48

Using the Uterine-Specific Bakri Balloon in the Management of Postpartum Hemorrhage: Case Series and Conceptual/Practical Guidelines

C. Georgiou

INTRODUCTION

Various approaches have been advocated for the management of postpartum hemorrhage (PPH) due to uterine atony[1,2]. These range from massage of the uterine fundus, to the use of pharmacological agents, embolization procedures, compression sutures, vascular occlusion and ultimately hysterectomy[3]. Many of these approaches, however, require the availability of specialized equipment and/or personnel (embolization procedures), a degree of surgical dexterity (compression sutures/vascular occlusion by surgical ligation), or the presence of a hemodynamically stable patient (embolization procedures)[4,5].

In contrast, studies that use the recently introduced uterine balloon tamponade technology suggest that it is easily used, rapidly deployed, has minimal complications, may avoid a laparotomy and, in conjunction with the 'tamponade test', can serve as an orderly stepwise approach to the management of PPH[6–8].

Although the Bakri balloon (Cook Medical, Bloomington, IN, USA) has been specifically designed for use in the uterus, in 168 published cases where the balloon type is specified, 76% use other non-uterine-specific (NUS) balloons (Figure 1)[7,9–11]. These balloons may have been otherwise used in other cavities where bleeding is problematic (i.e. esophagus and bladder)[12,13]. Furthermore, studies of evaluations of effectiveness, prospective trials and feasibility studies of balloon tamponade in the management of PPH are not only based on NUS devices, but also these balloons require modification prior to usage (such as folding or removing a potentially perforating drainage tip), possess no drainage channel and may require prior sterilization[6–8,14].

Assuming genital tract trauma, retained products of conception and device damage prior to placement are excluded, one might expect 100% success if the balloons were effective regardless of how they were used in the management of an atonic uterus. However, data from confidential enquiries and from peripartum hysterectomies suggest that using balloon tamponade in the management of PPH is not always effective[15,16]. One of the reasons why this is the case may be the methodological variation used for uterine-specific and NUS balloons[9].

Despite methodological variation, the paucity of data in the literature and a reporting bias toward NUS devices, recent PPH management guidelines call for the use/availability of tamponade balloons in the management of PPH[3,17] without any recommendation regarding which one(s) should be used and how they should be applied in the clinical situation.

The primary aim of this chapter is to provide a conceptual and practical guide to the use of a uterine-specific tamponade balloon based on a personal case series that utilizes a consistent method of balloon placement and insufflation that relates to the clinical outcome of the so-called tamponade test.

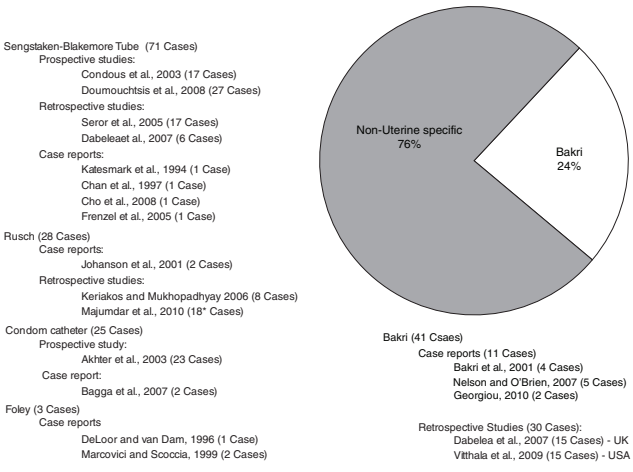

Figure 1 Reporting bias of non-uterine-specific balloons. In 168 published cases of using a specified balloon in the management of PPH, 127 cases are non-uterine-specific and 41 cases involve the uterine-specific Bakri balloon. *Cases greater than 20 weeks' gestation

METHODS

Ethics approval was obtained from the University of Wollongong/Wollongong Hospital Human Research Ethics Committee (HE/09/374) in order to review the medical records of patients in whom a Bakri balloon was used in the management of PPH in which the author was involved

Fifteen cases were identified over a 4-year period from three hospitals within the same area health region in which the author has/had a clinical appointment (Table 1). The medical records of these cases were reviewed with respect to demographic data (maternal age, gestational age and previous pregnancies), risk factors, mode of delivery, cause of PPH and the specific methodology used (mode of insertion, use of ultrasound scan, mechanism used to prevent balloon displacement, total duration of use and deflation regimen (Table 1)). The Bakri balloon was used in all cases, as this was the only uterine-specific balloon available in Australia at the time of the study.

DEFINITIONS

Postpartum hemorrhage

Although PPH was defined as greater than 500 ml estimated blood loss (regardless of mode of delivery or whether the PPH was primary or secondary), the actual amount of estimated blood loss was not an indication for the use the Bakri balloon. The decision to use a Bakri balloon was based on the 'failure' of first-line uterotonics to arrest hemorrhage (see below).

First-line uterotonics

First-line uterotonics were used in all cases described ('oxytocics' in Table 1). These included 10 IU Syntocinon® following the delivery of the baby (IV or IM), a 40 IU Syntocinon infusion, misoprostol 800 μg PR and intramyometrial injection of prostaglandin F2α (PGF2α) (1–3 mg). 'Failure' was defined as continued bleeding following the use of first-line uterotonics after retained placenta and genital tract trauma were excluded.

Tamponade test

The tamponade test involved insufflating the Bakri balloon with normal saline within the uterine cavity and assessing whether this was successful in stopping uterine bleeding. The test was considered 'positive' if the bleeding was successfully minimized or stopped (Figure 2).

The tamponade method

The tamponade method is the methodology by which the tamponade test is applied. It is based on a clinical outcome. It involves initially filling the balloon with 200 ml normal saline and then assessing blood loss from around the cervix as well as from the drainage channel of the Bakri balloon. If bleeding continues, a further 50 ml normal saline is insufflated into the balloon and blood loss is re-assessed. This cycle is continued until bleeding has stopped or is significantly reduced[13]. If 500 ml of normal saline (the recommended capacity of the balloon) is insufflated and the bleeding is still ongoing, the tamponade test is considered negative (Figure 2).

