EFFECTIVENESS OF UTERINE TAMPONADE DEVICES FOR REFRACTORY POSTPARTUM HAEMORRHAGE AFTER VAGINAL BIRTH: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Abstract

Objectives: to describe available uterine tamponade devices for the management of postpartum haemorrhage, and to evaluate its effectiveness as a treatment of refractory PPH. Search strategy: Databases searched included PubMed, EMBASE, CINAHL, LILACS and POPLINE. Study selection: To describe uterine tamponade devices any type of study was included; only randomised and non-randomised comparative studies were included to assess the effectiveness of uterine tamponade devices. Outcomes: The primary outcomes were: a composite outcome including surgical interventions or maternal death, and hysterectomy. Results: Twenty-four types of tamponade devices were identified. The Bakri and the condom-catheter balloon were the most frequently reported. One randomised controlled trial suggests non-significant increases in the composite outcome (RR 2.33, 95%CI 0.76-7.14) and hysterectomy (RR 4.14, 95%CI 0.48-35.93) associated with the condom-catheter balloon vs. no device. Another RCT suggests a non-significant reduction in the composite outcomes (RR 0.60; 95%CI 0.16-2.31) and hysterectomy (RR=0.5; 95%CI 0.05-5.25) with the Bakri balloon vs the condom-catheter balloon. A stepped-wedge study suggests an increase in the composite outcome (RR 4.08, 95%CI 1.07-15.58), and a non-significant increase in hysterectomies (RR 4.38, 95% CI 0.47-41.09) associated with the introduction of condom-catheter or surgical glove balloon into clinical settings. Conversely, non-randomised studies showed a non-statistically significant reduction (RR=0.61, 95%CI 0.27-1.40) in the composite outcome and no effect on hysterectomy associated with the use of the Bakri balloon. Conclusions: The effect of UBT for the management of atonic refractory PPH after vaginal delivery is unclear, as is the role of the type of device and the setting.

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ABSTRACT

Objectives: to describe available uterine tamponade devices for the management of atonic postpartum haemorrhage (PPH), and to evaluate its effectiveness for atonic refractory PPH, and the effect of introducing uterine tamponade devices as a treatment of refractory PPH in clinical settings.

Search strategy: Databases searched included PubMed, EMBASE, CINAHL, LILACS and POPLINE.

Study selection: To describe uterine tamponade devices any type of study was included; only randomised and non-randomised comparative studies were included to assess the effectiveness of uterine tamponade devices.

Outcomes: The primary outcomes were: a composite outcome including surgical interventions (laparotomy for artery ligations, uterine compressive sutures or hysterectomy) or maternal death, and hysterectomy.

Results: Twenty-four types of tamponade devices were identified. The Bakri and the condom-catheter balloon were the most frequently reported. One randomised controlled trial suggests non-significant increases in the composite outcome (RR 2.33, 95%CI 0.76-7.14) and hysterectomy (RR 4.14, 95%CI 0.48-35.93) are associated with the use of the condom-catheter balloon vs. no device. Another RCT suggests a non-significant reduction in the composite outcomes (RR 0.60; 95%CI 0.16-2.31) and hysterectomy (RR=0.5; 95%CI 0.05-5.25) with the Bakri balloon vs the condom-catheter balloon. Three comparative studies assessed the e*ffect of introducing UBTs into clinical settings.* A stepped-wedge study suggests an increase in the composite outcome (RR 4.08, 95%CI 1.07-15.58), and a non-significant increase in hysterectomies (RR 4.38, 95% CI 0.47-41.09) associated with the use of the condom-catheter or surgical glove balloon. Conversely, the pooled estimate of the non-randomised studies showed a non-statistically significant reduction (RR=0.61, 95%CI

0.27-1.40) in the composite outcome and no effect on hysterectomy associated with the use of the Bakri balloon.

Conclusions: The effect of UBT for the management of atonic refractory PPH after vaginal delivery is unclear, as is the role of the type of device and the setting.

TWEETABLE ABSTRACT

This systematic review and meta-analisys was conducted to describe available uterine tamponade devices for the management of atonic postpartum haemorrhage (PPH), and to evaluate the clinical effectiveness of different uterine tamponade devices for atonic refractory PPH, and the effect of introducing uterine tamponade devices as a treatment of refractory PPH in clinical settings. Twenty-four types of purpose-designed or improvised tamponade devices were identified for the management of suspected atonic PPH after vaginal birth**.** The effect of UBT for the management of atonic refractory PPH after vaginal delivery is unclear, as is the role of the type of device and the setting.

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KEY WORDS

Maternal death, postpartum haemorrhage, uterine atony, vaginal delivery, Bakri Balloon, condom UBT, hysterectomy

Introduction

Haemorrhage continues to be the largest direct cause of maternal death, accounting for 661,000 deaths worldwide between 2003 and 2009.[1] Most of these deaths occur during the immediate postpartum period and are due to uterine atony, a condition characterized by the failure of the uterus to contract adequately after the delivery of the placenta.[2]

The majority of women with postpartum haemorrhage (PPH) respond well to first line interventions (uterotonics, uterine massage, tranexamic acid). However, 10% to 20% are unresponsive to these interventions – a subgroup (denoted as "refractory PPH") where most of the PPH-related morbidity and mortality are concentrated.[3] Between one-third and one-half of refractory PPH cases are due to uterine atony. Laparotomy for compressive sutures, ligation of uterine bood supply or hysterectomy are frequently needed to prevent deaths among these women.[4,5] Embolization of uterine arteries by interventional radiology is also an option, although availability in low resource settings is very limited.[2]

Effective non-surgical interventions to manage refractory PPH are critical to avoiding surgical treatment. Surgical interventions are associated with increased risk of severe morbidity and mortality, and are not widely available in low-resource settings. The non-surgical interventions currently recommended by the World Health Organization (WHO) for the treatment of refractory PPH due to uterine atony include: manual compressive measures (bimanual uterine compression and external aortic compression), uterine balloon tamponade (UBT), and a second dose of tranexamic acid.[2,6]

