Does keeping the Bakri balloon in place for longer than 12 hours provide favourable clinical outcomes in the treatment of uterine atony?

Bakri balonun 12 saatten daha uzun süre uygulanması postpartum uterus atonisi tedavisinde olumlu klinik sonuçlar sağlar mı?

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Abstract

Aim: If the initial treatment techniques fail, intrauterine balloon tamponade (IUBT) devices such as Bakri balloon tamponade (BBT) is an effective treatment for reducing the bleeding in uterine atony patients. However, the duration of the Bakri balloon varies widely in clinical practice, and there is no consensus in this issue. This study aimed to compare the clinical outcomes of the Bakri balloon removed in less or more than 12 hours in patients with severe postpartum haemorrhage (PPH).

Materials and methods: This retrospective study included 108 patients who underwent Bakri balloon for severe PPH after vaginal delivery. Patients were divided into two groups as the duration of Bakri balloon 8-12 hours (Group I) and >12 hours (Group II). BBT was considered to be successful if the bleeding was stopped, and the patient did not require additional invasive procedures. Age, parity, gestational week, cause of bleeding, presence of co-morbidity that may increase bleeding (multiple gestation, magnesium sulphate infusion), estimated blood loss (EBL) before and after Bakri balloon, postpartum infection, erythrocyte and fresh frozen plasma requirement and invasive procedure requirement of the groups were compared.

Results: In group I, 26 patients (52%) underwent erythrocyte transfusion, and 18 patients (36%) underwent both erythrocyte and fresh frozen plasma (FFP) transfusion. In group II, 28 patients (41.2%) underwent erythrocyte transfusion, and 21 patients (30.9%) underwent both erythrocyte and FFP transfusion. These differences were not statistically significant (p=0.42 and p=0.21, respectively). Bacri balloon was failed to reduce bleeding in one patient (2%) in group I and one patient (1.5%) in group II, and these patients had to undergo invasive surgical procedures (hysterectomy). There was no statistically significant difference between the groups in terms of failed to reduce bleeding rates (p=0.52).

Conclusion: Keeping the Bakri balloon in place for longer than 12 hours does not provide favourable clinical outcomes compared to keeping in place for less than 12 hours.

Keywords: Postpartum haemorrhage, bakri balloon, postpartum hysterectomy.

Öz

Amaç: *Uterin atonisi olan hastalarda başlangıçta uygulanan tedavi yöntemleri başarısız olursa, Bakri balonu gibi rahim içi tamponad cihazları kanamayı azaltmada etkin bir tedavi yöntemidir. Ancak, klinik uygulamada Bakri balonun uygulama süresi büyük değişkenlik göstermektedir ve bu konuda bir fikir birliği yoktur. Bu çalışmanın amacı, şiddetli postpartum hemorajisi olan hastalarda 12 saatten daha az veya daha fazla sürede çıkarılan Bakri balonun klinik sonuçlarını karşılaştırmaktır.*

Gereç ve yöntem: Bu retrospektif çalışmaya vajinal doğumdan sonra şiddetli postpartum hemoraji nedeniyle Bakri balonu uygulanan 108 hasta dahil edildi. Hastalar Bakri balonun uygulama süresi 8-12 saat (Grup I) ve >12 saat (Grup II) olmak üzere iki gruba ayrıldı. Kanamanın durması ve hastanın ek cerrahi girişim gerektirmemesi durumunda Bakri balon uygulaması başarılı olarak kabul edildi. Grupların yaş, parite, gebelik haftası, kanamayı arttırabilecek ko-morbidite varlığı (çoğul gebelik, magnezyum sülfat infüzyonu), tahmini kan kaybı, doğum sonrası enfeksiyon, eritrosit ve taze donmuş plazma gereksinimi ve invaziv işlem gereksinimi karşılaştırıldı.

Bulgular: Grup I'de 26 hastaya (%52) eritrosit transfüzyonu, 18 hastaya (%36) eritrosit ve taze donmuş plazma (TDP) transfüzyonu yapıldı. Grup II'de 28 hastaya (%41,2) eritrosit transfüzyonu, 21 hastaya (%30,9) eritrosit ve TDP transfüzyonu yapıldı. Bu farklılıklar istatistiksel olarak anlamlı değildi (sırası ile, p=0.42 and p=0.21). Bakri balonu grup I'de 1 hastada (%2), grup II'de 1 hastada (%1,5) kanamayı azaltmada başarısız oldu ve bu hastalar invaziv cerrahi prosedüre (histerektomi) tabi tutuldu. Kanama oranlarını düşürmede başarısızlık açısından gruplar arasında istatistiksel olarak anlamlı bir farklılık yoktu (p=0.52).

