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Expert Reviews | Expert Review

Traditional uterine tamponade and vacuum-induced uterine tamponade devices in obstetric hemorrhage management

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Abstract

Obstetric hemorrhage is the leading cause of maternal morbidity and mortality worldwide, and rates of severe hemorrhage are increasing. There is a critical need to expand treatment options for hemorrhage to address this global crisis. Over the last decade, the evolution of hemorrhage control devices has contributed to advancements in the management of obstetric hemorrhage. The number of existing hemorrhage control devices and techniques have increased markedly in recent years, and new devices are in development. In this review, we summarize the current evidence for established and investigational hemorrhage control devices. Two main categories of devices exist: traditional uterine tamponade and vacuum-induced uterine tamponade. While traditional intrauterine balloon tamponade devices are currently used widely in management of postpartum hemorrhage, novel hemorrhage control devices and techniques have been developed. These include the mini-sponge tamponade device, the Jada System, a modified Bakri balloon technique, and a suction tube uterine tamponade technique. Reassuring safety data and preliminary efficacy data from pilot studies of these novel techniques support the powerful role intrauterine devices can play in management of obstetric hemorrhage. We aim through this review to improve awareness of device options so that continued efforts can be made to integrate new technology into hemorrhage management protocols. Well-designed studies inclusive of new hemorrhage control devices are essential in order to understand where new technology fits into pre-existing obstetric hemorrhage algorithms. Additionally, access to new tamponade technology remains limited on a global scale. Programs aimed at increasing both access

to devices and expanding educational initiatives are essential to make new technology a standard component for hemorrhage management.

Condensation

Hemorrhage control device techniques are rapidly evolving and are on the forefront of improvements in obstetric hemorrhage management.

Introduction

Obstetric hemorrhage is the leading cause of maternal morbidity and mortality worldwide and evidence suggests that both hemorrhage rates and severity are increasing (1,2). Large population studies attribute increasing hemorrhage rates to rising rates of uterine atony (1,3). Markers indicative of severe hemorrhage are also increasing, with a rise in hemorrhage requiring blood transfusion and hemorrhage requiring additional procedures such as tamponade use, uterine artery embolization, or hysterectomy(4).

New strategies are urgently needed to identify and promptly treat postpartum hemorrhage (PPH) in both low and high resource settings. Over the past decade, considerable effort has been invested in developing novel devices and techniques for uterine tamponade.

Intrauterine balloon tamponade (IUBT) was first introduced into practice in 1999 and consists of passing a transcervical catheter that is inflated with saline once it is intrauterine (5). IUBT has become a mainstay of refractory hemorrhage treatment worldwide. While the Bakri balloon is a commonly utilized IUBT device in the United States, multiple types of IUBT exist and are used globally. New tamponade devices, such as the mini-sponge dressing are being developed. Additionally, there are new and innovative hemorrhage control devices and techniques are being developed that utilize different mechanisms of action to achieve hemorrhage control.

Our review summarizes the current literature surrounding established and investigational hemorrhage control devices. The two main categories of hemorrhage control devices include traditional uterine tamponade and vacuum-induced uterine tamponade.

Physiology of Hemorrhage and Uterine Tamponade

Etiologies of PPH vary widely and most commonly include uterine atony and placental site bleeding (eg. retained placenta or placenta accreta spectrum) but can also be due to tissue trauma or underlying coagulopathy. Existing tamponade techniques apply different physiology to achieve hemorrhage control and have basic differences in their proposed mechanism of action. Traditional tamponade devices apply positive pressure to the intrauterine myometrial wall and compress the arterial bed within the endometrial lining. The proposed mechanisms of action for these balloons include increasing the intrauterine pressure to greater than the systemic arterial pressure or by increasing the

pressure on the uterine arteries (6–8). Intrauterine balloon tamponade devices are generally left in place and monitored for 12 to 24 hours prior to device removal. Preliminary data suggests that the novel mini-sponge tamponade device may achieve bleeding control in significantly less time, with an average treatment time of 1 hour (9). Vacuum-induced tamponade devices involve negative pressure created inside the uterus which may encourage uterine myometrial contraction and improved uterine tone (10–12). When using a vacuum source, negative pressure is applied symmetrically inside the uterine cavity, facilitating uterine contraction and possibly constriction of myometrial blood vessels. The physiology of vacuum-induced tamponade mimics the natural forces of uterine contraction, lending to biologic plausibility of this method. Preliminary studies indicate that the indwelling time during clinical application of vacuum-induced tamponade is short, approximately 1 to 3 hours (12–14).

