Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review and meta-analysis

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OBJECTIVE: To assess the efficacy, effectiveness, and safety of uterine balloon tamponade for treating postpartum hemorrhage.

STUDY DESIGN: We searched electronic databases (from their inception to August 2019) and bibliographies. We included randomized controlled trials, nonrandomized studies, and case series that reported on the efficacy, effectiveness, and/or safety of uterine balloon tamponade in women with postpartum hemorrhage. The primary outcome was the success rate of uterine balloon tamponade for treating postpartum hemorrhage (number of uterine balloon tamponade success cases/total number of women treated with uterine balloon tamponade). For meta-analyses, we calculated pooled success rate for all studies, and relative risk with 95% confidence intervals for studies that included a comparative arm.

RESULTS: Ninety-one studies, including 4729 women, met inclusion criteria (6 randomized trials, 1 cluster randomized trial, 15 nonrandomized studies, and 69 case series). The overall pooled uterine balloon tamponade success rate was 85.9% (95% confidence interval, 83.9—87.9%). The highest success rates corresponded to uterine atony (87.1%) and placenta previa (86.8%), and the lowest to placenta accreta spectrum (66.7%) and retained products of conception (76.8%). The uterine balloon tamponade success rate was lower in cesarean deliveries (81.7%) than in vaginal deliveries (87.0%). A meta-analysis of 2 randomized trials that compared uterine balloon tamponade vs no uterine balloon tamponade in postpartum hemorrhage due to uterine atony after vaginal delivery showed no significant differences between the study groups in the risk of surgical interventions or maternal death (relative risk, 0.59; 95% confidence interval, 0.02—16.69). A meta-analysis of 2 nonrandomized before-and-after studies showed that introduction of uterine balloon tamponade in protocols for managing severe postpartum hemorrhage significantly decreased the use of arterial embolization (relative risk, 0.29; 95% confidence interval, 0.14—0.63). A nonrandomized cluster study reported that use of invasive procedures was significantly lower in the perinatal network that routinely used uterine balloon tamponade than that which did not use uterine balloon tamponade (3.0/1000 vs 5.1/1000; $P < .01$). A cluster randomized trial reported that the frequency of postpartum hemorrhage—related invasive procedures and/or maternal death was significantly higher after uterine balloon tamponade introduction than before uterine balloon tamponade introduction (11.6/10,000 vs 6.7/10,000; $P = .04$). Overall, the frequency of complications attributed to uterine balloon tamponade use was low (≤6.5%).

CONCLUSION: Uterine balloon tamponade has a high success rate for treating severe postpartum hemorrhage and appears to be safe. The evidence on uterine balloon tamponade efficacy and effectiveness from randomized and nonrandomized studies is conflicting, with experimental studies suggesting no beneficial effect, in contrast with observational studies. Further research is needed to determine the most effective programmatic and healthcare delivery strategies on uterine balloon tamponade introduction and use.

Key words: Bakri balloon, cesarean delivery, condom UBT, hysterectomy, maternal mortality, placenta previa, uterine atony, uterine bleeding, uterotonics, vaginal delivery

Postpartum hemorrhage (PPH) is the leading cause of maternal mortality and morbidity around the world.[1] In 2017, maternal hemorrhage was responsible for more than 38,000 deaths, of which more than 90% occurred in low- and middle-income countries (LMICs).[1,2] More than 1.5 million women annually have complications related to hemorrhage during pregnancy and the postpartum period.[3] While the prevalence of PPH ranges from 7% to 12% in high-income countries (HICs), it is as high as 25.7% in sub-Saharan Africa.[4,5] The prevalence of PPH has progressively increased in HICs. A Canadian population-based study reported a 27% increase in the rate of PPH from 2000 to 2009,[5] whereas a US nationwide study showed that incidence of severe PPH doubled from 1998 to 2008.[6]

Predisposing factors and etiologies for PPH include multiple pregnancy, fetal macrosomia, abnormal placentation, grand multiparity, older age, obesity, rapid or prolonged labor, labor induction, cesarean delivery, chorioamnionitis, uterine atony, retained placenta, genital tract lacerations, retained products of conception, and coagulation disorders, among others.[7—25] Appropriate treatment of PPH includes uterine massage, uterotonics, tranexamic acid, and, in cases of refractory bleeding, uterine balloon tamponade (UBT), uterine arterial embolization, and other surgical procedures.[26—28] Access to these critical interventions is often lacking in low-resource settings and therefore contributes to the high morbidity and mortality rates attributed to PPH.

Compared to other interventions used to treat refractory PPH, UBT requires

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AJOG at a Glance

Why was this study conducted?

This study was conducted to evaluate the efficacy, effectiveness, and safety of uterine balloon tamponade for the management of postpartum hemorrhage.

Key findings

The overall pooled success rate of uterine balloon tamponade in the treatment of postpartum hemorrhage was 85.9%. The success rate was higher in women with postpartum hemorrhage due to uterine atony and placenta previa than in women with postpartum hemorrhage due to placenta accreta spectrum or retained products of conception. The frequency of complications associated with the use of uterine balloon tamponade was low. To date, uterine balloon tamponade appears to have no adverse consequences on subsequent reproductive function.

What does this add to what is known?

Findings from this study indicate that uterine balloon tamponade has a high success rate for treating severe postpartum hemorrhage with a low complication rate. The evidence on uterine balloon tamponade efficacy and effectiveness from randomized and nonrandomized studies is conflicting, with experimental studies suggesting no beneficial effect, in contrast with observational studies.

minimal local resources and does not entail extensive training or complex equipment. UBTs can be used by a variety of healthcare providers and are recently becoming more affordable.[29] However, uncertainty still exists regarding the evidence on the efficacy of UBT for the management of PPH.

A systematic review published in 2013, including 13 observational studies with a total of 241 women, concluded that UBT is effective for the treatment of PPH in low-resource settings.[30] Other systematic reviews have been limited only to the use of the Bakri balloon (Cook Medical, Bloomington, IN) for the treatment of PPH.[31,32] Since then, considerable additional research on UBT has been published, including individual and cluster randomized trials and before-and-after studies of effectiveness. Therefore, examination of the current evidence on the efficacy of this intervention is justified. We conducted a systematic review and meta-analysis to determine the efficacy, effectiveness, and safety of UBT for the treatment of PPH.

Materials and Methods

This systematic review and meta-analysis was performed and reported according to the PRISMA statement.[33] The protocol was registered with PROSPERO in July 2018 (CRD42018102643; available at https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=102643). At least 2 of the authors (S.S., D.S.R., and A.B.P.) independently retrieved and reviewed studies for eligibility, assessed their risk of bias, and extracted data. Any disagreements encountered in the review process were resolved through discussion between the reviewers.

Literature search

A literature search was conducted by Harvard library services. PubMed, Ovid MEDLINE, EMBASE, POPLINE, Web of Science, African Index Medicus, LILACS/BIREME, Cochrane Library, and Google Scholar were searched from their inception to August 31, 2019, using a combination of terms related to PPH and UBT (Appendix: I. Search Strategy), without language restrictions. Reference lists of identified studies were also searched.

Eligibility criteria

Randomized controlled trials (RCTs), nonrandomized studies of interventions, and case series that reported on efficacy, effectiveness, and/or safety of UBT device placement in women with PPH after vaginal and/or cesarean delivery were included. Studies were excluded if they (1) reported on surgical techniques simultaneous with UBT use (eg, B-Lynch suture plus UBT); (2) were case reports, editorials, letters to the editors, or reviews without original data; or (3) reported on use of UBT for hemorrhage associated with pregnancy loss before 20 weeks of gestation. Studies with cases of UBT placement after failure of a surgical procedure for PPH were included. In cases of duplicate publications, only the most recent or complete version was included.

Outcome measures

The primary outcome was the success rate of UBT for the treatment of all causes of PPH. UBT success rate was defined as the number of "UBT success" cases divided by the total number of women treated with UBT, regardless of the definition of UBT success in each individual study. Cases of PPH where bleeding was arrested without maternal death and additional surgical or radiological interventions after UBT placement were defined as "UBT success." Cases of PPH where maternal death occurred or where additional surgical or radiological interventions were performed were defined as "UBT failures." For randomized trials and nonrandomized studies, the primary outcome was a composite of maternal death and/or surgical (artery ligation, uterine compression sutures, or hysterectomy) or radiological (arterial embolization) interventions. Secondary outcomes included success rate of UBT for the treatment of individual causes of PPH, frequency of hysterectomy and other invasive procedures (artery ligation, uterine compressive sutures, and arterial embolization), maternal death, mean blood loss, blood loss >1000 mL, blood transfusion, mean change in hemoglobin and hematocrit, admission to the intensive care unit, length of hospital and intensive care unit stay, and complication rates. Complications were defined as undesirable and unintended

events that were likely a direct result of UBT placement, such as infection, trauma, or reproductive consequences.

Risk of bias assessment

The risk of bias of included RCTs, nonrandomized studies, and case series was assessed according to the Cochrane Handbook for Systematic Reviews of Interventions,[34] the ROBINS-I tool (Risk Of Bias In Non-randomized Studies of Interventions),[35] and a modified version of the tool proposed by Murad et al,[36] respectively. Detailed description of these tools are included in the Appendix (II. Tools Used for Assessing the Risk of Bias).

Data extraction and synthesis

A data extraction form was used to collect information on study characteristics (authors, year of publication, design, prospective or retrospective data collection, definition of PPH, risk of bias, and method of assessment of blood loss); setting (country, income level, urban vs rural, number of facilities, and facility type); patient characteristics (inclusion and exclusion criteria, type of delivery, cause of PPH, baseline characteristics, and date of recruitment); details of intervention (type of UBT device, indication for UBT use, time of UBT placement, volume of fluid placed in UBT device, duration of placement, time to UBT device removal, and co-interventions); and outcomes (definitions used, number of outcome events/total number, and mean ± standard deviation for each outcome). Results from different studies were combined to produce a pooled success rate with 95% confidence interval (CI) using random-effects models. For RCTs and nonrandomized studies, estimates of success rate were obtained from the UBT intervention group only. Results were stratified according to study design, mode of delivery, and cause of PPH. Subgroup analyses were performed according to UBT device (Bakri balloon vs condom UBT) and stratified by cause of PPH (all causes of PPH vs uterine atony) and income (HICs vs LMICs). Sensitivity analyses were performed based on risk of bias and inclusion of data from abstracts of studies published only in abstract form or unobtainable articles.

Estimates of treatment effect were obtained from meta-analyses of RCTs and nonrandomized studies. These analyses compared the results of patients who were treated with UBT devices with those of a control group that was not treated with UBT devices. We calculated the pooled relative risk (RR) for dichotomous data and mean difference (MD) for continuous data with an associated 95% CI. If means were not reported in individual studies, we estimated them using the sample size, median, and interquartile ranges.[37] Heterogeneity of the results among studies was tested with the quantity I^2.[38] We pooled results from individual studies using a fixed-effects model if substantial statistical heterogeneity was not present ($I^2 < 30\%$). If I^2 values were ≥30%, a random-effects model was used to pool data across studies.

We assessed the overall quality of the evidence using the GRADE approach[39] for the following outcomes: composite of maternal death and/or surgical or radiological interventions, maternal death, surgical interventions, hysterectomy, artery ligation, uterine compressive sutures, and arterial embolization. GRADE has 4 levels of evidence: high, moderate, low, and very low (Appendix: III. Quality of Evidence).

Descriptive statistical analyses were performed using RStudio version 1.0.153 (RStudio, Inc, Boston, MA). Meta-analyses were conducted using MedCalc version 19.03 (MedCalc Software, Ostend, Belgium) and Review Manager 5.3.5 (The Nordic Cochrane Centre, Copenhagen, Denmark).

Results

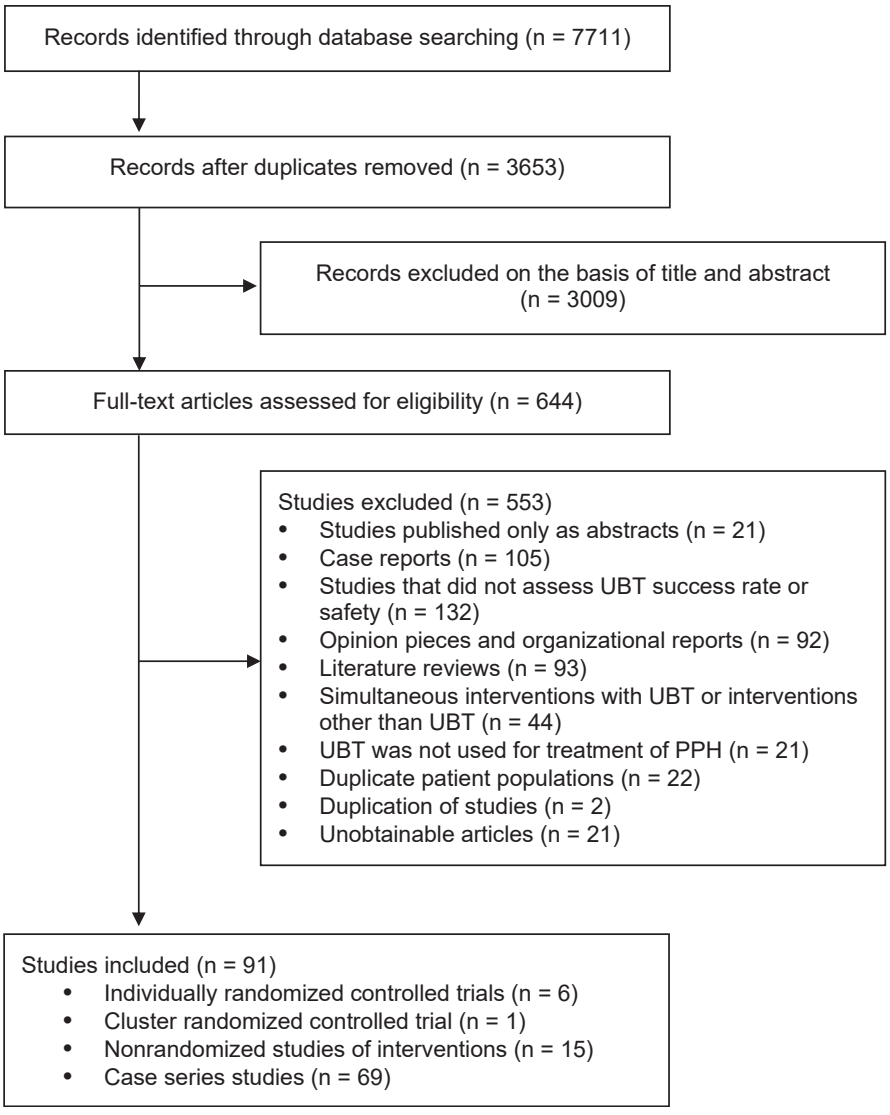
Study selection and characteristics

We identified 3653 studies in our literature search, of which 644 met initial screening criteria and were further assessed for eligibility (Figure 1). Ninety-one studies including a total of 4729 women met inclusion criteria, of which 6 were RCTs,[40–45] 1 was a cluster RCT,[46] 15 were nonrandomized studies of interventions,[47–61] and 69 were case series.[62–130] Three nonrandomized studies of interventions[123,126,129] had control groups that precluded their analysis as nonrandomized studies, but these studies provided data as case series. The corresponding authors of 2 studies were contacted to obtain additional information on relevant unpublished data.[57,120] A nonrandomized study[54] that used the same patient population as a case series[115] was included to evaluate the effectiveness of UBT, so data from the nonrandomized study[54] were excluded from meta-analyses of UBT success rate (for a total of 90 studies included in meta-analyses).

The main characteristics of the studies included in the systematic review are presented in Supplementary Table 1 (Appendix). Forty-six studies (52%) were conducted in 12 Asian countries,[41,42,45,48,49,52,53,55,58–60,63,72,74–76,79,81,87,89–91,94–96,100,101,103–105,107,108,110,112,114,117–119,122,124–129] 22 studies (25%) in 8 European countries,[47,51,64,65,68–71,73,77,78,80,82,85,86,88,92,97,99,102,115,123] 9 studies (10%) in 4 African countries,[40,44,56,61,67,106,109,111,130] 4 studies (4%) in 2 Latin American countries,[83,98,113,121] and 5 studies (6%) in the United States[50,66,84,93,116]; the remaining 4 were multicenter studies conducted in 10 countries.[43,46,62,120] Forty-eight (53%) studies were conducted in LMICs and 42 (47%) were conducted in HICs. Of the studies conducted in LMICs, 5 (10%) were RCTs,[40,42–45] 1 (2%) was a cluster RCT,[46] 9 (19%) were nonrandomized studies,[48,52,55–61] and 33 (69%) were case series.[63,67,72,74–76,81,83,89,91,94–96,98,100,101,104–106,108–111,113,114,117,118,120,121,126–128,130] Of the studies conducted in HICs, 1 (2%) was an RCT,[41] 5 (12%) were nonrandomized studies,[47,49–51,53] and 36 (86%) were case series.[62,64–66,68–71,73,77–80,82,84–88,90,92,93,97,99,102,103,107,112,115,116,119,122–125,129]

The median number of women treated with a UBT device for PPH was 64 (range, 7–120), 40 (range, 13–142), and 29 (range, 4–407) for RCTs, nonrandomized studies, and case series, respectively. The most-used UBT devices were Bakri balloon and condom catheter (Figure 2), which were used in 44 (49%) studies,[41,42,47–53,55,59,61,70,

FIGURE 1
Summary of evidence search and selection



PPH, postpartum hemorrhage; *UBT*, uterine balloon tamponade.

