

# Uterine balloon tamponade for the treatment of postpartum haemorrhage in resource-poor settings: a systematic review

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**Background** Effective interventions addressing postpartum haemorrhage (PPH) are critically needed to reduce maternal mortality worldwide. Uterine balloon tamponade (UBT) has been shown to be an effective technique to treat PPH in developed countries, but has not been examined in resource-poor settings.

**Objectives** This literature review examines the effectiveness of UBT for the treatment and management of PPH in resource-poor settings.

**Search strategy** Publications were sought through searches of five electronic databases: Medline, Cochrane Reference Libraries, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Embase and Popline.

**Selection criteria** Titles and abstracts were screened for eligibility by two independent reviewers. Each reviewer evaluated the full text of potentially eligible articles by defined inclusion criteria, including the presentation of empirical data and use of UBT in resource-poor settings to treat PPH.

**Data collection and analysis** Full text of all eligible publications was collected and systematically coded.

**Main results** The search identified 13 studies that met the inclusion criteria: six case reports or case series, five prospective studies and two retrospective studies for a total of 241 women. No randomised controlled trials were identified. The studies used various types of UBT, including condom catheter ( $n = 193$ ), Foley catheter ( $n = 5$ ) and Sengstaken–Blakemore oesophageal tube ( $n = 1$ ). In these studies, primarily conducted in tertiary-care settings rather than lower-level health facilities, UBT successfully treated PPH in 234 out of 241 women.

**Conclusions** UBT is an effective treatment for PPH in resource-poor settings. Further study of UBT interventions is necessary to better understand the barriers to successful implementation and use in these settings.

**Keywords** Maternal mortality, postpartum haemorrhage, resource-poor settings, treatment, uterine balloon tamponade.

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## Background

Ninety-nine percent of all maternal deaths occur in resource-poor settings.<sup>1</sup> More than 30% of these deaths are attributed to postpartum haemorrhage (PPH).<sup>2</sup> However, death from PPH can largely be avoided through proper prevention, diagnosis and management.<sup>3,4</sup> Unfortunately, many women in resource-scarce settings do not have access to good-quality care or to skilled birth attendants for their delivery. They are therefore at high risk of morbidity or death consequent to PPH.<sup>4,5</sup>

Current options for managing PPH in well-resourced settings include pharmacological treatment with uterotonics, arterial embolisation and surgical treatments such as bilateral uterine artery ligation, B-lynch sutures and emergency hysterectomy.<sup>4,6,7</sup> In recent years, uterine balloon tamponade (UBT) has been included as a second-line treatment for PPH.<sup>6</sup> The UBT procedure entails insertion of a balloon into the uterine cavity and inflation to achieve a tamponade effect. Since 1983, when Goldrath<sup>8</sup> published evidence that insufflating a Foley catheter in the uterus could achieve tamponade, case series and other studies have suggested that various

UBT devices may be effective in treating PPH.<sup>9,10</sup> In 2007, Doumouchstis et al.<sup>9</sup> conducted a systematic review of conservative, nonsurgical treatment options for PPH and found that the reported 84% success rate of UBT does not significantly vary from surgical treatment outcomes. However, virtually all of the reported cases took place in well-resourced tertiary-care settings, the findings of which may not readily translate to resource-poor settings. The effectiveness of UBT in the resource-poor environment may differ from tertiary-care settings because of factors such as the lack of available uterotonics, trained medical personnel, resuscitation supplies, operating theatres, or, more importantly, the use of cheap, alternative UBT devices. Few studies have assessed the effectiveness of UBT as a useful additional tool for PPH in resource-poor settings.<sup>4,11–13</sup> We conducted a systematic literature review to examine the effectiveness of UBT for the treatment and management of PPH in such settings.

## Methods

### Literature search

We conducted a literature search using the following databases: Medline, Cochrane Reference Libraries, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Embase and Popline. The following text search terms and Medical Subject Headings (MeSH) were used: uterine balloon tamponade, uterine balloon, uterine tamponade, intra-uterine tamponade, intrauterine balloon, balloon tamponade, hydrostatic tamponade, balloon dilatation, embolisation-therapeutic, condom catheter, Bakri balloon, Sengstaken-Blakemore tube, Rusch balloon or Foley catheter in combination with postpartum haemorrhage, pregnancy and haemorrhage, uterine haemorrhage, uterine atony and uterine bleeding. We conducted a secondary search of Google using specific phrase combinations, e.g. (Postpartum haemorrhage) (tamponade OR condom OR balloon) (resource poor OR developing country). Two reviewers from our research team independently conducted these searches, which were restricted to human studies. The searches were not limited by language or date of publication, and included all articles through to the completion of the search in June 2011. In addition to the studies identified through the search, key references from included studies were also examined.

