Clinical outcomes and cost-effectiveness of a vacuum intra-uterine device compared to intrauterine balloon tamponade for treatment of postpartum hemorrhage

Alexander Azzo, MD, PhD[1,2] | Jia Shi, BS[1] | Bertha Ben Khallouq, MA[1] | Teresa Lance, MSN, APRN-CNS[1] | Stanislaw Miaskowski, MD, FACOG[1,2]

Introduction

Postpartum hemorrhage (PPH) is a significant complication that occurs after childbirth, characterized by excessive bleeding. It is a leading cause of maternal morbidity and mortality worldwide, with a rate of 3-5% within the United States. PPH can have severe and immediate effects, including hypovolemic shock, organ failure, and death if not promptly managed. The condition also has long-term impacts, such as anemia and postpartum depression, which affect overall maternal well-being. Effective and timely intervention are crucial to mitigating the risks associated with PPH and ensuring maternal health. A novel vacuum induced intra-uterine device was developed to improve maternal outcomes and decrease the financial burden to the patient and healthcare system.

Purpose

The vacuum induced intra-uterine device was developed for treatment of PPH for the management of the third stage of labor with several studies demonstrating efficacy. This single center had not made the vacuum intra-uterine device available prior to initiation of this study. Previously available intrauterine device utilized at this facility includes the pressure balloon device that tamponades uterine bleeding, which requires prolonged admission to the ICU. Thus, the current device leads to significant costs to patients and hospital. The institution intends to use the novel device at its academic service line before making it available to all providers. The goal is to demonstrate efficacy, cost savings, and provider satisfaction at the institution and implement its use within the PPH protocol across the organization comparing the results to currently available therapy.

Methods

This study design was a prospective non-randomized trial of the vacuum intra-uterine device over a 1-year period (2023-2024) with historical controls for balloon tamponade device over a similar time period (2022-2023). Inclusion criteria for both groups included suspicion for uterine atony as the primary source of hemorrhage, and documented quantitative blood loss (QBL). Exclusion criteria included hemorrhage suspected to be due to alternative source. Mode of delivery was not an exclusion criteria and data was collected on both vaginal deliveries and cesarean section. All participating providers received on site simulation training with the novel device and the devices were inserted using manufacturer's recommended protocol. Data was collected through the electronic medical record. We collected all datapoints necessary to perform our institutional assessment and comparison of the vacuum and tamponade intrauterine devices. Additionally, a multi-disciplinary survey was distributed to assess satisfaction of use during our study period. A cost-benefit analysis of the two devices will be completed in a future study. The data was entered in REDCap, a HIPPA compliant platform accessible only to the research team. All data analysis was performed using the R programming language version 4.3.2. This study was approved by the Orlando Health Institutional review board.

Results

	Vacuum (n=26)	Balloon (n=32)	P-value
Age	30.7	33.5	0.113
Gravida	2.5	2.9	0.386
Gestational age	38.7	38.7	0.918
BMI	32.7	34.0	0.468
Pre-eclampsia	8/26 (30.8%)	7/32 (21.9%)	0.640
QBL Prior to Vacuum (mL)	1945	1682	0.241
QBL After Vacuum (mL)	264	90	0.200
# of pRBCS	1.81	1.75	0.920
Time from delivery to postpartum unit transfer (hours)	12.4	33.1	3.59E-6*
Time from delivery to discharge (days)	2.74	3.04	0.299
Admission Hgb - Lowest Postpartum Hgb	3.60	3.02	0.228

Table 1. Baseline characteristics and efficacy comparisons between vacuum intrauterine device and intrauterine balloon tamponade. Statistical testing utilized either Student's t-test for continuous variables or Chi-squared for categorical variables, both with Tukey's HSD post-hoc analysis for multiple comparisons. * $p < 0.05$

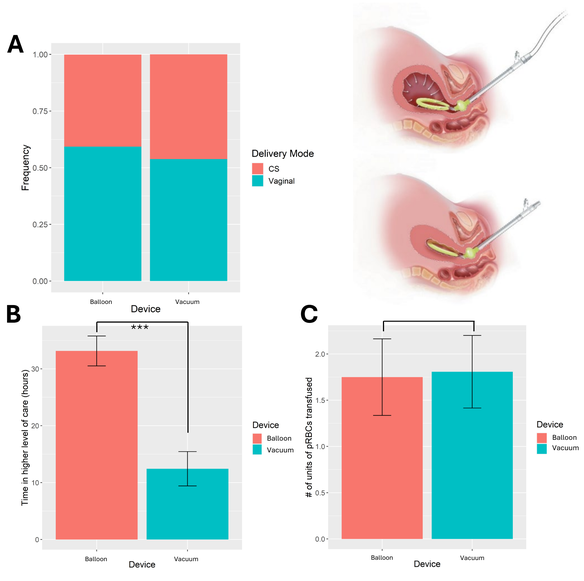

Fig 1. Vacuum intrauterine device was associated with decreased time in higher level of nursing care, but showed no difference in transfusion requirements compared to balloon tamponade device. A) Frequency of vaginal delivery vs cesarean section for balloon and vacuum placements. B) Time (in hours) post delivery spent in level of nursing care higher than postpartum med-surg status (e.g. L&D floor, PCU, ICU status). C) Mean units of packed red blood cells transfused per patient for balloon vs vacuum devices. Statistical testing utilized Student's t-test with Tukey's HSD post-hoc analysis for multiple comparisons. *** $p < 0.001$

