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Bakri Balloon as Last Non-Surgical Therapeutic Action to Control Postpartum Hemorrhage

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Abstract

Postpartum hemorrhage is defined as blood loss greater than 500 ml after vaginal delivery or 1000 ml after caesarean section. This alteration is among the most frequent obstetric complications and with the highest mortality rate, in fact, postpartum haemorrhage is currently one of the leading causes of maternal death worldwide, considering that 25% of maternal death is caused by this complication, that is why its early diagnosis and management should be known by any doctor, regardless of the level at which they are. It is also important to highlight the role of this complication, both due to its magnitude and the need to develop methods that manage to mitigate the problem, thus causing the existence of various tools available to avoid or minimize its occurrence, currently counting on multiple medical interventions, surgical and non-surgical potentially effective for its treatment, such as the Bakri Balloon. Which is considered a non-invasive, fast and safe method to treat postpartum hemorrhage mainly secondary to uterine atony?

Keywords: Hemorrhage; Postpartum; Bakri balloon; Control; Blood loss; Therapeutic measure

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Introduction

Postpartum hemorrhage or also known by its acronym as PPH, is considered blood loss greater than 1000 millilitres or bleeding associated with signs/symptoms of hypovolemic within the first 24 hours after birth, regardless of the route of delivery, other authors define it as any blood loss greater than 500 milliliters after a vaginal delivery or greater than 1000 milliliters after a caesarean section, or any blood loss after delivery that causes hemodynamic instability, always taking into account the type of delivery performed [1]. However, despite advances in the field of obstetrics, obstetric hemorrhage remains one of the main causes of maternal death in several countries, in fact, it was estimated that at least 25% of deaths are due to these haemorrhages and, additionally, 14 million women suffer from postpartum hemorrhage and of these it is estimated that more than 125,000 women die of PPH in the world annually, likewise, it is well known that 99% of these deaths occur in developing countries with an onset of characteristic signs and symptoms in women such as: dizziness, loss of consciousness, presence of hypotension, acceleration of heart rate, and an abnormal reduction in urine during a period of twenty-four hours [2]. Therefore, without a doubt, the authors affirm that it is a significant obstetric emergency, for this reason it is very important that the doctor detects the risk factors Table 1 of the patient and possible

causes, for a correct prevention during consultations for prenatal controls, for a subsequent early diagnosis and thus provide the most appropriate treatment, according to the needs of the case [3, 4] **(Table 1)**.

Among the causes, the most common capable of triggering postpartum hemorrhage is uterine atony, which complicates 1 in 40 births in the United States and is responsible for at least 75% of cases of postpartum hemorrhage, followed by trauma that Generally, damage resulting from precipitous or uncontrolled delivery or instrumental delivery of a large infant is considered; however, they can occur after any delivery due to lacerations and surgical incisions. Other widely described causes are retention of placental tissue and coagulation defects, as shown in Figure 1. In the first case, it refers to the absence of expulsion of the placenta. placenta after 30 min after delivery, this period can be extended to 90-120 minutes in deliveries in the second trimester and the main risk factor for retained placenta is gestational age less than 26 weeks and in the latter case, disease Von Will brand's is the most common hereditary coagulopathy with a prevalence of 1.3%, however, coagulopathies acquired in pregnancy are more frequent, which can be due to various obstetric disorders, including placental abruption, excess thromboplastic due to a retained fetal death, fluid embolism among others [5,6] **(Figure 1)**.

In addition to knowing the causes and risk factors of postpartum hemorrhage, it is also essential for the doctor to know the time elapsed since the start of the hemorrhage to prevent mortality; for this, there is a classification of hemorrhages after childbirth. Such classification is divided into two aspects as shown in Figure 2, in the first instance there is primary or early postpartum hemorrhage that occurs within the first 24 hours of the puerperium and according to the medical literature, uterine atony is the most frequent cause that It triggers it where it causes a failure in the myometrium contraction mechanism, promoting the inability of the uterus to contract and restore itself, after the delivery of the fetus, while, in the second instance, there is late or secondary postpartum hemorrhage that occurs after the 24 hours up to 6 weeks, although some authors mention 12 weeks after vaginal delivery or caesarean section, whose Etiology may be due to retention of products of conception, infection or both [7] **(Figure 2)**.

Table 1. Risk factors that can induce postpartum hemorrhage and their classification.