RESULTS (CASE SERIES)

Postpartum hemorrhage incidence

During the 4-year retrospective audit period (April 2007–April 2010), 12,229 deliveries occurred across the three hospital sites. These deliveries included 1272 cases (9.6%) of PPH, 90 cases (0.7%) of which were accompanied by greater than 1500 ml estimated blood loss. In addition, three cases underwent peripartum hysterectomy for PPH after first-line uterotonics were unsuccessful. In two of these, a clinical decision to proceed with hysterectomy was made with no attempt at balloon tamponade. In the remaining case, the Bakri balloon had not yet been introduced at that site. The author was not involved in these three cases.

During the study period, one case was noted in which a Bakri balloon was used after a B-Lynch suture was found to be unsuccessful in managing the PPH. This case is included despite the balloon being used following a failed surgical intervention (B-Lynch) and not immediately following the failure of first-line uterotonics. There were no other cases during the study period in which another procedure, other than balloon insertion, was attempted when first-line uterotonics failed.

There were no maternal deaths during this period and incidence data on secondary PPH was not available from any of the hospital sites.

Bakri balloon insertions

In total, 15 Bakri balloon insertions were made during this period (Table 1). All cases resulted in a positive tamponade test. In one case, the balloon was forcibly removed following extubation by the agitated patient. A second balloon was subsequently reinserted. This was not considered a failure of balloon tamponade, although it did result in a subsequent PPH and required a second Bakri balloon to be inserted (case 8).

Demographics

Maternal and gestational age

Patients' ages ranged from 20 to 43 years with a median of 32 years. The gestational age at delivery ranged from 33 weeks and 6 days to 40 weeks and 6 days.

Table 1 Patient demographics, details of PPH and methodological parameters when using the Bakri balloon

Case	*Age*	*Risk factors*	*Previous pregnancy*	*Gestation at delivery* (weeks + days)	*Node of delivery*	*Time of PPH*	*Cause of PPH*	*Oxytocics*	*Use of USS*	*Tamponade test positive (volume:* ml)	*Mechanism to ensure remains in uterus*	*Analgesia (insertion)*	*Postoperative care (location)*	*Total time duration of balloon in uterus* (h)	*Deflation regimen*	*Final PPH* (l)	*Placental pathology*
1	34	Augentation of labor –	1 MISC	40 + 2	Em LSCS/ failed B-Lynch	At LSCS	Atonic uterus	S10, S40, Miso, PGF	No	300	None mentioned	RA->GA	HDU	24	33% (13 h), 33% (22 h), 33% (30 h)	3.5	Not sent
2	43		1 MISC, 2 SVD	39 + 6	SVD	Return to theater (+4 h)	Atonic uterus	S10, S40, Miso, PGF	No	500	Vaginal pack	GA	HDU	24	50% (14 h), 50% (18 h)	2.8 (including primary repair)	Not sent
3	43	Prev. placenta, placenta; augmentation of labor	1 TOP, 1 LSCS (breech)	36 + 5	EL LSCS	At LSCS	Placenta previa/ accreta/atonic uterus	S10, S40, Miso, PGF	No	400	None mentioned	GA	HDU	24	50% (14 h), 50% (18 h)	3	Not sent
4	36	Pre-eclampsia	–	40 + 6	Em LSCS	At LSCS	Atonic uterus	S10, S40, PGF	No	450	None mentioned	RA	HDU	30	33% (13 h), 33% (22 h),	3	Accreta
5	33	Prev PPH, low placenta, augmentation of labor	1 SVD, 1 MISC, 1 LSCS (PP)	37 + 4	Em LSCS	At LSCS	Atonic uterus	S10, S40	No	500	None required	RA (spinal)	HDU	40	33% (30 h) 33% (15 h), 67% (40 h)	4	Normal
6	31	FTP (2nd stage), ruptured uterus	1 LSCS (twins)	41 + 1	Em LSCS	At LSCS	Atonic uterus	S10, S40, PGF	No	360	Vaccum	RA (spinal)	HDU	22	50% (12 h), 50% (22 h)	2.8	Not sent
7	28	Retained placenta	–	37 + 3	SVD	SVD	Atonic uterus	S10, S40, Miso, PGF	No	350	Vaccum	GA	HDU	18	50% (14 h), 50% (18 h)	2.5	Normal
8	20	Secondary Prev PPH	1 TOP, 1 MISC	39 + 5	SVD	8 days	Atonic uterus	S40	Yes	450/500	Vaccum, vaginal packs	GA	HDU	30	25% (20 h), 25% (24 h), 25% (28 h), 25% (30 h)	3.5 and 2.3	Not sent
9	35	Placenta previa IV, APH	–	35	Em LSCS	At LSCS	Atonic uterus	S10, S40	No	400	None required	GA	PNW	18	50% (13 h), 50% (18 h)	2	Not sent
10	31	Placenta previa IV, APH	–	33 + 6	Em LSCS	At LSCS	Atonic uterus	S10, S40, Ergo	No	500	Vaccum	GA	PNW	19	30% (12 h), 30% (16 h), 40% (19 h)	3.5	Normal
11	30	–	4 SVD	38 + 5	EL LSCS	Return to theater (+9 h)	Atonic uterus	S10, S40, Ergo, Miso, PGF	Yes	300	Vaccum	GA	PNW	20	50% (13 h), 50% (20 h)	2.4	Not sent
12	36	None	–	38 + 2	EL LSCS	2 weeks	Atonic uterus/ endometritis	S40	Yes	400	Vaccum	GA	NDU	34	25% (16 h), 75% (34 h)	2.3	Endometritis in uterine curretings
13	22	Prev PPH	1 SVD	40 + 6	SVD	SVD	Atonic uterus	S10, S40, Ergo, Miso, PGF	No	400	Vaccum	GA	LW-PNW	30	25% (14 h), 25% (22 h), 50% (30 h)	3.6	Normal
14	24	None	–	39 + 5	SVD	SVD	Atonic uterus	S10, S40, Ergo, Miso, PGF	No	500	Vaccum	GA	LW-PNW	26	50% (18 h), 50% (26 h)	2.3	Not sent
15	31	None	3 TOP EDIU (16 weeks), 1 SVD	39 + 4	SVD	Ongoing (6 h)	Retained products, atonic uterus	S10, S40, Ergo, Miso, PGF	No	250	Vaccum	GA	PNW	22	50% (12 h), 50% (22 h)	2.5	Normal retained products

