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Review Article

A narrative review comparing clinical effectiveness of commonly used uterine balloon tamponade devices for postpartum haemorrhage management in India

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ABSTRACT

WHO recommends using uterine balloon tamponade (UBT) for refractory atonic postpartum haemorrhage (PPH) management provided treatment protocols and surgical recourse is possible. This review collated literature from three electronic databases between January 2010 to December 2019 to compare clinical effectiveness, safety and use related parameters for condom-UBT, Bakri balloon and every second matters (ESM) UBT devices used in India. Thirty-three eligible studies reported effectiveness in managing all PPH causes ranging from 84.2% to 98.3% for condom- UBT and from 65.3% to 94.8% for Bakri-UBT. Three ESM-UBT studies reported PPH survival rates of 94% to 97.4%. Mean UBT effectiveness in controlling atonic PPH was 92.3% for condom-UBT, 84.3% for Bakri-UBT and 97.3% for ESM-UBT. Condom-UBT and Bakri-UBT were comparable across parameters whereas limited ESM-UBT evidence reported success in preventing maternal deaths. For limitations and heterogeneity in methodology and outcome parameters with existing evidence, a robust comparative RCT between UBT devices in India is recommended.

Keywords: Clinical effectiveness, Bakri balloon UBT, Condom-UBT, ESM-UBT, Post-partum haemorrhage

INTRODUCTION

Haemorrhage is the foremost direct cause of maternal mortality globally. Around two-third of maternal deaths due to bleeding worldwide is due to postpartum haemorrhage (PPH).[1] PPH is defined as maternal blood loss of 500 ml or more within 24 hours after childbirth affecting nearly 5% of all women.[2] The commonest aetiology for PPH is atony of the uterus.[3]Uterotonics along with fluid resuscitation and uterine massage is the recommended choice for PPH treatment.[4] WHO endorses using intrauterine balloon tamponade (UBT) for refractory atonic PPH cases that are unresponsive to uterotonics after vaginal delivery.[5] If medical and conservative measures fail, surgical interventions are considered.[4] UBT is a relatively simple lifesaving technique that can reduce the requirement for surgery and aid as a temporizing measure during patient referral. UBT technique involves insertion of a balloon device into the uterus, incrementally filling it with liquid to increase pressure above systemic arterial pressure to prevent further blood loss and aid uterus contraction.[6] The Indian guidelines recommend using UBT in refractory atonic PPH cases.[7,8] Specifically designed or improvised UBT devices are available. Bakri balloon, condom catheter/modifications, Sengstaken-Blakemore oesophageal tube, Every second matters

(ESM-UBT) and Rusch balloon have been used globally.[6,9] An improvised condom-UBT device assembled using health facility available resources is currently the recommended choice of UBT device in India.[8,10] Bakri-UBT, a US-FDA approved ready to use device is used globally and in certain Indian facilities. It is available as a sterile pack, with a port to assess ongoing blood loss, however more expensive. Given the emerging evidence for another comparatively low-cost PPH specific alternative such as the US-FDA approved ESM-UBT device, the Indian government is assessing the choice of UBT device that would be most cost-effective in Indian public health settings.

This narrative review was undertaken as part of a larger health technology assessment to evaluate cost-effectiveness of UBT devices used in Indian public health context. This review confines to three UBT devices namely condom-UBT, Bakri-UBT and ESM-UBT devices relevant to Indian decision-making. Evidence from a recently concluded systematic review assessed effectiveness of UBT intervention as a whole in PPH management.[9]

The objective of this study was to collate and compare available clinical effectiveness evidence for individual UBT devices assessed by its ability to control atonic PPH bleeding without any further intervention, safety with device and use related parameters regarding choice of UBT considered.

METHODS

Literature search

A literature search was conducted using three electronic databases namely Medline via PubMed, Cochrane and Web of Science. Following search terms were included; uterine balloon, uterine tamponade, uterine balloon tamponade, intrauterine tamponade, balloon dilatation, condom catheter, modified condom catheter, Bakri balloon, ESM-UBT in combination with clinical effectiveness, postpartum haemorrhage, uterine haemorrhage, uterine atony, side-effects, adverse events, complications.

Inclusion and exclusion criteria

Studies published between January 2010 to December 2019 were included. Systematic reviews, Randomized Control Trials (RCTs), non-randomized trials, observational studies and case-series study designs with women getting UBT intervention for atonic PPH management as study population were considered. Only studies evaluating use of condom-UBT, Bakri-UBT or ESM-UBT devices exclusively in atonic PPH cases or additionally along with other causes of PPH for lack of disaggregated atonic PPH data from these studies were considered eligible. Studies in languages other than English were excluded.

Outcomes measured

The primary outcome measure for this review was assessment of clinical effectiveness of individual UBT devices in managing atonic PPH alone or additionally along with other causes of PPH as reported by the studies. Clinical effectiveness was defined as placement of UBT resulting in control of bleeding and not necessitating further intervention. Secondary outcomes included time taken to arrest bleeding with UBT, need for blood transfusion, UBT retention time, adverse events related to UBT, surgical intervention needed for uncontrolled cases and maternal deaths due to PPH.

Data analysis

Data from included studies was extracted to get information on study characteristics, UBT type, definitions, specifications related to UBT device and maternal outcomes measured. The review descriptively summarizes data specific to three chosen UBT devices. Continuous data are reported as mean and range across each UBT type. A pooled summary of primary clinical effectiveness for individual UBT devices specifically for uterine atony and across all PPH types was derived by computing arithmetic mean of reported effectiveness obtained from respective studies.

