A review of current practice in using Balloon Tamponade Technology in the management of postpartum haemorrhage

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The use of various Balloon tamponade technologies has steadily increased over the last five years in the management of postpartum haemorrhage. New methodologies and applications have been included beyond the original descriptions. Furthermore, novel approaches and mechanisms of action have also been suggested. No comparative trials involving “uterine/fertility sparing” approaches such as Balloon Tamponade Technology have been performed comparing the safety, efficiency and long term effects on endometrial and myometrial functions. However, balloon tamponade technology is rapidly becoming accepted as a preferred second line approach following failed first line uterotonic therapies in many obstetric units.

This paper reviews the current use of various balloon tamponade technologies in the management of postpartum haemorrhage.

Background

Obstetric haemorrhage is a significant contributor to worldwide maternal morbidity and mortality (MMM).¹,² Since the WHO millennium Goal directives, the relative position that this specific direct cause of MMM occupies, has recently improved in some countries.³ For example in the United Kingdom (UK) from 1985–2005, direct maternal deaths from postpartum haemorrhage (PPH) usually occupied position three.⁴ In the latest United Kingdom triennial Confidential Enquiry in to Maternal Deaths (2006–2008), it now occupies position six.⁵ Many factors contribute to this ultimate position and in Japan, recent publications suggest that both maternal age and place of delivery are closely correlated to the mortality rate from PPH.⁶ In the UK a study addressing specific second-line therapies for PPH suggests another contributing factor. This is the ubiquitous use of balloon tamponade in the management of PPH.⁷ At present various guidelines for the management of PPH include the use of uterine balloon tamponade after the exclusion of retained products and genital tract trauma.⁸ In these situations, the balloon is usually used as a form of treatment following the failed use of first line uterotonic therapies (FLU) such as oxytocin, ergometrine, misoprostol and prostaglandin F₂α. In such studies successful balloon tamponade outcomes have been reported in the range of 80–100%.⁹,¹⁰

Both uterine specific and non-uterine specific balloons appear to have been adopted into the armamentarium of second line approaches (SLA), such as uterine artery embolisation and compression sutures. However, the relative hierarchy of balloon tamponade technology (BTT) use with respect to these other SLA has not been established.⁹,¹⁰ In addition, the theoretical complications that exist in association with balloon usage such as: perforation, necrosis and rupture of the uterus, were largely based on the use of balloons in other organ systems such as the oesophagus.¹¹,¹² However, with time complications involving BTT, such as uterine perforation and uterine rupture, have since been described.¹³,¹⁴ Finally, the long-term surrogate effects following the use of BTT, such as subsequent menses, fertility and pregnancies have only recently been reviewed.¹⁵ The purpose of this paper is to review the various uterine balloon tamponade technologies available and how they are currently being used in the management of PPH.
Balloon tamponade technology

With respect to Obstetrics and Gynaecology, BTT refers to the use of a balloon-like structure that is insufflated, usually with saline, within the uterine cavity, and more recently in the vagina, to create a “tamponade” effect. This technology, that is currently used for both gynaecological and obstetric bleeding conditions, was originally used in the management of haemorrhage in other systems, such as the oesophagus and bladder.

Uterine specific and non-uterine specific balloons

In addition to the original uterine-specific Bakri balloon (Cook Medical, Bloomington, Indiana), there are currently two other uterine-specific balloons: The BT-Cath (Utah Medical Products Inc. West Midvale, Utah) and the Ebb two-balloon system (Glenveigh Medical LLC, Chattanooga, Tennessee) (Figure 1). The comparative features of these balloons are listed in Table 1.

In contrast to the Bakri balloon, the BT-Cath contains a more pronounced umbilicated drainage channel and the silicone balloon layer is thinner. The Ebb system is fundamentally different from the Bakri balloon and the BT-Cath, in that it contains a double-balloon system. The proximal balloon of the Ebb balloon, is designed to be insufflated within the vagina in order to maintain the distal balloon within the uterine cavity (Figure 1). Unlike the materials used for other balloons, namely silicone or latex/rubber, the Ebb balloons are comprised of thin but durable polyurethane material (< 1 mm). The vast majority of published literature involves the Bakri balloon with minimal publications for the other uterine-specific balloon products.

