

Feasibility, acceptability and adaptation of S-Condom Uterine Balloon Tamponade (UBT) in managing atraumatic post-partum hemorrhage at a tertiary care facility in Bangladesh

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Abstract

Background

Postpartum hemorrhage (PPH) is the leading cause of maternal mortality in Bangladesh. Condom Uterine Balloon Tamponade (UBT) is an effective second-line treatment, but improvised devices present operational and sterility challenges. We evaluated the feasibility, acceptability, and adaptation of a prepackaged, preassembled, sterilized device ("S-Condom-UBT") costing < 5 USD.

Methods

This prospective observational mixed-methods study (January 2023–March 2024) enrolled 70 women with refractory atraumatic PPH receiving S-Condom-UBT at Chittagong Medical College Hospital. Quantitative outcomes included success rate, time to hemostasis, fluid volume, catheter duration, hospital stay, and adverse events. Qualitative interviews with 12 providers assessed acceptability, barriers, and facilitators. Patient satisfaction was assessed pre-discharge.

Results

S-Condom-UBT achieved a 100% treatment success rate in controlling bleeding without requiring surgical escalation. The mean time to hemostasis was 3.31 minutes (95% CI: 2.68–3.95), with a mean saline inflation volume of 240.43 mL (95% CI: 222.28–258.58). Mean catheter retention time was 24.78 hours, and hospital stay averaged 6.07 days. Overall patient satisfaction was 98.6%, with minimal pain during retention (mean VAS score 1.2) and no major adverse events. Providers rated the device highly favorably for its single-person operation, one-way valve, firm structure, and preassembled readiness. Initial barriers, such as saline push resistance and early batch leakages, were resolved through adaptation and manufacturer collaboration.

Conclusion

S-Condom-UBT is a highly feasible, safe, and acceptable intervention for managing atraumatic PPH. Its low cost and preassembled design address the limitations of both commercial (e.g., Bakri balloon) and improvised UBTs, supporting its potential for future large-scale implementation and evaluation.

Background

Postpartum hemorrhage (PPH) is the leading cause of maternal mortality and morbidity worldwide, especially in low- and middle-income countries (1–4) according to the Bangladesh Maternal Mortality and Health Care Survey (2016), postpartum hemorrhage (PPH) is the leading direct cause of maternal

mortality in Bangladesh, accounting for approximately 31% of all maternal deaths (5). In 79% instances, uterine atony is the primary reason for PPH (6).

Uterotonic medicines are the first-line treatment for atonic uterus, according to international standards (7). Second-line treatments include uterine balloon tamponade (UBT), vascular embolization, systemic devascularization (e.g., surgical artery ligation), B-Lynch sutures, or hysterectomy (8). Uterine artery embolization is expensive and requires competent doctors, making it unavailable in developing nations (9). Uterine balloon tamponade (UBT) is a device used as a second-line treatment for uncontrolled postpartum bleeding. The International Federation of Gynecology and Obstetrics (FIGO) and WHO suggest it as a second-line treatment for severe uncontrolled PPH (10–13).

UBT is less invasive, more efficient, cheaper, and better for low-resource areas (14). In several countries, it is recommended for atonic uterus when first-line therapy fails to stop bleeding. A balloon is inserted into the uterus and inflated with saline in UBT. This increase in intrauterine pressure should reduce blood flow and encourage uterine coagulation (15). Sengstaken-Blakemore and Bakri Balloon are commercially available purpose-designed devices for high-income environments (15, 16). These devices are expensive for low- and middle-income countries (Cost 250–400 USD). The WHO Guideline Development Group (GDG) recognizes balloon tamponade using various devices and inexpensive methods such as condoms and surgical gloves (13).

Professor Sayeba Akhter and her team in Bangladesh invented the Condom UBT to treat PPH using condoms, Foley catheters, and sutures (17). The inexpensive nature of these materials made Condom UBT suitable for resource-constrained areas. Women who got commercial or condom-catheter UBTs had 75% to 94% bleeding arrest rates, which is also promising (14). However, there are few operational challenges in using Condom UBT. First, the devices need to be assembled together, consuming time and exerting mental pressure on attending doctors/providers during a life-threatening emergency. Second, the application of Condom UBT's also require at least two persons to secure the device, prevent tamponade slippage, and tightening the knot. During application, keeping the device sterile is also a challenge.

