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Original Article

Analysis of prophylactic Bakri balloon tamponade failure in patients with placenta previa

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ABSTRACT

Objective: Recently, Bakri balloon (BBT) was effective for women with placenta previa to reduce hemorrhage. However, about 10% of women needed to receive an invasive strategy. Thus, the identification of risk factors and the development of additional measurements for BBT failure was needed. The aim of our study is to investigate the cause and measurements of failing prophylactic BBT in women with placenta previa.

Materials and methods: Women with placenta previa who underwent cesarean section and had a prophylactic BBT inserted during the operation at our institution between January 2015 and December 2017 were enrolled. Patients requiring additional procedures after cesarean section for massive hemorrhage were defined as BBT failures. Additionally, the patterns and risk factors of BBT failure were retrospectively evaluated.

Results: Seventy women met the inclusion criteria. Of them, 9 (13%) were in the balloon failure group and 61 (87%), in the balloon success group. Between two groups, the median of postoperative blood loss was 1153 g vs. 70 g ($p < 0.01$) and the total blood loss 2409 g vs. 971 g ($p < 0.01$). There were two types of failures in the balloon failure group: balloon prolapse in eight patients (89%) and accidental placental retention in one patient (11%). The hemorrhage was controlled in all patients with balloon prolapse by reinsertion and inflation of the balloon. The patient with placental retention required a uterine artery embolization (UAE). Although three patients required a blood transfusion, none required a hysterectomy. The logistic regression for the risk of balloon failure revealed classification of major previa to be the highest risk factor (Hazard Ratio; 19.1, 95% Confidence Interval; 3.17–367.9, $p < 0.01$).

Conclusion: The major cause of BBT failure was balloon prolapse. It could be treated with non-invasive methods; however, patients with placental retention could not avoid invasive treatment to stop the hemorrhage.

Introduction

Placenta previa, occurring in 0.4% of all pregnancies, is a severe complication for pregnant women [1]. Because of the refractory intraoperative and postpartum hemorrhage that may occur, placenta previa can be associated with maternal and perinatal mortality and morbidity. For these reasons, effective procedures to reduce bleeding are essential [2–4].

In recent years, many reports have shown the efficacy of the Bakri balloon (BBT) to reduce intraoperative and postpartum hemorrhage [5–9]. In these reports, a BBT was inserted during a massive hemorrhage after cesarean section. Consequently, in some cases, the amount of bleeding increased during the confirmation of hemorrhage which resulted in disseminated intravascular coagulation (DIC) being induced. These cases inevitably received additional invasive procedures, such as UAE and hysterectomy [8,10]. Based on these facts, we performed the rapid insertion of BBT

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prophylactically, just after spontaneous separation of placenta during cesarean section, for all women with placenta previa [11]. As a result, prophylactic insertion of BBT drastically reduced a hemorrhage not only during, but also after cesarean section in women with placenta previa [11]. Although most women did not develop a massive postpartum hemorrhage, about 10% of women needed to receive an invasive strategy, such as blood transfusion and UAE. Thus, the identification of risk factors and the development of additional measurements for BBT failure was needed to reduce massive hemorrhage more effectively.

Herein, the purpose of the present study was to investigate the causes of failing BBT to better control the hemorrhage of placenta previa and to analyze the clinical characteristics of cases that did not achieve hemostasis by prophylactic use of BBT.

Materials and methods

This retrospective study was approved by the institutional review board of National Defense Medical College. The present study analyzed the maternal histories and intraoperative information using medical and operative records. Records/information of all women were anonymized and de-identified prior to analysis. All women with singleton pregnancies who underwent cesarean section for placenta previa at our hospital between January 2015 and December 2017 were identified and enrolled. These women also underwent prophylactic placement of a BBT (Cook Reproductive Health, Bloomington, IN, USA) during cesarean section at our hospital [11].

The classification of placenta previa, timing of cesarean section, and surgical procedure were performed as previously reported [11]. Briefly, we classified placenta previa into major previa and minor previa as the previous report [12]. In brief, Major previa was defined as the placenta which covered the internal cervical os. Minor previa was defined as the leading edge of the placenta which was located in the lower uterine segment but did not cover the cervical os [12]. Warning bleeding was defined as painless genital bleeding from the placenta. Elective cesarean sections were fundamentally performed until the end of 37 weeks' gestation. Surgical procedure was as follows: (*a*) The uterine incision was performed transversely into the lower segment of the uterus. (*b*) After delivery, oxytocin 5 IU in a 500-mL saline drip was administrated intravenously. After the spontaneous separation of the placenta, the BBT was inflated with 50 ml of sterile water and inserted into the uterine cavity from the opened uterus. (*c*) Following the skin closure, BBT was inflated with 100 ml–150 ml of water to ensure tamponade the balloon position was carefully checked using ultrasonography. (*d*) The drainage port of the BBT was connected to a fluid collection bag to monitor bleeding from the uterine cavity. (*e*) Sterile gauze was packed into the vagina to prevent the balloon prolapsing from the uterus. (*f*) The BBT was kept inflated up to 24 h after the operation.