More frequent	Moderately frequent	Others
● Retention of placental material ● Second progress failure labor stage ● Adherent placenta ● Lacerations	● Instrumental delivery ● Newborn large for age gestational ● Hypertensive pathology ● Labor induction	● Personal or family history of previous postpartum hemorrhage ● Uterine distention ● Obesity ● High parity ●Asian race or Hispanic ●Hasty labol ●Chorioamnionitis ●Uterine inversion ●Leiomyoma ●Anemia
Clasificacion del Riesgo		
Low risk	**Medium risk**	**High risk**
● Less than or equal to four deliveries previous vaginal ● Without previous surgery. ● No history of bleeding postpartum. ● No bleeding disorders acquaintances	● More than four vaginal deliveries previous. ● Multiple Gestation ●Chorioamnionitis ●Large fibroids ● History of postpartum hemorrhage	●Adherent placenta, placenta previa or low placenta. ● Hematocrit less than 30% more ● Other risk factors. ● Active bleeding ● Known coagulopathy ● Platelets less than one hundred thousand

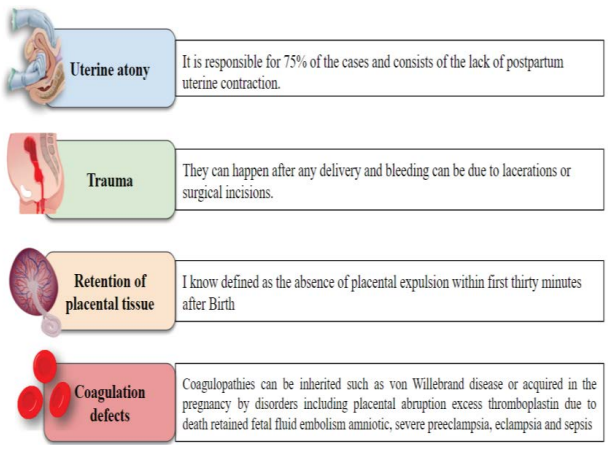

Figure 1 Main causes that can cause postpartum hemorrhage.

According to the WHO, global maternal mortality has been reduced by approximately 44% between 1990-2015, despite the decrease in the percentage of deaths; the figures remain high in developing countries, mostly due to deaths after hemorrhages. Postpartum. Due to these figures, the current goal to reduce the rate of maternal death due to hemorrhage in the world is less than 70/100,000 live births in a period between 2016-2030 [8]. For this and what has been mentioned throughout In this bibliographic review, it is considered important to highlight the role of this complication, both due to its magnitude and the need to develop methods that manage to mitigate the problem, thus causing the existence of various tools available to avoid or minimize its occurrence, currently counting on multiple potentially effective medical and surgical interventions for its treatment as shown in **(Table 2)** [9, 10, 11].

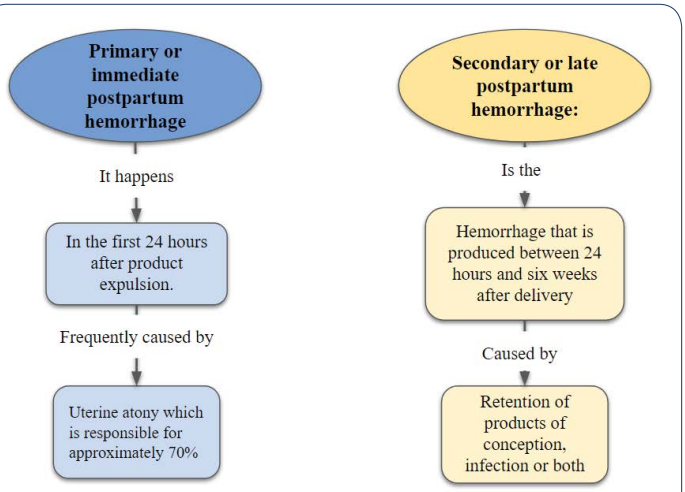

Figure 2 Classification of Postpartum Hemorrhage.

Among the interventions described to treat postpartum hemorrhage, there are the non-surgical ones that arise with the purpose that doctors, in any kind of hospital, regardless of their level, can provide the best management of the complication in question, in a simple way. fast and safe. This prevents a permanent invasive surgical procedure and death. Among the non-surgical techniques highlighted as the latest therapeutic action is the Bakri balloon, discovered in 1992 by Bakri, which is made up of

Table 2. Possible interventions for the treatment of postpartum hemorrhage.