We have adapted the Sayeba's procedure using a local supplier's prepackaged, preassembled, sterilized low-cost device UBT kit, "S-Condom-UBT," and which can be made available in the labour room. This device costs less than 5 USD, is pre-assembled to reduce application time, and addresses sterility concerns.

While Sayeba's method has been practiced by obstetric specialists in Bangladesh with promising results in controlling hemorrhage, systematic documentation of the feasibility, acceptability, and usability of this adapted version has not been undertaken. Provider experience with UBT remains understudied compared to quantitative outcomes such as hemorrhage control and patient survival (16). Furthermore, patient satisfaction with this method has not been assessed. The objective of this study was therefore threefold: to determine the feasibility of S-Condom-UBT by measuring time to bleeding control and

procedural parameters; to assess its acceptability among both healthcare providers and patients; and to understand the barriers and facilitators influencing its adaptation in routine practice.

Methods

Study design, and setting

We conducted a prospective observational feasibility study using a mixed-methods approach at the Department of Obstetrics and Gynaecology of Chittagong Medical College Hospital (CMCH), a tertiary care facility in Bangladesh with 24/7 emergency obstetric care and functional maternal and neonatal intensive care units. The study was conducted from January 2023 to March 2024. The site was purposively selected based on high patient volume (686 and 786 PPH cases admitted in 2019 and 2020, respectively) and existing experience with condom UBT. This study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies (18).

Participants

Quantitative

We enrolled 70 women aged ≥ 18 years presenting with atraumatic PPH refractory to first-line uterotonic therapy who subsequently received S-Condom-UBT. During the study period, the facility managed 718 PPH cases, of which 599 were atonic and 119 were traumatic. Among the atonic cases, 100 received UBT; our study enrolled 70 of these patients. Atraumatic PPH was defined as excessive bleeding (> 500 mL following vaginal delivery or > 1000 mL following cesarean section) due to uterine atony in the absence of genital tract trauma. Patients with stage 3 or 4 hypovolemic shock or those unable to provide informed consent were excluded. The rationale for excluding patients with advanced shock was to ensure patient safety, as these critically ill individuals require immediate, definitive surgical intervention, and any delay for device insertion could be life-threatening. Given the exploratory nature of this feasibility study and the average annual condom UBT usage of approximately 50 cases at the facility, we enrolled all eligible patients ($n = 70$) presenting during the 15-month study period. This sample size provides sufficient preliminary estimates for treatment success and procedural parameters in this resource-limited setting. For the primary outcome of treatment success rate (expected 96.7% based on previous studies), a sample of 70 patients yields a precision of approximately $\pm 5.2\%$ (95% confidence interval width), which is acceptable for an exploratory feasibility study.

Qualitative

We purposively selected 12 healthcare providers (obstetricians, registrars, assistant registrars, and medical officers) who had received standardized training on PPH management and S-Condom-UBT insertion and had used the device in clinical practice. The qualitative sample size was guided by the

principle of data saturation, which was achieved after 12 interviews when no new themes emerged from the data (Supplementary Table 2).

Description of the S-Condom UBT Device

S-Condom-UBT is a prepackaged, preassembled, sterilized device comprising a male condom fitted with a catheter/tube (Fig. 1). The tube has a lumen with a blunt open proximal end to allow saline passage into the condom and a distal end with a one-way valve preventing saline backflow. After optimal inflation (evidenced by bleeding cessation), a vaginal pack is inserted, and the catheter is strapped to the thigh for the desired duration. The device is sterilized using Ethylene Oxide gas, with biological and chemical indicators confirming sterilization completion. The device was manufactured by JMI Hospital Requisite Mfg. Ltd., a leading medical device manufacturing company in Bangladesh.

Study procedure

Patients with atraumatic PPH refractory to first-line management received S-Condom-UBT insertion. The device was connected to a syringe, and the balloon was inflated with sterile saline (target volume: 200–500 mL) until active bleeding ceased. Vaginal packing was applied to prevent expulsion, and the catheter was secured to the patient's thigh. Standardized antibiotic prophylaxis was administered to all patients according to departmental protocols, while maternal resuscitation (intravenous fluids and blood transfusion) continued concurrently.

