

CADTH Horizon Scan

Vacuum-Induced Uterine Tamponade for Postpartum Hemorrhage

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Key Messages

- Horizon Scan reports provide brief summaries of information regarding new and emerging health technologies; Health Technology Update articles typically focus on a single device or intervention.
- These technologies are identified through the CADTH Horizon Scanning Service as topics of potential interest to health care decision-makers in Canada.
- This Horizon Scan summarizes the available information regarding an emerging technology, the Jada System, for the management of postpartum hemorrhage.

The Jada System: A Vacuum Device for Controlling Postpartum Hemorrhage

Started as a senior graduate project with a goal to develop a device to manage postpartum hemorrhage, the Jada System is now an FDA authorized medical device.

Obstetric hemorrhage is the leading preventable cause of morbidity and mortality during birthing around the world, accounting for 25% of maternal deaths related to obstetric causes.^{1,2} Postpartum hemorrhage is traditionally defined as blood loss of more than 500 mL in the first 24 hours following vaginal delivery or 1,000 mL following Caesarean section.³ Most postpartum hemorrhage is caused by uterine atony (when the uterus fails to contract after childbirth).¹ Uterine atony can generally be managed using medications that help the uterus to contract and/or physical manipulation. Multiple methods are often used together to manage the excessive bleeding.¹ Fundal massage (manually massaging the uterus from inside and outside the abdomen) may be the first step in treatment. If this does not work, medications (e.g., oxytocin, ergonovine, carbetocin, misoprostol) are administered before initiating any more invasive therapies like surgery.

When physical manipulation and medications fail to control the hemorrhage, intrauterine interventions can be considered, such as uterine tamponade. Balloon tamponade is the current approach to uterine tamponade.⁴ Balloon tamponade is when a uterine balloon is placed within the uterus and inflated with sterile saline solution to put sustained pressure on the uterus from the inside.¹ These balloons need to be used for 12 to 24 hours to slow or stop uterine hemorrhage.² Surgical measures, such as uterine curettage, laceration repair, or hysterectomy, may be required if physical and drug therapies are unable to slow the bleeding.¹

The Jada System is a single-use device that has the potential to be an alternative to balloon tamponade. The Jada System uses intrauterine vacuum to stimulate uterine contraction to stop bleeding, rather than putting internal pressure on the uterus like the balloon.¹

How It Works

The Jada System is a vacuum system used to control abnormal uterine bleeding or postpartum hemorrhage when conservative management is deemed appropriate. It is intended to be used to rapidly control postpartum hemorrhage caused by uterine atony

that does not respond to drug therapy or when drug therapy is contraindicated.² The device uses low-level vacuum (80 mm Hg \pm 10 mm Hg) to encourage the uterus to contract, in turn compressing open blood vessels and slowing bleeding.²

The device is made of silicone in the shape of a loop to be placed inside the uterus. The loop contains 20 vacuum pores, each 4 mm in diameter.² There is a cervical seal that is placed at the external cervical os and filled with sterile fluid to limit the vacuum to the uterine cavity.² The cervix must be dilated to at least 3 cm to allow for safe insertion of the device. Once in place, the device is connected to a regulated vacuum source and the suction begins.² The clinician is able to monitor the progress of uterine collapse through transabdominal palpation or direct observation in the case of a Caesarean section where the abdominal incision has not yet been closed.² The amount of blood evacuated from the uterus can be monitored as it is collected in a graduated canister. The Jada System may be in place for a minimum of 1.5 hours, up to a maximum of 24 hours.² The Jada System has not been evaluated for use in uteri less than 34 gestational weeks in size, patients with coagulopathy, or placenta accreta.² If a patient is not responding well to the use of intrauterine vacuum tamponade, more aggressive treatments may be required.

Who Might Benefit?

Postpartum hemorrhage caused by uterine atony occurs in about 1 in every 13,000 deliveries in Canada. Of the 31 perinatal deaths reported in Canada in 2018, 5 (16%) were the result of postpartum hemorrhage.⁵ Some individuals are at greater risk of postpartum hemorrhage based on demographic factors and certain comorbidities. The Jada System may be particularly beneficial to these groups. Some risk factors for postpartum hemorrhage include: prior postpartum hemorrhage, first pregnancy, comorbid hypertension, or comorbid diabetes.⁶

Availability in Canada

The Jada System is not currently licensed or otherwise available for sale or use in Canada.

The Jada System was first cleared for use in the US by the US FDA (FDA) in August 2020.⁷ The device's clearance was updated in October 2021 to accommodate a new kit configuration, new design of the device meant to improve the device's ease of use, and new packaging.⁷ The updated version of the device is anticipated to be available in the US beginning in January 2022.⁷

What Does It Cost?

