

ELLAVI UTERINE BALLOON TAMPONADE

A low-cost, pre-assembled, pressure controlled UBT designed for treatment of postpartum hemorrhage in all healthcare settings, including in LMICs

BACKGROUND

Excessive bleeding after childbirth, or postpartum hemorrhage (PPH), is globally the single most common cause of maternal mortality, accounting for approximately 25 percent of maternal deaths. PPH is dangerous, life-threatening, and can lead to long-lasting health effects, including severe anemia. The condition can be treated if the bleeding is immediately controlled and managed. Deaths and serious complications from PPH are most likely to occur in sites lacking trained providers and appropriate interventions. The consequences of PPH are devastating to families and costly to health care systems. Women who survive can face serious adverse effects including hysterectomies, and in the year following PPH, women are more likely to die from complications related to extreme blood loss. First-line treatments for PPH include uterine massage and administration of oxytocin, a drug that helps the uterus contract. When these treatments don't work, and the woman continues to lose blood, a uterine balloon tamponade (UBT) can be used to stop the bleeding. Health care professionals in wealthy countries have used UBTs for years, and there are several approved UBT medical devices on the market. However, these typically cost hundreds of dollars. The availability of UBTs in African countries is low, but there is anecdotal evidence of limited use, restricted mostly to higher-level facilities due to high cost. In some cases, crude UBTs are assembled at the site of treatment using condoms or surgical gloves.

TECHNOLOGY DESCRIPTION

A UBT is a minimally invasive intervention that can effectively treat and manage severe PPH. When inserted into the uterus and slowly filled with water, it exerts pressure on the uterus causing the bleeding to stop in approximately 5 to 15 minutes. The technology works rapidly and effectively, reducing the need for risky and costly surgical interventions and blood transfusions. However, the use of UBT in many settings has been restricted due to the high costs of such devices. Sinapi Biomedical, in partnership with PATH, has developed the Ellavi UBT, an affordable, pressure-controlled device, which can be used to reduce maternal mortality in low resource settings. A recent research study has shown that, the use of a low-cost UBT in African countries could save up to 6,500 lives and avert nearly 11,000 surgeries in sub-Saharan Africa alone (Herrick et al., 2017).

VALUE PROPOSITION

The Ellavi UBT is the first pre-assembled, pressure-controlled, affordable UBT developed for use in low-and middle-income countries (LMICs). It is a fully assembled system with a gravity-fed filling mechanism that makes it easier and faster to use and

designed to conform to the shape of the uterus and applies optimal pressure to stop bleeding. This affordable device allows for wider access to and use of this intervention with the potential to significantly impact the mortality and morbidity rates of women suffering from PPH.

CURRENT STATUS

The Ellavi UBT has been tested in a clinical case series in South Africa, which demonstrated its efficacy and ease of use. Further testing is underway in the hands of midwives and in a remote rural setting. A CE mark has been obtained for the device and it is ready for implementation in public and private healthcare settings.

INTELLECTUAL PROPERTY STATUS & PUBLICATIONS

- Advancing the Ellavi Uterine Balloon Tamponade (UBT): A low-cost UBT designed specifically for treatment of postpartum hemorrhage. (https://path.azureedge.net/media/documents/DT_UBT_br.pdf)
- Theron GB. Management of postpartum hemorrhage with free-flow pressure controlled uterine balloon. *Int J Gynaecol Obstet*, 142(3):371-373. 2018.

OPPORTUNITIES

The innovators are seeking international partners to assist with market entry strategies into LMICs, as well as partners for assistance with regulatory approvals of the device in Africa.



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