

# Bakri Balloon Application in Postpartum Haemorrhage; Our 6-Year Experience

## Postpartum Kanamada Bakri Balon Uygulamasının Yeri; 6 Yıllık Tecrübemiz

Ayla AÇAR ESER,<sup>a</sup>  
Aydın KÖŞÜŞ,<sup>a</sup>  
Sevgi YILDIRIM ASLANER,<sup>a</sup>  
İlknur İNEGÖL GÜMÜŞ,<sup>a</sup>  
İkbal KAYGUSUZ,<sup>a</sup>  
Nermin KÖŞÜŞ,<sup>a</sup>  
Deniz HIZLI,<sup>a</sup>  
Zehra Candan İLTEMİR DUVAN,<sup>a</sup>  
Hasan KAFALI<sup>b</sup>

<sup>a</sup>Department of Obstetrics and Gynecology, Turgut Özal University Faculty of Medicine,  
<sup>b</sup>Department of Obstetrics and Gynecology, Gazi University Faculty of Medicine, Ankara

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Yazışma Adresi/Correspondence:  
Ayla ESER  
Turgut Özal University Faculty of Medicine,  
Department of Obstetrics and Gynecology,  
Ankara,  
TÜRKİYE/TURKEY  
aylaacar76@yahoo.com.tr

**ABSTRACT Objective:** To evaluate effectiveness of Bakri Balloon in post-partum haemorrhage treatment. Post-partum haemorrhage is the most common cause of maternal death in the world. It is potentially fatal complication of both vaginal and caesarean deliveries. In situations where medical interventions are unsuccessful in achieving haemostasis in cases of post-partum haemorrhage, either conservative or invasive surgical therapies are needed. Ultimately hysterectomy may be required. Invasive surgical interventions are associated with co-morbidities and potential implications for future fertility. Among the more conservative interventions are intrauterine balloon tamponade such as the Bakri balloon. **Material and Methods:** In this retrospective, observational study, records of 25 patients who were treated for post-partum haemorrhage in the Obstetrics and Gynecology Clinic of Turgut Ozal University Hospital, between January 2009 and August 2014 were examined. Frequency and efficacy of interventions were investigated in terms of haemostasis achievement without recourse to hysterectomy. **Results:** In 12 women who underwent Bakri balloon placement, haemostasis was achieved in all patients without subsequent hysterectomy. By contrast, of 9 women who underwent arterial ligation, 77.8% required hysterectomy as opposed to 31.3% of the 16 women who did not undergo arterial ligation. Use of combinations of surgical techniques was also significantly associated with higher risk of hysterectomy when compared to single techniques. **Conclusion:** Use of Bakri balloon is a highly effective method in achieving haemostasis in post-partum haemorrhage without necessity of hysterectomy.

**Key Words:** Postpartum hemorrhage; uterine balloon tamponade

**ÖZET Amaç:** Postpartum kanama tedavisinde Bakri balonun etkinliğini değerlendirmek. Postpartum kanama dünyada doğum sonrası anne ölümlerinin en yaygın sebebidir. Hem vajinal hem de sezaryenle doğumlarda potansiyel ölümcül bir komplikasyondur. Medikal tedavilerle kanama kontrolünün başarısız olduğu postpartum kanama olgularında hem konservatif hem de invaziv cerrahi müdahaleler gereklidir. Son aşamada histerektomi gerekli olabilir. İnvaziv cerrahi müdahaleler komorbidite ve gelecekteki fertilitenin etkilenme potansiyeli ile ilişkilidir. Bakri balon gibi intrauterin balon tamponad sistemleri daha konservatif müdahaleler arasındadır. **Gereç ve Yöntemler:** Bu retrospektif gözlemsel çalışmada Turgut Özal Üniversitesi Hastanesi Kadın Hastalıkları ve Doğum kliniğinde Ocak 2009 ve Ağustos 2014 tarihleri arasında postpartum kanama nedeni ile tedavi edilen 25 hastaya ait kayıtlar incelendi. Yapılan müdahalelerin sıklığı ve histerektomiye gerek duyulmadan kanamanın durdurulması açısından müdahalelerin etkisi araştırıldı. **Bulgular:** Bakri balon uygulaması yapılan 12 hastanın tamamında kanama histerektomiye gerek kalmadan durduruldu. Buna karşın arteriyel ligasyon uygulanan 9 kadının %77,8'inde histerektomiye gerek duyulmuşken, arteriyel ligasyon uygulanmayan 16 kadının %31,3'ünde histerektomi gerekli olmuştur. Tek bir cerrahi uygulamaya kıyasla birden fazla cerrahi tekniğin birlikte uygulanması da yüksek histerektomi riskiyle önemli ölçüde ilişkilidir. **Sonuç:** Bakri balon uygulaması histerektomiye gerek-tirmeksizin postpartum kanamanın durdurulmasında oldukça etkili bir yöntemdir.