Results

A total of 33 articles met eligibility criteria after screening of article titles, abstracts and full papers. One systematic review, three RCTs, fifteen prospective, twelve retrospective and two before/after studies were included. Only one-fifth of included studies had control/comparator groups. Three eligible randomized controlled trials primarily reported effectiveness of condom-UBT intervention, one of which compared it to Bakri balloon and was included in the review.[11] A second RCT compared adjunct addition of UBT to standalone existing medical management.[12] The third RCT was a step-wedge cluster study that compared UBT intervention and control time periods.[13] Details in Table 1.

The review included twelve condom-UBT, nineteen Bakri and three ESM-UBT studies. Condom-UBT studies comprised of a systematic review, three RCTs and eight prospective studies. All condom-UBT studies were undertaken in developing or LMIC countries.[14] Reviewed Bakri-UBT literature comprised of one comparative RCT, four prospective, twelve retrospective and two before/after studies. Only two-fifth Bakri studies were from developing countries. Included ESM-UBT studies were multi-country case-series studies that assessed survival and safety profile of UBT in developing countries. Details in Table 1.

Indications for use of UBT

Four condom, five Bakri and one ESM-UBT studies including an RCT, specified inclusion of atonic PPH cases

exclusively. These accounted for a total of 1219 atonic PPH cases across all three UBT devices. The RCT comparing condom-UBT with Bakri balloon was the only comparative RCT for atonic PPH, accounting for 33 cases each across the two UBT devices. Remaining condom and Bakri-UBT studies additionally included other PPH causes Two of three limited ESM studies did not specify type of PPH.[15,16] For all reported cases across each UBT type, 56.7% of condom-UBT insertions, 70% of Bakri-UBT insertions and 43% of ESM-UBT were specifically for uterine atony.

A near standard protocol of first line PPH management with active management of third stage of labour (AMTSL), uterotonics, uterine massage, placenta removal along with supportive care was commonly followed before considering eligibility for UBT insertion. A few exceptions of using UBT intervention as first line treatment, or after failure of devascularization procedure were reported.[17-19]

Nearly 70% studies reported using UBT both in vaginal and caesarean sections.[11-13,20-23]

Outcomes reported

The three eligible RCT studies reported need for recourse to invasive procedures i.e.; control of bleeding as the primary outcome. Remaining non-randomized condom and Bakri-UBT studies reported UBT effectiveness assessed in terms of achieving control of bleeding or requirement of further surgical intervention. The three ESM-UBT studies assessed either adverse event, complications, safety and survival profiles of UBT use as their primary outcome. One ESM-UBT study specifically measured survival and complication outcomes of UBT placement after atonic PPH. Only three of the thirty-three studies, one across each UBT type reported cost of device.[15,24,25] Details in Table 1.

UBT effectiveness

Primary outcome for this review i.e., successful use of UBT in atonic PPH management was reported by six condom-UBT, sixteen Bakri-UBT and one ESM-UBT study. Condom-UBT success rate specifically for atonic PPH cases ranged between 84.8 to 100% across six studies with the comparative RCT reporting effectiveness rate of 84.8%. These accounted for a total of 551 out of 597 women (mean effectiveness of 92.29%) with atonic PPH controlled with condom-UBT insertion. Condom-UBT effectiveness for all PPH types ranged from 84.2 to 98.3% across twelve studies. Of these, the three RCTs reported condom-UBT effectiveness rates of 87.5%, 84.8% and 84.2% respectively. A total of 981 cases out of 1062 condom-UBT insertions (mean effectiveness of 92.3%) across all PPH causes were controlled without need for further intervention. For Bakri-UBT, all except three included studies reported success rates specifically in atonic PPH.[26-28] Bakri-UBT effectiveness in uterine atony across sixteen studies ranged from 62.7 to 96.9% with the single comparative RCT reporting Bakri-UBT effectiveness of 90.9%.[11] A total of 1202 out of 1426 atonic PPH cases (mean effectiveness of 84.29%) were controlled after Bakri-UBT intervention. Bakri-UBT effectiveness in managing any PPH type ranged from 65.3 to 94.8% across nineteen studies. A total of 1720 out of 2028 women (mean effectiveness of 84.8%) experiencing PPH were controlled with Bakri-UBT insertion. Only one ESM-UBT study exclusively considered atonic PPH cases and reported survival success rate of 97.4%.[29] Including this study, all three ESM-UBT case-series studies primarily reported survival rates of 94%, 94.5% and 97.4%. Details in Table 2.

The comparative RCT reported significantly shorter time to control bleeding with Bakri balloon in comparison to condom-UBT. Seven of the twelve condom-UBT studies reported mean time to arrest all PPH causes ranging from 4 to 15 minutes while Bakri-UBT studies reported a range of 2 to 15 minutes.[30,31]

For management of all PPH types, mean retention time for condom-UBT ranged from 9.11 to 27.5 hours across six studies. Mean retention time for Bakri-UBT reported by seven non-randomized studies ranged from 5.3 to 25 hours, while for the ESM-UBT study it was 14.15 hours in 174 PPH cases.[15] Details given in Table 3.

Three condom-UBT studies including one RCT reported blood loss outcomes exclusively among atonic PPH.[11,30,31] Three Bakri-UBT studies reported mean blood loss among atonic PPH cases ranging from 964 to 1562 ml.[22,32,33] The mean estimated blood loss with condom-UBT and Bakri UBT ranged from 663 to 2200 ml and 964 to 4981 ml respectively. Blood/blood products transfused during course of PPH management with condom-UBT and Bakri UBT ranged from 2 to 4 mean units & 2 to 3.3 mean units respectively.[34]

The RCT by Dumont et al reported 40% PPH cases had required blood transfusion. Although ESM-UBT studies did not report blood loss estimation, two studies reported 26% and 44% cases to have respectively required blood transfusion.[15,29] Details given in Table 4.

