# Control of Postpartum Hemorrhage Using Vacuum-Induced Uterine Tamponade

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Running Title: Vacuum-Induced Uterine Tamponade

# Précis

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Vacuum-induced uterine tamponade may be an effective alternative to balloon tamponade systems for treating patients with postpartum hemorrhage due to atony.

# ABSTRACT

**BACKGROUND**: Postpartum hemorrhage is the leading cause of maternal mortality worldwide. Vacuum-induced uterine tamponade is a possible alternative approach to balloon tamponade systems for the treatment of postpartum hemorrhage due to atony.

**METHOD***:* In a prospective proof-of-concept investigation of 10 women with vaginal deliveries in a hospital setting who failed first-line therapies for postpartum hemorrhage, tamponade was employed. Vacuum-induced uterine tamponade was created through a device inserted transvaginally into the uterine cavity. An occlusion balloon built into the device shaft was inflated at the level of the external cervical os, to create a uterine seal. Negative pressure was created by attaching [wall suction?]

**EXPERIENCE*:***In all 10 cases, the suction created an immediate seal at the cervical os, 50-250 milliliters (ml) of residual blood was evacuated from the uterine cavity, the uterus collapsed and regained tone within minutes, and hemorrhaging was controlled. The device remained in place for a minimum of one hour and up to 6.5 hours in one case while vaginal and perineal lacerations were easily repaired.

**CONCLUSION***:* This preliminary investigation suggests that a device designed to create vacuum-induced uterine tamponade may be a reasonable alternative to other devices used to treat atonic postpartum hemorrhage.

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## INTRODUCTION

Postpartum hemorrhage is the leading cause of maternal mortality worldwide. The global prevalence of postpartum hemorrhage is 6%. In Africa and Asia, where most maternal deaths occur, postpartum hemorrhage accounts for more than 30% of all maternal deaths. (1)(2) Even developed countries are challenged by this life-threatening complication of childbirth, causing 10.6% of maternal deaths in the UK, and 12% of maternal deaths in the USA. (4)

Primary postpartum hemorrhage is the most common form of major obstetric hemorrhage and approximately 75% of primary postpartum hemorrhage is due to uterine atony. The traditional definition for primary postpartum hemorrhage is blood loss from the genital tract of >500 ml or that which causes hemodynamic changes, within 24 hours of the birth of a baby. Postpartum hemorrhage protocols are activated with the first signs of excess bleeding before severe postpartum hemorrhage or hemodynamic changes occur, to prevent blood loss that requires drastic measures or becomes life-threatening. (3)(6)(5)(7)(8)(9)

Active management of the third stage of labor, AMTSL, consisting of administering uterine active pharmaceuticals, controlled cord traction, and uterine massage, decreases maternal blood loss and reduces the incidence of postpartum hemorrhage by approximately 60%. This conservative triad facilitates normal post partum tetanic myometrial contractions that constrict placental bed vasculature. A device that creates an intrauterine vacuum was designed to take advantage of this physiologic mechanism for establishing hemostasis after childbirth.

Since at least the 1800s, uterine packing has been used to tamponade hemorrhaging internal uterine surfaces of the atonic uterus. This treatment strategy has long been associated with worry about hidden bleeding from soaked packing and infection.(10) Since the middle of the 20th century, balloons of various kinds and configurations have been inserted into the uterus to produce uterine cavity balloon tamponade by exerting pressure outward on the endometrial surface.

The primary objective of the vacuum-induced tamponade device procedure is to effectively and rapidly control excessive bleeding when first-line conservative therapies have failed and in so doing, reduce blood loss and associated maternal morbidity and mortality in patients with postpartum hemorrhage due to uterine atony.

## METHOD

The vacuum-induced tamponade device (Figure 1a), manufactured by InPress Technologies, Inc., is a low cost (less than $100), one piece, comes in a sterile package designed for one-time use, and is made of medical grade silicone. Retractors, and a ring forceps placed on the anterior cervical lip for guidance, facilitate insertion. The distal loop with pores, positioned in the uterine cavity, is connected directly to a regulated vacuum pump. The device’s occlusion balloon is positioned at the external cervical os and is inflated with saline through a separate internalized line with occlusion balloon valve near the end of the vacuum port (Figure 1b). The occlusion balloon ensures the uterine-cervical cavity is rendered a sealed space. When this cavity is subjected to 70mmHg of symmetrically distributed and manually regulated vacuum force, the differential pressure between the inside and outside of the uterus, causes the space to collapse into and onto itself (Figure 1c; see simulation video). This collapse-generated-tamponade also stimulates normal physiologic tetanic uterine contractions. These contractions constrict the vasculature serving the placental bed.