Description of the intervention

Under the umbrella of uterine tamponade devices for treating refractory PPH, two categories were considered: uterine balloon tamponade (UBT) devices and uterine suction tamponade (UST) devices. Briefly, UBTs consist of inserting a rubber, silicone or plastic balloon into the uterine cavity, and inflating the balloon with normal saline solution.[7] The inflated balloon exerts outward pressure on the uterus achieving a tamponade effect to prevent further bleeding. [8] The UBT can be achieved either using improvised or purpose-designed devices.[9] Improvised devices are those balloon catheters designed for other purposes and used off-label for PPH treatment (i.e. the Sengstake-Blakemore tube, the Rusch balloon, the Foley catheter), or those based on the use of condoms and surgical gloves attached to Foley or other catheters. The purpose-designed UBTs for

refractory PPH treatment are the Bakri® balloon, the EBB® tamponade system (Belfort-Dildy), the Ellavi balloon (by Sinapi Biomedical), and the BT-Cath® balloon.[2,7,10,11] More recently, a novel type of device that uses vacuum force to retract the uterus has been proposed as an alternative to the UBT.[12] Such USTs could be considered a physiologically plausible alternative for the management of unresponsive PPH, as the mechanism of action mimics physiologic uterine retraction. Similar to UBT, there are UST purpose-designed and improvised devices.[8]

Why it is important to do this review

The previous WHO recommendation on UBT was based on case series and studies with no control population, leading to a conditional recommendation. Such conditional recommendation does not support widespread application of UBT in all clinical situations. Since the WHO recommendation was published, several additional studies have been reported, including randomised controlled trials (RCTs). Given the importance of UBT as a potential life-saving intervention and the popularity of the intervention globally, it is relevant to systematically review all data available to-date, including the findings of these newer studies, to assess whether the benefits of UBT outweigh the harms.

The proliferation of UBT devices over the years, with variable rates of success in terms of reduction of PPH-related morbidity, demands a careful assessment of reported tamponade devices to determine their comparative effectiveness and safety. We undertook the present systematic review aiming to address three key objectives:*Objective 1* , describe available uterine tamponade devices for the management of atonic refractory PPH; *Objective 2* , evaluate the clinical effectiveness and safety of different uterine tamponade devices used for treatment of atonic refractory PPH, compared to no tamponade devices or alternative tamponade devices; and *Objective 3* , evaluate the effect of introducing uterine tamponade devices as a treatment of refractory PPH in clinical settings.

Methods

This systematic review and meta-analysis was conducted following a protocol specifically designed for this purpose and reported according to the recommendations of the PRISMA statement (Table S1). The protocol was registered in PROSPERO (CRD42019120486).

Type of study designs

To achieve the first objective, any report on uterine tamponade devices for the management of atonic refractory PPH was included in the review. Systematic reviews and meta-analyses without original data were excluded after verifying that all citations were included in this systematic review.

For the second objective, all RCTs and cohort studies that evaluated the effectiveness of a uterine tamponade device in women who developed atonic refractory PPH after vaginal birth were eligible for inclusion.

For the third objective, all quasi-RCTs, controlled before-and-after studies (CBAs), uncontrolled before-and-after studies (UBAs), interrupted time series (ITSs), controlled interrupted time series (CITSs) and cohort studies that evaluated the effect of introducing uterine tamponade devices as a treatment of refractory PPH in clinical settings were eligible for inclusion.

Type of participants

The review considered all women who developed atonic PPH after vaginal birth and who did not respond to first-line PPH treatment as defined by the study authors.

Studies reporting data on both vaginal and caesarean births were included only if it was possible to assess the effect of the UBT after vaginal births separately. The main reasons why we decided to focus our study in women with PPH after vaginal birth were that: (i) UBT is more frequently used after vaginal births, (ii) invasive procedures are mediated by the mode of delivery, and (iii) studies that included caesarean sections might not clarify if UBT was used for intraoperative or post-operative PPH.

Type of intervention

We assessed the following types of interventions:

1. Any type of uterine tamponade device versus no device in women with refractory PPH after vaginal birth (woman-level intervention). The "no device" group included those who received medical treatment (uterotonics, tranexamic acid and IV fluids), bimanual uterine compression and/or external aortic compression.
2. Any type of uterine tamponade device versus other tamponade devices in women with refractory PPH after vaginal birth (woman-level intervention).
3. Interventions, programs or policy decisions to introduce uterine tamponade devices as a treatment of refractory PPH in clinical settings, compared to no or alternative intervention (facility-level intervention).

We excluded studies in which the effect of the UBT was not possible to isolate from other used interventions.

Although the mechanism of action of UST is different from that of UBT, we use the term uterine tamponade devices to refer collectively to any intrauterine devices for the control of PPH, since it is a term frequently used in the literature.

Type of outcomes

Primary outcomes were: (a) a composite outcome including surgical interventions (laparotomy for artery ligations, uterine compressive sutures or hysterectomy) or maternal death, (b) hysterectomy.

Secondary outcomes were: blood loss, shock, coagulopathy, maternal death, organ dysfunction, blood transfusion, transfer to higher level of care, women's sense of wellbeing, acceptability and satisfaction with the intervention, breastfeeding, and other adverse effects.

The selected outcomes are consistent with those suggested by the CORE outcomes initiative. [13] We excluded studies that did not report any of the outcomes previously listed.

Search strategy

The search strategy was developed with the assistance of a librarian experienced in electronic search strategies for systematic reviews. The search strategy for the first objective included the following generic terms adapted to each electronic database: uterine balloon tamponade, uterine tamponade, tamponade, balloon, condom-catheter balloon, Bakri balloon, Sengstaken Blakemore tube, Rusch balloon, Foley catheter, InPress device and vacuum, in combination with postpartum haemorrhage. For the second and third objectives, the above search was combined with the terms related to clinical trials.

The search was run from inception to October 2019 in the following electronic databases: PubMed, EMBASE, CINAHL, LILACS, POPLINE (Appendix S1). The search was complemented by reviewing the references of all articles selected for full-text reading, and by looking for unpublished studies through contacts with investigators who are experts in the PPH field. There were no language restrictions.

Data extraction and synthesis

Citations were downloaded from the reference manager RIS to Covidence, a web-based platform used to support the conduct of systematic reviews. Titles and abstracts of all imported citations were screened using Covidence and those that were potentially eligible were selected for full-text review. At least two independent reviewers performed the process of study selection and data extraction (MW, VP, GC). Two forms specifically designed for this review were used to extract data from included studies. The first form was used to list and describe the uterine tamponade devices identified and the second form was used to extract data from the research studies (Annex). Disagreements were discussed until consensus was reached and if required, a third reviewer was consulted. Where information from an article was not clear, authors were contacted to provide additional details.

