Intrauterine balloon tamponade for postpartum hemorrhage

Tamponamento por balão intrauterino no tratamento da hemorragia pós-parto

Michel Marcos Dalmedico [1*]
Felipe Mendes Barbosa [2]
Caroline Machado de Toledo [2]
Waleska Alves Martins [2]
Angela do Rocio Fedalto [2]
Sergio Ossamu Ioshii [1]

[1] Pontifícia Universidade Católica do Paraná (PUCPR), Curitiba, PR, Brazil
[2] Universidade Positivo (UP), Curitiba, PR, Brazil

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*** Correspondence:** micheldalmedico@yahoo.com.br

Abstract

Introduction: Postpartum hemorrhage is an obstetric emergency with high prevalence and significant morbidity and mortality, especially in areas with reduced access to specialized health services. **Objective:** To evaluate the effectiveness of intrauterine balloon tamponade in controlling postpartum hemorrhage, with the aim to reduce the need for emergency surgical interventions and decrease maternal mortality. **Methods:** A systematic review of randomized clinical trials, guided by the Cochrane Handbook for Systematic Reviews of Interventions and reported through the Preferred Reporting Items for Systematic Reviews and Meta-Analyses. Randomized clinical trials that evaluated the use of different types of balloons for intrauterine tamponade as a strategy for reducing or stopping postpartum hemorrhage compared to other interventions (pharmacological or surgical) were considered for inclusion. **Results:** Four studies evaluated 498 patients. In 80% of the reported cases, hemorrhage cessation was observed within a mean interval of 15 min after device insertion. The device permanence time was 24 h. No serious adverse events were reported. Due to clinical heterogeneity between studies, it was not possible to perform a quantitative synthesis. **Conclusion:** We did not find enough evidence to support the routine use of uterine tamponade devices as a protocol practice in the control of refractory postpartum hemorrhage. However, the use of these devices seems to be promising in cases where first line interventions fail and may play an important role in decreasing maternal morbidity and mortality and in uterine preservation.

Keywords: Evidence-based emergency medicine. Postpartum hemorrhage. Systematic review. Uterine balloon tamponade.

Abstract

Introdução: *A hemorragia pós-parto trata-se de uma emergência obstétrica com elevada prevalência e morbimortalidade significativa, sobretudo em contextos de baixa acessibilidade a serviços especializados de saúde.* ***Objetivo:*** *Avaliar a efetividade do tamponamento por balão intrauterino no controle da hemorragia pós-parto, redução da necessidade de intervenções cirúrgicas de emergência e redução da mortalidade materna.* ***Métodos:*** *Revisão sistemática de ensaios clínicos randomizados, orientada pelo* Cochrane Handbook for Systematic Reviews of Interventions *e relatada através do* Preferred Reporting Items for Systematic Reviews and Meta-Analyses*. Foram considerados como critérios de elegibilidade ensaios clínicos randomizados que avaliaram o uso de diferentes tipos de balão para tamponamento intrauterino enquanto estratégia para a redução ou cessação da hemorragia pós-parto quando comparados a outras intervenções (farmacológicas ou cirúrgicas).* ***Resultados:*** *Quatro estudos avaliaram 498 pacientes para os desfechos preconizados. Em 80% dos casos relatados observou-se a cessação da hemorragia em um intervalo médio de 15 minutos, após a inserção dos dispositivos. O tempo de permanência dos dispositivos foi de 24 horas. Não foram relatados eventos adversos graves. Devido à heterogeneidade clínica entre os estudos, não foi possível realizar síntese quantitativa.* ***Conclusão:*** *Os achados obtidos não fornecem evidências suficientes para sustentar a utilização rotineira dos dispositivos de tamponamento uterino enquanto prática protocolar no controle da hemorragia pós-parto refratária. A utilização destes dispositivos, no entanto, parece ser promissora diante da falha das intervenções de primeira linha, podendo desempenhar um importante papel em termos de redução de morbimortalidade materna e preservação uterina.*

Palavras-chave: *Medicina de emergência baseada em evidências. Hemorragia pós-parto. Revisão sistemática. Tamponamento com balão uterino.*

