

## Vacuum-induced control device beneficial for postpartum hemorrhage

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Rapid and effective bleeding control can be achieved using a U.S. Food



and Drug Administration-cleared intrauterine vacuum-induced hemorrhage control device for both vaginal and cesarean births, according to a study published online Sept. 14 in *Obstetrics & Gynecology*.

Dena Goffman, M.D., from the New York-Presbyterian/Columbia University Irving Medical Center in New York City, and colleagues examined the real-world effectiveness and safety of an FDA-cleared intrauterine vacuum-induced hemorrhage control device for postpartum hemorrhage management at 16 centers in the United States from October 2020 through March 2022. Overall, 800 individuals were treated with the device (530 vaginal births; 270 cesarean births); 94.3 percent had uterine atony.

The researchers found that the median total blood loss at device insertion was 1,050 and 1,600 mL in vaginal and cesarean births, respectively. The treatment success rate was 92.5 and 83.7 percent for vaginal births and cesarean births, respectively, across all bleeding causes (95.8 and 88.2 percent, respectively, in isolated atony).

The median indwelling time was 3.1 and 4.6 hours in vaginal and cesarean births, respectively. Fourteen serious adverse events (SAEs) were reported among 13 individuals in vaginal births (2.5 percent), while 22 SAEs were reported among 21 individuals in cesarean births (7.8 percent). Of the SAEs, three (0.4 percent) were deemed as possibly related to the device or procedure. There were no reports of uterine perforations or deaths.

"This study provides further evidence that the device is an important new tool for managing a leading cause of severe maternal morbidity and maternal mortality, and timely utilization may help to improve outcomes," the authors write.



Several authors disclosed ties to Organon/Alydia Health, which funded the study, and to pharmaceutical and medical technology companies.

**More information:** Dena Goffman et al, Real-World Utilization of an Intrauterine, Vacuum-Induced, Hemorrhage-Control Device, *Obstetrics & Gynecology* (2023). DOI: 10.1097/AOG.000000000005366

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