Risk of bias assessment

Two reviewers assessed the risk of bias by using the 'Risk of bias' tool described in the *Cochrane Handbook for Systematic Reviews of Interventions* for randomised studies, and the ROBINS-I tool (Risk of Bias in Non-Randomised Studies of Interventions) for non-randomised studies.[14,15] For randomised studies, random sequence generation and allocation concealment were assessed at the study level. The following were assessed at the outcome level: blinding of participants and personnel, and outcome assessors; incomplete outcome data, selective reporting; other bias. Quality assessment criteria used to assess non-randomised studies were: bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, bias in selection of the reported result and overall bias. We assessed the risk of bias for each criterion as 'low risk', 'high risk', and 'unclear risk' (Table S2 and Table S3).

In addition, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Criteria[16] were used to assess the certainty of evidence for the outcomes prioritized in this review: composite of surgical intervention(s) or maternal death, hysterectomy, surgical intervention(s), maternal death, blood transfusion(s) and transfer to a higher level of care. The overall certainty in the evidence was classified in one of four categories: high, moderate, low or very low.

Strategy for analysis and data synthesis

To address the first research question, we listed all reported purpose-designed and improvised uterine tamponade devices for the treatment of PPH. We measured the frequency of reporting and described the main characteristics of the devices.

To address the second and third questions, we assessed the clinical effectiveness according to the type of interventions under comparison:

- Any type of uterine tamponade device vs no device in women with atonic refractory PPH (woman-level intervention)
- Any type of uterine tamponade device vs other tamponade device (woman-level intervention)
- The introduction of uterine tamponade devices as a treatment of refractory PPH in clinical settings, compared to no or alternative intervention (facility-level intervention).

While the studies assessing individual-level interventions were analysed with the number of all women with PPH as the denominator, the studies assessing facility-level interventions were analysed with only women having vaginal birth as the denominator. This is because facility-level interventions could have an effect on PPH detection rates. Thus, the most comparable populations between periods or hospitals are all women having vaginal births during the study periods.

For each comparison, we pooled estimates of treatment across studies with similar methodology for each pre-specified outcome using the random-effects model of meta-analysis. Therefore, for each comparison we present pooled estimates of treatment for randomised studies and non-randomised studies separately. We calculated risk ratios (RR) with 95% confidence intervals (CI). We applied the generic inverse-variance model if the combination of clustered and non-clustered data required this approach. For each comparison, we quantified the inconsistencies across studies with the I2 statistic. An I2 of $> 60\%$ was defined as revealing substantial heterogeneity. We interpreted the significance of the I2 test in light of (i) the magnitude and direction of effects, and (ii) the strength of evidence for heterogeneity (for example, a confidence interval for the I2, or the p-value as compared to the χ^2 test).

Whenever possible, we conducted additional pre-specified subgroup analyses by type of device (purpose-designed and improvised devices) and by setting: low- and middle-income countries (LMICs) and high-income countries (HICs).

The summary statistics for each of the included studies were reported in tables and shown graphically as forest plots. Review Manager 5.3 was used to conduct statistical analyses and to design forest plots. Initially, funnel plot was to be performed to assess risk of publication bias but the scarce number of studies by outcome did not permit this analysis.

Results

Description of studies

The search strategy yielded a total of 9,430 citations. After screening titles and abstracts, the reviewers selected 621 citations for full-text review. After excluding 336 citations, 285 citations were included for qualitative synthesis to describe the uterine tamponade devices available for the management of PPH. Twenty-one studies were evaluated for the quantitative synthesis. Five out of 21 citations were ultimately included to assess the clinical effectiveness and safety of different uterine tamponade devices used for the treatment of refractory atonic PPH after vaginal birth. [17-21] (Figure S1) The excluded studies and their reasons are described in table S5. There were no studies assessing the effectiveness of suction devices. Studies included for the quantitative synthesis were published between January 2007 and October 2019.

Studies included to describe reported devices (objective 1)

The 285 articles included in the qualitative synthesis reported on 24 different types of uterine tamponade devices (Table 1). Eight devices were purposely designed for the treatment of PPH, of which five were UBTs and three were USTs. In addition, 16 improvised devices were reported, of which 12 were UBTs, two were USTs, and two involved a balloon combined with other technologies (such as cervical balloon impregnated with tranexamic acid or balloon combined with endoscopic photocoagulation). Tables 1 and 2 show the characteristics of improvised and purpose-designed tamponade devices, respectively. Across all included reports, the most frequently reported device among the purpose-designed and improvised devices were the Bakri balloon (143/163) and the condom-catheter balloon (55/144), respectively.

Assessment of clinical effectiveness (objectives 2 and 3)

Table 3 presents the main characteristics of the five included studies.

Any type of uterine tamponade device vs no device

One study assessed the effectiveness of improvised devices for the treatment of women with refractory PPH.[19] This RCT was conducted in LMICs (Benin and Mali).[19]

Any type of uterine tamponade device vs other tamponade devices:

Only one study met our eligibility criteria.[21] The study was a RCT conducted in Egypt that compared the effect of the Bakri balloon against the condom-catheter balloon on women with refractory PPH after vaginal birth. There were no eligible studies assessing facility-level interventions.

Effect of introducing the uterine tamponade devices in clinical settings

Three studies assessed the effects at the facility-level of introducing UBT devices as a treatment option for refractory PPH after vaginal birth. One study was a cluster RCT using a stepped-wedge design conducted in Uganda, Senegal and Egypt [17]; the other two were non-randomized studies conducted in France: one compared outcome rates at the hospital-level before and after introduction of UBT[18] while the other comparedoutcomes between one perinatal network using the UBT and one control network[20]. One study evaluated the Bakri balloon[18], one tested either Bakri or EBB®[20], and one assessed an improvised device (condom or globe catheter)[17]. All studies used medical treatment or standard care as control groups. Two studies were conducted in HICs.[18,20] The studies conducted by Revert and Laas analysed women that had either vaginal deliveries or caesarean sections. For both studies, we included only the data on women with vaginal deliveries.