**Anahtar Kelimeler:** Postpartum kanama; uterin balon tamponadı

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Post-partum haemorrhage (PPH) is the most common cause of maternal death in the world. It is a potentially fatal complication for both vaginal and caesarean deliveries. PPH is defined as blood loss of 500 ml or more within the first 24 hours after the delivery, while severe post-partum haemorrhage (SPPH) is defined as blood loss of 1000 ml in the same period.<sup>1</sup> Associated potential morbidities include blood transfusion, renal failure, coagulation deficiencies and anaemia while invasive surgical procedures including hysterectomy carried out to reduce blood flow have potential consequences for future maternal fertility.<sup>1</sup> While uterine atony is the most common cause of PPH, especially in low and middle-income countries, other causes include retained placenta, uterine rupture due to tearing of uterine scar tissue or coagulopathies.<sup>1</sup> Risk factors include placenta praevia, placenta increta, antepartum haemorrhage during the current pregnancy, hypertension or pre-eclampsia, uterine abnormalities, previous PPH, general anaesthesia, large for gestational age (LGA) newborn and induced labour.<sup>2-5</sup>

In situations where medical interventions are unsuccessful in managing PPH, either conservative or invasive surgical therapies are necessary. Invasive interventions include arterial embolization, uterine, ovarian or hypogastric arterial ligation or compression sutures. Ultimately, hysterectomy may be unavoidable. The invasiveness of these methods, with their associated co-morbidities and potential implications for future fertility, mean that more conservative interventions are often attempted in the first instance. One such intervention is intrauterine balloon tamponade, which has been suggested as an effective and relatively easily administered intervention to control uterine bleeding, without compromising future maternal fertility.<sup>6,7</sup> These devices are believed to work by exertion of inward to outward uterine pressure, thus relieving both capillary and venous bleeding from the endometrium and the myometrium.<sup>8</sup> One example of an intrauterine balloon tamponade is the Bakri balloon.

The Bakri balloon is a latex-free device with a silicone catheter. Since it was mentioned in the

American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin of 2006, which cited its specifically tailored design for conservative management of uterine bleeding for various PPH causes, its use has grown internationally.<sup>9</sup> Many recent case series have described use of either vaginally or abdominally placed Bakri balloon in cases of PPH. Success rates in achieving successful haemostasis have generally been reported as high, ranging typically from approximately 75.5% up to 100%.<sup>10-18</sup> However, one recent retrospective cohort study on 35 women with PPH maintained that success rate was closer to 67.57%, where failure was defined as the need for another form of haemorrhage control.<sup>19</sup>

Some studies have reported a high success rate when using the Bakri balloon in conjunction with uterine compression sutures in the so-called 'uterine sandwich' technique, even in cases of high-risk patients such as those with placenta accreta or placenta percreta.<sup>20-24</sup> In one series of 20 cases of severe PPH, 60% were successfully treated with Bakri balloon alone, with 30% being successfully treated with the balloon and the B-Lynch suture together.<sup>21</sup> However, a recent review of the literature on Bakri balloons points to a paucity of publications and suggests a necessity for randomised control trials of the device compared to uterotonics alone.<sup>25</sup>

In this study, we retrospectively analysed records of patients who experienced PPH in our hospital to determine what interventions were most effective in restoring women to haemostasis and avoiding hysterectomy. Our results add to the literature suggesting the effectiveness of the Bakri balloon in restoring haemostasis without recourse to hysterectomy.