The target population for this open label, non-randomized, prospective clinical investigation were birthing mothers who developed post-partum hemorrhage and required intervention when first line therapies have failed. Other patient screening characteristics included: 1) uterus size ≥ 34 weeks as measured by fundal height prior to delivery, 2) blood loss less than 1500ml, 3) normal Prothrombin Time (PT), Partial Thromboplastin time (PTT), and International Normalized Ratio (INR). Women who presented with retained placenta, uterine lacerations, uterine scar or for any other conditions outside of atonic post-partum hemorrhage were excluded.

Ethics committee approval was obtained from the Faculty of Medicine, University of Indonesia, on July 7, 2014. Ten patients who experienced postpartum hemorrhage were treated in three hospitals in Jakarta Indonesia with a standard infusion of IV Oxytocin as a part of AMTSL. When bleeding was noted to be excessive, the IV oxytocin infusion rate was increased and Misoprostol, 1000 micrograms, was given sublingually or per rectum . Methergine, 0.2 mg, was sometimes administered by unit protocol in addition to oxytocin and Misoprostol for postpartum hemorrhage. When estimated blood loss exceeded 500ml based on pad and towel assessments and the diagnosis of postpartum hemorrhage was made, the vacuum-induced tamponade device was deployed in place of balloon tamponade. The infusion of oxytocin was maintained throughout the treatment. Ultrasound was used to document normal uterine anatomy, absence of retained products of conception (POC), proper device placement, and stability of the device.

All data from the investigation were entered into a customized relational database and maintained by the Genae Group, a Belgium based contract research organization. Standard operating procedures were followed to assure the data were regularly monitored, the database was validated, and the data were accurate. InPress personnel were not involved in the data capture or analysis. Descriptive statistics were generated using JMP Statistical Software, Version 11.0, SAS Institute, Cary, North Carolina, USA.

**EXPERIENCE**

The average age for the 10 treated women was 25.4 ± 6.2 years (range 17.5-36.3 years). Six of the 10 women (60%) were having their first child. For the women who were multiparous, two women had one prior child, another had two prior children, and the third woman had three prior children. None of the women had a history of postpartum hemorrhage or had prior Caesarian sections. Estimated blood loss prior to placement of the device ranged from 650-1000cc.

All cases established a tight vacuum seal immediately and 50-250mL of residual blood was evacuated from the uterine cavity. Thereafter, no case exhibited continued excessive or unusual blood loss after the initial 2 minutes of vacuum seal as measured by no change in the volume in the canisters. The vacuum-induced tamponade device was used for about 1-hour in four cases, and for 2-6.5 hours in the other six cases [Table 1]. The range of blood loss before implementing treatment with the vacuum induced tamponade device was estimated to range from 600-1000 ml. The range of total blood loss measured by towel and pad weight for the hemorrhage events after treatment was 670-1180 ml. Although pre- and post-treatment blood losses were similar, estimated blood loss (EBL) was always less than measured blood loss (MBLA), and towel and pad weights and canister volumes objectified only the post treatment volumes in this small number of cases. Before complete removal of the device, patients were determined to be stable and the device was left in place for several minutes after disengaging vacuum and deflating the occlusion balloon to ensure that the uterus remained firm and bleeding did not recur. The device could be re-deployed while still in place and left in for up to 24 hours, if needed. There was no need for re-deployment in any of the ten cases and no additional procedures were required. All patients tolerated placement of the device and removal without issue. Patient demographic data and case detail summaries are listed in Table 1.

All cases established a tight vacuum seal immediately. The vacuum-induced tamponade device was left in for a minimum of 1 hour. In all cases, uterine hemorrhaging was controlled and uterine contractions started to establish normal postpartum tone within 2 minutes. The vacuum-induced tamponade device was used for about 1-hour in four cases, and for 2-6.5 hours in the other six cases [Table 1]. Blood loss measured by towel and pad weight following treatment with the device ranged from 670-1180cc. Before complete removal of the device, patients were assessed to be stable and the device was left in place for several minutes after disengaging vacuum and deflating the occlusion balloon to ensure that the uterus remained firm and bleeding did not recur. The device could be re-deployed while still in place and left in for up to 24 hours, if needed. There was no need for re-deployment in any of the ten cases and no additional procedures were required. All patients tolerated placement of the device and removal without issue. Patient demographic data and case detail summaries are listed in Table 1.