Cervical length was measured within one week before the cesarean section. The amount of intraoperative bleeding was measured from the time of skin incision to the time of wound closure. The amount of postoperative hemorrhage was defined from the end of cesarean section to 24 h later. Many surgeons performed this cesarean section according to this protocol. In this study, we defined a case of “balloon failure” as the patient needing additional hemostatic procedures including: reinsertion of the balloon, additional inflation of balloon, vaginal packing, and UAE within 24 h of the completion of the cesarean section. A case utilizing only the prophylactic BBT, without the aforementioned hemostatic procedures, was defined as “balloon success.” First, we reviewed the reports and records to determine any patterns for failing prophylactic BBT. Subsequently, we analyzed the clinical factors of those who tended to fail the prophylactic BBT.

The statistical analysis was performed using JMP 10.0.0 software (SAS Institute, Inc., Tokyo, Japan). 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

During the study period, 70 women with placenta previa were identified. Among them, there were nine women (13%) in the balloon failure group and 61 women (87%) in the balloon success group (Fig. 1).

Patients' details from the balloon failure group are shown in Table 1. The cause of prophylactic tamponade failure was balloon prolapse in cases 1 to 8 and was placental retention in case 9. The ranges of postoperative blood loss and total blood loss were 784 g–3050 g and 1212 g–4230 g, respectively. Regarding postoperative blood loss, all patients with balloon prolapse tended to have more bleeding from the vagina than from the drainage port. On the other hand, the patient in case 9 had massive hemorrhaging from the drainage port. All patients with balloon prolapse had the BBT reinserted. Among cases with balloon prolapse, patients in cases 4 to 8 had uterine body atony complications that required additional balloon volume to control hemorrhage. The patients in cases 3,7, and 8, received Quikclot® (Z-Medica, LLC, Wallingford, CT, USA), a type of gauze used in combat to accelerate clotting, to stop the continuous bleeding from the outwardly turned external cervical os. The patient in case 9 developed massive hemorrhage due to placental retention. The bleeding could not be stopped by reinsertion of the BBT so the patient underwent UAE and received a blood transfusion. Although the patients in cases 5 and 7 also

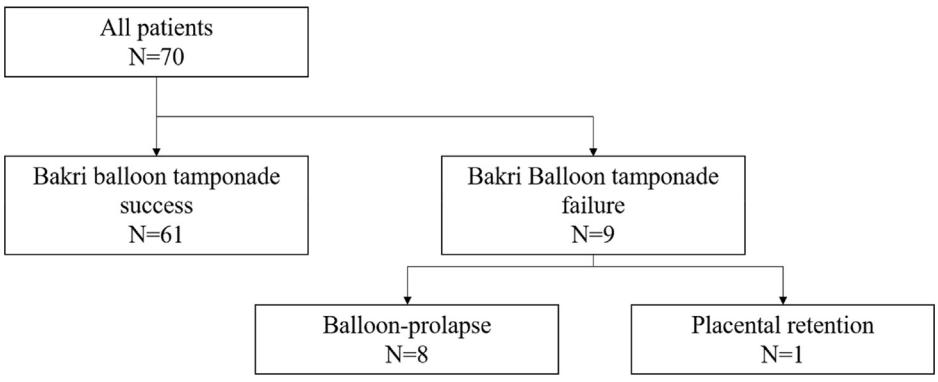

Fig. 1. Study design.

Table 1
The patients' details of balloon failure group.