Introduction

Postpartum hemorrhage is defined as an obstetric emergency caused by excessive and/or cumulative blood loss (greater than 1,000 mL) within 24 hours (primary or early) or after this period (secondary) due to uterine atony or failure of the uterus to contract and retract after the child is born, regardless of the mode of delivery, resulting in signs and symptoms of hypovolemia and hemorrhagic shock.[1-4]

This condition is one of the most common complications in clinical obstetric practice, notably in its most severe form (hemorrhage > 1,500 mL), accounting for about 30% of maternal deaths. It requires immediate recognition and management to avoid significant morbidity and mortality.[4,5] The prevalence of this complication is disproportionately higher in resource-poor settings, in which obstetric surgical capacity, emergency transport, and the supply of blood components are limited.[1,3]

In addition to death, severe adverse events resulting from postpartum hemorrhage include hypovolemic shock, acute respiratory distress syndrome, disseminated intravascular coagulation, dilutional coagulopathy secondary to fluid resuscitation, and infertility due to the need for emergency peripartum hysterectomy.[2,6]

A study with more than 154,000 births in primiparous women reported 666 cases (0.4%) that progressed to hemorrhagic conditions.[7] Factors significantly associated with hemorrhage were placental retention, inability to progress during the second stage of labor, morbidly adherent placenta, tract lacerations, use of forceps, macrosomia (> 4,000 g), hypertensive diseases during pregnancy, induction of labor, prolonged labor, and first or second stage of labor.[7]

Despite the identification of many characteristics associated with postpartum hemorrhage, most parturients with significant hemorrhage present no recognizable risk factors. Due to the inability to reliably predict patients at high risk for obstetric hemorrhage, all parturients should be considered susceptible.[8]

The first line of treatment for postpartum hemorrhage involves the use of uterotonic pharmacological agents (oxytocin, ergometrine, and misoprostol),[9,10] and/or drugs that act on blood clotting (tranexamic acid).[11] It is noteworthy that 10 to 20% of patients do not respond to these interventions (a subgroup called refractory postpartum hemorrhage), where most of the morbidity and mortality related to postpartum hemorrhage is concentrated.[6]

In cases that are refractory to conventional treatment, intrauterine arterial compression measures are necessary. Second-line interventions include the use of intrauterine tamponade with a balloon or gauze and uterine compression sutures. If these therapies do not stop the hemorrhage, patients may undergo radiological

uterine artery embolization, pelvic devascularization, or hysterectomy.[12]

In this context, intrauterine balloon tamponade is a non-surgical intervention (conservative treatment) that is less invasive, easy to apply, and can adequately control the hemorrhagic condition (success rate greater than 85% in cases refractory to conventional treatment).[13-15] Their use can avoid hemorrhagic shock and the use of more complex surgical techniques that often aggravate the clinical condition, such as hysterectomy and bilateral ligation of the internal iliac arteries.[16,17]

The characteristics of uterine tamponade include low operating cost, easy insertion into the cervix or using a surgical incision through hysterotomy, low displacement rate, minimal training, adequate conformability to the hemorrhagic area, and the possibility of monitoring blood loss through the drainage lumen.[16-19]

This review aimed to evaluate the effectiveness of intrauterine balloon tamponade for the treatment of postpartum hemorrhage, which could reduce the need for emergency surgical interventions and decrease maternal mortality.

Methods

A systematic review of randomized clinical trials, contemplating the steps contained in the Handbook for Systematic Reviews of Interventions (Version 6.2)[20] and reported through the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) was conducted.[21] This review was registered on the International Prospective Register of Systematic Reviews (PROSPERO; registration number: CRD42019135960).

Systematic reviews consist of a secondary study, delineated from a defined research question, that seek to provide a robust overview of the effectiveness of an intervention, problem, or research field. The methodological structure includes: question formulation; study location and selection; critical evaluation of studies; data collection; data analysis and presentation; and data interpretation.[20]

The detailed specification of the review question requires the consideration of several key components that can be encompassed by the mnemonic PICO (population/problem, intervention, comparison, and outcome). Thus, the following question was formulated: how effective are different intrauterine balloon tamponade technologies in controlling postpartum hemorrhage (primary or secondary) compared to conventional treatments for the following: hemorrhage cessation, need for surgical interventions, and maternal mortality?

