Bakri balloon placement effectively treats uterine atony and placenta previa

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ABSTRACT
The aim of this study was to explore the success rates of Bakri balloon placement in patients with placenta previa and uterine atony. In addition, we compared bilateral internal iliac artery ligation (B-IIAL) and Bakri balloon placement in terms of their ability to inhibit haemorrhage in postpartum placenta previa patients. The hospital reports filed annually from 2010 to 2015 were reviewed. In total, 54 patients were evaluated: 42 patients with placenta previa and uterine atony were treated with Bakri balloons, and 12 placenta previa patients with postpartum haemorrhage underwent B-IIAL when medical treatment failed. The results showed that the success rates of Bakri balloon placement rate in placenta previa and uterine atony patients were 71.4% and 89.2%, respectively. The comparative analysis of placenta previa patients treated via Bakri balloon placement and B-IIAL showed that the requirements for packed red blood cell and fresh frozen plasma, pre- and post-partum haemoglobin levels, pre- and post-partum platelet counts, and hospitalization times differed significantly between the two groups (all $p < 0.05$). Bakri balloon tamponade could be considered an effective treatment for placenta previa and uterine atony. The technique is minimally invasive and can serve as a second-line treatment for patients with postpartum haemorrhage when medical procedures fail.

Subjects and methods
This retrospective study assessed 54 patients with PPH treated via Bakri balloon placement and B-IIAL at a tertiary hospital between 2010 and 2015. Ethics approval was obtained from the relevant committee of Gazi Yasargil Research and Training Hospital; hospital data were reviewed. Between 2010 and 2012, 12 PPH cases attributable to placenta previa were treated with B-IIAL when medical treatment failed. After 2012, Bakri balloons were used to manage PPH. Overall, 42 patients with uterine atony and placenta previa, treated with Bakri balloons, were included in the study. A flowchart of the study cohort is shown in Figure 1.

Introduction
Postpartum haemorrhage (PPH) is difficult to treat and contributes significantly to maternal morbidity and mortality [1,2]. PPH has various causes, of which uterine atony, placenta previa, anomalies of placental invasion, and uterine rupture are the most common [3–5]. As Cesarean section (CS) rates increase annually, haemorrhage at the site of placental implantation, attributable to placenta previa, remains a serious obstetric complication [6,7].

PPH management requires the establishment of a careful protocol and use of a step-by-step approach. Inadequate medical care (i.e. care that does not adhere to generally accepted standard measures) and a lack of clinical treatment skills remain major problems when PPH occurs [8].

The aim of the present study was to evaluate the success rate of Bakri balloon placement in terms of controlling PPH in patients with placenta previa and uterine atony. We also compared the utility of Bakri balloon placement to that of bilateral internal iliac artery ligation (B-IIAL) in patients with placenta previa.
postpartum period. PPH after CS is defined as an estimated blood loss of more than 1000 mL [9].

The third stage of labour was actively managed; a prophylactic uterotonic agent (oxytocin; 10 IU) was administered. Uterine atony was confirmed after excluding the other possible causes of PPH (genital tract lacerations, placental retention, uterine rupture or uterine inversion) by examination; if bleeding continued despite the administration of uterotonic agents such as oxytocin (40 IU; 125 mL/h), methylergonovine (0.25 mg, intramuscularly) and/or misoprostol (800–1000 μg), we performed bimanual compression and uterine massage. If these measures failed, a Bakri balloon was inserted. If this failed, we performed (sequential) B-Lynch compression suture, bilateral uterine artery ligation and ligation of ligamentum ovarii proprium. Total abdominal hysterectomy (TAH) was the final recourse. Fibrinogen (2 g, intravenously) was given if disseminated intravascular coagulation was evident. After 2012, our hospital administrators began to purchase Bakri balloons for the control of PPH. Prior to 2012, B-IIAL was the first treatment option for placenta previa cases with continuing PPH despite medical treatment.

All balloons were inserted transabdominally (prior to Kerr incision closure) in women who underwent CS. All balloons were observed throughout placement, and surgical assistants performed transvaginal examinations to ensure correct placement. The balloons were deployed transvaginally after vaginal labour. Each balloon was filled with saline (200–450 mL) depending on the size and capacity of the uterus. A drainage bag was placed to evaluate bleeding. All patients were monitored in our intensive care unit. Bakri balloon placement was considered successful if the drainage flow was less than 50 mL/h. Balloons were gradually drained no earlier than 8 h after insertion when the blood flow fell to 20 mL/h or less. Bakri balloon therapy was considered unsuccessful when an additional procedure (B-IIAL or TAH) was required. Transfusion was considered for patients whose haemoglobin level was below 8 g/dL with instability (ongoing bleeding, hypotension, tachycardia, etc.). Prophylactic antibiotics were given to all patients.