APH, antepartum hemorrhage; EL LSCS, elective lower segment cesarean section; Em LSCS, emergency lower segment cesarean section; Ergo, ergometrine 250–500 μg; FDIU, fetal death *in utero*; FTP, failure to progress; GA, general anesthetic; HDU, high dependency unit; IOL, induction of labor; LW-PNW, labor ward-postnatal ward; MISC, miscarriage; Miso, misoprostol (800 μm per rectum); MOD, mode of delivery; PGF, prostaglandin PGF2 α; PP, placenta previa; Prev PPH, previous PPH; SVD, spontaneous vaginal delivery; S10, 10 IU Syntocinon (oxytocin); S40, 40 IU Syntocinon (oxytocin infusion, over 4 h); TOP, termination of pregnancy; RA, regional anesthetic
*Ultrasound scan used for teaching technique of balloon placement

Parity

Two women (cases 1 and 8) experienced PPH following the birth of their first pregnancy, six women had had previous pregnancies (cases 4, 7, 9, 10, 12 and 14).

Mode of delivery

Six cases of PPH followed vaginal deliveries (cases 2, 7, 8 and 13–15), three followed elective cesarean section (cases 3, 11 and 12) and six were subsequent to emergency cesarean section (cases 1, 4–6, 9 and 10).

Risk factors

Although some cases had identifiable risk factors (cases 1, 3, 5, 10 and 13), others had none (cases 2, 11, 12, 14 and 15).

Timing of PPH

Primary PPH was diagnosed at delivery in ten out of the 13 cases (cases 1, 3–7, 9, 10, 13 and 14). Two cases were diagnosed at 4 and 6 h, respectively, after a vaginal delivery (cases 2 and 15) and one case was diagnosed 9 h after following an elective cesarean section (case 11). The remaining two cases represented secondary PPH at 8 days and 2 weeks postpartum (cases 8 and 12, respectively).

Cause of PPH

Uterine atony was considered the cause in all primary PPH, whereas the secondary PPH was attributed to endometritis. In one of these cases *Proteus mirabilis* infection was demonstrable from uterine curettings (case 12).

Uterotonics used

Most cases received all available first-line uterotonics (Table 1). However, relative contraindications such as the presence of hypertension occasionally restricted their use (e.g. case 4).

PPH volumes

Although the actual PPH volume was not an absolute indication for insertion of the Bakri balloon, the final PPH volumes ranged from 2 to 4 l of blood (average of 3.1 l).

Site of placement

In the majority of cases, the Bakri balloon was inserted in the operating room. In one case (case 8), an attempt was made to insert the balloon in the high dependency unit (HDU). However, the amount of bleeding obscured the view and the patient's discomfort with the procedure (vaginal and speculum examination), resulted in this attempt being abandoned. The balloon was then successfully inserted in the operating room.

Mode of insertion

In all cases the Bakri balloon was inserted via a transvaginal (anterograde) direction, i.e. from the vagina into the uterine cavity (Figure 3). In cases of PPH that occurred during a cesarean section, the lower segment incision was closed in two layers and the bleeding reassessed from the vaginal aspect *before* the final decision was made to insert the balloon.

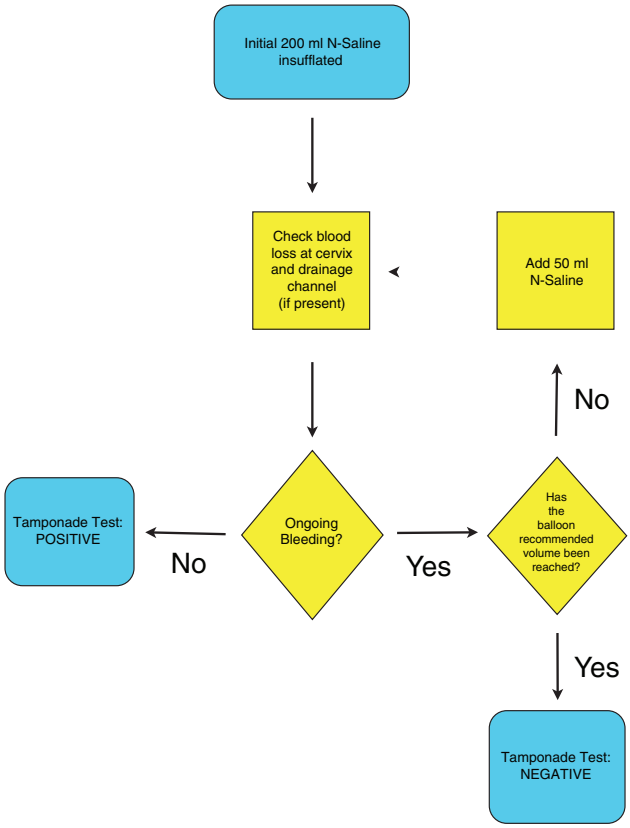

Figure 2 The tamponade method in relation to the tamponade test in the management of PPH. N-Saline, normal saline

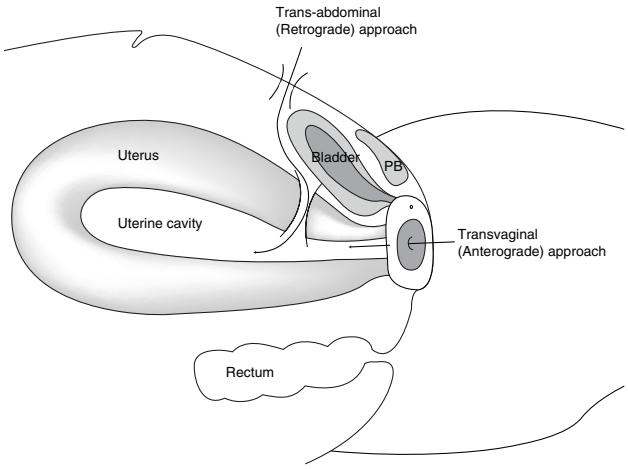

Figure 3 Transvaginal (anterograde) and transabdominal (retrograde) approaches to the uterine cavity for balloon placement. PB, pubic bone

Tamponade test

A tamponade test was performed in all cases involving the 'tamponade method' (Figure 2). The volume of normal saline insufflation that resulted in a positive tamponade test ranged from 250 to 500 ml (average 410 ml). The manufacturer's recommended maximal volume of 500 ml was not exceeded.