Traditional Uterine Tamponade

Intrauterine Balloon Tamponade

Intrauterine balloon tamponade (IUBT) devices have been used in cases of PPH particularly those related to uterine atony and placental related bleeding (including placenta previa and placenta accreta spectrum complications). There have been several types of IUBT devices described, including the Bakri, Ebb, Foley, Segstaken-Blakemore, Rush, condom catheter and Cook cervical ripening balloons. Each balloon has a different recommended maximum volume from the manufacturer (Table 1). The Rusch and condom catheter do not allow drainage of the uterine cavity, as neither has a continuous

inner channel (15). Use of the Barki with uterine compression sutures or uterine artery ligation has been described as well (16).

Intrauterine balloons can be placed after vaginal delivery or cesarean delivery. Techniques described for placement include transvaginal, with or without ultrasound guidance or via the hysterotomy at the time of cesarean. In the case of placement during a cesarean, the balloon is insufflated after closure of the hysterotomy to avoid suturing the balloon during the closure. Vaginal packing has been applied in cases of a dilated cervix, and was recommended by the Bakri manufacturer to avoid expulsion (8). The Ebb balloon is a two-chambers system, one to be placed intrauterine and the other outside of the cervix for additional tamponade and to avoid expulsion (17).

The optimal duration of IUBT use after placement for cases of PPH is not well studied in the literature. Einerson et al performed a retrospective cohort study of 274 women to evaluate the clinical outcomes following IUBT removal at greater than 12 hours versus 2 to 12 hours after PPH (18). The clinical outcomes included estimated blood loss after IUBT placement, blood product transfusion, and further invasive procedures (embolization or hysterectomy). There was no significant difference in any of these outcomes in the >12 versus 2-12 hour removal groups, however IUBT placement greater than 12 hours was associated with higher frequency of postpartum fever (27% versus 15%, p=0.047). Because of this, the authors concluded that removal can be considered at <12 hours after hemorrhage has abated.

While no randomized controlled trials have been published that evaluate the effectiveness of IUBT versus a control group, several observational studies have evaluated the

effectiveness of IUBT in management of postpartum hemorrhage. A systematic review and meta-analysis of 91 studies, including 4729 individual patients, found the overall success rate of IUBT was 86% (19). They defined success as the percentage of cases with IUBT that did not result in maternal death or additional surgical intervention, divided by the total cases with IUBT placement. The highest success rates in this review were in cases of atony (87%) and lowest in PAS (66%). In this series, 49% of studies used either the Bakri balloon or condom catheter. The success rate was slightly higher with vaginal deliveries (87%) compared to cesarean deliveries (82%).

Recent data indicates that small intervals of "delay" in PPH management can result in significantly increased blood loss. In a retrospective review of 128 cases of PPH (defined as blood loss greater than 500 mL in a vaginal delivery and 1000 mL in a cesarean delivery) by Knoll *et al*, they found each 5 minute delay from PPH onset to uterotonic administration resulted in a 26% higher odds of hypotension (21). In vaginal deliveries, this 5 minute delay was associated with a 31% and 34% higher odds of hypotension and transfusion, respectively. Therefore, several studies have evaluated timing of IUBT placement and found adding it to routine protocols and earlier placement reduces the need for further invasive procedures (22,23). Revert *et al* compared two systems, a "pilot system" with protocolized IUBT placement during hemorrhage management after uterotonic use and a separate protocol without this practice (22). The authors found the need for invasive procedures was significantly lower in the pilot network (3.0/1,000 vs 5.1/1,000, $p < 0.01$). After controlling for potential confounding factors, the risk of an invasive procedure among women who delivered vaginally remained significantly lower

in the pilot network (aOR 0.14, 95% CI 0.08-0.27), but not for women who delivered by cesarean (aOR 1.19, 95% CI 0.87-1.61). Kong *at al* evaluated 81 cases of IUBT placement and found placement at less than 1400 mL and a positive tamponade test (≤ 50 mL of blood drained from the uterus within the first 30 minutes after insertion of IUBT) were good predictors for success of IUBT (23).

