



## Tranexamic Acid Coated or Eluted Uterine Balloon and Co-Attached Cervical Shutter In Post Partum Haemorrhage. A New Combatant in the Armamentarium, Not Merely a Balloon but More

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### Abstract

Described herein a Tranexamic Acid (TXA) - Coated or Eluted Uterine Balloon for use in an intra uterine location for primary management of postpartum haemorrhage (PPH). It enforces the tamponade effect of currently used non medicated uterine balloons with an additional inbuilt mechanism of local steady release of the antifibrinolytic TXA into uterine cavity that has been evidenced to contribute to haemostasis in cases of PPH. The invention ushers a new era of utilizing the uterine balloon surface coat as a delivery vehicle for TXA. This can be achieved via different techniques including and not limited to matrix coating or eluting of nanoparticulate TXA in the outermost layer of the balloon. TXA coated or eluted balloon replenish non medicated balloons with a therapeutic modality of the TXA related – antifibrinolysis is especially in hemorrhages known to be associated with coagulopathy. This potential for topical application of TXA rather than systemic administration of the drug avails the merit of avoiding TXA –related theoretical risk of thromboembolism. Moreover, drug coating of the balloon surface is not limited to TXA, but it may utilize other haemostatics and coagulants like thrombin, fibrinogen and activated F11v as well. Additionally, this invention offers an innovative solution for the technical difficulty of retaining the released drug inside an open hollow uterine cavity and its fast escape through the cervix by the co attached cervical shutter or "Barricade". The latter was designed to provide sustained residency and efficient drug transfer into the uterine cavity, thus contributing to a consistent and efficient TXA delivery at the site of action. Moreover, the cervical shutter exerts an additional function of extra counter pressure on the lower uterine segment which may be the bleeding site in cases of abnormally adherent placenta.

### Field of the Invention

This invention relates to a functional development of currently used uterine balloons in cases of PPH, in the field of Obstetrics and modifying them to be a delivery vehicle for drugs known of their haemostatic action onto the bleeding site, i.e. uterine cavity. TXA coated or eluted uterine balloon will avail the non medicated uterine balloons in use nowadays for management of PPH with a dual integrated pharmaco -mechanical mechanism, along with an innovative mechanism, that is, the cervical shutter which safeguards against external fast escape of the medication from the uterine cavity, thus allowing drug retention inside the uterine cavity for a reasonable time so as to achieve its therapeutic effect. Utilization of outer coat of balloon as a polymer-based vehicle used for delivering tranexamic acid and other haemostatic agents can be brought about by the use of a drug coating or eluting matrices technology and a variety of different water soluble and lipid soluble specialized polymers. The latter will be selected according to which suits better the most efficient steady state of intra cavitary drug release.

### Background of the Invention

The object of this invention is to enforce a dual pharmaco-mechanical effect of TXA medicated intrauterine balloon in the armamentarium of managing postpartum hemorrhage (PPH). Since PPH is one of the leading causes of maternal mortality worldwide, various strategies have been developed to prevent and control it. World Health Organization, the International Federation of Gynecology and Obstetrics, and the Royal College of Obstetricians and Gynaecologists all recommend a uterine

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