More recently, various “cervical ripening” balloons (CRB) have been used in the management of PPH (Figure 2). These balloons have recommended balloon capacities of 40–150 mls, significantly less than that of the uterine-specific balloons. Previous studies have described using small volume balloons, such as the Foley catheter and the Sengstaken-Blakemore tube (SBT), and filling them in excess of their recommended volumes in order to achieve a positive tamponade test. However, the intentional use of smaller volumes in achieving haemostasis involves the concomitant use of other cervical procedures such as: cervical suturing or use of a vaginal pack, essentially preventing the balloon from being displaced. However, they potentially prevent blood loss through the cervical canal and this may contribute to their ultimate mechanism of action (See “Mechanisms of action” below).

Balloon volume and the tamponade test

The initial “balloon” used for the management of PPH was in fact a group of eight silicone Foley catheters, each of which was filled with 35–75 mls of N-saline. The subsequently designed Bakri “SOS” (Surgical Obstetric Silicone) balloon could accommodate 500 mls, but there does not appear to be any specific data why 500 mls was chosen as the balloon capacity. However, the literature has provided examples of volumes ranging from 50–1500 mls N-saline that have been effective in controlling bleeding from an atonic uterus. Studies evaluating balloon volume and pressure relationships
within the uterus clearly identify uterine compliance as an inherent variable to the final uterine volume necessary to stop bleeding.\textsuperscript{30,31} As there is no obvious method of assessing uterine compliance, guestimating the required volume in order to achieve haemostasis without integrating a clinical evaluation during insufflation, may result in a negative tamponade test.\textsuperscript{31}

Practical considerations of use

Incorporation of BTT into PPH protocols has been reported in published guidelines during the management of PPH.\textsuperscript{32} Practical and theoretical “stages of use” have also been described in order to facilitate appropriate integration into a suitable management plan. This involves a five-step approach to help with training, audit and root-cause analysis of complications involved in using BTT (Table 2).\textsuperscript{33}

It has been suggested that, in addition to the timing that interventions are instigated in the management of PPH, differences in methodologies may also contribute to the overall success rate.\textsuperscript{7,33} Some of these methodological variants include: method of insertion of the balloon into the uterine cavity (anterograde or retrograde), filling methods and prevention of balloon displacement.

Insertion of balloon

Various approaches of balloon insertion have been documented.\textsuperscript{10} In some studies the balloon is inserted via a transvaginal (anterograde) direction. In others, the balloons are inserted in a transabdominal (retrograde) direction via the lower segment uterine incision during the caesarean section (CS).\textsuperscript{33} There are also clinically-based approaches, whereby the initial decision to use a Bakri balloon may occur intra-operatively during a CS. However, following uterine incision closure, this decision is later modified dependant on the evaluation of ongoing blood loss from the vagina. If bleeding continues then the balloon is inserted transvaginally.\textsuperscript{31,33} The theoretical differences in time between decision-to-insufflation of the balloon using either approach is similar. However, re-evaluation from the vaginal aspect allows for abandonment of balloon use, as closure of the uterus may in-of-itself be sufficient in achieving haemostasis.

Transabdominal insertion requires specific considerations with respect to the proximal design of the balloon shaft particularly with respect to the ease of insertion through an undilated cervix.\textsuperscript{10} For example during CS for the presence of placenta praevia (Figure 1 and 3).\textsuperscript{34} In one case involving placenta praevia/accreta, the proximal end of the balloon was drained via the abdomen.\textsuperscript{35}

Rapid insufflation of the balloon

The initial methodology by which the balloons were insufflated involved multiple exchanges of N-Saline filled syringes until the required volume was achieved.\textsuperscript{18} The “required” volume is either based on the “Tamponade test” or alternatively “predetermined”.\textsuperscript{36,37} Some balloon manufacturers have since modified the filling process of their devices.\textsuperscript{19,37} These so-called “rapid instillation components” or Easyfill modifications enable the balloons to be filled without the repetitive nature of alternating syringes. Although no data is available to suggest that delay in filling the balloon results in an increase maternal morbidity, the advantage in the rapidity...
of filling is that the recommended maximum balloon volume is reached sooner. Therefore, if a “negative tamponade test” results, the necessary subsequent steps are expediated. Use of these “rapid-filling” modifications does not necessarily result in an increase in positive clinical-based outcomes (i.e., a positive tamponade method). However, they may result in “over-distending” the uterus by insufflating “blindly” if a concurrent clinical evaluation of the insufflation process does not occur.