Sonuç: Bakri balonun 12 saatten daha uzun süreli uygulanması, 12 saatten daha kısa süre ile uygulanması ile karşılaştırıldığında, olumlu klinik sonuçlar sağlamamaktadır.

Anahtar Sözcükler: Postpartum hemoraji, bakri balon, postpartum histerektomi.

Introduction

Postpartum haemorrhage (PPH) is the most common cause of maternal death (1). In the literature, the prevalence of PPH varies between 1% and 10% of all deliveries (2). The incidence of PPH increases continuously. This is due to an increase in advanced maternal age pregnancies, multiple pregnancy rates, cesarean delivery rates and abnormal placentation rates due to previous cesarean deliveries (3). American College of Obstetricians and Gynecologists (ACOG) stated that PPH cannot be defined in a single way (4). The most commonly used definition is blood loss of more than 500mL following vaginal delivery and more than 1000 mL following cesarean delivery. Severe PPH, defined as the condition where cumulative blood loss is more than 1000 mL and accompanied by hypovolemia symptoms, occurs in 2.5% of all deliveries (5). If the diagnosis of severe PPH is delayed or severe PPH is not appropriately managed, it becomes a life-threatening condition causing hypovolemic shock and/or coagulopathy (6). The most common causes of PPH are uterine atony, retention of placenta, abnormal placentation, uterine rupture, lower genital tract lacerations and coagulation abnormalities (7). In a study conducted in our region, the incidence of emergency postpartum hysterectomy rate was 0.77 in 1000 delivery, and the most frequent reason (64.5%) for postpartum hysterectomy was uterine atony (8).

The first-line treatment of PPH consists of uterine massage and administration of uterotonic drugs (9). If the initial treatment methods fail, ACOG and WHO recommended intrauterine balloon tamponade (IUBT) devices such as Bakri balloon tamponade (BBT) (10). The bleeding-reducing effects of these devices are due to compression of the vascular placental bed, stimulating uterine contractility, and direct hydrostatic pressure on the uterine arteries (11). The efficacy of BBT, defined as the absence of a need for any other invasive procedure (embolisation, surgery), is 83-98% (12, 13). The advantages of these balloons are the ability to measure the amount of blood loss by providing drainage and can be easily inserted through both transabdominal and transvaginal route (14, 15). However, in the literature, data on the optimal duration time of the Bakri balloon remain unclear. In this study, we aimed to compare the clinical outcomes of the Bakri balloon removed in less or more than 12 hours in patients with severe PPH.

Material and methods

This retrospective study included 108 patients who underwent BBT for severe PPH after vaginal delivery in the Diyarbakır Gazi Yaşargil Training and Research Hospital Department of Obstetrics and Gynecology between 2014 and 2019. Approval of the study was obtained from the ethics committee of the same hospital.

In all vaginal deliveries in our clinic, we aimed to reduce PPH by following the stepwise management protocol. Accordingly, active management is performed in the third stage of all vaginal deliveries (16). The components of active management are as follows: 10 units of oxytocin

administration, uterine massage and umbilical cord traction (17). In case of severe bleeding after removal of the placenta, the bladder was emptied with a Foley catheter (because bladder distension is one of the causes of uterine atony), the genital tract was explored for traumatic damage, and the uterine cavity was observed with the ultrasound (US) for retained placental tissue (17). Concurrently uterine massage was performed until adequate contraction occurs, and uterotonic drugs such as oxytocin (40 units, 125 mL/h), methylergonovine (0.25 mg) and/or misoprostol (800-1000 µg) were administered (17). If excessive bleeding persisted despite these treatments and uterine atony was considered as the cause of bleeding, Bakri balloon (Cook Medical Inc, Bloomington, Indiana, USA) was inserted through transvaginal route into the uterine cavity. The Bakri balloon's intrauterine placement was observed by the US. After the Bakri balloon was placed in the uterine cavity, it was filled with 400-800 mL of sterile saline depending on the surgeon's preference and uterine resistance. Oxytocin infusion was continued. All patients received prophylactic antibiotics during their hospitalisation. If there was no bleeding from the cervix or balloon drainage 15 minutes after the balloon placement, the patient was decided to follow up in the intensive care unit. The duration time of the Bakri balloon was determined by the clinician. When it was decided to remove the Bakri balloon, the balloon was gradually deflated and then removed. The patient was transferred to the delivery unit.