## DISCUSSION

The vacuum-induced tamponade device worked within minutes to control hemorrhage. The controlled introduction of low vacuum forces into the sealed uterine space quickly collapsed the uterine cavity, generating a prompt self-tamponade. The uterus then quickly regained normal tone.

This physiologic method for controlling postpartum hemorrhage may represent an improvement over use of uterine packing or intrauterine balloon strategies. In addition, the vacuum-induced tamponade device is designed to minimize the risk of injury, to distribute the low vacuum forces symmetrically, to assure a complete seal for immediate effect, and to allow for direct observation and measurement of any persistent bleeding in the collection container.

Rapid, effective, inexpensive treatment for post partum hemorrhage is a high priority in the efforts to reduce maternal mortality and morbidity. The vacuum-induced tamponade device can be used in most low-resourced settings with a regulated vacuum pump. The device allows direct measurement of blood loss and on-going treatment of lower genital tract lacerations if needed. It mimics physiologic uterine contractions, in contrast to balloon devices which exert outward pressure on the uterine cavity, which may promote improved uterine tone and function after the device is removed. The benefits of the device and procedure are the speed and completeness of hemorrhage control once deployed as well as its ease of use.

This is a limited proof-of-concept investigation. In order to demonstrate that the vacuum-induced tamponade device is superior to the current balloon tamponade devices, a randomized controlled trial comparing the two devices is needed. End points including maternal mortality and morbidity, secondary hemorrhage, transfusion and infection rates, complications and costs will need to be evaluated.

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## LEGEND

**Figure 1a:** The vacuum-induce tamponade device with labeled components.

**Figure 1b**: The postpartum hemorrhage placed within an atonic postpartum uterus, occlusion balloon inflated and vacuum just turned on

**Figure 1c**: The postpartum hemorrhage within a postpartum uterus, only minutes after administration of vacuum

### **Table 1.** Patient Demographics and Procedure Outcomes

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Patient Demographics | | | | Procedure Outcomes | | | |
| Patient # | Age | G | P | GA | EBLB | MBLA | Time | Total |
| 1 | 22 | 1 | 0 | 40-41 | 750 | \*1180 | 1-2 | 60 |
| 2 | 22 | 1 | 0 | 39 | 950 | 1150 | < 2 | 60 |
| 3 | 22 | 2 | 1 | 38-39 | 1000 | 1100 | < 2 | 170 |
| 4 | 36 | 4 | 3 | 40 | 700 | \*\*1100 | < 2 | 180 |
| 5 | 33 | 3 | 2 | 39 | 700 | 750 | < 2 | 115 |
| 6 | 21 | 1 | 0 | 38 | 600 | 670 | < 2 | 67 |
| 7 | 30 | 1 | 0 | 41 | 670 | 850 | < 2 | 390 |
| 8 | 18 | 1 | 0 | 39-40 | 750 | 825 | < 2 | 60 |
| 9 | 26 | 1 | 0 | 39 | 650 | 800 | < 2 | 60 |
| 10 | 28 | 2 | 1 | 40 | 700 | 775 | < 2 | 215 |

Age-in years, G-Gravida, P-Parity, GA-Gest Age-weeks, EBL-estimated blood loss,

EBLB-Estimated Blood Loss Before insertion of the vacuum-induce tamponade device

MBLA-Measured Blood Loss After placement of the InPress device using blood soaked towels and pads

#- Time (minutes) for vacuum-induce tamponade device to control hemorrhage once vacuum deployed at 70mmHg

\*300cc blood loss was from external lacerations.

\*\*150cc blood loss from external lacerations

POSSIBLE CHANGES

All cases established a tight vacuum seal immediately and 50-250mL of residual blood was evacuated from the uterine cavity. Thereafter, in no case was continued excessive or unusual blood loss after 2 minutes of vacuum seal as measured by no change in the volume is the cannisters after the initial 2 minutes. The vacuum-induced tamponade device was used for about 1-hour in four cases, and for 2-6.5 hours in the other six cases [Table 1]. Total blood loss measured by towel and pad weight for the hemorrhage event was 670-1180 ml, including loss following treatment with the device ranged from 670-1180cc, very similar to the estimated blood loss prior to system placement.Before complete removal of the device, patients were assessed to be stable and the device was left in place for several minutes after disengaging vacuum and deflating the occlusion balloon to ensure that the uterus remained firm and bleeding did not recur. The device could be re-deployed while still in place and left in for up to 24 hours, if needed. There was no need for re-deployment in any of the ten cases and no additional procedures were required. All patients tolerated placement of the device and removal without issue. Patient demographic data and case detail summaries are listed in Table 1.