Treatment success was defined as complete cessation of bleeding within 15 minutes of balloon inflation. Continued bleeding beyond 15 minutes was defined as treatment failure, prompting immediate surgical management. In this study, no patient experienced bleeding beyond the 15-minute threshold. The device was made accessible in the labor ward 24 hours a day. Prior to study initiation, all participating healthcare providers completed a half-day training workshop covering PPH management protocols and hands-on simulation with the S-Condom-UBT. Standardized PPH management algorithm posters were visually displayed throughout the labor facility.

Data collection

Quantitative data

Two trained physicians collected data using structured service record forms and patient questionnaires. Service record forms captured clinical parameters including time to bleeding control, fluid volume required, catheter duration in situ, ICU admission, hospital stay, and adverse events. Patient questionnaires assessed sociodemographic characteristics and satisfaction levels. Patients were followed up by telephone at 2 and 6 weeks postpartum to assess late adverse events. The patient

questionnaire used in this study was developed specifically for this research by the study investigators. An English language version of the questionnaire is provided as Supplementary File 1.

Patient acceptability and tolerance

Prior to hospital discharge, trained research assistants conducted face-to-face structured interviews to collect patient acceptability and tolerance data. All responses were directly entered into paper-based CRF. Medical record reviews were performed concurrently to extract clinical, baseline, and transfusion data.

Qualitative data

A trained anthropologist conducted in-depth interviews with healthcare providers using a semi-structured interview guide in English or Bangla. Interviews were audio-recorded, transcribed verbatim, and translated into English. The interview guide explored provider perceptions of device design, ease and convenience of use, confidence in administration, barriers and facilitators to use, training effectiveness, and recommendations for improvement. The semi-structured interview guide used for provider interviews was developed by the research team based on existing literature on UBT acceptability and feasibility. An English language version of the interview guide is provided as Supplementary File 2.

A summary of data collection methods, indicators, tools, and respondents for each objective is provided in Supplementary Table 1.

Measurement

Primary Outcomes

Treatment Success Rate was defined as the complete cessation of vaginal bleeding within 15 minutes of balloon inflation, recorded as a binary outcome (Yes/No). This 15-minute threshold aligns with WHO recommendations and clinical guidelines indicating that non-responsive PPH within this timeframe necessitates immediate surgical escalation (8, 10). Bleeding control was assessed via direct visualization by the attending physician.

Time to Bleeding Control was defined as the interval in minutes from S-Condom-UBT insertion to complete visual cessation of bleeding. Time was recorded using a stopwatch, initiated upon device insertion into the uterus and stopped when active bleeding ceased. Measurements were recorded by the attending physician and verified by a secondary observer when available.

Time for Balloon Inflation was measured in minutes using a stopwatch, starting from syringe attachment to the one-way valve until optimal inflation was achieved, marked by palpable balloon resistance and bleeding arrest.

Fluid Volume Required for Inflation was defined as the total volume of sterile normal saline (0.9% NaCl) in milliliters (mL) required to achieve optimal inflation and bleeding control, measured using syringe markings with an expected target range of 200–500 ml.

Secondary Feasibility Outcomes

Catheter Retention and Hospitalization were assessed by recording the duration of catheter retention in hours from insertion to removal following 24 hours of bleeding control [16], ICU admission as a binary outcome with stay duration in days and clinical indications documented, and overall hospital stay duration in days from admission to discharge extracted from service records.

Adverse Events were systematically monitored during hospitalization and at 2- and 6-week follow-up visits. During hospitalization, the following events were assessed: abdominal pain, fever (temperature $\geq 38^{\circ}\text{C}$), latex allergy, foul-smelling vaginal discharge, condom slippage, and condom rupture. At follow-up visits, the following events were assessed: pruritus, foul-smelling vaginal discharge, fever, abdominal pain, and re-hospitalization. All events were documented as binary outcomes (present/absent).

Blood Product Requirements were recorded as cumulative units of blood products transfused per patient across whole blood, packed red blood cells (PRBC), fresh frozen plasma (FFP), platelets, and cryoprecipitate.

Acceptability Outcomes

Patient Satisfaction and Tolerance were evaluated prior to discharge. Patient satisfaction was assessed using a structured 5-point Likert scale ranging from very satisfied to very dissatisfied. Tolerance parameters included insertion discomfort categorized as none, mild, moderate, or severe, continuous pain during device retention measured using a 0–10 Visual Analog Scale (VAS), and overall patient experience categorized as positive, neutral, or negative.

