

Treating PPH: A novel vacuum-induced hemorrhage control device

A new FDA-cleared device is an option for PPH management, but further studies are needed to evaluate its effectiveness compared with other devices for PPH. These experts, with experience in its use, explain how it works and discuss treatment success rates reported in a prospective study.

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Postpartum hemorrhage (PPH) continues to be a leading cause of maternal morbidity and mortality both worldwide and in the United States.¹⁻³ A PPH is defined as the cumulative blood loss of 1,000 mL or more, or blood loss accompanied by signs or symptoms of hypovolemia, within 24 hours following the birth process (including intrapartum loss).⁴

Approximately 70% to 80% of hemorrhages are due to abnormal uterine tone.⁵ Bimanual massage and medical management, the primary treatments for uterine atony, attempt to restore the normal uterine tone that compresses the vessels in the placental implantation site and limits bleeding. For

women in whom the primary treatments are not effective, only uterine compression sutures in a laparotomy can achieve physiologic contraction of the uterus. The second-line treatment option, intrauterine tamponade, places pressure over the placental implantation site while distending the uterus.

In October 2020, the US Food and Drug Administration (FDA) granted clearance to a novel device that offers an alternative treatment option. The Jada System (Alydia Health), an intrauterine vacuum-induced hemorrhage control device, is placed in the uterus and uses wall suction to induce physiologic contraction of the uterus to control bleeding.⁶

In this article, within the context of a case vignette, we discuss the recent study on the Jada System and how this device can be used in the management of PPH.⁶



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CASE Woman with PPH history fears repeat hemorrhage

Ms. B. is a 25-year-old woman (G2P1) who presents for prenatal care at 10 weeks' gestation. Her medical history is significant for asthma and PPH after her first delivery. When you review her prior delivery records, you learn that she had a protracted labor and delivered a healthy 10 lb 8 oz baby boy after 3 hours of pushing. After delivery, she received postpartum intravenous oxytocin followed by intramuscular uterotonics when her bleeding was heavy during her laceration repair. Her estimated blood loss at

TABLE Risk factors for postpartum hemorrhage⁷⁻⁹

Antepartum	Intrapartum	Postpartum
Multiple gestation	Labor induction	Operative vaginal delivery
Grand multiparity	Protracted labor	3rd or 4th degree laceration
Prior uterine incision(s)	Labor augmentation	Sulcal or cervical laceration
History of postpartum hemorrhage	Intrauterine infection	Cesarean delivery
Macrosomia	Magnesium sulfate use	Precipitous delivery
Polyhydramnios	Abruption	Shoulder dystocia
Morbid obesity		Retained placenta
Abnormal placentation		Uterine inversion
Known coagulopathy		
Thrombocytopenia		

delivery was 600 mL. The team was called back to her bedside for the continued bleeding. Uterine atony was diagnosed. Although she received additional uterotonics, the bleeding continued. An intrauterine tamponade balloon was placed, and the bleeding ultimately was controlled. The total estimated blood loss (EBL) was 2.5 L, and the patient then was transfused with 2 U of packed red blood cells.

Currently, Ms. B. is very worried about having another hemorrhage as the bleeding terrified her and her partner, disrupted breastfeeding initiation while the tamponade was in place, and made her anxious about having another baby.

What steps would you take to prepare for a potential PPH in this patient?

Risk factors

While PPH often is unpredictable, many risk factors have been identified (TABLE).⁷⁻⁹ Some risk factors are present during the antepartum period while others arise during labor. In some cases, obstetric clinicians may be able to intervene during prenatal care, such as by giving iron supplementation to address anemia. Other factors, however, are not modifiable, including multiparity, polyhydramnios, and multiple gestations. On presentation to the labor unit, new risk factors may arise, such as magnesium sulfate use, chorioamnionitis, protracted labor, or the need for general anesthesia. In addition, the presence

of a fibroid uterus or a uterine inversion can impede effective uterine contractions.⁵

Various tools are available for assessing these risk factors on admission, during labor, and after delivery, such as the AWHONN postpartum hemorrhage risk assessment table and the CMQCC obstetric hemorrhage toolkit.^{10,11}

CASE continued Patient's history reveals risk factors

You review with Ms. B. that she had several risk factors present during labor. She had a large baby and a protracted labor. Knowing her history in this pregnancy will allow the clinical team to be prepared for a potential recurrent hemorrhage and to respond proactively to bleeding.