### Study selection and eligibility

Two reviewers conducted preliminary screening of the titles and abstracts for eligibility. Studies that addressed our primary research question were included. Further inclusion criteria included randomised controlled trials, prospective and retrospective observational studies, and case series and reports related to the effectiveness of UBT to treat PPH. Opinion-based articles (e.g. editorials) or articles without empirical data on the use of UBT to treat PPH were

excluded. If either reviewer considered an article eligible for inclusion, each reviewer independently evaluated the full text. Studies that reported a protocol including surgical techniques concurrent with UBT to control PPH (e.g. B-Lynch suture and UBT) were excluded. However, cases in which surgical procedures had been attempted before UBT placement, and had failed, were included. We included studies that used the following UBT technologies: Bakri balloon, condom catheter, Foley catheter, Rusch balloon, and Sengstaken-Blakemore tube. Studies not published in peer-reviewed journals were excluded. The remaining studies were manually sorted for application to resource-poor settings; we included only studies that reported on UBT in emerging and developing countries, as defined by the International Monetary Fund's World Economic Outlook Report, April 2011.<sup>14</sup> In the event that the two reviewers disagreed on a study's inclusion after reviewing the full text, a third reviewer reviewed it, and the group deliberated until consensus was achieved.

Some studies included the use of UBT in addressing uterine haemorrhage more broadly than just for PPH. Consequently, to specifically focus on the use of UBT for PPH, cases were excluded from our analysis when UBT was used prophylactically, was intentionally inflated in the vagina, or was used for uterine haemorrhage following termination of pregnancy or spontaneous miscarriage.<sup>15,16</sup>

## Results

Thirteen studies met the inclusion criteria. Our initial search of academic databases had identified 833 articles. A manual review of titles and available abstracts for these articles identified 99 articles for further review and articles that did not relate to the treatment of PPH or evaluate UBT as a treatment were excluded. Subsequent review of the full-text articles identified 39 studies that included empirical data on UBT to treat PPH. Of these, nine were conducted in developing countries. One additional study was identified through a search of the references of key articles. Finally, a review of the first 100 hits of the secondary Google search produced three additional studies that met the review's inclusion criteria (Figure 1).

The 13 studies comprise: six case reports or case series, five prospective studies and two retrospective studies, ranging from one to 73 cases of PPH treated with UBT. Thirty-two cases were excluded from our analysis for use of UBT for indications other than PPH (four from Thapa et al.<sup>15</sup> and 28 from Shivkar et al.<sup>16</sup>), leaving a combined database of 241 clinical cases of UBT use. No randomised controlled trials were identified during the review. The reports, all published in the last decade, describe cases in seven countries, ten from South and Southeast Asia and three from Sub-Saharan Africa (Table 1). Ten of the studies