Provider and Implementation Metrics were assessed through semi-structured qualitative in-depth interviews. These explored healthcare provider perceptions across key domains including device design, ease of use, technical confidence, and operational usability relative to conventional condom UBT. Implementation dynamics including institutional facilitators, workflow barriers, and training adequacy were evaluated to determine routine applicability.

Covariates

Covariates were selected a priori based on previous literature and their potential relevance to PPH outcomes, treatment response, and device performance (5, 9, 17, 19, 20). Sociodemographic characteristics included age, place of residence, education, occupation, and monthly household income. Obstetric and clinical characteristics included parity, gestational age at delivery, mode and onset of labour, onset of PPH, PPH risk factors, preventive measures, first-line treatment, and need for additional

interventions. Provider-related characteristics included provider level, years of experience in PPH management, and prior training in PPH management or S-Condom-UBT. Variables were categorized as specified in Supplementary Table 3.

Data analysis

Quantitative data were analyzed using Stata version 16.0 (StataCorp, College Station, TX, USA). Descriptive statistics (frequencies, percentages, means, 95% confidence intervals [CIs]) summarized categorical and continuous variables. Two-sample t-tests and one-way analysis of variance (ANOVA) compared continuous outcomes across subgroups. For the occupation variable, due to the small sample size in the “Others” category (n = 2), statistical comparisons were interpreted with caution and reported as exploratory findings. Multivariable linear regression evaluated factors influencing key outcomes (time to bleeding control, fluid volume, catheter duration, hospital stay), reporting adjusted estimates with 95% CIs and p-values.

Thematic analysis was performed using an inductive-deductive approach (21). Open codes were generated, grouped into categories, and synthesized into themes related to perceptions, barriers, facilitators, and adaptation. A framework was developed to organize findings (Fig. 2). Qualitative findings helped contextualize the quantitative feasibility outcomes. Providers perceived the preassembled design and one-way valve as facilitating rapid deployment, while quantitative data demonstrated short post-insertion time to bleeding control. However, preparation time was not measured comparatively.

Data quality assurance

Data collectors received standardized training on the study procedures, measurement protocols, operational definitions, and ethical considerations. Service records were reviewed regularly for completeness and inconsistencies. Inter-rater reliability for time-based measurements was assessed in 10% of cases using independent observations. Quantitative data were double-entered and validated through systematic data cleaning and quality checks.

Results

Participant characteristics

A total of 70 women with refractory atraumatic PPH were enrolled. The mean age was 28 years (range 18–45). The majority resided in rural areas (91.4%, n = 64), had education above primary level (60.0%, n = 43), and were homemakers (97.1%, n = 68). Regarding monthly family income, 37.1% (n = 26) earned ≤ 10,000 BDT, 34.3% (n = 24) earned 10,001–20,000 BDT, and 28.6% (n = 20) earned > 20,000 BDT. Parity was distributed as 40.0% (n = 28) primiparous and 60.0% (n = 42) multiparous. Normal vaginal delivery accounted for 61.3% (n = 43) of births and cesarean section for 38.7% (n = 27). Known risk factors for PPH were present in 60.0% (n = 42), and 67.1% (n = 47) of PPH cases were identified in-hospital (Table 1).

Table 1
Distribution of enrolled women by
background characteristics, presented in
frequency and percent distribution (N = 70).

Characteristics	N	%
Age (in years)		
<25	34	48.57
>=25	36	51.43
Place of residence		
Rural	64	91.43
Urban	6	8.57
Education		
Primary or below	28	40.00
Above primary	42	60.00
Occupation		
Housewife	68	97.14
Others	2	2.86
Monthly income (in Taka)		
≤10,000	26	37.14
10,001–20,000	24	34.29
>20,000	20	28.57
Parity		
Primi	28	40.00
Multi	42	60.00
Mode of delivery		
Vaginal Delivery	43	61.30
LSCS	27	38.70
Any risk factor presents	42	60.00
Onset of PPH		
Inpatient	47	67.14

Characteristics	N	%
Age (in years)		
Others	23	32.86

For the qualitative component, 12 healthcare providers participated in in-depth interviews, including 3 registrars, 7 assistant registrars, 1 medical officer, and 1 trainee. All were female, aged 25–50 years, with MBBS qualifications in Gynecology and Obstetrics and a median professional experience of 8 years (range: 2–15 years) (Supplementary table 2).

