# Intrauterine Vacuum Device for Management of Refractory Postpartum Hemorrhage (PPH)

## What is known already?

Obstetric haemorrhage is the leading cause of maternal mortality, accounting for 27% of all maternal deaths worldwide each year. The majority of these deaths are due to postpartum haemorrhage. [1] Once bleeding is refractory to medical management, intrauterine tamponade devices (balloon or vacuum) are commonly used to manage PPH. [2-4].

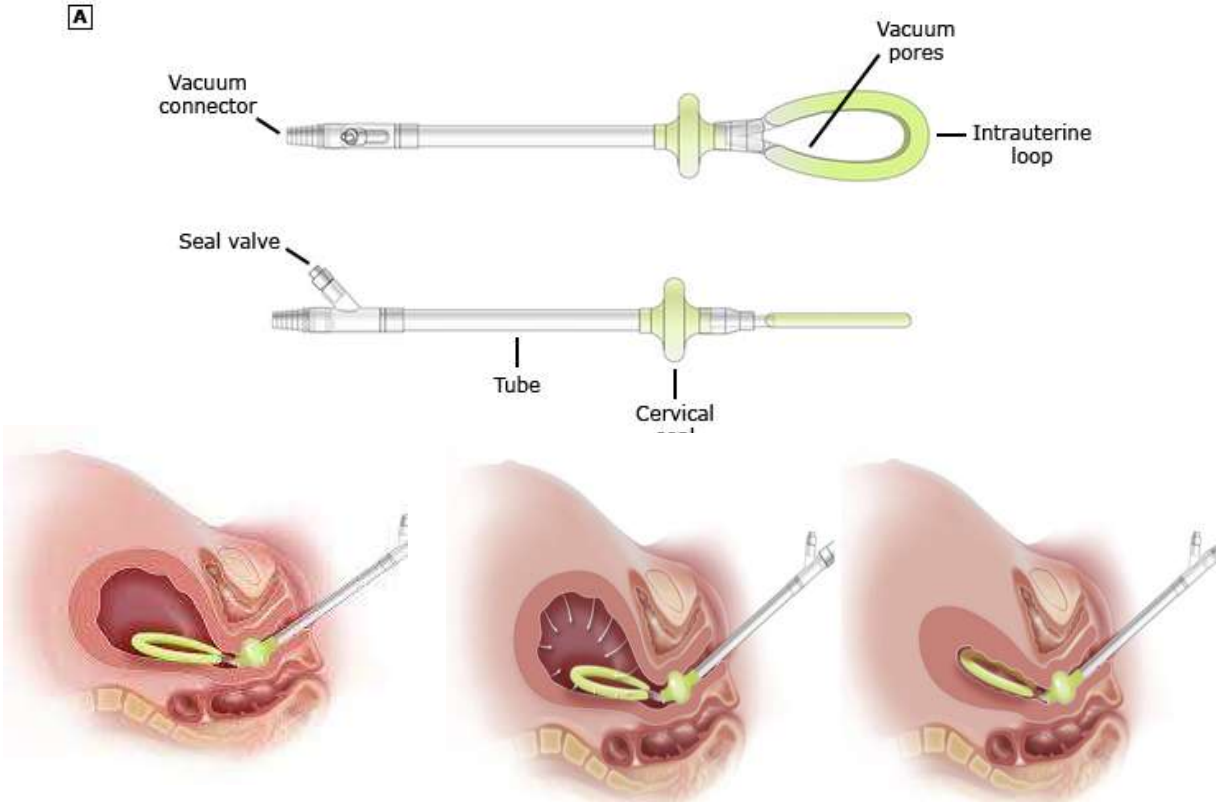
In a meta-analysis including over 4700 patients with PPH (7 randomized or cluster randomized trials, 15 nonrandomized studies, 69 case series), the overall pooled uterine balloon tamponade success rate was 85.% (95% CI 83.9-87.9), with the highest success in uterine atony (87.1 %) and placenta previa (86.8%) and the lowest in placenta accreta spectrum (66.7%) and retained products of conception (76.8 %) [4]. In this study hemorrhage stopped more frequently when balloons were placed after vaginal compared with cesarean birth (87% versus 82%, respectively) [4].

Despite its widespread use in current obstetric practice, the mechanism of intrauterine balloon tamponade, is counterintuitive to the physiologic uterine contraction that occurs after delivery to control bleeding, and data on its effectiveness are mixed [5].