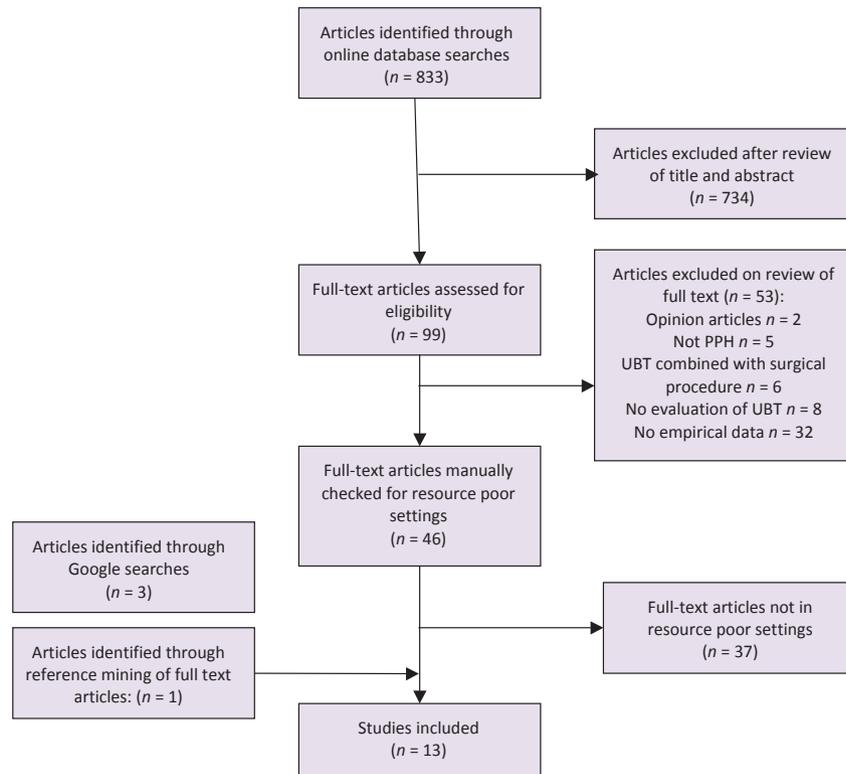


Figure 1. Literature flow.

report use of UBT in tertiary-care settings, one in a rural ‘cottage’ hospital and two did not report the type of facility (although the authors for each were affiliated with tertiary-care facilities).

In the sections below, we describe key review findings along the following domains: presentations of PPH; treatment of PPH before UBT; and effectiveness of tamponade by type of device (e.g. condom catheter).

### Presentations of PPH

Eleven of the studies reported PPH following vaginal births, three following instrument-assisted births and nine following caesarean section (see Table 1). Additional cases of UBT use in response to PPH included: two stillbirths at 20 weeks, a twin delivery and a stillbirth at 31 weeks.<sup>17–19</sup> Women who underwent UBT for PPH ranged in parity from one to ten, and were aged 18–40 years. Nine studies documented attempts to prevent PPH with the active management of the third stage of labour or the use of uterotonics (Table 2).

The estimated blood loss before UBT varied widely in the 13 reports—from 550 to 5000 ml. One study did not report estimated blood loss.<sup>16</sup> The highest reported estimated blood loss successfully managed by UBT was 5000 ml.<sup>15</sup> In 18 cases of PPH, the women were reportedly in frank shock before treatment with UBT.<sup>20,21</sup> All 18 survived subsequent to UBT and resuscitation.

tion included transfusion of whole blood, packed red blood cells and fresh frozen plasma (reported in Table 1).

Uterine atony was the most commonly reported cause of PPH. Additional causes of PPH included coagulopathy, placenta accreta, placenta praevia and retained placenta. Uterine atony or placenta accreta was reported as the cause of PPH in all seven instances of UBT failure (Table 1). Bagga et al.<sup>18</sup> reported two women in whom cervical or vaginal tears were repaired before UBT was attempted; the severity of these lacerations was not described. Bleeding from PPH associated with coagulopathy was stopped mechanically by UBT in three of the studies, allowing treatment of coagulopathy and resuscitation when necessary (28 women).<sup>15,16,18</sup> Airede and Nnadi<sup>17</sup> and Nahar et al.<sup>22</sup> each reported one additional case of PPH with coagulopathy, using UBT when women developed disseminated intravascular coagulopathy (DIC), which in each woman ultimately resulted in death. In the study by Airede and Nnadi, UBT controlled the uterine haemorrhage but complications from DIC precipitated maternal death. Nahar et al.<sup>22</sup> was unclear whether uncontrolled PPH or DIC caused their only reported death.

### Treatment of PPH before UBT

Pharmacological or surgical management of PPH was attempted in most women before the use of UBT. Akhter et al.<sup>20</sup> reported the only exception of 12 women who