Preventing balloon displacement

Of the patients with a dilated cervix, vacuum drainage was used in the majority of cases (9/12) to prevent caudal migration of the insufflated balloon[18]. However, in one case (case 8), the patient forcibly displaced an intact fluid-filled Bakri balloon into the vagina by pulling on the balloon shaft whilst being agitated following extubation. No cervical trauma was evident during the reinsertion of a second Bakri balloon, suggesting that the balloon was able to re-mould itself with the original quantity of fluid during expulsion. Following the subsequent positive tamponade test, a vaginal pack was used in addition to the vacuum method in this patient.

Analgesia

Regional and general anesthesia was used to insert the balloon, particularly if the PPH occurred during an ongoing cesarean delivery. One case was converted from a regional to a general anesthetic because of patient discomfort secondary to the prolonged operating time (case 1).

In another case (case 5), 50 ml of the balloon volume was removed in the recovery area as the patient experienced significant cyclical period-type discomfort. The cyclical discomfort was more tolerable following this reduction in balloon volume.

Location of postinsertion care

Initially all cases were managed in the high dependency units (HDU) (cases 1–7). As familiarity of using the balloon in the management of PPH occurred with hospital staff at different locations, the postinsertion management migrated transiently via the labor ward and eventually directly to the postnatal ward (cases 9–11 and 13–15). However, some cases required specific HDU or intensive care unit (ICU) management (e.g. intubation or coagulopathic issues, in cases 8 and 12, respectively).

Duration of balloon insertion

Factors such as the time of day/night of initial placement and management of other co-morbidities affected the total duration of the balloon placement. This ranged from 18 to 40 h (average 25 h).

Deflation regimen

Depending on the time of insertion and other co-morbidities, various regimens were used. The main emphasis was to ensure the initial and final balloon volumes of normal saline were removed during 'working hours' rather than at times when staff availability was reduced.

Placental pathology

Of the five placentas that were sent for histologic examination in the 13 cases of primary PPH, only one case of placenta accreta was identified (case 4).

Success rate

In this series, all cases in which a Bakri balloon was used were successful.

COMMENTS

The management of PPH invariably involves the use of physical and pharmacological agents to facilitate uterine contraction while excluding genital tract trauma and retained products of conception[3]. Although evidence-based data on the use of uterotonics recommends them as first-line management, it is not clear which of the multitude of secondary approaches are to be used first when uterotonics prove to be ineffective for the commonest cause of PPH, namely uterine atony[19]. Specifically, there is no evidence for a hierarchy of use in relation to arterial ligation, compression sutures or hysterectomy. The subsequent course of action is usually dependent on operator preference and the facilities available within the respective units.

Although placenta accreta/previa was the initial circumstance in which the uterine-specific Bakri balloon was used[20], this technology can be used for a variety of other PPH scenarios including endometritis and secondary PPH in the presence of coagulopathy (cases 8 and 12, respectively). Therefore, the case mix in this series reiterates the reality that balloon tamponade in the management of PPH is broadly applicable to a variety of atonic bleeding situations. It also has the advantage of not requiring specialized personnel or equipment other than the balloon itself.

Limitations of this study

Although other studies involving the Bakri balloon report an overall success rate of 80–90%[10,14], the 100% success rate in this case series must be viewed with caution. In this particular series, the author was involved as soon as the first-line uterotonics were considered ineffective and the Bakri was inserted in a timely manner. This early intervention is likely to have contributed significantly to the high success rate[15].

Additional limitations include the small sample size and patient selection. With respect to the latter, three cases within the study period had a peripartum hysterectomy. Although the decision to proceed with this was not based on a failed tamponade test, it is unclear whether these cases would have been successfully managed with the Bakri balloon alone.

UTERINE-SPECIFIC BALLOON GUIDELINES

As previously mentioned, a number of NUS balloons have successfully been used in the management of PPH and contribute to the majority of the published literature (Figure 1). However, there are no comparative studies between these NUS balloons and the uterine-specific balloons to enable a direct comparison of the various balloons or methodologies used. Although 'failures' of the tamponade balloons are mentioned in prospective studies of peripartum hysterectomies and audits of PPH, the reasons for failure are not always discussed or explained[15,16]. This knowledge deficit makes it difficult to determine whether there are any specific methodological contributions to the success, or failure, of balloon tamponade technology. Therefore, it is possible that the success rates reported for each balloon device may be attributed to the methodology used in that particular study.

Published recommendations exist for the NUS Rusch balloon, and these may be considered applicable to the uterine-specific Bakri balloon[8]. However, a few noteworthy points pertain to the *method* by which the NUS balloon is filled. The principle of insufflating the balloon until 'a resistance (is) felt' with 'the pressure required (being) equivalent to that used when inflating a Foley catheter balloon' is ambiguous[8].

Unfortunately, similar methodological ambiguity exists in published case series using the Bakri balloon. For example 'the amount of saline instilled…(depends) on the size and capacity of the uterus'[10], and the 'procedure was successful, if the bleeding is stopped after the balloon was inflated' without defining how an effective final volume is reached[10]. In another series using the Bakri balloon, the balloon was inflated 'until the uterine fundus was firmly palpable or bleeding was controlled'[14]. Furthermore, the product information supplied from Cook Medical (J-SOS1106) states the intraluminal volume is to be 'determined by direct examination or ultrasound scan'.

THE TAMPONADE TEST

The tamponade test is based on a clinical outcome[6]. This outcome is likely to be dependent on a specific insufflated volume of normal saline for the individual uterus concerned. Since it is the clinical outcome that is paramount, and not the volume used or pressure generated, it is imperative that the amount of fluid used is directly correlated to the tamponade test and not estimated or predetermined[18]. Surprisingly, the NUS (Rusch) balloon guidelines, Cook Medical information leaflets and published cases involving the Bakri balloon, do not mention the tamponade test[8,10,14].

Stages of use

In an attempt to consolidate the methodological variations that exist within various studies, a series of stages is described in relation to the use of tamponade balloons (Table 2). It is envisioned that these stages may be universally implemented for both uterine- and non-uterine-specific balloons, to provide a consistent reference for usage, regardless of the methodologies used.