Feasibility of S-Condom-UBT

Treatment success and procedural efficiency

The S-Condom-UBT achieved a 100% success rate in controlling bleeding among all 70 enrolled women, with no patient requiring surgical escalation due to device failure. The mean time to hemostasis was 3.31 minutes (95% CI: 2.68–3.95). The mean volume of saline required for inflation was 240.43 mL (95% CI: 222.28–258.58), with a mean inflation time of 2.17 minutes (SD 0.88). The mean catheter retention time was 24.78 hours (95% CI: 23.01–26.55), and the mean duration of hospitalization was 6.07 days (95% CI: 5.43–6.72). Only 3 patients (4.3%) required ICU admission for hypovolemic shock resuscitation and monitoring (Supplementary Fig. 1).

Subgroup analyses revealed that multiparous women achieved significantly faster bleeding control compared with primiparous women (mean difference: -1.39 minutes, 95% CI: -2.66 to -0.12, $p = 0.033$). Women with risk factors for PPH required longer time to control bleeding compared with those without risk factors (mean difference: +1.19 minutes, 95% CI: -0.09 to 2.70, $p = 0.068$), though this did not reach statistical significance. No statistically significant differences in fluid volume requirements were observed across background characteristics (Table 2).

Table 2

Distribution of fluid amount needed (ml) for inflation of S-Condom-UBT and time required to control bleeding (min) by background characteristics

Characteristics	Fluid amount needed (ml)		Time required to control bleeding (min)	
	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Age (in years)				
< 25	252.35 (227.19-277.51)	0.205	3.82 (2.59–5.07)	0.120
≥ 25	229.17 (202.41-255.92)		2.83 (2.39–3.27)	
Place of residence				
Rural	237.19 (218.14-256.24)	0.248	3.35 (2.66–4.05)	0.684
Urban	275.00 (199.98-350.02)		2.88 (1.83–3.93)	
Education				
Primary or below	241.43 (211.66–271.20)	0.929	3.05 (2.39–3.70)	0.497
Above primary	239.76 (215.89-263.64)		3.49 (2.50–4.48)	
Occupation				
Housewife	238.67 (220.27-257.09)	0.265	3.07 (2.64–3.50)	< 0.001
Others	300.00 (200.25-399.75)		11.50 (5.46–28.46)	
Monthly income (in Taka)				
≤ 10,000	240.00 (213.81-266.19)	0.121	3.01 (2.35–3.67)	0.208
10,001–20,000	219.17 (188.77-249.57)		2.89 (2.50–3.28)	
> 20,000	266.50 (228.86-304.14)		4.21 (2.22–6.20)	
Parity				

Characteristics	Fluid amount needed (ml)		Time required to control bleeding (min)	
	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Age (in years)				
Primi	256.78 (226.03-287.54)	0.143	4.15 (2.66–5.63)	0.033
Multi	229.52 (206.82-252.23)		2.76 (2.37–3.15)	
Mode of delivery				
VD	240.98 (216.44-265.51)	0.822	3.14 (2.53–3.74)	0.419
LSCS	245.18 (217.03-273.34)		3.68 (2.26–5.11)	
Risk factor				
No	243.93 (213.44-274.41)	0.756	2.60 (2.19–3.01)	0.068
Yes	238.10 (214.63-261.56)		3.79 (2.77–4.81)	
Onset of PPH				
Inpatient	240.21 (217.74-262.69)	0.973	3.48 (2.55–4.41)	0.460
Others	240.87 (207.58-274.16)		2.97 (2.47–3.47)	
Total	240.43 (222.28-258.58)		3.31 (2.68–3.95)	

Women who delivered vaginally had significantly shorter catheter duration (23.32 hours, 95% CI: 22.55–24.09) compared with those who delivered by cesarean section (26.96 hours, 95% CI: 22.60–31.32, $p = 0.047$). Women from high-income households (> 20,000 BDT) had longer catheter duration compared with those from low-income households (mean difference: +4.15 hours, 95% CI: -0.15 to 8.45, $p = 0.048$). Cesarean section was associated with significantly longer hospital stay (6.89 days, 95% CI: 6.20–7.58) compared with vaginal delivery (5.37 days, 95% CI: 4.43–6.30, $p = 0.019$) (Table 3).