Mini-Sponge Uterine Tamponade

The mini-sponge uterine tamponade device was adapted from the Xstat™ mini-sponge trauma device and is specific for management of PPH (9,24). In trauma models, the Xstat™ mini-sponge dressing effectively manages acute, traumatic, and non-compressible bleeding analogous to PPH and is capable of rapid cessation of high-flow arterial bleeding (25–27). In preliminary studies for PPH, the mini-sponges are deployed within a strong and flexible pouch that can be easily removed with gentle traction. Each mini-sponge is compressed to 4 to 5 mm but can expand to 40-50 mm within 20 seconds of blood contact. With blood contact, the sponges rapidly expand and exert an outward force, increasing intrauterine pressure to facilitate tamponade. During acute obstetric bleeding, the tip of the device is manually placed into the lower uterine segment and the mini-sponges are then deployed by pressure on the obturator. The device should remain in place until adequate control of bleeding is observed, and clinical stability is noted. In an early feasibility study, the sponges were left in place for 24 hours without evidence of infection or uterine trauma (24). The mini-sponges differ from the fixed shape of the IUBT devices, in that the mini-sponges expand rapidly within the space they are

deployed in and conform to the natural contour of the uterine cavity, exerting pressure throughout. The sponges are distensible, and easily removed back out through the cervix, with steady traction on the portion of the device that remains external.

In 2017, Rodriguez *et al* described the development of an obstetrical mini-sponge tamponade device prototype and preliminary safety and efficacy data in desktop and animal models (24). This report was the basis for a subsequent feasibility trial conducted in Zambia evaluating the placement, removal, and efficacy of the mini-sponge tamponade device in management of obstetric hemorrhage (9). The device was successfully placed in 9 patients who experienced bleeding of 500 mL or greater due to atony after vaginal delivery. Placement was fast with a mean insertion time of 62 seconds and effective with definitive bleeding control achieved in less than 1 minute in all cases. No sponges were expelled prematurely and all devices were successfully removed intact. Treatment length was at the discretion of the individual provider based on each patient's clinical course. Mean treatment duration for the 9 cases was 1 hour (range 0.5 to 14 hours). There were no adverse events related to device placement or removal. Individuals who were experiencing hemorrhage with hemodynamic instability were ineligible for device placement. This device has not been tested in women undergoing cesarean delivery.

Vacuum-Induced Tamponade

Jada System

Currently, the Jada System is the only vacuum-induced tamponade device approved by the U.S. Food and Drug Administration for use when excess bleeding is

identified at the time of delivery secondary to uterine atony. The Jada System can be utilized during obstetric hemorrhage at the time of vaginal delivery or cesarean delivery provided the cervix is dilated to 3 cm or greater (11). In a large U.S. based clinical trial, the Jada system was implemented when a quantitative blood loss (QBL) of 500 to 1,500 mL was encountered following vaginal delivery or 1,000 mL to 1,500 mL for cesarean delivery (12).

The Jada System is designed for single use and is comprised of medical-grade silicone. Its individual components include an intrauterine loop with shielded vacuum pores, a cervical seal with a seal valve for infusing saline, and a vacuum connector port to apply suction (Figure 2). The intrauterine loop is located on the distal end of a tube and contains 20 shielded vacuum pores oriented inward along the loop. This shielded design facilitates intracavitary suction by protecting maternal tissue from the vacuum source and preventing plugging of the vacuum pores with tissue or clot.

During acute PPH, the shielded loop is introduced through the cervix into the intrauterine cavity. The cervical seal should be immediately outside of the external cervical os and is then filled with sterile fluid (60 to 120 mL) to create a seal (Figure 3). The vacuum connector port is applied to low-level suction (80 ± 10 mm Hg) and the vacuum source should be applied for at least one hour and up to 24 hours. Once adequate hemorrhage control is established, the vacuum source is disconnected from the vacuum connector port and the cervical seal emptied. Subsequently, the device remains in place for a minimum of 30 minutes to monitor for reoccurrence of bleeding and is then removed.

There are no definitive recommendations for antibiotic prophylaxis while the Jada System is in place and treatment remains at the discretion of individual providers. Contraindications to the Jada System include ongoing intrauterine pregnancy, untreated uterine rupture, known uterine anomaly, current cervical cancer, unresolved uterine inversion, or purulent infection of the vagina, cervix, or uterus (10). In existing clinical studies, patients were excluded if there was retained placenta without easy removal, a diagnosis of maternal coagulopathy, or a QBL of 1,500 mL prior to device placement (12). The Jada System has not been studied in cases of placenta accreta spectrum (10).

