanisms of action of Bakri balloon tamponade is to increase uterine stiffness followed by the induction of uterine contraction [14].

In the present study, the median (third-first quartile range) volume of the infused saline for Bakri balloon was 200 mL (300-150 mL). Taking the high success rate into consideration, our inflation volume of the Bakri balloon may be sufficient. However, controversy persists regarding the appropriate inflation volume. Gronvall et al. [6] reported a mean inflation volume of 367 mL (range 30-500 mL). None of the patients with balloon inflation $<$250 mL needed additional procedures. Vitthala et al. [8] reported that the amount of

saline used to inflate the balloon ranged from 250 to 500 mL. In Bakri's original study, balloon infusion ranged from 300 mL to 500 ml. Other studies of the Bakri balloon used mean inflation volumes of 571 (range: 240-1,300 mL) [7] and 345 mL (250-455 mL) [15]. Kaya et al. [7] reported that the inflation volume of the Bakri balloon was adjusted according to the type of PPH, and that a volume exceeding 500 mL may be necessary for the successful treatment of uterine atony. Thus, the inflated volume may depend on the severity of uterine atony or placenta previa, the size and capacity of the uterus, the parity, and the presence or absence of multiple pregnancies. Further studies are needed to determine a suitable inflation volume of Bakri balloon.

In our study, the median (third-first quartile range) duration of Bakri balloon placement was 24 hours (24-11 hours). The indwelling time in the other studies was 12.7 hours (range 1-28 hrs) [6], 21 hours (range 10 min to 48 hrs) [11], 20.8 hours (12-24 hrs) [3], 11 hours (10-24 hrs) [9], and 24 hours [15]. Although the duration of Bakri balloon placement depends on the case and the amount of blood passing through the drainage lumen, at least 12 hours appears to be needed.

The sausage-like spindle-shaped Bakri balloon seems to have the merit of a lower slipping rate than the globe-shaped metreurynter. The shape of the Bakri balloon is easily conformable to the hemorrhagic areas of the uterine cavity by inflating or deflating the balloon [5]. This feature must be important for the hemostatic effects of the Bakri balloon [16]. The Bakri balloon also has the advantage of allowing blood loss to be monitored through the drainage lumen [3]. Although most hemostatic packing techniques do not allow the volume of bleeding after packing to be measured, Bakri balloon enables us to monitor the accurate bleeding and apply additional surgical hemostasis in a timely manner.

Use of the Bakri balloon may decrease blood loss and maternal death due to PPH, and help avoid the need for surgical hemostatic intervention such as UAE and IIAL. However, there is currently a paucity of publications on Bakri balloon tamponade. Before its clinical utilization is established, randomized clinical trials that compare uterotonics alone versus with the Bakri balloon are warranted [8,17]. Based on the results of the present study, we conclude that Bakri balloon tamponade is useful in the treatment of massive PPH in placenta previa and uterine atony. The Bakri balloon has advantages including its easy transvaginal or transabdominal insertion [5] and conformability to the hemorrhagic area due to its shape and material [5,16]. In addition, the Bakri balloon allows blood loss to be monitored through the drainage lumen [3], which is clinically invaluable [5,18].

CONFLICT OF INTEREST

All authors declare that they have no conflict of interest.

INFORMED CONSENT

All procedures were conducted in accordance with institutional guidelines and the Helsinki Declaration of 1964 and its later amendments. Informed consent was obtained from the patients included in the study.

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