Table 3
Duration of condom catheter in situ (hours) and hospital stay duration (days) by background characteristics

Characteristics	Duration of condom catheter in situ (hours)		Hospital stay duration (days)	
	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Age (in years)				
< 25	25.13 (21.81–28.44)	0.700	5.59 (4.89–6.29)	0.148
≥ 25	24.44 (22.83–26.04)		6.53 (5.44–7.61)	
Place of residence				
Rural	24.86 (22.90-26.82)	0.779	6.05 (5.36–6.73)	0.807
Urban	24.00 (24.00–24.00)		6.33 (3.71–8.96)	
Education				
Primary or below	25.68 (21.64–29.72)	0.414	6.29 (4.98–7.59)	0.593
Above primary	24.18 (22.71–25.66)		5.93 (5.25–6.61)	
Occupation				
Housewife	24.78 (23.01–26.55)	-	6.00 (5.36–6.64)	0.201
Others	-		8.50 (1.52–15.48)	
Monthly income (in Taka)				
≤ 10,000	24.09 (23.69–24.48)	0.048	5.50 (4.78–6.22)	0.319
10,001–20,000	22.91 (21.71–24.11)		6.67 (5.20–8.13)	
> 20,000	28.24 (22.08–34.39)		6.10 (5.04–7.16)	
Parity				
Primi	25.12 (21.08–29.15)	0.752	5.96 (4.55–7.38)	0.789
Multi	24.54 (23.21–25.87)		6.14 (5.56–6.73)	
Mode of delivery				
VD	23.32 (22.55–24.09)	0.047	5.37 (4.43–6.30)	0.019
LSCS	26.96 (22.60-31.32)		6.89 (6.20–7.58)	
Risk factor				
No	25.29 (20.95–29.63)	0.653	6.32 (5.38–7.26)	0.532

Characteristics	Duration of condom catheter in situ (hours)		Hospital stay duration (days)	
	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Age (in years)				
Yes	24.46 (23.14–25.78)		5.90 (5.00–6.81)	
Onset of PPH				
Inpatient	25.27 (22.73–27.82)	0.400	6.15 (5.34–6.96)	0.735
Others	23.63 (23.05–24.22)		5.91 (4.76–7.06)	
Total	24.78 (23.01–26.55)		6.07 (5.43–6.72)	

Regression analysis

Multivariable linear regression analysis revealed several significant associations (Fig. 3). For duration of catheter in situ, education above primary level was associated with significantly shorter catheter duration (adjusted estimate: -4.62 hours, 95% CI: -9.21 to -0.03, $p = 0.048$). High monthly income (> 20,000 BDT) was associated with significantly longer catheter duration (adjusted estimate: +6.74 hours, 95% CI: 1.41 to 12.06, $p = 0.014$). Cesarean section showed a trend toward longer catheter duration that approached statistical significance (adjusted estimate: +3.50 hours, 95% CI: -0.07 to 7.07, $p = 0.054$).

For hospital stay duration, cesarean section was significantly associated with longer hospitalization (adjusted estimate: +1.72 days, 95% CI: 0.47 to 2.97, $p = 0.008$). Middle-income status (10,001–20,000 BDT) was significantly associated with longer hospital stay compared with low-income status (adjusted estimate: +1.82 days, 95% CI: 0.17 to 3.47, $p = 0.031$). The presence of risk factors showed a trend toward longer time to bleeding control (adjusted estimate: +1.29 minutes, 95% CI: -0.03 to 2.61, $p = 0.055$). No covariates showed statistically significant associations with fluid volume required for inflation in the adjusted model.

Safety and patient tolerance

The device demonstrated an excellent safety profile. No patients developed abdominal pain, allergic reactions to latex, foul-smelling vaginal discharge, or condom slippage/rupture. Only one patient (1.4%) developed fever during hospitalization, which resolved with standard management (Supplementary Fig. 2).

No adverse events were reported by any of the 70 women at 2-week or 6-week telephone follow-up. Assessment of patient tolerance revealed that the device was well-tolerated. No patients reported

moderate or severe discomfort during insertion; 91.4% (n = 64) rated discomfort as none and 8.6% (n = 6) as mild. Pain during device retention, assessed using a 0–10 VAS, had a mean score of 1.2 (SD 0.8), indicating minimal pain. Overall patient experience was rated as positive by 97.1% (n = 68) and neutral by 2.9% (n = 2); no patient rated their experience as negative (Supplementary Fig. 3).