Data analysis

Data are presented as mean values with standard deviation (±SD) and range (minimum–maximum). NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) was used for statistical analysis. Besides descriptive statistics, to compare qualitative variables, t-test, Chi-square test and Fisher’s exact test were used. Values of p < 0.05 were considered to indicate statistically significant differences.

Results and discussion

The mean maternal age, gravidity, parity and gestational weeks were 30.48 ± 7.08 years, 3.81 ± 2.32, 3.02 ± 1.95 and 36.3 ± 2.59 weeks, respectively. Twenty-two patients delivered vaginally (one aided by vacuum extraction). A total of 28 patients diagnosed with uterine atony and 14 patients with placenta previa were treated with Bakri balloons. Overall, 7 out of 28 patients required labour induction. The risk factors for PPH were placenta previa, cephalopelvic disproportionality, multiparity, twin-pregnancy-arrested labour, tocolysis and vacuum extraction. Of such patients, 33.3%, 4.7%, 4.7%, 4.7%, 2.3%, 2.3% and 2.3% (respectively) were treated with Bakri balloons.

Of 42 patients treated with balloons, 7 (16.6%) required additional procedures. B-Lynch compression sutures were placed and uterine artery ligation and B-IIAL were performed to stop bleeding in 1 out of 28 uterine atony cases treated with a Bakri balloon. A total of 2 of 28 patients required TAH after B-Lynch compression suture and B-IIAL failed. Four of fourteen placenta previa patients treated with Bakri balloons required TAH after B-Lynch suture, uterine artery ligation and B-IIAL. Two of four patients had placenta accreta (as confirmed by a pathologist). Prior to 2012, 12 of 54 patients (as a control group) underwent B-IIAL to stop bleeding and prevent TAH; 4 of these 12 required TAH, and 2 of the 4 patients were pathologically confirmed to have placenta accreta.

When we compared the patients treated with Bakri balloons in terms of their diagnoses, both the estimated blood loss and hospitalization time were significantly higher in placenta previa than in other patients (both p < 0.05). The requirements for packed red blood cells and fresh frozen plasma, the pre-/post-operative haemoglobin levels, pre-/post-partum platelet counts, balloon...
infusion volume, duration of balloon insertion and the drainage level did not differ significantly between the uterine atony and placenta previa patients. Bakri balloon therapy was successful in 89.2% (25 of 28) and 71.4% (10 of 14) of patients with atony and placenta previa (Table 1), respectively.

When we compared the placenta previa patients by treatment mode, the requirements for erythrocyte suspensions and fresh frozen plasma were significantly higher in the Bakri balloon group, but the duration of hospitalization was significantly higher in the B-IIAL group (all \( p < 0.05 \)). The success rate was 71.4% in the Bakri balloon group and 66.6% in the B-IIAL group; these values did not differ significantly (Table 2).

An earlier paper reported that intrauterine balloon tamponade to control PPH obviated the need for hysterectomy in about 88% of patients [10]. In our study, the Bakri balloon success rate in all patients was 83.3%, and 89.2% and 71.4% in patients with uterine atony and placenta previa, respectively. These data are comparable to previous reports [11–13]. Vintejoux et al. [14] found that Bakri balloon placement in uterine atony patients afforded a success rate of 69%; and when success was defined as bleeding cessation, the rate rose to 77%.

The increasing CS rates worldwide will in turn increase the numbers of placenta previa patients at high risk of intraoperative blood loss and other complications. Various treatments are available. Bakri balloon tamponade prevents bleeding and obviates the need for hysterectomy in PPH patients. The balloon increases intrauterine pressure to a level above that of the systemic arterial pressure. Kumru et al. [15] found that Bakri

### Table 1. Comparison of Bakri balloon effectiveness according to diagnose.

|               | Atony (n = 28) | Previa (n = 14) | \( p \) |
|---------------|---------------|----------------|--------|
| Age (years)   | 27.86 ± 7.15  | 33.21 ± 5.65   | 0.019  |
| Gravidity     | 3.61 ± 3.01   | 4.14 ± 0.95    | 0.522  |
| Parity        | 3.21 ± 2.49   | 3.29 ± 1.2     | 0.920  |
| Gestational week | 37.36 ± 2.54 | 34.86 ± 2.69   | 0.005  |
| Mode of delivery |          |                |        |
| Vaginal       | 22            | 0              | 0.00%  |
| CS            | 6             | 14             | 100.00% 0.0001 |
| TAH           | 26            | 10             | 71.43% |
| Performed     | 22            | 8              | 10.14% |
| Not performed | 4             | 2              | 28.57% |
| Estimated blood loss (mL) | 1225 ± 225.46 | 1828.57 ± 358.26 | 0.001 |
| Requirement of RBC (U) | 4.5 ± 1.23 | 5.14 ± 1.75 | 0.174 |
| Requirement of Fresh Frozen Plasma (U) | 4.75 ± 1.43 | 5.29 ± 1.73 | 0.292 |
| Preoperative Hb (g/dL) | 10.83 ± 1.46 | 10.16 ± 1.13 | 0.142 |
| Preoperative Platelet (g/dL) | 187.36 ± 66.74 | 151.07 ± 45.41 | 0.075 |
| Postoperative Hb (g/dL) | 8.59 ± 1.37 | 8.47 ± 1.14 | 0.783 |
| Postoperative Plt (g/dL) | 174.46 ± 61.42 | 144.5 ± 67.49 | 0.157 |
| Time between insertion and removal (hours) | 13.46 ± 7.79 | 15.29 ± 4.62 | 0.426 |
| Drainage volume (mL) | 161.79 ± 102.2 | 190.71 ± 52.98 | 0.328 |
| Hospitalization time (hours) | 53.43 ± 18.22 | 76.29 ± 27.18 | 0.002 |
| Filling volume (mL) | 321.43 ± 61.51 | 292.86 ± 58.37 | 0.157 |
| B-IIAL         | 25            | 10             | 71.43% |
| Successful     | 25            | 10             | 71.43% |
| Unsuccessful   | 3             | 4              | 28.57% |