The hypothetical risks of “over-distension” and “pressure” effects on the endometrium and myometrium secondary to filling are difficult to address as a term uterus can achieve a volume capacity that exceeds 400 mls. However, over-distension may have contributed to uterine rupture and subsequent hysterectomies in two cases of PPH in which BTT was used.

Prevention of balloon displacement

One of the common difficulties encountered when a balloon is inserted into the postpartum uterus, is balloon migration from the original fundal cavity location. This is particularly problematic in cases of balloon usage following a vaginal delivery or CS at full, or near-full, cervical dilatation. The displacement is due to the lower segment area having greater compliance in comparison to the uterine fundus. In addition, the uterus is rarely completely atonic and fundal contractions may occur, even though they may not necessarily result in haemostasis. This uterine activity may be elicited by the use of concurrent uterotonics or secondary to uterine/cervical stretching caused by the insufflated balloon.

The original descriptions using BTT involved the use of the balloon following a CS. The balloon therefore, could be placed on traction following trans-abdominally insertion at CS. This further facilitated haemostasis by applying contact to the placental bed as the cases involved placenta praevia. Subsequent publications in which the balloon was used following vaginal deliveries, proposed vaginal packing with gauze in order to maintain the balloon in the uterine cavity.

The two-balloon system of the Ebb balloon is one possible solution to the balloon displacement problem. The proximal balloon is inflated in the vagina to maintain the distal balloon within the uterine cavity. However, others advocate the use of vacuum connected to the balloon drainage channel to maintain the balloon within the uterine cavity, transfixing the distal tip of the balloon shaft through the uterine fundus and out through the abdomen or suturing/clamping the cervix around the balloon shaft.

Images in some of these displaced examples depict the balloon in the lower segment, but the balloon is not necessarily out of the uterus. Although this is sometimes referred to as “incorrect positioning of the balloon”, the majority of these cases do not require balloon re-deployment, as bleeding is often controlled. One explanation is that haemostasis was achieved prior to displacement. However, others explanations include a mechanism of action at the level of the uterine arteries or cervical/lower uterine segment mediating uterine activity.
(See Mechanisms of action below).

New indications for use

Since the initial studies of the BTT, there has been a steady increase in the number of publications involving both non-uterine and uterine specific balloons. Furthermore, case series data suggest a significant reduction in invasive procedures and potential benefits in low resource settings.\(^{32,43}\)

Although studies have used BTT as a treatment modality for bleeding in the management of uterine atony, recently the balloons have also been used in other circumstances. These include: (1) Prophylaxis of PPH in cases of placenta praevia, (2) For the treatment for PPH secondary to vaginal lacerations, (3) In the prevention of recurrent uterine inversion, (4) In the absence of blood resources and facilitating the transfer of patients to tertiary centres, (5) In the presence of DIC secondary to excessive blood loss and (6) During a negative tamponade test.

Prophylactic use

Foley catheters, SBT and the Bakri balloon have been used in the management of PPH after delivery in cases of placenta praevia.\(^{18,44,45}\) However, the concept of using BTT in order to prevent PPH following delivery of the placenta praevia is novel.\(^{46}\) Although the presence of a placenta praevia does not necessarily result in PPH that cannot be treated with pharmacological agents, a study involving women undergoing a CS for placenta previa demonstrated a trend towards “benefit in placing a Bakri balloon prophylactically at the time of CS”.\(^{47}\) However, a statistically significant reduction in the need for additional medical/surgical measures to control blood loss, or a reduction in the subjective/objective blood loss was not demonstrated.

The use of the balloon in a prophylactic modality may also be useful in other situations. This may include the use of balloons in patients who refuse blood products. For example following complicated deliveries such as retained products of conception requiring manual removal in patients who refuse blood and blood products even if the blood loss at the time of the original procedure is not considered extreme (Case 6 Ref. 15).

Vaginal lacerations

Although uterine atony is the commonest cause of PPH, PPH may also occur secondary to genital tract trauma. During childbirth the vagina may experience multiple lacerations and develop raw bleeding surfaces as well as haematomas. Topical sutures and vaginal packing are the traditional treatment methods that are employed.\(^{48}\) However, there have been examples in which various balloons have been used as a substitute for a vaginal gauze pack.\(^{49–52}\) In such cases air may be used to insufflate the balloons.

The potential advantage of using the balloons in these situations includes that the balloon device will not absorb blood that may otherwise result in a delay diagnosing ongoing bleeding. Secondly, in balloons with a drainage channel, ongoing blood loss may be continually assessed.