There is one ongoing study[22] that compares early versus later use of Belfort-Dildy intrauterine balloon tamponade for primary PPH after vaginal birth (650 women, due to be complete in August 2020). In this study, all women receive first response treatment (oxytocin and uterine massage). In the case of first response failure, the intervention group receives UBT simultaneously with second response uterotonic treatment with prostaglandins (early UBT); the control group receives UBT if second response treatment fails (late UBT).

Risk of Bias

To assess validity of included studies, we rated individual criteria for each study, which were specific for randomised and non-randomised studies. Details of the quality of each individual study are described in Figure 1, where the individual quality criteria are rated for each study. A more detailed, methodological quality assessment of included randomised and non-randomised was also conducted (Table S4).

In concordance with the Cochrane Agency for Healthcare Research and Quality (AHRQ) standards, and given that all three RCTs had at least two domains listed as high risk of bias, these studies were rated as low-quality trials. randomisedAlthough the included non-randomised studies were judged as high-to-moderate quality; they have the biases inherent to their respective study designs.

Risk assessment of randomised studies

Randomisation criteria were successfully met by one RCT, while the other two RCTs were judged as either unclear or high risk of bias for one criterion: one trial did not describe the method used for randomisation[17] and the other showed no evidence that the allocation was concealed[19].

Blinding of participants and researchers was not possible due to the nature of the intervention. Although outcomes are not likely to be influenced by unblinded participants, they might be influenced by unblinded providers. Consequently, risk of performance bias was classified as high for all three RCTs, given that unblinded personnel can introduce performance bias by affecting clinical decisions and outcomes.[17,19,21] All three trials were classified as having high risk of detection bias given that the same unblinded provider assessed research outcomes.[17,19,21]

Among the three trials, two[17,19] were classified as low-risk of attrition bias, while one[21] was classified as high-risk given that, for certain outcomes, the authors excluded data in which treatment failed to control the haemorrhage. Unclear risk of reporting bias was identified in one trial[17] given that the outcomes listed in the registered study protocol did not match the outcomes reported and discussed in the publications.

While two trials were classified as having low risk of other potential bias, one randomised study was classified as high-risk given that unbalanced baseline characteristics related to estimated blood loss were not adjusted at the analysis.[19]

In addition, the Dumont trial showed problems in quality assurance and adherence to the intervention, such as suboptimal and heterogeneous training within and between the participating sites, and delays in diagnosis and treatment[19]. Training could have increased surgical interventions in facilities that were not well-equipped and functioning in the Anger study.[17]The Darwish trial was small.[21]

Risk assessment of non-randomised studies

One of the non-randomised studies was considered to have high risk of bias due to confounding.[18] Both non-randomised studies were classified as having low risk of bias for selection of participation, classification of the intervention, deviation from intended interventions, missing data, measurement of outcomes and selection of reported results.[18,20]

Effect of the interventions

Effect of any type of uterine tamponade device vs no device in women with refractory PPH

Figure 2 shows the effect of any type of uterine tamponade device vs no device in women with atonic refractory PPH (woman level intervention) on the primary outcomes: (a) the composite of surgical interventions—artery ligation, compressive sutures, hysterectomy— or maternal deaths, and (b) only hysterectomy.

Only one RCT reported the effect on surgical interventions or maternal death.[19] There was a two-fold increase in surgical interventions or death associated to the use of the condom-catheter balloon plus misoprostol compared to misoprostol alone, although this increase was not statistically significant (RR 2.33, 95%CI 0.76-

7.14). The same RCT[19] reported a non-significant increased risk of hysterectomy associated with the use of an improvised balloon tamponade (RR 4.14, 95%CI 0.48-35.93). (Figure 2)

This trial showed similar effects with non-significant increased risk for surgical interventions (2.07; 95%CI 0.54-7.88) and maternal death (RR 6.21, 95%CI 0.77-49.98) associated with use of the improvised balloon tamponade. Blood transfusions and transfer to a higher level of care showed a non-statistically significant increase of approximately 50% and 30% respectively (RR 1.49, 95%CI 0.88-2.51; RR 1.29, 95%CI 0.55-3.04 respectively) (Figure S2).

Subgroup analysis by device or setting were not possible. The included RCT evaluated an improvised device and was conducted in Benin and Mali, two low-income countries.[19]

Effect of any type of uterine tamponade device vs other tamponade in women with refractory PPH

One RCT assessed the effectiveness of the Bakri balloon vs the condom-catheter balloon on the composite outcome (surgical interventions or maternal death) and showed a non-statistically significant 40% reduction (RR 0.60; 95%CI 0.16-2.31).[21] (Figure 3) A non-significant effect on hysterectomy was observed favouring the Bakri balloon (RR=0.5; 95%CI 0.05-5.25). Similarly, a non-significant risk reduction associated with the Bakri balloon was observed on surgical interventions (RR 0.60; 95%CI 0.16-2.31), and transfer to a higher level of care (RR=0.5; 95%CI 0.05-5.25).[21] No effect was observed on need of blood transfusion (RR=1.04, 95%CI 0.85.1.25). (Figure S3)

Effect of introducing UBTs into clinical settings vs either a previous period in which the UBT was not used or other clinical settings without introducing UBT.

The experimental study by Anger *et al.* used a stepped-wedge design and showed a four-fold statistically significant increase in surgical interventions or maternal deaths associated with introducing improvised UBTs (RR 4.08, 95%CI 1.07-15.58).[17] Two non-randomised studies measured the effect introducing purspose-designed UBTs on this outcome.[18,20] Conversely to the Anger study, the pooled estimate of the non-randomised studies showed a 39% non-statistically significant reduction (RR=0.61, 95%CI 0.27-1.40) in surgical interventions or maternal deaths, associated with introducing purspose-designed UBTs into clinical settings, with no evidence of heterogeneity (p= 0.3, I^2=9%). (Figure 4)

The study by Revert *et al.* considered artery embolization as one of the surgical interventions included in the primary outcome, and the authors conducted the analysis and interpretation of the results on that basis.[20] As we did not include that invasive non-surgical interventions among the surgical interventions in our primary outcome, we analysed the Revert study data excluding women receiving such procedure. The results of this study, including artery embolization in the composite outcome as reported by the authors, shows a statistically significant reduction in the surgical interventions and deaths associated with the use of UBTs (adjusted RR 0.14, 95%CI 0.08- 0.27), while no effect is observed when excluding artery embolization (RR 0.91, 95%CI 0.31-2.71). The meta-analysis with the Revert data including artery embolization as one of the surgical interventions is shown in figure S4.