The first report of vacuum-induced tamponade was published in 2016. This study was based out of Indonesia and included 10 women who developed postpartum hemorrhage that required additional intervention when first line hemorrhage therapies failed. Hemorrhage control was rapidly achieved in all cases without any safety concerns (28). Subsequently, a large multicenter treatment study conducted in the United States demonstrated that the Jada System was effective and safe. Definitive treatment success rate occurred in 94% of patients overall (100/106 patients, 95% CI 88 – 98%) (12). In cases of successful treatment, the initial collapse of the uterus occurred rapidly, with a median time of 1 minute (interquartile range (IQR) 1-2). Definitive bleeding control was reported in a median of 3 minutes (IQR 2-5).

Treatment length was at the discretion of the providers and based on clinical course (minimum 1 hour and maximum 24 hours). The median time of treatment duration was 144 minutes (IQR 86-296) with a total indwelling time of 191 minutes (IQR 133-366). Importantly, once treatment with the Jada System was implemented, blood loss

measured during treatment within the tubing or canister was low (median 110 mL, IQR 75-200). Providers in this study found the device easy to use and would recommend this device for management of acute PPH.

Modified Bakri Balloon System

In 2021, Haslinger *et al* described a novel vacuum-induced tamponade technique utilizing the Bakri balloon device (13). In this technique, the Bakri balloon should only be inflated with 50 to 100 mL of sterile saline, anchoring the device within the endometrial cavity. The Bakri balloon catheter can then be connected to a vacuum source. The authors applied suction at 60 to 70 kPa (450 to 500 mmHg). After placement, the authors recommend confirmation of device placement and assessment of the uterine cavity with bedside ultrasound. The device should remain in place for at least an hour. If hemorrhage control is established, the vacuum source is disconnected and the patient is observed for one additional hour prior to device removal. If no bleeding reoccurs, the balloon is deflated and the device is removed. This technique is considered an off-label use of the Bakri balloon. Compared to other vacuum-induced tamponade techniques, this technique employs significantly higher vacuum pressure.

Data surrounding efficacy and safety of this technique is limited to a single, observational cohort study of 66 women based out of Switzerland (13). Adequate placement and vacuum occurred in all cases. Success rates were higher in cases attributed to uterine atony (86%) compared to placental pathology (73%). Success rates with this technique were observed to improve over the study time period and success rate in the setting of

uterine atony was 100% in the second half of the observation period. Importantly, patients tolerated this technique well and there were no adverse reactions reported. A major limitation to this study is the lack of any control cohort for comparison.

Suction Tube Uterine Tamponade Technique

Hofmeyr *et al* described a suction tube uterine tamponade (STUT) technique using an inexpensive and widely available wide-bore suction catheter (FG24 to FG36 Levin stomach tube). The tube is inserted trans-cervically. A speculum is placed to visualize the cervix and the cervix is cleansed with antiseptic solution. The suction tube is introduced through the cervix into the uterine cavity until the proximal side-hole is 5 cm beyond the cervix. Traction can be applied to the cervix with a ring forceps for stabilization and control as needed. The device is held in place until the suction is activated, the uterus collapses, and the tube is thus fixed in place. The recommended vacuum pressure is between 100 and 200 mmHg. In clinical trials, vacuum pressure at 500 mmHg or greater was associated with collapse of the suction tube and inability to adequately generate intrauterine suction (14). The device should remain in place for one hour and if adequate hemorrhage control occurs, the suction is then disconnected from the vacuum source. If no significant bleeding is observed after 20 minutes, the suction is re-connected to ensure that no blood has accumulated within the uterine cavity and the device is removed. Reports indicate that STUT insertion is fast (less than one minute) and effective. Despite the absence of a cervical seal (a component of the Jada System) or an anchoring balloon (a component of the modified Bakri balloon technique), preliminary reports on this simple suction tubing indicate that collapse of the uterine cavity and increased uterine

tone are sufficient to keep the device anchored securely in place. An initial feasibility study of STUT placement was conducted in 45 postpartum women following cesarean without hemorrhage (29). This report described stability of the tube within the uterus and successful aspiration of intracavitary blood without tube blockage. Additionally, this study evaluated suction tube placement in an early cohort (immediately after hysterotomy closure) and a late cohort (after skin closure) and found no difference in functionality of the STUT between these groups.