PPH management with condom-UBT intervention was associated with difficulties in UBT placement, failure of insertion, need for reinsertion, inflation failure, displacement, rupture UBT and expulsion.[11-13,19,25,35] Similarly, Bakri-UBT was associated with reported difficulty in placement, failure of insertion, displacement and expulsion.[17,27,32,36,37] Table 3 describes reported UBT placement related difficulty among reviewed studies. The details of interventions undertaken after UBT failure for each study is mentioned in Table 2. Majority studies assessed occurrence of maternal complications after UBT insertion. The comparative RCT reported a total of four cases of fever, three disseminated intravascular coagulation (DIC) and six ICU admissions across both

UBT arms with no statistically significant differences. Two of the three RCTs reported ICU admission rates of 9.1% and 17% respectively.[11,12] Across condom-UBT studies, fever, DIC, pain, discharge and endometriosis were reported. Bakri-UBT studies reported cases of fever, pain, DIC, endometriosis and infection.[11,19,22,27,33,35,38,41,42] Four condom-UBT studies including two RCTs reported cases of maternal deaths.[12,13,18,25] One non-randomized condom-UBT study reported a case of death due to DIC after failure of UBT and conservative surgical procedures.[25] Among Bakri-UBT, two non-randomized studies reported cases of maternal deaths, while onereported four deaths the other reported one.[43] Further details are enlisted in Table 3 and 4.

Table 1: Details of studies evaluating effectiveness of UBT devices included in this review.

Authors, year	Study design	Study setting	Type of UBT	Reported outcomes	Sample size adequacy
Condom-UBT					
Darwish et al, 2018[11]	RCT	Egypt Hospital setting	Condom-UBT Bakri-UBT	Control of bleeding Time to control bleed Blood transfusions Maternal morbidity	Met predefined sample size calculation Identifies small sample size as a study limitation
Dumont et al, 2017[12]	RCT	Benin, Mali Three levels of care	Condom-UBT	Recourse to surgery or deaths Blood loss estimation Maternal morbidity	Met predefined sample size calculation Identifies small sample size as a limitation for the study to be underpowered to detect statistically significant reduction in outcome
Anger et al, 2019[13]	Stepped wedge, cluster randomized trial	Uganda, Egypt, Senegal Secondary level setting	Condom-UBT	Recourse to surgery and/or death in case vs. control Blood transfusions	Met predefined sample size criteria Non-randomization of individual participants is identified as a limitation
Tindell et al, 2013[18]	Systematic Review	South Asia and Sub-Saharan Africa Tertiary hospital setting	Condom-UBT Foley's catheter	Effectiveness of UBT	No predefined sample size calculation Number of cases ranged from 1 to 73 across 13 studies
Rathore et al, 2012[19]	Single arm prospective	India Tertiary setting	Condom-UBT Foley's catheter Sengstaken Blakemore tube	Effectiveness of UBT Time to control bleed Maternal morbidity Technical difficulties	No predefined calculation for sample size estimation Identifies small sample size as a limitation to assess rare complications and technical difficulties
Yadav et al, 2019[23]	Prospective comparative	India Primary level setting	Modified condom-UBT	Effectiveness of UBT Time parameters of UBT	No predefined calculation for sample size estimation
Mishra et al, 2019[25]	Prospective observational case-series	India Tertiary setting	Modified condom-UBT	Effectiveness of UBT Blood loss estimation Time parameters related to balloon Cost & consistency of UBT	No predefined calculation for sample size estimation Does not report adequacy of sample size

Continued.

Authors, year	Study design	Study setting	Type of UBT	Reported outcomes	Sample size adequacy
Santhanam, Viswanathan et al, 2018[30]	Prospective descriptive Single arm	India Tertiary setting	Condom-UBT	Effectiveness of UBT Need for further intervention Time to control bleed Maternal morbidity	Exceeded predefined estimated sample size
(Lohano et al, 2016)[31]	Single-arm prospective	Pakistan Hospital setting	Condom-UBT	Effectiveness of UBT	Reports predefined criteria for sample size estimation
(Hasabe et al, 2016[34]	Single-arm prospective	India Tertiary setting	Condom-UBT	Effectiveness of UBT	No predefined calculation for sample size estimation
Kandeel et al, 2016[35]	Prospective observational	Egypt Hospital setting	Condom-UBT	Effectiveness of UBT Maternal morbidity	No predefined calculation for sample size estimation. Identifies small sample size as a study limitation
Aderoba et al, 2017[41]	Prospective observational	Nigeria Hospital setting	Condom-UBT	Effectiveness of UBT Factors for success Maternal morbidity	Identifies large sample size as an important strength of the study to broaden range of findings and analyse results.
Bakri-UBT					
Darwish et al, 2018[11]	RCT	Egypt Hospital setting	Bakri-UBT Condom-UBT	Control of bleeding Time to control bleed Blood transfusions Maternal morbidity	Met predefined sample size calculation Identifies small sample size as a study limitation
Mathur et al, 2018[17]	Retrospective review	Singapore Hospital setting	Bakri-UBT	Control of bleeding	No predefined calculation for sample size estimation Reports no selection bias by being retrospective however identifies small sample size as a limitation
Guo et al, 2018[20]	Retrospective cohort	China Hospital setting	Bakri-UBT with or without vaginal packing	Effectiveness of UBT plus vaginal packing against standalone Bakri-UBT	No predefined calculation for sample size estimation
Grange et al, 2018[21]	Retrospective review	France Three levels of care	Bakri-UBT	Effectiveness of UBT Estimated blood loss, time Predictors of failure	No predefined calculation for sample size estimation Reports potential selection bias in choosing health facilities and acknowledges failure to truly identify factors due to type 2 error
Çetin et al, 2019[22]	Retrospective comparative review	Turkey Tertiary setting	Bakri-UBT	Effectiveness of UBT vs. Hayman sutures	No predefined calculation for sample size estimation

Continued.

