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Editorial
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Intrauterine Balloon Tamponade for Severe Postpartum Hemorrhage: Retrospective and New Perspectives

Souhail Alouini[1] and Younes Noaman Bakri[2]*

[1]*Department of Gynecologic Surgery and Obstetrics, The Regional Hospital of Orleans, France*

[2]*Department of Oncologic Gynecology, Macon, USA*

Editorial

Each year, approximately 14 millions of women will suffer from Post-Partum Hemorrhage (PPH) in the world [1]. Severe PPH remains the leading cause of maternal mortality worldwide and most of the maternal mortality occurs in low-income countries. However, even in developed and high-income countries, the pospartum hemorrhage is among the leading causes of maternal mortality [1]. Before the Bakri balloon device, severe PPH were managed by embolization or invasive surgical procedures. Even a very efficient embolization was rarely performed because only few maternities have it. In addition, specialized radiologists in uterine embolization are rare and this procedure takes approximately 2 h to be effective. Thus, in case of severe and rapid PPH it is too long to wait two hours. In these cases, an emergency laparotomy is indicated. Conservative treatments such a multiple square sutures [2], B Lynch sutures [3] with a high success of controlling PPH and preserving fertility were developed. However, even conservative, these surgical procedures remained highly invasive. Some attempts to stop PPH with Blakemore or Foley catheters were tried but they were not judged sufficiently efficient and adapted to the obstetrical context of PPH to be universally adopted.

In 1998, the first effective intrauterine balloon made for Obstetrics Hemorrhage and created by Younes Bakri [4] was born and became accessible to all Gynecologists and Obstetricians. A case series of stopping PPH by intrauterine Bakri balloon tamponade was published [4,5]. The BAKRI balloon was the new minimally invasive method to treat PPH and replaced in most cases the uterine embolisation. However, the first year of commercialization of Bakri Balloon, only 32 balloons were used in the world to control PPH. After, everybody knew the increase and large success of BAKRI Balloon Tamponade (BBT) which became recognized worldwide and more and more used [6-9]. In 2013, a large study [10] was published by our team that showed the high efficiency of BBT to stop PPH after vaginal delivery or caesarean section. We also found that women who desired pregnancy after a BBT procedure for PPH achieved a pregnancy and delivered healthy newborns. Thus, we can make a very important conclusion that fertility is preserved after BBT. Many research studies followed and found the same results. Few years after BBT implantation in many maternities, the rate of laparotomy procedures to stop PPH dramatically decreased [6].

The device was easy to use and the learning curve very rapid to achieve. We have a minimally invasive device, available in delivery rooms and in theatres immediately. All obstetricians know that the PPH must be controlled very quickly before coagulation troubles. In addition: with this device we did not experience and there were no reported allergies or other adverse events. After 21 years commercialization of the BBT the success of the BBT continues and each year hundreds of thousands of balloons are used to stop PPH (around 500.000 BAKRI balloons are sold each year). However, we experienced some failures of BBT and we have some critics about it even if its high success to control PPH is proved. Indeed, in some cases, it is being expelled from uterus and thus fails to stop PPH. We found some techniques enabling Bakri balloon not to be expelled such as vaginal meshes or sutures to close partially the cervix. It was also contraindicated in cases of chorioamnionitis which is a cause of PPH. BAKRI balloon is also too large for small uterus. Thus, they cannot be inserted in case of PPH after first or second trimester of pregnancy in case of abortion. Conversely, the volume of the balloon is not enough large for larger uterine cavities as in twin pregnancies or hydramnios. Finally, we found that the price of the BBT was too high for many countries, especially for the low-income ones. For example, our colleagues from some African countries complain regularly that the price of BBT is high and the only alternative for them is inefficient condoms to tamponade. Indeed, condoms cannot be inflated more than 200 ml which is largely not enough to stop PPH; moreover,

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Correspondence:
Souhail Alouini, Department of Gynecologic Surgery and Obstetrics, The Regional Hospital of Orleans, CHR Orleans 14 Avenue de l'hôpital, 45100, Orleans la source, France; E-mail: alouini.s@orange.fr **Received Date**: *13 Sep 2019* **Accepted Date:** *20 Sep 2019* **Published Date:** *27 Sep 2019*

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the texture of condoms is not sufficiently rigid to stop uterine bleeding and they often collapse in the uterine cavity letting the patient die bleeding. Is it ethical to let our colleagues without efficient balloon to stop PPH in 2019? Whereas, in developed countries BBT is included in all guidelines of Obstetricians and Gynecologic Colleges to manage PPH (e.g. AJOG, RCOG, CNGOF). A new Bakri balloon one is created after the synthesis of these considerations and experiences. The BAKRI one is created to correct the defects of the "old BAKRI balloon" and to administrate topical treatments. In addition; the price of the BAKRI one will be accessible to all maternities, even for low-income countries. The new balloon BAKRI one will not be expelled and easier to insert. The catheter of insertion will be more rigid. It will be available in 3 sizes:

- Small size filled with 100 ml of physiologic serum for post-abortion PPH, molar pregnancies.
- A medium size filled with 300 ml of physiologic serum will be indicated for PPH of in late trimester of pregnancy in case of termination for foetal abnormalities or menace for maternal life or legal abortion.
- The large size could be filled up to 600 ml for PPH for pregnancies at term, and larger uterine cavities as in twin pregnancies and hydramnios.

In addition, topical treatment could be delivered by the catheter of the balloon:

Antibiotics in case of chorioamnionitis could be administrated topically through a catheter connected to the balloon. Tranexamic acid which is used intravenously in case of PPH and topically effective in operative hysteroscopies or other specialties as surgery of knees could be also administrated topically. Finally, low prices of the new BAKRI one balloon will make it accessible and available to all women worldwide.

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