Randomized clinical trials that evaluated the use of different types of balloons for intrauterine tamponade as a strategy for reducing or stopping postpartum hemorrhage compared to other interventions (pharmacological or surgical) were considered for inclusion.

There were no restrictions regarding the publication date, sample size, and publication language. The exclusion criteria were studies with another methodological design, or that described the use of other hemorrhagic control strategies or the use of uterine tamponade devices in post-abortion obstetric hemorrhage, traumatic conditions, and prepartum.

To identify the relevant studies, a systematic search was conducted in the PubMed/MEDLINE, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL) databases using the Medical Subject Headings (MeSH terms): postpartum hemorrhage and intrauterine balloon tamponade. The combination of descriptors and their synonyms was achieved through the use of Boolean operators represented by the connectors AND (restrictive combination) and OR (additive combination) and the truncation symbols "*" (Cochrane and PubMed) and "$" (Web of Science), which identify singular or plural words and linguistic variations for the same descriptor (Table 1).

A manual search for gray literature was also performed in the ClinicalTrials.gov database (US National Library of Medicine). Furthermore, the reference lists of the retrieved clinical trials were searched to identify potentially eligible studies that were not otherwise found using the above search strategy.

Two reviewers performed the search independently. Each reviewer selected potentially eligible studies using the inclusion criteria. The two lists obtained were compared, and in case of differences (for the inclusion or exclusion of studies), a third reviewer participated in the decision-making process.

From the list of included studies, each clinical trial was scrutinized by the two reviewers, who determined the internal validity and collected qualitative data (authors, year of publication, country of origin, journal, and publication database) and clinical data (total

number of participants, distribution of subjects in the control and intervention arms, number of subjects, and type of intervention) as well as data on the segment time, segment loss, analyzed outcomes, and adverse events.

The level of agreement between reviewers regarding the inclusion or exclusion of studies was determined by the Kappa measurement. Internal validity was determined using the Cochrane Collaboration tool to assess the risk of bias of randomized clinical trials (risk of bias tool), available in Review Manager (version 5.3).[22]

Table 1 - Search strategy and databases

Databases	Keywords
Pubmed MEDLINE	(((((((("uterine compression"[Title/Abstract] OR "uterine compression"[All Fields]) OR "postpartum balloon"[Title/Abstract]) OR "postpartum balloon"[All Fields]) OR "intrauterine balloon tamponade"[Title/Abstract]) OR "intrauterine balloon tamponade"[All Fields]) OR "bakri balloon"[Title/Abstract]) OR "bakri balloon"[All Fields]) AND "postpartum h*emorrhage"[Title/Abstract]) OR "postpartum h*emorrhage"[All Fields] AND ((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials as topic[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading])
Web of Science	(("postpartum hemorrhage") AND ("intrauterine balloon tamponade" OR "uterine compression" OR "postpartum balloon" OR "Bakri balloon")) AND TOPIC: ((trial))
Cochrane CENTRAL	SEARCH #1: "uterine compression*":ti,ab,kw SEARCH #2: "postpartum balloon":ti,ab,kw SEARCH #3: "intrauterine balloon tamponade": ti,ab,kw SEARCH #4: "bakri balloon":ti,ab,kw SEARCH #5: "postpartum h*emorrhage":ti,ab,kw SEARCH #6: (#1 OR #2 OR #3 OR #4) AND #5

In this evaluation, the data from the studies were judged for the following domains: selection bias (generation of the randomization sequence), performance bias (blinding of participants and professionals), reporting bias (selective outcome report), attrition bias (incomplete outcomes), and detection bias (blinding of outcome evaluators). The domains were classified as "low risk of bias," "high risk of bias", and "undetermined risk of bias".

The included studies were also classified according to the allocation concealment defined by the Cochrane Handbook (6.2). Category A: appropriately described allocation process. Category B: although the allocation process has not been described, the study points to randomization. Category C: allocation concealment was conducted inappropriately. Category D: there was no evidence of randomization.