In contrary to uterine balloon tamponade, intrauterine vacuum-induced hemorrhage-control device (Jada System N5106 FDA approved) facilitates physiologic uterine contraction when connected to low-level vacuum (70 to 90 mmHg) [5]. It safely and effectively controlled bleeding in 94% of individuals, with median of 3 minutes [6]. However, outcome data regarding vacuum-induced tamponade are limited as the recruitment was largely at academic centers, which could affect generalizability to rural, community, or limited-resource settings [7].

**Vacuum-Induced Hemorrhage Control Device (Jada System®)**

The Intrauterine Loop is covered by a Shield which overhangs the Vacuum Pores to protect tissue from vacuum and the vacuum pores from plugging with tissue and blood clots. The device is placed trans-vaginally and remains in place for 1.5 hours at minimum and 24 Hs. at maximum.




**Application** **Vacuum connected** **Uterine contraction**

Mary D'Alton Kara Rood, Hyagriv Simhan, Dena Goffman, Profile of the Jada® System 1 Expert Rev Med Devices.;18(9):849. Aug 6. 2021

# What is New?

In an observational, multicenter, postmarket registry medical record review conducted from October 8, 2020, to March 31, 2022, across 16 centers in the United States (clinicaltrials.gov, NCT04995887). Centers study (N5106), the device safely and effectively controlled bleeding were selected based on their ability to reliably collect data on device use.
In the registrational in 94% of individuals, with definitive bleeding control in a median of 3 minutes.[8]

## What is the clinical implication?

This device is an important new tool for managing a life-threatening condition, and may improve postpartum hemorrhage outcomes.

For births in real-world settings complicated by PPH, rapid, effective, and safe control of bleeding was achieved with an FDA-cleared intrauterine vacuum-induced hemorrhage-control device.

## References:


1, World Health Organization the postpartum haemorrhage bundle Guideline Development Subgroup, Aug 14, 2023

2. World Health Organization (WHO) recommendation on uterine balloon tamponade for the treatment of postpartum haemorrhage. Weeks Andrew, Akinola Oluwarotimi Ireti FWACS,Amorim, Melania ,Carvalho Brendan , Deneux-Tharaux, Catherine ,Liabsuetrakul Tippawan ,Meremikwu Martin ,Miller Suellen , Nabhan, Ashraf, Nagai Mari , Wahabi, Hayfaa Walker, Dilys . Obstetrics & Gynecology 139(3):p 458-462, March 2022

3. Jaclyn M Phillips , Catherine Eppes 2, Maria Rodriguez , Sara Sakamoto ,. Traditional uterine tamponade and vacuum-induced uterine tamponade devices in obstetrical hemorrhage management. Am J Obstet Gynecol FM ;5(2S): 100739 Feb.2023

4. Sebastian Suarez , Agustin Conde-Agudelo , Anderson Borovac-Pinheiro , Daniela Suarez-Rebling , Melody Eckardt , Gerhard Theron and Thomas F Burke . Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review and meta-analysis , Am J Obstet Gynecol ;222(4):293.e1-293.e52. Apr 2020.

5. T L Jackson, Methodius G Tuuli, Intrauterine Postpartum Hemorrhage-Control Devices Obstet Gynecol 1;142(5):1000-1005. Oct 5. 2023

6-Mary E D'Alton 1, Kara M Rood, Marcela C Smid, Hyagriv N Simhan, Daniel W Skupski, Akila Subramaniam, Kelly S Gibson, Todd Rosen, Shannon M lark, Donald Dudley, Sara N Iqbal, Michael J Paglia, Christina M Duzyj, Edward K Chien, Karen J Gibbins, Kathryn D Wine, Nana Ama A Bentum, Michelle A Kominiarek, Methodius G Tuuli, Dena Goffman. Intrauterine Vacuum-Induced Hemorrhage-Control Device for Rapid Treatment of Postpartum Hemorrhage. Obstet Gynecol;136(5):882-891. Nov.2020

7. Christian Haslinger, Kathrin Weber, and Roland Zimmermann. Vacuum-Induced Tamponade for Treatment of Postpartum Hemorrhage. Obstet Gynecol. 138(3): 361–365. Sep 2021. .

8. Dena Goffman, Kara M. Rood, Angela Bianco, Joseph R. Biggio,, Paul Dietz Kelly Drake, Erica Heilman, Maeve Hopkins, Monique De Four Jones, Tyler Kat, Courtney Martin, Mona Prasad, Marcela C. Smid, Kathryn. Robert Ryan, , Candice Yong, Patricia I. Carney, and Hyagriv N. Simhan. Real-World Utilization of an Intrauterine,Vacuum-Induced,Hemorrhage-Control Device. Obstetrics & Gynecology 142, NO. 5,1006-1016. November 2023