BALLOON PLACEMENT FOR UTERINE TAMPONADE

1. AIM

- Appropriate use and management of Uterine Tamponade Balloon (Bakri®) to control uterine bleeding, using an aseptic technique

2. PATIENT

- Woman who requires advanced management of ongoing primary postpartum haemorrhage secondary to bleeding from the placental bed or partial uterine atony

3. STAFF

- Medical, nursing and midwifery staff

4. EQUIPMENT

- Uterine Tamponade Balloon Pack
- Drainage bag
- Normal saline - 500mLs
- Urinary catheter
- Vaginal packing gauze

5. CLINICAL PRACTICE

- Check for any contraindications for use of Uterine Tamponade Balloon (Bakri ®):
  - Arterial bleeding requiring surgical exploration or angiographic embolisation
  - Complete uterine atony bleeding, although it may be effective in partial atony
  - 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

- **Administer prophylactic antibiotics**
  - Administer a single dose of cefazolin 1g intravenous (IV) prior to insertion of the uterine tamponade balloon (Bakri®) after vaginal birth[4]
  - Administer single dose IV antibiotics as outlined in surgical bundle LOP, for caesarean section or laparotomy. Consider giving an additional dose IV after four hours if intra-operative blood loss >1500mL

- **Placement of the balloon**
  - **Transvaginal Placement (after vaginal birth or caesarean section)**
    - Place a Foley catheter in woman's bladder to collect and monitor urine output hourly

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- Ensure uterus is empty of any retained placental fragments, arterial bleeding/lacerations are secured/repaired, and the woman has no contraindications to use of the uterine tamponade (Bakri®) balloon – see educational notes
- Estimate uterine volume by physical examination or ultrasound
- Insert the balloon portion of the catheter in the uterus, making certain the entire balloon is past the cervical canal and internal os
- Avoid excessive force when inserting the balloon into the uterus

- **Transabdominal Placement – Caesarean Delivery**
  - Ensure uterus is empty of any retained placental fragments, arterial bleeding/lacerations are secured/repaired
  - Pass the uterine tamponade (Bakri®) balloon via the caesarean incision, inflation port first, through the uterus and cervix
  - Have an assistant pull the shaft of the balloon through the vaginal canal until the deflated balloon base meets the internal cervical os
  - Close the incision as usual prior to balloon inflation taking care to avoid puncturing the balloon while suturing

- **Instructions for balloon inflation**
  - Measure 500mL of sterile fluid (e.g. normal saline, sterile water, sodium lactate solution) into a jug
  - Fill the balloon to the required volume (max 500mL) using the enclosed syringe. Alternatively, rapid inflation can be achieved by attaching a 500mL bag of normal saline directly to the balloon catheter with the stopcock – see device instructions.
  - 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 woman's leg or attach a weight (max 500g)
  - Ensure correct placement of balloon with ultrasound
  - Maximize tamponade effect by packing the vagina where necessary with iodine or obstetric cream-soaked vaginal gauze. Do not extend packing into the uterus.
  - Clearly document numbers of packs, if used, on the operation report.
- **Monitoring of Woman**
  - Connect the drainage port to a fluid collection bag to monitor hemostasis
  - Flush the balloon drainage port and tubing to clear clots if required with sterile isotonic saline
  - Monitor woman for signs of increased bleeding, disseminated intravascular coagulation (DIC), uterine rupture, or deteriorating condition
  - Monitor urine output while the uterine tamponade (Bakri ®) balloon is in situ
- **Removal of Balloon**
  - Remove uterine tamponade (Bakri®) balloon when bleeding is well controlled and woman is clinically stable - generally four to six hours is adequate, maximum indwelling time is 24 hours[3]
  - Remove balloon during daylight hours in the presence of appropriate senior obstetric staff in case further intervention is necessary[3]
  - Remove tension from balloon shaft and remove any vaginal packing
  - Aspirate the contents of the balloon until fully deflated
  - Gently retract the balloon from the uterus and vaginal canal and discard
  - Continue to monitor the woman for signs of uterine bleeding