## MATERIAL AND METHODS

### STUDY DESIGN

This was a retrospective, observational study, carried out at the Obstetrics and Gynecology Clinic of Turgut Ozal University Hospital between January 2009 and August 2014.

## STUDY ETHICS

This study was approved by Turgut Ozal University Ethical Committee and complied with the Helsinki Declaration.

## PATIENTS

Computer records and patient files were obtained for a total of 25 patients who gave birth in the Obstetrics and Gynecology Clinic of Turgut Ozal University Hospital between January 2009 and August 2014 and had been treated for PPH.

## STATISTICAL ANALYSIS

The Statistical Package Program for the Social Sciences (SPSS 16.0; SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Data were examined with Shapiro-Wilk test in terms of normal distribution. Continual data were denoted as median (minimum-maximum); mean±SD was used for normally distributed data. For comparison categorical data (number and percentage), the chi-square test was applied.  $P < 0.05$  was considered significant.

## RESULTS

Patients ( $n=25$ ) included in this study had an average age of  $31.6 \pm 4.6$  year, gravidity 2 (1-5), parity 0 (0-2), average weight  $63.3 \pm 11.3$  kg before pregnancy and  $76.4 \pm 13.1$  kg at birth, gestation week of  $38.0 \pm 1.7$  weeks and infant birthweight of  $3425.5 \pm 601.1$  g. Twenty three patients (92.0%) gave birth by caesarean section, of whom 11 (44%) delivered under general anaesthesia. One patient had a history of PPH in her last delivery, and four patients (16%) had antenatal bleeding during the current pregnancy. Three patients (12%) had tocolysis at the time of pregnancy, five patients (20%) had labour induction with oxytocin, five patients (20%) had placenta praevia totalis and one had placenta praevia marginalis (Table 1). Two patients (8%) had myoma uteri, which can be a risk factor for postpartum bleeding. Placenta accreta was diagnosed in three patients (12%) and placenta percreta in two patients (8%) intra-operatively. Three of the babies (12%) had birthweight between 4000-4500 g, and one was  $>4500$  g.

**TABLE 1:** Placental localization for patients treated for postpartum haemorrhage.

	n	%
<b>Placenta-internal cervical ostium relationship</b>		
Normal-away from cervix	16	64.0
Low lying-unrelated cervix	3	12.0
Placenta praevia marginalis	1	4.0
Placenta praevia totalis	5	20.0
<b>Placental localization</b>		
Anterior wall	16	64.0
Posterior wall	9	36.0

**TABLE 2:** Causes and time of postpartum haemorrhage.

	n	%
<b>Cause of bleeding</b>		
Uterine atony	18	72.0
Placental attachment area	7	28.0
Total	25	100.0
<b>Time of bleeding</b>		
Prepartum-preoperative	1	4.0
Intrapartum-intraoperative	14	56.0
Postpartum-postoperative		
0-2 hours	6	24.0
2-16 hours	2	8.0
after 48 hours	2	8.0
Total	25	100.0

The cause of bleeding in 18 of the patients (72%) was uterine atony. It was established that 14 of the patients (56%) bled in the intra-operative phase (Table 2). Total median oxytocin dose of 50 (20-100) U, methylergonovine dose of 0.4 (0.2-1.8) mg and misoprostol dose of 600 (400-1800) µg were used in medical treatment. Median blood and blood products transfusions carried out were complete blood 3 (1-10) U, erythrocyte suspension of 4 (1-11) U, fresh frozen plasma of 5 (2-11) U and platelets suspension of 3.5 (2-5) U.