**Table 1.** Balloon mechanics and resuscitation efforts

Author (year)	Setting	No. of cases	Balloon device	Reported cause of PPH (cases)	Volume in balloon average (ml)	Minutes to arrest bleeding (cases)	Time to removal (cases)	Blood loss (ml)	Correction of hypovolaemia	Successful management of PPH
Sheikh et al. <sup>23</sup> (2011)	Pakistan tertiary-care facility	15*	Undefined	Placenta praevia, uterine atony	>200	NR	NR	≥1500	88% received blood components***	15/15
Airede & Nnadi <sup>17</sup> (2008)	Nigeria tertiary-care facility	4	Condom catheter	Placenta praevia, uterine atony	300–500	≤10 minutes	12–18 hours	≥500	Intravenous crystalloids and blood	4/4**
Akhter et al. <sup>20</sup> (2003)	Bangladesh tertiary-care facility	23	Condom catheter	Placenta praevia, uterine atony	250–500 (336.4)	≤15 minutes	24 hours (7), 36 hours (8), 48 hours (8)	≥1000	Crystalloid and red cells, average 3.23 units (2–10)	23/23
Bagga et al. <sup>18</sup> (2007)	India (NR - tertiary-care facility)	2	Condom catheter	Coagulopathy, HELLP syndrome,	250, NR	4 hours, NR	32 hours, 24 hours	1000	3–5 units FFP, 3–5 units blood	2/2
Manaktala et al. <sup>25</sup> (2011)	India tertiary-care facility	2	Condom catheter	Uterine atony	760, 300	12 minutes, 4 minutes	30 hours, 18 hours	1500, 1000	2 units whole blood and 2 units FFP	2/2
Nahar et al. <sup>22</sup> (2009)	Bangladesh tertiary-care facility	53	Condom catheter	Placenta accreta, placenta praevia, uterine atony	250–300	NR	24 hours (32), 24–48 hours (21)	≥1000	NR	52/53 (98.1%)**
Rather et al. <sup>21</sup> (2010)	India tertiary-care facility	26	Condom catheter	Uterine atony	250–500 (342.8)	≤10 minutes (25)	24–72 hours	500–1000	2–5 units whole blood and crystalloids	25/26 (96.2%)
Shivkar et al. <sup>16</sup> (2003)	India tertiary-care facility	73*	Condom catheter	Coagulopathy, placenta accreta, placenta praevia, uterine atony	350–400	3–6 minutes (52), >7 minutes (16)	6–8 hours	NR	NR	68/73 (93.2%)
Thapa et al. <sup>15</sup> (2010)	Nepal tertiary-care facility	10*	Condom catheter	Coagulopathy, retained placenta, uterine atony	350–500	≤15 minutes	12–14 hours	550–5000	NR	10/10
Ikechebelu et al. <sup>27</sup> (2005)	Nigeria (NR tertiary-care facility)	2	Foley catheter	Retained placenta, unknown	30	Immediate	6–10 hours	900	NR	2/2
Sheikh et al. <sup>24</sup> (2006)	Pakistan tertiary-care facility	2*	Foley catheter	Uterine atony	NR	NR	NR	≥1500	Packed red blood cells	2/2
Turner <sup>19</sup> (2002)	Zimbabwe Rural Cottage Hospital	1	Foley catheter	Unknown	30	Immediate	72 hours	3000	6 units packed cells	1/1
Japaraj & Raman <sup>26</sup> (2003)	Malaysia tertiary-care facility	1	Sengstaken–Blakemore tube	Placenta praevia	200	NR	6 hours	≥2000	6 units whole blood, 3 units cryoprecipitate 8 units FFP	1/1

FFP, fresh frozen plasma; HELLP, haemolysis, elevated liver enzymes, low platelet count; NR, not reported.

\*Cases excluded when selected for review.

\*\*Maternal Mortality Reported.

\*\*\*Blood components include: packed red blood cells, platelets, plasma, and cryoprecipitate.