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73,80,82–84,86,88–90,94,97–104,107,111,112,114,116,118,119,121,123–126,129 and 18 (20%) studies,[43,45,46,58,63,67,72,74,81,91,105,106,108–110,113,117,120,127] respectively. Sengstaken–Blakemore balloons (C.R. Bard Inc., Covington, GA) were used in 6 (7%) studies,[62,64,68,69,79,87] Foley UBTs in 4 (4%),[56,75,76,128] and Rusch balloons (Teleflex Medical, Wayne, PA) in 4 (4%).[65,71,78,92] Belfort-Dildy ("ebb") Complete Tamponade Systems (Glenveigh Medical, LLC, Chattanooga, TN, currently marketed by Clinical Innovation, Salt Lake City, UT),[93] double-balloon cervical ripening catheters,[95] ESM-UBTs (Ujenzi Charitable Trust, Medford, MA),[120] El-Menia,[40] BT-Caths (Utah Medical Products, Inc., Midvale, UT),[96] Ellavi (Sinapi Biomedical, Stellenbosch, South Africa),[130] Linton-Nachlas (Coloplast, Rosny-sous-Bois cedex, France),[85] Metreurynters (Fuji-Metro; Fuji Latex Co., Ltd., Tochigi, Japan and Mini-Metro; Soft Medical Co., Ltd., Tokyo, Japan),[122] and Zhukovsky balloons (Ginamed, Moscow, Russia)[57] were used in 1 study each. Four studies reported a combination of UBT devices.[44,60,66,115] One study did not report the type of UBT device(s) used.[77]

Twelve (13%) studies included only women who delivered vaginally,[40,43–46,58,67,85,105,117,123] and 15 (17%) included only women who delivered by cesarean section.[41,42,48,49,53,56,59,61,76,79,89,103,104,126,128] The remaining studies included vaginal and cesarean deliveries.[47,50–52,55,60,62–66,68–75,77,78,80–84,86–88,90–102,106–116,118–122,124,125,127,129,130]

The indications for using a UBT device for the treatment of PPH included uterine atony in 22 (25%) studies,[40,41,43,44,47,48,50,58,59,67,72,73,83,97,100,105,111,113,117,120,127,130] placenta previa in 8 (9%),[42,49,53,61,79,89,96,103] and placenta accreta spectrum (PAS) in 2 (2%).[56,126] Eleven (12%) studies did not report the causes of PPH for which a UBT device was used.[45,51,70,75,77,91,104,110,114,118,129] The remaining 47 (52%) studies reported the use of UBT for the management of multiple causes of PPH, such as uterine atony, placenta previa, PAS, retained products of conception, coagulopathy, and trauma, among others.

Risk of bias

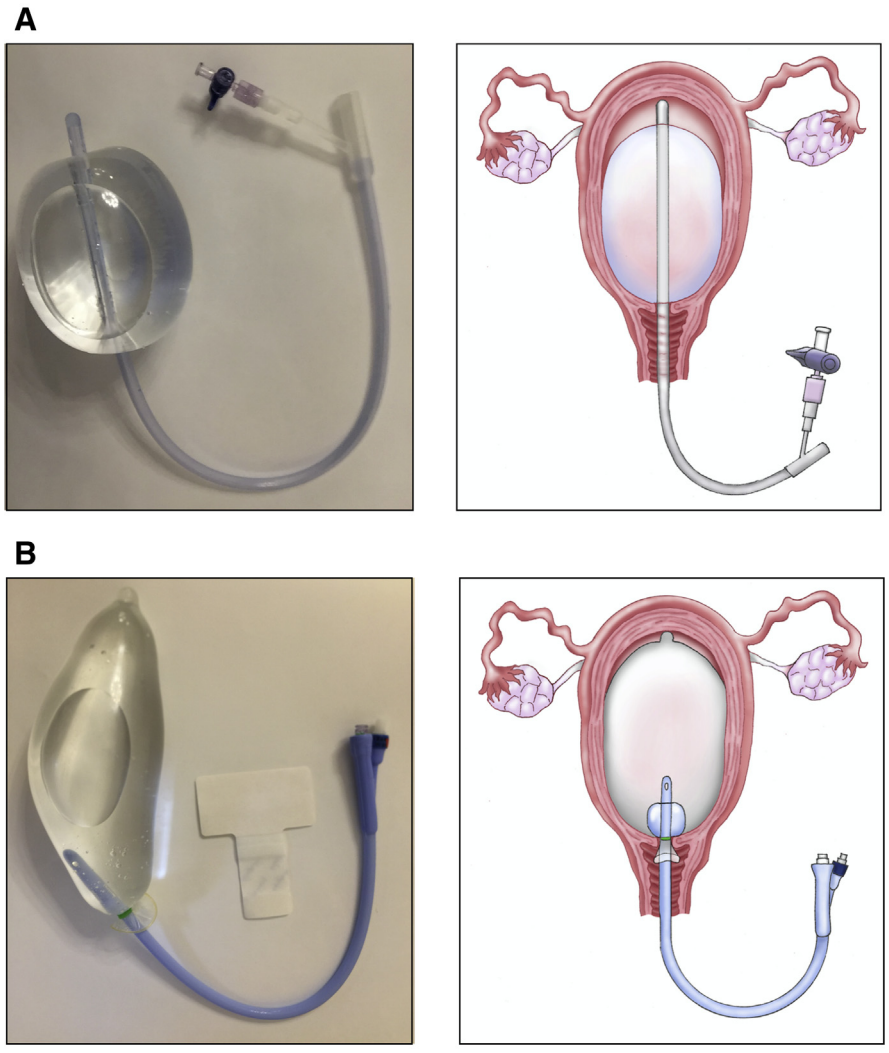
Randomized controlled trials

The risk of bias in each included RCT is shown in Supplementary Table 2 (Appendix). Only 1 RCT fulfilled at least 6 of the 7 criteria for "low" risk of bias.[44] All but 1 RCT[42] had an adequate generation of allocation sequence. Concealment of allocation was adequate in 3 studies and unclear in the remaining 3. Blinding healthcare providers and women in whom UBT devices were placed was not possible. However, because most outcomes were objectively measured, the included RCTs were considered at "low" risk of bias despite lack of outcomes assessment blinding. Among the 4 RCTs that reported estimated blood loss,[41–43,45] 1 assessed it visually,[43] 2 used objective methods,[42,45] and the 1 remaining[41] did not report the method used. One RCT[40] was at "high" risk of performance bias because UBTs were placed

in 19 (16%) women in the control group due to persistent hemorrhage. Movement of participants from the control group to the intervention group (UBT) may have reduced the observed difference between groups, leading to the estimated effect of being biased toward the null. In a study[41] that was stopped early, the treatment effect may have been overestimated and the data on safety and subgroup treatment effects less robust than reported.

The study by Dumont et al[43] had multiple methodological concerns that were likely to favor the control group, implying a decrease in the effect estimate of the UBT device. First, PPH was not measured objectively, as stated in the protocol, but instead was measured through visual estimation of blood loss and patient status. Second, training on UBT use was potentially suboptimal. Despite "frequent turnover of the staff," training sessions occurred every 11−16 months in each participating center with a duration of only half a day. Third, at randomization, there was imbalance between the treatment groups in estimated blood loss ≥1000 mL (42% in the UBT group vs 26% in the control group). This baseline variable is strongly related with the outcome measures and its imbalance likely caused bias in the intervention effect estimate. In addition, women in the UBT group had a higher frequency of manual removal of placenta than women in the control group (19% and 10%, respectively). Overall, women in the UBT group had more severe PPH before randomization than women in the control group. Fourth, misoprostol was not administered within 30 minutes of PPH diagnosis in 54% of women in the UBT group vs 37% in the control group. This implies that second-line uterotonics were administered late more frequently in the UBT group than in the control group. Finally, UBT devices were inserted within 30 minutes of PPH diagnosis in only 58% of women, and 4 of the 57 women allocated to the UBT group did not receive the intervention. Overall, there were significant problems in adherence to the intervention in the UBT group as prespecified in the trial protocol, which could have affected the outcomes.

FIGURE 2
Most-used uterine balloon tamponade devices: A, Bakri balloon; B, condom catheter



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Nonrandomized studies

Of 15 nonrandomized studies, 12 were rated as "critical" risk of bias, 2 as "serious" risk of bias, and 1 as "moderate" risk of bias (Appendix: Supplementary Table 3). The bias was mainly caused by lack of identification of and adjustment for confounding variables at baseline and during intervention. Five studies had "serious" risk of bias in classification of interventions, whereas the risk of bias in selection of participants into the study was "serious" in 3 studies. All studies were at "low" risk of bias due to missing data and in measurement of outcomes. Most studies were at "moderate" risk of bias in selection of reported results.

Case series

Among case series, 34 (49%) fulfilled ≥5 "low" risk criteria for bias, whereas the remaining 35 (51%) fulfilled ≤4 "low" risk criteria (Appendix: Supplementary Table 4). The most common shortcomings were related to patient selection, reporting, and

TABLE 1
Meta-analysis of success rate for uterine balloon tamponade according to study design, mode of delivery, and cause of postpartum hemorrhage

Cause of postpartum hemorrhage	Randomized controlled trials			Nonrandomized studies			Case series			Overall		
	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)
Vaginal birth												
Uterine atony	3	243	92.8 (75.4–99.9)	3	96	85.5 (77.9–91.7)	9	337	86.8 (78.1–93.5)	15	676	88.1 (81.7–93.3)
Undifferentiated	2	170	81.8 (71.2–90.4)	1	48	97.9 (93.9–100.0)	41	974	86.2 (82.7–89.3)	44	1192	86.3 (83.0–89.3)
Total[a]	5	413	89.0 (75.7–97.5)	4	144	89.6 (81.1–95.7)	48	1311	86.6 (83.4–89.4)	57	1868	87.1 (84.1–89.8)
Cesarean delivery												
Uterine atony	1	25	80.0 (64.3–95.7)	3	72	77.1 (66.9–85.8)	4	18	70.0 (32.1–95.5)	8	115	75.2 (63.4–85.4)
Placenta previa	1	7	100.0 (56.1–100.0)	3	121	88.7 (67.7–99.4)	5	159	86.2 (76.6–93.6)	9	287	88.3 (80.2–94.5)
Placenta accreta spectrum	-	-	-	2	46	52.5 (4.0–97.7)	2	26	88.7 (70.3–98.8)	4	72	74.8 (49.0–93.6)
Undifferentiated	-	-	-	1	12	100.0 (69.9–100.0)	39	1077	80.3 (75.4–84.8)	40	1089	80.9 (76.1–85.3)
Total[a]	2	32	87.2 (63.6–99.3)	8	251	83.6 (75.2–90.5)	49	1280	81.0 (76.7–84.9)	59	1563	81.7 (78.0–85.1)
Unknown mode of delivery												
Uterine atony	-	-	-	3	133	87.3 (80.4–93.0)	8	725	92.4 (85.5–97.2)	11	858	90.9 (85.4–95.2)
Placenta previa	-	-	-	2	44	89.8 (48.1–97.7)	4	99	84.6 (66.7–96.4)	6	143	87.0 (71.0–97.2)
Undifferentiated	-	-	-	2	88	83.0 (62.7–96.3)	10	209	80.8 (73.6–87.1)	12	297	81.3 (74.9–86.9)
Total[a]	-	-	-	4	265	86.0 (81.7–89.9)	14	1033	87.1 (81.9–91.5)	18	1298	86.7 (82.8–90.2)
Overall[b]												
Uterine atony	4	268	90.2 (74.1–98.9)	8	301	84.5 (79.9-88.6)	43	1942	87.3 (83.9–90.3)	55	2511	87.1 (84.1–89.9)
Placenta previa	1	7	100.0 (56.1–100.0)	5	165	89.3 (73.8-98.4)	32	516	85.6 (81.1–89.9)	38	688	86.8 (82.3–90.6)
Placenta accreta spectrum	-	-	-	3	74	75.1 (32.9-99.3)	10	69	64.1 (48.0–78.7)	13	143	66.7 (49.4–81.9)
Retained placenta	-	-	-	-	-	-	13	82	76.8 (65.3–86.5)	13	82	76.8 (65.3–86.5)
Undifferentiated	2	170	81.8 (71.2–90.4)	3	120	82.1 (46.6-99.7)	41	1015	82.9 (78.5–86.9)	46	1305	82.8 (78.4–86.8)
Total[a]	7	445	88.8 (77.7–96.4)	14	660	85.2 (80.5-89.4)	769	3624	85.7 (83.4–87.9)	90	4729	85.9 (83.9–87.9)

CI, confidence interval; *UBT*, uterine balloon tamponade.

[a] Total number of studies does not represent the sum of individual causes of postpartum hemorrhage given multiple causes of postpartum hemorrhage reported across studies; [b] Total number of studies and women does not represent the sum of individual causes of postpartum hemorrhage. Although some studies reported mode of delivery, they did not report results for cause of postpartum hemorrhage according to mode of delivery.

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exclusion of alternative causes for observed outcomes.

Efficacy of uterine balloon tamponade

Success rate of uterine balloon tamponade

Among the 90 studies that reported efficacy data, the overall pooled UBT success rate was 85.9% (95% CI, 83.9−87.9%) (Table 1). The highest pooled UBT success rates corresponded to cases of PPH due to uterine atony (87.1%; 95% CI, 84.1−89.9%) and placenta previa (86.8%; 95% CI, 82.3−90.6%), whereas the lowest corresponded to PAS (66.7%; 95% CI, 49.4−81.9%) and retained products of conception (76.8%; 95% CI, 65.3−86.5%). The pooled UBT success rate from all causes of PPH was slightly higher in vaginal deliveries (87.1%; 95% CI, 84.1−89.8%) than in cesarean deliveries (81.7%; 95% CI, 78.0−85.1%). The pooled success rates of UBT in PPH due to uterine atony was higher in vaginal deliveries (88.1%; 95% CI, 81.7−93.3%) than in cesarean deliveries (75.2%; 95% CI, 63.4−85.4%). There were no substantial differences among the pooled UBT success rates for all causes of PPH estimated from RCTs (88.8%), nonrandomized studies (85.2%), and case series (85.7%).

Of the 42 unobtainable articles or case series published only in abstract form, data from 36 were available to perform a sensitivity analysis, which showed a similar pooled UBT success rate (85.8%; 95% CI, 84.0−87.5%; n = 6489) to that obtained in the primary analysis (Appendix: Supplementary Table 5). A sensitivity analysis of UBT success rates stratified by risk of bias among case series showed little difference between studies at "low" risk of bias in ≥5 explanatory questions (85.6%; 95% CI, 82.1−88.7%) and those at "low" risk of bias in <5 explanatory questions (86.0%; 95% CI, 82.8−88.9%) (Appendix: Supplementary Table 6). Given the low number of RCTs and the high risk of bias in the nonrandomized studies, a sensitivity analysis according to risk of bias was not performed for these studies.

A subgroup analysis showed that the pooled UBT success rate for treating all causes of PPH was greater among women treated with a condom UBT (90.4%; 95% CI, 87.7−92.8%) than among women treated with a Bakri balloon (83.2%; 95% CI, 80.5−85.8%) (Appendix: Supplementary Table 7). Similar results were obtained in a subgroup analysis that included only women with PPH due to uterine atony (Appendix: Supplementary Table 8). The only RCT[44] that compared Bakri balloon with condom UBT in women with PPH due to uterine atony after vaginal delivery (n = 66) did not show a significant difference in the success rate between study groups (91.0% for Bakri balloon vs 84.8% for condom UBT; $P = .20$). A further subgroup analysis stratified by country income levels showed a pooled success rate of 90.4% (95% CI, 87.7−92.8%) for condom UBT in LMICs (Appendix: Supplementary Table 9). The pooled UBT success rates among women treated with Bakri balloon in HICs and LMICs for all causes of PPH were 80.8% (95% CI, 77.6−83.9%) and 86.4% (95% CI, 82.4−89.9%), respectively.

Uterine balloon tamponade vs no uterine balloon tamponade in postpartum hemorrhage due to uterine atony after vaginal delivery

We identified 1 retrospective nonrandomized study that compared use of UBT plus standard care (n = 35) vs standard care alone (n = 49) in women with PPH due to uterine atony after vaginal delivery.[57] Use of UBT was associated with a significant decrease in mean blood loss (759 ± 29 mL vs 1582 ± 107 mL; MD, -823 mL, 95% CI, -792 to -854 mL), surgical interventions (14% vs 63%; RR, 0.23, 95% CI, 0.10−0.52), and blood transfusions (11% vs 65%; RR, 0.18, 95% CI, 0.07−0.45) (very low-quality evidence for all).

Two RCTs compared UBT vs no UBT for treatment of PPH due to uterine atony after vaginal delivery.[40,43] One RCT,[40] conducted in Egypt, reported that use of UBT was associated with significant reductions in blood transfusions and intensive care unit length of stay, and increased hemoglobin and hematocrit at discharge. Moreover, this RCT reported a nonsignificant decrease in the frequency of surgical interventions associated with use of UBT. The other RCT[43] was conducted in Benin and Mali and reported that use of UBT was associated with a significant increase in the risk of PPH >1000 mL and a nonsignificant increase in the risk of maternal death and/or surgical interventions. Table 2 shows a meta-analysis of the 2 studies. Overall, there were no significant differences between the UBT and no-UBT groups in the risk of maternal death and/or surgical interventions (RR, 0.59; 95% CI, 0.02−16.69), maternal death (RR, 6.21; 95% CI, 0.77−49.98), hysterectomy (RR, 0.90; 95% CI, 0.03−24.76), uterine compressive sutures (RR, 1.02; 95% CI, 0.04−24.71), and artery ligation (RR, 0.84; 95% CI, 0.25−2.83) (very low-quality evidence for all).