Pharmacological interventions	
Drug	Dose
Oxytocin	10 to 40 units in 500 to 1000ml in saline solution infused at a speed sufficient to control atony or 10 intramuscular units
Tranexamic acid	Infuse 1g (10ml of a 100mg / ml solution) for 10 to 20 minutes; if bleeding persists after 30 minutes, a second 1g dose
Ergotamines	Methylergonovine 0.2 mg IM every 2 to 4 hours or ergometrine 0.5 mg IV or IM or ergonovine 0.25 IM or IV every 2 hours.
Misoprostol	800 to 1000 mcg rectally
Dinoprostone	20 mg vaginal or rectal every two hours
Recombinant factor VIIa human	50 to 100 mcg / kg every two hours
Surgical interventions	
Laceration repair| Curettage Uterine suture Uterine artery ligation Utero-ovarian artery ligation Pelvic packing Uterine tourniquet Focal myometrial excision Internal iliac artery ligation Aorta / iliac artery compression Hysterectomy	
Endovascular Interventional Procedures	
• Selective arterial embolization • Intermittent aortic artery occlusion with balloon • Intermittent common iliac artery balloon occlusion	
Blood bank	
• Packed blood cells • Platelets • Fresh frozen plasma • Cryoprecipitate	
Non-surgical interventions	
• Uterine massage • IV fluids • Uterine tamponade • Bakri's ball	

Source: Dahlke DJ, Mendoz-Figueroa H, Maggio L, Hauspurg AK, Sperling JD, Chauhan SP, Rouse DJ. Prevention and management of postpartum hemorrhage: a comparison of 4 national guidelines. Am J Obstet Gynecol.

100% silicone (without latex) as shown in **Figure 3**, with a ductile shape that allows it to conform to the uterine anatomy. It has a probe with two pathways: One for balloon inflation and the other to drain the uterine cavity (occult bleeding), where it allows the application of up to 500 g of traction tension. Once deflated it is very easy to remove, which is why it is considered a non-surgical procedure. In addition to the catheter, a 50 mL syringe, drainage bag, saline solution (500 mL), Foley catheter, and antiseptic gauze for vaginal plug are required. It can be inserted transvaginally or abdominally, depending on the type of delivery, provided that uterine rupture, tears and retention of placental fragments is ruled out [12]. Generally, this measure is used to control hemorrhage. In fact, massive blood loss must be avoided through three basic manoeuvres and a fourth action, which is the application of the Bakri balloon. The three established containment manoeuvres are: abdominal aortic compression, bimanual compression and vaginal clamping of the uterine arteries, and lastly the use of a Bakri balloon, the latter being the first paradigm shift, which aims to prevent bleeding by immediately closing the site of bleeding originating after delivery [13]. Similarly, it is well known that among the advantages of this technique, the Bakri ball is a very useful and easy method to perform, which requires a minimum level of training, in addition, it has a high level of safety, with a rate of success reported in the different series that ranges between 75 and 97%, where postpartum hemorrhage was stopped and surgical resolution was avoided, this device manages to stop bleeding, without requiring invasive or permanent techniques, nor does it associate long-term complications, which it becomes a last form of therapeutic action although some authors mention it as a first-line use [14].

Materials and Methods

A detailed bibliographic search of the most relevant published information is carried out in the databases PubMed, scielo, medline, national and international libraries specialized in the topics covered in this review article. The following descriptors were used: Hemorrhage, Postpartum, Bakri balloon, Control, Blood loss, Therapeutic measure. The data obtained range between 5 and 40 records after the use of the different keywords. The search for articles was conducted in Spanish and English, limited by year of publication, and studies published from 2013 to the present were used.

