

## Innovations in Postpartum Hemorrhage Care: A Systematic Review of Vacuum Hemorrhage Control Devices (Protocol)

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### ADMINISTRATIVE INFORMATION

**Support** - N/A.

**Review Stage at time of this submission** - Risk of bias assessment.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY2023100058

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 October 2023 and was last updated on 17 October 2023.

### INTRODUCTION

**Review question / Objective** This systematic review aims to evaluate the efficacy and safety of vacuum hemorrhage control devices (e.g. Jada system) in the management of postpartum hemorrhage.

**Condition being studied** Postpartum hemorrhage is a leading cause of maternal mortality worldwide. Uterine atony causes 80% of the cases of postpartum hemorrhage in both vaginal and cesarean delivery. Safe and effective management of PPH is imperative to reducing maternal mortality worldwide, and current trends demand further research efforts geared towards establishing novel treatment methods.

### METHODS

**Search strategy** A literature search was conducted with Sacred Heart University Health

Sciences librarian on October 4, 2023, through EBSCOHost and the databases searched included: CINAHL Ultimate, Academic Search Premier, Cochrane Central Register of Controlled Trials, Cochrane Database of systematic Reviews, MEDLINE with Full Text, and PubMed. The following Boolean search string was used: (postpartum or postnatal) AND (hemorrhage or haemorrhage or hemorrhaging or haemorrhaging) AND (vacuum device or JADA). Limits used were: peer reviewed studies. Due to the novelty of vacuum hemorrhage devices in PPH management and limited published research, no publication date limitations were applied. Two independent reviewers (LMC & AVK) used Covidence to screen titles and abstracts; these reviewers similarly evaluated full-text articles to confirm eligibility. For eligible studies, data were independently extracted by two reviewers. Any conflicts were resolved by a consensus-based discussion or arbitration by a third reviewer (SJR). The reference lists of included

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studies were also manually searched to identify additional qualifying studies.

**Participant or population** Patients with postpartum hemorrhage with failed first line therapy (oxytocin, uterotonic agents) requiring further intervention.

**Intervention** Vacuum hemorrhage control device (e.g. Jada system).

**Comparator** None.

**Study designs to be included** Randomized control trials, nonrandomized studies of intervention, and case studies.

**Eligibility criteria** Eligible studies included randomized control trials, nonrandomized studies of interventions, and case studies that reported quantitative data on efficacy, effectiveness, and/or safety profiles. Additional inclusion criteria applied were atonic postpartum hemorrhage and studies written in the English language. Studies reporting quantitative data on efficacy and/or safety profiles, atonic postpartum hemorrhage, studies written in the English language.

**Information sources** Electronic databases will be searched. The reference lists of included studies were also manually searched to identify additional qualifying studies.

**Main outcome(s)** Efficacy defined as hemorrhage control without the need for escalatory intervention or recurrence of bleeding. Safety defined as minimization of reported adverse effects or harms with treatment.

**Quality assessment / Risk of bias analysis** The risk of bias of included nonrandomized studies and case series was independently assessed by two independent reviewers (LMC & AVK) according to the Joanna Briggs Institute (JBI) critical appraisal checklist for cohort studies and case series tools.

**Strategy of data synthesis** Data was extracted and synthesized using Microsoft Excel.

**Subgroup analysis** Subgroup analysis of success rate using vacuum hemorrhage device versus balloon tamponade device for postpartum hemorrhage management planned.

**Sensitivity analysis** No sensitivity analysis planned at this time.

**Language restriction** English.

**Country(ies) involved** United States.

**Keywords** postpartum hemorrhage; hemorrhage; Jada; vacuum; vacuum hemorrhage device; vacuum tamponade.

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