Uterine balloon tamponade vs no uterine balloon tamponade in postpartum hemorrhage due to placenta previa during cesarean delivery

Three nonrandomized studies conducted in Saudi Arabia[49,53] and Egypt[56] compared use of UBT vs no UBT in women with PPH secondary to placenta previa during cesarean delivery. A meta-analysis of the 3 studies showed that use of UBT was associated with a significant reduction in surgical interventions (RR, 0.44; 95% CI, 0.28−0.71; low-quality evidence), hysterectomy (RR, 0.34; 95% CI, 0.12−0.96; low-quality evidence), mean blood loss (MD, -321 mL; 95% CI, -188 to -454 mL), and mean length of hospital stay (MD, -0.9 days; 95% CI, -0.6 to -1.2 days) (Table 3).

TABLE 2
Meta-analysis of randomized controlled trials of uterine balloon tamponade vs no uterine balloon tamponade in postpartum hemorrhage due to uterine atony after vaginal delivery

Outcome	No. of trials	UBT	No UBT	RR or MD (95% CI)	*P* value	I^2, %
Primary outcome						
Maternal death and/or surgical[a] or radiological[b] interventions	2[40,43]	9/177 (5.1%)	9/179 (5.0%)	0.59 (0.02−16.69)	.76	79
Secondary outcomes						
Surgical interventions[a]	1[40]	0/120 (0.0%)	5/120 (4.2%)	0.09 (0.01−1.63)	.10	NA
Maternal death	2[40,43]	6/177 (3.4%)	1/179 (0.6%)	6.21 (0.77−49.98)	.09	NA
Hysterectomy	2[40,43]	4/177 (2.3%)	4/179 (2.2%)	0.90 (0.03−24.76)	.95	70
Uterine compressive sutures	2[40,43]	2/177 (1.1%)	2/179 (1.1%)	1.02 (0.04−24.71)	.99	55
Artery ligation	2[40,43]	4/177 (2.3%)	5/179 (2.8%)	0.84 (0.25−2.83)	.78	24
Blood loss >1000 mL	1[43]	43/54 (79.6%)	31/59 (52.5%)	1.52 (1.15−2.00)	.003	NA
Blood transfusion	1[43]	23/57 (40.4%)	16/59 (27.1%)	1.49 (0.88−2.51)	.14	NA
Admission to ICU	1[43]	10/57 (17.5%)	8/59 (13.6%)	1.29 (0.55−3.04)	.56	NA
Mean stay in ICU (days)	1[40]	1.0 (0.5) 120	1.5 (0.5) 120	-0.50 (-0.63, -0.37)	<.00001	NA
Mean hemoglobin at discharge (g/dL)	1[40]	9.7 (0.2) 120	8.78 (1.6) 120	0.92 (0.63, 1.21)	<.00001	NA
Mean hematocrit at discharge (%)	1[40]	29.0 (0.7) 120	26.7 (4.5) 120	2.30 (1.49, 3.11)	<0.00001	NA

Data are n/N or mean (standard deviation) N.

CI, confidence interval; *ICU*, intensive care unit; *MD*, mean difference; *NA*, not applicable; *RR*, relative risk; *UBT*, uterine balloon tamponade.

[a] Artery ligation, uterine compression sutures, or hysterectomy; [b] Arterial embolization.

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Effectiveness of uterine balloon tamponade

Nonrandomized before-and-after studies on the impact of introducing uterine balloon tamponade for managing severe postpartum hemorrhage

Two nonrandomized before-and-after studies assessed the impact of UBT introduction into protocols for management of severe PPH in obstetrics units of 2 French hospitals.[47,51] Both studies compared outcomes of all patients with PPH who were unresponsive to prostaglandins before and after the introduction of a UBT protocol. A meta-analysis of the 2 studies showed that the rate of arterial embolization significantly decreased after introduction of UBT (1.9% after UBT vs 6.3% before UBT; RR, 0.29; 95% CI, 0.14−0.63; low-quality evidence) (Table 4). The introduction of UBT was also associated with a nonsignificant reduction in the use of surgical or radiological interventions (8.0% after UBT vs 16.2% before UBT; RR, 0.41; 95% CI, 0.15−1.10), artery ligation or uterine compressive sutures (6.0% after UBT vs 9.9% before UBT; RR, 0.43; 95% CI, 0.09−2.07), and hysterectomy (1.0% after UBT vs 2.2% before UBT; RR, 0.47; 95% CI, 0.08−2.70) (very low-quality evidence for all). In the largest study,[47] the use of surgical or radiological interventions significantly decreased after introduction of UBT among women who delivered vaginally (4.1% after UBT vs 14.4% before UBT; RR, 0.29; 95% CI, 0.14−10.59) but not among women who delivered by cesarean section (15.8% after UBT vs 13.5% before UBT; RR, 1.17; 95% CI, 0.64−2.15).

Nonrandomized cluster studies comparing use of uterine balloon tamponade vs nonuse of uterine balloon tamponade

One population-based retrospective study conducted in France compared the rates of invasive procedures (artery ligation, arterial embolization, and hysterectomy) for hemorrhage control between a perinatal network (10 maternity units) that routinely used UBT and another perinatal network (9 maternity units) that did not use UBT in the management of PPH.[54] During the study period, 35,133 women delivered in the perinatal network that used UBT and 37,396 in the network that did not use UBT. The rate of women that underwent at least 1 invasive procedure was significantly lower in the perinatal network that routinely used UBT than in the network that did not use UBT (3.0 per 1000 vs 5.1 per 1000; RR, 0.60; 95% CI, 0.47−0.76); $P < .0001$; moderate-quality evidence). After adjustment for potential confounding factors, the risk of an invasive procedure among women with PPH who delivered vaginally remained significantly lower in the network that routinely used UBT (adjusted odds ratio, 0.14; 95%

TABLE 3
Meta-analysis of nonrandomized studies of uterine balloon tamponade vs no uterine balloon tamponade in postpartum hemorrhage due to placenta previa during cesarean delivery

Outcome	No. of trials	UBT	No UBT	RR or MD (95% CI)	*P* value	I^2, %
Primary outcome						
Maternal death and/or surgical[a] or radiological[b] interventions	3[49,53,56]	20/125 (16.0%)	57/229 (24.9%)	0.44 (0.28−0.71)	.0006	0
Secondary outcomes						
Surgical[a] interventions	3[49,53,56]	20/125 (16.0%)	56/229 (24.4%)	0.44 (0.28−0.71)	.0007	0
Maternal death	3[49,53,56]	0/125 (0.0%)	1/229 (0.4%)	3.62 (0.15−84.75)	.42	NA
Hysterectomy	3[49,53,56]	4/125 (3.2%)	25/229 (10.9%)	0.34 (0.12−0.96)	.04	0
Uterine compressive sutures	2[49,53]	8/85 (9.4%)	13/191 (6.8%)	0.74 (0.29−1.88)	.52	0
Artery ligation	2[53,56]	13/112 (11.6%)	20/78 (25.6%)	0.61 (0.21−1.83)	.38	45
Mean blood loss (mL)	2[53,56]	112	78	-321 (-454, -188)	<.00001	0
Blood transfusion	3[49,53,56]	59/125 (47.2%)	199/229 (86.9%)	0.82 (0.51−1.32)	.41	88
Admission to ICU	3[49,53,56]	24/125 (19.2%)	169/229 (73.8%)	0.62 (0.12−3.07)	.55	93
Mean hospital stay (days)	2[53,56]	112	78	-0.90 (-1.23, -0.57)	<.00001	24
Mean postoperative hemoglobin (g/dL)	2[53,56]	112	78	0.13 (-0.11, 0.37)	.30	38

Data are n/N or total number.

CI, confidence interval; *ICU*, intensive care unit; *MD*, mean difference; *NA*, not applicable; *RR*, relative risk; *UBT*, uterine balloon tamponade.

[a] Artery ligation, uterine compression sutures, or hysterectomy; [b] Arterial embolization.

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CI, 0.08−0.27); it did not significantly differ among women who delivered by cesarean section.

Cluster randomized controlled trials on the impact of introducing uterine balloon tamponade for managing severe postpartum hemorrhage

We identified a stepped-wedge cluster RCT that assessed the effectiveness of condom-catheter UBT introduction for treatment of refractory PPH after vaginal delivery in 18 secondary-level hospitals located in Uganda, Egypt, and Senegal.[46] There were 28,183 and 31,928 deliveries in the control (before UBT introduction) and intervention (after UBT introduction) periods, respectively. UBT was used for 9 of 1357 women and 55 of 1037 women diagnosed with PPH in control and intervention periods, respectively. UBT introduction was associated with a significant increase in the composite outcome of PPH-related invasive procedures and/or maternal death (6.7/10,000 deliveries in the control period vs 11.6/10,000 deliveries in the intervention period). The unadjusted and adjusted incident rate ratios were 1.72 (95% CI, 0.99−2.99) and 4.08 (95% CI, 1.07−15.58), respectively (low-quality evidence). However, the increase in the composite endpoint was not statistically significant in sensitivity analyses excluding outlier hospitals, restricting analyses to outcomes associated with PPH due to uterine atony, and adjusting for interaction of temporal trends by site or country. Several reasons could explain the lack of beneficial effects of introducing UBT reported in this study. First, after introduction of UBT, only a small fraction (5.3%) of women diagnosed with PPH received a UBT device for treatment of PPH. Second, 29 of 37 women (78.4%) who had PPH-related surgery or maternal death in the intervention period did not receive UBT. Third, only 50% of UBT devices were inserted within 30 minutes of PPH diagnosis (range, 0−510 minutes). Fourth, providers had a problem with UBT use in 52% of women and reported blood shortage for almost half of PPH-related deaths. Finally, 66.7% of women with PPH-related invasive surgery or death had PPH complicated by causes other than uterine atony for which UBT is less efficacious. According to the study authors, the outcomes observed after UBT introduction may be partly explained by temporal trends and outlier sites.

Safety of uterine balloon tamponade

Short-term follow-up

Thirty-nine of 90 included studies (43%) reported on complications related to use of UBT. Seven studies reported a total of 29 cases of fever or infection after the placement of a UBT device among 445 women (6.5%).[44,79,81,99,106,109,117] Three studies reported a total of 7 cases of endometritis attributed to the use of UBT among 308 women (2.3%).[47,59,115] Other reported complications included cervical tears (2 among 120 women; 1.7%),[40] acute colonic pseudo-obstruction (1 among 49 women;

TABLE 4
Meta-analysis of nonrandomized before-and-after studies on the effect of introducing uterine balloon tamponade in the management of women with severe postpartum hemorrhage who received prostaglandins

Outcome	No. of trials	After introducing UBT	Before introducing UBT	RR (95% CI)	*P* value	I^2, %
Primary outcome						
Maternal death and/or surgical[a] or radiological[b] interventions	2[47,51]	39/486 (8.0%)	59/364 (16.2%)	0.41 (0.15–1.10)	.08	77
Secondary outcomes						
Surgical[a] or radiological[b] interventions	2[47,51]	39/486 (8.0%)	59/364 (16.2%)	0.41 (0.15–1.10)	.08	77
Artery ligation or uterine compressive sutures	2[47,51]	29/486 (6.0%)	36/364 (9.9%)	0.43 (0.09–2.07)	.29	83
Maternal death	2[47,51]	0/486 (0.0%)	0/364 (0.0%)	Not estimable	NA	NA
Hysterectomy	2[47,51]	5/486 (1.0%)	8/364 (2.2%)	0.47 (0.08–2.70)	.40	47
Arterial embolization	2[47,51]	9/486 (1.9%)	23/364 (6.3%)	0.29 (0.14–0.63)	.002	0
Artery ligation	1[51]	4/91 (4.4%)	12/74 (16.2%)	0.27 (0.09–0.81)	.02	NA
Uterine compressive sutures	1[51]	1/91 (1.1%)	7/74 (9.5%)	0.12 (0.01–0.92)	.04	NA
Blood transfusion	2[47,51]	80/486 (16.5%)	50/364 (13.7%)	1.23 (0.90–1.68)	.19	0
Decrease in hemoglobin ≥2 g/dL	1[47]	194/395 (49.1%)	183/290 (63.1%)	0.78 (0.68–0.89)	.0002	NA

Data are n/N.

CI, confidence interval; *ICU*, intensive care unit; *NA*, not applicable; *RR*, relative risk; *UBT*, uterine balloon tamponade.

[a] Artery ligation, uterine compression sutures, or hysterectomy; [b] Arterial embolization.

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2.0%),[99] laceration of the lower segment of the vagina (1 among 21 women; 4.8%),[48] uterine incision rupture (1 among 53 women; 1.9%),[96] and uterine perforation (1 among 49 women; 2.0%).[124] The remaining 25 studies reported no complications attributed to the use of UBT.

Long-term follow-up

Four studies reported on potential long-term consequences associated with use of UBT.[92,99,102,129] A retrospective cohort study followed 200 women with severe PPH, of which 39 received a Bakri balloon and 161 did not.[129] Most women (87%) in the UBT group had normal menstrual patterns in the 12 months after the index delivery as well as in the most recent 12 months. After exclusion of patients using contraception, the subsequent pregnancy rate was 43% (9/21) in the UBT group compared to 46% (28/61) in the control group ($P = .81$). There were no significant differences in subsequent live birth rates, return of menses, cycle regularity, duration of flow, amount of flow, or presence of dysmenorrhea between the study groups.

A second study followed 31 women who had been treated for PPH with a Rusch balloon to evaluate the subsequent fertility and pregnancy rate.[92] Follow-up visits ranged between 4 and 108 months. Seven women (23%) became pregnant again, of which 4 delivered at term without complications, 2 had early abortions, and 1 had an ectopic pregnancy. Among the 24 women who did not get pregnant again, only 1 had difficulty conceiving.

A third study evaluated the impact of using Bakri balloons on subsequent fertility outcomes at 6 or more months follow-up visits.[99] Among 24 women contacted by phone, 2 considered their menses shorter and lighter and 2 became pregnant soon after their previous delivery, giving birth to healthy babies.

A fourth study assessed fertility after Bakri balloon use for treatment of PPH in 38 women.[102] Nine women expressed a desire for pregnancy and became pregnant again after an average of 23 months (standard deviation, 8 months). Three women delivered healthy newborns, 4 remained pregnant at the time of study publication, 1 voluntarily terminated her pregnancy, and 1 had an ectopic pregnancy.

Comment

Main findings

Our study indicates that UBT has a high success rate to treat PPH, with an overall pooled estimate of 85.9%. Subgroup analyses suggest that (1) UBT has a higher success rate in women with PPH due to uterine atony and placenta previa than in women with PPH due to PAS or retained products of conception; (2) UBT has a higher success rate in women with PPH after vaginal delivery than in women with PPH after cesarean delivery; (3) UBT has a higher success rate in women with PPH resulting from uterine atony after vaginal delivery than in women with PPH resulting from uterine atony after cesarean delivery; (4) condom UBT success rates are at least as comparable as Bakri balloon success rates; and (5) the evidence on UBT efficacy and effectiveness from randomized

and nonrandomized studies is conflicting, with experimental studies suggesting no beneficial effect, in contrast with observational studies.

There is some conflicting evidence regarding the efficacy of UBT to reduce surgical interventions or maternal deaths among women with severe PPH due to uterine atony. A small nonrandomized study[57] and 1 RCT[40] showed beneficial effects of UBT, whereas another RCT[43] suggested that UBT could be harmful. Evidence from nonrandomized studies[49,53,56] suggests that UBT is more efficacious than nonuse of UBT in reduction of surgical interventions among women with PPH due to placenta previa after cesarean delivery. Evidence from 2 nonrandomized before-and-after studies[47,51] and 1 large, methodologically sound nonrandomized cluster study[54] strongly suggests that introduction of UBT in protocols for the management of PPH among obstetric units in HICs is effective in reducing PPH-associated surgical interventions and arterial embolization after vaginal delivery. However, a stepped wedge cluster RCT[46] reported that introduction of condom-catheter UBT in secondary-level hospitals in 3 African countries may have increased the risk of PPH-related maternal deaths and invasive procedures. Additionally, UBT appears safe and possesses few adverse effects on subsequent menstrual and reproductive function.

Overall, it appeared that condom UBTs had higher success rates than Bakri balloon in management of PPH. A possible explanation is that in resource-limited settings, birth attendants may invoke use of UBT earlier, as UBT may often be the only available option. In high-resource settings, where there are no studies on condom UBTs, there are more human resources and more treatment options, but PPH may be more complex or severe when a UBT device is used. There is strong evidence suggesting that a prolonged time between onset of hemorrhage and placement of UBT results in worse outcomes.[115,118,120] Another potential explanation for the observed difference in outcomes between condom and Bakri UBTs is that women in HICs may undergo UBT device placement as an interim measure before embolization or other procedures. These cases were considered treatment failures in this systematic review. Regardless of setting, the success rate of UBT was >80%. It is noteworthy that success rates of Bakri balloon and condom UBT were similar in LMICs (86.4% vs 90.4%). This suggests that condom UBTs are at least as efficacious as Bakri balloon and that success rates may be more dependent on setting than on the device.

