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Second generation of intrauterine balloon tamponade: new perspective

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COMMENTARY

Every day in the year 2015, about 830 women died of childbirth and pregnancy complications. Almost all these deaths occurred in low resource settings, and most could have been prevented. The primary causes of death were *haemorrhage, hypertension and sepsis*.¹

The last two decades witnessed global efforts, including Public Health, clinical, academic, administrative and socio-economic, to save lives at birth, worldwide.

In low-income and middle-income countries, the risk of a woman dying of a maternal-related cause during her lifetime is about 33 times higher, compared with a woman living in a developed country. The number of women dying of complications during pregnancy and childbirth has decreased by 43%, from an estimated 532 000 deaths in the year 1990, down to 303 000 deaths in the year 2015, a testimonial that Global collaborative efforts 'work'.¹

Progress was achieved in the management of maternal postpartum haemorrhage (PPH) of vaginal birth and Caesarean section²⁻⁷; however, less progress was attained in case of pregnancy-related bacterial sepsis, including puerperal sepsis and postabortion sepsis, particularly unsafe abortion's intrauterine infection. Sepsis is one of the leading causes of maternal mortality, worldwide.

Introduced in the year 1999, *Bakri SOS Tamponade Balloon*,^{4 8-10} was the first uterine tamponade balloon system for the treatment of PPH.^{4 9 11} Multiple other devices followed, including: condom catheters,¹² BT-Cath,¹³ ESM-UBT (Every Second Matters - Uterine Balloon Tamponade),¹⁴ Ebb balloon¹⁵ and Zhukovsky balloon.¹⁶

Successful outcome (haemorrhage control) without the need for additional treatments such as embolisation,² B-Lynch compression,⁴ B-LUVS sutures

and multiple square sutures,^{4 17} uterine-hypogastric artery ligation, hysterectomy were reported. All other treatments except embolisation,² required an open laparotomy surgery to control PPH. Tamponade devices' complications of migration/expulsion, rupture/leakage, uterus perforation and infection were reported.

Pregnancy-related haemorrhage and sepsis (including unsafe abortion and molar pregnancy), are the leading causes of maternal death in the low-resources regions worldwide.

A recent WHO 2016 report estimated that during the time period of 2010–2014, there were 35 abortions per 1000 women (aged 15–44) worldwide. This translates to over 56 million abortions per year. An earlier WHO 2008 report the following estimates that 21.6 million women experience 'unsafe abortion' worldwide each year and most of them occurred in low-income and middle-income countries. Death due to 'unsafe abortion' remains close to 13% of all maternal deaths.

Types of currently available tamponade devices.

The following balloon catheters were designed for placement in the uterus for tamponade control of PPH, occurring after vaginal or Caesarean section birth⁴:

▶ Bakri tamponade balloon catheter—the Bakri tamponade balloon catheter is the first uterine tamponade balloon system designed specifically for the treatment of obstetric haemorrhage.⁴ It consists of a silicone balloon (maximum recommended fill volume 500 mL), connected to a 24 French silicone catheter 54 cm in length. The collapsed balloon is inserted into the uterus when filled with fluid, the balloon adapts to the configuration of the uterine cavity to tamponade uterine bleeding. The central lumen of the catheter allows drainage and is designed to monitor ongoing bleeding above the level of the balloon. The device is intended for one-time use.



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- ▶ BT-Cath—the BT-Cath⁴ is a silicone balloon (maximum recommended fill volume 500 mL) with an inverted pear shape to conform to the shape of the uterine cavity. In contrast to the Bakri tamponade balloon catheter, BT-Cath's end of the catheter is flush with the end of the balloon. One lumen of the dual lumen catheter is used to infuse saline and expand the balloon, while the other lumen allows drainage of blood from the fundus. It is intended for one-time use.
 - ▶ ebb tamponade system⁴—The ebb tamponade system is a dual polyurethane balloon device containing an upper uterine balloon (maximum recommended fill volume 750 mL) and a lower vaginal balloon (maximum recommended fill volume 300 mL). A central drain allows for monitoring of possible ongoing or recurrent haemorrhage from above the uterine balloon. The device is intended for one-time use. Other devices that have been used for uterine tamponade, but are not intended for this purpose, include the following:
 - Sengstaken-Blakemore tube (used for treatment of bleeding oesophageal varices).
 - Single or multiple Foley catheters (used for bladder drainage).
 - Rusch urological balloon (used for stretching the bladder).
 - Condom catheter (a condom is placed over the end of a Foley-type catheter, the base of the condom is ligated to the catheter to prevent leakage and then the condom is filled with up to 500 mL fluid via the catheter).
 - Size 8 surgical glove tied to an intravenous infusion or other catheter, and then filled with up to 500 mL fluid.
- Rusch balloons, surgical glove and condom catheters are made of latex rubber; the other devices are made of silicone or polyurethane.

INTRAUTERINE BALLOON: SECOND GENERATION

BakriOne balloon is a new second generation tamponade balloon design system, for the treatment of pregnancy-related uterine haemorrhage and infection, is a novel technology design system which takes into consideration all possible variations in the clinical presentation of pregnancy-related uterine haemorrhage and/or sepsis. It brings a bold, off the beaten path treatment approach, applicable to all pregnancy trimesters and covers normal or abnormal pregnancies including, abortion, miscarriage and hydatidiform mole pregnancies.

Trademark Application for: 'BakriOne.'

US Trademark Application No: 87937508.

Our Matter Docket No: 00510.003-TM-USW (BakriOne).

Status: allowed.

The *BakriOne* is a multisize, multimaterial, multiport and multifunction system. A variety of tube-catheter sizes from 24 Fr. to 48 Fr. Meets patient tube sizing needs. A variety of balloon component sizes from 50cc to 750cc Meets patient balloon sizing needs including abortion, pregnancy trimesters, twins, hydatidiform mole. The clear silicone or polyvinyl chloride (PVC)

Table 1 Functions of the BakriOne

Tamponade	For haemorrhage control
Drainage	Prevents concealment of bleeding
Intrauterine infusion-instillation	For uterotonics, antibiotics, tranexamic acid
Intra-uterine lavage	For puerperal sepsis and septic abortion
Diagnostic functions	
(A) Collecting tissues/fluids from the uterine cavity, for lab function tests, to guide antibiotic therapy in septic abortion and puerperal sepsis.	
(B) 'Tamponade test' ^{3,4,7} to evaluate effectiveness of internal compression treatment.	

shaft, allows for better visualisation of flow and helps in care and maintenance. Separate medication port for intrauterine topical treatments, for example, uterotonics, antibiotics, tranexamic acid as the efficiency of these treatment were reported in other studies.^{18–20} Radiopaque stripe for X-ray placement verification. Drainage obstruction will be easy to identify with the translucent silicone or PVC tubing.

The PVC 'Carus-Curve' (size 48 Fr. tubing option), conforms to the anatomy of the birth canal and helps preventing expulsion of the balloon, a problem which occurs in about 10% of currently available balloons.

The *BakriOne* balloon is hereby proposed to treat the pregnancy-related haemorrhage and intrauterine infections/complications as deemed appropriate.

Functions of the BakriOne are included in [table 1](#).

The versatility of the *BakriOne* system's technology extends its benefits and applications to all global geographic regions, including, the lower resources regions. It is designed as a safe, simple, cost-effective and easy-to-use technology. User-friendly—does not require assembly. Readily available to apply in emergency situations, even in remote rural locations.

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