Three studies reported hysterectomy rates. While the Anger trial found a non-significant increase on hysterectomies associated to improvised devices (RR 4.38, 95% CI 0.47-41.09), the non-randomised studies[18,20] showed no effect in the risk of hysterectomies associated with the use of purpose-designed UBTs (pooled RR 1.26, 95% CI 0.37 to 4.32), without evidence of heterogeneity (p = 0.37; I^2 = 0%). (Figure 4)

The effect of introducing uterine tamponade devices as a treatment for refractory PPH in clinical settings on secondary outcomes are shown in the Figure S4. Regarding the subsequent need for surgical interventions (artery ligation, compressive sutures, hysterectomy), no effect was observed for UBT use compared to the control group in non-randomised studies (RR=0.61, 95%CI 0.27-1.40). Maternal deaths were reported only in two studies and the results are not consistent. (Figure S4) While the Anger study reported a non-significant increase in maternal deaths in the UBT group (RR 2.23, 95% CI 0.35 to 14.21), no deaths due to PPH were reported in the Laas study. Maternal death after vaginal delivery was not assessed in the Revert study. A

non-significant increase in blood transfusions was reported by Anger (RR=1.24, 95%CI 0.86-1.80) as well as in the non-randomised study by Laas (RR=1.40, 95%CI 0.74-2.65).

It was not possible to analyse effects by device or setting. The study by Anger evaluated an improvised device and was conducted in LMICs, while the non-randomised studies evaluated a purpose-designed device and were conducted in HICs.

Quality of the evidence according to GRADE assessment

Table 4 shows details on the quality of evidence according to GRADE criteria for the two comparisons of interest.

For the first comparison—any type of uterine tamponade devices compared to no devices—we found low quality of evidence for the composite outcome in studies that evaluated the UBT at the individual- and facility-levels, independently of the study design. The quality of evidence was low to very low for all secondary outcomes: hysterectomy, surgical interventions, maternal death, blood transfusion and transfer to a higher level of care. These results were consistent across different study designs (randomised and non-randomised) and level of intervention (individual or facility).

For the second comparison—any type of uterine tamponade device versus other tamponade device—only one of all included studies compared Bakri versus condom-catheter balloon. The quality of the evidence for the reported outcomes—hysterectomy, surgical interventions and transfer to a higher level of care—is very low.

Discussion

Summary of main results

Among 282 reports describing tamponade devices available for the management of atonic PPH, we identified 24 different types of devices (eight purpose-designed and 16 improvised devices). Nineteen were UBT devices and five were UST devices. The Bakri balloon and the condom-catheter balloon were the most frequently reported devices.

Five studies assessing the effectiveness and safety of UBTs for the treatment of atonic refractory PPH after vaginal delivery were included. The evidence from the RCT assessing the effect of improvised UBT devices in women with refractory PPH did not show a reduction in the use of surgical interventions or maternal deaths or hysterectomy alone when compared with no device use. Similar results were observed for the RCT evaluating the effects of introducing UBTs into health care facilities. Moreover, an increase of these adverse events associated with the use of UBTs in women with refractory PPH or with the introduction of UBTs in health facilities cannot not be excluded. Conversely, the non-randomised studies analysing the effect of introducing purpose-designed UBTs into clinical settings showed a reduction in the same outcomes. The single study comparing UBTs with other tamponade devices showed no significant benefits on surgical interventions or deaths when comparing the Bakri balloon to the condom catheter.

While the RCTs evaluated the improvised UBTs in LMICs, the non-randomised studies assessed purpose-designed UBTs and were conducted in HICs. Therefore, it was not possible to disentangle the effect by type of device or by setting.

Overall completeness, quality of the studies and quality of the evidence

After a detailed quality assessment of the three RCTs included in this systematic review, we identified substantive methodological flaws and judged all three RCTs as having a 'high' risk of bias. Consequently, for the systematic review primary outcomes, the certainty of the evidence was graded as low due to study limitations, imprecision and inconsistency of the findings.

Factors that may be determinants of the effect of UBT

Improvised UBTs versus purpose-designed UBTs

The study comparing the condom-catheter to Bakri balloon reported longer time to control bleeding with condom-catheter balloon.[21] Furthermore, in the Dumont trial[19], the condom-catheter balloon was only inserted 30 minutes or more following the diagnosis of PPH in 58% of the cases, despite efforts to improve the availability of the different components of the UBT device. Finally, the stepped-wedge cluster RCT by Anger*et al* . mentioned that providers reported a problem with the condom-catheter balloon in 52% of the cases.

The setting

The effective management of refractory PPH requires an expeditious stepwise approach, in which the availability of resources and a well-operating health system are essential.[23] It is plausible that in settings where the identification and quality of PPH care is more likely to be substandard, the effect of the UBT may be different than in settings with good availability of resources and quality of care. The Dumont *et al* . trial reported that frequent delays in the diagnosis and treatment of uterine atony were observed, with a high proportion of women having received a late injection of oxytocin for the first response of treatment.[19]Similarly, the stepped-wedge cluster RCT by Anger *et al.* [17] reported that blood shortages were a problem for almost half of PPH-related deaths in the study, including some cases in which, despite bleeding stopping after administration of the UBT, the woman did not recover because timely blood replacement was unavailable. The authors suggested that "interventions such as UBT may have limited effectiveness in improving maternal outcomes when introduced into[18-21] resource-constrained health systems with unreliable access to other essential components of emergency care".[17]

Another potentially important aspect related to the setting has to do with whether the UBT procedure is performed at the delivery room or at the surgical theatre. Typically, in some HICs like UK and US, the procedure is conducted at the surgical theatre, following exploration of the uterine cavity to exclude trauma as the cause of the bleeding. Conversely, in LMICs the procedure is usually performed in the delivery room, frequently without exploration of the uterine cavity. On one hand, performing the procedure in the surgical theatre after excluding other causes may avoid applying the UBT in cases with no uterine atony, thus avoiding delays to administer the correct treatment. Additionally, if the UBT fails, surgical treatment can be started without delay. On the other hand, in low-resource settings, such requirements may contribute to delay of the UBT procedure. In the Dumont trial, a large proportion of the UBT procedures were performed at the operating theatre of referral hospitals. The authors reported that "the recurring unavailability of the theatre had an important consequence in the delays for the experimental group".[19]

Strengths and limitations

The strengths of this systematic review include following rigorous Cochrane methods and the PRISMA protocol for reporting. The broad search strategy captured a large number of published and unpublished studies. To assess the effectiveness, we tightly restricted eligibility to studies that selected women with suspected uterine atony and refractory PPH and reported additional surgical interventions or maternal death. We included all types of studies that compared the effectiveness of UBT with medical treatment, local standard of care or other type of UBT. Case reports were not included to assess effectiveness. Given that systematic review informs clinical and policy decision-making, comparative effectiveness evidence is required. Although the timeframe for this review included a long period of time in order to identify a wide range of devices reported in the literature, most included studies for the quantitative synthesis were published recently. Due to the heterogeneity of the reports, studies were grouped by type of intervention and the type of study design to make comparisons possible. As the included studies used different types of UBT devices and were conducted in different countries, effort was made to highlight these distinctions throughout the analysis.