The findings of this systematic review reveal a discrepancy between nonrandomized studies and RCTs on the efficacy and effectiveness of UBT in the treatment of severe PPH. UBT success rates were consistently high across all study types. However, 2 randomized studies concluded there is no benefit to introduction of UBT in management of refractory PPH, despite reporting high success rates in the intervention arms.[43,46] One of these studies[43] was not truly an efficacy trial but an effectiveness trial of programmatic implementation of UBT for the treatment of PPH. This study[43] had multiple methodological concerns that likely favored the control group, implying a high risk of bias toward erroneous results. However, the weaknesses of this effectiveness trial remind us of the importance of future research on implementation strategies that lead to desired uptake and optimal performance of interventions designed to improve maternal outcomes. Examples of future recommended strategies include more frequent and higher quality training, improved appropriate use of uterotonics, scale of tranexamic acid, earlier identification of PPH, systematization of PPH emergency care, and reduction in the time between diagnosis of PPH and placement of a UBT device. Finally, conclusions about efficacy of UBT devices should not be based on an effectiveness trial that did not use UBT consistently.

Strengths and limitations

The main strengths of this study include the following: (1) use of rigorous methodology for performing the systematic review and meta-analysis; (2) use of a prospective protocol designed to address a specific research question; (3) assessment of UBT's efficacy, safety, and effectiveness; (4) inclusion of RCTs, nonrandomized studies, and case series to estimate pooled success rates for UBT; (5) comprehensive literature search without language restrictions; (6) strict risk of bias assessment; (7) performance of subgroup analyses according to study design, mode of delivery, cause of PPH, and country income level; (8) comparison of success rates between Bakri balloon and condom UBT; and (8) inclusion of a relatively large number of studies, most of which were recently published.

Several potential limitations of our review must be considered. First, it is limited by the quality of the original data. Most RCTs and nonrandomized studies were considered to be at "high" risk of bias, whereas only half of case series met at least 5 methodological criteria for "low" risk of bias. Thus, the findings should be interpreted with some caution. However, a sensitivity analysis among case series showed only slight differences in success rate between studies that fulfilled at least 5 criteria and those that fulfilled fewer than 5 criteria for "low" risk of bias. Second, we excluded 42 studies that were published as abstracts only or unobtainable. Nevertheless, a sensitivity analysis that included data from abstracts of studies published only in abstract form or unobtainable articles showed that pooled UBT success rates were similar to those obtained in the primary analysis. Third, the limited number of RCTs and nonrandomized studies that assessed efficacy of UBT in the treatment of uterine atony did not allow us to provide conclusive evidence on this topic. Nevertheless, evidence from 3 large nonrandomized studies (2 before-and-after studies[47,51] and 1 cluster nonrandomized study[54]) at low risk of bias strongly suggests that introduction of UBT for managing severe PPH due to uterine atony is effective in reducing use of surgical and radiological interventions. Fourth, underlying causes of PPH might have been difficult to identify in the original

studies because distinction among them is not always easy and some underlying disorders can overlap in the same patient. Finally, most studies did not report safety outcomes, which increases the likelihood of reporting bias. However, the best available evidence suggests that UBT appears to be safe in the treatment of PPH.

To date, this is the most comprehensive systematic review and meta-analysis on the efficacy, effectiveness, and safety of UBT for the treatment of severe PPH. The consistency of study results on the use of UBT indicates that these devices have a high success rate for treating PPH and appear safe. It is not surprising that emergency interventions with high success rates, such as UBT for PPH, fall short of improving outcomes when implementation programs do not adequately integrate interventions into systems of emergency care. There is an urgent need for high-quality studies that help identify strategies that optimize provider and health system performance in delivery of all emergency care interventions among women with PPH.

Conclusions

There is persuasive evidence that UBT devices have a high success rate for arresting bleeding among women with severe PPH unresponsive to uterotonics and initial therapies. In addition, most evidence suggests that use of UBT is associated with a significant reduction in the rate of PPH-related invasive procedures such as artery ligation, uterine compression sutures, hysterectomy, and arterial embolization. The evidence on UBT efficacy and effectiveness from randomized and nonrandomized studies is conflicting, with experimental studies suggesting no beneficial effect, in contrast with observational studies. To optimize maternal outcomes, high-quality implementation research is needed to determine the most effective programmatic and healthcare delivery strategies on UBT introduction and use. ■

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Appendix

I. Search Strategy

PubMed

Search	Search query
#1	Search "Uterine Balloon Tamponade"[mesh]
#2	Search ("uterus"[mesh] OR "Uterus"[title/abstract] OR "uterine"[title/abstract] OR "intrauterine"[title/abstract] OR "intra uterine"[title/abstract]) AND (Bakri[title/abstract] OR Belfort Dildy[title/abstract] OR BT Cath[title/abstract] OR ebb balloon [title/abstract] OR ebb balloons[title/abstract] OR ebb tamponade[title/abstract] OR el menia[title/abstract] OR Rusch[title/abstract] OR Sengstaken Blakemore[title/abstract])
#3	Search ("uterus"[mesh] OR "Uterus"[title/abstract] OR "uterine"[title/abstract] OR "intrauterine"[title/abstract] OR "intra uterine"[title/abstract]) AND "Catheters"[Mesh] AND (foley[title/abstract] OR foley's[title/abstract] OR foleys[title/abstract])
#4	Search ("uterus"[mesh] OR "Uterus"[title/abstract] OR "uterine"[title/abstract] OR "intrauterine"[title/abstract] OR "intra uterine"[title/abstract]) AND ("foley catheter"[title/abstract] OR "foley's catheter"[title/abstract] OR "foleys catheter"[title/abstract] OR "foley catheters"[title/abstract] OR "foley's catheters"[title/abstract] OR foleys catheters [title/abstract])
#5	Search ("uterus"[mesh] OR "Uterus"[title/abstract] OR "uterine"[title/abstract] OR "intrauterine"[title/abstract] OR "intra uterine"[title/abstract]) AND (balloon[title/abstract] OR balloons[title/abstract] OR tamponade[title/abstract] OR tamponades[title/abstract] OR condom[title/abstract] OR condoms[title/abstract] OR condoms[mesh] OR "Balloon Occlusion"[mesh])
#6	Search ("uterus"[mesh] OR "Uterus"[title/abstract] OR "uterine"[title/abstract] OR "intrauterine"[title/abstract] OR "intra uterine"[title/abstract]) AND (dilatation[title/abstract] OR dilation[title/abstract] OR "fluid filled"[title/abstract] OR gauze [title/abstract] OR hydrostatic[title/abstract] OR packing[title/abstract] OR sponge[title/abstract] OR sponges[title/abstract] OR Dilatation[mesh] OR "Surgical Sponges"[mesh])
#7	Search (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8	Search (Abruptio Placentae[title/abstract] OR "surgical Blood loss"[title/abstract] OR "Blood Transfusion"[title/abstract] OR Placenta Accreta[title/abstract] OR Placenta Previa[title/abstract] OR Shock[title/abstract] OR "Abruptio Placentae"[mesh] OR "Blood Loss, Surgical"[mesh] OR "Blood Transfusion"[mesh] OR "Maternal Death"[mesh] OR "Maternal Mortality"[mesh] OR "Metrorrhagia"[mesh] OR "Placenta Accreta"[mesh] OR "Placenta Previa"[mesh] OR "Postpartum Hemorrhage"[mesh] OR "Shock, Hemorrhagic"[Mesh:NoExp] OR "Uterine Inertia"[mesh] OR "Uterine Hemorrhage"[mesh])
#9	Search (Mothers[mesh] OR mother[title/abstract] OR mothers[title/abstract] OR Maternal[title/abstract] OR postpartum [title/abstract] OR "post partum"[title/abstract]) AND (death[mesh] OR death[title/abstract] OR mortality[mesh] OR mortality[title/abstract] OR mortality[mesh] OR Mortality[MeSH Subheading])
#10	Search postpartum hemorrhag*[title/abstract] OR postpartum haemorrhag*[title/abstract] OR "post partum" hemorrhag*[title/abstract] OR "post partum" haemorrhag*[title/abstract]
#11	Search ("uterus"[mesh] OR "Uterus"[title/abstract] OR "uterine"[title/abstract]) AND (atony[title/abstract] OR atonic[title/abstract])
#12	Search ("atonic uterus"[title/abstract]) OR "uterine atony"[title/abstract]) OR "uterine inertia"[title/abstract]
#13	Search (#8 OR #9 OR #10 OR #11 OR #12)
#14	Search (#7 AND #13)

OVID MEDLINE

Search	Search query
#1	Search Uterine Balloon Tamponade.ti,ab,de. or ((uterus adj7 balloon* adj7 tamponade*) or (uterine adj7 balloon* adj7 tamponade*) or (intrauterine adj7 balloon* adj7 tamponade*) or ("intra uterine" adj7 balloon* adj7 tamponade*)).ti,ab.
#2	Search uterus/ or (intrauterine or "intra uterine" or uterine or intrauterine).ti,ab.
#3	Search (Bakri or Belfort Dildy or BT Cath or ebb balloon* or ebb tamponade or "el menia" or Rusch or Sengstaken Blakemore).ti,ab. or (catheter* adj7 foley*).ti,ab,de. or exp Balloon Occlusion/ or (balloon* adj7 occlu*).ti,ab. or (condom* or dilatation or dilation or "fluid filled" or gauze or hydrostatic or packing or sponge*).ti,ab,de.
#4	Search 2 and 3
#5	Search 1 or 4
#6	Search (Abruptio Placentae or Blood Loss Surgical or Blood Transfusion or Maternal Mortality or Maternal Death or Metrorrhagia or Placenta Accreta or Placenta Previa or shock or Postpartum Hemorrhage or Shock Hemorrhagic or Uterine Hemorrhage).ti,ab,de.
#7	Search (Mother* or maternal or "postpartum hemorrhage*" or "post partum hemorrhag*" or "postpartum haemorrhag*" or "post partum hemorrhag*").ti,ab,de. and ((death or mortality).ti,ab,de. or mo.fs.)
#8	Search ((uterus or intrauterine or "intra uterine" or uterine) adj7 (atony or atonic or inertia)).ti,ab. or Uterine Inertia/
#9	Search 5 and (6 or 7 or 8)
#10	Search remove duplicates from 9
#11	Search (10 and humans/) or (10 not animals/)

EMBASE

Search	Search query
#1	Search ('uterine atony'/de OR 'atonic uterus':ti,ab,kw OR 'uterine atony':ti,ab,kw OR 'uterine inertia':ti,ab,kw OR (('uterus'/de OR 'uterus':ti,ab,kw OR 'intra uterine':ti,ab,kw OR 'intrauterine':ti,ab,kw OR 'uterine':ti,ab,kw) AND ('atony':ti,ab,kw OR 'atonic':ti,ab,kw OR 'inertia':ti,ab,kw))
#2	Search ('postpartum hemorrhage'/de OR 'postpartum hemorrhag*':ti,ab,kw OR 'postpartum haemorrhag*':ti,ab,kw OR 'post partum hemorrhag*':ti,ab,kw OR 'post partum haemorrhag*':ti,ab,kw)
#3	Search ('mother'/exp OR 'mother' OR 'mother*':ti,ab,kw OR maternal:ti,ab,kw OR 'puerperium'/exp OR 'puerperium' OR 'postpartum':ti,ab,kw OR 'post partum':ti,ab,kw OR 'puerperium':ti,ab,kw) AND ('death'/exp OR 'death':ti,ab,kw OR 'mortality'/exp OR 'mortality':ti,ab,kw)
#4	Search ('blood transfusion'/exp OR 'dystocia'/exp OR 'maternal death'/exp OR 'solutio placentae'/exp OR 'operative blood loss'/exp OR 'hemorrhagic shock'/exp OR 'maternal mortality'/exp OR 'metrorrhagia'/exp OR 'placenta accreta'/exp OR 'placenta previa'/exp OR 'postpartum hemorrhage'/exp OR 'uterus bleeding'/exp OR 'shock'/exp OR 'abruptio placentae':ti,ab,kw OR 'blood transfusion':ti,ab,kw OR 'hemorrhagic shock':ti,ab,kw OR 'haemorrhagic shock':ti,ab,kw OR 'maternal death':ti,ab,kw OR 'maternal mortality':ti,ab,kw OR 'metrorrhagia':ti,ab,kw OR 'placenta accreta':ti,ab,kw OR 'placenta previa':ti,ab,kw) AND ('postpartum hemorrhage':ti,ab,kw OR 'postpartum haemorrhage':ti,ab,kw OR 'shock':ti,ab,kw OR 'surgical blood loss':ti,ab,kw OR 'uterine hemorrhag*':ti,ab,kw OR 'uterine haemorrhag*':ti,ab,kw OR 'uterine inertia':ti,ab,kw)
#5	Search (#1 OR #2 OR #3 OR #4)
#6	Search ('uterus'/de OR 'uterus':ti,ab,kw OR 'intra uterine':ti,ab,kw OR 'intrauterine':ti,ab,kw OR 'uterine':ti,ab,kw) AND ('dilatation'/exp OR 'gauze'/exp OR 'surgical sponge'/de OR 'dilation':ti,ab,kw OR 'dilatation':ti,ab,kw OR 'fluid filled':ti,ab,kw OR 'gauze':ti,ab,kw OR 'hydrostatic':ti,ab,kw OR 'packing':ti,ab,kw OR 'surgical sponge*':ti,ab,kw)
#7	Search ('uterus'/de OR 'uterus':ti,ab,kw OR 'intra uterine':ti,ab,kw OR 'intrauterine':ti,ab,kw OR 'uterine':ti,ab,kw) AND ('occlusion balloon catheter'/de OR 'condom catheter'/de OR 'balloon*':ti,ab,kw OR tamponade*:ti,ab,kw OR 'condom*':ti,ab,kw OR 'balloon occlusion':ti,ab,kw)
#8	Search ('uterus'/de OR 'uterus':ti,ab,kw OR 'intra uterine':ti,ab,kw OR 'intrauterine':ti,ab,kw OR 'uterine':ti,ab,kw) AND ('foley balloon catheter'/exp OR 'foley*':ti,ab,kw)

(continued)

(continued)

Search	Search query
#9	Search ('uterus'/de OR 'uterus':ti,ab,kw OR 'intra uterine':ti,ab,kw OR 'intrauterine':ti,ab,kw OR 'uterine':ti,ab,kw) AND ('b-t cath':dn,ti,ab,kw OR 'bakri':dn,ti,ab,kw OR 'bakri balloon':dn,ti,ab,kw OR 'bakri balloon tamponade':dn,ti,ab,kw OR 'bakri intrauterine balloon':dn,ti,ab,kw OR 'bakri rusch balloon':dn,ti,ab,kw OR 'bakri tamponade':dn,ti,ab,kw OR 'belfort-dildy':dn,ti,ab,kw OR 'belfort-dildy obstetrical tamponade system':dn,ti,ab,kw OR 'bt-cath':dn,ti,ab,kw OR 'condom catheter':dn,ti,ab,kw OR 'ebb':dn,ti,ab,kw OR 'ebb balloon':dn,ti,ab,kw OR 'ebb device':dn,ti,ab,kw OR 'ebbcomplete tamponade system':dn,ti,ab,kw OR 'postpartum balloon':dn,ti,ab,kw OR 'rusch':dn,ti,ab,kw OR 'sengstaken-blakemore tube':dn,ti,ab,kw OR 'sos bakri':dn,ti,ab,kw)
#10	Search ('uterine balloon'/exp OR 'uterine balloon' OR 'intrauterine balloon'/exp OR 'intrauterine balloon' OR 'uterine balloon':ti,ab,kw OR 'intrauterine balloon':ti,ab,kw OR 'intra uterine balloon':ti,ab,kw)
#11	Search (#6 OR #7 OR #8 OR #9 OR #10)
#12	Search (#5 AND #11)

EBM Reviews — Cochrane Database of Systematic Reviews

ID	Search query
#1	Search (uterus or uterine or "intra uterine" or intrauterine or utero*).ti,ab,kw. and (Bakri or balloon* or Belfort Dildy or BT Cath or condom* or ebb or foley* or foley or "el menia" or occlusion or Rusch or Sengstaken Blakemore or tamponade or gauze or sponge* or fluid filled or hydrostatic or packing).tx.
#2	Search ((mother* or maternal) and (death or mortality)).tx.
#3	Search ((postpartum or "post partum") and (hemorrhag* or haemorrhag* or blood or bleed* or shock)).tx.
#4	Search (inertia or atony or dystocia or abruptio placentae or metrorrhagia or solutio placentae or placenta accreta or placenta previa).tx.
#5	Search 1 and (2 or 3 or 4)

LILACS, IBECS, CUMED, BINACIS, MedCarib, BDENF—Nursing, PAHO

Search	Search query
#1	Search (uterus OR uterine OR intrauterine OR "intra uterine") AND (Balloon$ OR Tamponade$ OR bakri OR belfort dildy OR bt cath OR ebb OR "el menia" OR rusch OR sengstaken blakemore OR foley$ OR condom$ OR gauze OR packing OR sponge$ OR dilatation OR dilation OR "fluid filled" OR hydrostatic)

