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Successfulness of the Bakri Intrauterine Balloon For Uterotonic-Unresponsive Postpartum Haemorrhage Treatment: Systematic Review and Meta-Analysis.

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ABSTRACT

The main purpose of this meta-analysis was to quantify the successfulness of Bakri balloon in managing postpartum haemorrhage (PPH) unresponsive to uterotonics.
We performed a literature search using the MEDLINE (accessed via PubMed) database from inception to October 2019, for clinical trials and observational studies. Meta-analysis was performed applicating the random-effects model. Primary outcome was the successfulness of the Bakri balloon in stopping PPH unresponsive to uterotonics.
Twenty-eight publications (n=1868 applications of Bakri balloon) matched the inclusion criteria for the meta-analysis. Ten studies referred the incidence of Bakri balloon applications with a 0.335% (1004/299124; 95% CI, 0.2–0.4%) rate. Success rate of the haemostatic balloon in stopping PPH without requiring other procedures was 82% (1597/1868; 95% CI, 78–86%), while further procedures were needed for 271 patients (13,83%; 95% CI, 11–21%). Bakri balloon plus additional procedures were effective in the control of the PPH in the 95% of all cases (1645/1868; 95% CI, 93–98%). Hysterectomy was performed in the 5% (78/1597; 95% CI, 2–6%) of all women who needed a Bakri balloon.
Bakri balloon represents a successful therapeutic option for blocking PPH when unresponsive to uterotonics.

Keywords: Post-partum haemorrhage, postpartum haemorrhage, Bakri balloon tamponade, Bakri balloon

Introduction

Post-partum haemorrhage (PPH) is the commonest cause of maternal morbidity among the direct causes of death (1) and uterine atony is its principal cause. It is capable of significant maternal mortality and it is a crucial cause of reanimation admissions and major surgery in the postpartum period (2-4). The World Health Organization, ACOG, as well as several national and international maternal-fetal medicine societies recommend the administration of uterotonics after every delivery, in the immediate postpartum period, in order to prevent the PPH (5-7), as the active approach during the third stage of labor has been referred to reduce the incidence of PPH (7, 8). If uterotonics and conservative methods have not reached an appropriate control of the PPH, prompt management by surgical measures is mandatory and includes uterine tamponade (Bakri balloon), compressive sutures (like the B-Lynch procedure), embolization of pelvic arteries and, even, hysterectomy. It is good practice to start with the less invasive methods to control the PPH, if maternal conditions allow this. The first-line surgical intervention is the uterine balloon tamponade which was introduced in 1991 by the eponymous Bakri et al. (9). The underlying mechanism of management of bleeding is mediated by a hydrostatic pressure effect to the

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uterine arteries, similarly to mechanical uterine artery embolization or ligation (10). Hydrostatic pressure to the uterine cavity has also been proposed as the mechanism for the bleeding control obtained with the balloon tamponade (11). A recent population-based study reported suboptimal rates in use of the Bakri balloon for the management of PPH (12). This might be interpreted as a lack of confidence in the effectiveness of this device. The goal of this systematic review and meta-analysis was therefore to evaluate the successfulness of the Bakri intrauterine haemostatic balloon in controlling PPH unresponsive to uterotonics.

Materials and Methods

Search strategy: The research protocol for this quantitative analysis, including methods for the literature screening, articles examination, and extraction and analysis of data, was designed a priori,. Searches were performed using the PubMed database, from inception to October 2018. The Meta-Analysis was carried out according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) [13] as well as the Meta-Analysis Of Observational Studies in Epidemiology (MOOSE) statement guidelines [14]. The keywords and MeSHs terms used were "postpartum haemorrhage" or "post-partum haemorrhage" and "Bakri balloon" or "Bakri balloon tamponade" or "Bakri SOS balloon" or "Bakri surgical obstetric silicone balloon" or "Bakri balloon" or "intrauterine balloon" or "intrauterine balloon tamponade". This systematic review is registered to PROSPERO register (International prospective register of systematic reviews).