In the US, the 2020 sale price of the Jada System to private health clinics had been reported to be US\$1,000 for 1 single-use device.⁸ No pricing information from the manufacturer was identified.

Current Practice

The Society of Obstetricians and Gynaecologists of Canada guidelines (reaffirmed in 2018) regarding active management of the third stage of labour outline the recommended options for the prevention and treatment of postpartum hemorrhage.³ These guidelines largely focus on prevention and medical therapy. Uterine tamponade is recommended if medical therapy fails. This recommendation is based on expert opinion, and low levels of published evidence.³

What Is the Evidence?

A multicenter, prospective, single-arm treatment study of 107 participants was conducted in the US to evaluate the safety and effectiveness of the Jada System to control postpartum hemorrhage or abnormal postpartum uterine bleeding.⁹ The primary clinical effectiveness end point was the proportion of participants for whom the device was able to control their abnormal intrauterine bleeding without the need for more invasive intervention.⁹ The primary safety end point was the occurrence of adverse events related to the device.

Abnormal bleeding was defined as blood loss of 500 mL to 1,500 mL after vaginal delivery or 1,000 mL to 1,500 mL following Caesarean delivery.⁹ Eighty-five percent of the deliveries were vaginal and the primary cause for abnormal bleeding or hemorrhage was uterine atony.⁹ D'Alton and colleagues reported a success rate of 94% in the intention-to-treat cohort (100 of 106 participants) with a median of 3 minutes (interquartile range = 2.5 to 5.0) after the initiation of the vacuum required to control the abnormal bleeding.⁹ There was no comparator group included in this clinical study; therefore, although the results appear to demonstrate the effectiveness of the device, there is no way to determine its effectiveness relative to other available treatment options based on this study. This study was funded by Alydia Health, the manufacturer of the Jada System.⁹

Safety

No significant safety issues associated with the use of the Jada System were described in the identified clinical trial.⁹ The authors reported 8 adverse events that were deemed to be possibly related to the use of the device. All reported adverse events were resolved with treatment and did not result in serious long-term issues.⁹ Blood transfusion of 1 to 3 units was required for 35 study participants. Five participants required transfusion of 4 or more units of red blood cells.⁹ No cases of serious events such as uterine rupture, lower genital tract laceration, or uterine incision dehiscence related to the use of the Jada System were reported.

Forty-three records were identified in the FDA Manufacturer and User Facility Device Experience (MAUDE) database regarding reported injury or malfunction of the Jada System from market entry to the end of 2021.¹⁰ The causal relationship between the events and the device have not been confirmed. Loss of suction and failure of the device to stop uterine bleeding were the most reported issues.¹⁰

Issues to Consider

Postpartum hemorrhage is a worldwide issue. Therefore, low-cost methods for managing postpartum hemorrhage are important to ensure equitable affordability and accessibility across all settings. The reported ease of use of the device may allow for it to be used in areas where traditional methods to manage postpartum hemorrhage are unavailable. Many rural and remote health centres do not have the necessary equipment or expertise to handle complicated, or sometimes even routine, childbirth. This lack of access to this kind of care often leads pregnant people to have to travel away from their homes to give birth safely.¹¹

Related Developments

A research team in Switzerland tested vacuum-induced tamponade using a modified intrauterine Bakri balloon system for the treatment of postpartum hemorrhage.¹² A Bakri balloon system was inserted into the uterus using ultrasound guidance and partially inflated with saline solution.¹² The balloon was then connected to a vacuum device and intrauterine vacuum was applied with 60 kPa to 70 kPa pressure for at least 1 hour up to 24 hours.¹² The modified balloon appeared to be effective at controlling the bleeding.

A mini-sponge tamponade device is undergoing clinical testing. The XSTAT is an adapted dressing that was developed for use intended for use in trauma situations in combat settings.¹³ The device contains compressed mini-sponges in a mesh pouch enclosed in a tube applicator to aid placement of the device. The sponges both contain the excess blood and also put pressure on the uterus to stop the bleeding.¹³ The device can be used from 1 to 24 hours.

Looking Ahead

Further clinical studies comparing the Jada System with conventional balloon tamponade for the treatment of postpartum hemorrhage may be required to establish its comparative effectiveness and safety in relation to the current standard procedure. Longer term follow-up data are also needed to assess safety of the Jada System in the context of long-term, post-procedure outcomes and to determine any potential effects on subsequent deliveries. If the Jada System becomes available on the Canadian market, consideration will need to be made in terms of its cost in a Canadian context (e.g., price per unit, potential effects on health care costs, training costs, etc.).

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