Consider the management options

The initial treatment for PPH includes bimanual massage, oxytocin, and other uterotonics (methylergonovine, 15-methyl prostaglandin F_{2α}, and misoprostol). While various algorithms are available on the order of treatment, a single agent has not been shown superior to others.¹² The antifibrinolytic medication tranexamic acid also was shown to reduce the risk of death from obstetric hemorrhage in the international WOMAN trial.¹³

While these agents often are used simultaneously to achieve hemostasis, their systemic effects are associated with contraindications. Specifically, F_{2α} prostaglandins cannot be

used in patients with asthma or active hepatic, pulmonary, or cardiac disease. Ergot derivatives cannot be used in patients with hypertension, pre-eclampsia, or cardiovascular disease. Given the rising rate of medical comorbidities during pregnancy, such contraindications limit the treatment options for many patients.

In cases in which medical management is not sufficient or is contraindicated for controlling hemorrhage, second-line treatment includes the use of tamponade techniques, such as intrauterine packing or balloons. The tamponade applies pressure directly to the placental implantation site for 12 to 24 hours, which allows time for the uterus to contract and return to normal tone. While this method may seem counterintuitive to achieving uterine tone, studies suggest a success rate between 75% and 86% with balloon tamponade.¹²

Third-line treatment options are increasingly invasive but should be used to prevent further maternal morbidity and mortality. These include uterine artery embolization and surgery. Uterine artery embolization is an option for a stable patient at a center with available interventional radiology services. If embolization is either not successful or not available, an exploratory laparotomy should be performed. Uterine compression sutures can be placed along with vascular ligation sutures of the uterine arteries (O'Leary sutures) and the hypogastric arteries. If all other methods have failed, a hysterectomy is the definitive treatment for hemorrhage.

CASE continued Patient desires an alternative to tamponade if needed

Following your visit, Ms. B. has an ultrasound scan that shows a dichorionic diamniotic twin pregnancy. She also has a microcytic anemia. After you discuss iron supplementation with the patient, she asks if there are any other options should medical management fail in the event of a recurrent hemorrhage. While intrauterine tamponade balloon did treat her hemorrhage, she was not happy with the length of time it had to remain in place, the discomfort while it was used, and the disruption to her planned recovery. You inform her of a new treatment option available for PPH, a vacuum-induced hemorrhage control device that was recently FDA cleared.

New device controls bleeding fast

In 2020, D'Alton and colleagues reported on their multicenter, prospective single-arm treatment study on the effectiveness and safety of an intrauterine vacuum-induced hemorrhage control device.⁶ This device, the Jada System, uses low-level vacuum to induce uterine contraction to control bleeding from uterine atony. The prospective study, which followed a 2016 feasibility study, enrolled more than 100 women at 12 centers across the United States.^{6,14} Women were eligible to participate if they delivered at a gestational age of 34 weeks or later and had an EBL between 500 and 1,000 mL after a vaginal delivery or an EBL between 1,000 and 1,500 mL after a cesarean delivery.

Treatment with the vacuum device was successful in 94% (100/106, 95% confidence interval, 88%–98%) of women, and definitive control of abnormal bleeding was achieved in a median of 3 minutes (interquartile range [IQR], 2.0–5.0) after connection to the vacuum device.⁶

CASE continued Patient has questions

Your patient expresses interest in this device, but she wants to understand how it works. Would it require transfer to another unit or prolonged monitoring?

How the device works

Compared with intrauterine tamponade balloon devices, which apply pressure by distending the uterus, the Jada System applies low-level intrauterine vacuum to facilitate the physiologic forces of uterine contractions to constrict myometrial blood vessels and achieve hemostasis.⁶ The device is made of medical-grade silicone. Its distal end, which is placed in the uterus, is an elliptical loop. The loop's inner surface contains 20 vacuum pores protected by a shield that facilitate creation of a vacuum within the uterine cavity. The loop is soft and smooth to limit the chance of tissue damage during insertion, treatment, and removal of the device. The device's proximal end has a vacuum connector. The vacuum source is hospital-grade wall suction, but a portable vacuum source also can be used (FIGURE 1).