Authors, year	Study design	Study setting	Type of UBT	Reported outcomes	Sample size adequacy
					Reports study to be largest cohort comparison between Bakri balloon and Hayman suturing
Brown et al, 2016[24]	Prospective observational intervention	Kenya Hospital setting	Bakri-UBT	Need for further surgical intervention	No predefined calculation for sample size estimation Identifies small sample size and non-randomized enrolment as a study limitation.
Alkiş et al, 2015[26]	Retrospective review	Turkey Tertiary setting	Bakri-UBT	Effectiveness of UBT	No predefined calculation for sample size estimation Reports sample size to be large for Bakri balloon evaluation but identifies sample non-randomization as a limitation
Gauchotte et al, 2017[27]	Before and after	France Tertiary setting	Bakri-UBT	Recourse to surgery	No predefined calculation for sample size estimation Reports study to be underpowered to assess endpoints clearly
Kadioglu et al, 2016[28]	Retrospective review	Turkey Hospital setting	Bakri-UBT	Recourse to surgery Maternal complications	No predefined calculation for sample size estimation
Kaya et al, 2014[30]	Prospective cohort	Turkey Hospital setting	Bakri-UBT	Effectiveness of UBT	No predefined calculation for sample size estimation
Vintejoux et al, 2015[32]	Retrospective cohort	France Hospital setting	Bakri-UBT	Effectiveness of UBT	No predefined calculation for sample size estimation
Wang et al, 2018[33]	Prospective cohort observational	China Hospital setting	Bakri-UBT	Effectiveness of UBT	No predefined calculation for sample size estimation Reports study as the largest sample for Bakri balloon in China but reports possible sample selection biases
Son et al, 2017[36]	Retrospective cohort	USA Hospital setting	Bakri-UBT	Need for further intervention Estimated blood loss	No predefined calculation for sample size estimation Reports study to be a relatively large study but identifies it to be underpowered to detect smaller but clinically meaningful effectiveness differences.

Continued.

Authors, year	Study design	Study setting	Type of UBT	Reported outcomes	Sample size adequacy
Revert et al, 2017[37]	Prospective cohort	France Maternity unit setting	Bakri-UBT Ebb balloon	Effectiveness of UBT	No predefined calculation for sample size estimation Identifies large sample size as a strength to identify factors related to UBT use
Martin et al, 2015[38]	Retrospective comparative case-series	France Secondary and tertiary setting	Bakri-UBT	Effectiveness of UBT Safety of UBT	No predefined calculation for sample size estimation
Ogoyama et al, 2017[40]	Retrospective comparative	Japan Tertiary setting	Bakri-UBT	Effectiveness of UBT Effect of holding cervix to prevent UBT prolapse	No predefined calculation for sample size estimation The study reports no controls and selection bias in decision-making for invasive procedures as a study limitation
Olsen et al, 2013[41]	Retrospective cohort	USA Tertiary setting	Bakri-UBT	Blood loss estimation Need for further intervention Maternal morbidity	No predefined calculation for sample size estimation Reports study to be based on real world evaluation. Identifies sample for balloon failure to be small for confounding variable identification
Laas et al, 2012[42]	Before and after	France Hospital setting	Bakri-UBT	Need for further surgical intervention	No predefined calculation for sample size estimation Reports sample to be the largest before/after UBT study The comparative groups especially vaginal sub-group were reported to be comparable
Kong and To, 2018[43]	Retrospective review	Hong Kong Hospital setting	Bakri-UBT	Prognostic factors associated with success of Bakri-UBT	No predefined calculation for sample size estimation Reports study to be undertaken in a large cohort with normal practise of UBT use in practise
ESM-UBT					
Burke et al, 2016[15]	Prospective case series	Kenya, Sierra Leone, Nepal, Senegal All levels of care	ESM-UBT	All cause survival, PPH survival Maternal morbidity	No predefined calculation for sample size estimation Reports study as the largest case-series for ESM-UBT with sample from varied clinical settings across four countries

Continued.

Authors, year	Study design	Study setting	Type of UBT	Reported outcomes	Sample size adequacy
Ramanathan et al, 2018[16]	Prospective/ Retrospective case series	Kenya, Sierra Leone All levels of care	ESM-UBT	Safety profile by follow up assessing adverse events	No predefined calculation for sample size estimation Reports study to be the largest case-series reporting safety of ESM-UBT Identifies potential recall bias as a study limitation
Burke et al, 2016[29]	Prospective case series	Kenya, Senegal, Sierra Leone, Tanzania All levels of care	ESM-UBT	Outcomes of UBT placement in cases of haemorrhagic shock	No predefined calculation for sample size estimation Reports study as the largest cohort reporting UBT effectiveness in women with advanced haemorrhagic shock Absence of control group is identified as a limitation

Table 2: Study success rate, intervention failure definition and course of intervention for UBT failures as given by the studies included in this review.

Authors, year	Cause of PPH	Study sample size	Success rate (%)	Atonic PPH cases	Atonic PPH success rate (%)	UBT failure definition	Number of failures	Course of interventions
Condom-UBT								
Darwish et al, 2018[11]	Uterine atony	33	28/33 (84.8)	33	28/33 (84.8)	Bleeding uncontrolled after 15 minutes of UBT placement	5	B-Lynch/compression sutures-3 Hysterectomy-2
Dumont et al, 2017[12]	Uterine atony, Other	57	48/57 (84.2)	NR	NR	Bleeding uncontrolled after 15 minutes of UBT placement	9	B-Lynch/compression-2 Ligation surgery- 4 Hysterectomy-4
Anger et al, 2019[13]	Uterine atony, Other	64	56/64 (87.5)	NR	NR	Not defined	8	Conservative surgery-2 Conservative surgery followed by Hysterctomy - 2 Hysterectomy-3
Tindell et al, 2013[18]	Uterine atony Other	193	186/193 (96.4)	NR	NR	Not defined	7	B-Lynch/compression sutures and or Ligation surgery-5 Hysterectomy-1
Rathore et al, 2012[19]	Non-traumatic causes	18	17/18 (94.4)	NR	NR	Bleeding uncontrolled after 15	1	Hysterectomy-1

Continued.