Acceptability of S-Condom-UBT

Patient satisfaction

Patient acceptability was notably high (Fig. 4). Of the 70 women interviewed before discharge, 87.1% (n = 61) reported being satisfied and 11.4% (n = 8) reported being very satisfied with the S-Condom-UBT management, yielding a combined satisfaction rate of 98.6%. Only 1.4% (n = 1) expressed a neutral response, and no patients reported dissatisfaction. Patients who were satisfied or very satisfied commonly cited the rapid control of bleeding, minimal discomfort during insertion, and the avoidance of surgical interventions as reasons for their positive experience.

Provider acceptability

Healthcare providers expressed high acceptability of the device across several operational dimensions. A key theme was the device's technical efficiency, specifically the one-way valve and cord-screw mechanism, which allowed for controlled drainage without the risk of saline backflow:

"The device includes a cord and screw mechanism, facilitating the controlled release of water... It operates on a one-way system, ensuring that actions, even if mistaken, do not allow saline backflow automatically. Once a predetermined amount of water is dispensed, further flow ceases." (Assistant Registrar, IDI-03)

Another major driver of acceptability was the minimal manpower requirement. Providers highlighted that unlike the conventional method, which required at least two people to tie the condom securely, the S-Condom-UBT could be managed by a single provider:

"This design is quite simple and easy to understand... Time management is also easier, making it more convenient for me to manage without any help of other colleagues." (Registrar, IDI-09)

Furthermore, the ready-to-use, sterile nature of the device significantly reduced the stress and chaos typically associated with PPH emergencies, further boosting provider confidence:

"The device is ready for immediate use, saving our valuable time. Additionally, postpartum haemorrhage is quickly being brought under control, resulting in the preservation of the patient's life and positive prognosis." (Trainee, IDI-12)

Providers attributed the rapid and sustained hemostasis to the device's structural design. Unlike the soft latex of conventional condoms, the firmer catheter and secure locking mechanism of the S-Condom-UBT prevented displacement once inserted:

"The catheter in the current device is comparatively firmer than before... the current one remains intact during usage. Hence, there is no repeated slippage, and there is no need to change positions while serving." (Assistant Registrar, IDI-05)

Qualitative findings provided context for the rapid procedural efficiency observed quantitatively. Providers emphasized that the pre-assembled nature of the device eliminated the 10–15 minutes previously required to manually assemble a conventional condom UBT during an emergency:

"By using [the] manual UBT catheter, it took 10 minutes to prepare and then install on [the] human body. But now, through this device, it doesn't take as much time and can introduce the patient faster. Only my responsibility is to insert four times 50-cc saline; that's all." (Assistant Registrar, IDI-05)

Adaptation: barriers, facilitators, and recommendations

Barriers to use

While overall adaptation was positive, providers identified two initial operational barriers. First, a few providers experienced physical resistance when pushing saline through the catheter. Second, devices from the very first manufacturing batches exhibited minor leakage post-insertion. However, both barriers were transient; providers developed adaptive techniques for fluid insertion, and the research team communicated the leakage issue to the manufacturer, who resolved it in subsequent batches:

"The challenge is pushing fluid while inserting. I had trouble with that, but now I'm used to using it and don't have any problems." (Assistant Registrar, IDI-04)

"Initially, we noticed some leakage from a few devices in the first batch. However, after reporting this to the manufacturer, subsequent batches showed no such issues. The quality assurance process has improved significantly." (Assistant Registrar, IDI-06)

Facilitators for adaptation

The most powerful facilitator for routine adaptation was the perception of the S-Condom-UBT as a life-saving device. Providers noted that it was particularly effective in severe cases where bleeding is typically difficult to control, allowing for rapid stabilization and preventing the need for hysterectomy:

"Conditions such as placenta previa covering the cervix, which causes bleeding, are extremely harmful for patients... In such cases, healthcare providers have been able to save several patients and immediately stop

bleeding within 5 minutes by using this device." (Registrar, IDI-08)