Table 2 Five 'stages' in the use of balloon tamponade technology in the management of PPH

Stage	*Description*
1	Risk factors, indication for use and location of insertion
2	Patient positioning and access to the uterine cavity
3	Tamponade test and prevention of balloon displacement
4	Postinsertion observation and supportive treatment
5	Removal of balloon and follow-up

In particular, the use of these stages may serve to enhance training in order to identify factors that result in balloon tamponade failure or success. It is anticipated that others will publish not only their successful cases, but also complications and reasons for failure with respect to these stages, so that a consistent method of usage can be established, thereby allowing comparisons and improvements in the methodologies used.

The five stages are described with a series of 'consider', 'preparation' and 'potential complications' comments. In clinical practice these stages are continuous and conceptually overlap.

Stage 1: Risk factors, indications for use and location of insertion

Consider

- Risk factors (emergency box)
- Timing (early recourse to theater)
- Indications (cause of bleeding)

Risk factors may not always be present for PPH, but their presence should help to alert the care giver that there may be a need to use a tamponade balloon.

Timing is also likely to be a significant contributor to the eventual outcome of the uterine tamponade technique. Therefore, the inclusion of a Bakri balloon in the labor ward 'emergency/PPH box' or the 'obstetric emergencies' theater box will help to minimize the decision-to-tamponade test interval.

Indications for using balloon tamponade should be for ongoing bleeding after failure of first-line uterotonics in the management of an atonic uterus. Exclusion of retained products and genital tract trauma is paramount to a successful tamponade test.

Preparation

Although the balloon can be inserted on the birthing unit, postnatal ward or recovery bay, it is important to be able to exclude genital tract trauma and retained products of conception. The operating theater environment provides excellent lighting conditions, a table that can be put into the Trendelberg position,

appropriate instruments and the opportunity to proceed to laparotomy if the tamponade test is negative (see stage 3, Figure 2).

Potential complications

Although the balloon has been used for vaginal lacerations[21], examples in the literature demonstrate that a failure of uterine tamponade occurs if genital tract trauma is overlooked[6,22]. In addition, if the uterine cavity contains retained products or collections of blood clots, correct placement of the balloon may prove to be difficult.

Stage 2: Patient positioning and access to the uterine cavity

Consider

- Patient positioning
- Transvaginal (anterograde) placement of the balloon
- Ultrasound to assist/monitor balloon placement

If the use of a Balloon is anticipated prior to the beginning of a cesarean section, for example in placenta previa, the patient can be initially positioned, and draped, in a lithotomy position with the thighs in a horizontal position. If the balloon is going to be inserted, the legs may be subsequently flexed to improve exposure to the vagina. This preoperative positioning will minimize re-draping with potentially breaching of the sterile field as the balloon is placed prior to closure of the laparotomy site. If the PPH occurs unexpectedly during a cesarean section, the 'frog-leg' position is useful once the uterus is closed and the laparotomy site is covered with a sterile drape.

Alternatively, if the PPH follows a vaginal delivery, or as a secondary PPH, a lithotomy position is preferable.

Access to the uterine cavity for balloon placement will depend on whether the uterine cavity has already been exposed, e.g. at cesarean section. Although transabdominal (retrograde) placement, i.e. from the uterine cavity to the vagina, has been advocated, practical problems may arise. These include trauma to the undilated cervix, damage to the balloon device on subsequent uterine cavity closure and suboptimal uterine closure. Conversely, inserting the balloon from the vagina to the uterine cavity (transvaginal) involves a 'smoother' conical passage of the device and is preferred (Figure 3). Furthermore, a two-layer closure of the lower segment incision may alleviate the need for balloon insertion when bleeding is subsequently re-assessed from the cervix.

The routine use of ultrasound is controversial. In the absence of a recent uterine scar or the necessity to curette the uterine cavity (as in secondary PPH), ultrasound is not necessary for balloon placement. However, confirming the position following the insertion of the balloon device may be useful if the tamponade test is negative when the maximal balloon volume is reached. Furthermore, the use of ultrasound provides a visual guide to balloon placement, and is therefore a valuable teaching tool in balloon placement (Figure 4).

Preparation

Balloon access to the uterine fundus can be challenging in the presence of PPH. Use of a Rampley's forceps on the cervical lip provides gentle countertraction when inserting the balloon via the vagina (transvaginal placement). This helps to ensure the tip of the balloon reaches the fundus.

When a speculum cannot provide adequate visual access to the cervix, consider using fingers to not only guide the balloon into the uterus, but also to maintain the balloon in position (See stage 3 and Figure 4).

If PPH occurs during a cesarean section and the cervix is not dilated sufficiently to pass the balloon device, Hagar dilators may be used to dilate the cervix from below prior to transvaginal (anterograde) placement. Alternatively, a finger may be used to dilate the cervical canal from within the uterus if a transabdominal (retrograde) approach is being contemplated (Figure 3).

Potential complications

If the balloon is placed in a transabdominal manner with subsequent uterine incision closure, damage to the balloon may occur or uterine closure may be compromised in an attempt to avoid balloon damage. In addition, the transabdominal (retrograde) approach has the potential to cause cervical trauma when attempted in the presence of a closed cervix. Although the collapsed diameters of the Bakri balloon at the proximal and distal ends are approximately 2 cm, the transvaginal (anterograde) approach results in a smoother, more conical entry through the cervix due to the shape of the drainage tip. It is assumed that the detachable two-way tap is removed prior to insertion when

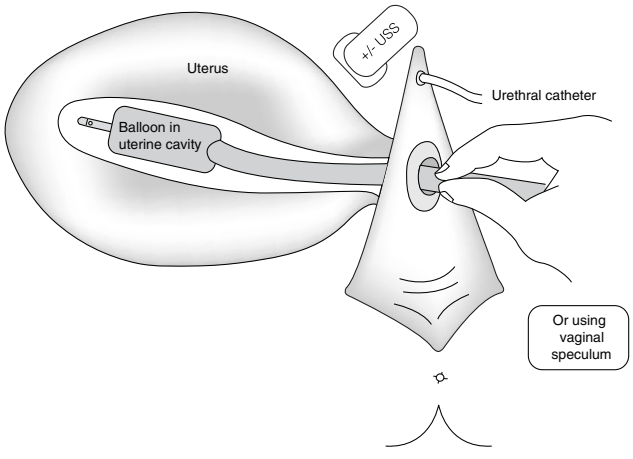

Figure 4 Ensuring the balloon is inserted and maintained at the fundus as the balloon is insufflated. +/- USS, with or without the use of ultrasound scanning (to demonstrate/ensure appropriate placement)

contemplating the transabdominal (retrograde) approach.