Prevention of recurrent uterine inversion

Uterine inversion is an obstetric situation that is frequently followed by an atonic uterus and results in a PPH. BTT (Rusch Balloon) has been used in these situations following the re-establishment of normal uterine anatomy.\(^{53}\) Unfortunately, in some cases uterine inversion recurs and treatment of this uterine re-inversion, using a Bakri balloon has also been described.\(^{54}\) However, a novel approach is the use of a Bakri balloon to prevent recurrence.\(^{55}\)

Lack of available (Blood) resources

In certain situations, although transfusion with blood and blood products is indicated, it may not be possible due to lack of local resources. Although the balloon is not a blood substitute, the use of such a device may serve to staunch the bleeding to facilitate whatever resuscitation is possible (Diagram 1). Thus, the balloon may not only provide a definitive treatment procedure, but may also reduce the bleeding significantly to facilitate transfer of the patient to another appropriate site.\(^{56}\)

Disseminated Intravascular Coagulopathy (DIC)

The Bakri balloon is not indicated for the use in the presence of DIC.\(^{30}\) However, in such a situation the use of the balloon may reduce the loss of blood to facilitate resuscitation and correct the coagulopathy before a more definitive procedure such as a re-laparotomy is performed. For example following a recent caesarean with a PPH suspected to be caused by genital tract trauma following a failed tamponade test (See below; Unpublished data).

Negative tamponade test

The basis of the “tamponade test” in the management of PPH will “identify those who will or will not need surgery”.\(^{36}\) Failure of the tamponade test may be due to a number of reasons. This will include methodological problems such as the failure to incorporate a clinical outcome/assessment during insufflation of the balloon, or other cause of PPH not amenable to BTT. The latter is exemplified in case studies where failure of the tamponade test has been associated with genital tract trauma that was originally overlooked.\(^{50}\)

However, despite a negative tamponade test, the use of BTT may result in continual bleeding at a slower
Current use of Balloon tamponade technology in the management of postpartum haemorrhage

rate than if the balloon was absent. This may provide an opportunity to resuscitate a patient before a proposed laparotomy.

Mechanisms of action

Currently there are a number of proposed mechanisms by which the balloons are thought to exert their “tamponade” effect. The initial theory of the intrauterine balloon acting by exerting in inward-to-outward pressure “that is greater than the systemic arterial pressure” to prevent continual bleeding has been challenged (Table 3). Studies of actual intrauterine pressures do not suggest that this is necessary, and alternative mechanisms of action have been proposed. These include: hydrostatic pressure effect on the uterine arteries, endometrial contact, vascular compression via myometrial stretch and myometrial activity secondary to myometrial stretching.

Recently, cervical dilation resulting in myometrial activity has been demonstrated by electromyography. This may serve to explain the effectiveness of the low volume cervical ripening balloon positioned in the lower uterine segment/cervical canal. Similarly, obstructing the outflow of the uterus by cervical clamping in the absence of a balloon, may allow the collection of blood/clots within the uterus. This may also contribute to the previously suggested mechanisms of action involving lower uterine/cervical stretching.

Table 3. Intraluminal pressures and corresponding blood pressure readings when a positive tamponade test was achieved in seven cases (Reproduced from Georgiou, 2012.)

<table>
<thead>
<tr>
<th>Case</th>
<th>Final volume (mls) in balloon</th>
<th>Positive Tamponade Test</th>
<th>Corresponding Intraluminal pressure (mmHg)</th>
<th>Range of patient’s blood pressure (Systolic/diastolic - mmHg)</th>
<th>Average blood pressure (mmHg)</th>
<th>Average mean arterial pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>360</td>
<td></td>
<td>83</td>
<td>80–110/40–65</td>
<td>92/46</td>
<td>61</td>
</tr>
<tr>
<td>2</td>
<td>350</td>
<td></td>
<td>43</td>
<td>90–140/50–60</td>
<td>110/55</td>
<td>73</td>
</tr>
<tr>
<td>3</td>
<td>350</td>
<td></td>
<td>76</td>
<td>75–110/45–60</td>
<td>87/49</td>
<td>62</td>
</tr>
<tr>
<td>4</td>
<td>450</td>
<td></td>
<td>118</td>
<td>90–120/45–60</td>
<td>103/52</td>
<td>69</td>
</tr>
<tr>
<td>5</td>
<td>350</td>
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<td>154</td>
<td>80–140/40–85</td>
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<tr>
<td>6</td>
<td>500</td>
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<td>90</td>
<td>90–130/45–90</td>
<td>98/59</td>
<td>72</td>
</tr>
<tr>
<td>7</td>
<td>300</td>
<td></td>
<td>81</td>
<td>95–130/55–100</td>
<td>121/62</td>
<td>82</td>
</tr>
</tbody>
</table>

Diagram 1. Using a 24-h clock to manage when to resuscitate the patient and plan the removal of saline within the balloon following the achievement of a positive tamponade test.