**Table 2.** Ancillary measures to UBT use

Author (year)	Setting	Balloon device	Type of delivery (cases)	Vaginal Packing	Uterotonics before PPH	Uterotonics as treatment for PPH	Uterotonics during tamponade	Antibiotics used
Sheikh et al. <sup>23</sup> (2011)	Pakistan tertiary-care facility	Undefined	Caesarean section, vaginal delivery	NR	Uterotonics	Misoprostol 600 mg, Oxytocin infusion	Oxytocin infusion	NR
Airede & Nnadi <sup>17</sup> (2008)	Nigeria tertiary-care facility	Condom catheter	Vaginal delivery	Roller gauze	NR	Ergometrine IV, Oxytocin infusion	Oxytocin infusion	Ampicillin/cloxacillin 500 mg qid, Metronidazole 400 mg tid
Akhter et al. <sup>20</sup> (2003)	Bangladesh tertiary-care facility	Condom catheter	Caesarean section (6), instrumental delivery (3), vaginal delivery (14)	Roller gauze	Ergometrine or Oxytocin	Ergometrine or Oxytocin	Oxytocin infusion 6 hours	Amoxicillin 500 mg qid, metronidazole 500 mg tid, gentamicin 80 mg tid
Bagga et al. <sup>18</sup> (2007)	India (NR - tertiary-care facility)	Condom catheter	Vaginal delivery	Roller gauze	Oxytocin	Misoprostol 800 µg rectally, Prostaglandin F2α 250 µg IM (three doses)	Oxytocin infusion, 12 hours	Prophylactic
Manaktala et al. <sup>25</sup> (2011)	India tertiary-care facility	Condom catheter	Caesarean section	NR	NR	Carboprost 250 µg IM (three doses), Methergin 0.2 mg IV (two doses), Misoprostol 800 µg rectally, 20 units oxytocin in 500 ml Ringer's solution	NR (1), Oxytocin during removal only (1)	Prophylactic
Nahar et al. <sup>22</sup> (2009)	Bangladesh tertiary-care facility	Condom catheter	Caesarean section (4), instrumental delivery (2), vaginal delivery (47)	Roller gauze	NR	Ergometrine, Misoprostol, Oxytocin, Prostaglandin F2α	Oxytocin infusion	Prophylactic
Rather et al. <sup>21</sup> (2010)	India tertiary-care facility	Condom catheter	Caesarean section (2), vaginal delivery (24)	Unspecified packing	Uterotonics	Carboprost, Ergometrine, Misoprostol, Oxytocin	Oxytocin infusion 24 hours	Prophylactic

Table 2. (continued)

Author (year)	Setting	Balloon device	Type of delivery (cases)	Vaginal Packing	Uterotonics before PPH	Uterotonics as treatment for PPH	Uterotonics during tamponade	Antibiotics used
Shivkar et al. <sup>16</sup> (2003)	India tertiary-care facility	Condom catheter	Caesarean section (6), vaginal (67)	Roller Gauze	NR	Methergin, Oxytocin, Prostaglandin	NR	NR
Thapa et al. <sup>15</sup> (2010)	Nepal tertiary-care facility	Condom catheter	Caesarean section (3), instrumental delivery (1), vaginal delivery (6)	Unspecified packing	NR	Carboprost, Ergometrine, Misoprostol, Oxytocin for 30 minutes	Oxytocin infusion	Prophylactic
Ikechebelu et al. <sup>27</sup> (2005)	Nigeria (NR tertiary-care facility)	Foley catheter	Caesarean section (1), vaginal delivery (1)	No packing used	0.5 mg Ergometrine IV	Ergometrine 0.5 mg IV, Oxytocin 20 IU IV	Ergometrine 0.5 mg intracervically	Ampiclox 500 mg, Metronidazole 400 mg
Sheikh et al. <sup>24</sup> (2006)	Pakistan tertiary-care facility	Foley catheter	Vaginal delivery (1)	NR	Uterotonics	Ergometrine 0.4 mg, Misoprostol 600 mg OR Prostaglandin F2 $\alpha$ , Oxytocin 10 IU	Oxytocin infusion	NR
Turner <sup>19</sup> (2002)	Zimbabwe Rural Cottage Hospital	Foley catheter	Vaginal delivery	O-Vycryl Shiroodkar type purse-string suture around cervix	NR	Ergometrine and Oxytocin	NR	NR
Japaraj & Raman <sup>26</sup> (2003)	Malaysia tertiary-care facility	Sengstaken –Blakemore tube	Caesarean section	No packing used	40 IU oxytocin in 500 ml	Carboprost 250 mg IM, Oxytocin 80 IU infusion	Oxytocin 80 IU 12 hours	IV antibiotics 7 days

IM, intramuscular; IV, intravenous; NR, not reported; TID, three times daily; qid, four times daily.

