ORIGINAL RESEARCH PAPER
Volume - 11 | Issue - 10 | October - 2022 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

IS THE BAKRI BALLOON EFFECTIVE IN PREVENTING HYSTERECTOMY IN PATIENTS WITH POSTPARTUM HEMORRHAGE?

Health Science

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ABSTRACT

Objective: To determine the efficacy of the Bakri balloon in the prevention of hysterectomy due to postpartum hemorrhage versus conventional management with uterotonics. **Material and method:** Retrospective observational cross-sectional study in women with postpartum uterine hemorrhage treated at La Samaritana University Hospital in the city of Bogotá, Colombia, between 2013 and 2019. Clinical records were reviewed and divided into two groups: Bakri balloon and uterotonics (no Bakri balloon). **Results:** Overall, 81 patients with postpartum uterine hemorrhage were included, 27 patients (33.3%) were considered exposed (Bakri balloon) and 54 patients (66.6%) unexposed (no Bakri). The success rate defined as stopping the bleeding and not requiring hysterectomy with the Bakri balloon was 96.3%, versus the no Bakri group, 68.52% (p = 0.04). In addition, the Bakri balloon reduced the risk of hysterectomy by 99% (OR = 0.01; 95% CI 0.008-0.38; p = 0.01), when adjusting for age and gestations. **Conclusions:** The use of the balloon demonstrated a high rate of effectiveness, decreased the risk of hysterectomy and was shown to be an easy and safe method for the management of postpartum hemorrhage due to uterine atony. aThe Bakri balloon is available to health institutions in countries with limited resources such as ours, where it constitutes an essential tool to deal with a pathology associated with a high risk of mortality as is the case with postpartum hemorrhage.

KEYWORDS

Bakri balloon; Postpartum hemorrhage; Complications of pregnancy; maternal bleeding

BACKGROUND

Postpartum hemorrhage (PPH) is the main cause of maternal mortality, accounting for almost 28% of deaths, which means that, in the world, one woman dies every 4 minutes due to PPH (1, 2). Management options for this complication include, first of all, the use of uterotonics and bimanual uterine massage, followed by uterine tamponade and, ultimately, in refractory bleeding, surgical techniques such as the B-Lynch procedure, pelvic arterial embolization and even hysterectomy (2-4). The latter is associated with longer length of stay and a higher risk of gastrointestinal and urinary tract injury (2).

Based on the above, it is important to recognize non-invasive techniques such as intra-uterine tamponade using balloons to apply hydrostatic pressure on the uterus. The Bakri balloon is a 58 cm long, double-lumen silicone medical device which allows to monitor and quantify the amount of bleeding coming from the cavity, through one of the lumens. Although it has a maximum capacity of 800 ml, it is advisable to inflate it with 250-500 ml, depending on the size and capacity of the uterus. It is the sole device approved by the FDA for postpartum bleeding control (5, 6). There are reports in the literature showing that women with balloon tamponade did nor require additional procedures and had a shorter length of hospital stay (7), making it a fast and safe option for the treatment of non-traumatic postpartum bleeding where retained placental tissue has been ruled out. However, in Colombia, current evidence supporting its benefits is still limited. Recommended procedures in cases of PPH are the use of uterotonics, placement of the Bakri balloon if the bleeding persists and, if management is unsuccessful, hysterectomy as the last resort. Therefore, the aim of this work is to determine the efficacy of the Bakri balloon in preventing hysterectomy due to postpartum hemorrhage at La Samaritana University Hospital in Bogotá, Colombia

MATERIAL AND METHOD:

Descriptive cross-sectional study aimed at determining the relationship between the use of the Bakri balloon and the likelihood of hysterectomy in women with postpartum hemorrhage.

The clinical records of patients that gave birth either by vaginal delivery or cesarean section at La Samaritana University Hospital between 2013 and 2019 and who developed postpartum hemorrhage were reviewed. Postpartum hemorrhage was defined as bleeding greater than 500 cc for vaginal delivery, or greater than 1000 cc for cesarean section, or smaller bleeding with signs of shock with an etiology of uterine atony, managed uterotonics as first-line treatment. The exposed group was defined as the group of women with postpartum hemorrhage who required hemostatic or Bakri balloon and the non-exposed group was defined as the group of women who developed postpartum hemorrhage managed with uterotonics alone (no balloon group).

