Management of Postpartum Hemorrhage with the SOS Bakri Tamponade Balloon Catheter

1. Introduction: The Problem of Obstetrical Bleeding -- Management and Conservation

Obstetrical bleeding (intrapartum/postpartum) secondary to placenta previa with variable degrees of accretism is not uncommon. Postpartum bleeding is bleeding that occurs immediately after the placenta is delivered. With an incidence of one in twenty deliveries, it is one of the leading causes of maternal mortality [10, 11].

Although various management measures are utilized for control of bleeding caused by this clinical abnormality the conservative approach is becoming increasingly used instead of hysterectomy.

Hysterectomy can be an undesirable action to take, and this is especially true in the case of a low parity patient. Usually, this step is taken when other traditional measures to stop hemorrhage fail [4].

Uterine packing has been used successfully in many cases to conservatively manage postpartum bleeding; however, removing such packing can sometimes require a separate surgical procedure to dilate and extract the materials. Therefore, packing sometimes falls short of an ideal treatment option.

The ideal choice for managing a patient's postpartum hemorrhage might offer control of capillary/venous bleeding and surface oozing in order to avoid hysterectomy to preserve the patient's reproductive potential.

Cook Ob/Gyn has designed such a device that will aid in the conservative management of postpartum hemorrhage when other conservative agents might have failed. The SOS Bakri Tamponade Balloon Catheter by Cook Ob/Gyn is easily administered, and removes as easily as it is applied, thus removing the need for a separate surgical procedure to remove tamponade agents.

2. Definitions

Placenta Previa:	Condition in which the placenta is implanted in the lower segment of the uterus and covers the cervical opening either partly or completely.
Placenta Accreta:	Condition in which the placenta infiltrates the lining of the uterus (decidua) and implants into the tissue of the cervix or the myometrium (muscle of the body of the uterus) making it difficult for the placenta to separate after delivery of the baby.
Postpartum:	Pertaining to, or occurring after childbirth.
Embolization:	The introduction of certain substances into vessels and arteries for the therapeutic occlusion of vasculature.
Abruptio Placentae:	Premature separation of the normally implanted placenta from its uterine attachment.
Uterine Atony:	Loss of muscular tone of the uterus, which may result in failure of progress of labor or postpartum hemorrhage.
Primigravida:	A woman in her first pregnancy.
Consumption Coagulopathy:	A condition marked by great reduction in the circulating levels of platelets and of certain coagulation factors due to the utilization of platelets in excessive

	blood clots throughout the body.
Logothetopulos:	The name of a Greek obstetrician who described a plastic infusion bag filled with sponge to work as a packing of the uterus.
Morbidity:	The condition of being diseased or morbid, also the sick rate.

3. Indications for use of the SOS Bakri Tamponade Balloon Catheter

The SOS Bakri Tamponade Balloon Catheter is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

While the device is intended as a temporary means of establishing hemostasis in cases indicating conservative management of postpartum uterine bleeding, the application of this device should be concomitant with close monitoring for signs of arterial bleeding, atony bleeding, and/or disseminated intravascular coagulation (DIC).

The use of this product is contraindicated in the presence of:

- arterial bleeding requiring surgical exploration or angiographic embolization.
- uterine atony bleeding.
- cases indicating hysterectomy.
- pregnancy.
- cervical cancer.
- purulent infections of the vagina, cervix, or uterus.
- untreated uterine anomaly.
- disseminated intravascular coagulation.
- a surgical site which would prohibit the device from effectively controlling bleeding.

Close patient monitoring is required at all times during balloon use.

4. Steps For Effective Application

Catheter Placement

Vaginal Delivery -- Transvaginal Placement

1. Determine uterus is clear of any retained placental fragments, arterial bleeding, or lacerations.
2. Determine approximate uterine volume by ultrasound or direct examination.
3. Insert the balloon portion of the catheter in the uterus, making certain that the entire balloon is inserted past the cervical canal and internal ostium, under ultrasound guidance.
4. **Caution: Avoid excessive force when inserting the balloon into the uterus.**
5. If not already indwelling, place a Foley catheter in patient bladder to collect and monitor urine output.

6. To ensure maintenance of correct placement and maximize tamponade effect, the vaginal canal may be packed with iodine or antibiotic soaked vaginal gauze at this time.