Finally, inadequate visualization of access to the cervix can lead to suboptimal placement and an inability to perform the tamponade method (Figures 2 and 5).

Stage 3: Tamponade test and prevention of balloon displacement

Consider

- The tamponade test and the tamponade method
- Maintenance of the balloon at the uterine fundus
- Additional surgical methods (e.g. B-Lynch)

The tamponade *test* is a clinical indicator of successful tamponade and formalizes the need to resort to other procedures such as laparotomy or hysterectomy. The tamponade test can only be effectively applied if the balloon is in the correct location within the uterine cavity and the cervix around the balloon shaft can be visualized to assess blood loss (Figure 5).

The tamponade *method* involves a cyclical assessment of bleeding following sequential insufflation of the balloon with normal saline within the uterine cavity (Figure 2). This method of uterine filling is based on a clinical outcome (ongoing blood loss) and does not depend on 'estimating' or guessing the amount of fluid required. If the balloon maximum is reached and bleeding is ongoing, the tamponade test is negative and subsequent steps to control bleeding must be taken (Figure 2).

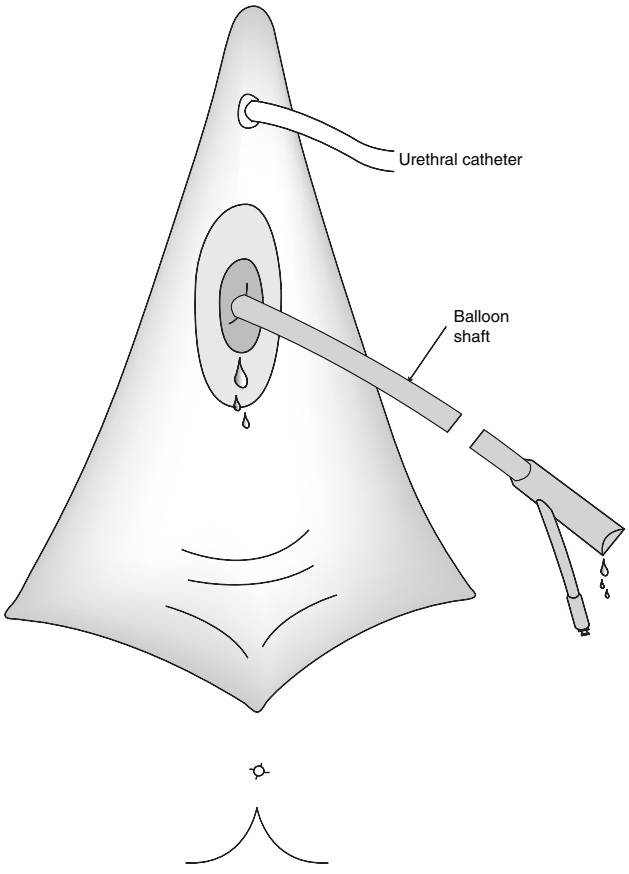

Figure 5 Monitoring blood loss from the cervix and drainage channel (if present) in order to determine a clinical outcome in relation to balloon insufflation

Maintaining the balloon in the uterus can be problematic during placement. Furthermore, using traction as originally described by Bakri, may result in displacement of the balloon into the vagina despite successful intrauterine placement following a vaginal delivery[20].

If the cervix is fully/partially dilated prior to placement of the balloon, a number of options can be used to maintain the balloon in the correct position. For example, placing a gauze pack in the vagina is useful, but it is imperative that the tamponade test is positive prior to packing the vagina, as ongoing blood loss may not be detected due to the absorbent quality of the gauze. Another option is to connect the drainage channel to a suction drain[18]. The vacuum generated thus maintains the balloon within the cavity.

Finally, once a positive tamponade test has been achieved, ensure the input valve of the balloon is secured, perhaps with tape, so that it is not inadvertently opened during patient transfer.

Preparation

As the balloon in insufflated with normal saline, it expands within the area of least resistance. Following a vaginal delivery this area is generally through the cervical canal and into the vagina (Figure 6). Therefore, the balloon should be maintained at the uterine fundus during insufflation with saline. This may be achieved by using a Rampley's forceps gently applied at the base of the balloon. Alternatively, the balloon can be maintained in place by maintaining the shaft at the base of the balloon within the vagina using fingers as an assistant insufflates the balloon with saline (Figure 4).

Potential complications

To date there have been no reports of perforation of the balloon devices through the uterus following placement. However, such examples have been reported for the Sengstaken–Blakemore tube in the esophagus[23]. One particular advantage of using the Bakri balloon is in eliminating the need to 'trim' the rather long drainage stalk of the Sengstaken–Blakemore tube, which potentially could result in uterine perforation[7].

Although, the postpartum uterine cavity is compliant, it is difficult to determine how much volume is required to achieve a positive tamponade test. 'Guesstimating' the volume required does not constitute a tamponade test and underfilling the balloon may result in a negative tamponade test. The test should not involve estimations of required volumes. The endpoint of the tamponade test is a clinical one (Figure 2). The bleeding either stops (test positive) or continues at an unacceptable rate (test negative). Conversely, overdistending the uterine cavity may result in uterine scar dehiscence following a cesarean section or subsequent adverse effects on the endometrium.

If the Bakri balloon is used in conjunction with other surgical approaches, other 'complications' may occur[24]. An example would be failing to gain access to the uterine cavity when a B-Lynch suture is used[14]. According to the original B-Lynch publication, a cavity should exist after suture placement to allow drainage[25]. It is in this area that the Bakri balloon will enter. Therefore, modifications of the B-Lynch suture that eliminate this cavity resulting in approximation of the anterior and posterior uterine walls will not allow placement of the Bakri balloon[26].

The Bakri balloon can theoretically be used in combination with uterine artery embolization and selective devascularization. However, there are no data to support a hierarchy when using these surgical approaches.