Study Selection: The studies identified from our search were considered for inclusion if they fulfilled the following criteria: (a) PPH matching the ACOG definition (15). (b) PPH should be unresponsive to uterotonics, defined by the need of additional procedures to control PPH after first-line conventional medical therapy. Conventional medical therapy included oxytocin (20 to 40 IU in 1L of normal saline) as well as carboprost (250 mcg IM or into myometrium, methylergonovine (0.2 mg IM), misoprostol (800 to 1000 mcg rectally or 600 to 800 mcg sublingually) and tranexamic acid (1 g IV).

Studies were included only if they were in English language. Exclusion criteria were: case studies with six or fewer patients, review articles, letters to editor, use of the Bakri balloon for purposes not related to PPH control, and non-English language publications. The risk of bias in each study was assessed by 2 authors (M.L.V. and M.M.) with Newcastle-Ottawa Scale (NOS) (Supplementary Table 1). Any disagreement was overcome with the involvement of a third reviewer (P.D.F.)

Outcomes: To quantify the rate of use of the Bakri balloon we recorded the total number of deliveries during the study period, when reported. The use of the tamponade device was considered to be successful when there was no need of additional procedures to control the PPH. When the Bakri balloon failed to control the PPH, the use of the following additional procedure was recorded: uterine compressive sutures, radiological embolization of uterine arteries, radiological embolization plus uterine compressive sutures, hypogastric artery ligation, cervical cerclage (in order to keep the balloon inside the uterine cavity). Every additional procedure needed was considered as a complication if it had to be performed after the placement of the balloon rather than before or together. From each included study two authors (M.L.V. and M.M. extracted the following data: (a) number of cases managed with the Bakri balloon; (b) number of cases successfully managed with the Bakri balloon; (c) number and kind of additional procedures needed when the Bakri balloon failed; (d) maternal anamnestic data: age, BMI; (e) obstetric data: gestational age, number of previous deliveries, fetal birth weight; (f) kind of previous deliveries (vaginal or cesarean section) and (g) primary cause of PPH.

Statistical Analysis: In a conservative approach, the primary outcome was evaluated as the random-effects estimates of event proportion (ES), calculated with the Random effects model of DerSimonian and Laird after Freeman-Tukey Double Arcsine Transformation for variance stabilization. Therefore, confidence interval was extracted with the exact method. We evaluated heterogeneity by means of the Higgins I^2 index, with 25, 50 and 75% set as cut-off points for low, moderate and high heterogeneity. To further investigate heterogeneity, we performed subgroup analyses according to the study design (prospective, retrospective or randomized trial) and the region in which the study was performed (i.e. Europe vs. others). Statistical analysis was performed using the software STATA, version 14.1 (StataCorp., College Station, Texas, USA), for all the analyses.

