

Intrauterine vacuum-induced haemorrhage-control device: A novel approach for PPH

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Madam, Postpartum haemorrhage (PPH), defined as postpartum blood loss of > 1000 mL, is a life-threatening emergency and the leading cause of maternal mortality accounting for 25% of maternal deaths worldwide.¹ PPH can lead to significant morbidity, including shock, ARDS, coagulopathy, infertility due to hysterectomy, and even mortality.⁴

Uterine atony is the most common cause, accounting for 80% of all cases of PPH.^{1,2} Active management of the third stage of labour consisting of a triad of oxytocin, controlled cord traction, and uterine massage can reduce the incidence of PPH by 60%.⁵ If abnormal uterine bleeding ensues, PPH protocols are activated, including uterine balloon tamponade, uterine packing, uterine artery embolization, or hysterectomy.^{1,2}

The Jada System (novel intrauterine vacuum-induced haemorrhage-control device) approved by the U.S. FDA in August 2020, utilizes a low-level vacuum to induce negative pressure in the uterine cavity that facilitates uterine contraction to constrict myometrial blood vessels that can help with uterine atony.¹ The device is used in patients with PPH where standard PPH treatments have failed or are contraindicated.¹ It is a soft medical-grade silicone that attenuates the risk of tissue trauma and can be placed trans-vaginally after 3 cm of cervical dilation after vaginal birth and C-section.^{1,2} Ultrasound is used to check correct device placement, along with real-time quantification of the expelled blood from the uterine cavity into the graduated canister. The device can be placed for 1.5 hours to 24 hours inside the uterus. The device can be removed after evaluation of evacuated blood and palpation for a firm uterus, both signifying control of the haemorrhage.²

A First-in-Human (FIH) feasibility study conducted in Indonesia on 10 participants with atony-related PPH

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showed that the device was placed effectively, and bleeding was controlled in under 2 minutes with no unfavourable outcome in any participants.^{1,3} The study was conducted with 107 participants of which two-thirds had atony-related PPH with failed medical treatment.¹ The Per Protocol showed a 99% success rate in effectively controlling PPH.² Bleeding halted in a minimum of 3 minutes, the treatment duration was around 3.2 hours and 98% of users regarded it as convenient to use.¹ Adverse events included endometritis and vaginal infections all of which were resolved with adequate treatment.²

The Jada system is a minimally invasive device that could benefit low-resource settings. It can be used with a regulated vacuum pump followed by an ultrasound to confirm placement. For doctors, the short monitoring and treatment time, rapid cessation of bleeding, convenient usage, and low risk of complications could be key advantages, specifically in under-staffed settings. It may render it worthy of being included in PPH management that could help with fatal complications like hysterectomy and mortality, thereby improving maternal outcomes.

Disclaimer: None.

Conflict of interest: None.

Funding disclosure: None.

DOI: <https://doi.org/10.47391/JPMA.9602>

Submission completion date: 12-04-2023

Acceptance date: 03-06-2023

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