PPH was defined as the blood loss of more than 500 mL following vaginal delivery (4). The inclusion criteria in the study were that the patient had delivered after the twenty-fourth week of pregnancy, had PPH failed to respond to the first-line treatment, and was administered Bakri balloon instead of invasive procedures to reduce bleeding (Figure-1). BBT was considered to be successful if the bleeding was stopped, and the patient did not require additional invasive procedures. Postpartum infection defined as the temperature over 38.6°C during the first 24 hours after delivery or over 38°C on any two of the early 10 postpartum days after day one (18). Patients were divided into two groups as the duration of Bakri balloon 8-12 hours (Group I) and >12 hours (Group II). Age, parity, gestational week, cause of bleeding, presence of co-morbidity that may increase bleeding (multiple gestation, magnesium sulphate [MgSO4] infusion), estimated blood loss (EBL) before and after Bakri balloon, postpartum infection, erythrocyte and fresh frozen plasma requirement and invasive procedure requirement of the groups were compared.
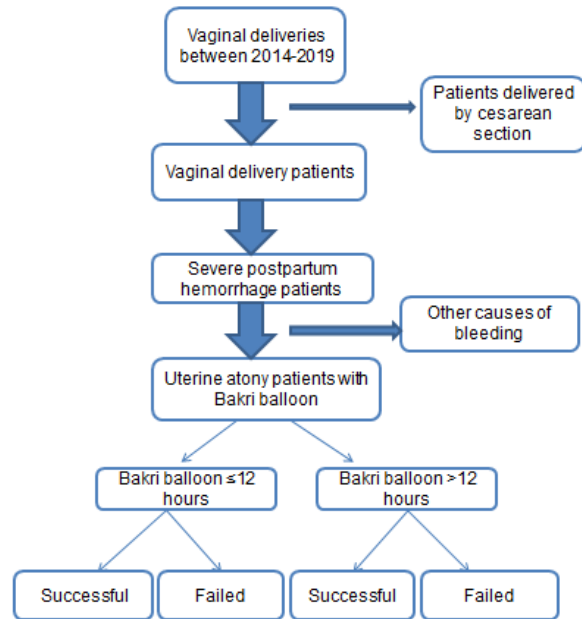
Statistics

SPSS 16.0 for Windows (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Numerical data were expressed as mean and standard deviation, and categorical data were expressed as frequency and percentage. The comparison of categorical data in the groups was made with Chi-square and Fisher exact tests. Student's t-test was used to compare the normally distributed data, while the Mann-Whitney U test was used to compare the non-normally distributed data. In all comparisons, $p < 0.05$ was considered statistically significant.

Results

Bakri balloon was administered to 118 patients who had severe and failed to respond to the first-line management uterine atony following vaginal delivery. There were 50 (42.4%) patients who had a Bakri balloon duration of 8-12 hours (group I) and 68 (57.6%) patients with a Bakri balloon duration of more than 12 hours (group II). The duration range of group I was 8 hours to 12 hours, the duration range of group II was 13 hours to 24 hours (Table-1).

Table-1. Demographic characteristics and clinical outcomes of the groups.

	Group I Bakri balloon 8-12 hours (n=50)	Group II Bakri balloon >12 hours (n=68)	P value
Age*	31.4±5.7	30.1±5.5	0.23
Gestational age (week)*	39.6±2.6	40.0±1.8	0.34
Nulliparous**	23 (46.0)	28 (41.2)	0.18
Co-morbidity**			
Multipl gestation	3 (6.0)	4 (5.8)	0.56
MgSO4 infusion	3 (6.0)	5 (7.3)	0.24
EBL before Bakri balloon (mL)*	1.350±540.0	1.540.6±540.0	0.19
EBL after Bakri balloon (mL)*	325.0±112.2	295±108.4	0.27
Lowest hemoglobin value ≤6.0 mg/dL	2 (4.0)	3 (4.4)	0.52
Transfusion of blood products**			
Erythrocyte	26 (52.0)	28 (41.2)	0.42
Erythrocyte+FFP	18 (36.0)	21 (30.9)	0.21
Transfusion of 4 or more units RBC**	8 (16.0)	11 (16.2)	0.17
Total duration (hours)	10 (8-12)	21 (17-24)	P<0.001
Hysterectomy**	1 (2.0)	1 (1.5)	0.52
Postpartum infection**	3 (6.0)	5 (7.3)	0.42

*: mean±std, **: n (%), ***: median (minimum-maximum)
EBL: Estimated Blood loss, FFP: Fresh Frozen Plasma