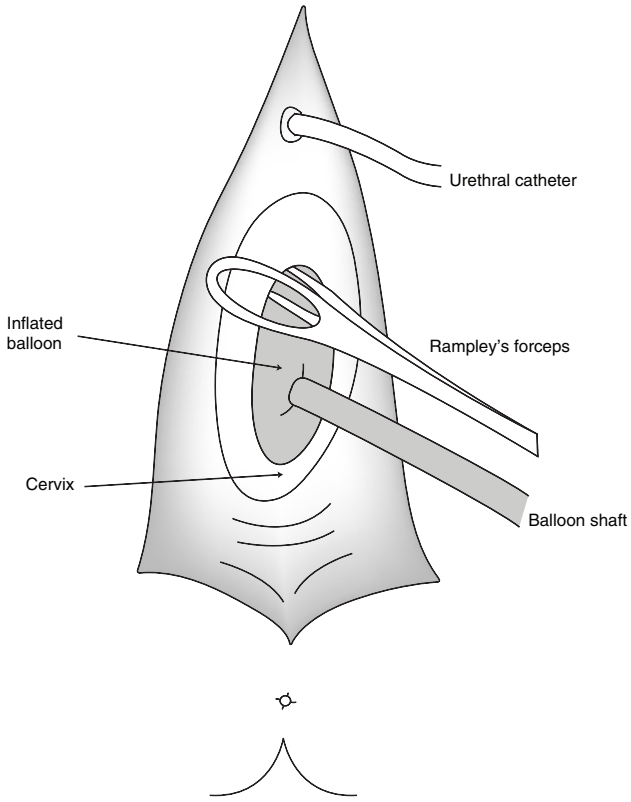

Figure 6 Using a Rampley's forceps to provide counter traction of the cervix when inserting the balloon. If the balloon is not maintained in position within the uterine cavity, the balloon is seen extruding from the cervical canal as it is being insufflated with normal saline

Stage 4: Postinsertion observation and supportive treatment

Consider

- Resuscitation
- Assessment of blood loss
- Ongoing oxytocin infusion, antibiotics and analgesia

Assessing any ongoing blood loss following a positive tamponade test is critical in determining whether balloon tamponade is successful.

Following balloon insertion, and after the first aliquot of saline is removed after 8–12 h (Figure 7) perineal pads should be collected at 15 min intervals over the first hour period ('golden hour'). This will give a visual estimation of blood loss. Alternatively, these pads may be weighed.

Although blood loss from the balloon's drainage channel will also give an indication of ongoing bleeding, normal/corrected coagulation usually results in clot formation within this channel. Flushing the channel, as suggested by the Bakri instruction leaflet (J-SOS1106), will not prevent this.

The patient should be resuscitated following a positive tamponade test, as the cessation of bleeding is only one component of the patient's management. Therefore, multidisciplinary involvement including hematology, anesthetics and ICU/HDU staff is usually necessary to re-establish normal parameters once the bleeding has been controlled (Figure 7).

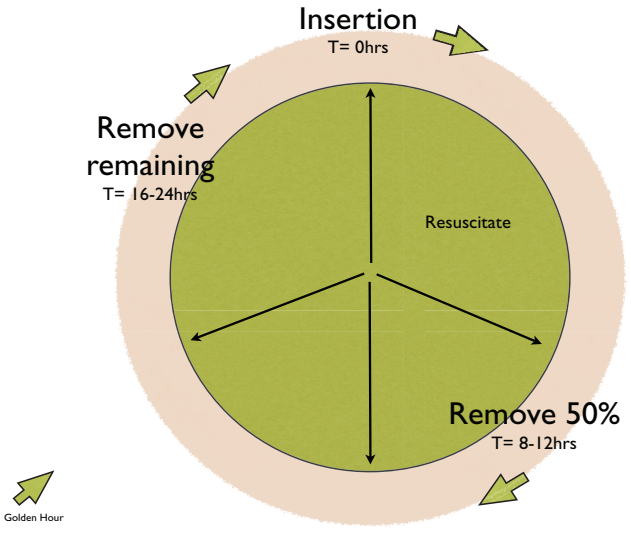

Figure 7 Using a 24-hr clock to manage when to resuscitate the patient and plan removal of the saline within the balloon following the achievement of a positive tamponade test. T, time from successful tamponade test

Preparation

The location of the patient postoperatively is paramount. Whether this is in ICU/HDU owing to other medical problems or a postnatal ward, the 'golden hour' must be emphasized to minimize the delay of diagnosing failure of the balloon tamponade technique.

Antibiotic cover with a broad-spectrum antibiotics such as a cephalosporin with or without metronidazole is advisable to minimize iatrogenic infection secondary to the balloon placement method[9].

Ongoing oxytocin infusion is logical but not empirical. Therefore, if the risk of fluid overload is to be minimized secondary to the crossreaction of oxytocin with vasopressin receptors, sodium ion

concentrations should be assessed throughout this time period, particularly in the presence of reduced urine output.

Analgesia may need to be provided, as uterine distension may give rise to spasmodic uterine pain.

Potential complications

Unidentified ongoing bleeding may occur by not checking the perineal pads and being falsely reassured by minimal blood loss from an occluded balloon drainage channel.

Failure to consider other co-morbidities such as acute renal failure as well as iatrogenic infection, hyponatremia and inadequate analgesia are also possible complications of this stage.

Stage 5: Removal of balloon and follow-up

Consider

- Timing of removal
- Monitor blood loss and systemic parameters
- Follow-up

There is considerable variation as to when, and how, the balloon should be removed[9]. One method is to remove 50% of the balloon volume within 12–18 h of insertion during office hours in case bleeding restarts (Figure 7). The balloon can always be re-inflated at this stage to allow consideration of subsequent management options if bleeding ensues. Otherwise, the remaining balloon volume can then be removed within 24 h of insertion. Sometimes this time scale may need to be extended, but there is no evidence that leaving the balloon longer improves the outcome (Table 1). Furthermore, any deleterious effect on the endometrial function such as menstruation, synechae formation and subsequent implantation is as yet unknown. However, two pregnancies following the use of a Bakri 'sandwich' (balloon with a B-Lynch suture) have been reported[24].