In addition, the checklist of the Template for Intervention Description and Replication (TIDieR) was used. TIDieR is a tool designed to improve the description of interventions in randomized clinical trials by establishing standards for reporting these procedures, which includes the identification of the type of intervention to facilitate the link with similar reports, clinical indication, rational justification for the technology under study, complete description of materials, execution protocol, and information about the intervener, method of intervention delivery, characteristics or circumstances of the place of performance, dose, and scheduled use.[23] Other elements covered are the report of adaptations and modifications during the process, if they occurred, adherence of the researcher or participant in the integrity of the treatment, and evaluation of the intervention performed.[23]

There are no funding sources or conflicts of interest to declare in relation to this systematic review.

Results

The literature search resulted in the retrieval of 973 studies (Figure 1). The results agreement by the Kappa index was 0.166 (p = 0.022, CI95%).

Of the studies excluded in the second screening, 12 analyzed other obstetric conditions that resulted in hemorrhagic events, and 17 explored other interventions for the treatment of obstetric hemorrhage.

The internal validation of the four studies included a risk of bias assessment for the selection, performance, detection, attrition, and reporting domains. The reviewers' judgment for each domain made it possible to infer the general methodological quality of each study (Figure 2). The inter-rater agreement (Kappa) for the individual classification of domains was 0.573 (p < 0.001, CI95%).

All selected studies were classified as having a low risk of selection bias and used allocation methods such as a lottery[24,25] and computer-generated random sequence.[26,27]