Bakri balloon was used in 12 of the patients (48%). Supracervical hysterectomy was carried out on 11 patients (45.8%) and total abdominal hysterectomy was carried out on 1 patient (4%) in order to stop bleeding. One patient did not receive either Bakri balloon or hysterectomy; only arterial ligation (uterine + hypogastric artery ligation) was

**TABLE 3:** The relation of intervention before hysterectomy and hysterectomy operation.

			Hysterectomy		Total	p
			No	Yes		
Uterine a. ligation	no	n	13	7	20	0.015
		% procedure	65.0	35.0	100.0	
		% hysterectomy	100.0	58.3	80.0	
	yes	n	0	5	5	
		% procedure	0.0	100.0	100.0	
		% hysterectomy	0.0	41.7	20.0	
Ovarian a. ligation	no	n	13	10	23	0.220
		% procedure	56.5	43.5	100.0	
		% hysterectomy	100.0	83.3	92.0	
	yes	n	0	2	2	
		% procedure	0.0	100.0	100.0	
		% hysterectomy	0.0	16.7	8.0	
Hypogastric a. ligation	no	n	11	7	18	0.202
		% procedure	61.1	38.9	100.0	
		% hysterectomy	84.6	58.3	72.0	
	yes	n	2	5	7	
		% procedure	28.6	71.4	100.0	
		% hysterectomy	15.4	41.7	28.0	
B-Lynch suture	no	n	13	9	22	0.096
		% procedure	59.1	40.9	100.0	
		% hysterectomy	100.0	75.0	88.0	
	yes	n	0	3	3	
		% procedure	0.0	100.0	100.0	
		% hysterectomy	0.0	25.0	12.0	
Bakri Baloon	no	n	1	12	13	<0.001
		% procedure	7.7	92.3	100.0	
		% hysterectomy	7.7	100.0	52.0	
	yes	n	12	0	12	
		% procedure	100.0	0.0	100.0	
		% hysterectomy	92.3	0.0	48.0	

P<0.05 was considered significant.

carried out for this patient. Other invasive surgical methods that were used apart from hysterectomy included uterine, ovarian or hypogastric ligation, either individually, together or in combination with uterine compression using B-Lynch suture (Table 3). Only application of Bakri balloon was highly effective in achieving haemostasis without subsequent hysterectomy; of the 12 patients to whom Bakri balloon was applied, none had subsequent hysterectomies (Table 3). By contrast, none of the other interventions were associated with significant avoidance of subsequent hysterectomy (Table 3). Table 4 shows the distribution of surgical methods other than hysterectomy in the treat-

**TABLE 4:** The distribution of surgical methods other than hysterectomy in treatment of postpartum bleeding.

	n	%
No	16	64.0
Only uterine artery ligation	2	8.0
Only hypogastric artery ligation	2	8.0
Uterine + hypogastric artery ligation	2	8.0
Hypogastric artery ligation + B-Lynch	1	4.0
Ovarian + hypogastric arter + B-Lynch	1	4.0
Uterine + hypogastric + ovarian artery ligation + B-Lynch	1	4.0
Total	25	100.0

ment of postpartum bleeding. Hysterectomy rate was significantly higher among the patients who

**TABLE 5:** Effect of arterial ligation for prevention of hysterectomy operation.

		Hysterectomy			p
		No	Yes		
Artery ligation	No	N	11	5	0.041
		% artery ligation	68.8	31.3	
		% hysterectomy	84.6	41.7	
		% Total	44.0	20.0	
Yes	Yes	N	2	7	
		% artery ligation	22.2	77.8	
		% hysterectomy	15.4	58.3	
		% Total	8.0	28.0	

**TABLE 6:** The effect of combined surgical methods on hysterectomy development.

		Hysterectomy			p
		No	Yes		
Combination	No	n	11	7	0.202
		% combined	61.1	38.9	
		% hysterectomy	84.6	58.3	
		% Total	44.0	28.0	
Yes	Yes	n	2	5	
		% combined	28.6	71.4	
		% hysterectomy	15.4	41.7	
		% Total	8.0	20.0	

underwent arterial ligation. Of the 9 patients who underwent arterial ligation of any kind in any combination, 7 (77.8%) required hysterectomy (Table 5). By contrast, for the 16 patients who did not undergo any form of arterial ligation, only 5 (31.3%) needed hysterectomy. Combined surgical procedures were associated with significantly increased risk of subsequent hysterectomy compared to single interventions (Table 6). All of the patients were discharged with cure after a median discharge interval of 4 (2-10) days.