Case	Cause of failure	Maternal age (year-old)	Primipara	Gestational age at delivery,	Previa classification	Intraoperative blood loss (g)	Postoperative blood loss (g)			Total blood loss (g)	balloon volume (ml)			Uterine body atony	Additional procedures
							Vaginal	Drainage-port	Total		Initial	Additional	Total		
1	Balloon-prolapse	38	No	36–5	Major	1123	960	50	1010	2133	150	50	200	No	
2	Balloon-prolapse	30	Yes	37–0	Major	1394	645	150	795	2189	150	0	150	No	
3	Balloon-prolapse	26	No	36–4	Major	428	584	200	784	1212	150	50	200	No	QuikClot
4	Balloon-prolapse	38	Yes	35–5	Major	1196	710	240	950	2146	150	200	350	Yes	
5	Balloon-prolapse	35	Yes	36–6	Major	850	1850	300	2150	3000	150	200	350	Yes	Blood transfusion
6	Balloon-prolapse	33	No	37–1	Major	1955	1225	180	1405	3360	150	100	250	Yes	
7	Balloon-prolapse	39	Yes	37–2	Major	1202	2717	311	3028	4230	150	250	400	Yes	QuikClot. Blood transfusion
8	Balloon-prolapse	38	No	37–4	Minor	1256	988	165	1153	2409	150	150	300	Yes	QuikClot
9	Placental retention	31	Yes	36–5	Major	770	500	2550	3050	3820	150	250	400	No	Blood transfusion. UAE

UAE, uterine artery embolization.

needed a blood transfusion, the reinsertion of the BBT stopped the hemorrhage. While these patients needed blood transfusions they only required reinsertion of the BBT and did not require other hemostatic procedures. Also, all patients in the balloon failure group avoided hysterectomy.

Subsequently, we analyzed the clinical characteristics of the balloon failure group and compared them to those of the balloon success group. The patients' characteristics are shown in Table 2. Eight of nine patients in the failure were classified as having major previa ($p < 0.01$). The median postoperative blood loss (1153 g vs. 70 g, $p < 0.01$) and total blood loss (2409 g vs. 971 g, $p < 0.01$) was higher in the failure group.

We investigated the risk factor of balloon prolapse based on preoperative variables (Table 3). Univariate analysis revealed that major previa was the only risk factor for balloon prolapse (Hazard ratio; 19.1, 95% Confidence interval; 3.17–367.9, $p < 0.01$).

Discussion

The present study identified two causes of increased hemorrhage after cesarean section with prophylactic BBT, "balloon prolapse" and "placental retention." The first cause, balloon prolapse, was characterized by the increased vaginal hemorrhage from the side of the BBT. The second cause, placental retention, was characterized by the successive bleeding from the drainage port of BBT. Furthermore, the classification of major previa was a risk factor of balloon failure.

Our study showed balloon prolapse to be the main problem causing further hemorrhage as previously reported [13]. In addition, 7 (87.5%) of the 8 patients from the balloon failure due to balloon prolapse cases were classified as having major previa. Atony of the lower uterine segment sometimes occurs in placenta previa [14] and the contractile capacity of the thin myometrium of the lower uterine segment is limited [15]. Additionally, complete placenta previa was a high risk for massive bleeding due to a larger vascular bed at the placenta separation site [16,17]. Based on these facts, the vulnerability of the lower uterine segment in placenta previa coupled with the abundant blood flow in that area could make the cervix more vulnerable in patients with major previa. This could cause extrusion of the balloon. Fortunately, all the patients with balloon prolapse were treated by reinsertion and more inflation of BBT with 50 ml–250 ml. Many studies on BBT for placenta previa employed 150 ml–200 ml for initial balloon volume [5,18] Thus, 150 ml as the initial volume in our study was not low but a larger initial volume might be the appropriate strategy for cases with major previa.

Furthermore, some cases with balloon prolapse received QuikClot as gauze packing in addition to reinsertion and more inflation of BBT. QuikClot has been reported as an effective and safe agent for cervical and vaginal hemorrhage when used as vaginal packing [19]. Therefore, the mechanism of our method is that the reinsertion and inflation of the BBT increased the compression of lower uterine segment and uterine atony while the QuikClot decreased leaking and bleeding. Thus, QuikClot with reinsertion of the BBT is an effective treatment for failures due to balloon prolapse.

Placental retention was the other problem leading to BBT failure. Even if a placenta separated spontaneously, it is possible for a small segment of the placenta to accidentally remain in situ [10]. BBT was not effective for massive bleeding because of focal placental retention [10,13]. Therefore, if successive bleeding from the tube occurs, caused by placental retention, the next step in hemostatic management should be performed immediately [13]. Similarly, in our study, cases with placenta retention developed more bleeding from the drainage port and immediately received UAE. Thus, the bleeding was minimized and this patient did not suffer from a

Table 2
Patients' characteristics and outcomes between Bakri balloon failure and success groups.