Authors, year	Cause of PPH	Study sample size	Success rate (%)	Atonic PPH cases	Atonic PPH success rate (%)	UBT failure definition	Number of failures	Course of interventions
						minutes of UBT placement		
Yadav et al, 2019[23]	Uterine atony	122	117/122 (95.9)	122	117/122 (95.9)	Bleeding uncontrolled after 30 - 40 minutes of UBT placement	5	Hysterectomy-5
Mishra et al, 2019[25]	Uterine atony, Other	60	59/60 (98.3)	51	NR	Persistent bleeding in spite of 500ml UBT balloon inflation	1	B-Lynch/compression sutures -1
Santhanam, Viswanathan et al, 2018[30]	Uterine atony	61	59/61 (96.7)	61	59/61 (96.7)	Bleeding uncontrolled after 30 minutes of UBT placement	2	B-Lynch/compression sutures and or Ligation surgery-1 Hysterectomy-1
(Lohano et al, 2016)[31]	Uterine atony	139	126/139 (90.6)	139	126/139 (90.6)	>100 ml bleeding up to 48 hours after UBT placement	13	NR
(Hasabe et al, 2016[34]	Uterine atony, Non traumatic causes	36	34/36 (94.4)	NR	NR	Uncontrolled bleeding beyond 10 minutes of UBT placement	2	B-Lynch/compression-1 Hysterectomy-1
Kandeel et al, 2016[35]	Uterine atony, Other	50	48/50 (96.0)	28	28/28 (100)	Bleeding uncontrolled after 15 minutes of UBT placement	2	Hysterectomy-2
Aderoba et al, 2017[41]	Uterine atony, Other	229	203/229 (88.6)	214	193/214 (90.2)	Hemodynamic instability and uncontrolled bleeding after 60 minutes of monitoring	26	B-Lynch/compression sutures-2 Ligation surgery- 7 Hysterectomy-14 Uterine packing-14
Bakri-UBT								
Darwish et al, 2018[11]	Uterine atony	33	30/33 (90.9)	33	30/33 (90.9)	Bleeding uncontrolled after 15 minutes of UBT placement	3	B-Lynch/compression sutures-2 Hysterectomy-1
Mathur et al, 2018[17]	Uterine atony, Other	49[#]	40/49 (81.6)	17	14/17 (82.4)	Need for hysterectomy	9	B-Lynch/compression sutures

Continued.

Authors, year	Cause of PPH	Study sample size	Success rate (%)	Atonic PPH cases	Atonic PPH success rate (%)	UBT failure definition	Number of failures	Course of interventions
						to achieve haemostasis		followed by hysterectomy -4 Hysterectomy-9
Guo et al, 2018[20]	Uterine atony, Other	305	288/305 (94.4)	142	131/142 (92.3)	Continuous bleeding after UBT insertion*	17	Embolization-9 Uterine / Vaginal tampon - 5
Grange et al, 2018[21]	Uterine atony, Other	80	80/108 (74.1)	39	26/39 (66.7)	Need for invasive procedure to control bleeding	28	Embolization-19 B-Lynch/ compression and or Ligation surgery -9 Hysterectomy -5
Çetin et al, 2019[22]	Uterine atony	39	29/39 (74.4)	39	29/39 (74.4)	Uncontrolled bleeding after UBT placement	10	Ligation surgey-5 Hysterectomy-5
Brown et al, 2016[24]	Uterine atony, Traumatic causes, Other	58	55/58 (94.8)	55	52/55 (94.5)	Uncontrolled bleeding and hemodynamic instability*	3	Surgical interventions & Hysterectomy-3
Alkiş et al, 2015[26]	Uterine atony, Other	47	43/47 (91.5)	20	NR	Need for surgical intervention	4	Hysterectomy-4
Gauchotte et al, 2017[27]	Uterine atony, Traumatic causes, Other	38	35/38 (92.1)	NR	NR	Need for intervention due to persistent bleeding	3	Embolization-2 Hysterectomy -1
Kadioglu et al, 2016[28]	Uterine atony, Other	42	42/50 (84)	NR	NR	Not defined	8	Ligation surgey-2 Hysterectomy-2 Cases referred-4
Kaya et al, 2014[30]	Uterine atony, Other	45	34/45 (75.6)	34	27/34 (79.4)	Persistent bleeding in spite of adequate UBT balloon inflation	11	B-Lynch/compression sutures-1 Ligation surgey-5 Hysterectomy-5
Vintejoux et al, 2015[32]	Uterine atony	36	25/36 (69.4)	36	25/36 (69.4)	Bleeding uncontrolled after 5-10 minutes of UBT placement	11	Embolization-7 Ligation-1 Ligation plus Hysterectomy-1 Hysterectomy-1 Ligation plus uterine plication -1
Wang et al, 2018[33]	Uterine atony	407	373/407 (91.6)	407	373/407 (91.6)	Need for surgical intervention	34	Embolization-12 B-Lynch/compression sutures-1 Ligation surgey-7 Hysterectomy-11 Cervical cerclages-3
Son et al, 2017[36]	Uterine atony,	306	239/306 (78.1)	241	190/241 (78.8)	Need for intervention	67	Embolization-41 Hysterectomy -21

Continued.