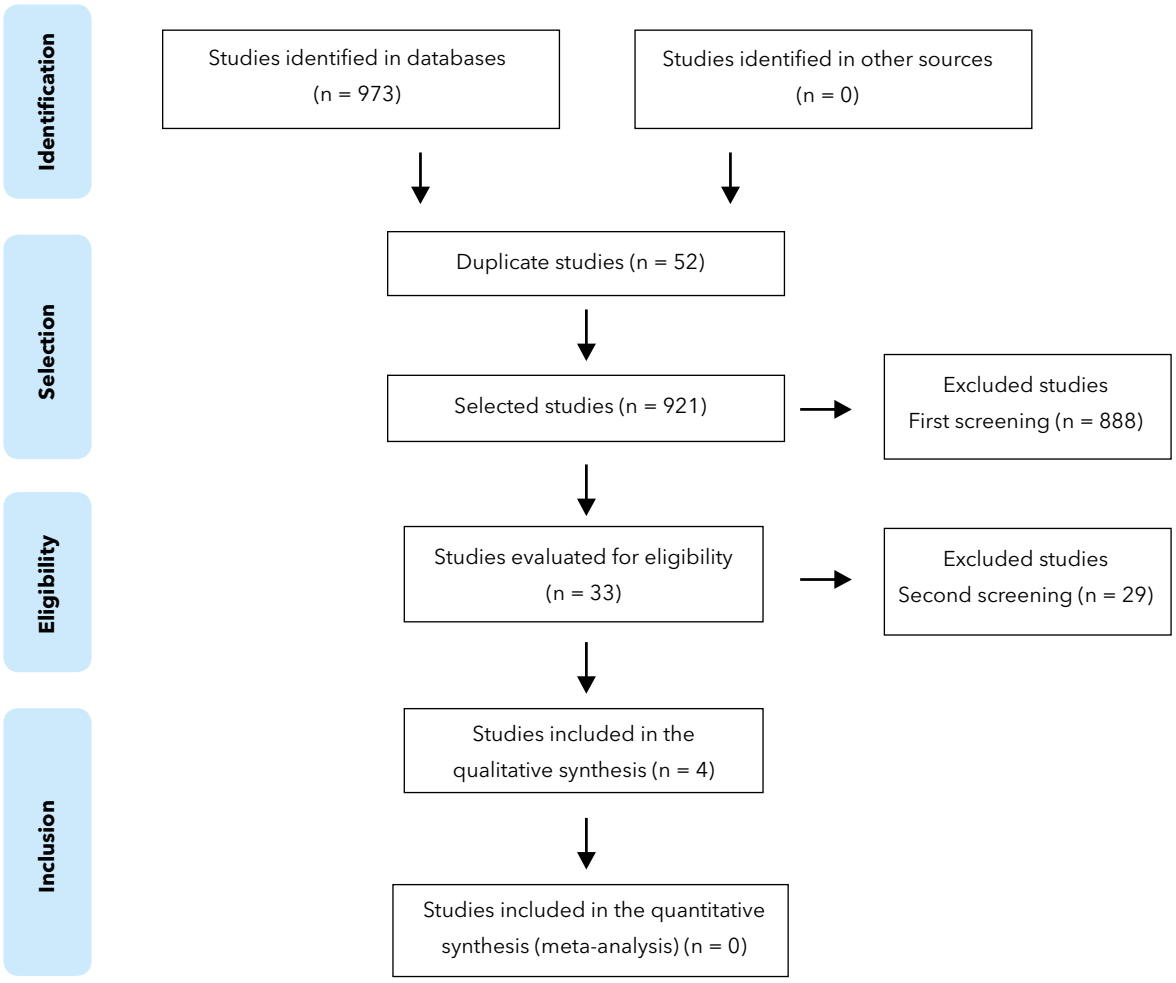

Figure 1 - PRISMA flowchart with the phases of the systematic review. Review Manager version 5.3.

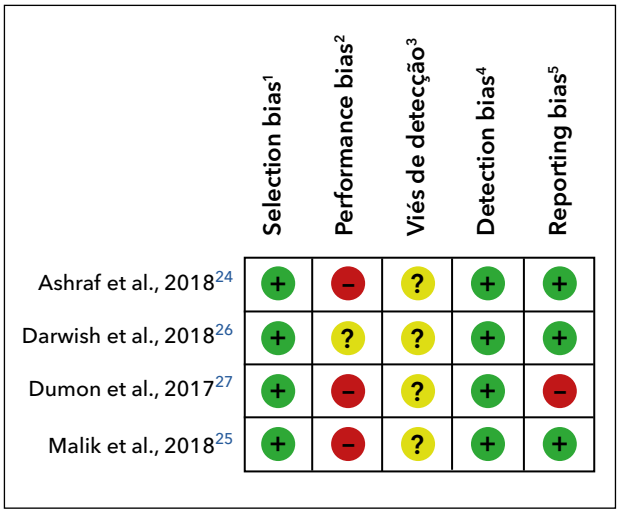

Figure 2 - Bias risk summary. Review Manager 5.3., 2021.

Note: [1]Allocation concealment; [2]Blinding of participants and personnel; [3]Blinding of outcome assessment; [4]Incomplete outcome data; [5]Selective reporting. + Low risk of bias – High risk of bias ? Undetermined risk of bias.

Significant clinical heterogeneity was present in 75% of the studies, resulting in a high risk of performance bias. No study showed significant segment losses in the treatment and control groups or disproportionately distributed participants between the intervention and control groups.

Despite the non-compliance with selective reporting of results, one study received funding and was therefore classified as having a high risk of reporting bias.[27] Nevertheless, the funding of this study by the United

Nations Children's Fund was justified due to the limited resources available where the study was conducted.

The critical evaluation of the studies for allocation concealment showed that four trials were classified as category A, as they adequately described the allocation process.

The evaluation of the quality of the intervention report found that all of the clinical trials described the intervention and scientific basis for its use. Only one study did not provide details of the materials used in the intervention.[24] Two studies detailed the execution of the intervention,[26,27] while one did not provide enough descriptive data.[24] None of the studies provided enough information about the intervener's skills.

All interventions were conducted in a hospital environment due to the characteristics of the studied problem. The patients received the intervention only once, with variations in the insufflation volume of the devices and in their permanence time. Intervention modifications or adaptations were not mentioned due to the individual conditions of patients. The studies did not discriminate the assessment of the fidelity of the studied interventions.

A list of the selected studies with their respective references, authors, year of publication, title, and journal/base is presented in Table 2. The clinical data, including the number of participants, intervention and control arm, main evaluated outcomes, and adverse events, are summarized in Table 3.

