First large real-world study of FDA-cleared device to treat postpartum hemorrhage finds device highly safe and effective

February 10 2023

Credit: Unsplash/CC0 Public Domain

Postpartum hemorrhage—severe bleeding after childbirth—is a leading cause of maternal deaths worldwide. There have been few innovations in

treatment in recent years.

In a new study to be presented today at the Society for Maternal-Fetal Medicine's (SMFM) annual meeting, The Pregnancy Meeting—published in the *American Journal of Obstetrics & Gynecology*—researchers will unveil findings that suggest a new tool to manage postpartum hemorrhage is safe and effective in treating hemorrhage after both vaginal and cesarean births.

The Jada System, an intrauterine vacuum-induced hemorrhage control device, was cleared by the FDA in August 2020 after the PEARLE IDE (investigational device exemption) study found the device to be safe and effective for treating postpartum hemorrhage. The IDE study included 107 patients, and the vast majority of deliveries (85 percent) were vaginal.

The objective of this new study was to report on the device's safety and effectiveness in real-world use. Researchers analyzed 800 individuals who were treated with the device from October 2020-April 2022 at 16 hospitals across the United States. Of those patients, 94.3 percent had uterine atony. Uterine atony is the most common cause of postpartum hemorrhage and occurs when the uterus doesn't contract sufficiently to stop bleeding after childbirth.

Researchers found that the device successfully treated postpartum hemorrhage in 92.5 percent of vaginal births and 83.7 percent of cesarean births. In a subset of the patients where time to bleeding control was captured, for vaginal births, bleeding was controlled in 73.8 percent of patients in five minutes or less. In cesarean births, bleeding was controlled in 62.2 percent of patients in five minutes or less. Mean indwelling time—the average length of time from when the device was inserted into the uterus to when it was removed—was 4.6 hours for vaginal births and 6.3 hours for cesarean births.

"After the PEARLE IDE study was published and the device became available, we knew institutions across the country would start using this device. In our study, we wanted to assess the safety and effectiveness of the device in real-world use for a larger number of patients for both vaginal and cesarean births," says the study's lead author Dena Goffman, MD, a maternal-fetal medicine subspecialist and professor and vice chair for quality and patient safety in the Department of Obstetrics and Gynecology at Columbia University Irving Medical Center in New York.

"What stood out in our study was that this device worked in real-world settings. It worked quickly and was highly effective in controlling postpartum hemorrhage, after both vaginal and cesarean birth, in a high proportion of patients. In addition, the device was safe and only had to remain in place for a few hours after placement allowing for a more streamlined postpartum care experience.

"As clinicians, we need to have more options to treat this potentially life-threatening condition, and this device gives us another tool to add to our toolbox to optimize postpartum hemorrhage management."

More information: Dena Goffman et al, Real-world utilization of an intrauterine vacuum-induced hemorrhage-control device, *American Journal of Obstetrics and Gynecology* (2023). DOI: 10.1016/j.ajog.2022.11.1308

Provided by Society for Maternal-Fetal Medicine