Results

After applying the search strategies in the different databases, between 5 and 30 records were obtained that met the inclusion criteria. The study by Aibar et al. aimed to evaluate the effectiveness of the Bakri balloon (BBT) in the treatment of postpartum hemorrhage. After the analysis of 24 women with postpartum hemorrhage treated with a Bakri balloon as a conservative therapeutic option. The Bakri balloon managed to control bleeding in 87.5% of women. It was effective in all women with vaginal delivery (five out of five) and in all women with uterine atony who did not respond to medical uterotonic therapy (eight out of eight) [15]. Likewise, Gronval et al. present a series of cases where they conclude that the bakri balloon is a simple, easily available, effective and safe procedure for the treatment of PPH in selective cases. Even if BBT fails, it can provide temporary packing and time to prepare for other interventions or transport from the local hospital to the tertiary center. From their results with an overall success rate of 86% [16]. However, in a study where the effectiveness of the Bakri balloon was estimated for the treatment of postpartum hemorrhage in 35 women, the success rate was 67.57%. Bakri failure was associated with caesarean section (67% versus 16%, $p = 0.031$) and Pitocin before delivery (67% versus 28%, $p = 0.003$) and with more ICU admissions (58% versus 4%, $p = 0.0003$), transfusions (5.4 units of red blood cells vs. 1.6, $p = 0.007$) and days of hospitalization (5.65 vs. 3.75, $p = 0.011$). The reasons for failure were continuous bleeding or extrusion of the balloon [17]. Other reports report that the Bakri balloon is the quick and least invasive method for the treatment of bleeding due to placenta previa with minimal complications, since the Bakri tamponade was effective in 22 cases (88%) and in the cases in which that failed required additional procedures such as hypo gastric artery ligation, B-Lynch suture, and hysterectomy [18]. BBT is an effective, easy-to-use, and safe procedure for

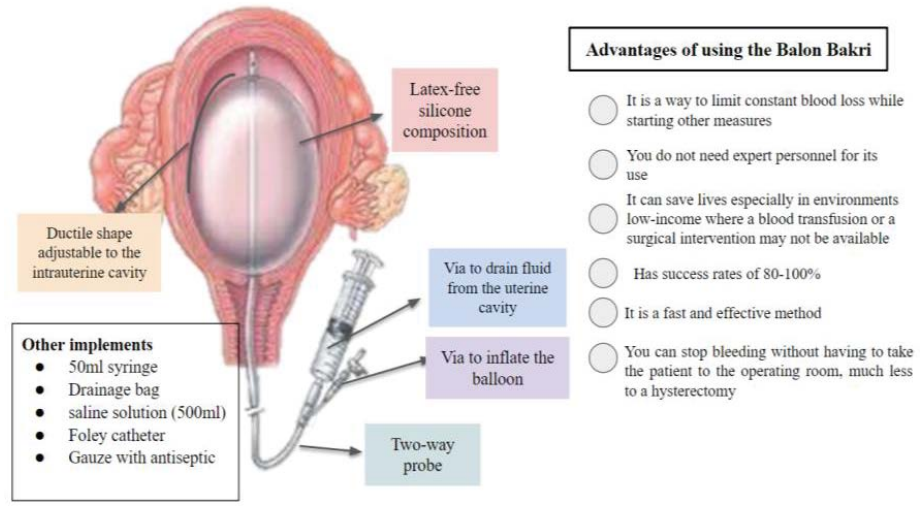

Figure 3 Parts of the Bakri balloon and advantages of its use as the last non-surgical therapeutic action to control postpartum hemorrhage.