Prior to placing the device, a manual sweep of the uterine cavity is performed. If

FAST TRACK

A prospective study of 106 women found that treatment with an intrauterine vacuum-induced hemorrhage control device was successful in 94%, and definitive abnormal bleeding control was achieved in a median of 3 minutes

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FIGURE 1 Intrauterine vacuum-induced hemorrhage control device, the Jada System

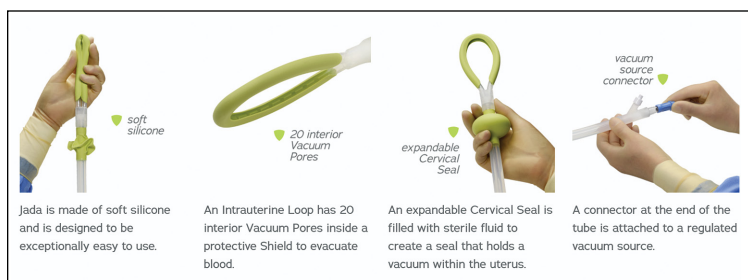
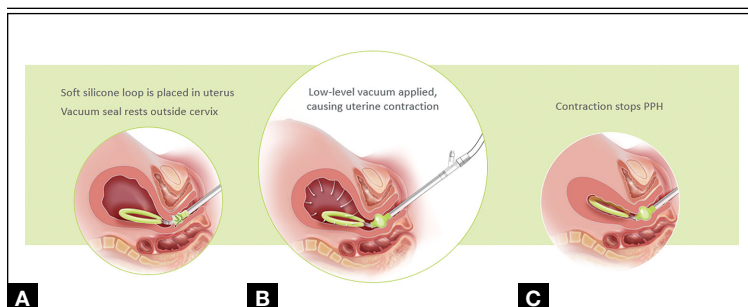


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FIGURE 2 Placement of the intrauterine vacuum-induced hemorrhage control device (A) with low-level vacuum connected (B) and uterine contraction (C)



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needed, ultrasonography can be used with the manual sweep to ensure that there is no retained placental tissue or clot. The loop of the Jada System is then inserted in the uterine cavity, and the circular cervical seal, just outside the external cervical os, is filled with sterile water.

Low-level vacuum (80 ± 10 mm Hg) is applied so that pooled blood is evacuated from the uterus as it collapses (FIGURE 2). The volume of any ongoing bleeding is measured in the suction tubing while the uterine response to treatment can be palpated. Once there is no bleeding without any need for further treatment, the device should remain in the uterus for at least 1 hour. The suction is then turned off, and bleeding is monitored for 30 minutes. If bleeding remains controlled, the device can be removed.

CASE continued The question of complications

Ms. B. is concerned about safety and asks about potential complications with the device's use.

Safety findings

In the prospective study and FDA review, the device was deemed safe. There were 8 possibly related adverse events (endometritis, laceration disruption, and vaginal infection), which all resolved without serious clinical sequelae. Forty women (38%) received a blood transfusion, but only 5 required 4 U or more of red blood cells.⁶

CASE continued What do other physicians think?

Your patient is curious about the time it takes for the device to work and whether other clinicians like using this new device for hemorrhage treatment.

Duration of treatment

The times to achieve uterine collapse and control of hemorrhage are both relatively short. In the prospective study, the initial collapse of the uterus took a median of 1 minute (IQR, 1–2 min) from the time of vacuum connection.⁶ Bleeding was controlled in less than 5 minutes in 82% of women, with an overall median time of 3 minutes (IQR, 2–5 min). The median duration of vacuum treatment was 144.0 minutes (IQR, 85.8–295.8 min), which includes the required minimum of 60 minutes for vacuum treatment time and 30 minutes of observation without the vacuum connected but with the device still in place.⁶

When polled, the majority of clinicians—98%—reported that the intrauterine vacuum-induced hemorrhage control device was easy to use, and 97% would recommend its use for future patients.⁶

Further, recognizing the device's potential, the Cleveland Clinic cited it as one of the top 10 health care innovations for 2021 for offering a low-tech and minimally invasive tool for obstetric clinicians.¹⁵

CASE continued Final questions

Ms. B. thanks you for the information and asks, should she know anything else about the device?