Our review also has limitations. We found very few studies reporting the effect of UBT in atonic refractory PPH after vaginal delivery. We excluded 16 analytical studies because outcomes were measured in all births, without disaggregating the data according to mode of birth (Table S5), with a quarter to half of included cases ending in caesarean deliveries. It was possible to extract data after vaginal birth in only two studies.[18,20]

Finally, the inability to pool risk estimates due to the heterogeneity in the study designs should be noted. The heterogeneity in the estimation of blood loss and the definition of refractory PPH is also a limitation of this study.

Agreements and disagreements with other reviews

In 2020, Suarez *et al.* published a comprehensive systematic review, including RCTs (n=7), non-randomised studies of interventions (n=15), and case series (n=69) that reported on the efficacy, effectiveness, and/or safety of UBT device placement in women with PPH due to a variety of causes, after vaginal and/or caesarean delivery.(275) The main outcome was the UBT success -defined as bleeding arrested without maternal death and additional surgical or radiological interventions in women in which the UBT was placed.

This systematic review differs from Suarez *et al.* in that we did not include case report studies, given their key limitation of not having a comparison group. Additionally, we restricted our focus to atonic refractory PPH after vaginal delivery only. Both reviews acknowledge the conflicting evidence from RCTs compared to non-randomised studies.

CONCLUSION

According to the body of evidence currently available, the effect of UBT for the management of atonic refractory PPH after vaginal delivery is unclear. The results of this systematic review suggest substantial heterogeneity in outcomes. Whether the type of device or the setting are important factors associated with UBTs' effect is unknown. In summary, the evidence from RCTs suggests no beneficial effect of either the use or introducing UBTs into clinical settings, and a harmful effect cannot be reasonably excluded.

Implications for practice

There is uncertainty about the effectiveness and safety of UBT for the treatment of women with refractory PPH after vaginal delivery in low resource settings with unreliable access to good quality PPH care. Our view is that UBT should be considered for routine refractory PPH care only in settings where birth attendants are appropriately trained to use tamponade devices and manage PPH, where access to surgical interventions and blood products are available if needed, where differential diagnosis of other causes of PPH can be performed, and where the resources required for PPH management are routinely available and maternal status can be appropriately monitored.

Implications for research

In low-resource settings not meeting the criteria mentioned above, the efficacy and safety of UBT for the treatment of women with refractory PPH after vaginal delivery should be evaluated through good quality RCTs. In well-resourced settings, it is a priority to assess the comparative efficacy of different purpose-designed UBTs against improvised devices. The effectiveness of UST devices should also be assessed though high-quality RCTs.

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AUTHOR CONTRIBUTIONS

Study conceptualization: FA and MW. FA, MW, GC, AC and VP contributed to drafting the protocol. MW, GC and VP selected studies for inclusion and extracted data. AC and VP conducted data analysis. FA, MW, VP, AC and GC contributed to drafting the review. VP, MW, AC, GC, KB, CD, MG, JH, OO and FA reviewed, provided comments and edits, and approved the manuscript.

CONFLICTS OF INTERESTS

VP, MW, FA, AC, GC, CD, MG, OTO have no conflicts of interest. GJH initiated the use of the Levin suction catheter as a uterine suction tamponade device. He did not participate in decisions regarding inclusion of reports on the Levin tube method in the review. KB has been participating in a European expert meeting Challenges in the Current Management of Postpartum Haemorrhage (PPH) organized by CSL Behring.

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Table 1. Characteristics of purpose-designed uterine tamponade devic

Name

Table 1. Characteristics of purpose-designed uterine tamponade devic

BT-Cath

Name	Brief description
Condom catheter balloon (ESM-UBT, Akhter, CG)	The condom catheter balloon is prepared by
Sengstaken-Blakemore	Double-balloon tamponade system developed
Rusch	Urinary balloon catheter that was originally
Foley catheter balloon	Device originally designed to provide continu
Surgical globe	A rubber catheter is fitted within the glove i
Metreurynter	Device used to induce abortion by dilating th
Urinary catheter balloon	No details reported.
Tandem balloon tamponade	Combination of a Fuji balloon catheter place
Linton-Nachlas	Single gastric balloon for treating varices in t
Prostatic balloon catheter	No details reported.
Cervical rippling balloon	Developed to perform mechanical dilation of
El Menia	This device is composed of a latex balloon (c
Suction Uterine Tamponade	**Suction Uterine Tamponade**
FG36 Levin stomach washout tube	This is an inexpensive, 12-mm diameter soft
Vacuum tamponade system based on Bakri (University Hospital Zurich)	This method involves using an intrauterine d
Devices that involves a balloon combined with another technology	**Devices that involves a balloon combin**
Cervical balloon impregnated with tranexamic acid	Cervical rippling balloon wrapped in gauze in
UBT with optional endoscopic photocoagulation	A balloon tamponade is fitted into the uterus

Table 3. Main characteristics of included studies for the evaluation of effectiveness

Research question
Q1. Any type of uterine tamponade device vs no device (woman-level intervention)
Q2. Any type of uterine tamponade device vs. other tamponade devices in women with refractory PPH after vaginal birth
Q3. Interventions, programs, or policy decisions to introduce uterine tamponade devices as a treatment of refractory PPH i

Table 4: Summary of findings and quality of the evidence according to GRADE assessment

