Control of Postpartum Hemorrhage Using Vacuum-Induced Uterine Tamponade

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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 resulting from 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 used. 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 a self-contained, mobile, electrically powered, pressure-regulated vacuum pump with a sterile graduated canister.

EXPERIENCE: In all 10 cases, the suction created an immediate seal at the cervical os, 50–250 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 1 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 atomic postpartum hemorrhage.

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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 United Kingdom and 12% of maternal deaths in the United States.3

Primary postpartum hemorrhage is the most common form of major obstetric hemorrhage and approximately 75% of primary postpartum hemorrhage is the result of uterine atony. The traditional definition for primary postpartum hemorrhage is blood loss from the genital tract of greater than 500 mL or that which causes hemodynamic changes within 24 hours of the birth of a neonate. 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.4-9

Active management of the third stage of labor, 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 postpartum 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. 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 resulting from uterine atony.

**METHOD**

The vacuum-induced tamponade device (Fig. 1A), manufactured by InPress Technologies, Inc, is low cost (less than $400), 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 (Fig. 1B). The occlusion balloon ensures the uterine–cervical cavity is rendered a sealed space. When this cavity is subjected to 70 mm Hg 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 (Fig. 1C; Video 1, available online at http://links.lww.com/AOG/A817). Although the fallopian tube channels are patent, they are not structurally held in an open position. They are potential spaces existing in a compressed state during pregnancy and the postpartum period. Vacuum forces would not counter this potential but closed and

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**Video 1.** Animated simulation of vacuum-induced uterine tamponade for treatment of postpartum hemorrhage. Video created by Marily Mallison. Used with permission.

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**Fig. 1.** A. The vacuum-induced tamponade device with labeled components. B. The postpartum hemorrhage device placed within an atonic postpartum uterus, occlusion balloon inflated, and vacuum just turned on. Arrows represent initiation of symmetrically applied vacuum forces. C. The postpartum hemorrhage device within a postpartum uterus, only minutes after administration of vacuum. Courtesy of InPress Technologies, Inc. Used with permission.

compressed status, rather, would add to the certainty that these spaces remain in a closed state. The cervical lumen is a much larger channel, especially after labor, and therefore requires our occlusion balloon to ensure a seal to contain the vacuum forces applied to the uterocervical space. 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 was birthing mothers, recruited over a period of 7 months, who developed postpartum hemorrhage and required intervention when first-line therapies had failed. Other patient screening characteristics included: 1) uterus size 34 weeks or greater as measured by fundal height before delivery, 2) blood loss less than 1,500 mL, and 3) normal prothrombin time; partial thromboplastin time, and international normalized ratio. Women who presented with retained placenta, uterine lacerations, uterine scar, or for any other conditions outside of atonic postpartum hemorrhage were excluded.

Ethics committee approval was obtained from the Faculty of Medicine, University of Indonesia, on July 7, 2014, to treat primary postpartum hemorrhage resulting from atony with the vacuum-induced tamponade device in lieu of balloon tamponade in properly informed and consented patients. Ten patients who experienced postpartum hemorrhage were treated in three hospitals in Jakarta Indonesia with a standard infusion of intravenous oxytocin as a part of active management of the third stage of labor. When bleeding was noted to be excessive, the intravenous oxytocin infusion rate was increased and 1,000 micrograms misoprostol were given sublingually or per rectum. Methergine, at 0.2 mg, was sometimes administered by unit protocol in addition to oxytocin and misoprostol for postpartum hemorrhage. When estimated blood loss exceeded 500 mL based on pad and towel assessments and the diagnosis of postpartum hemorrhage was made, the vacuum-induced tamponade device was deployed in place of the device and removal without issue.

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 cesarean deliveries. Estimated blood loss before placement of the device ranged from 600 to 1,000 mL. The diagnosis of postpartum hemorrhage and the decision to treat with the vacuum-induced tamponade device were triggered by estimated blood loss only.

All cases established a tight vacuum seal immediately and 50–250 mL of residual blood was evacuated from the uterine cavity. Thereafter, no patient 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 approximately 1 hour in four patients and for 2–6.5 hours in the other six patients (Table 1). The range of blood loss before implementing treatment with the vacuum-induced tamponade device was estimated to range from 600 to 1,000 mL. The range of total blood loss measured by combining towel and pad weight for the hemorrhage event, with measured canister volumes, after treatment, was 670–1,180 mL. Although pretreatment and posttreatment blood losses were similar, estimated blood loss was always less than measured blood loss, and towel and pad weights and canister volumes objectified only the posttreatment volumes in this small number of patients. 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. Tone was established in the standard clinical manner by palpating the uterus transabdominally to assess uterine size and muscle tone to document a retracted size and firm tone associated with the normal postpartum state. The device could be redeployed while still in place and left in for up to 24 hours, if needed. There was no need for redeployment in any of the 10 patients and no additional procedures were required. All patients tolerated placement of the device and removal without issue.
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 postpartum hemorrhage is a high priority in efforts to reduce maternal mortality and morbidity. The vacuum-induced tamponade device is superior to the current balloon tamponade devices, a randomized controlled trial comparing the two devices is needed. Endpoints including maternal mortality and morbidity, secondary hemorrhage, transfusion and infection rates, complications, and costs will need to be evaluated.

REFERENCES