Authors, year	Cause of PPH	Study sample size	Success rate (%)	Atonic PPH cases	Atonic PPH success rate (%)	UBT failure definition	Number of failures	Course of interventions
	Other					due to persistent bleeding		Embolization plus Hysterectomy -5
Revert et al, 2017[37]	Uterine atony, Other	226	188/226 (83.2)	183	155/183 (84.7)	Uncontrolled bleeding requiring further invasive procedure	38	Embolization-19 (2-failed) Hysterectomy-6
Martin et al, 2015[38]	Uterine atony, Other	49	32/49 (65.3)	42	28/42 (66.7)	Need for invasive procedure to control bleeding	17	Embolization-1 B-Lynch/compression sutures-4 Ligation surgey-5 Hysterectomy -11
Ogoyama et al, 2017[40]	Uterine atony, Other	71	66/71 (93)	32	31/32 (96.9)	Need for invasive procedure to control bleeding	5	Embolization-2 B-Lynch/compression sutures-1 Hysterectomy -2
Olsen et al, 2013[41]	Uterine atony, Other	37	25/37 (67.6)	24	17/24 (70.8)	Need for surgical intervention	12	Embolization and or B-Lynch compression suture and or Ligation surgery and or Hysterectomy -12
Laas et al, 2012[42]	Uterine atony	43	37/43 (86)	43	37/43 (86)	Continuous bleeding after UBT insertion	6	Embolization-3 B-Lynch/compression sutures and or Ligation surgery - 2 Hysterectomy-1
Kong and To, 2018[43]	Uterine atony Traumatic causes, Other	81	59/81 (72.8)	59	37/59 (62.7)	Need to move to other management modalities	22	Embolization-5 B-Lynch/compression sutures-5 Hysterectomy -11 Embolization plus compression suture-2
ESM-UBT								
Burke et al, 2016[15]	NR	201	190/201 (94.5) $	NR	NR	Not defined	-	Hysterectomy -2
Ramanathan et al, 2018[16]	NR	201	189/201 (94) $	NR	NR	Not defined	NR	
Burke et al, 2016[29]	Atony	306	298/306 (97.4) $	306	298/306 (97.4)^	Not defined	-	Hysterectomy or another emergency procedure - 8

Note: Other causes- May include placenta praevia, retained placenta, placenta accrete, adherent placenta, abruption placenta, uterine inversion, uterine rupture, coagulopathy, jaundice; *- not specifically defined; $ - survival success; # - success definition is different; ^ - survival success; and NR- not reported.

Table 3: Specification details of UBT device use.

Authors, year	Fluid volume in UBT balloon (ml)	Time to arrest bleeding	UBT retention time (Hours)	UBT placement difficulties
Condom-UBT				
Darwish et al, 2018[11]	≤400-500	11.76±7.23	NR	5 cases of rupture requiring reinsertion
Dumont et al, 2017[12]	500 (IQR 400-600)	NR	Median-9 (4-14)	2 cases of rupture or expulsion
Anger et al, 2019[13]	NR	NR	NR	25 cases of difficulty in use (15 cases of reinsertion 10 cases of displacement)
Tindell et al, 2013[18]	250-500	4-15	(6-72)	1 failure, details not mentioned
Rathore et al, 2012[19]	409 (250-760)	6.2 (4-12)	27.5±9.4 (18-48)	2 cases of difficulty in insertion
Yadav et al, 2019[23]	416 (success) 418 (failure)	7.13 (success) 15.32 (failures)	22.67 (success) 24.67 (failure) (2-48)	-
Mishra et al, 2019[25]	222±41 (CI 181-263)	8.75±5.7	22.8±5.3	3 cases of inflation failure requiring reinsertion and re-inflation
Santhanam, Viswanathan et al, 2018[30]	250-300	<15-80.3% 15-30-14.8% >30-4.9%	12-24	-
Lohano et al, 2016[31]	250-500	NR	≤24	2 cases of expulsion of balloon
Hasabe et al, 2016[34]	350	NR	24 - 72	-
Kandeel et al, 2016[35]	350 (200-650)	NR	20 (18-27)	2 cases of inflation failure 2 cases of displacement
Aderoba et al, 2017[41]	250-500	12.76±9.2	12.8±4.7	-
Bakri-UBT				
Darwish et al, 2018[11]	Up to 400-500	9±6.1	NR	-
Mathur et al, 2018[17]	277±120	NR	22±15	3 cases of balloon displacement
Guo et al, 2018[20]	250-350	NR	≤24	-
Grange et al, 2018[21]	420±103 (success) 458±48 (failure)	NR	NR	-
Çetin et al, 2019[22]	≤1000	NR	NR	-
Brown et al, 2016[24]	246 (80-500)	NR	25±12	-
Alkiş et al, 2015[26]	Up to 500	NR	5.3 at site 1 14.2 at site 2	-
Gauchotte et al, 2017[27]	400 (100-600)	NR	23.13 (11.30-41.10)	1 case of UBT placement failure
Kadioglu et al, 2016[28]	250-500	NR	19.4±4.1	-
Kaya et al, 2014[30]	571±264 (240-1300)	9 cases immediate 9 cases <5 min 6 cases 5-15 min	20.4±9.5	6 cases of spontaneous expulsion

Continued.

Authors, year	Fluid volume in UBT balloon (ml)	Time to arrest bleeding	UBT retention time (Hours)	UBT placement difficulties
Vintejoux et al, 2015[32]	363 (120-500)	2 (0-30)	23 (2-72)	2 insertion failures
Wang et al, 2018[33]	300 - 600	NR	0.5-48	-
Son et al, 2017[36]	NR	NR	NR	3 cases excluded on account of placement difficulty
Revert et al, 2017[37]	457±140 (success) 473±154 (failure)	162/165 cases controlled in 15 minutes	NR	7 cases of insertion failure
Martin et al, 2015[38]	489±26 (success) 499±3.8 (failure)	NR	NR	1 case of displacement
Ogoyama et al, 2017[40]	Median 150 in success (100-200) Median 300 in failure (160-350)	NR	NR	9 cases of expulsion
Olsen et al, 2013[41]	NR	NR	NR	-
Laas et al, 2012[42]	400-500	NR	NR	-
Kong and To, 2018[43]	335±90	56/58 cases controlled in 30 minutes	NR	-
ESM-UBT				
Burke et al, 2016[15]	300-500	NR	14.15 (174 cases)	14 cases of displacement (10 had to be replaced)
Ramanathan et al, 2018[16]	NR	NR	NR	-
Burke et al, 2016[29]	NR	NR	NR	-

Table 4: Details of maternal outcomes related to use of UBT device.