Research question	Research question	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outc
		Outcomes Composite outcome (woman-level)	Outcomes Composite outcome (woman-level)	**Anticipated absolute effects*** (95% CI) **Risk with no devices**	**Anticipated absolute effects*** (95% CI) **Risk with no devices**	**Anticipated absolute effects*** (95% CI) **Risk with any type of uterine devices**	**Anticipated absolute effects*** (95% CI) **Risk with any type of uterine devices**	Relative effect (95% CI)	of studies	of studies	of studies	of studies	Cert of th evid
Q1. Any type of uterine tamponade device vs no device (woman-level intervention)	Composite outcome	Composite outcome	153 per 1000	153 per 1000	**355 per 1000** (116 to 1000)	**355 per 1000** (116 to 1000)	**RR 2.33** (0.76 to 7.14)	**RR 2.33** (0.76 to 7.14)	**RR 2.33** (0.76 to 7.14)	(1 RCT)	(1 RCT)	??OO LOW [a,b]	??O LOW [a,b]
	Hysterectomy	Hysterectomy	17 per 1000	17 per 1000	**70 per 1000** (8 to 609)	**70 per 1000** (8 to 609)	**RR 4.14** (0.48 to 35.93)	**RR 4.14** (0.48 to 35.93)	**RR 4.14** (0.48 to 35.93)	(1 RCT)	(1 RCT)	?OOO VERY LOW [a,d]	?OO VER LOW [a,d]
	Surgical interventions (BL, AL, HT)	Surgical interventions (BL, AL, HT)	51 per 1000	51 per 1000	**105 per 1000** (27 to 401)	**105 per 1000** (27 to 401)	**RR 2.07** (0.54 to 7.88)	**RR 2.07** (0.54 to 7.88)	**RR 2.07** (0.54 to 7.88)	(1 RCT)	(1 RCT)	??OO LOW [a,b]	??O LOW [a,b]

Research question	Research question	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outc
	Maternal death	Maternal death	17 per 1000	17 per 1000	**105 per 1000** (13 to 847)	**105 per 1000** (13 to 847)	**RR 6.21** (0.77 to 49.98)	**RR 6.21** (0.77 to 49.98)	**RR 6.21** (0.77 to 49.98)	(1 RCT)	(1 RCT)	?OOO VERY LOW [a,d]	?OO VER LOW [a,d]	
	Blood transfusion	Blood transfusion	271 per 1000	271 per 1000	**404 per 1000** (239 to 681)	**404 per 1000** (239 to 681)	**RR 1.49** (0.88 to 2.51)	**RR 1.49** (0.88 to 2.51)	**RR 1.49** (0.88 to 2.51)	(1 RCT)	(1 RCT)	??OO LOW [a,b]	??OO LOW [a,b]	
	Transfer to higher level of care	Transfer to higher level of care	136 per 1000	136 per 1000	**175 per 1000** (75 to 412)	**175 per 1000** (75 to 412)	**RR 1.29** (0.55 to 3.04)	**RR 1.29** (0.55 to 3.04)	**RR 1.29** (0.55 to 3.04)	(1 RCT)	(1 RCT)	??OO LOW [a,b]	??OO LOW [a,b]	

Research question	Research question	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outc
Q2. Any type of uterine tamponade device vs. other tamponade devices in women with refractory PPH after vaginal birth (woman-level intervention)	Hysterectomy	Hysterectomy	61 per 1000	61 per 1000	**30 per 1000** (3 to 318)	**30 per 1000** (3 to 318)	**RR 0.50** (0.05 to 5.25)	**RR 0.50** (0.05 to 5.25)	**RR 0.50** (0.05 to 5.25)	(1 RCT)	(1 RCT)	?OOO VERY LOW [a,b]	?OO VER LOW [a,b]
	Surgical interventions	Surgical interventions	152 per 1000	152 per 1000	**91 per 1000** (23 to 350)	**91 per 1000** (23 to 350)	**RR 0.60** (0.15 to 2.31)	**RR 0.60** (0.15 to 2.31)	**RR 0.60** (0.15 to 2.31)	(1 RCT)	(1 RCT)	?OOO VERY LOW [a,b]	?OO VER LOW [a,b]
	Transfer to a higher level of care	Transfer to a higher level of care	121 per 1000	121 per 1000	**61 per 1000** (12 to 309)	**61 per 1000** (12 to 309)	**RR 0.50** (0.10 to 2.55)	**RR 0.50** (0.10 to 2.55)	**RR 0.50** (0.10 to 2.55)	(1 RCT)	(1 RCT)	?OOO VERY LOW [a,b]	?OO VER LOW [a,b]

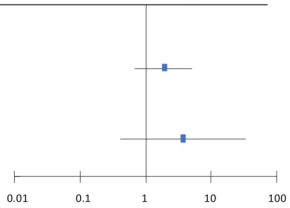
Research question	Research question	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outc
Q3. Interventions, programs, or policy decisions to introduce uterine tamponade devices as a treatment of refractory PPH in clinical settings, compared to no intervention	Composite outcome (RCT)	Composite outcome (RCT)	1 per 1000	1 per 1000	**1 per 1000** (1 to 2)	**1 per 1000** (1 to 2)	**RR 1.72** (0.99 to 2.99)	**RR 1.72** (0.99 to 2.99)	**RR 1.72** (0.99 to 2.99)	(1 RCT)	(1 RCT)	??OO LOW [b,c]	??OO LOW [b,c]	
Q3. Interventions, programs, or policy decisions to introduce uterine tamponade devices														