**Chi-square test.**

### Table 2. Comparison of two different treatment modalities in placenta previa patients.

|               | BAKRI group (n = 14) | IIAL group (n = 12) | \( p \) |
|---------------|----------------------|---------------------|--------|
| Age           | 33.21 ± 5.65         | 33.42 ± 6.47        | 0.933  |
| TAH           |                      |                     |        |
| Yok           | 10                   | 8                   | 66.67% |
| Var           | 4                    | 4                   | 33.33% |
| EBL (estimated blood loss /mL) | 1828.57 ± 358.26 | 1900 ± 359.29 | 0.617 |
| Requirement of RBC (U) | 5.14 ± 1.75 | 3.75 ± 1.06 | 0.024 |
| Requirement of FFP (U) | 5.29 ± 1.73 | 3.92 ± 1.17 | 0.029 |
| Hospitalization (hours) | 76.29 ± 27.18 | 96 ± 16.97 | 0.035 |
| Effectiveness |                      |                     |        |
| Successful    | 10                   | 8                   | 66.67% |
| Unsuccessful  | 4                    | 4                   | 33.33% |

\( t \)-Test. Mann–Whitney U-test plus chi-square test.
balloons were effective in 88% of placenta previa patients. Recently, Cho et al. [16] reported that 75% of placenta previa cases were successfully treated with Bakri balloons. Several studies have shown that the failure of Bakri balloon tamponade depends on whether the placenta previa is associated with an invasive abnormality [17–19]. In our study, the success rate of balloon placement did not differ significantly between cases of placenta previa and uterine atony (71.4% and 89.2%, \( p > 0.05 \)). The estimated blood loss and hospitalization duration were higher in placenta previa patients treated with Bakri balloons. No complication associated with balloon treatment was observed. To the best of our knowledge, no prior study has compared the effectiveness of Bakri balloon placement in cases of placenta previa and uterine atony.

We found that Bakri balloon tamponade effectively controlled PPH in placenta previa patients compared to those who earlier underwent B-IIAL as a second-line therapy. Among placenta previa patients, the overall success rate of Bakri balloon placement was 71.4% (10 of 14) compared to 66.6% (8 of 12) for B-IIAL. This difference was not significant. The requirements for packed red blood cells, fresh frozen plasma and the hospitalization duration were significantly different between patients undergoing the two treatment modalities (\( p < 0.05 \)).

Kavak et al. [20] compared the endouterine haemostatic square suture and Bakri balloon tamponade methods for the treatment of placenta previa; Bakri balloon tamponade was the better option in terms of a shorter operative time and less blood loss.

In a study on near-miss cases (i.e. not fully diagnosed), neither primary B-Lynch suturing nor Bakri balloon uterine tamponading was completely effective to relieve PPH, regardless of the cause of peripartum bleeding [21]. Also, use of a balloon (alone) to stop PPH may be unpredictable in both uterine atony and placenta accreta patients [21]. However, we found that the Bakri balloon was effective to treat both uterine atony and placenta previa patients.

Our study, however, has some limitations. First, we did not address technical problems associated with the balloon procedure (e.g. balloon displacement); these may have caused the success rates to be underestimated. Also, different among-surgeon diagnostic criteria and the choice of how to control PPH may have affected our results. The small number of cases is also problematic; however, the conditions that we studied are rare. The major strengths of our study lie in that we compared different PPH treatment modalities, and we compared the success rates of Bakri balloon placement in both placenta previa and uterine atony patients.

**Conclusions**

Bakri balloon tamponade could be considered an effective treatment both in placenta previa and in uterine atony. Balloon placement effectively controls PPH and should be used as the second-line treatment when medical procedures fail. Balloon placement is of non-surgical in nature, giving the surgeon time to consider alternatives. Moreover, bleeding is adequately controlled.

**Disclosure statement**

No potential conflict of interest was reported by the authors.

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