Table 2 - Narrative synthesis of the general data of the studies

Author/Year	Country	Title	Journal/Database
Dumont et al., 2017[27]	France	Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: a randomised controlled trial in Benin and Mali	BMJ Open/Pubmed
Ashraf et al., 2018[24]	Pakistan	Efficacy and safety of intrauterine balloon tamponade versus uterovaginal roll gauze packing in patient presenting with primary postpartum hemorrhage after normal vaginal delivery	Annals of King Edward Medical University/Web of Science
Darwish et al., 2018[26]	Egypt	Bakri balloon versus condom-loaded Foley's catheter for treatment of atonic postpartum hemorrhage secondary to vaginal delivery: a randomized controlled trial	J Matern Fetal Neonatal Med/ Pubmed
Malik et al., 2018[25]	Pakistan	Comparison of intrauterine balloon tamponade and B Lynch suture in severe postpartum hemorhage	Pak Armed Forces Med J/ Web of Science

Table 3 - Narrative synthesis of the clinical data from the included studies

Study	Intervention group	Control group	Main outcomes
Dumont et al., 2017[27]	Handmade intrauterine balloon closure: male condom adapted to Foley catheter associated with Misoprostol (n = 57)	Rectal and sublingual misoprostol (n = 59)	The proportion of women who needed interventions (arterial ligatures, uterine compression, sutures, hysterectomy) did not differ between the intervention (16%, 9/57) and control groups (7%, 4/59). The mortality rate was higher in the intervention group (10%, 6/57) than in the control group (2%, 1/59) (p = 0.059).
Ashraf et al., 2018[24]	Handmade intrauterine balloon tamponade: male condom adapted to a Foley catheter (n = 106)	Uterine tamponade with gauze pads	In the intervention group, treatment was effective in 82 (77.4%) cases, while in the control group, treatment was effective in 63 cases (59.4%).
Darwish et al., 2018[26]	Bakri balloon (n = 33)	Handmade intrauterine balloon tamponade: male condom adapted to Foley catheter (n = 33)	The Bakri balloon was effective in 91% of cases compared to 85% of patients in the control group.
Malik et al., 2018[25]	Balloon tamponade with four Foley catheters (number 24) inserted simultaneously (n = 52)	B-Lynch compressive sutures (n = 52)	The success rate of the B-Lynch suture was 88.46% compared to intrauterine balloon tamponade (67.31%).

Discussion

A total of 498 patients from four randomized clinical trials were included in this review. The included studies used different tamponade techniques, such as the Bakri balloon,[26] a product specifically designed to control postpartum uterine bleeding, a handmade system consisting of a male condom adapted to a Foley catheteor preservativo masculino adaptado ao cateter Foley,[24,26,27] and simultaneous insertion of four Foley probes.[25]

The overall success rate was 80% within about 15 min after the intervention. The mean volume of saline solution used to fill the different devices ranged between 400 and 500 mL. After the cessation of the hemorrhagic condition, the permanence time of the balloons varied between 4 and 24 h. No adverse events were reported.

One of the tests compared the Bakri balloon and handmade tamponade technique. The time required for hemorrhagic control (between device insertion and hemorrhage cessation) was shorter in the Bakri group than in the control group (9.09 and 11.76 min, respectively.[26] One of the limitations of condoms is that they do not support insufflation with volumes greater than 250 to 300 mL, causing the device to break. Furthermore, its texture does not allow for adequate compression of the uterine cavity.[28]

Blood loss estimation was performed visually,[27] through clinical evidence of a changed hemodynamic status (blood pressure and heart rate),[26] and amount of blood-saturated swabs.[24,25] Intervention failure was defined as the persistence of hemorrhage 15 min after the insertion and inflation of the artifact, or as balloon displacement with the need for additional interventions to control the hemorrhage. Intervention failure was observed in 58 cases (20%), in which the patients underwent procedures such as uterine artery ligation, uterine compression, B-Lynch suture, or hysterectomy. Two trials did not describe the interventions used for hemorrhagic control after the failure of uterine tamponade devices.[24,25]