		Failure group (n = 9)		Success group (n = 61)		p value
Maternal age (year-old)	≥35	5	(55%)	33	(54%)	0.93
	<35	4	(45%)	28	(46%)	
Gestational age at delivery, (weeks)	≥37	4	(45%)	31	(51%)	0.72
	<37	5	(55%)	30	(49%)	
Parity	Primipara	4	(45%)	29	(47%)	0.86
	Multipara	5	(55%)	32	(53%)	
IVF pregnancy	Yes	1	(11%)	15	(25%)	0.34
	No	8	(89%)	46	(75%)	
Tocolytic agent use	Yes	5	(55%)	33	(54%)	0.93
	No	4	(45%)	28	(46%)	
Warning bleeding	Yes	4	(45%)	15	(25%)	0.23
	No	5	(55%)	46	(75%)	
Cervical length (mm)	≥25	7	(78%)	56	(92%)	0.23
	<25	2	(22%)	5	(8%)	
Repeat cesarean section	Yes	3	(33%)	8	(13%)	0.15
	No	6	(67%)	53	(87%)	
Cesarean section mode	Emergency	2	(22%)	8	(13%)	0.48
	Elective	7	(78%)	53	(87%)	
Previa classification	Major previa	8	(89%)	18	(30%)	<0.01
	Minor previa	1	(11%)	43	(70%)	
Main placenta location	Anterior wall	2	(22%)	4	(7%)	0.17
	Posterior wall	7	(78%)	57	(93%)	
Birth weight (g)	median (range)	2762	(2156–3018)	2634	(1692–3262)	0.56
Intraoperative blood loss (g)	median (range)	1196	(428–1955)	891	(275–2289)	0.41
Postoperative blood loss (g)	median (range)	1153	(784–3050)	70	(10–600)	<0.01
Total blood loss (g)	median (range)	2409	(1212–4230)	971	(287–2369)	<0.01

IVF, in vitro fertilization.

Table 3
Univariate analysis of balloon tamponade failure based on pre-operative factors.

Factors		HR	95% CI	*p* value
Maternal age (year-old)	≥35 vs. <35	1.06	(0.26–4.65)	0.93
Gestational age at delivery (weeks)	≥37 vs. <37	0.77	(0.18–3.19)	0.72
Parity	Primipara vs. Multipara	0.88	(0.20–3.65)	0.86
IVF pregnancy	Yes vs. No	0.38	(0.02–2.35)	0.34
Tocolytic agent use	Yes vs. No	1.06	(0.26–4.65)	0.93
Warning bleeding	Yes vs. No	2.45	(0.55–10.5)	0.23
Cervical length (mm)	>25 vs. <25	0.31	(0.05–2.46)	0.24
Repeat cesarean section	Yes vs. No	3.31	(0.61–15.5)	0.15
Cesarean section mode	Emergency vs. Elective	1.89	(0.25–9.67)	0.49
Previa classification	Major vs. Minor	19.1	(3.17–367.9)	<0.01
Main placenta location	Anterior vs. Posterior	4.07	(0.50–25.3)	0.17

IVF, in vitro fertilization; HR, hazard ratio; CI, confidence interval.

severe condition such as DIC. Thus, when bleeding from the drainage port occurs, an immediate decision to perform an additional hemostatic procedure needs to be made.

Several studies showed the efficacy of BBT for placenta previa [5–9]. However, our results could not be sufficient than other reports because the protocol and endpoint of our study were different form these reports. The fact that hemorrhage of placenta previa occurred both intraoperatively and postoperatively was well-known. Furthermore, the exact predictive model of intraoperative and postoperative hemorrhage of placenta previa has not been established. Thus, we had developed the routine rapid insertion of BBT as the new method and successfully decreased the intraoperative and postoperative hemorrhage [11], but it was not perfect. Therefore, our study examined the cause and treatment for cases with Bakri failure. As results, only one of 70 patients needed further hemostatic procedure such as uterine embolization, which was caused by placental retention. In future, the new strategy to remove placental retention would be needed.

The limitations of this study were its retrospective nature and the small number of cases. However, this study identified that BBT failure is a quite important problem and we believe the present study was significantly meaningful. Thus, further investigations are necessary based on larger number of patients with placenta previa.

In conclusion, we demonstrated that balloon prolapse and placental retention were main causes of failing prophylactic BBT for placenta previa and the risk factor was major previa. We believe that prophylactic use of BBT during cesarean section should be the first choice of hemostatic procedures for women with placenta previa because it is highly effective, easy to use, and non-invasive. However, development of a strategy for both conditions, balloon prolapse and placental retention, is needed.

Conflict of interest statement

None.

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