massive PPH that can minimize recourse to hysterectomy after failed medical treatment, reflected in 43 women where its use was successful with an overall success rate 91.4%, since the remaining 4 cases required an additional surgical procedure [19]. In addition, rapid diagnosis or prognosis of PPH, in combination with early use of the Bakri postpartum balloon, is important. The success rate is quite similar between studies, it was 91.65% (373/407 women) in another report. Furthermore, blood loss before and after balloon insertion was significantly higher in the Bakri balloon failure group (1700 ± 1429.88 mL before and 1209.58 ± 1139.72 mL after balloon use) than in the success group [918 ± 493.92 ml before (P = 0.002) and 266.57 ± 361.60 ml after using the balloon (P = 0.001)] [20]. Brown et al. They carried out a retrospective study including 58 patients, in whom postpartum bleeding was controlled without further surgical intervention in 55 (95%) with the use of the Bakri balloon, successfully controlling PPH in 52 women [21]. A single-blind randomized controlled trial conducted at Assiut Women's Health Hospital compared condom-loaded Foley catheter versus Bakri balloon in the treatment of primary atonic postpartum hemorrhage (PPH) secondary to vaginal delivery in 66 women, the results indicate that Both treatment modalities successfully controlled primary atonic PPH without a statistically significant difference [30/33 (91.0%) and 28/33 (84.84%), p = .199; respectively]. But the Bakri balloon had the advantage of requiring a shorter time to stop uterine bleeding (9.09 min vs. 11.76 min, p = 0.042, respectively) [22]. Other studies have tested the Bakri balloon with other therapeutic techniques in combination to be more effective than the use of BBT alone, as indicated by the results of Guo et al. where a group of study patients underwent double compression, and these patients had a better clinical efficacy rate of 96.3% (157 of 163), while the efficacy in cases using the Bakri balloon alone (group control) was 87.3% (124 of 142). Postoperative complication rates for these two groups were 9.4% and 8.7%, respectively [23]. It is also important to note that the introduction of the Bakri balloon is consistent with a decrease in the postpartum hysterectomy rate from 7.8/10,000 deliveries to 2.3/10,000 deliveries (p = 0.01) [24]. The same thing happened in the report by Maher et al. where they identified one hundred fifty-one cases such as low-lying placenta and PP, of which 114 developed PPH. Two patients were unstable and required immediate hysterectomy. The remaining 112 cases were managed using balloon (72 cases) or non-balloon (40 cases) protocols. The balloon only achieved haemostasis in 87.5% of cases. When specifically analyzed, balloon success was associated with no accreta (odds ratio 0.001, confidence interval 0.000–0.974) and short operative time (odds ratio 1.143, confidence interval 1.018–1.282), so they concluded that the application of the Bakri balloon for the management of PPH after caesarean section in cases of PP is an effective strategy [25]. In the report by Soyama et al. Of the 266 women with placenta previa, 50 were in the balloon group and 216 in the non-balloon group. The amounts of bleeding were significantly less in the balloon group than in the non-balloon group: intraoperative bleeding (991 vs. 1250 g, p < 0.01), postoperative bleeding (62 vs. 150 g, p < 0.01) and total bleeding (1066 vs. 1451 g, p < 0.01). In addition, the mean duration of surgery was shorter in the balloon group than in the non-balloon group (30 vs. 50 min, p < 0.01). In the balloon group, five patients experienced increased bleeding due to balloon prolapse from the uterus postoperatively, but the bleeding was controlled by balloon reinsertion without additional haemostatic procedures. Therefore, using a Bakri balloon during caesarean section significantly decreased intraoperative and postoperative bleeding [26]. In the presentation of a clinical case of a 29-year-old woman who had PPH at the time of caesarean delivery, which was effectively controlled by placing an intraoperative Bakri balloon. On examination, approximately 1000 ml of blood loss was estimated and the uterus was still stunned, so at this time, a Bakri balloon was aseptically removed and placed in the uterine cavity, and 150 ml of normal saline to distend the balloon (refer to the discussion portion of the case report for full details of the placement technique). Slowly, the tamponade effect of the Bakri balloon improved the bleeding. Therefore, Bakri balloon tamponade is usually indicated as second-line therapy for severe PPH only when initial trials of bimanual compression of the uterus and uterotonic drugs fail to control bleeding. This appears to have minimal adverse effects on subsequent reproductive and menstrual function when intrauterine balloon tamponade is used for the treatment of severe PPH. Early use of intrauterine balloon tamponade is a way to effectively limit on-going uterine blood loss while other measures are initiated, and can be easily implemented by providers with minimal training [27].

Discussion

The results of the studies analyzed in this systematic review reveal the existence of a technique that replaces surgical therapy in cases of postpartum hemorrhage. It was Bakri who initially described (1992) the use of the balloon for the control of obstetric hemorrhage due to placenta previa accreta [28]. Recently, a summary of studies showed that intrauterine balloon tamponade (IUBT), such as the Bakri balloon (Cook Medical, Bloomington, IN, USA), is an effective tool to avoid invasive procedures treating persistent PPH, and 75% of women do not need further treatment after IUBT [29]. It is made of silicone, has a drainage lumen, and is shaped like a sausage-like spindle. The study by Sayori et al. agree with our results, as their findings suggest that Bakri balloon tamponade can be applied for the treatment of massive PPH in uterine atony and placenta previa. The Bakri balloon appears to have the following merits: (1) easy insertion into the uterine cavity and low slip rate, (2) adequate adaptability to the haemorrhagic area due to its spindle shape, (3) ability to control blood loss through the drainage lumen even after insertion. The median (third and first quartile ranges) duration of stay in the Bakri balloon was 24 hours (24-11 hours). The overall success rate of Bakri balloon tamponade was 90% (9/10) [30]. Additionally, the study by Cetin et al. He compared the therapeutic action of the Bakri balloon with the Hayman compression suture and his results indicate that the success rates of both methods were similar (76.7% in the Hayman group and 74.4% in the BBT group). In both groups, the success rate increased with the addition of arterial ligations (93% in the Hayman group and 87.2% in the BBT) [31]. Therefore, the literature reports that Bakri balloon tamponade is an effective, safe and practical method in the treatment of postpartum hemorrhage, based on the findings of a report, where the frequency of massive postpartum hemorrhage