Results

The electronic search yielded 180 potentially eligible citations, of which 25 were excluded because they were a duplicate. After review of the title or abstract 77 citations were further excluded, leaving 78 studies for full-text review. Out of those seventy-eight articles, 50 were excluded as they did not matched the inclusion criteria. Twenty-eight articles were included for meta-analysis (16-44) with 1868 women included in the statistical analysis (Figure 1). Results of quality assessment are shown in Supplementary Table 1. The majority of the included studies reached at least one star in each of the three sections: the selection and comparability of the study cohorts, and ascertainment of the investigated outcome. The main weaknesses of these studies were their retrospective design and the small sample size. Nineteen out of the 28 studies (67.9%) were retrospective analyses of Bakri balloon placement (16, 17, 19-21, 25, 28-30, 32, 34, 35, 37-39, 41-43), seven studies (25%) had a prospective design (16, 21, 22, 24, 30, 33, 38), two studies (7.1%) were randomized clinical trials (22, 33). Only ten studies (12,5%) reported the number of total deliveries during the study period (16, 18, 19, 23, 25, 29, 32, 36, 37, 39) with the overall rate of use Bakri Balloon being 0,335% (1004/299124; 95% CI, 0.2%–0.4%), In seven reports (17, 19, 21, 23, 32, 33, 40) the usage of the Bakri balloon was limited to women delivering with a cesarean section. (Table 1), while in two studies included only women with a vaginal birth were included (22, 43). The overall success rate of the Bakri balloon in the control of PPH was 82 % (1597/1868; 95% CI, 78–86%), with additional procedures needed to stop the persistent PPH limited to 271 women (13,83%; 95% CI, 11–21%). The success rate of the Bakri balloon was 86% (321/356; 95% CI, 77-94%) after cesarean delivery and 81% (110/141; 95% CI, 75-87%) after vaginal delivery (Supplementary Figure 1) The association of the Bakri balloon with additional procedures controlled the PPH in the 95% of all cases (1645/1868; 95% CI, 93–98%). Nevertheless, hysterectomy was performed in the 5% (78/1597; 95% CI, 2–6%) of all patients. The additional procedures reported were different and highly dependent on the local setting and resources and from the preferences and confidence of the clinicians involved in the management the PPH. The additional procedure most widely used was the embolization of uterine arteries, which was performed in 38% (104/271; 95% CI, 6–40%) of women. Hypogastric artery ligation was performed in the 18% (48/271; 95% CI, 6–34%) of women and uterine sutures in the 7% (19/271; 95% CI, 0–11%) of women. The main cause of PPH was also recorded in all but three studies (18,25,36). In four reports (21, 23, 28, 33) the usage of the Bakri balloon was limited to the cases of placenta previa, while in four reports it was only used to control PPH due to uterine atony (17, 22, 32, 40). Uterine atony (table 1) was reported as the underlying etiology of PPH in 57% of women (95% CI, 36–76%). The remaining causes of PPH were placenta previa in 25% (95% CI, 8–47%); placenta previa accreta in 2% (95% CI, 0–8%); placenta accreta spectrum in 1% (95% CI, 0–4%). In the 1% of cases (95% CI, 0–5%) there was a uterine, vaginal or cervical lesion; in 1% (95% CI, 0–4%) there were retained products of conception (RPOC); in eight patients (95% CI, 0–1%) a placental abruption was the main cause of PPH and finally, in two cases the etiology of the PPH was a uterine rupture (95% CI, 0–1%). Significant statistical heterogeneity (Figure 2) was found between studies, with I^2=80.3% for the primary outcome. This was mostly due to variability in population characteristics among different studies and different designs of the included studies. Sensitivity analyses of the study design and the geographic area was also performed. According to the study design (Figure 3), overall heterogeneity remained high. However, when limiting the analysis to prospective studies heterogeneity decreased from high to low (I^2=46.9), with overall success rate of 89% (95% CI: 85-93%). Sensitivity analysis for the geographic area (Figure 4) found moderate heterogeneity among European studies (I^2=56.0).

Discussion

The findings from this systematic review and meta-analysis show that the Bakri tamponade device is a useful tool for the treatment of PPH unresponsive to uterotonics, with a success rate of 82%. Uterine balloon tamponade (UBT) has gained popularity since its marketization in 1991 by Dr. Bakri (9). Starting from that point, its use has been rising over years leading to recommendations on the use of the Bakri balloon in many international guidelines (45-48). A multitude of studies have been carried out to prove the effectiveness of the UTB. Among the several types of UBT the authors described the condom catheters, the Foley catheters and a Sengstaken–Blakemore esophageal tube. However,