Exclusion criteria were pregnant women with blood dyscracia or disseminated intravascular coagulation (DIC).

Means and standard deviations were used in the descriptive analysis for numerical variables with normal distribution.

The Kolmogorov- Smirnova normality test, the variance difference test and the Student t test were carried out for mean differences between the groups; the chi square test was performed for categorical variables; finally, a multivariate analysis by logistic regression was done, using the Hosmer-Lemeshow goodness-of-fit test. Data were processed using the STATA 16 software package.

The research was considered to be of no risk in accordance with Colombian resolution number 8439 of 1993 and, therefore, no informed consent was required. The principles of the 1975 Declaration of Helsinki revised in 2013 were followed.

RESULTS

Overall, 81 patients with uterine postpartum hemorrhage were included; 27 patients were considered exposed (Bakri balloon) and 54 (66.6%) were considered non-exposed. The mean age of the exposed population was 23.88 ± 6.73 years. The most frequent cause of postpartum hemorrhage was uterine atony in 78 patients (96.3%), followed by obstetric trauma in 2 patients (2.47%) and, lastly, retained placental tissue in 1 patient (1.23%).

The most frequent delivery route in the balloon group was cesarean section (51.85%), while vaginal delivery was more frequent (59.26%) in the no-balloon group, but with no statistically significant difference.

The percentage of success, defined as stopped hemorrhage and no need for hysterectomy, was 96.3% for the Bakri balloon versus 68.52% in the no-balloon group (p=0.04). Time to balloon removal was 29.74 ± 9.02 hours, with a mean volume of 404.09 ± 134.47 cc.

Hysterectomy was more frequent in the no-balloon group in 17 patients (31.48%) as compared to 1 patient (4.3%) in the Bakri balloon

group. No statistically significant differences were found between the two groups in terms of age, number of gestations, number of childbirths, delivery route, need for blood products, bleeding, and pre-hemorrhage and post-hemorrhage hemoglobin. The other baseline characteristics of the population are described in Table 1.

Average length of stay was greater in patients with the Bakri balloon (8 ± 7.28 days) when compared with the no-balloon group (5.38 ± 4.26 days), with a statistically significant difference of p=0.04.

To determine the relationship between the use of the Bakri balloon and the likelihood of hysterectomy, a univariate analysis was initially carried out, with the finding that the balloon reduces the risk of hysterectomy by 92% (odds ratio [OR]=0.08; 95% CI 0.01-0.66; p=0,019). Other factors that reduce the risk of hysterectomy include vaginal delivery (78% [OR=0.22; 95% CI 0.06-0.69; p=0,01]), and having had less than 2 gestations (75% [OR=0,25; 95% CI 0.75-0.82; p=0.014]).

In the univariate analysis, risk factors that increased the risk of hysterectomy were as follows: age, 1.1 times (OR=1.1; 95% CI 1.02-1.19; p=0.014); cesarean section 5.2 times (OR=5.2; 95% CI 1.63-16.53; p=0.005); and re-bleeding 12.72 times (OR=12.72; 95% CI 2.84-56.89; p=0.01) (See Table 2).

The multivariate regression found a 99% reduction in the risk of hysterectomy with the Bakri balloon (p=0.01), 99% risk reduction with vaginal delivery (p=0.002), and a 51.25 times higher risk of hysterectomy with re-bleeding (p= 0.003), adjusting for age and gestation with adequate goodness-of-fit of the multivariate model using the Hosmer-Lemeshow test (see Table 3).