WOS, BCI, BIOSIS, CABI, CCC, DRCI, DIIDW, KJD, MEDLINE, RSCI, SCIELO, ZOOREC

Search	Search query
#1	Search (TS=(uterus NEAR/7 Balloon NEAR/7 Tamponade) OR TS=(uterine NEAR/7 Balloon NEAR/7 Tamponade) OR TS=(intrauterine NEAR/7 Balloon NEAR/7 Tamponade) OR TS=("intra uterine" NEAR/7 Balloon NEAR/7 Tamponade)
#2	Search TS=(uterus NEAR/7 dilatation) OR TS=(uterine NEAR/7 dilatation) OR TS=(intrauterine NEAR/7 dilatation) OR TS=("intra uterine" NEAR/7 dilatation) OR TS=(uterus NEAR/7 dilation) OR TS=(uterine NEAR/7 dilation) OR TS=(intrauterine NEAR/7 dilation) OR TS=("intra uterine" NEAR/7 dilation) OR TS=(uterus NEAR/7 "fluid filled") OR TS=(uterine NEAR/7 "fluid filled") OR TS=(intrauterine NEAR/7 "fluid filled") OR TS=("intra uterine" NEAR/7 "fluid filled") OR TS=(uterus NEAR/7 gauze) OR TS=(uterine NEAR/7 gauze) OR TS=(intrauterine NEAR/7 gauze) OR TS=("intra uterine" NEAR/7 gauze) OR TS=(uterus NEAR/7 hydrostatic) OR TS=(uterine NEAR/7 hydrostatic) OR TS=(intrauterine NEAR/7 hydrostatic) OR TS=("intra uterine" NEAR/7 hydrostatic) OR TS=(uterus NEAR/7 packing) OR TS=(uterine NEAR/7 packing) OR TS=(intrauterine NEAR/7 packing) OR TS=("intra uterine" NEAR/7 packing) OR TS=(uterus NEAR/7 sponge*) OR TS=(uterine NEAR/7 sponge*) OR TS=(intrauterine NEAR/7 sponge*)OR TS=("intra uterine" NEAR/7 sponge*)
#3	Search TS=(uterus NEAR/7 Bakri) OR TS=(uterine NEAR/7 Bakri) OR TS=(intrauterine NEAR/7 Bakri) OR TS=("intra uterine" NEAR/7 Bakri) OR TS=(uterus NEAR/7 "Belfort Dildy") OR TS=(uterine NEAR/7 "Belfort Dildy") OR TS=(intrauterine NEAR/7 "Belfort Dildy") OR TS=("intra uterine" NEAR/7 "Belfort Dildy") OR TS=(uterus NEAR/7 "BT Cath") OR TS=(uterine NEAR/7 "BT Cath") OR TS=(intrauterine NEAR/7 "BT Cath") OR TS=("intra uterine" NEAR/7 "BT Cath") OR TS=(uterus NEAR/7 ebb) OR TS=(uterine NEAR/7 ebb) OR TS=(intrauterine NEAR/7 ebb) OR TS=("intra uterine" NEAR/7 ebb) OR TS=(uterus NEAR/7 "el menia") OR TS=(uterine NEAR/7 "el menia") OR TS=(intrauterine NEAR/7 "el menia") OR TS=("intra uterine" NEAR/7 "el menia") OR TS=(uterus NEAR/7 Rusch) OR TS=(uterine NEAR/7 Rusch) OR TS=(intrauterine NEAR/7 Rusch) OR TS=("intra uterine" NEAR/7 Rusch) OR TS=(uterus NEAR/7 "Sengstaken Blakemore") OR TS=(uterine NEAR/7 "Sengstaken Blakemore") OR TS=(intrauterine NEAR/7 "Sengstaken Blakemore") OR TS=("intra uterine" NEAR/7 "Sengstaken Blakemore") OR TS=(uterus NEAR/7 foley* NEAR/7 catheter*) OR TS=(uterine NEAR/7 foley* NEAR/7 catheter*) OR TS=(intrauterine NEAR/7 foley* NEAR/7 catheter) OR TS=("intra uterine" NEAR/7 foley* NEAR/7 catheter*) OR TS=(uterus NEAR/7 condom* NEAR/7 catheter*) OR TS=(uterine NEAR/7 condom* NEAR/7 catheter*) OR TS=(intrauterine NEAR/7 condom* NEAR/7 catheter*) OR TS=("intra uterine" NEAR/7 condom* NEAR/7 catheter*) OR TS=(uterus NEAR/7 Balloon* NEAR/7 Occlusion) OR TS=(uterine NEAR/7 Balloon* NEAR/7 Occlusion) OR TS=(intrauterine NEAR/7 Balloon* NEAR/7 Occlusion) OR TS=("intra uterine" NEAR/7 Balloon* NEAR/7 Occlusion)
#4	Search TS=("Abruptio Placentae" OR "Surgical Blood Loss" OR "Blood Transfusion*" OR "Maternal Mortality" OR "Maternal Death*" OR Metrorrhagia OR "Placenta Accreta" OR "Placenta Previa" OR shock OR "Uterine Hemorrhage*" OR "Uterine Haemorrhage*" OR "Postpartum Hemorrhage*" OR "post partum hemorrhag*" OR "postpartum haemorrhag*" OR "post partum hemorrhag*" OR " Uterine Inertia" OR "uterine atony" OR "atonic uterus" OR "inert uterus")
#5	Search (#3 OR #2 OR #1)
#6	Search (#5 AND #4)

POPLINE

Search	Search query
#1	Search (bleeding OR hemorrhage OR haemorrhage OR maternal death OR maternal mortality OR atony OR inertia) AND (ubt OR balloon OR tamponade OR bakri)
#2	Search (bleeding OR hemorrhage OR haemorrhage OR Menorrhagia OR maternal death OR maternal mortality OR atony OR inertia) AND (foley OR gauze OR packing OR sponge)

Google Scholar

Search	Search query
#1	Search (site:.org |site:.edu) AND ("uterine balloon" | "el menia balloon" | "uterine tamponade" |"bakri balloon"| "belfort dildy" |"bt cath" |"ebb balloon" |"rusch balloon" | "sengstaken blakemore")
#2	Search (site:.org |site:.edu) AND ("postpartum hemorrhage"|"postpartum haemorrhage"| Menorrhagia "maternal death"|"maternal mortality"| atony) AND ("foley catheter"| gauze|hydrostatic |"fluid filled"|packing)

WHO

Search	Search query
#1	Search (uterus OR uterine) AND (UBT OR balloon OR tamponade OR bakri OR ebb OR rusch OR sengstaken)

PATH

Search	Search query
#1	Search ubt OR tamponade OR balloon OR bakri OR rusch OR sengstaken

National Library of Medicine's Indexcat

Search	Search query
#1	Search (uterus OR uterine)) AND (tamponade OR balloon)
#2	Search (Keyword:(Hæmorrhage (Uterine, Treatment and prevention of) in pregnancy, labor, and puerperal state))

II. Tools Used for Assessing the Risk of Bias

1. Tool for assessing the risk of bias in randomized controlled trials[34]

Random sequence generation

"Low" risk of bias: Investigators described a random component in the sequence generation process, such as random number table, computer random number generator, shuffling of cards or envelopes, drawing of lots, or computerized minimization.

"High" risk of bias: Investigators described a nonrandom component in the sequence generation process, such as odd or even date of birth, based on date or day of admission, based on hospital or clinical record number, or allocated by judgment of the clinician; preference of the participant; availability of the intervention; or results of laboratory tests.

"Unclear" risk of bias: information insufficient to permit judgment of "low risk" or "high risk."

Allocation concealment

"Low" risk of bias: Investigators used an adequate method to conceal allocation, such as central allocation (including telephone or web-based randomization) or sequentially numbered, opaque, sealed envelopes.

"High" risk of bias: Investigators used a nonadequate method to conceal allocation, such as open random allocation schedule (eg, a list of random numbers), assignment envelopes without appropriate safeguards, alternation or rotation, date of birth, or case record number.

"Unclear" risk of bias: information insufficient to permit judgment of "low risk" or "high risk."

Blinding of participants and personnel

"Low" risk of bias: As insertion of uterine balloon tamponade cannot be blinded to healthcare providers and to most participants, we considered adequate blinding of participants and personnel if review authors judged that the outcome was not likely to be influenced by lack of blinding.

"High" risk of bias: the outcome was likely to be influenced by lack of blinding.

"Unclear" risk of bias: information insufficient to permit judgment of "low risk" or "high risk."

Blinding of outcome assessment

"Low" risk of bias: We considered blinding of outcome assessment to be adequate in either of the following: (1) no blinding of outcome assessment, but review authors judged that outcome measurement was not likely to be influenced by lack of blinding; or (2) blinding of outcome assessment ensured, and unlikely that blinding could have been broken.

"High" risk of bias: either of the following: (1) no blinding of outcome assessment, and outcome measurement was likely to be influenced by lack of blinding; or (2) blinding of outcome assessment, but likely that blinding could have been broken, and that outcome measurement was likely to be influenced by lack of blinding.

"Unclear" risk of bias: information insufficient to permit judgment of "low risk" or "high risk."

Incomplete outcome data

"Low" risk of bias: any 1 of the following: (1) no missing outcome data; (2) reasons for missing outcome data unlikely to be related to true outcome; (3) missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; (4) for dichotomous outcome data, proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; (5) for continuous outcome data, plausible effect size among missing outcomes not enough to have a clinically relevant impact on observed effect size; or (6) missing data imputed by appropriate methods.

"High" risk of bias: any 1 of the following: (1) reasons for missing outcome data likely to be related to true outcome, with imbalance in numbers or reasons for missing data across intervention groups; (2) for dichotomous outcome data, proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; (3) for continuous outcome data, plausible effect size among missing outcomes enough to induce clinically relevant bias impact on observed effect size; (4) "as-treated" analysis done with substantial departure of the intervention received from that assigned at randomization; or (5) potentially inappropriate application of simple imputation.

"Unclear" risk of bias: reporting of attrition/exclusions insufficient to permit judgment of "low risk" or "high risk."

Selective reporting

"Low" risk of bias: any 1 of the following: (1) study protocol was available, and all of the study's prespecified outcomes that were of interest in the review were reported in the prespecified way; or (2) the study protocol was not available, but it was clear that published reports included all expected outcomes, including those that were prespecified.

"High" risk of bias: any 1 of the following: (1) not all of the study's prespecified primary outcomes were reported; (2) 1 or more primary outcomes were reported using measurements, analysis methods, or subsets of data that were not prespecified; (3) 1 or more reported primary outcomes were not prespecified; (4) 1 or more outcomes of interest in the review were reported incompletely, so that they could not be entered into a meta-analysis; or (5) the study report failed to include results for a key outcome that would be expected to have been reported for such a study.

"Unclear" risk of bias: information insufficient to permit judgment of "low risk" or "high risk."

Other bias

"Low" risk of bias: Study appeared to be free of other sources of bias.

"High" risk of bias: At least 1 important risk of bias was present. For example, the study (1) had a potential source of bias related to the specific study design used; or (2) has been claimed to have been fraudulent; or (3) had extreme baseline imbalance; or (4) used blocked randomization in unblinded trials; or (5) had differential diagnostic activity; or (6) had some other problem.

"Unclear" risk of bias: information insufficient to assess whether an important risk of bias existed, or rationale or evidence insufficient to suggest that an identified problem will introduce bias.

2. Tool for assessing the risk of bias in nonrandomized studies of interventions (ROBINS-I)[35]

Domain	Explanation
Preintervention	Risk of bias assessment is mainly distinct from assessments of randomized trials
Bias due to confounding	Baseline confounding occurs when 1 or more prognostic variables (factors that predict the outcome of interest) also predicts the intervention received at baseline ROBINS-I can also address time-varying confounding, which occurs when individuals switch between the interventions being compared and when postbaseline prognostic factors affect the intervention received after baseline
Bias in selection of participants into the study	When exclusion of some eligible participants, or the initial follow-up time of some participants, or some outcome events is related to both intervention and outcome, there will be an association between interventions and outcome even if the effects of the interventions are identical This form of selection bias is distinct from confounding: a specific example is bias due to the inclusion of prevalent users, rather than new users, of an intervention
At intervention	Risk of bias assessment is mainly distinct from assessments of randomized trials
Bias in classification of interventions	Bias introduced by either differential or nondifferential misclassification of intervention status Nondifferential misclassification is unrelated to the outcome and will usually bias the estimated effect of intervention towards the null Differential misclassification occurs when misclassification of intervention status is related to the outcome or the risk of the outcome, and is likely to lead to bias
Postintervention	Risk of bias assessment has substantial overlap with assessments of randomized trials
Bias due to deviations from intended interventions	Bias that arises when there are systematic differences between experimental intervention and comparator groups in the care provided, which represent a deviation from the intended intervention(s) Assessment of bias in this domain will depend on the type of effect of interest (either the effect of assignment to intervention or the effect of starting and adhering to intervention).
Bias due to missing data	Bias that arises when later follow-up is missing for individuals initially included and followed (such as differential loss to follow-up that is affected by prognostic factors); bias due to exclusion of individuals with missing information about intervention status or other variables such as confounders
Bias in measurement of outcomes	Bias introduced by either differential or nondifferential errors in measurement of outcome data. Such bias can arise when outcome assessors are aware of intervention status, if different methods are used to assess outcomes in different intervention groups, or if measurement errors are related to intervention status or effects
Bias in selection of the reported result	Selective reporting of results in a way that depends on the findings and prevents the estimate from being included in a meta-analysis (or other synthesis)

Interpretation of domain-level and overall risk of bias judgments in ROBINS-I

Judgment	Within each domain	Across domains	Criterion
"Low" risk of bias	The study is comparable to a well-performed randomized trial with regard to this domain	The study is comparable to a well-performed randomized trial	The study is judged to be at low risk of bias for all domains
"Moderate" risk of bias	The study is sound for a nonrandomized study with regard to this domain but cannot be considered comparable to a well-performed randomized trial	The study provides sound evidence for a nonrandomized study but cannot be considered comparable to a well-performed randomized trial	The study is judged to be at low or moderate risk of bias for all domains
"Serious" risk of bias	The study has some important problems in this domain	The study has some important problems	The study is judged to be at serious risk of bias in at least 1 domain, but not at critical risk of bias in any domain
"Critical" risk of bias	The study is too problematic in this domain to provide any useful evidence on the effects of intervention	The study is too problematic to provide any useful evidence and should not be included in any synthesis	The study is judged to be at critical risk of bias in at least 1 domain
No information	No information on which to base a judgment about risk of bias for this domain	No information on which to base a judgment about risk of bias	There is no clear indication that the study is at serious or critical risk of bias and there is a lack of information in 1 or more key domains of bias (a judgment is required for this)

The following prespecified confounding factors could potentially influence the intervention: primary causes of postpartum hemorrhage, type of delivery, severity of hemorrhage, length of time from onset of hemorrhage to receive either a uterine balloon tamponade or other intervention or no intervention, availability of intensive care unit, and use of surgical and nonsurgical maneuvers to hold the uterine balloon tamponade in place. The following cointerventions were prespecified: use of misoprostol, ergotamine, tranexamic acid, and carbetocin.

3. Tool for assessing the risk of bias in case series studies[36]

Domain	Leading explanatory questions
Selection	Does the patient(s) represent(s) the whole experience of the investigator (center) or is the selection method unclear to the extent that other patients with similar presentation may not have been reported?
Ascertainment	Was the exposure adequately ascertained?
	Was the outcome adequately ascertained?
Causality	Were other alternative causes that may explain the observation ruled out?
	Was follow-up long enough for outcomes to occur?
Reporting	Is the case(s) described with sufficient details to allow other investigators to replicate the research or to allow practitioners make inferences related to their own practice?

"Low" risk of bias: answering "yes" to the explanatory question.

"High" risk of bias: answering "no" to the explanatory question.

"Unclear" risk of bias: insufficient information to answer the explanatory question. If the risk of bias was unclear, the domain was scored as "high" risk of bias.

III. Quality of Evidence

The GRADE approach[39] takes into account 5 domains—risk of bias, inconsistency, indirectness, imprecision, and publication bias—and categorizes the certainty of the evidence into the following 4 levels:

(1) High: We are very confident that the true effect lies close to that of the estimate of the effect, and further research is unlikely to change our confidence in the estimate of the effect.

(2) Moderate: We are moderately confident in the effect estimate, and the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

(3) Low: Our confidence in the effect estimate is limited, and the true effect may be substantially different from the estimate of the effect.

(4) very low: we have very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of effect.

The evidence can be downgraded from "high quality" by 1 level for serious (or by 2 levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates, or potential publication bias.

SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Individually randomized controlled trials						
Soltan,[40] 2007	Egypt	2003–2004	• Inclusion: Women who delivered vaginally either in hospital or at home and were complicated with atonic PPH • Exclusion: Traumatic PPH, retained placental tissues, other cause and after cesarean delivery.	• El-Menia balloon (n = 120) • Control: Uterine massage and uterotonics (n = 120)	No need for surgical operations to control PPH	El-Menia balloon: 100 Control: 84
Khalil,[41] 2011	Saudi Arabia	2004–2009	• Inclusion: Women with severe atonic PPH during emergency CS, following failed attempts at medical treatment • Exclusion: Women who were less than 28 weeks pregnant; traumatic PPH; PP	• Bakri balloon + traction stitch (n = 25) • Bakri balloon (n = 25)	If the bleeding was minimized and if another surgical was not needed to stop the bleeding	Bakri balloon + traction stitch: 96 Bakri balloon: 80
Kavak,[42] 2013	Turkey	2011–2012	• Inclusion: Pregnant women with a preoperative diagnosis of complete PP who had intractable bleeding after delivery • Exclusion: Serious medical, hematological or surgical diseases; placental implantation anomalies; history of thromboembolism; emergency CS; macrosomia; polyhydramnios; preeclampsia; gestational diabetes; intrauterine growth retardation; and presence of multiple gestations.	• Bakri balloon (n = 7) • Endouterine hemostatic square suture (n = 6)	Achievement of complete hemostasis	Bakri balloon: 100 Sutures: 100
Dumont,[43] 2017	Benin, Mali	2013–2015	• Inclusion: Women delivering vaginally who had clinically diagnosed PPH that was suspected to be due to uterine atony, who were resistant to the first-line treatment (oxytocin). • Exclusion: Contraindication to prostaglandins, uterine rupture or placenta accreta.	• Condom UBT + intrarectal or sublingual misoprostol (n = 57) • Control: intrarectal or sublingual misoprostol alone (n = 59)	Women who did not require an invasive surgery (arterial ligatures, uterine compressive sutures, hysterectomy) and who did not die before hospital discharge	Condom UBT: 84 Control: 93

Suarez et al. Uterine balloon tamponade for treating postpartum hemorrhage. Am J Obstet Gynecol 2020. *(continued)*

SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Darwish,[44] 2018	Egypt	2014–2015	• Inclusion: All women who delivered vaginally in the Labor Ward who developed primary atonic PPH and did not respond to the first line of treatment (oxytocin + misoprostol). • Exclusion: CS delivery, traumatic PPH, placental abruption, PP, chorioamnionitis, pregnancy complicated by preeclampsia, diabetes, anemia, rheumatic heart disease or women known to have coagulation defects	• Condom UBT (n = 33) • Bakri balloon (n = 33)	If the bleeding stopped within 15 minutes after proper balloon application without any need for surgical intervention	Condom UBT: 85 Bakri balloon: 91
Ashraf,[45] 2018	Pakistan	Not reported	• Inclusion: PPH after VD with gestational age >37 weeks and did not respond to medical treatment • Exclusion: Previous CS, PPH due to perineal, cervical or vaginal tear, episiotomy, retained placenta, coagulation disorder, secondary PPH	• Condom UBT (n = 106) • Uterovaginal roll gauze packing (n = 106)	If bleeding was stopped within 15 minutes after uterovaginal packing or UBT and patient remained hemodynamically stable, and if no complications occurred after applying or removing balloon tamponade or intrauterine packing.	Condom UBT: 77 Uterovaginal roll gauze packing: 59
Cluster randomized controlled trials						
Anger,[46] 2019	Senegal, Egypt and Uganda	2016-2018	• Inclusion: Secondary-level public hospitals with an approximate weekly average of 160 vaginal deliveries that agreed integrating UBT into standard care. The study population was women with vaginal delivery. The intervention was • Exclusion: Previous CS, PPH due to perineal, cervical or vaginal tear, episiotomy, retained placenta, coagulation disorder, secondary PPH	• Intervention period: training and introduction of UBT into routine practice for refractory PPH. Condom UBT used in 55 women • Control period: use of pre-existing practices for refractory PPH. Condom UBT used in 9 women	Women who did not require an invasive surgery (arterial ligatures, uterine compressive sutures, repair of uterine rupture, hysterectomy) and who did not die before hospital discharge	Condom UBT: 88 Control: not reported

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Nonrandomized studies						
Laas,[47] 2012	France	2005–2010	• Inclusion: Women who gave birth (VD or CS) in the maternity unit of the hospital and developed a PPH due to uterine atony that was unresponsive to sulprostone. • Exclusion: PP, placenta accreta, or uterine rupture.	• Local PPH protocol + Bakri balloon (n = 43) • Control: Local PPH protocol	Arrest of bleeding that did not require further interventions	Bakri balloon: 86
Kaya,[48] 2016	Turkey	2009–2013	• Inclusion: Women who underwent the Bakri balloon and the B-Lynch suture due to uterine atony, and who were unresponsive to medical therapy during CS. • Exclusion: Cases managed with concurrent artery ligation; accidental puncture of Bakri, B-Lynch after unsuccessful balloon	• Bakri balloon (n = 21) • B-Lynch procedure (n = 24)	If vaginal bleeding stopped while in lithotomy position and internal iliac artery ligation was not required	Bakri balloon: 76 B-Lynch: 79
Othman,[49] 2016	Saudi Arabia	2012–2015	• Inclusion: Women with PP and PPH of more than 1000 mL who had uncontrolled bleeding despite the use of oxytocin, carboprost, and figure 8 stitches in the bleeding site of the placental bed • Exclusion: Unreported	• Bakri balloon (n = 13) • Control: PPH management without Bakri balloon (n = 151)	Arrest of bleeding that did not require additional interventions to control the bleeding	Bakri balloon: 100 Control: 78
Lo,[50] 2017	USA	2002–2013	• Inclusion: Women who delivered after gestation week 20 and had PPH refractory to uterotonic agents • Exclusion: Patients with placenta accreta	• Local PPH protocol + Bakri balloon (n = 43) • Control: Local PPH protocol	Arrest of bleeding that did not require hysterectomy or B-Lynch procedures	Bakri balloon: 81
Gauchotte,[51] 2017	France	2008–2013	• Inclusion: Women treated with sulprostone for PPH in the obstetrics unit • Exclusion: Unreported	• Local PPH protocol + Bakri balloon (n = 38) • Control: Local PPH protocol	Arrest of bleeding that did not require surgery or interventional radiology	Bakri balloon: 92

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Tahaoglu,[52] 2017	Turkey	2010-2015	• Inclusion: Women with PPH due to uterine atony when conservative measures failed and were treated via Bakri balloon placement and bilateral IIAL at a tertiary hospital • Exclusion: Women with PPH due to genital tract lacerations, placental retention, uterine rupture, or uterine inversion	• Bakri balloon (n = 14) • Bilateral IIAL (n = 12)	If the bleeding drainage flow was <50 mL/h	Bakri balloon: 71 IIAL: 67 (for placenta previa group)
Maher,[53] 2017	Saudi Arabia	2013–2015	• Inclusion: Women of any age, parity, carrying single or multiple pregnancies and with a gestational age suitable for neonatal care according to protocols, prepared for CS because of low-lying placenta or PP • Exclusion: Uterine and placental implantation anomalies and refusal to participate in study	• Bakri balloon (n = 72) • Control: Non-Bakri balloon PPH protocol (n = 40)	No bleeding within 10 min and no further surgical intervention was required	Bakri balloon: 88 Control: 80
Revert,[54] 2018	France	2011–2012	• Inclusion: Hospitalizations of women of reproductive age (12–55 years) from the ICD-10 code Z37, called "birth outcome" • Exclusion: Women who gave birth outside either network but transferred into the network delivery and women who gave birth within 1 of the networks and then transferred out	• Pilot network that used UBT in standard practice (n = 35,133) • Control: Network that did not use UBT in standard practice (n = 37,396)	The need of arterial embolization or surgery (pelvic vessel ligation or hysterectomy) for hemorrhage control	Not reported
Guo,[55] 2018	China	2010–2015	• Inclusion: Women who delivered via CS with persistent active PPH or bleeding above 500 mL after uterine massage and use of a uterotonic • Exclusion: Unreported	• Bakri balloon (n = 142) • Bakri balloon + vaginal gauze (n = 163)	Arrest of bleeding and did not require uterine artery embolization or hysterectomy	Bakri balloon: 87 Bakri + gauze: 96

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Thabet,[56] 2018	Egypt	2013–2016	• Inclusion: Women who underwent elective CS with PP diagnosed by color flow Doppler or magnetic resonance imaging in the third trimester of pregnancy, and confirmed intraoperatively (during CS) • Exclusion: Multifetal pregnancy, medical conditions complicating pregnancy, blood diseases or bleeding tendencies, or moderate or severe antepartum hemorrhage	• Foley UBT (n = 40) • Control: Treatment for PP without Foley UBT (n = 38)	Arrest of bleeding without requirement of IIAL	Foley UBT: 80 Control: 53
Osmonova,[57] 2018	Kyrgyz Republic	2015–2016	• Inclusion: At-term pregnant women who had single spontaneous vaginal delivery and PPH due to uterine atony ≥500 mL • Exclusion: Abnormal placenta attachment (PP), premature detachment of normally located placenta (accidental hemorrhage), severe preeclampsia, polyhydramnios, multi-fetal gestation, uterine anomalies	• Zhukovsky UBT + standard therapy (n = 35) • Control: Standard therapy (n = 49)	The need for organ-preserving surgical hemostasis: ligation of uterine and ovarian arteries, uterine hemostatic compression sutures and internal iliac artery ligation; and the need for hysterectomy	Zhukovsky UBT + standard therapy: 86 Standard therapy: 37
Dalia,[58] 2018	India	2017	• Inclusion: All women who delivered vaginally and those who developed nontraumatic PPH not responding to medical management • Exclusion: Women with retained placenta, uterine rupture, chorioamnionitis, and known uterine anomaly	• Condom UBT (n = 10) • Condom UBT with tip cut (n = 10) • CG balloon (n = 10)	If bleeding was successfully controlled and no additional intervention was required	Condom UBT: 80 Condom UBT + tip cut: 90 CG balloon: 100
Cetin,[59] 2018	Turkey	2014–2017	• Inclusion: Women diagnosed with uterine atony during their CS who failed to respond to uterotonic agents and who were treated with either a Hayman suture or Bakri balloon tamponade • Exclusion: Unreported	• Bakri balloon (n = 39) • Hayman suture (n = 43)	If bleeding stopped after the balloon was inflated without ligation of the uterine artery	Bakri balloon: 74 Hayman suture: 77

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Mishra,[60] 2019	India	2014–2016	• Inclusion: Women having PPH (defined as loss of >500 mL after vaginal delivery and >1 L after CS and/or deteriorating hemodynamic changes due to bleeding) refractory to first-line management (uterine massage and uterotonics, if atony) or failed attempt at surgical repair in lower genital tract tears • Exclusion: Allergy to latex, retained placenta, uterine rupture, genital infection suspected (rupture of membranes for >18 h), genital anomaly or malignancy	• Condom UBT (n = 14) • Chhattisgarh condom balloon device (n = 46)	Successful tamponade after balloon insertion	Condom balloon: 100 Chhattisgarh condom: balloon 98
El Gelany,[61] 2019	Egypt	2012–2017	• Inclusion: Women with previous CS and PP with suspect morbidly adherent placenta who underwent elective CS between 35 and 38 weeks and who were keen to preserve their fertility; cases were only included if partial separation occurred at CS, resulting in major bleeding • Exclusion: Women with previous CS with PP/accreta and women who had preoperative diagnosis of placenta percreta who opted to have an elective hysterectomy or in whom placenta percreta was confirmed intraoperatively	• Bakri balloon (n = 42) • Bakri balloon + bilateral uterine artery ligations (n = 40) • Bilateral uterine artery ligations + cervical tamponade using 2 or 3 simple interrupted stitches (n = 43)	If the procedure controlled the bleeding at the placental bed and there was no need for hysterectomy	Bakri balloon: 69 Bakri balloon + bilateral uterine artery ligations: 72 Bilateral uterine artery ligations + cervical tamponade: 90
Case series						
Condous,[62] 2003	United Kingdom Singapore	Not reported	• Inclusion: Women with intractable PPH who were managed by the tamponade test when they were unresponsive to oxytocic agents and prostaglandin analogues • Exclusion: Unreported	Sengstaken–Blakemore (n = 16)	If no or minimal bleeding is observed via the cervix or through the gastric lumen of the catheter and surgical intervention avoided	88

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Akhter,[63] 2003	Bangladesh	2001–2002	• Inclusion: Women with PPH that occurred as a result of atonicity or morbid adhesion (accreta) that could not be controlled by uterotonics or a surgical procedure • Exclusion: Unreported	Condom UBT (n = 23)	Arrest of bleeding	100
Seror,[64] 2005	France	1999–2003	• Inclusion: Women with PPH who underwent treatment by UBT with a Sengstaken–Blakemore tube after failure of conventional medical treatment • Exclusion: Unreported	Sengstaken–Blakemore (n = 17)	If the bleeding stopped with no need for additional interventions	71
Keriakos,[65] 2006	United Kingdom	2001–2004	• Inclusion: All women with PPH who had undergone initial medical management but failed to control the bleeding • Exclusion: Traumatic PPH	Rusch balloon (n = 8)	If hemorrhage stopped after placement of the device	88
Dabelea,[66] 2007	USA	2003–2005	• Inclusion: Women with PPH unresponsive to medical therapy as part of a management protocol for PPH • Exclusion: Unreported	• Bakri balloon (n = 15) • Sengstaken–Blakemore (n = 5)	If bleeding stopped with balloon inflation without the need for additional procedures	Bakri balloon: 87 Sengstaken–Blakemore: 100
Airede,[67] 2008	Nigeria	2004–2006	• Inclusion: Persistent PPH despite massage of the uterus, emptying of uterus, emptying of the bladder, and repeated doses of intravenous ergometrine and oxytocin infusion • Exclusion: Uterine rupture and genital tract laceration	Condom UBT (n = 4)	If hemorrhage ceased after 30 minutes of placement (by direct observation of cervix)	100
Doumouchtsis,[68] 2008	United Kingdom	2002–2006	• Inclusion: Women of at least 20 weeks' gestation with ongoing PPH • Exclusion: Traumatic PPH or retained products	Sengstaken–Blakemore (n = 27)	If no or minimal bleeding is observed via the cervix or through the gastric lumen of the catheter and further intervention avoided	81

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Nicolas,[69] 2009	United Kingdom	2003–2006	• Inclusion: Women with massive primary PPH who had a balloon placed after failure of routine procedures including AMTSL and administration of at least 2 ecobolic drugs • Exclusion: Unreported	Sengstaken–Blakemore (n = 7)	Cessation of bleeding and avoidance of further medical or surgical interventions	86
Vitthala,[70] 2009	United Kingdom	2002–2006	• Inclusion: Women with PPH who underwent Bakri balloon insertion after unsuccessful medical management of PPH • Exclusion: Traumatic PPH requiring surgery	Bakri balloon (n = 15)	If bleeding is stopped after the balloon was inflated and if another surgical procedure was not needed to stop bleeding	80
Majumdar,[71] 2010	United Kingdom	2008	• Inclusion: All women with PPH who had failed medical therapy and in whom the Rusch balloon was used • Exclusion: Unreported	Rusch balloon (n = 18)	Patients that required no further interventions after balloon tamponade	72
Rather,[72] 2010	India	Not reported	• Inclusion: Women who did not respond to conventional medical management to restore the tone of uterus • Exclusion: Traumatic PPH	Condom UBT (n = 26)	If bleeding stopped within 10 minutes of tamponade and did not require any further intervention	96
Rodó Rodriguez,[73] 2010	Spain	2006	• Inclusion: Women with immediate PPH and persistent bleeding from the uterus despite the realization of uterine massage and the administration of uterine drugs • Exclusion: Unreported	Bakri balloon (n = 5)	If mechanical hemostasis was obtained	100
Thapa,[74] 2010	Nepal	2008–2010	• Inclusion: Women with PPH of more than 500 mL or who continued to bleed despite use of pharmacologic measures for at least 30 minutes • Exclusion: Unreported	Condom UBT (n = 10)	If bleeding stopped within 30 minutes of tamponade application and surgical intervention was not sought	100
Yaqub,[75] 2010	Pakistan	2009–2010	• Inclusion: Women who developed PPH after delivering in the hospital • Exclusion: Massive PPH	Foley UBT (n = 40)	If UBT arrested the bleeding and no uterine packing or surgical procedure were necessary	78

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Albayrak,[76] 2011	Turkey	2005–2010	• Inclusion: All women who delivered via CS with PPH from the lower uterine segment secondary to placenta previa/accreta where standard conservative measures failed to control bleeding • Exclusion: PPH from uterine atony and genital laceration	Foley UBT (n = 15)	If intraoperative hemostasis was achieved after balloon placement	100
Varatharajan,[77] 2011	United Kingdom	2008	• Inclusion: All women who experienced massive primary PPH (total blood loss >1500 mL) • Exclusion: Unreported	Unknown (n = 13)	If bleeding was arrested and no further surgical procedure was performed	77
Keriakos,[78] 2012	United Kingdom	2005–2009	• Inclusion: Women with major PPH who had undergone initial medical management, but failed to control the bleeding, and who underwent insertion of Rusch balloon catheter • Exclusion: Traumatic PPH or latex allergy	Rusch Balloon (n = 31)	If bleeding stopped without requiring other surgical interventions, such as B-Lynch and hysterectomy	84
Ishii,[79] 2012	Japan	2007–2009	• Inclusion: Women who underwent CS due to PP/low-lying placenta with PPH resistant to medical therapy • Exclusion: Unreported	Sengstaken–Blakemore (n = 10)	If hemostasis was achieved and no additional procedure was performed	100
Diemert,[80] 2012	Germany	2005–2010	• Inclusion: Women diagnosed to have a severe PPH and unsuccessful medical treatment with uterotonic agents • Exclusion: Unreported	Bakri balloon (n = 20)	If the bleeding stopped within 15 minutes after the balloon was inflated and B-Lynch and hysterectomy were prevented	60
Rathore,[81] 2012	India	2009–2011	• Inclusion: Women with PPH after failure of medical management, defined as failure to control bleeding in spite of maximum dosage of uterotonic drugs or hemodynamic instability that required surgical intervention • Exclusion: Trauma or retained tissue	Condom UBT (n = 18)	Control of hemorrhage within 15 minutes of balloon placement	96

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(continued)

SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Aibar,[82] 2013	Spain	2010–2011	• Inclusion: Women who were treated with a Bakri balloon if they had PPH that did not respond to standard management consisting of uterine massage, volume replacement, and uterotonic medical treatment • Exclusion: Unreported	Bakri balloon (n = 24)	Control of PPH not requiring any further nonpharmacological intervention	88
Rodriguez-Kovacs,[83] 2013	Venezuela	Not reported	• Inclusion: Women who presented vaginal PPH due to uterine atony refractory to medical management after a pregnancy equal to or greater than 28 weeks • Exclusion: Retained tissue, uterine inversion, uterine rupture, uterine scars, uterine malformations, lower genital tract lacerations, placenta accreta, cervical cancer, purulent discharge through the cervix or vagina, and secondary PPH secondary to abdominal trauma	Bakri balloon (n = 15)	If there was minimal bleeding (100 cm^3 or less) through the cervix or the lumen of the balloon within 5 minutes of placement	100
Olsen,[84] 2013	USA	2008–2010	• Inclusion: All women diagnosed with PPH at our 2 facilities who failed treatment with uterotonic agents (American College of Obstetricians and Gynecologists guidelines), and who received a Bakri balloon if bleeding persisted	Bakri balloon (n = 37)	Arrest of hemorrhage without needing to proceed with another form of hemorrhage control	68
Florian,[85] 2013	French Guiana	2008–2011	• Inclusion: Persistence of PPH despite medical treatment with sulprestone and implementation of the hospital protocol • Exclusion: Unreported	Linton–Nachlas balloon (n = 25)	If bleeding stopped, with or without confirmation of balloon positioning by transabdominal ultrasonography	96
Grönvall,[86] 2013	Finland	2008 –2011	• Inclusion: Women who had bleeding >1000 mL before insertion of a Bakri balloon and women with expected high risk of PPH but bleeding <1000 mL before insertion of a Bakri balloon • Exclusion: Unreported	Bakri balloon (n = 50)	If hemostasis was achieved and other procedures were not needed	86

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Chan,[87] 2013	Hong Kong	2006–2011	• Inclusion: Women with a gestational age of at least 24 weeks and massive primary PPH • Exclusion: Unreported	Sengstaken–Blakemore (n = 12)	No requirement for rescue hysterectomy	75
Vrachnis,[88] 2013	Greece	2008–2011	• Inclusion: Women diagnosed with PPH who underwent Bakri balloon tamponade • Exclusion: Unreported	Bakri balloon (n = 18)	If balloon placement arrested the bleeding.	94
Kumru,[89] 2013	Turkey	2009–2012	• Inclusion: Women diagnosed to have severe PPH with PP and failed medical treatment with uterotonic agents who were treated with the Bakri balloon • Exclusion: Unreported	Bakri balloon (n = 25)	If the bleeding was stopped and additional surgical procedures were not needed	88
Kong,[90] 2013	Hong Kong	2011–2012	• Inclusion: Women with severe PPH following delivery who underwent UBT placement • Exclusion: Unreported	Bakri balloon (n = 19)	If bleeding was arrested and hysterectomy prevented with UBT as the only procedure	79
Yan,[91] 2014	China	2008–2009	• Inclusion: Women who experienced primary PPH unresponsive to first-line therapies including uterine massage, administration of uterotonics, and treatment of the presumed cause • Exclusion: Unreported	Self-made balloon (n = 4)	Control of PPH without need for additional management or hysterectomy	75
Ferrazzani,[92] 2014	Italy	2002–2012	• Inclusion: PPH after failure of medical treatment • Exclusion: Traumatic PPH	Rusch balloon (n = 52)	If the "tamponade test" stopped bleeding and other surgical measures were not necessary	75
Dildy,[93] 2014	USA	2010–2012	• Inclusion: Women with a diagnosis of PPH who had the "ebb" device placed • Exclusion: Unreported	Belfort–Dildy ("ebb") Complete Tamponade System (n = 51)	Arrest of bleeding without other surgical interventions	78

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Kaya,[94] 2014	Turkey	2011–2013	• Inclusion: Women who bled more than 1000 mL and unresponsive to standard medical management (including oxytocin) • Exclusion: Traumatic PPH requiring surgery, hemodynamic instability at the time of Bakri balloon insertion, and hereditary coagulation disorders	Bakri balloon (n = 45)	If bleeding stopped within 15 minutes of the balloon's inflation by observing the amount of hemorrhage drained through the catheter, and no further procedure was performed	76
Kavak,[95] 2014	Turkey	2012–2013	• Inclusion: Women who underwent VD with bleeding from cervix and upper parts of vagina and women who underwent CS due to PP and showed intractable bleeding from lower segments of uterus • Exclusion: Unreported	Double-balloon cervical ripening catheter (n = 7)	If bleeding was successfully controlled intraoperatively	100
Uygur,[96] 2014	Turkey	2011–2013	• Inclusion: Women treated with a BT-Cath after unsuccessful medical treatment of PPH due to PP, confirmed by transvaginal ultrasound examination on admission • Exclusion: Unreported	BT Cath (n = 53)	If bleeding ceased and no further surgical procedures were performed to treat PPH or to treat complications from UBT insertion (perforation)	85
Vintejoux,[97] 2015	France	2010–2011	• Inclusion: Women with primary PPH who received the Bakri balloon secondary to uterine atony and subsequent routine drug treatment were identified • Exclusion: Unreported	Bakri balloon (n = 36)	No bleeding within 5–10 minutes and no further surgical interventions were necessary	69
Vargas-Aguilar,[98] 2015	Mexico	2009–2011	• Inclusion: Pregnant women with obstetric hemorrhage that did not stop with uterotonics • Exclusion: Unreported	Bakri balloon (n = 19)	Arrest of bleeding after placement of the Bakri balloon and no further surgical interventions were necessary (hysterectomy)	95

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Martin,[99] 2015	France	2011–2012	• Inclusion: All women who underwent balloon tamponade treatment for persistent primary PPH and if conservative steps had failed • Exclusion: Unreported	Bakri balloon (n = 49)	Arrest of the hemorrhage after balloon tamponade, with no subsequent invasive procedures	65
Cekmez,[100] 2015	Turkey	2010–2013	• Inclusion: Women with PPH due to uterine atony and managed with medical treatment who were subsequently treated with various interventions • Exclusion: Unreported	Bakri balloon (n = 10)	If bleeding stopped and no additional interventions were required	60
Alkis,[101] 2015	Turkey	2011–2013	• Inclusion: Women in whom standard medical treatment failed to stop the PPH and who were managed with intrauterine Bakri balloon tamponade • Exclusion: Women with bleeding due to lacerations in which surgery was needed	Bakri balloon (n = 47)	If the bleeding stopped after the balloon was inflated, and no other surgical intervention was needed	91
Alouini,[102] 2015	France	2009–2013	• Inclusion: Bakri balloon was placed after VD or CS when hemorrhage did not have an identifiable uterine or vascular wound • Exclusion: Unreported	Bakri balloon (n = 61)	If bleeding stopped and no additional surgical interventions were required	90
Cho,[103] 2015	Korea	2009–2014	• Inclusion: Women who underwent elective CS due to PP or low-lying placenta and who underwent Bakri balloon catheter placement for uncontrolled PPH of more than 1000 mL • Exclusion: Chorioamnionitis, retained placenta, trauma of cervix and vagina, inherited coagulopathy and DIC.	Bakri balloon (n = 64)	Arrest of PPH after proper placement and inflation of the balloon catheter, without the need for additional treatments	75
Açar Eser,[104] 2015	Turkey	2009–2014	• Inclusion: Women who gave birth and had been treated for PPH • Exclusion: Unreported	Bakri balloon (n = 12)	Restoring hemostasis without recourse to hysterectomy	100

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Lohano,[105] 2016	Pakistan	2012	• Inclusion: Women aged 18–35 years, parity 1–6, and gestational age 31-41 weeks who developed or were admitted with primary PPH due to uterine atony in whom medical treatment had failed • Exclusion: PPH due to retained products and genital tract trauma	Condom UBT (n = 139)	Ability of the balloon tamponade to arrest bleeding after 24 hours	91
Kandeel,[106] 2016	Egypt	2011–2012	• Inclusion: Women with primary PPH when standard measures failed • Exclusion: Traumatic PPH, retained placenta, coagulopathy, and severe systemic diseases	Condom UBT (n = 50)	Arrest of bleeding after the balloon catheter was properly inflated for 15 minutes, without the need for additional procedures	96
Nagai,[107] 2016	Japan	2013	• Inclusion: Women with massive PPH who were treated with Bakri balloon tamponade • Exclusion: Unreported	Bakri balloon (n = 10)	If hemostasis was achieved without any additional surgical interventions	90
Ahmad,[108] 2016	India	2013–2014	• Inclusion: All women who delivered vaginally or by CS and developed nontraumatic PPH that did not respond to medical management • Exclusion: Traumatic PPH or retained tissue in uterus	Condom UBT (n = 33)	If hemorrhage was successfully controlled after UBT removal, 12–24 hours after insertion, and no hysterectomy was performed	94
Aderoba,[109] 2017	Nigeria	2012–2014	• Inclusion: Women with a singleton pregnancy who delivered at the obstetric unit and had PPH that was not amenable to first-line therapy • Exclusion: Genital tract lacerations, chorioamnionitis, haemoglobinopathies, Hb <11 g/L, and suspicion of uterine rupture	Condom UBT (n = 229)	Cessation of significant bleeding, improved hemodynamic status, and no need for additional intervention	89
Hasabe,[110] 2016	India	2013–2015	• Inclusion: Women who developed intractable PPH in the hospital and did not respond to the conventional medical management • Exclusion: Traumatic PPH	Condom UBT (n = 36)	If blood loss was <50 mL and did not require further intervention	94

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Brown,[111] 2016	Kenya	2013–2015	• Inclusion: Women with PPH unresponsive to standard intervention • Exclusion: age <18 years; arterial bleeding requiring surgical exploration or angiographic embolization; immediate need for hysterectomy; ongoing pregnancy; cervical cancer; infections; uterine anomaly; active DIC; a surgical site that would prevent the Bakri tamponade balloon from effectively controlling bleeding; referral for obstructed labor; and ruptured uterus	Bakri balloon (n = 58)	If UBT controlled the bleeding without further surgical intervention	95
Kwon,[112] 2016	Korea	2010–2015	• Inclusion: Women with massive PPH (>1500 mL after delivery) who failed conservative management with uterotonic agents and were subsequently treated with UBT • Exclusion: Women with bleeding who need surgical procedure after VD due to lower genital tract lacerations	Bakri balloon (n = 57)	If bleeding from drainage catheter arrested or was <100 mL during 10 minutes and no further intervention was needed	82
Sandoval García-Travesí,[113] 2016	Mexico	2015	• Inclusion: Women with PPH due to uterine atony who did not respond to uterine massage or uterotonic drugs after 10–15 minutes • Exclusion: Traumatic PPH, chorioamnionitis, women with a known latex allergy	Condom UBT (n = 40)	If the bleeding stopped, the patient remained hemodynamically stable, and there was no need for surgical intervention	95
Kadioglu,[114] 2016	Turkey	2013–2016	• Inclusion: Women who developed massive PPH following a VD or CS in whom medical treatment had failed • Exclusion: PPH due to uterine and cervical trauma or retained placental tissue	Bakri balloon (n = 50)	If hemostasis was obtained and no further procedure was performed	84
Revert,[115] 2017	France	2010–2013	• Inclusion: Women treated by UBT as an initial second-line treatment for severe PPH unresponsive to prostaglandins • Exclusion: Unreported	• Bakri balloon (n = 198) • Belfort–Dildy ("ebb") Complete Tamponade System (n = 28)	No bleeding through either the cervix or the balloon drainage channel after 15 minutes	Bakri balloon: 83 Ebb tamponade system: 82

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(continued)

SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Son,[116] 2017	USA	2007–2014	• Inclusion: All adult women who underwent placement of an intrauterine balloon after delivery, due to uterine atony, placental site/bed bleeding, or abnormal placentation • Exclusion: If catheter placement was unsuccessful due to the inability of the operator to either insert or inflate it	Bakri balloon (n = 306)	Arrest of bleeding that did not require UAE or hysterectomy	78
Parpillewar,[117] 2017	India	2015	• Inclusion: Women with atonic PPH who delivered vaginally after 28 weeks of gestation and who failed to respond to routine medical methods of management • Exclusion: Women who delivered by CS, traumatic PPH, PPH due to coagulation defects, and women with secondary PPH	Condom UBT (n = 23)	Control of bleeding without further intervention	78
Wang,[118] 2018	China	2015	• Inclusion: Women with live deliveries after 28 weeks of gestation with PPH who failed to respond to the first-line conservative management and underwent placement with the Bakri balloon • Exclusion: Women who received the Bakri balloon, but who did not reach the criteria for PPH	Bakri balloon (n = 407)	If PPH was stopped and no further surgical interventions were necessary	92
Ogoyama,[119] 2017	Japan	2013–2016	• Inclusion: All women with PPH when genital tract laceration sutures, uterotonic agents, uterine massage, or bimanual uterine compression failed to achieve hemostasis • Exclusion: Intra-abdominal bleeding, uterine rupture, suspected amniotic fluid embolism, or severe bleeding where hysterectomy or transarterial embolization was considered better to be immediately employed without Balloon application	Bakri balloon (n = 77)	Achieving hemostasis with no requirement of additional invasive procedures	93

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Burke,[120] 2017	Kenya, Senegal, Sierra Leone, Tanzania	2012–2016	• Inclusion: All women with uncontrolled PPH originating from an atonic uterus who had an ESM-UBT device placed • Exclusion: Traumatic PPH, uterine rupture, or DIC due to sepsis	ESM-UBT (n = 306)	If no additional interventions were required to control bleeding	92
De la Luna y Olsen,[121] 2017	Mexico	2016	• Inclusion: All women in inpatient medical care units with a PPH unresponsive to medical treatment • Exclusion: Unreported	Bakri balloon (n = 20)	If bleeding was <150–200 mL and hypovolemic signs disappeared within 24 hours	95
Yorifuji,[122] 2018	Japan	2009–2014	• Inclusion: Cases of persistent massive hemorrhage (>1000 mL) despite conventional treatments such as bimanual uterine compression and administration of uterotonic agents • Exclusion: Unreported	Metreurynters balloon (n = 66)	The rate of hemostasis after UBT placement.	94
Grange,[123] 2018	France	2011–2015	• Inclusion: Women with persistent PPH after failure of bimanual uterine massage and uterotonics to stop bleeding after vaginal delivery • Exclusion: UBT placement after cesarean delivery	Bakri balloon (n = 108)	If no additional interventions were required to stop bleeding (such as pelvic arterial embolization, vessel ligation, uterine compression, or peripartum hysterectomy)	74
Mathur,[124] 2018	Singapore	2013–2015	• Inclusion: All women who had a Bakri inserted for the management of PPH • Exclusion: Unreported	Bakri balloon (n = 49)	Achievement of definitive hemostasis without the need of hysterectomy	82
Kong,[125] 2018	Hong Kong	2011–2016	• Inclusion: All women with severe PPH (blood loss ≥1000 mL) and had UBT inserted to arrest bleeding • Exclusion: Unreported	Bakri balloon (n = 39)	If UBT arrested bleeding and no further procedures were necessary	75

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SUPPLEMENTARY TABLE 1
Characteristics of studies included in the review *(continued)*

First author, year	Country	Study period	Inclusion and exclusion criteria	Intervention(s) (sample size)	Definition of intervention success	Intervention success rate (%)
Pala,[126] 2018	Turkey	2012–2016	• Inclusion: Women who were diagnosed with placenta accreta or increta preoperatively and intraoperatively and treated with Bakri balloon tamponade or cesarean hysterectomy • Exclusion: Unreported	Bakri balloon (n = 19)	<100 mL of blood from drainage catheter during first 10 minutes after placement of UBT	84
Santhanam,[127] 2018	India	2015–2016	• Inclusion: Women who developed intractable atonic PPH not responsive to conventional medical management (uterotonics) following VD/CS • Exclusion: Obstetric hemorrhage <28 weeks of gestation; traumatic PPH; allergic to latex; acute uterine infection	Condom UBT (n = 69)	Uterine bleeding that stopped or decreased within 30 minutes of balloon inflation that did not require additional procedures	97
Tahir,[128] 2018	Pakistan	2016–2017	• Inclusion: All women who underwent a CS who developed PPH and were treated with UBT • Exclusion: Unreported	Foley UBT (n = 26)	Arrest of bleeding without requiring hysterectomy	96
Kong,[129] 2018	Hong Kong	2012–2017	• Inclusion: Women who had had UBT attempted as the initial second-line procedure after failed medical treatment • Exclusion: Unreported	Bakri balloon (n = 81)	Bleeding that was effectively controlled shortly after inflation of the balloon and no further intervention was required	73
Theron,[130] 2018	South Africa	2016–2017	• Inclusion: All women with PPH where emergency measures were applied, and medical treatment failed • Exclusion: Unreported	Ellavi UBT (n = 17)	If no additional interventions were needed to arrest hemorrhage	82

AMTSL, active management of the third stage of labor; *CS*, cesarean section; *DIC*, disseminated intravascular coagulopathy; *IIAL*, internal iliac artery ligation; *PP*, placenta previa; *PPH*, postpartum hemorrhage; *UAE*, uterine artery embolization; *UBT*, uterine balloon tamponade; *VD*, vaginal delivery.