The patients who have treated with Bakri Balloon had average age of  $30.3 \pm 3.8$  year and an average gestational week of  $37.8 \pm 2.2$ . Two patients had antenatal bleeding history during their pregnancy, 2 patients had tocolysis at the time of pregnancy, 3 patients had labour induction with oxytocin, 2 patients had placenta praevia totalis and one had placenta praevia marginalis, only 1 patient had placenta accreta-increta which can be a risk

factor for postpartum bleeding (Table 7). All of the patients gave birth by caesarian section, of whom 5 delivered under general anaesthesia and 7 delivered under combined regional anaesthesia (spinal+epidural) (Table 7).

The patients who have treated with B Lynch suture had an average age of  $28.6 \pm 8.8$  year and an average gestational week of  $38.1 \pm 0.8$ . None of the patients had a history of tocolysis, labour induction, placenta praevia or placentation abnormalities, but only one patient had a history of antenatal bleeding during the current pregnancy. Two patients gave birth by caesarean section who delivered under combined regional anaesthesia (spinal+epidural).

## DISCUSSION

High success rates in achieving successful haemostasis, ranging typically from approximately

**TABLE 7:** Clinical characteristics of patients treated with Bakri Balloon.

Bakri Balloon	No	Yes	p
Age (year)	32.0±4.3	30.3±3.8	0.188
Prepregnancy weight (kg)	64.3±14.0	61.3±7.2	0.696
Weight at delivery (kg)	75.9±14.1	81.0±12.5	0.420
Gestational week	37.7±1.5	37.8±2.2	0.854
Infant birthweight	3270.0±537.9	3612.0±646.7	0.190
Infant sex (n %)			0.428
Girl	6 46.2	8 66.7	
Boy	7 53.8	4 33.3	
History of antenatal bleeding (n %)			1.000
No	11 84.6	10 83.3	
Yes	2 15.4	2 16.7	
History of tocolysis (n %)			0.593
No	12 92.3	10 83.3	
Yes	1 7.3	2 16.7	
Labour Induction			1.000
No	10 76.9	9 75.0	
Yes	3 23.1	3 25.0	
Placenta (n %)			0.627
Normal	9 69.2	7 58.3	
Low laying	1 7.7	2 16.7	
Placenta previa marginalis	0 0.0	1 8.3	
Placenta previa totalis	3 23.1	2 16.7	
Anomalies of Placentation (n %)			0.287
No	9 69.2	11 91.7	
Acreata-increata	2 15.4	1 8.3	
Percreata	2 15.4	0 0.0	
Type of delivery (n %)			0.480
Vaginal	2 15.4	0 0.0	
Cesarean section	11 84.6	12 100.0	
Kind of anesthesia (n %)			0.684
General anesthesia	6 54.5	5 41.7	
Combined regional anesthesia	5 45.5	7 58.3	

P<0.05 was considered as significant.

75.5% up to 100%, have been reported for use of the Bakri balloon for treatment of PPH.<sup>10-18</sup> In this study, we share our experience of use of Bakri balloon, among other interventions in cases of PPH, over the past six years. Among 25 patients who were treated for PPH over this period, Bakri balloon was used in twelve of them. Of these twelve women, haemostasis was successfully achieved in all without requirement of subsequent hysterectomy. Thus, our retrospective, descriptive study

adds to the literature suggesting that Bakri balloon is an effective, simple and safe approach for treatment of PPH.

Use of intrauterine balloon tamponade such as Bakri balloon has been proposed as an effective and relatively easily administered method for controlling PPH, with minimization of risk to future maternal fertility.<sup>6,7</sup> In our study, use of arterial ligation was associated with a significantly higher rate of hysterectomy. Combination of surgical procedures was also associated with a higher risk than single procedures. Use of Bakri balloon, on the other hand, successfully controlled PPH in all cases in which it was used and removed the need for more aggressive procedures, preserving future maternal fertility and reducing morbidity.