Results

A Vacuum Device

WICU admissions	3 (13%)
Need for additional procedure	4 (17%)
Hysterectomy	2 (8%)
Balloon after Vacuum	0 (0%)
Dilation and Curettage	2 (8%)
Banjo	1 (4%)
Laparotomy	2 (9%)
B-Lynch sutures	0 (0%)
Uterine artery ligation	0 (0%)
Uterine artery embolization	0 (0%)

B Balloon Tamponade Device

WICU admission	5 (16%)
Need for additional procedure	24 (75%)
Hysterectomy	2 (6%)
Vacuum after Balloon	0 (0%)
Dilation and Curettage	20 (62%)
Banjo	9 (28%)
Laparotomy	2 (6%)
B-Lynch sutures	0 (0%)
Uterine artery ligation	0 (0%)
Uterine artery embolization	2 (6%)

Table 2. Comparison of poor obstetric outcomes and need for additional procedures in vacuum group compared to balloon group. A) Markers of morbidity and frequency of additional procedures apart from device placement in vacuum group. B) Markers of morbidity and frequency of additional procedures apart from device placement in balloon group.

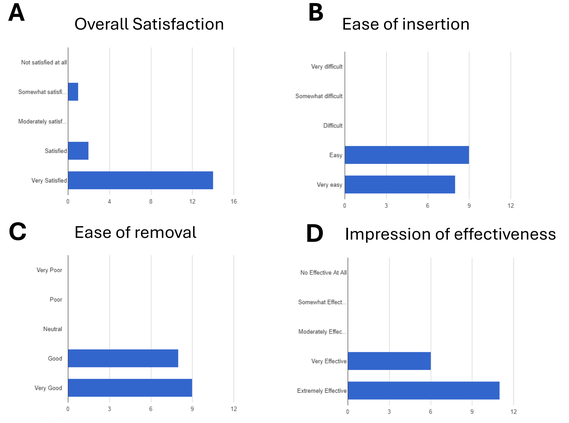

Fig 2. Results of provider survey depicting overall satisfaction/dissatisfaction with vacuum device. A) Overall satisfaction. B) Ease of insertion and manufacturer's instructions. C) Satisfaction with removal of vacuum device. D) Provider's subjective impression of vacuum effectiveness for control of postpartum hemorrhage.

Discussion

Patient demographics were consistent across both groups, indicating no significant differences. The quantified blood loss (QBL) prior to device placement was approximately 250 mL higher in the vacuum induced device group, however this difference was not statistically significant. QBL post device placement was approximately 150 mL higher in the vacuum induced device group, though this difference was not statistically significant. Groups showed no significant differences in the need for blood transfusions or the decrease in hemoglobin levels in the postpartum period. Notably, there was a significant reduction in the time spent in higher-level care for patients managed with the vacuum induced intrauterine device, averaging 12 hours compared to 33 hours. There was no overall difference in the time from delivery to discharge between the two groups. The need for additional interventions was significantly lower in the vacuum induced intrauterine device group, with only 17% requiring further procedures compared with 75% in the intrauterine balloon tamponade group. Lastly, multidisciplinary clinician satisfaction was exceptional for the vacuum induced intrauterine device.

Conclusions

The vacuum induced intra-uterine device for postpartum hemorrhage demonstrates a similar safety and efficacy profile in comparison to the balloon tamponade intra-uterine device. The vacuum induced intra-uterine device, however, had a decrease in cost burden associated with a higher level of nursing care as well as additional surgical interventions for postpartum hemorrhage. A cost-benefit analysis will be completed in the future. Additionally, as the healthcare system becomes familiar with the device, earlier intervention with the vacuum induced intrauterine device in the postpartum hemorrhage algorithm may demonstrate improved efficacy for the third stage of labor. Overall, multi-disciplinary satisfaction with the utilization of the device was exceptional, even with new users.

References

1. D'Alton, M. E., Rood, K. M., Smid, M. C., Simhan, H. N., Skupski, D. W., Subramaniam, A., ... & Goffman, D. (2020). Intrauterine vacuum-induced hemorrhage-control device for rapid treatment of postpartum hemorrhage. Obstetrics and gynecology, 136(5), 882.
2. D'Alton, M., Rood, K., Simhan, H., & Goffman, D. (2021). Profile of the Jada® System: the vacuum-induced hemorrhage control device for treating abnormal postpartum uterine bleeding and postpartum hemorrhage. Expert Review of Medical Devices, 18(9), 849-853.
3. Goffman, D., Rood, K.M., Bianco, A., ... & Simhan, H.N. (2023). Real-World Utilization of an Intrauterine, Vacuum-Induced, Hemorrhage-Control Device. Obstetrics & Gynecology 142(5):p 1006-1016.
4. Gerber, R. P., De Four Jones, M., Nimaroff, M., Rochelson, B., & Gulersen, M. (2022). Vacuum-induced hemorrhage control device versus uterine balloon tamponade for management of postpartum hemorrhage. *American Journal of Obstetrics & Gynecology*, 226(1, Supplement), S716.
5. Seasely, A. R., Szychowski, J. M., Saxon, N., Casey, B. M., Tita, A., & Subramaniam, A. (2021). Vacuum-induced hemorrhage control versus balloon tamponade for management of postpartum hemorrhage (PPH): Single center experience. *American Journal of Obstetrics & Gynecology*, 224(2, Supplement), S501.
6. Simhan, H., Sakamoto, S., Seasely, A. R., Subramaniam, A., & Rood, K. M. (2021). Balloon tamponade versus a novel vacuum-induced hemorrhage control device for treatment of postpartum uterine bleeding. *American Journal of Obstetrics & Gynecology*, 224(2, Supplement), S683.