Uterine Balloon Tamponade

Technology Opportunity Assessment

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Summary

Postpartum hemorrhage (PPH) is the leading direct cause of maternal death worldwide. PPH can be prevented and treated, but if standard methods fail or are not available, women in low-resource settings may not have access to additional care. Uterine balloon tamponade (UBT) has been recognized as a relatively easy-to-use and effective second-line option for managing severe PPH, but cost and other factors limit its use in low-resource settings. With further research and development, a lower-cost, appropriate UBT device has the potential to vastly improve treatment for PPH and save women’s lives.

Statement of need

Obstetric hemorrhage is estimated to cause 25% of all maternal deaths and is the leading direct cause of maternal mortality worldwide. Postpartum hemorrhage (PPH), defined as vaginal bleeding in excess of 500 mL after delivery, accounts for most cases of obstetric hemorrhage. It occurs in more than 10% of all births and is associated with a 1% case fatality rate.

Although active management of the third stage of labor can prevent up to 60% of PPH cases, PPH continues to have a devastating impact on women in low-resource settings. Obstetric hemorrhage accounts for 34% of maternal deaths in Africa, 31% in Asia, and 21% in Latin America and the Caribbean. Among women who do survive PPH, approximately 12% will have severe anemia. Also, women who survive severe PPH (greater than 1,000 mL of blood loss) are significantly more likely to die during the following year.

Most cases of primary PPH are caused by uterine atony, often a result of prolonged labor, preeclampsia, or a history of PPH in a previous pregnancy. The risk of death is greatest for women who are anemic or have other underlying health problems that make them less able to deal with blood loss.

Most cases of severe PPH can be prevented if the bleeding is controlled and managed immediately. This is often accomplished by administering one of a group of drugs called uterotonic. However, this and other options sometimes fail to control severe PPH or are not available. For this reason, effectively reducing death and injury due to PPH requires a combination of approaches and the adoption of second-line interventions that are appropriate for health facilities in low-resource settings. Uterine balloon tamponade (UBT) is one promising option.

Uterine balloon tamponade

UBT is a relatively simple and effective approach to managing and treating PPH. The minimally invasive intervention involves inserting a balloon device into the uterus and then incrementally filling the balloon.
with liquid, which slowly applies pressure to the uterus until the bleeding stops. If the balloon tamponade
is effective in stopping the hemorrhage, the patient is less likely to require surgical interventions and
blood transfusions, with their related risks and costs. Even when UBT cannot completely control severe
PPH, it still serves a critical role by reducing blood loss until the woman can be transported to a facility
with surgical management and other treatment options. Effective tamponade occurs rapidly, within 5 to
15 minutes after insertion and inflation of the balloon.

The World Health Organization (WHO), the International Federation of Gynecology and Obstetrics
(FIGO), the American College of Obstetricians and Gynecologists, the Royal College of Obstetricians
and Gynaecologists, and the International Confederation of Midwives (ICM) recognize balloon
tamponade as a method that could significantly improve the management of intractable PPH, especially in
low-resource areas where blood transfusions are not available and surgical interventions are not an
option.5-7

The precise mechanism of action for UBT is still unclear. The placenta is a low-pressure system, so it
seems likely that when the placenta is the source of hemorrhage, the direct pressure of the balloon, even
well below systemic pressure, will halt bleeding. When the hemorrhage is instead from an arterial source
in the endometrium, it is possible that the balloon’s exerted pressure exceeds the arterial pressure and thus
promotes clot formation. A third possibility is that the introduction of the balloon in the atonic uterus
causes it to contract.8 Further study is needed to determine the mechanism of action, which will in turn
help ensure proper placement and monitoring.

Use in low-resource settings

Since 1983, when Goldrath published evidence that inserting a Foley catheter in the uterus and inflating it
with water could achieve tamponade, case series and other studies have suggested that various UBT
devices may be effective in treating PPH.9-11 The studies used various types of UBT devices, including a
condom catheter, a Foley catheter, the Sengstaken-Blakemore Esophageal Tube, the Rusch Balloon, and
the Bakri Uterine Balloon. In 2007, Doumouchtsis et al. conducted a systematic review of treatment
options for PPH and found that the reported 84% success rate of UBT does not significantly vary from
surgical treatment outcomes.10

However, few studies have addressed the effectiveness of UBT in resource-limited settings, where other
treatments for PPH may not be feasible due to limited resources and the lack of well-trained providers. No
randomized control studies of UBT have been conducted to date. A systematic review of the effectiveness
of UBT in resource-poor settings in developing countries was conducted by Tindell et al. (2013).12 The
team identified 13 studies and described cases in 7 countries; 10 cases were in South and Southeast Asia
and 3 in sub-Saharan Africa. All studies but one were conducted in tertiary care settings. A review of
these studies suggests that UBT is effective in the treatment of PPH across a wide variety of indications
and techniques for use. UBT successfully treated PPH in 234 out of 241 cases reviewed.