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6. DOCUMENTATION

- Medical record

7. EDUCATIONAL NOTES

- In a 2014 audit of 339 women who had an estimated blood loss of 2500mL or higher, the use of uterine tamponade balloon avoided the need for hysterectomy in 91% of cases[1]
- Balloon tamponade can be used alone or in combination with other surgical interventions, such as internal iliac artery ligation and the B-Lynch suture
- Although there is a lack of high quality evidence for the efficacy of prophylactic antibiotic use with uterine tamponade balloon placement, one single-centre retrospective study showed no increase in the rates of endometritis with Bakri® balloon placement when a single dose of prophylactic antibiotics was given IV prior to balloon placement (with an additional dose given in caesarean section deliveries when intraoperative blood loss >1500mL) [4]
- Large trials show that a single preoperative dose of surgical antibiotic prophylaxis is sufficient to prevent postoperative infection for the vast majority of clean and clean–contaminated procedures and is as effective as longer courses. Intraoperative re-dosing may be necessary if[5]:
  - after prophylaxis is given, there is a significant delay in starting the operation
  - a short-acting antibiotic is used (e.g. cefoxitin, cefazolin) and more than two half-lives of the drug have elapsed since the previous dose (half-life for cephazolin 1.2-2.2 hours)
  - there is excessive blood loss during the procedure (e.g. 1.5 L or more)
- For a small minority of procedures identified throughout the antibiotic guidelines, there are inadequate data to show that a single dose of prophylaxis (with or without intraoperative doses) is as effective as 24 hours of prophylaxis. Postoperative doses may be considered but prophylaxis should not continue beyond 24 hours[5]
- 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 haemostatic 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- insertion
- Its pull-strength allows for the application of up to 500g of tension to aid tamponade achievement
- Once deflated the Bakri® Balloon is easily removed transvaginally without the need for an additional surgical procedure

8. RELATED POLICIES / PROCEDURES / CLINICAL PRACTICE GUIDELINES

- Postpartum Haemorrhage - Prevention and Management
- Adult Urethral Catheterisation for the Acute Care Setting NSW Health GL2015_016
- Infection Prevention and Control Policy NSW Health PD2017_013
- Manual Removal of Placenta
- Clinical Emergency Response System (CERS) – Management of the deteriorating patient
- Surgical Bundle for Abdominal Surgery

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9. RISK RATING

- Low

10. NATIONAL STANDARD

- Standard 5 – Comprehensive care
- Standard 8 – Recognising and responding to the deteriorating patient

11. REFERENCES

1 Lennox C, Marr L; Reproductive Health Programme, Healthcare Improvement Scotland. *Scottish Confidential Audit of Severe Maternal Morbidity: reducing avoidable harm.* 10th Annual Report. Edinburgh: Healthcare Improvement Scotland; 2014.

2 Cook Medical. *Instructional Resource: Bakri® Postpartum Balloon with Rapid Instillation Components*. March 2020, (www.cookmedical.com/data/resources/RH-D54670-EN-F_M3_1585061971661.pdf)

3 RCOG Greentop Guideline. *Prevention and management of postpartum haemorrhage*. 16 December 2016.

4 Nagase Y, Matsuzaki S, Kawanishi Y, et al. Efficacy of Prophylactic Antibiotics in Bakri Intrauterine Balloon Placement: A Single-Center Retrospective Analysis and Literature Review. AJP Rep. 2020;10(1): e106-e112.

5 Therapeutic Guidelines (eTG), 2019, Principles of surgical antibiotic prophylaxis. https://tgldcdp.tg.org.au.acs.hcn.com.au/viewTopic?topicfile=surgical-antibiotic-prophylaxis-principles&sectionId=abg16-c96-s10#abg16-c96-s10

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