presented in shock from blood loss and were immediately treated with simultaneous UBT and oxytocin. In all other cases, providers initially attempted to manage PPH with medications: oxytocin was used in all 13 studies, ergometrine and misoprostol in eight, carboprost/prostaglandin F<sub>2α</sub> in seven and metherginin in two. Most often, medications used before UBT were given in combination, the most common being oxytocin and ergometrin (see Table 2). Oxytocin was administered alone in some of the women reported by Sheikh et al.<sup>23</sup> Uterine massage and bimanual compression were reportedly performed concurrent with medication administration in eight studies.<sup>16,17,19–21,23–25</sup> Three of the reports describe how surgical procedures, such as B-Lynch suture, haemostatic suture and bilateral arterial ligation were performed to control PPH following caesarean section. In each case described below, this procedure failed before the successful use of UBT.<sup>20,25,26</sup> Akhter et al.<sup>20</sup> describes one woman with PPH that was unresponsive to B-Lynch sutures during caesarean section but that was controlled within 15 minutes by UBT. Manaktala et al.<sup>25</sup> present two cases of PPH during caesarean section, one was unsuccessfully controlled by arterial ligation and B-Lynch sutures and the second by haemostatic sutures. The PPH was controlled, respectively, in 12 and 4 minutes by UBT. In Japaraj and Raman,<sup>26</sup> in one woman, the PPH was unresponsive to haemostatic sutures and bilateral uterine artery ligation but was controlled by UBT.

### Findings by type of device

In most of the women reported on in the thirteen studies UBT effectively controlled their PPH ( $n = 234$  of 241). Ten studies reported UBT to be effective in every case ( $n = 39$  women), whereas a total of seven failures were reported among the remaining three studies ( $n = 152$ ). The type of UBT varied in the studies reviewed, including condom catheter ( $n = 193$ ), Foley catheter ( $n = 5$ ) and Sengstaken–Blakemore oesophageal tube ( $n = 1$ ). The final study did not specify the type of UBT ( $n = 15$ ), and is considered separately (Table 1).

We report below on the application of these devices, technical details of their use, and clinical outcomes.

### Condom catheter

The condom catheter UBT method was used to treat 193 cases of PPH and was successful in 186 cases.<sup>15–18,20–22,25</sup> The materials used to assemble the condom catheter varied little: condom, catheter (Foley or simple rubber tubing), sterile string (silk, catgut or cotton), saline, syringe and sterile gauze. The condom catheter was assembled by placing the open end of the condom around the tip of the catheter and securing it with sterile string (Figure 2).

The process of inserting and inflating the condom catheter varied considerably. Some studies noted the use of

forceps to insert the condom catheter into the uterus. Multiple authors used gravity inflation and an intravenous infusion set to inflate the condom, rather than using a syringe.<sup>16–18,20,21</sup>

Once inside the uterus, the condom was most often filled with 250–500 ml saline. However in one case, the condom was inflated with 760 ml (Table 1). In most cases, inflation of the condom was stopped when there was resistance to more saline or when bleeding ceased.<sup>17,18,22,25</sup> The time required for PPH to be controlled after placement of the condom catheter ranged from 4 to 15 minutes. One outlying case required 4 hours to arrest bleeding, with no further interventions used to control PPH (Table 1).<sup>18</sup> Once the cessation of bleeding was confirmed, seven of the eight studies ( $n = 191$  women) described using a vaginal pack (composed of sterile roller gauze) to prevent the condom catheter from falling out of the uterus. One study did not report any procedure to maintain placement of the UBT ( $n = 2$ ).<sup>25</sup> No study reported the UBT falling out before it was deliberately removed (Table 2).

Six of the studies ( $n = 118$  women) described running an oxytocin infusion for up to 6 hours from the time of insertion until the time of removal. Shivkar et al.<sup>16</sup> did not report the use of any uterotonics concurrent with condom catheter ( $n = 73$ ). In one successful case reported by Manaktala et al.,<sup>25</sup> oxytocin was administered only during the removal of the condom catheter (Table 2).

The length of time reported between insertion of the condom catheter and removal ranged widely, from 6 hours to as long as 72 hours. Three studies ( $n = 87$  women) reported durations of placement <24 hours.<sup>15,16,19</sup> In many cases, providers determined the duration based on the severity of EBL. The time taken to deflate the UBT varied—from as low as 10–15 minutes (average volume: 340 ml), to one case of more than 6 hours (volume 760 ml) (Table 1).<sup>20,21,25</sup>



Figure 2. Condom catheter.