Table 1. Characteristics of Studies Included In Quantitative Analysis

study, year	Country, clinical setting	Study Design	No. of total deliveries	No. of bakri balloon	Additional procedures	hysterectomy	Vaginal birth	Cesarean delivery	Uterine atony
Grange Josephine et al., 2018 Oct	France	Retrospective	91880	108	28	5	108	0	39/108
Choi Wah Kong et al., 2018 Jul,	China	Retrospective	22860	81	22	11	21	57	53/81
Berna Aslan Cetin et al., 2018	Turkey	Retrospective	NA	39	10	4	0	39	39/39
Dongyu Wang et al., 2018 Aug	China	Prospective	58002	407	34	11	67	340	NA
Yuna Guo et al., 2018 May	China	Retrospective	78708	142	7	0	0	142	62/142
Manisha Mathur et al., 2018 Jan	Singapore	Retrospective	NA	49	20	9	11	38	17/49
Hiroaki Soyama et al., 2017 Sep	Japan	Retrospective	NA	50	0	0	0	50	0/50
Atef M. Darwish et al., 2018 Mar	Egypt	Randomized controlled trial	NA	33	3	1	33	0	33/33
Mohammad Ahmed Maher et al, 2017 Mar	Saudi Arabia	Prospective	31101	72	9	1	0	72	0/72
Brett D Einerson et al, 2016 Oct	USA	Retrospective	93825	314	43	1	174	140	NA
Haywood L. Brown et al., 2016 Dec	Kenya	Prospective	NA	58	3	3	NA	NA	55/58
Anderson Lo et al., 2016	USA	Retrospective	30817	43	8	0	NA	NA	NA
Sayori Nagai et al., 2015	Japan	Prospective	NA	10	1	0	1	9	4/10
Baris Kaya et al., 2016	Turkey	Retrospective	NA	21	4	1	0	21	21/21
Hee Young Cho et al., 2015	Korea	Retrospective	NA	64	16	5	35	29	0/64
Emmanuelle Vintejoux et al., 2015	France	Retrospective	19440	36	11	2	28	8	36/36

Ismet Alkıs et al., 2015	Turkey	Retrospective	NA	47	4	4	7	40	20/47
Cekmez Y. et al., 2015	Ireland	Retrospective	NA	10	3	2	7	3	9/10
Bariş Kaya et al.,2014	Turkey	Prospective	21677	45	11	5	16	29	34/45
Salih Burcin Kavak et al., 2013	Turkey	Randomized controlled trial	NA	7	0	0	0	7	0/7
Nikolaos Vrachnis et al., 2013	Greece	Retrospective	NA	18	1	1	10	8	11/18
Richelle Olsen et al., 2013	USA	Retrospective	NA	37	25	12	25	12	24/37
Enora Laas et al., 2012	France	Prospective	12082	43	6	1	31	12	NA
Grönvall M. et al., 2013	Finland	Retrospective	14599	50	7	4	29	21	8/50
Aibar L et al., 2013	Spain	Retrospective	NA	24	3	2	5	19	8/24
Anke Diemert et al., 2012	Germany	Retrospective	9838	20	8	1	4	16	11/20
Mohamed I. Khalil et al., 2011	Saudi Arabia	Prospective	NA	25	5	2	0	25	25/25
Vitthala et al.,2009	United Kingdom	Retrospective	NA	15	3	8	7	10	7/15

in a systematic review of 12 observational studies [49] the authors could not show the effectiveness of the use of the Bakri balloon to minimize the morbidity with PPH. Interestingly, in the current year, a systematic review (50) on the safety and effectiveness of Bakri balloon in the control of PPH has been carried out. Surprisingly, the authors came up to opposite conclusions in comparison to this study, stating that the Bakri balloon showed little effectiveness in the management of PPH. We believe the conclusions of the authors might depend on the variables considered to define the effectiveness in the PPH control. In fact, as the authors clearly pointed out, despite a displacement rate of the 9% (95%CI: 5-15%), the need for vascular ligation to control PPH after the placement of the balloon was very low, being 0.2% (95%CI; 0-8%), and importantly, hysterectomy was required only in 1% (95%CI; 0-8%) of the women. Unfortunately, the authors did not perform a meta-analysis to quantify the cumulative success rate of the Bakri balloon to provide a clear estimate of the effectiveness of this technique. Only 2 randomized controlled trials (RCT) were identified from the literature review. The first one (22) was a comparison between the feasibility and successfulness of a condom-loaded Foley's catheter in reference to Bakri device in the management of atonic PPH after vaginal birth. In the second one (33) the authors compared the effectiveness of endouterine hemostatic square sutures and the one of the Bakri balloon in the treatment of intractable PPH in a population of women with complete placenta previa. As expected, none of these 2 RCTs compared the use of the Bakri balloon with no treatment, as such a trial would pose relevant ethical issues and would therefore be unfeasible.