Research question	Research question	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outc
	Composite outcome (NRS)	Composite outcome (NRS)	2 per 10000	2 per 10000	**1 per 10000** (1 to 3)	**1 per 10000** (1 to 3)	**RR 0.61** (0.27 to 1.40)	**RR 0.61** (0.27 to 1.40)	**RR 0.61** (0.27 to 1.40)	(2 NRS)	(2 NRS)	??OO LOW[e]	??OO LOW
	Hysterectomy (RCT)	Hysterectomy (RCT)	0 per 1000	0 per 1000	**0 per 1000** (0 to 1)	**0 per 1000** (0 to 1)	**RR 1.64** (0.65 to 4.11)	**RR 1.64** (0.65 to 4.11)	**RR 1.64** (0.65 to 4.11)	(1 RCT)	(1 RCT)	??OO LOW[b,c]	??OO LOW[b,c]
	Hysterectomy (NRS)	Hysterectomy (NRS)	1 per 10000	1 per 10000	**2 per 10000** (1 to 5)	**2 per 10000** (1 to 5)	**RR 1.26** (0.37 to 4.32)	**RR 1.26** (0.37 to 4.32)	**RR 1.26** (0.37 to 4.32)	(2 NRS)	(2 NRS)	??OO LOW[e]	??OO LOW
	Surgical interventions (BL, AL, HT) (RCT)	Surgical interventions (BL, AL, HT) (RCT)	0 per 1000	0 per 1000	**1 per 1000** (0 to 2)	**1 per 1000** (0 to 2)	**RR 2.01** (0.99 to 4.08)	**RR 2.01** (0.99 to 4.08)	**RR 2.01** (0.99 to 4.08)	(1 RCT)	(1 RCT)	??OO LOW[b,c]	??OO LOW[b,c]
	Surgical interventions (BL, AL, HT) (NRS)	Surgical interventions (BL, AL, HT) (NRS)	2 per 10000	2 per 10000	**1 per 10000** (1 to 3)	**1 per 10000** (1 to 3)	**RR 0.61** (0.27 to 1.40)	**RR 0.61** (0.27 to 1.40)	**RR 0.61** (0.27 to 1.40)	(2 NRS)	(2 NRS)	??OO LOW[e]	??OO LOW
	Maternal death (RCT)	Maternal death (RCT)	0 per 1000	0 per 1000	**0 per 1000** (0 to 1)	**0 per 1000** (0 to 1)	**RR 1.32** (0.59 to 2.95)	**RR 1.32** (0.59 to 2.95)	**RR 1.32** (0.59 to 2.95)	(1 RCT)	(1 RCT)	??OO LOW[b,c]	??OO LOW[b,c]
	Maternal death (NRS)	Maternal death (NRS)	0 per 1000	0 per 1000	**0 per 1000** (0 to 0)	**0 per 1000** (0 to 0)	not estimable (No events)	not estimable (No events)	not estimable (No events)	(1 NRS)	(1 NRS)	-	-

Research question	Research question	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outc
	Blood transfusion (RCT)	Blood transfusion (RCT)	10 per 1000	10 per 1000	**10 per 1000** (8 to 11)	**10 per 1000** (8 to 11)	**RR 0.97** (0.83 to 1.14)	**RR 0.97** (0.83 to 1.14)	**RR 0.97** (0.83 to 1.14)	(1 RCT)	(1 RCT)	??OO LOW [b,c]	??OO LOW [b,c]
	Blood transfusion (NRS)	Blood transfusion (NRS)	2 per 1000	2 per 1000	**3 per 10000** (1 to 5)	**3 per 10000** (1 to 5)	**RR 1.40** (0.74 to 2.65)	**RR 1.40** (0.74 to 2.65)	**RR 1.40** (0.74 to 2.65)	(1 NRS)	(1 NRS)	?OOO VERY LOW [b, e]	?OO VER LOW [b, e]
	Transfer to higher level of care (RCT)	Transfer to higher level of care (RCT)	1 per 1000	1 per 1000	**0 per 1000** (0 to 1)	**0 per 1000** (0 to 1)	**RR 0.67** (0.35 to 1.29)	**RR 0.67** (0.35 to 1.29)	**RR 0.67** (0.35 to 1.29)	(1 RCT)	(1 RCT)	??OO LOW [b,c]	??OO LOW [b,c]
	Transfer to higher level of care (NRS)	Transfer to higher level of care (NRS)	not pooled	not pooled	not pooled	not pooled	not pooled	not pooled	not pooled	(0 studies)			

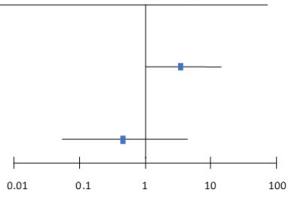
Research question	Research question	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outcomes	Outc
The risk in the intervention group is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***The risk in the intervention group** is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio.	***Th risk in the inter- vention grou** is base on the as- sume risk in the com- parison grou and the **rel- a- tive ef- fect** of the inter- vention (and its 95% CI). **CI:** Con- fi- denc inter- val; **RR:** Risk ratio.
GRADES of evidence: High certainty: We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRADES of evidence: High certainty:** We	**GRA of evi- denc Hig cer- tain** We

Outcome / *Design* / Study	Log Risk Ratio (SE)		Risk Ratio (95% CI)		Risk Ratio (95% CI)
Composite outcome					
RCTs					
Dumont 2017 (improvised device)	0,8454	(0.5715)	2,33	(0.76, 7.14)	
Hysterectomy					
RCTs					
Dumont 2017 (improvised device)	1,4208	(1.1025)	4,14	(0.48, 35.93)	



Note: the composite outcome includes surgical interventions (artery ligation, compressive sutures, hysterectomy) or maternal death

Outcome / *Design* / Study	Log Risk Ratio (SE)		Risk Ratio (95% CI)		Risk Ratio (95% CI)
Composite outcome					
RCTs					
Darwish 2017 (Bakri vs condom)	-0,5108	(0.6876)	0,6	(0.16, 2.31)	
Hysterectomy					
RCTs					
Darwish 2017 (Bakri vs condom)	-0,6931	(1.1997)	0,5	(0.05, 5.25)	



Outcome / *Design* / Study	Log Risk Ratio (SE)		Risk Ratio (95% CI)		Risk Ratio (95% CI)
Composite outcome					
RCTs					
Anger 2019 (improvised device)	1,4068	(0.6833)	4,08	(1.07, 15.58)	
Non-randomized					
Laas 2012 (purpose-designed device)	-0,9415	(0.5915)	0,39	(0.12, 1.24)	
Revert 2018 (purpose-designed device)	-0,0917	(0.5563)	0,91	(0.31, 2.71)	
Subtotal (95% CI)			0,61	(0.27, 1.40)	
Hysterectomy					
RCTs					
Anger 2019 (improvised device)	1,477	(1.1388)	4,38	(0.47, 40.81)	
Non-randomized					
Laas 2012 (purpose-designed device)	-0,7184	(1.2247)	0,49	(0.04, 5.38)	
Revert 2018 (purpose-designed device)	0,5732	(0.7303)	1,77	(0.42, 7.42)	
Subtotal (95% CI)			1.26	(0.37, 4.32)