The mean age of the patients in group I was 31.4±5.7 years, and in group II was 30.1±5.5 years. The mean gestational age of the patients in group I was 39.6±2.6 weeks, and in group II was 40.0±1.8 weeks. 23 (19.4%) patients in group I, and 28 patients in group II were nulliparous. 3 (2.5%) patients in group I and 4 (3.3%) patients in group II were multiple gestations. Simultaneous intravenous infusion of MgSO4 was given to 3 (2.5%) patients in group I and 5 (4.2%) patients in group II due to severe preeclampsia. In group I, 26 patients (52%) underwent erythrocyte transfusion, and 18 patients (36%) underwent both erythrocyte and fresh frozen plasma (FFP) transfusion. In group II, 28 patients (41.2%) underwent erythrocyte transfusion, and 21 patients (30.9%) underwent both erythrocyte and FFP transfusion. Bakri balloon was failed to reduce bleeding in one patient (2%) in group I and one patient (1.5%) in group II, and these patients had to undergo invasive surgical procedures (hysterectomy). There was no statistically significant difference between the groups in terms of failed to reduce bleeding rates. The postpartum infection rate was 2.5% in group I and 4.2% in group II. This difference was not statistically significant.

Discussion

In the literature, many studies have shown that Bakri balloon and other IUBT devices successfully reduce bleeding in severe PPH (19). Mostly, invasive procedure requirement ratios are used as an objective indicator of this. In a recent study by Tahaoglu et al., the rate of bilateral internal iliac artery ligation rate was 10.71% (20). None of the postpartum atony patients who underwent Bakri balloon required a hysterectomy, and the success rate of Bakri balloon was 89.29%. In our study, since the total hysterectomy rate was 1.7%, we can say that the Bakri balloon successfully reduced severe bleeding after vaginal deliveries. When both groups were examined separately, the hysterectomy rate was 2% in group I and 1.5% in group II (p=0.52). According to this result, this study suggests that keeping a Bakri balloon in place for more than 12 hours has no positive effect on clinical outcomes. Few studies have been conducted on the optimal duration of the Bakri balloon. In a 2007 study, the median duration was reported to be 11 hours (21). But, the range was 10 hours to 24 hours, and the effect of different durations on clinical outcomes

was not considered. In a study conducted with 109 patients in 2014, the mean retaining time of IUBT was 22.0±3.0 hours in the success group, but they did not report the clinical outcomes of different durations (22). In the study of Alouni et al., the mean duration of Bakri balloon was 7 hours (23). They suggested that the prolonged time with the Bakri balloon in place was due to the persistence of haemorrhage. Furthermore, the long time of Bakri balloon placement was complicated by 10% chorioamnionitis. In the study conducted by Einerson et al. in 2016 which examined the association between IUBT duration and PPH outcomes, they suggested that keeping IUBT in place for more than 12 hours was not beneficial to reduce excessive bleeding (24). In the same study, a Bakri balloon of more than 12 hours may be associated with postpartum fever. In our study, there was no statistical difference between the two groups in terms of postpartum infection.

In studies, the transfusion requirement rates of erythrocyte and other blood products vary. In the study of Alouni et al., 63% of patients underwent red blood cells transfusion (23). In the study of Einerson et al., the rate of blood and blood product transfusion was 59% (24). In our study, blood and blood product transfusion rate was 78.8%. The rate of patients who may be complicated with PPH has referred to our hospital, and the delivery rate of such patients was high.

In 2018, Grange et al. examined the predictors of failed IUBT for persistent PPH after vaginal delivery (25). They reported that body mass index, labour duration, estimated blood loss and more than four packed of erythrocyte transfusion were statistically significant in predicting the failure of IUBT. In the same study, the rate of more than four packed of erythrocyte transfusion in the failed IUBT group was 92.9%, in all patients was 47.2%. In our study, this ratio was 17.6%, and this rate is one of the reasons for the high success rate of Bakri balloon in our study.

The strength of this study is that, to the best of our knowledge, there is only one other study in the literature, compare the outcomes of Bakri balloon placement less or more than 12 hours. The lack of consensus among clinicians on this subject may make the study attractive. The limitations of the study are the retrospective nature of the study and the lack of predictors such as BMI and labour duration that may affect the success of Bakri balloon. Further research of larger series on this subject is needed.

Conclusion

According to our findings, keeping the Bakri balloon in place for longer than 12 hours does not provide favourable clinical outcomes compared to keeping in place for less than 12 hours.

Conflict of interest: The authors have not declared any conflict of interest in this study.

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