DISCUSSION:

Postpartum hemorrhage is one of the main preventable causes of maternal mortality. Surgical techniques such as uterine tamponade can stop bleeding immediately and help with the prompt decision regarding the need for hysterectomy. Some factors have been associated with postpartum hemorrhage, including age under 18 years, placental abnormalities, cesarean delivery, prolonged labor, and fetal macrosomia (8). Recently, scales have been used to try to predict the risk of hemorrhage (9, 10) leading to the following recommendations: early use of uterotonics (11), pelvic arterial embolization through interventional radiology (12) or the Bakri balloon. The latter is one of the tools recommended by various organizations (13) and clinical practice guidelines like the American College of Obstetricians and Gynecologists (ACOG) and the World Health Organization (WHO) for the management of postpartum hemorrhage which does not respond to uterotonics (14).The Bakri balloon has even been used in patients with placenta accreta as prophylaxis for uterine bleeding (15).

Some case series have reported success with the use of the Foley catheter, the Sengstaken–Blakemore esophageal catheter and the condom as effective tamponade methods for the management of postpartum hemorrhage due to uterine atony that is not responsive to medical treatment (16, 17).

Bleeding assessment is underestimated by 42% of multidisciplinary teams, affecting response times in cases of massive bleeding, and increasing the risk of prolonged hypovolemic shock and secondary end organ damage (18).

This paper describes the experience using the Bakri balloon in a university hospital, with successful results in 96.3% of cases. With average dwelling time of 29.74 ± 9.02 hours, these results were very similar to those of a study conducted in 265 patients also in a tertiary hospital, which found a 90% success rate using the Bakri balloon with a mean tamponade time of 18.5 hours (19). Although the success rate in our study is higher, tamponade lasted almost 30% more than in other studies, and were no complications.

Likewise, the Bakri balloon was found to reduce the risk of hysterectomy by 99%, when adjusting by age, delivery route, gestations and re-bleeding (p=0,01). Although bleeding reduction of 349.8 ml (-515 to 1215; p=0.42) was found, the difference with no Bakri balloon was not statistically significant. A Cochrane Collaboration systematic review found similar results: although not statistically significant, the Bakri balloon reduced the risk of hysterectomy by 86% (RR 0.14, 95% CI 0.01 - 2.74) and diminished the amount of bleeding by 426 ml (95% CI -631.28 to -220.72), with no findings of an increased risk of mortality, bleeding or side effects (20). Studies in the literature are diverse: one study found that the use of the Bakri balloon was associated with a higher risk of bleeding (OR 7.82; 95% CI 2.68 to 22.84, p = 0.004)(21), while a meta-analysis of 91 studies with 4729 women found that the overall success rate of balloon tamponade was 85.9% (95% CI, 83.9-87.9%)(22). The highest success rates with the Bakri balloon were found in cases of uterine atony (87.1%) and placenta previa (86.8%), while the lowest were found for the placenta accreta specturm (66.7%) and for retained products of conception (76.8%)(22).

In this study, the success rate with the Bakri balloon was 100% in vaginal deliveries and 92.8% in cesarean deliveries. In the meta-analysis described above, results were similar, with the success rate of uterine tamponade being lower in cesarean deliveries (81.7%) than in vaginal deliveries (87.0%)(22).

The uterine balloon works through a hydrostatic mechanism that acts on the uterine wall to reduce bleeding. It has been used for more than 30 years and although studies regarding its use are diverse, it has been shown to be more than 90% effective in reducing the risk of hypovolemic shock, the frequency of transfusions and the signs of tissue hypoperfusion. Likewise, it has been shown to be low-cost, safe and useful in patients seeking to have children in the future (1, 23-25). However, there are certain factors that can increase the risk of balloon failure such as obesity, transfusion of more than 7 units of red blood cells, previous cesarean section, prior uterine intervention such as curettage, a history of placenta previa or placenta accreta, and coagulopathy (26).

The limitations of the study include the small population exposed to the Bakri balloon and the fact that it is a retrospective, observational, descriptive study. An attempt was made at compensating for these limitations with the type of statistical analysis performed.