Perhaps the most provocative outstanding questions about UBT concern how and whether it could be
used by non-physicians (less-trained “frontline” health workers) in community or peripheral care
facilities. In low-resource settings, it is here that women are most likely to suffer and die from PPH; frontline health workers are their first and often only point of contact with the health care system. Anecdotal reports from frontline health workers in sub-Saharan African countries suggest that they are already successfully using condom catheters as a temporizing method—that is, as a way to stabilize women enough to get them to a facility with a higher level of care. More evidence is needed to support these findings. Research may also confirm a widespread belief that midwives and skilled birth attendants (who already perform tasks of similar complexity, including cervical exams, delivery, and catheterization) could, with training, safely and effectively provide UBT.\textsuperscript{13}

In addition to its effectiveness as a second-line intervention for the treatment and management of severe PPH, UBT is very cost effective. Few available interventions can match the method’s low cost: US$1 per disability adjusted life year averted.\textsuperscript{14}

WHO included balloon tamponade in their 2009 \textit{Guidelines for the Management of Postpartum Haemorrhage and Retained Placenta} and recommended collection of further evidence as a high priority.\textsuperscript{7} In 2012, WHO updated the \textit{Guidelines for the Management of Postpartum Haemorrhage and Retained Placenta} to state: “The use of intrauterine balloon tamponade is recommended for the treatment of PPH due to uterine atony. This recommendation is now stronger than the previous guidelines. It can be used for women who do not respond to uterotonic or if uterotonic is not available. This procedure potentially can avoid surgery and is appropriate while awaiting transfer to a higher-level facility.”\textsuperscript{15}

Furthermore, FIGO included UBT as a recommended second-line intervention for the treatment of PPH in their updated guidelines issued in 2012.\textsuperscript{16} In conclusion, UBT has the potential to be an effective treatment for PPH in low-resource settings. Further study in these settings will help the treatment community better understand UBT’s potential for reducing maternal injury and death.

\textbf{Technology solutions landscape}

Effective interventions for PPH are critically needed to reduce maternal mortality worldwide, and UBT appears to have great potential. It is simple to use and has low health risks. UBT should be included in emergency obstetric protocols for PPH in low-resource settings, along with appropriate training, monitoring, and evaluation.

Several types of uterine-specific and non-uterine balloons have been successfully used to manage and treat PPH. Although these differ slightly from each other, they all generally follow the same principle and have the same indications and contraindications for use. All UBT devices are inflated with fluid in amounts that are determined by the health care provider based on how fast the bleeding stops. The balloon is inflated incrementally until the bleeding is controlled—this is often referred to as the “tamponade test.” On average, from 250 ml to 350 ml of fluid are needed to control bleeding.

Although UBT devices are most commonly used for PPH caused by uterine atony,\textsuperscript{12} they have also been used for bleeding following cesarean sections, in cases of placenta previa and accrete, and for
postabortion care. Contraindications of use are pregnancy, arterial bleeding, cervical or uterine cancer, danger of uterine rupture, infections, and uterine anomaly. Standard instructions stress that before inserting the balloon, it is important to be sure that the uterus is clear of any retained placenta and that no lacerations are evident. In some cases, the vagina can be packed with gauze to ensure that the balloon does not migrate out through the cervix. The woman should be monitored for continued or renewed bleeding and her vital signs checked regularly. UBT devices can be kept in place for up to 24 hours after insertion, if needed.

The following review describes three balloon tamponade devices designed specifically for uterine application, along with the condom catheter balloon device that has been widely used in low-resource countries to manage severe PPH. There have been a few case reports of the use of the Sengstaken-Blakemore Esophageal Tube, the Rusch Balloon, and the Foley catheter for tamponade following severe uncontrolled PPH. Because this review focuses on uterine-specific balloons, these devices have been excluded.

**The Bakri balloon tamponade**

The Bakri balloon tamponade, also called the Bakri Postpartum Balloon, is an inflatable balloon made of silicone. It is 58 cm long with a double lumen shaft. The device can be filled to a maximum of 800 ml, but recommended use is not to exceed 500 ml of normal saline. The tip of the silicone tube has two holes for drainage, so ongoing bleeding can be detected after insertion of the balloon.

The Bakri balloon has US Food and Drug Administration (USFDA) 510(k) clearance for specific application to PPH. The device comes with two 60-ml syringes for filling. Distribution and sale of the device is restricted to physicians in developed countries because it is expensive and can only safely be used once before it must be discarded.

**The Ebb® Complete Tamponade System**

Marketed under the trade name Ebb®, the Belfort-Dildy Complete Tamponade System is designed for use to control and treat PPH. It is made of polyurethane material and is intended to be inflated using an intravenous (IV) bag. The Ebb® includes two balloons, an upper balloon for insertion into the uterus and a lower balloon for insertion into the vagina. The upper uterine balloon can be filled with up to 750 ml of fluid and has separate lumens to ensure inflation and deflation, irrigation, and drainage. The vaginal balloon also has a separate lumen for inflation and deflation. The maximum amount of fluid to be used in the vaginal balloon is 300 ml. The Ebb® balloon has the CE mark (also known as a European Conformity mark). Like the Bakri balloon, the Ebb® balloon’s use is limited in developing countries due to its high cost and one-time usage.