Authors, year	Estimated blood loss (ml)	Cases requiring blood transfusion (%)	Maternal complications after UBT use	ICU admission	Maternal deaths
Condom-UBT					
Darwish et al, 2018[11]	NR	100	Reported Occurred	2 cases 14%	NR
Dumont et al, 2017[12]	NR	40	Reported Did not occur	10 cases (17%)	7 deaths 6 in UBT group 4 deaths in uncontrolled bleeding after UBT insertion
Anger et al, 2019[13]	NR	NR	NR	NR	25 PPH deaths 15 deaths in intervention period 4 in UBT group 3 deaths after receiving UBT
Tindell et al, 2013[18]	500-5000	18 cases#	Reported Did not occur	NR	2 studies reported maternal deaths
Rathore et al, 2012[19]	1331±531 (800 - 2900)	100	Reported Occurred	NR	No deaths

Continued.

Authors, year	Estimated blood loss (ml)	Cases requiring blood transfusion (%)	Maternal complications after UBT use	ICU admission	Maternal deaths
Yadav et al, 2019[23]	663 (success) 1100 (failure) (400-1500)	53*	NR	NR	NR
Mishra et al, 2019[25]	1417±437	NR	Reported Did not occur	NR	1 death due to DIC
Santhanam, Viswanathan et al, 2018[30]	44.3% cases - mild 50.8% cases - moderate 4.9% cases - severe	55.7	Reported Did not occur	NR	NR
Lohano et al, 2016[31]	1155±350	NR	NR	NR	NR
Hasabe et al, 2016[34]	NR	**	Reported Did not occur	NR	NR
Kandeel et al, 2016[35]	2200 (750-4500)	42	Reported Occurred	8 cases (16%)	NR
Aderoba et al, 2017[41]	1496±1004 (550-5500)	72.1	Reported Occurred	25 cases (10.9%)	NR
Bakri-UBT					
Darwish et al, 2018[11]	NR	96.6	Reported Occurred	2 cases (6%)	NR
Mathur et al, 2018[17]	1840±1133	79.6	NR	34 cases (69.4%)	NR
Guo et al, 2018[20]	1040±509 (UBT plus vaginal packing) 776 ±307 (Only UBT)	NR	Reported Occurred	NR	NR
Grange et al, 2018[21]	1775±697 (success) 2980±879 (failure	12.5 (success) 28.6 (failure)	NR	8 (success) 18 (failure)	No deaths
Çetin et al, 2019[22]	1562±449	NR	Reported Occurred	NR	NR
Brown et al, 2016[24]	Group 1 - 1447±689 Group 2 - 1323±648	20.7[$]	NR	3/6 cases of failure	4 deaths, 1potentially due to UBT
Alkiş et al, 2015[26]	Median 2100 (700-7600)	**	Reported Occurred but not due to UBT	NR	NR
Gauchotte et al, 2017[27]	1234 (200-5000)	40.7	Reported Occurred	NR	NR
Kadioglu et al, 2016[28]	NR	**	Reported Did not occur	NR	NR
Kaya et al, 2014[30]	2371±1297 (800-6200)	**	Reported Occurred	7 cases (15.6%)	No deaths
Vintejoux et al, 2015[32]	1130 (500-3000)	**	Reported Did not occur	11 cases (30.6%)	NR

Continued.

Authors, year	Estimated blood loss (ml)	Cases requiring blood transfusion (%)	Maternal complications after UBT use	ICU admission	Maternal deaths
Wang et al, 2018[33]	964±615	46.4	Reported Occurred	NR	NR
Son et al, 2017[36]	190 (93-375)	62.7 (RBC) 25.3 (FFP) Only atonic	NR	30 atony cases (12.4%)	No deaths
Revert et al, 2017[37]	Success - 1064±476 Failure - 1508±675	58.7	Reported Occurred	139 cases (61.5%)	No deaths
Martin et al, 2015[38]	1685±912 (success) 3474±1619 (failure)	62.5 (success) 100 (failure)	Reported Occurred	NR	NR
Ogoyama et al, 2017[40]	Median-1900 (IQR 1185-2716)	NR	NR	NR	No deaths
Olsen et al, 2013[41]	1800 (success) 2750 (failure)	16.2	Reported Occurred	8 cases (21.6%) 7/8 (failure)	NR
Laas et al, 2012[42]	NR	NR	Reported Occurred	NR	No deaths
Kong and To, 2018[43]	1798±694 (success) 4981±1473 (failure) 3550±1629 (success with UBT plus other)	NR	NR	23 cases (38.9%)	1 death
ESM-UBT					
Burke et al, 2016[15]	NR	26 (49/189 cases)	Reported Occurred	NR	11 deaths
Ramanathan et al, 2018[16]	NR	NR	Reported Occurred	NR	12 deaths 1 death due to PPH could not be ruled out
Burke et al, 2016[29]	NR	44.1	NR	NR	8 deaths due to PPH

Note: #- Denominator not available; $- before UBT insertion; **- number of mean units mentioned; *- includes cases of condom and misoprostol interventions.