Preparation

Ensure that clear instructions are provided to the staff looking after the patient postinsertion with respect to the potential of re-bleeding. The meticulous observation of blood loss in the golden hour following any fluid removal is paramount in determining the success or otherwise of using the balloon in the postinsertion period (Figure 7).

Provide adequate opportunity to discuss/review with the patient the recent course of events prior to discharge and encourage follow-up in 6–8 weeks or when menses return. The experience can be quite overwhelming. An ultrasound scan at this follow-up stage may serve to reassure the patient of subsequent normal appearances of uterine anatomy.

Potential complications

Removing the balloon too soon may result in bleeding recurrence. There are no data on the shortest time that a balloon needs to be *in situ* to exert its effect. Conversely, maintaining the balloon for prolonged periods may potentiate uterine necrosis and ulceration, both of which have been reported in the esophagus when balloon tamponade technology was used[23].

PRACTICE POINTS

- Balloon tamponade technology can be successfully used for a variety of conditions that are associated with an atonic uterus
- Using defined stages, teaching concepts of balloon placement, insufflation and postoperative care can be facilitated
- Complications regarding the use of balloon tamponade technology in the management of PPH may be reported in relation to these stages to enable comparisons to be made between studies.

ACKNOWLEDGMENTS

The author would like to thank the labor wards, ICU/HDU, postnatal and theater staff from the participating hospitals involved in these cases (St George Hospital, Shoalhaven Hospital and Wollongong Hospital of the South Eastern Sydney and Illawarra Area Health Service, Australia)

Some of this work has been presented as an abstract/poster at the Royal Australian and New Zealand College of Obstetricians and Gynaecologist Annual Scientific Meeting as a poster in Adelaide, 21–24 March 2010.

References

1. Lalonde A, Daviss BA, Acosta A, Herschderfer K. Postpartum haemorrhage today: ICM/FIGO initiative 2004–2006. Int J Gynecol Obstet 2006;94:243–53
2. World Health Organization. Attending to 136 million births, every year: Make every mother and child count: Chapter 4: Risking death to give life. The World Health Report 2005. Geneva, Switzerland: WHO, 2005
3. Royal College of Obstetricians and Gynaecologists. Green-top Guideline No. 52. Prevention and Management of Postpartum Haemorrhage. London: RCOG, 2009
4. Doumouchtsis SK, Papageorghiou AT, Arulkumaran S. Systematic review of conservative management of postpartum hemorrhage: what to do when medical treatment fails. Obstet Gynecol Surv 2007:62:540–7
5. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No.76. Obstet Gynecol 2006;108: 1039–47
6. Condous GS, Arulkumarah S, Symonds I, et al. The "tamponade test" in the management of massive postpartum hemorrhage. Obstet Gynecol 2003;101:767–72
7. Doumouchtsis SK, Papageorghiou AT, Vernier C, Arulkumaran S. Management of postpartum haemorrhage by uterine balloon tamponade: prospective evaluation of effectiveness. Acta Obstet Gynecol Scand 2008;87:849–55

8. Keriakos R, Mukhopadhyay A. The use of the Rusch balloon for management of severe postpartum haemorrhage. J Obstet Gynaecol 2006;26:335–8
9. Georgiou C. Balloon tamponade in the management of postpartum haemorrhage: a review. BJOG 2009;116:748–57
10. Vitthala S, Tsoumpou I, Anjum ZK, Aziz NA. Use of Bakri balloon in post-partum hemorrhage: A series of 15 cases. Aust N Z J Obstet Gynaecol 2009;49:191–4
11. Majumdar A, Saleh H, Davis M, Hassan I, Thompson P. Use of balloon catheter tamponade for massive postpartum haemorrhage. J. Obstet Gynaecol 2010;30:586–93
12. Katesmark M, Brown R, Raju KS. Successful use of a Sengstaken-Blakemore tube to control massive postpartum haemorrhage. BJOG 1994;101:259–60
13. Johanson R, Kumar M, Obhrai M, Young P. Management of massive postpartum haemorrhage: use of a hydrostatic balloon catheter to avoid laparotomy. BJOG 2001;108:420–2
14. Dabelea V, Schultze PM, McDuffie RS. Intrauterine balloon tamponade in the management of postpartum hemorrhage. Am J Perinatol 2007;24:359–64
15. Knight M, on behalf of UKOSS. Peripartum hysterectomy in the UK: management and outcomes of the associated haemorrhage. BJOG 2007;114:1380–7
16. Brace V, Kernaghan D, Penney G. Learning from adverse outcomes: major obstetric haemorrhage in Scotland, 2003–05. BJOG 2007;114:1388–96
17. Condous G. Re – Vitthala et al. Use of Bakri balloon in post-partum haemorrhage: a series of 15 cases. Aust N Z J Obstet Gynecol 2009;49:445–6
18. Georgiou C. Intraluminal pressure readings during the establishment of a positive "tamponade test" in the management of postpartum haemorrhage. BJOG 2010;117:295–303
19. Mousa HA, Alfirevic Z. Treatment for primary postpartum haemorrhage. Cochrane Database Syst Rev 2007;(1): CD003249
20. Bakri YN, Amri A, Jabbar FA. Tamponade-balloon for obstetrical bleeding. Int J Gynecol Obstet 2001;74:139–42
21. Tattersall M, Braithwaite W. Balloon tamponade for vaginal lacerations causing severe postpartum haemorrhage. BJOG 2007;114:647–8
22. Seror J, Allouche C, Elhaik S. Use of Sengstaken – Blakemore tube in massive postpartum hemorrhage: a series of 17 cases. Acta Obstet Gynecol Scand 2005;84:660–4
23. Conn HO, Simpson JA. Excessive mortality associated with balloon tamponade of bleeding varices. JAMA 1967;202: 135–9
24. Nelson WL, O'Brien JM. The uterine sandwich for persistent uterine atony: combining the B-Lynch compression suture and an intrauterine Bakri balloon. Am J Obstet Gynecol 2007;196:e9–10
25. B-Lynch C, Coker A, Lawal AH, Cowen MJ. The B-Lynch surgical technique for the control of massive post partum haemorrhage: an alternative to hysterectomy? Five cases reported. BJOG 1997;104:372–5
26. Cho JH, Jun HS, Lee CN. Hemostatic suturing technique for uterine bleeding during cesarean delivery. Obstet Gynecol 2000;96:129–31