In the eight studies ( $n = 193$  women) using the condom catheter UBT method, there were no reports of increased infection rates concurrent with longer use of UBT. Seven of the studies ( $n = 120$ ) reported prophylactic use of broad-spectrum antibiotics, with antibiotic choices including ampicillin/cloxacillin, amoxicillin, metronidazole and gentamicin. Shivkar et al.<sup>16</sup> did not report using any antibiotics with the condom catheter, and reported no cases of infection or fever in their case series ( $n = 73$ ). No cases of sepsis, fever or endometritis were reported in any of the eight studies ( $n = 193$ ) (Table 2).

In five of the eight studies of PPH, no further interventions were required, or complications reported, subsequent to initiation of balloon UBT. Rather et al.<sup>21</sup> reported success in 25 of 26 women, with one failure to control secondary PPH caused by uterine atony. In this woman, bleeding continued for 2 hours around the condom catheter, and the woman ultimately underwent an emergency hysterectomy. Shivkar et al.<sup>16</sup> used condom catheters to successfully manage 68 of 73 cases with primary PPH. The cause of ongoing haemorrhage in the cases where UBT failed was not clear, but all five cases ultimately required surgical intervention. Nahar et al.<sup>22</sup> reported that the condom catheter was successful in 52 out of 53 cases of PPH, this single failure being a case with PPH and DIC described previously. No further details were provided regarding the one unsuccessful case or what further interventions were required.

### Foley catheter

Three out of the 13 studies used the Foley catheter balloon as the UBT ( $n = 5$  women). These treatments took place in Pakistan, Nigeria and Zimbabwe. Protocols varied among the three studies. For example, Ikechebelu et al.<sup>27</sup> used 30 ml sterile water to inflate the Foley catheter, Turner<sup>19</sup> used 30 ml boiled water and Sheikh et al.<sup>24</sup> did not give details of their inflation methods. None of the three studies reported how long the UBT was left *in situ* or the process of deflation. The Foley catheter arrested the haemorrhage in three of the five women but no further data were recorded for the other two women. Sheikh et al.<sup>24</sup> administered oxytocin simultaneously, whereas the other two studies did not report the use of uterotonics at all. None of the three studies reported a vaginal pack to secure the Foley catheter, rather, two other methods for closing the cervix were described. Ikechebelu et al.<sup>27</sup> used the administration of 0.5 mg ergometrine intracervically, while Turner<sup>19</sup> used an O Vicryl Shirodkar type purse-string suture (see Table 2).

The Foley catheter was kept *in situ* for 6–10 hours in one study and for 72 hours in another, whereas the third study did not report the time to removal. No further interventions were required (Table 1). Ikechebelu et al.<sup>27</sup>

reported the use of prophylactic antibiotics in two women and Sheikh et al.<sup>24</sup> reported fever that responded to antibiotics in one of two women. No sepsis was reported (Table 2).

### Sengstaken–Blakemore tube

Treatment of PPH with a Sengstaken–Blakemore tube was only reported in one successful case from a tertiary-care setting in Malaysia. The PPH had been unresponsive to uterotonics, repeat laparotomy, haemostatic sutures at the placental site, and bilateral arterial ligation.<sup>26</sup> Placement of UBT was accompanied by oxytocin infusion. No further interventions were required. Intravenous antibiotics were administered for 7 days, and the woman did not develop sepsis, fever or endometritis.

### Unspecified UBT

Sheikh et al.<sup>24</sup> described 15 women who were successfully treated with an unspecified UBT device. The hospital's protocol for managing PPH called for the use of multiple #24 Foley catheters or a 'special balloon tamponade' when available. The protocol also instructed providers to run an oxytocin infusion concurrent to UBT. Details about the inflation, placement, and removal of the UBT were not reported. No cases of sepsis, fever or endometritis were reported, nor was use of antibiotics.

## Discussion

In low-resource settings, access to the full range of PPH treatment modalities, such as uterotonics and surgical interventions, or resuscitation by blood products is frequently limited, putting many women at risk of morbidity and mortality from PPH. The 13 studies and 241 women included in this systematic review strongly suggest that UBT should be considered as an effective treatment for PPH in resource-poor settings.