Only one of the studies cited maternal mortality as a secondary outcome. The reported mortality was higher in the intervention group but, of the six patients who died, four did not actually undergo the intervention.[27]

A systematic review of non-randomized studies evaluating the use of different intracavitary uterine tamponade devices, including a condom catheter (ESM-UBT), Foley catheter, and Sengstaken-Blakemore esophageal tube in settings with few medical resources demonstrated success in controlling postpartum hemorrhage in 234 of the 241 patients evaluated.[18]

These findings corroborate a meta-analysis that evaluated studies with different designs. The overall success rate of uterine balloon tamponade was 85.9% (CI95%, 83.9-87.9%). Hemorrhage control was lower in cesarean deliveries (81.7%) compared to vaginal deliveries (87%). The frequency of complications attributed to the use of uterine balloon tamponade was low (≤ 6.5%).[29] It is noteworthy that the main findings described come from observational studies.

A retrospective cohort study of 72,529 women who delivered between 2011 and 2012 in 19 French maternity hospitals and were allocated to either a pilot group (balloon tamponade) or control group was reviewed. Invasive procedures (pelvic vessel ligation, arterial embolization, hysterectomy) were used in 298 women (4.1/1,000 deliveries, CI95% 3.7-4.6). The proportion of patients that underwent at least one invasive procedure was significantly lower in the pilot group (3.0/1,000 versus 5.1/1,000, $p < 0.01$). Of the women who had a vaginal delivery, the use of arterial embolization was also lower in the intervention group (0.2/1,000 versus 3.7/1,000, $p < 0.01$), as well as in those who had a cesarean section (1.3/1,000 versus 5.7/1,000, $p < 0.01$).[30]

In a case series of 163 women with refractory hemorrhage, 160 (98%) survived after the insertion of a uterine balloon.[31] The early implantation of these devices reduced the number of fatalities and the rate of hysterectomy in obstetric patients, both in primiparous and multiparous women with postpartum hemorrhage who did not respond to uterotonic drug treatment.[32] A decreased mortality rate was also observed when the devices were installed during the progression to shock conditions.[33]

Although the use of intrauterine balloon tamponade in patients with postpartum hemorrhage primarily aims to control the hemorrhage, this intervention is also considered to be "uterus sparing" and has been shown to affect menstrual outcomes, fertility, and future pregnancies minimally.[34,35]

Although the overall success rate reported in observational studies and clinical trials is significant, it is necessary to consider the predictors of intervention failure. Variables such as obesity, multiple pregnancies,

cesarean delivery, previous curettage, prolonged surgery, and placenta accreta spectrum have been identified as independent risk factors associated with uterine tamponade failure.[36,37]

Conclusion

We did not find enough evidence on the clinical effectiveness of uterine tamponade devices to recommend their use as a protocol practice in the treatment of patients with refractory atonic obstetric hemorrhage. The low methodological quality of the clinical trials included and the challenges in synthesizing and grading evidence from different types of studies due to clinical heterogeneity represent important obstacles in obtaining robust and reproducible evidence.

However, the use of an intrauterine balloon (including handmade methods) to control postpartum hemorrhages seems to be promising in cases with conventional pharmacological therapy failure. Furthermore, it is a conservative strategy that should precede surgical interventions. Intrauterine balloons could help decrease maternal morbidity and mortality and preserve fertility, especially in areas with limited access to specialized health services.

Prospective, multicentric, large-scale studies with better methodological quality need to be conducted in the future to achieve advances in obstetric clinical practice. In addition, the use of TIDieR is recommended for future studies as this would enable better study reproducibility in different contexts and result validation.

Authors' contribution

MMD: research project design, general orientation, manuscript writing, third reviewer. FMB: manuscript writing, search strategy, first reviewer, search strategy development, and execution. CMT: review and final writing, complementary searches, support with methodology (Cochrane Handbook). WAM: manuscript writing, search strategy, second reviewer, search strategy development, and execution. ARF: support with methodology (Cochrane Handbook, PRISMA, Review Manager, risk of bias tool, translation). SOI: review, final writing, and academic support.

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