Cesarean Delivery -- Transabdominal Placement

1. Determine uterus is clear of any retained placental fragments, arterial bleeding, or lacerations.
2. Determine uterine volume by intraoperative direct examination or postoperative ultrasound examination.
3. From above (via access of the Cesarean incision), pass the tamponade balloon, inflation port first, through the uterus and cervix.
4. Have an assistant pull the shaft of the balloon through the vaginal canal until the deflated balloon base comes in contact with the internal cervical ostium.
5. Close the incision per normal procedure, taking care to avoid puncturing the balloon while suturing.
6. If not already indwelling, place a Foley catheter in patient bladder to collect and monitor urine output.
7. To ensure maintenance of correct placement and maximize tamponade effect, the vaginal canal may be packed with iodine or antibiotic soaked vaginal gauze at this time.

Instructions for Balloon Inflation

1. **Warning: Always inflate the balloon with sterile liquid. Never inflate with air, carbon dioxide or any other gas.**
2. **Warning: Do not over inflate the balloon. Please refer to product label for maximum inflation volume.**
3. Ensure that indwelling Foley is placed in patient bladder at this time.
4. To ensure that the balloon is filled to the desired volume, it is recommended that the predetermined volume of fluid be placed in a separate container, rather than solely relying on a syringe count to verify the amount of fluid that has been instilled into the balloon.
5. Using the enclosed syringe, begin filling the balloon to the predetermined volume through the stopcock.
6. Apply gentle traction to the balloon shaft to ensure proper contact between the balloon and tissue surface. To maintain tension, secure the balloon shaft to the patient’s leg or attach to a weight, not to exceed 500 grams.
7. **Note: If balloon becomes dislodged due to shaft tension and cervical dilation, deflate, reposition, and reinflate. Use of vaginal packing may be indicated at that time to aid in balloon placement.**

Patient Monitoring

1. Once balloon is placed and is inflated, connect the drainage port to a fluid collection bag to monitor hemostasis.
2. **IMPORTANT: To adequately monitor hemostasis, the balloon drainage port and tubing should be flushed clear of clots with sterile isotonic saline.**
3. Patient should be monitored continuously for signs of increased bleeding, uterine cramping, or a deteriorating condition.
4. Patient monitoring should include, but not be limited to: blood pressure, pulse, urine output, cramping, pallor, and active bleeding.
5. **IMPORTANT: Signs of deteriorating or non-improving conditions should indicate more aggressive treatment and management of patient uterine bleeding.**
6. **IMPORTANT: This device is not a substitute for surgical management and fluid resuscitation of life-threatening postpartum hemorrhage.**

Catheter Removal

Maximum indwell time is twenty-four (24) hours. Balloon may be removed sooner upon physician determination of hemostasis or need to apply more aggressive treatment.

1. Remove tension from balloon shaft.
2. Remove any vaginal packing.
3. Using an appropriate syringe, aspirate the contents of the balloon until fully deflated.
4. Gently retract the balloon from the uterus and vaginal canal and discard.
5. Continue to monitor the patient for signs of uterine bleeding.

5. Comparison with Existing Manual Treatments

Bakri Balloon Catheter vs. Uterine Packing

The use of uterine packing for management of obstetrical hemorrhage has had both supporters and detractors. While the material cost of packing is nominal there are some concerns voiced about treatment capabilities and follow up. In general, these concerns include clot adhesion, concealed hemorrhaging, no record of blood loss, and uterine trauma.

Use of uterine packing has been believed to help conceal a hemorrhage in the uterine cavity. [10] Even if a hemorrhage were concealed, it might be evident immediately after the procedure. The use of such packing for PPH does generally present little risk to the patient, but removal can be painful. Sometimes uterine packing must be removed in a surgical setting and/or under anesthetic.

The Bakri balloon may be used quickly without anesthetic, and removes quite simply once deflated. The patent lumen in the balloon shaft allows for direct measurement of continued blood loss. Therefore, the likelihood of a concealed hemorrhage going undetected or delayed detection is diminished. Because the balloon is silastic and conforms to uterine shape/volume, there is less concern of uterine trauma. The nature of the silicone balloon is that it will deform more easily than perforate uterine tissue.