The reports so far suggest that UBT is helpful in managing PPH secondary to a wide variety of causes in resource-poor settings, including uterine atony, coagulopathy, retained placenta, placenta praevia and placenta accreta (Table 1).<sup>28</sup> Though in our review we found that indications and techniques for insertion and removal of the UBT as well as absence or presence of the use of concurrent therapies varied, the effectiveness of UBT was evident. For example, specifically, differences arose in how to assemble and inflate the condom catheter as well as more generally when to give concurrent uterotonics or prophylactic antibiotics; in the eight reviewed studies where a condom catheter was used, it was deemed to have failed in only seven out of 193 women. Complication rates were low in the use of all types of UBT, with no reported cases of uterine rupture and no increased risk of infection. These

facts, combined with low cost and ready availability, make UBT, especially the condom catheter with its low cost and ready availability, an ideal addition to the armamentarium against PPH in the low-resource setting.

Carefully designed research protocols may help to define a best-evidence uterine balloon device and placement protocol, including the optimal fluid infusion amounts for balloon efficacy, the role of concurrent uterotonics, antibiotics, vaginal packing and cervical closure, and optimal timing for balloon removal. Research may also help to delineate the precise mechanism of action for UBT, which remains poorly understood. In 2009, Georgiou<sup>29</sup> demonstrated that the pressure inside the balloon does not necessarily rise above the systemic pressure. Furthermore, all five cases using a single Foley inflated to 30 ml were successful in controlling PPH. Therefore, the mechanism of action of UBT may involve not only tamponade but also the release of natural prostaglandins.

Despite the many remaining questions, our review suggests that UBT is effective and should become well integrated in the treatment of PPH at all levels of the health system. The review by Doumouchtsis et al.<sup>9</sup> describes UBT as ‘the least invasive, easiest, and most rapid approach’, making UBT appropriate within and outside tertiary-care facilities. In developing-country settings, where most women deliver outside hospitals, use of UBT should be considered as part of the skill and commodity set for all healthcare workers who attend mothers at birth.

Although the 13 studies account for only 241 women, and the accompanying data are limited, the findings are compelling enough that we join the call for serious consideration for widespread deployment of UBT devices both at tertiary-care centres and at lower-level health facilities offering emergency obstetric care in resource-poor settings.<sup>30–33</sup> Whereas UBT devices in the studies reviewed were only placed by physicians, we support the belief that midwives and skilled birth attendants who are trained to perform cervical examinations should be able to perform UBT with careful training.<sup>34</sup>

## Limitations

This review has several limitations. The most important one is that there are no randomised controlled studies of UBT, casting a shadow of doubt upon any claims of cause-and-effect due to use of a uterine balloon. Additionally, there is no way to be certain whether a woman who had a uterine balloon placed would have had a different outcome had the balloon not been placed. It is well known that some women will surprisingly survive even if haemorrhage is massive. However, the short time from placement of the uterine balloon to the cessation of life-threatening haemorrhage in many of these cases is compelling.

As many of the studies analysed were case reports or series of women, the case descriptions and outcomes are subject to potential reporting bias. The low complication rates and high success rates of UBT should be viewed with a critical eye of caution given that unsuccessful treatments and complications may not have been submitted or accepted for publication. Previous studies have provided evidence about the effectiveness of sophisticated UBT, of which few examples were reported in this review. However, the evidence presented here shows that the cheap and simple condom catheter is also effective.

Finally, virtually all of the studies reviewed took place in tertiary-care settings rather than in lower-level health facilities and the only reported providers of UBT in these studies were physicians.

## Conclusions

Postpartum haemorrhage remains a leading cause of death in resource-poor settings. Effective interventions addressing PPH are critically needed to reduce maternal mortality ratios worldwide. UBT appears to have great potential as an effective treatment for PPH, is simple to use and appears to have low risk of harm. UBT should be included in emergency obstetric protocols for PPH in resource-poor settings, along with the provision of appropriate training, monitoring and evaluation. Further study of UBT interventions in resource-poor settings can help to understand the barriers to its use and opportunities to reduce global maternal mortality.

## Disclosure of interest

None declared.

## Contribution to authorship

All authors contributed to the writing and editing of the article. KT, TB, RA, EAH, RG and ME conceived the project. KT developed the objectives, designed the study, co-led data collection and analysis, and led preparation of the article, including writing. RG and KC co-led data collection and analysis, and co-led preparation of the article. RA, EAH, TB and ME provided oversight and technical guidance on study design and methodology, data analysis and article drafts.

## Details of ethics approval

Ethical approval was not necessary for this systematic review, because the review did not involve the use of human subjects.

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