Subsequently, Hofmeyr *et al.* reported a case series of 3 women where STUT was utilized as a last resort treatment in patients with ongoing hemorrhage who failed primary medical therapy. Rapid and adequate hemorrhage control was achieved in all 3 cases (14). Finally, a small internal pilot study was performed with 24 women randomized women to STUT or traditional uterine balloon tamponade. Data from this study are limited but describe comparable outcomes between STUT and IUBT in efficacy, tolerability, and usability but warrant further investigation (30).

Prevention of Obstetric Hemorrhage

In regard to prevention of PPH, only IUBT in cases of placenta previa or suspected placenta accreta spectrum have been reported in the literature. A small case series of 6 patients evaluated prophylactic IUBT placement in cases of low-lying placentas, however the outcomes reported included nadir hematocrit and duration of Bakri placement, making assessment of whether IUBT improved patient outcomes difficult (31). A small number of publications have compared prophylactic IUBT to other techniques such as

gauze placement in suspected placenta accreta spectrum cases, but have not compared IUBT to other management techniques limiting the generalizability (32). Therefore, while earlier IUBT placement at the initiation of PPH is supported by literature, prophylactic use to prevent PPH has not yet been well studied.

The mini-sponge uterine tamponade device and vacuum-induced hemorrhage technology are still under active investigation for acute obstetric hemorrhage management. There are no existing studies evaluating use of this technology for the prevention of PPH.

Conclusion

Hemorrhage control devices are at the forefront of innovative obstetric hemorrhage treatment. Over the past decade, the number and variety of described hemorrhage control devices and techniques have rapidly expanded. Each tamponade device and technique affords unique advantages and challenges depending on the clinical circumstance, delivery location resources, and provider comfort. There are important themes that differentiate traditional uterine balloon tamponade from the mini-sponge tamponade device and vacuum-induced tamponade techniques. The primary mechanism of action varies between techniques and ranges from positive pressure (IUBT) to blood absorption with positive pressure (mini-sponge tamponade) to negative pressure (vacuum-induced tamponade techniques). Vacuum-induced tamponade techniques focus on reducing uterine size, which may lead to myometrial contraction and/or constriction of uterine spiral arteries(13). The length of treatment time may be shorter in cases of mini-

sponge device application and vacuum-induced tamponade techniques. Among the vacuum-induced tamponade techniques, the amount of negative pressure recommended varies considerably. Currently, access to novel technology and techniques remains limited. Some techniques and devices that we describe are novel and early in development with minimal data to support large scale implementation without further investigation (eg. mini-sponge tamponade device, STUT). We anticipate that the device options obstetric providers have for managing hemorrhage will continue to evolve and expand.

The preferred hemorrhage control device may vary depending on clinical presentation, practice location, clinical availability, and hospital resources. More data is needed to better understand whether a particular device or technique may be best suited to treat specific clinical circumstances or hemorrhage etiologies (eg. uterine atony vs. placental site bleeding). Importantly, hemorrhage control devices do not stand alone in the management of postpartum hemorrhage and must be employed in conjunction with existing hemorrhage management interventions, such as resuscitation techniques, uterotonics, multidisciplinary team response, and other hemorrhage control procedures. We are no longer in an era of limited treatment modalities for obstetric hemorrhage management. With the rapidly evolving landscape in hemorrhage management, we empower providers to become familiar with the wide array of treatment modalities to avoid delay in aggressive management of refractory hemorrhage. Although there is currently no data which describe use of uterine tamponade devices or techniques in the

prevention of obstetric hemorrhage, rapid recognition and early intervention in hemorrhage treatment are key to limiting maternal morbidity and mortality.

Reassuring safety data and preliminary efficacy data from pilot studies of these novel techniques support the powerful role devices can play in management of obstetric hemorrhage. Being able to effectively manage a patient in the initial birth center without additional surgical intervention and before progressive blood loss and coagulopathy is encountered can decrease maternal morbidity and mortality rates. With increasing availability of new devices and techniques, additional high-quality, prospective, comparative, and adequately powered randomized studies evaluating the clinical utility of these devices is imperative to develop universal protocols and to better understand the role of each device and technique in hemorrhage management. Additionally, studies evaluating their use outside of large academic centers are critical to better understand how these devices fit into current hemorrhage management algorithms and how to most effectively deploy them to birth centers globally.