**BT-Cath®**

The BT-Cath® is made of silicone and comes equipped with a lumen that allows health providers to monitor intrauterine blood drainage and assess the effectiveness of the tamponade. The intrauterine drainage port is flush with the top of the inflated balloon (no tubing protruding from the balloon),
allowing placement near the uterine fundus. Check valves simplify and expedite the inflation process. The BT-Cath® is USFDA approved and patents are pending. Like the Bakri uterine balloon and the Ebb balloon, use of the BT-Cath® is limited in developing countries due to its high cost and one-time usage.19

**Condom catheter**

The idea of using a condom as a balloon tamponade was first generated and evaluated in Bangladesh in 2001 by Dr. Sayeba Akhter to fill a need and in response to the high cost of commercially available UBT devices.20 The condom catheter is assembled at the point of use and consists of readily available components (male latex condom, an 18 or 22+ rubber catheter, and a string to tie the condom to the rubber tube). An IV infusion set can be used to fill the condom catheter, or it can be filled using a plastic syringe (50 cc to 100 cc). The cost of the condom catheter is low, estimated in the range of US$3 to US$6. The condom catheter has been shown to be effective in managing severe PPH, but it is an improvised device that relies on the availability of the various components at the time of the PPH and the confidence of the health care provider in assembling and using the device. Furthermore, the global impact of the improvised condom catheter can be limited because aggregated purchase programs such as the United Nations Children’s Fund Procurement Division are restricted from buying and distributing products that are not manufactured under Good Manufacturing Practices and that have not been validated as being in compliance with international standards.

**Gap analysis**

Balloon catheters for uterine tamponade are most widely used in developed countries. The high cost of UBT devices puts them out of reach for most developing-country health programs or at least limits their use to a few selected tertiary-level hospitals in each country. A simple, consistent, low-cost, and commercially available balloon catheter could be more widely used and disseminated to maternal health programs, potentially saving lives. Although the condom tamponade is affordable—the device components are priced off the shelf at less than US$5—the intervention can be significantly improved. A low-cost, preassembled device specific for PPH could increase the quality of the intervention and make it easier to use, more acceptable, and relevant for health care workers and clients at all levels of the health system—particularly peripheral sites where the need is highest.

In addition, although evidence is building around the use of balloon tamponade, more research is needed to support its use in various applications and to understand its impact on maternal health outcomes. Information collected on these issues will provide guidance on the design and cost drivers for a “new” low-cost UBT device.

To better understand the role of UBT in PPH, a number of questions need to be addressed through further investigation:

- Can UBT be used safely and effectively at peripheral health facilities by trained frontline workers?
- What is the mechanism of action of UBT?
• Is there an optimal amount of fluid required for balloon inflation and efficacy?
• What is the role of concurrent uterotontics?
• What is the appropriate procedure for removal of the UBT device to minimize recurrent bleeding, trauma, or other adverse effects?

Advancing the use of UBT for the management and treatment of severe PPH will require a multipronged approach that addresses supply and distribution of a low-cost UBT device, a clearly planned pilot of UBT devices in peripheral facilities, policy and advocacy efforts, and monitoring and evaluation of outcome measures.

Investment opportunity

There is current donor and stakeholder interest in advancing second-line interventions for the management of PPH. UBT has a specific role in treatment; it should be introduced into PPH protocols and guidelines as a viable method when first-line interventions fail and before more costly and risky surgery is required. For UBT to be effective in this role, it should be introduced as one part of a larger continuum of care strategy that also includes health provider training and support, health infrastructure, facilities that can provide emergency medical care, and adequate supplies.

UBT is a very promising intervention for the management of postpartum hemorrhage. PATH proposes a strategy that will support wider use of this second-line intervention worldwide. Investment will support the following goals:

Develop a low-cost UBT device.
• Identify key product features.
• Determine optimal manufacturing process.
• Identify a commercialization partner and appropriate regulatory pathway(s).
• Validate the low-cost design in a Phase 1 feasibility trial.
• Develop a simple postpartum uterus model to use for training nurses and nurse midwives. The uterus model would be used for training on basic obstetric care, complications, and interventions.

Support studies in preparation for introduction and scale-up.
• Conduct randomized clinical trials of the new low-cost UBT device in two early-adopter countries.
• Conduct operational studies in anticipation of introduction activities.

Create a strong communications and advocacy plan to set the stage for introduction and scale-up.
• Collaborate closely with professional organizations such as FIGO and ICM to promote wider use of UBT.
• Engage WHO in discussions about including the low-cost UBT device on the WHO list of essential medical devices as a second-line treatment for severe uncontrolled PPH.
Stimulate market demand.

- Identify countries in Africa and several states in India to implement UBT within maternal health care programs.
- Investigate the supply and distribution of UBT devices through aggregated purchasing systems and other innovative approaches.
- Assess private-sector demand in both developing and developed countries.
References