Studying the effectiveness of the management strategies of the PPH is a complex process, as the study of the other complex obstetric syndromes (51-53). The situation is made even more difficult by the multiple etiologies responsible for PPH (54, 55), and by varying markers of maternal morbidity reported to assess effectiveness of the management strategies. In this scenario we believe

Supplementary Table 1. Quality assessment of the included studies according to Newcastle-Ottawa Scale

Author, Year	Selection	Comparability	Outcome
Grange Josephine et al., 2018 Oct	★ ★ ★	★	★ ★ ★
Choi Wah Kong et al., 2018 Jul,	★ ★ ★	★	★ ★ ★
Berna Aslan Cetin et al., 2018	★ ★ ★	★	★ ★
Dongyu Wang et al., 2018 Aug	★ ★	★	★ ★
Yuna Guo et al., 2018 May	★ ★ ★	★	★ ★
Manisha Mathur et al., 2018 Jan	★ ★ ★	★	★ ★
Hiroaki Soyama et al., 2017 Sep	★ ★ ★	★	★ ★ ★
Atef M. Darwish et al., 2018 Mar	★ ★ ★	★	★ ★ ★
Mohammad Ahmed Maher et al, 2017 Mar	★ ★ ★	★	★ ★
Brett D Einerson et al, 2016 Oct	★ ★ ★	★ ★	★ ★ ★
Haywood L. Brown et al., 2016 Dec	★ ★ ★	★ ★	★ ★ ★
Anderson Lo et al., 2016	★ ★ ★	★	★ ★
Sayori Nagai et al., 2015	★ ★	★	★ ★
Baris Kaya et al., 2016	★ ★ ★	★	★ ★ ★
Hee Young Cho et al., 2015	★ ★	★	★ ★
Emmanuelle Vintejoux et al., 2015	★ ★ ★	★	★ ★ ★
Ismet Alkıs et al., 2015	★ ★ ★	★	★ ★
Cekmez Y. et al., 2015	★ ★	★	★ ★
Bariş Kaya et al.,2014	★ ★ ★	★	★ ★ ★
Salih Burcin Kavak et al., 2013	★ ★ ★	★	★ ★
Nikolaos Vrachnis et al., 2013	★ ★ ★	★	★ ★ ★
Richelle Olsen et al., 2013	★ ★ ★	★	★ ★ ★
Enora Laas et al., 2012	★ ★ ★	★ ★	★ ★ ★
Grönvall M. et al., 2013	★ ★ ★	★ ★	★ ★ ★
Aibar L et al., 2013	★ ★ ★	★	★ ★
Anke Diemert et al., 2012	★ ★ ★	★	★ ★
Mohamed I. Khalil et al., 2011	★	★	★ ★
Vitthala et al.,2009	★ ★ ★	★	★ ★

A study can be receive a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

that this meta-analysis is a good indicator of succesfulness of the Bakri device in the control of PPH.

We acknowledge some limitations of this quantitative analysis. We choose to use the need for additional procedures to control the PPH as a measure of effectiveness. We strongly believe that this is an important outcome to provide a useful estimate of effectiveness to clinicians dealing with PPH. At the same time some other markers of severe maternal morbidity might have been used such as the estimated blood loss, the need for transfusions, the rate of intensive care unit admission. The analysis of these outcomes from the existing literature would have been tricky given the nature of the available studies, but we do not exclude that they might be of interest for further studies. One additional limitation was relative to the high heterogeneity, reflecting the difficulties of comparability of the included studies, which were conducted with different designs and on different populations. However, according to the sensitivity analyses, heterogeneity improved when the analysis was limited to prospective studies and European studies, with no impact on the primary outcome (Figure 3 and 4).

This systematic review and meta-analysis showed that the Bakri uterine device is a useful tool for the stopping the PPH unresponsive to uterotonics, with a success rate of 82%. In addition, the Bakri balloon used in combination with additional procedures led to effective control of the PPH in 95% of cases, limiting the need for hysterectomy to the 5% (78/1597; 95% CI, 2–6%) of women included. Interpretation of these findings might take into account the significant heterogeneity found among the available studies.

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