T, time from successful tamponade test. (Reproduced from Georgiou, 2009.)
Table 4. Subsequent menses, fertility and pregnancies from cases in which balloon tamponade technology was used in a preceding pregnancy as a second-line approach for the management of PPH (Modified references within “Case” column refer to this publication. Reproduced from Georgiou, 2014.)

<table>
<thead>
<tr>
<th>Index pregnancy</th>
<th>Post-partum</th>
<th>Subsequent Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case</strong></td>
<td><strong>Age</strong></td>
<td><strong>Gravity/Parity</strong></td>
</tr>
<tr>
<td>1&lt;sup&gt;(Ref. 60)&lt;/sup&gt;</td>
<td>19</td>
<td>NM</td>
</tr>
<tr>
<td>2&lt;sup&gt;(Ref. 61)&lt;/sup&gt;</td>
<td>NM</td>
<td>NM</td>
</tr>
<tr>
<td>3&lt;sup&gt;(Ref. 61)&lt;/sup&gt;</td>
<td>NM</td>
<td>NM</td>
</tr>
<tr>
<td>4</td>
<td>26</td>
<td>G1P0</td>
</tr>
<tr>
<td>5</td>
<td>28</td>
<td>G1P0</td>
</tr>
<tr>
<td>6</td>
<td>28</td>
<td>G4P3</td>
</tr>
<tr>
<td>7</td>
<td>25</td>
<td>G1P0</td>
</tr>
<tr>
<td>8</td>
<td>31</td>
<td>G2P1</td>
</tr>
</tbody>
</table>

PPH, postpartum haemorrhage; SLA, second line approaches; BTT, balloon tamponade technology; EBL, estimated blood loss; NM, not mentioned; VB, vaginal birth; C/S, caesarean section; SBT, Sengstaken-Blakemore tube.
Future pregnancies

An evaluation of women who experienced a PPH in their first pregnancy did not result in a statistically significant reduction in the proportion of these women returning for a second pregnancy.59 That paper however, did not specify the treatment modalities used to treat the PPH and furthermore, the study evaluated women experiencing a PPH at a time when BTT was being established into clinical practice (1986–2005). Therefore, the subsequent increase in BTT usage, particularly as a “uterine/fertility sparing” option, is likely to generate repeat pregnancies.

In the published literature there is a single pregnancy reported following the use of the multiple SLA culminating in the successful use of a Rusch balloon and two pregnancies following the use of a Bakri balloon in combination with a failed B-Lynch suture.60,61 Recently, five additional pregnancies have been described in which a Bakri balloon is solely used as a SLA in the management of PPH.15 In these cases information with respect to menses fertility and pregnancy appear to suggest minimal effect when using the Bakri balloon (Table 4).15

Summary

PPH is a potentially life-threatening event in which a number of SLA exist to compliment pharmacological approaches. The choice of these SLA is usually dependent on the availability of resources and technical ability of the attending O&G specialist.

Initially, the use of BTT within this armamentarium was as a “last resort” usually following more invasive SLA such as embolization or vessel ligations.60 Subsequently, combinations involving BTT were used. For example the Bakri B-Lynch sandwich technique.61–63 However, there are no comparative studies in which the reverse order is considered, whereby a balloon is used first and if unsuccessful, using a compression suture or vascular ligation.

The use of BTT has proven to be a popular and relatively simple technique with apparently minimal side effects and complications. Although considered a “fertility-sparing” option further long-term studies are required, as well as comparison data to other SLA, to determine whether BTT should be used as not only the SLA of choice when FLU have failed, but also to extend its repertoire of “indications of use” to include: prophylaxis, assisting in resuscitation for causes other than uterine atony and for the transfer of patients to more resourceful locations.

Furthermore, it would not be unrealistic to consider the use of BTT as a first choice after FLU have failed regardless of the resource settings and irrespective of the estimated blood loss and coagulation profile.

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Conflict of Interest

None.

References