DISCUSSION

This narrative review has enlisted and compared clinical effectiveness of three UBT devices used in atonic PPH management. Reviewed condom and Bakri-UBT studies reported clinical effectiveness as control of PPH bleeding whereas ESM-UBT studies reported maternal survival as the effectiveness outcome. Mean clinical effectiveness in atonic PPH management for ESM-UBT was 97.4% (survival) as compared to 92.3% for condom-UBT and 84.3% for Bakri-UBT. UBT effectiveness in controlling all causes of PPH was similar to that reported for exclusive atonic PPH management. All condom-UBT, ESM-UBT and two-fifth Bakri-UBT studies in the review were from developing country settings. Notably, three eligible RCTs in this review reported combined higher proportion of overall PPH cases (22/154 i.e.; 14.28%) uncontrolled after UBT insertion as compared to that reported by non-

randomized studies (59/908 i.e., 6.5%). One of these RCTs, by Anger et al saw an increase in surgical or maternal mortality outcomes in UBT intervention period however also reported it to be likely driven by unrelated temporal factors.[13] Similarly, the RCT by Dumont et al. observed that condom-UBT in addition to misoprostol did not significantly affect recourse to surgery.[12] However, the study highlighted limitations like sub-optimal implementation of research protocol, lack of provisioning of UBT to intervention group and inadequate or delayed initial PPH management as possible confounders to their reported results. The remaining comparative RCT reported reasonable UBT success with no significant differences between the devices other than time to arrest bleeding. Other than the two RCTs, one retrospective study undertaken by Olsen et al. observed that Bakri-UBT was not as successful in their study as otherwise reported.[44]

For uncontrolled cases after UBT insertion across devices, hysterectomy was the most frequent intervention undertaken across the review. Embolization procedure was however reported only among Bakri-UBT studies. Difficulties in UBT placement were reported across all three UBT devices suggesting no clear advantage for any particular UBT. Interestingly, balloon rupture was reported only by two condom-UBT studies. One of these was the comparative RCT that witnessed five cases of UBT rupture, all in condom-UBT arm. Given that condom-UBT is an assembled modified device as against the specifically designed devices, further comparative enquiry on parameters like balloon tensile strength may be warranted. Parameters like estimated blood loss, proportion of women requiring blood transfusion and mean units of blood or blood products transfused did not vary significantly with UBT except for a few reported outlier cases.[18,36,39,41] Maternal complication outcomes like fever, DIC, endometriosis and pain across UBT types did not suggest any obvious advantage for sterile packed Bakri or ESM-UBT over the assembled condom-UBT device. Robust evidence needs to be generated to comparatively assess various determinants affecting clinical outcomes. Maternal deaths due to uncontrolled PPH after UBT insertion were seen across devices and occurred either directly after UBT placement, due to PPH sequelae, any unrelated complications or due to health system limitations such as unavailability of intervention itself.

To summarize, all except two included RCTs and a non-randomized study recommended UBT use in atonic and across different PPH types as an effective, low-cost, easily available intervention that was safe and reduced need for further surgical interventions. ESM-UBT case-series studies reported the device to be safe and a promising intervention with need for future research to focus on a systems approach for PPH management. Two RCTs and one observational study reported caution with use of UBT intervention.

To our knowledge, this is the first such review that has comparatively assessed clinical effectiveness and safety of different UBT devices specifically for atonic PPH management. A systematic review assessing overall UBT effectiveness in PPH management is available and reports similar findings, however this present study compares specific findings for different UBT devices with collation of evidence available for low-cost ESM-UBT and globally used Bakri-UBT alternatives as compared to the improvised condom-UBT device recommended currently by the Indian guidelines. This study documents reported medical and surgical measures undertaken subsequent to UBT intervention and assesses additional parameters like complications, difficulty in use, maternal deaths, etc. relevant to clinical use of UBT in managing atonic PPH specifically and across all causes of PPH.

This review has limitations. Firstly, potential biases associated with narrative nature of review cannot be ruled out. Limited available evidence for ESM-UBT that primarily assessed survival outcomes made direct systematic comparison with other two devices difficult. Secondly, the review included studies from heterogeneous settings. The geographical areas wherein these studies were conducted, type of health infrastructure availability, accessibility especially for surgical procedures, preparedness of health system, overarching contextual social and economic factors across settings vary significantly and thus may impact overall outcomes beyond intervention itself. Qualitative findings such as provider perspectives related to UBT device choice preferences in terms of confidence of use, affordability, cost and parameters like accurate estimation of blood loss that play an important role in management were not explored in this review.

Although there is an ongoing debate over usefulness of UBT intervention in PPH management, the latest recommendation by WHO has conditionally recommended use of UBT intervention.[45] In limited resource Indian settings, UBT intervention can be lifesaving when immediate surgical interventions are not available or even during referral of a patient to a higher facility.

Undertaking an RCT to generate evidence to assess usefulness of UBT intervention itself may raise ethical concerns. Generating robust evidence to compare UBT devices for the Indian context can be considered to strengthen any recommendation. Moreover, beyond specific UBT intervention, availability of skilled healthcare providers, adequate infrastructure, medical supplies, emergency services, efficient transport for timely referrals, efficient management information systems, monitoring of services and public health programmes with well-defined indicators including near miss mortality are essential to save precious maternal lives.

CONCLUSION

This review could not identify any clear beneficial evidence for use of one particular UBT device over the

other. Literature available for UBT devices is restricted to limited RCT evidence that is obscured by methodological concerns and moreover evaluates only one type of UBT device. Across UBT devices, evidence is largely based from case-control or cohort studies. Furthermore, available studies do not uniformly measure comparable outcomes, thus weakening the strength for any clinical recommendation. It is recommended that future research focuses on robust comparison of clinical effectiveness between UBT devices over identical outcome measures like successful control of bleeding without need for further intervention.

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