was 0.61%. (n = 168). Among the 168 patients with massive postpartum hemorrhage, there were 50 patients in whom the Bakri balloon catheter was used and recovery was satisfactory [32]. It is also important to mention that in cases with placenta accreta/increta, with expected placental abruption and who are willing to preserve fertility, the application of uterine balloon tamponade devices before hysterectomy is encouraging with its advantages compared to hysterectomy. , as indicated by the results of Pala et al. since among the 36 patients diagnosed with placenta accreta or increta, 19 patients were treated with Bakri balloon tamponade while 17 cases were treated with hysterectomy. Intraoperative blood loss was 1,794 ± 725 ml in G1, less than in G2 (2,694 ± 893 ml). The amount of blood transfusion was 2.7 ± 2.6 units in G1, lower than that in G2 (5.7 ± 2.4 units) as well. The operation time was 64.5 ± 29 min and 140 ± 51 min in G1 and G2, respectively, showing significant differences between the two groups, obtaining a Bakri balloon success rate of 84.21% [33]. However, a meta-analysis by Suarez et al. They conclude that the evidence on the efficacy of uterine balloon tamponade and the effectiveness of randomized and non-randomized studies is conflicting, with experimental studies not suggesting any beneficial effect, in contrast to observational studies [34]. Which is consistent with the conclusion of Said et al. that the Bakri balloon appears to be a more effective tool for the treatment of PPH, either after vaginal or caesarean delivery, in addition to finding that displacement of the Bakri balloon from the uterine cavity was reported in five publications, with an overall rate of 9% (95% CI: 5-15%) [35]. Even so, measurements of balloon displacement during inflation showed that the shaft cover significantly prevented the Bakri balloon from displacement. The volume of residual fluid in the upper uterine cavity was significantly less with the Kyoto balloon system than with the Bakri balloon system, indicating the efficacy of the Kyoto balloon for tamponade of the upper uterine cavity [36]. Thus, the main cause of BBT failure was balloon prolapse [37]. Strange situations can also occur as in the case that describes a very rare complication of Bakri Balloon during the treatment of postpartum hemorrhage; massive hem peritoneum with hemodynamic shock, due to migration through the right broad ligament, with anterior rupture of the uterus and irreversible injury to the right uterine artery [38]. Despite its advantages, if we compare it with other techniques it could be limited. The advantages of the B-Lynch suture include rapid application without the need for a lithotomy position or additional material; while the Bakri balloon is less invasive and easier to learn, but more time consuming and expensive compared to the B-Lynch suture. Therefore, they suggest that the B-Lynch suture may be preferred in uterine atony during caesarean section in low-resource settings; however, the less invasive Bakri balloon should be the first line in full resource settings [39]. The clinical implications they recommend are: women should not be required to fast to remove the balloon; balloon removal should occur at 12 hours if considered stable and adequately resuscitated; deflation and balloon removal can occur at the same time; and antibiotics should be discontinued after balloon removal. This will allow women to mobilize and recover sooner, and will improve flow and performance in our high-acuity care areas [40].

Conclusion

In conclusion, the use of the intrauterine Bakri balloon is a safe and effective technique for early management of postpartum hemorrhage, with extremely high success rates greater than 75%, regardless of its Etiology. What makes it even more considerable, in addition to its use as a last therapeutic action or even as a first line, is its ability to stop bleeding, thus completely stopping bleeding, without requiring a high level of experience to carry out the procedure. , without the use of invasive or permanent techniques, or associated with long-term complications.

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