Table 1. Types of IUBT devices and manufacturer recommended volume (8,15,33,34)

Balloon Type	Manufacturer Recommended Volume (mL)
Condom Catheter	n/a
Foley	30
Cook cervical ripening	80
Sengstaken-Blakemore	Esophagus 150 Gastric 250
Bakri	500
Rusch	500-1500
Ebb	750

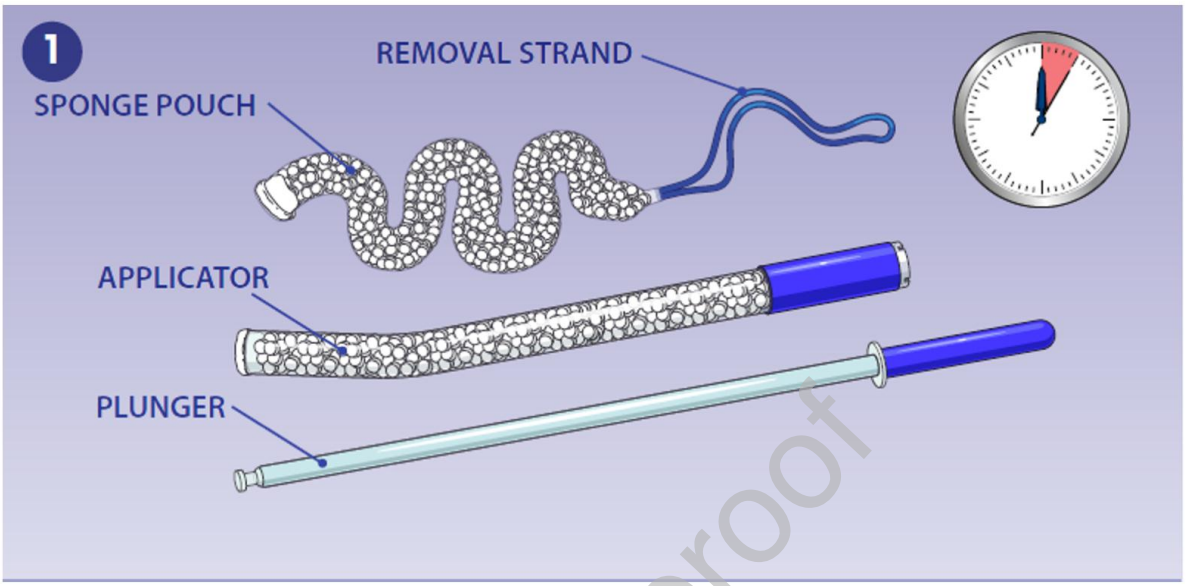

Figure 1. Components of the mini-sponge tamponade device

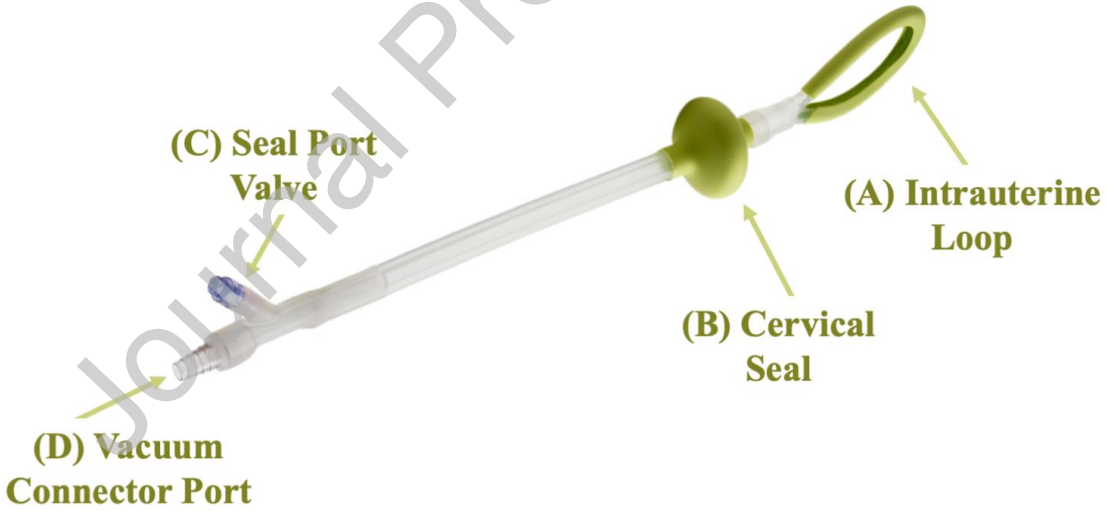

Figure 2. Components of the Jada System. (A) Intrauterine loop with shielded pores to be placed inside the uterus. (B) Cervical Seal to be placed just