Novel Vacuum-Induced Device For Treatment Of Postpartum Hemorrhage Is Safe, Effective And Easy To Use


Results

One hundred and seven (107) participants were enrolled, of which 106 were treated and evaluated for effectiveness.

EFFECTIVENESS

• Treatment success rate was 94% (100/106, 95% CI: 88% to 98%).
• Abnormal bleeding was controlled in median of 3 minutes from time of vacuum connection.

SAFETY

• Eight adverse events reported deemed “possibly related” to the procedure. All events were expected risks and resolved with treatment. Events included mild endometritis, mild presumed endometritis, mild bacterial vaginosis, mild vaginal candidiasis, mild laceration repair disruption (n=1), and moderate endometritis (n=3).

EASE OF USE

• Investigators reported the device was easy to use (98%), easy to insert (96%), and easy to remove (98%).
• Investigators achieved rapid device deployment: median time from opening package to device insertion was 2 minutes, followed by median time from insertion to vacuum connection of 2 minutes.
• Instructions for device use were rated as clear by 100%.

OVERALL INVESTIGATOR ASSESSMENT

• 98% reported device did not prohibit normal postpartum activities.
• 97% recommended device for treatment of abnormal postpartum uterine bleeding and hemorrhage.

Introduction and Objective

• Postpartum hemorrhage is the leading cause of maternal mortality worldwide.
• To facilitate improvement in outcomes, tools must be safe, effective and easy to use.
• A new vacuum-induced hemorrhage control (VHC) device (Jada® System, Alydia® Health) that controls bleeding by contracting the uterus is available in the US.

Methods

• Twelve United States sites participated in a prospective, multi-center, treatment study of an intrauterine vacuum-induced hemorrhage control device to treat abnormal postpartum uterine bleeding and postpartum hemorrhage.
• Primary effectiveness endpoint was VHC treatment success, defined as control of bleeding without further escalating intervention.
• Occurrence of device-related adverse events was assessed.
• Independent assessment of ease of device use completed by investigator after each case.

Conclusions

• VHC was safe, effective, and easy to use for treatment of abnormal postpartum uterine bleeding and postpartum hemorrhage.
• First-time user feedback in the form of high device usability ratings supports a minimal learning curve.
• Any healthcare provider trained in obstetrics can utilize VHC quickly and easily with the guidance of instructions included in the package.

Jada® System Set Up

Vacuum Pores
Cervical Seal
Intra-uterine Loop
Seal Valve
Tube
Vacuum Connector

Quick Reference Guide

(100% rated instructions and training as clear)