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SUPPLEMENTARY TABLE 2
Risk of bias in included randomized controlled trials

First author, year	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Soltan,[40] 2007	Low	Low	High	Low	Unclear	Unclear	Unclear
Khalil,[41] 2011	Low	Unclear	Low/high[a]	Low	Unclear	Unclear	High
Kavak,[42] 2013	Unclear	Unclear	Low/high[a]	Low	Low	Low	Unclear
Dumont,[43] 2017	Low	Low	High	Low	Low	Low	High
Darwish,[44] 2018	Low	Low	Low/high[a]	Low	Low	Low	Low
Ashraf,[45] 2018	Low	Unclear	Unclear/high[b]	Low	Unclear	Unclear	Unclear

[a] Participants blinded; personnel unblinded; [b] Insufficient information on blinding of participants; personnel unblinded.
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SUPPLEMENTARY TABLE 3
Risk of bias in included nonrandomized studies

Study	Confounding	Selection of participants	Classification of interventions	Deviations from intended interventions	Missing data	Measurement of outcomes	Selection of the reported result	Overall
Laas,[47] 2012	Critical	Low	Low	Serious	Low	Low	Moderate	Critical
Kaya,[48] 2016	Critical	Serious	Low	Low	Low	Low	Moderate	Critical
Othman,[49] 2016	Critical	Serious	Serious	Low	Low	Low	No information	Critical
Lo,[50] 2017	Critical	No information	Serious	No information	Low	Low	Moderate	Critical
Gauchotte,[51] 2017	Critical	Low	Low	Serious	Low	Low	Moderate	Critical
Tahaoglu,[52] 2017	Critical	Low	Low	Low	Low	Low	Serious	Critical
Maher,[53] 2017	Serious	Low	Low	Low	Low	Low	Moderate	Serious
Revert,[54] 2018	Moderate	Low	Low	Low	Low	Low	Low	Moderate
Guo,[55] 2018	Critical	Low	Serious	Low	Low	Low	Moderate	Critical
Thabet,[56] 2018	Serious	Low	Low	No information	Low	Low	Moderate	Serious
Osmonova,[57] 2018	Critical	Low	No information	No information	Low	Low	Moderate	Critical
Dalia,[58] 2018	Critical	Low	Low	No information	Low	Low	Moderate	Critical
Cetin,[59] 2018	Critical	Serious	Low	Low	Low	Low	Moderate	Critical
Mishra,[60] 2019	Critical	Low	Serious	No information	Low	Low	Moderate	Critical
El Gelany,[61] 2019	Critical	Low	Serious	Low	Low	Low	Low	Critical

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SUPPLEMENTARY TABLE 4
Risk of bias in included case series

Study (first author, year)	Selection	Ascertainment		Causality		Reporting
		Ascertainment of exposure	Ascertainment of outcome	Rule out of alternative causes	Follow-up	Description of cases
Condous,[62] 2003	High	Low	Low	Low	Low	Low
Akhter,[63] 2003	High	Low	Low	High	Low	High
Seror,[64] 2005	Low	Low	Low	Low	Low	Low
Keriakos,[65] 2006	High	Low	High	Low	Low	High
Dabelea,[66] 2007	Low	Low	Low	Low	Low	Low
Airede,[67] 2008	High	Low	Low	Low	Low	Low
Doumouchtsis,[68] 2008	Low	Low	Low	Low	Low	Low
Nicolas,[69] 2009	Low	Low	Low	High	Low	High
Vitthala,[70] 2009	High	Low	Low	Low	Low	Low
Majumdar,[71] 2010	High	Low	High	High	Low	High
Rather,[72] 2010	High	High	Low	High	Low	High
Rodó Rodriguez,[73] 2010	Low	High	High	High	Low	High
Thapa,[74] 2010	Low	Low	Low	High	Low	Low
Yaqub,[75] 2010	High	High	High	Low	Low	High
Albayrak,[76] 2011	Low	Low	Low	Low	Low	Low
Varatharajan,[77] 2011	Low	High	Low	High	Low	High
Keriakos,[78] 2012	High	High	High	High	Low	High
Ishii,[79] 2012	Low	Low	Low	Low	Low	Low
Diemert,[80] 2012	Low	Low	Low	High	Low	Low
Rathore,[81] 2012	Low	Low	Low	High	Low	Low
Aibar,[82] 2013	High	High	Low	High	Low	High
Rodriguez-Kovacs,[83] 2013	High	Low	Low	Low	Low	Low
Olsen,[84] 2013	High	Low	Low	Low	Low	Low
Florian,[85] 2013	Low	Low	Low	Low	Low	Low
Grönvall,[86] 2013	High	Low	Low	Low	Low	High
Chan,[87] 2013	Low	High	High	High	Low	High
Vrachnis,[88] 2013	High	Low	High	Low	Low	High
Kumru,[89] 2013	High	Low	Low	Low	Low	High

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SUPPLEMENTARY TABLE 4
Risk of bias in included case series *(continued)*

Study (first author, year)	Selection	Ascertainment		Causality		Reporting
		Ascertainment of exposure	Ascertainment of outcome	Rule out of alternative causes	Follow-up	Description of cases
Kong,[90] 2013	High	Low	Low	High	Low	High
Yan,[91] 2014	High	High	Low	Low	Low	High
Ferrazzani,[92] 2014	High	Low	Low	Low	Low	Low
Dildy,[93] 2014	High	High	High	High	Low	High
Kaya,[94] 2014	Low	Low	Low	Low	Low	Low
Kavak,[95] 2014	High	Low	Low	Low	Low	Low
Uygur,[96] 2014	Low	Low	Low	Low	Low	Low
Vintejoux,[97] 2015	Low	Low	Low	Low	Low	Low
Vargas-Aguilar,[98] 2015	High	High	Low	Low	Low	High
Martin,[99] 2015	Low	High	Low	Low	Low	High
Cekmez,[100] 2015	Low	High	High	High	Low	High
Alkis,[101] 2015	High	Low	Low	Low	Low	Low
Alouini,[102] 2015	Low	High	Low	Low	Low	High
Cho,[103] 2015	Low	Low	Low	Low	Low	Low
Açar Eser,[104] 2015	High	High	High	High	Low	High
Lohano,[105] 2016	High	High	Low	Low	Low	High
Kandeel,[106] 2016	Low	Low	Low	Low	Low	Low
Nagai,[107] 2016	High	High	Low	High	Low	High
Ahmad,[108] 2016	High	Low	Low	Low	Low	High
Aderoba,[109] 2016	Low	Low	Low	Low	Low	Low
Hasabe,[110] 2016	Low	Low	Low	High	Low	High
Brown,[111] 2016	High	Low	Low	Low	Low	Low
Kwon,[112] 2016	High	Low	Low	Low	Low	Low
Sandoval García-Travesí,[113] 2016	Low	Low	Low	High	Low	Low
Kadioglu,[114] 2016	High	Low	High	Low	Low	Low
Revert,[115] 2017	Low	Low	Low	Low	Low	Low
Son,[116] 2017	High	High	Low	High	Low	High
Parpillewar,[117] 2017	High	Low	Low	Low	Low	High

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(continued)

SUPPLEMENTARY TABLE 4
Risk of bias in included case series *(continued)*

Study (first author, year)	Selection	Ascertainment		Causality		Reporting
		Ascertainment of exposure	Ascertainment of outcome	Rule out of alternative causes	Follow-up	Description of cases
Wang,[118] 2018	Low	Low	Low	Low	Low	Low
Ogoyama,[119] 2017	Low	Low	Low	Low	Low	Low
Burke,[120] 2017	High	Low	High	Low	Low	High
De la Luna y Olsen,[121] 2017	High	Low	Low	High	Low	Low
Yorifuji,[122] 2018	High	Low	High	Low	Low	High
Grange,[123] 2018	Low	Low	Low	Low	Low	High
Mathur,[124] 2018	High	Low	Low	Low	Low	High
Kong,[125] 2018	Low	Low	Low	Low	Low	Low
Pala,[126] 2018	High	Low	Low	Low	Low	Low
Santhanam,[127] 2018	Low	Low	Low	Low	Low	Low
Tahir,[128] 2018	High	High	Low	Low	Low	High
Kong,[129] 2018	Low	Low	Low	Low	Low	Low
Theron,[130] 2018	High	High	High	Low	Low	High

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SUPPLEMENTARY TABLE 5

Sensitivity analysis of success rate for uterine balloon tamponade according to study design and cause of postpartum hemorrhage, including data from abstracts of studies published only in abstract form or abstracts of unobtainable articles[a]

Cause of postpartum hemorrhage	Randomized controlled trials			Nonrandomized studies			Case series			Overall		
	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)
Uterine atony	4[40,41,43,44]	268	90.2 (74.1–98.9)	8[47–50,52,55,58,59]	301	84.5 (79.9–88.6)	47	2066	87.5 (84.4–90.4)	57	2549	87.5 (84.6–90.1)
Placenta previa	1[42]	7	100.0 (56.1–100)	5[49,52,53,55,61]	165	89.3 (73.8–98.4)	34	533	86.0 (81.6–89.9)	40	705	87.0 (82.7–90.8)
Placenta accreta spectrum	-	-	-	3[53,55,56]	74	75.1 (32.9–99.3)	11	75	63.0 (48.1–76.7)	14	149	65.6 (49.1–80.4)
Retained placenta	-	-	-	-	-	-	13	82	76.8 (65.3–86.5)	13	82	76.8 (65.3–86.5)
Undifferentiated	2[45,46]	170	81.8 (71.2–90.4)	3[51,55,60]	120	82.1 (46.6–99.7)	75	2736	84.1 (81.2–86.8)	79	2988	83.7 (80.9–86.6)
Total[b]	7[40–46]	445	88.8 (77.7–96.4)	14[47–61]	660	85.2 (80.5–89.4)	108	5508	85.6 (83.7–87.5)	126	6489	85.8 (84.0–87.5)

CI, confidence interval; *UBT*, uterine balloon tamponade.

[a] References of abstracts can be provided on request to the corresponding author; [b] Total number of studies does not represent the sum of individual causes of postpartum hemorrhage, given multiple causes of postpartum hemorrhage reported across studies.

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SUPPLEMENTARY TABLE 6

Sensitivity analysis of uterine balloon tamponade's success rate in case series according to risk of bias

	Low risk of bias in ≥5 explanatory questions			Low risk of bias in <5 explanatory questions		
Cause of postpartum hemorrhage	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)
Vaginal birth						
Uterine atony	4	142	87.4 (68.7–98.2)	5	195	87.6 (79.7–93.7)
Undifferentiated causes	24	705	85.7 (81.2–89.6)	17	269	86.9 (80.9–91.9)
Total	26	847	86.1 (81.6–90.1)	22	464	87.0 (82.5–91.0)
Cesarean delivery						
Uterine atony	2	12	69.8 (10.9–99.5)	2	6	69.1 (11.1–99.7)
Placenta previa	4	134	87.0 (74.5–95.7)	1	25	88.0 (75.3–100.0)
Placenta accreta spectrum	2	26	88.7 (70.3–98.8)	-	-	-
Undifferentiated causes	20	826	79.1 (71.8–85.6)	19	251	81.8 (75.6–87.3)
Total	27	998	80.5 (74.5–85.9)	22	282	81.8 (75.9–87.0)
Unknown mode of delivery						
Uterine atony	3	110	96.5 (92.3–99.1)	5	615	89.3 (79.1–96.4)
Undifferentiated causes	2	63	63.7 (29.4–91.5)	8	245	82.3 (77.3–86.8)
Total	4	173	91.2 (79.3–98.4)	10	860	85.4 (79.2–90.6)
Overall						
Uterine atony	21	942	88.1 (83.1–92.3)	22	1000	86.5 (81.3–90.9)
Placenta previa	18	347	84.1 (79.5–88.2)	14	169	87.2 (77.1–94.6)
Placenta accreta spectrum	8	56	65.6 (46.3–82.6)	2	13	53.5 (28.9–77.2)
Retained placenta	6	40	78.6 (65.7–89.1)	7	42	69.6 (46.9–88.1)
Undifferentiated causes	19	633	78.9 (70.3–86.4)	22	382	85.8 (80.7–90.2)
Total[a]	34	2018	85.6 (82.1–88.7)	35	1606	86.0 (82.8–88.9)

CI, confidence interval; *UBT*, uterine balloon tamponade.

[a] Total number of studies does not represent the sum of individual causes of postpartum hemorrhage, given multiple causes of postpartum hemorrhage reported across studies.

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SUPPLEMENTARY TABLE 7

Comparison of success rates between Bakri balloon and condom uterine balloon tamponade in postpartum hemorrhage (all causes)

	Randomized controlled trials			Nonrandomized studies			Case series			Overall		
Type of UBT	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)
Vaginal birth												
Bakri balloon	1[44]	33	90.9 (81.1–100.0)	1[47]	31	83.9 (70.9–96.8)	20	468	82.6 (77.7–87.1)	23	532	83.2 (78.8–87.2)
Condom UBT	4[43–46]	260	82.0 (77.2–86.4)	1[58]	30	90.0 (79.3–100.0)	9	476	93.2 (89.9–95.9)	14	865	89.5 (85.7–92.7)
Cesarean delivery												
Bakri balloon	2[41,42]	32	87.2 (63.6–99.3)	6[47–49,53,59,61]	199	82.0 (72.0–90.2)	24	871	78.6 (72.0–84.5)	32	1102	80.0 (74.9–84.7)
Condom UBT	-	-	-	-	-	-	6	99	88.4 (75.3–97.0)	6	99	88.4 (75.3–97.0)
Unknown mode of delivery												
Bakri balloon	-	-	-	4[50–52,55]	265	86.0 (81.7–89.9)	9	741	86.1 (80.5–90.9)	13	1006	85.7 (81.6–89.3)
Condom UBT	-	-	-	1[60]	14	100.0 (73.2–100)	6	427	91.8 (89.1–94.2)	7	441	92.1 (89.4–94.4)
Overall												
Bakri balloon	3[43,44,46]	65	87.4 (76.7–95.2)	10[47–53,55,59,61]	495	83.5 (78.5–88.0)	34	2080	82.9 (79.4-86.1)	47	2640	83.2 (80.5-85.8)
Condom UBT	4[43–46]	260	82.0 (77.2–86.4)	2[58,60]	44	93.6 (80.3–99.7)	15	1002	91.9 (89.7-93.9)	21	1306	90.4 (87.7-92.8)

CI, confidence interval; *UBT*, uterine balloon tamponade.

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SUPPLEMENTARY TABLE 8
Comparison of success rates between Bakri balloon and condom uterine balloon tamponade in postpartum hemorrhage due to uterine atony

Type of UBT	Randomized controlled trials			Nonrandomized studies			Case series			Overall		
	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)
Vaginal birth												
Bakri balloon	1[44]	33	90.9 (81.1–100.0)	-	-	-	1	108	74.1 (65.8–82.3)	2	72	79.1 (52.3–96.6)
Condom UBT	2[43,44]	90	83.7 (75.5–90.5)	1[58]	30	90.0 (79.3–100.0)	3	166	87.6 (77.9–94.7)	6	286	87.4 (83.3–90.9)
Cesarean delivery												
Bakri balloon	1[41]	25	80.0 (64.3–95.7)	2[48,59]	60	74.2 (62.7–84.2)	-	-	-	3	85	75.6 (66.2–84.0)
Condom UBT	-	-	-	-	-	-	-	-	-	-	-	-
Unknown mode of delivery												
Bakri balloon	-	-	-	4[47,50,52,55]	176	87.0 (81.7–91.5)	19	649	83.8 (77.5–89.3)	23	825	84.4 (79.4–88.8)
Condom UBT	-	-	-	1[60]	14	100.0 (73.2–100)	8	693	92.5 (90.1–94.7)	9	706	92.8 (90.4–94.9)
Overall												
Bakri balloon	2[41,44]	58	85.2 (73.4–94.1)	6[47,48,50,52,55,59]	236	83.6 (77.4–89.0)	20	688	82.9 (76.7–88.4)	28	982	83.0 (78.6–87.1)
Condom UBT	2[43,44]	90	83.7 (75.5–90.5)	2[58,60]	43	93.3 (80.3–99.6)	11	859	91.9 (89.4–94.1)	15	992	91.2 (88.6–93.4)

CI, confidence interval; *UBT*, uterine balloon tamponade.

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SUPPLEMENTARY TABLE 9
Comparison of success rates between Bakri balloon and condom uterine balloon tamponade according to setting

		Randomized controlled trials			Nonrandomized studies			Case series			Overall		
Type of UBT	Setting	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)	No. of studies	No. of women	Pooled UBT success rate (%, 95% CI)
All causes of postpartum hemorrhage													
Bakri balloon	HICs	1[41]	25	80.0 (64.3–95.7)	5[47,49–51,53]	209	87.5 (82.0–92.2)	21	1329	79.2 (75.4–82.6)	27	1563	80.8 (77.6–83.9)
	LMICs	2[42,44]	40	91.4 (81.1–97.9)	5[48,52,55,59,61]	286	78.9 (70.6–86.2)	13	751	88.8 (84.5–92.5)	20	1077	86.4 (82.4–89.9)
Condom UBT	HICs	-	-	-	-	-	-	-	-	-	-	-	-
	LMICs	4[43–46]	260	82.0 (77.2–86.4)	2[58,60]	44	93.6 (80.3–99.7)	15	1002	91.9 (89.7–93.9)	21	1306	90.4 (87.7–92.8)
Uterine atony alone													
Bakri balloon	HICs	1[41]	25	80.0 (64.3–95.7)	2[47,50]	86	83.0 (74.5–90.1)	13	523	77.6 (70.7–83.8)	16	634	78.4 (73.0–83.4)
	LMICs	1[44]	33	90.9 (81.1–100)	4[48,52,55,59]	150	83.4 (73.1–91.7)	7	165	90.9 (82.0–96.9)	12	348	88.1 (82.1–93.0)
Condom UBT	HICs	-	-	-	-	-	-	-	-	-	-	-	-
	LMICs	2[43,44]	90	83.7 (75.5–90.5)	2[58,60]	43	93.3 (80.3–99.6)	11	859	91.9 (89.4–94.1)	15	992	91.2 (88.6–93.4)

CI, confidence interval; *HICs*, high-income countries; *LMICs*, low- and middle-income countries; *UBT*, uterine balloon tamponade.

Suarez et al. Uterine balloon tamponade for treating postpartum hemorrhage. Am J Obstet Gynecol 2020.