Vacuum device vs other treatments

The study by D'Alton and colleagues was a single-arm treatment trial that did not directly compare the effectiveness of the device with that of other PPH treatment options, such as balloon tamponade.⁶ At this point, we know that clinicians can safely and quickly use the device to treat uterine atony, but we do not know if it is superior to other treatments for PPH.

Key takeaways

Postpartum hemorrhage is a leading cause of maternal morbidity and mortality. When

first-line uterotonics fail, obstetric clinicians previously had only balloon tamponade or invasive procedures to treat patients. The novel intrauterine vacuum-induced hemorrhage control device takes a new approach that simulates the physiologic process of uterine contractions. The device can rapidly and effectively control abnormal postpartum uterine bleeding. More studies are needed, however, to compare the device's effectiveness with that of other PPH treatments and to consider its use in women with more severe degrees of postpartum hemorrhage as well as its cost-effectiveness. ●

References

1. Say L, Chou D, Gemmill A, et al. Global causes of maternal death: a WHO systematic analysis. *Lancet Glob Health*. 2014;2:e323-e333.
2. Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol*. 2012;120:1029-1036.
3. Centers for Disease Control and Prevention. Severe maternal morbidity in the United States. <http://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html>. Accessed November 6, 2020.
4. Menard MK, Main EK, Currihan SM. Executive summary of the reVITALize initiative: standardizing obstetric data definitions. *Obstet Gynecol*. 2014;124:150-153.
5. American College of Obstetricians and Gynecologists Committee on Practice Bulletins-Obstetrics. Practice bulletin no. 183: postpartum hemorrhage. *Obstet Gynecol*. 2017;130:e168-e186.
6. D'Alton ME, Rood KM, Smid MC, et al. Intrauterine vacuum-induced hemorrhage-control device for rapid treatment of postpartum hemorrhage. *Obstet Gynecol*. 2020;136:882-891.
7. Mavrides E, Allard S, Chandraharan E, et al; on behalf of the Royal College of Obstetricians and Gynaecologists. Prevention and management of postpartum hemorrhage. *BJOG*. 2016;124:e106-e149.
8. Lyndon A, Lagrew D, Shields L, et al. Improving health care response to obstetric hemorrhage, version 2.0 (California Maternal Quality Care Collaborative Toolkit to Transform Maternity Care). Developed under contract #11-10006 with the California Department of Public Health; Maternal, Child and Adolescent Health Division; Published by the California Maternal Quality Care Collaborative, March 17, 2015.
9. Main EK, Goffman D, Scavone BM, et al; National Partnership for Maternal Safety; Council on Patient Safety in Women's Health Care. National Partnership for Maternal Safety: consensus bundle on obstetric hemorrhage. *Obstet Gynecol*. 2015;126:155-162.
10. AWHONN Postpartum Hemorrhage Project. Postpartum hemorrhage (PPH) risk assessment table 1.0. https://mygnosis.com/Content/Chunks/3504/assets/pdfs/PPH_Risk_Assessment_Table-7-17-15.pdf. Accessed November 15, 2020.
11. Bingham D, Melsop K, Main E. CMQCC obstetric hemorrhage toolkit: hospital level implementation guide. 2010. California Maternal Quality Care Collaborative (CMQCC). Palo Alto, CA: Stanford University. <https://www.cmqcc.org/resource/1489/download>. Accessed November 15, 2020.
12. Likis FE, Sathe NA, Morgans AK, et al. Management of postpartum hemorrhage. Comparative effectiveness review no. 151. AHRQ publication no. 15-EHC013-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2015.
13. WOMAN Trial Collaborators. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial. *Lancet*. 2017;389:2105-2116.
14. Purwosunu Y, Sarkoen W, Arulkumaran S, et al. Control of postpartum hemorrhage using vacuum-induced uterine tamponade. *Obstet Gynecol*. 2016;128:33-36.
15. Cleveland Clinic Innovations. Cleveland Clinic unveils top 10 medical innovations for 2021. October 6, 2020. <https://innovations.clevelandclinic.org/Programs/Top-10-Medical-Innovations/Top-10-for-2021>. Accessed November 6, 2020.