Bakri Balloon Catheter vs. Sengstaken-Blakemore Balloon or Foley Catheters

The Sengstaken-Blakemore balloon is a naso-gastric balloon for tamponade of esophageal varicoceles and the introduction of contrast media. This balloon contains latex, does not necessarily take uterine shape, and is not specifically intended for application in the uterus.

Foley catheters are generally inexpensive, but are generally ineffective in a large uterine cavity. Their use tends to require application of multiple Foleys simultaneously. If they are applied individually (no overbag), they do not readily conform to uterine anatomy; and therefore, the potential for effective site-specific tamponade can be compromised. If they are applied jointly in a plastic covering or overbag, this does not allow for proper drainage, and can conceal uterine hemorrhage. In general, the application of multiple Foleys is cumbersome and less effective than the Bakri balloon.

The Bakri balloon is 100% silicone (no latex), and has a ductile shape which allows it to conform to the uterine anatomy. It allows for hemostatic cushion application, and limits clot adhesion. The large diameter lumen in the shaft and multi-ported, non-abrasive tip allows for constant drainage, so an ongoing uterine hemorrhage does not go undetected post-application. Its pull-strength allows for the application of up to 500g of tension to aid tamponade achievement. Finally, once deflated the Bakri balloon is easily removed transvaginally without the need for an additional surgical procedure.

6. References

If you wish to find more about the treatment options for Postpartum Hemorrhage, the following references cover the many treatment options for this complication.

1. Bakri YN, et al. Tamponade-balloon for obstetrical bleeding. Int. J. Gynecol. Obstet. 2001; 74: 139-142.
2. G. S. Condous, et al. The “Tamponade Test” in the Management of Massive Postpartum Hemorrhage. Obstetrics and Gynecology (2003) Vol. 101, No. 4:767-772.
3. Bakri YN. Balloon device for control of obstetrical bleeding. Euro J Obstet Gynecol Reprod Biol. 1999; 86:S84.
4. Zaki M.S. Zaki, et al. Risk factors and morbidity in patients with placenta previa accrete compared to placenta previa non-accreta. Acta Obset Gynecol Scand 1998; 77: 391-394.
5. Soloman Isayu, et al. The epidemiology of placenta previa in the United States, 1979 through 1987. Am J Obstet Gynecol., Vol. 168, No. 5.
6. S.J. Etuk, et al. Maternal mortality following PPH in Calabar: A 6 year review. WAJM Vol. 16, No. 3, August-September 1997.

7. Manyonda I.T., et al. Massive obstetric hemosshae due to placenta previa/accrete with prior cesarian section. Int. J Gynecol. Obstet., 1990, 34: 183-6.

8. McShane P, et al. Maternal and perinatal morbidity resulting from placenta previa. Obstet Gynecol., 1985; 65: 176.

9. Clark S, et al. Placenta previa/accrete and prior cesarian section. Obstet Gynecol. 1985; 66:89.

10. Maier R. Control of postpartum hemorrhage with uterine packing. Am J Obstet Gynecol. 1993; 169: 317-23.

11. Wittich A, et al. Uterine packing in the combined management of obstetrical hemorrhage. Military Medicine, Vol. 161, March 1996.

12. Bakri Y.N., Uterine tamponade-drain for hemorrhage secondary to placenta previa-accreta. Int J Gynecol Obstet., 1992; 37.

13. De Loor J., et al. Foley catheters for uncontrollable obstetric or gynecologic hemorrhage. Obstet Gynecol., 1996; 88-737.

14. Robie G. Logothetopulos pack for the management of uncontrollable postpartum hemorrhage. Am J Perinatology. 1990; Vol. 7: No. 4.

15. Wax J. Packing of the lower uterine segment-new approach to an old technique. Int J Gynecol Obstet., 1993; #43.

16. Hallack M. Transvaginal pressure pack for life-threatening pelvic hemorrhage secondary to placenta accrete. Obstet Gynecol., Nov. 1991; 78, No.5, Part 2.

17. Katesmart M., et al. Successful use of a Sengstaken-Blakemore tube to control massive postpartum haemorrhage. British J Gynecol Obstet., March 1994; Vol. 101: 259-60.