outside the external cervical os and filled with 60 to 120 mL of sterile fluid. (C) Seal port valve for sterile fluid infusion. (D) Vacuum connector port for connection to the vacuum source at 80 ± 10 mm Hg (10,11).

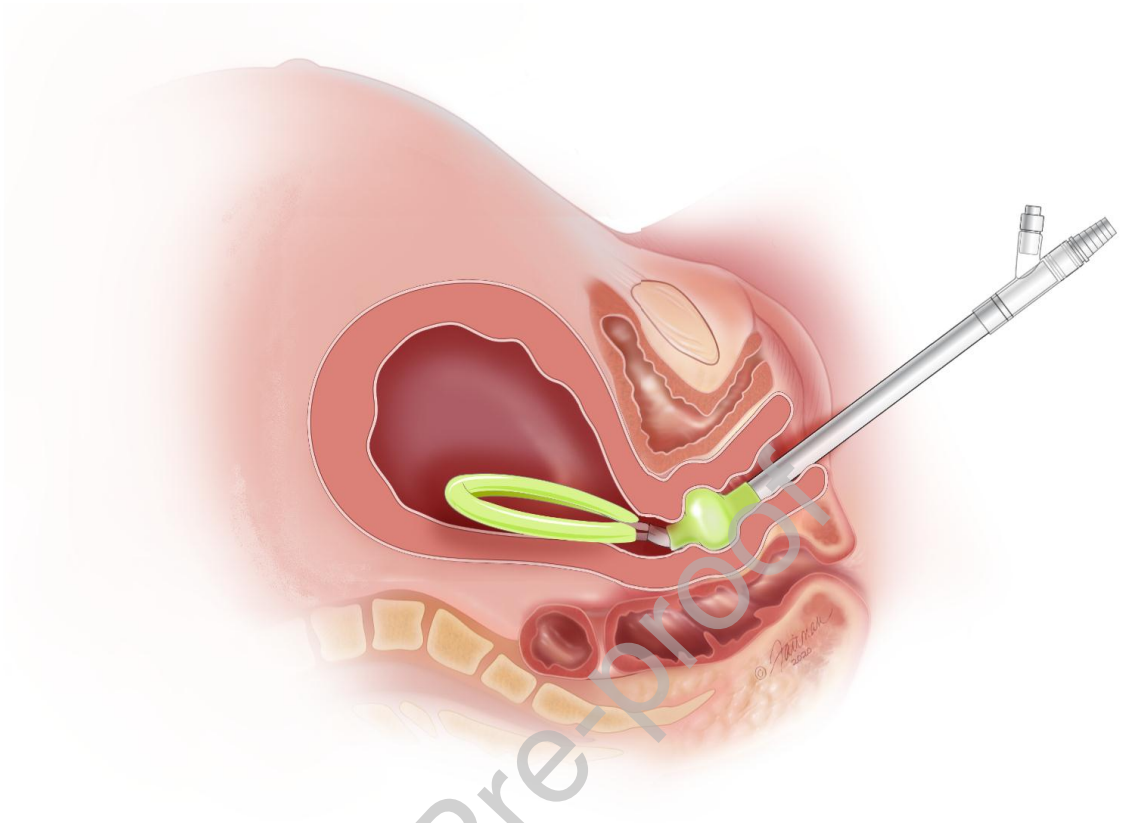

Figure 3. Intrauterine Jada System placement during obstetric hemorrhage. The shielded loop is passed through the cervix into the uterine cavity and the cervical seal is inflated with 60 to 120 mL of sterile fluid through the seal port valve (10,11).

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