This 100% success rate is consistent with other case series, such as in a series of ten patients who underwent therapeutic placement of Bakri balloon for PPH resultant from uterine atony, after spontaneous delivery and uterotonics administration.<sup>15</sup> Close to 100% success was also achieved in other case series, including a 93.6% success rate in a recent study on a series of 109 patients with PPH after unsuccessful first-line medication from thirteen hospitals in Guangdong in China in 2013 and a 94.2% success rate in 35 subjects in Mexico, where obstetric haemorrhage is the second leading cause of maternal death.<sup>11,12</sup>

However, as with our study most of the published case series are retrospective, descriptive studies. A recent review of the literature on Bakri balloons highlighted the paucity of publications.<sup>25</sup> Differences in success rates have been reported in some studies. For example, in one recent retrospective cohort study on 35 women, using data derived from charts, a lower success rate of 67.5% was reported, where failure was defined as need for another form of haemorrhage control.<sup>19</sup> Other studies have reported greater success with Bakri balloon in combination with other techniques. For example, in one study of 45 women with PPH who underwent Bakri balloon placement after initial management was not successful, haemostasis was achieved in 75.5% of cases with the balloon alone

whereas the success rate rose to 88.8% with additional bilateral internal iliac artery ligation (BIIAL) in six women.<sup>16</sup> Other studies have reported on effectiveness of using the Bakri balloon in conjunction with uterine compression sutures in the 'uterine sandwich' technique.<sup>20-24</sup> For example, in one series of 20 cases of severe PPH, 60% were successfully treated with Bakri balloon alone, with 30% being successfully treated if the Bakri balloon and the B-Lynch suture were used together.<sup>21</sup> In the light of all these studies, randomised control trials of Bakri balloon use, both alone and in combination with other interventions, are indicated for definitive assessment of effectiveness and safety of Bakri balloon.<sup>25</sup> However, despite the limitations of our study in terms of the retrospective, observational study design and the relatively small patient numbers, our results are consistent with others in suggesting that Bakri balloon is a safe and effective management technique for PPH control. Even studies suggesting a lower success rate report decreased maternal morbidity with the Bakri balloon.<sup>19</sup>

The utility of this method extends beyond treatment of PPH to prophylactic use, for example in high-risk patients with low-lying placenta after caesarean section.<sup>15</sup> When used therapeutically, it also affords achievement of temporary tamponade for long enough to allow preparation for other procedures or for movement of the patient to a more appropriate facility.<sup>17</sup> It has been reported to be readily removable, to not interfere with subsequent procedures and to not be associated with increased infection risk.<sup>26</sup> Its advantages over other intrauterine tamponade devices include the facts that it is made of silicone, allowing its use in patients with latex allergy, its shape which conforms more naturally to the uterine cavity, a reduced risk of uterine perforation and that it is available pre sterilized and ready to use.<sup>27</sup> Although there are some contraindications for its use, such as preg-

nancy, cervical cancer, some congenital uterine anomalies or pathologies that distort the uterus and suspected rupture of the uterus, these are few. Lack of complete clinical data has led to disseminated intravascular coagulation (DIC) being listed as a contraindication. However, in one recent report two cases were described in which Bakri balloon was used in conjunction with a non-pneumatic anti-shock garment (NASG) to successfully stabilize patients with massive PPH complicated with DIC, during transfusion, without any need for further surgical procedures.<sup>28</sup> This further highlights the potential versatility of the Bakri balloon and the need for randomized trials. Our study stands with others in supporting the effectiveness of this method in control of PPH, avoidance of hysterectomy and preservation of maternal ability to have future pregnancies.

## CONCLUSION

This retrospective study on 25 cases of PPH over a six year period showed that of twelve patients who were treated with Bakri balloon, there was a 100% rate in avoiding subsequent hysterectomy. This was in contrast to the 77.8% hysterectomy rate in the nine patients who underwent arterial ligation of any kind in any combination and the 71.4% of patients who underwent a combination of surgical procedures as opposed to a single procedure. This high success rate for avoidance of subsequent hysterectomy after use of Bakri balloon, as opposed to more invasive treatments, is consistent with the results of other retrospective studies. The results add to the evidence suggesting that Bakri balloon is a safe and effective management technique for achieving haemostasis in PPH control. However, randomized control trials of Bakri balloon use, either alone or in combination with other interventions, are recommended for definitively testing effectiveness and safety of the Bakri balloon in treatment of PPH.

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