CONCLUSIONS

This study confirms findings in the literature regarding the use of the Bakri balloon as a safe method associated with a high rate of effectiveness (96.3%), a reduced risk of hysterectomy and, therefore, fertility preservation. Moreover, it can be used in both vaginal as well as cesarean deliveries, and we believe that it should be included in Obstetrics and Gynecology training programs. Although no cost-effectiveness studies are available in our country, it is an essential tool to manage a condition associated with a high risk of maternal mortality as is the case of postpartum hemorrhage, particularly in centers with no access to an operating room or the specialized staff required to perform a hysterectomy.

Table1. Baseline Characteristics

	Patients with BAKRI balloon N=27 patients (33,3%)	Patients with Uterotonics N=54 patients (66.6%)	p
Numerical variables Means (Standard Deviation)			
Age	23.88 (6.73)	26.90 (6.60)	0.057
Number of pregnancies	2.03 (1.37)	2.61 (1.77)	0.14
Number of childbirths	1.77 (0.97)	2.18 (1.60)	0.229
Red blood cell units	1.55 (1.45)	1.31 (2)	0.58
Plasma units	0.55 (1.67)	0.72 (2.13)	0.72
Platelet units	0.11 (0.57)	0.70 (2.30)	0.19
Approximate blood loss	1288 (495)	1638 (2175)	0.42
Hemoglobin at the time of bleeding	11.18 (2.63)	11.68 (2.66)	0.39
Hemoglobin after bleeding	10.56 (1.91)	10.60 (1.83)	0.92
Length of stay	8 (7.28)	5.38 (4.26)	0.04
Categorical variables			

Number patients (%)			
Hysterectomy	1(3.7%)	17 (31.48%)	0.004
Age by tiers Under 20 years of age Between 21 and 40 Over 40 years of age	 10 (37,4%) 17(62,96%) 0(0%)	 8(14.8%) 44(81.48%) 2(3,7%)	0.054
Delivery route Vaginal Cesarean section Instrumented	 13(48.15%) 14 (51.85%) 0 (0%)	 32 (59.26%) 20(37.04%) 2(3.70%)	0.3
Number of gestations by tiers 2 or less Between 3 and 4 More than 5	 18 (66.67%) 7 (25.9%) 2(7.41%)	 30 (55.56%) 18(33.3%) 6(11.11%)	0.623
Death	0 (0%)	1 (1.85%)	0.47
Need for ICU	4 (14.81%)	11 (20.37%)	0.54
Need for vasopressor	4 (14.81%)	8 (15.09%)	0.97
Need for blood products	17 (62.96%)	22 (40.74%)	0.059
Re-bleeding	2(7.41%)	8 (14.81%)	0.33
Prior cesarean section	3 (11.11%)	10 (18.52%)	0.39
Marital Status			
Single	9 (33.33%)	16 (29.63%)	0.9
Free union	14 (51.85%	29 (53.70%)	
Married	4 (14.81%)	9 (16.67%)	

Table 2. Univariate analyses of factors associated with hysterectomy

Variable	OR	95% CI	p
Use of the Bakri balloon	0.08	0.01-0.66	0.019
Age	1.1	1.02-1.19	0.014
Age tiers			
Under 20 years	0.15	0.01-1.28	0.08
Between 20 and 40 years	1.84	0.47-7.19	0.37
Older than 40 years	1		NS
Route of delivery			
Vaginal	0.22	0.06-0.69	0.01
Cesarean section	5.2	1.63-16.53	0.005
Instrumented	1		NS
Gestations			
Two or less	0.25	0.75-0.82	0.014
Between 3 and 4	2.16	0.73-6.39	0.16
5 or more	4.21	0.93-18	0.061
Re-bleeding	12.72	2.84-56.89	0.01

Table 3. Multivariate model of hysterectomy-associated factors

Variable	OR	95% CI	p
Use of the Bakri balloon	0.01	0.008-0.38	0.01
Vaginal delivery	0.01	0.001-0.23	0.002
Age	1.034	0.89-1.19	0.64
Re-bleeding	51.25	3.84-683.53	0.003
2 or less gestations	0.2	0.027-1.58	0.12
5 or more gestations	0.82	0.05-11.77	0.88

Hosmer-Lemeshow goodness-of-fit test chi2= 1.21 p=0.99, correctly classified 87.65%.

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