Providers linked the high safety profile to the device's pre-packaged sterilization and its capacity to minimize ongoing blood loss, which reduced the risk of clinical deterioration:

"The patient's haemorrhage is diminishing compared to previous. So, [the] risk of clinical deterioration of [the] patient's condition is less which makes us confident to use it." (Registrar, IDI-07)

"The device's pre-sterilized packaging means we don't have to worry about infection risk during emergency insertion. This gives us confidence to use it even in the most urgent situations." (Medical Officer, IDI-10)

"The design is so straightforward that even junior doctors can learn to use it quickly. We don't need specialized training or complex equipment. It's truly adaptable to our setting." (Registrar, IDI-11)

Recommendations for broader scale-up

Providers identified five priorities for broader implementation of S-Condom-UBT. First, they recommended annual refresher training to maintain competency and orient newly recruited healthcare providers. Second, they advocated peripheral deployment with appropriate training to improve access to PPH management in underserved settings. Third, providers emphasized wider device availability, particularly through government or existing supply systems, to reduce delays in accessing treatment at tertiary facilities.

Fourth, providers recommended affordable pricing to facilitate access among economically disadvantaged populations. Finally, providers suggested improvements to the device package, including a 50-mL syringe and clear user instructions, as well as strengthened quality assurance to minimize leakage and resistance during saline insertion. These recommendations are summarized in Table 4.

Table 4
Thematic analysis with representative quotations

Theme	Sub-theme 1	Sub-theme 2	Type	Quotations
Perceptions about the use of S-condom UBT	Technical efficiency of the S-condom UBT device	Secure locking mechanism	Deductive	“The device includes a cord and screw mechanism, facilitating the controlled release of water. Opening either the cord or screw allows for automatic, normal saline discharge. This design simplifies usage across various settings. It operates on a one-way system, ensuring that actions, even if mistaken, saline back automatically. Once a predetermined amount of water is dispensed, further flow ceases. This indicates sufficient water for uterine irrigation and achieving effective outcomes.” (Assistant Registrar, Chittagong Medical College Hospital)
		High capacity fluid intake system by condom	Deductive	-
		Sterilized device & No side effect reported	Deductive	-
		Prevention of displacement of the UBT	Deductive	The catheter in the current device is comparatively firmer than before. While the previous one was soft like latex and in an incorrect position, the current one remains intact during usage. Hence, there is no repeated slippage, and there is no need to change positions while serving. (Assistant Registrar, Chittagong Medical College Hospital)
	Minimal blood loss		Deductive	“The patient's haemorrhage is diminishing compared to previous. So, risk of clinical deterioration of patients condition is less which makes us confident to use it”.

Theme	Sub-theme 1	Sub-theme 2	Type	Quotations
				<i>(Registrar, Chittagong Medical College Hospital)</i>
	Readymade and Time efficient		Deductive	" the installation process is straightforward, time-efficient, and requires no additional manpower. It [device] is readily available for use, and assistance from an aide suffices for its management. Furthermore, its usage is highly comfortable, convenient, and user-friendly." <i>(Trainee, Chittagong Medical College Hospital)</i> "The device is ready for immediate use, saving our valuable time. Additionally, postpartum haemorrhage (PPH) is quickly being brought under control, resulting in the preservation of the patient's life and positive prognosis." <i>(Trainee, Chittagong Medical College Hospital)</i>
	Simple process of introduction		Deductive	"By using manual UBT catheter, it took 10 minutes to prepare and then install on human body. But now, through this device, it doesn't take as much time and can introduce the patient faster. Only my [provider] responsibility is to insert four times 50-cc saline; that's all." <i>(Assistant Registrar, Chittagong Medical College Hospital)</i>
	Minimal manpower needed		Deductive	"This design is quite simple and easy to understand. Additionally, the catheter isn't overly flexible, which allows for smooth insertion. Time management is also easier, making it more convenient for me to manage without any help of other colleagues." <i>(Registrar, Chittagong Medical College Hospital)</i>

Theme	Sub-theme 1	Sub-theme 2	Type	Quotations
Barriers to address in future	Resistant to fluid insertion in the catheter		Inductive	"The challenge is pushing fluid while inserting. I [provider] had trouble with that, but now I'm used to using it and don't have any problems." (Assistant Registrar, Chittagong Medical College Hospital)
	Condom integrity against leakage		Inductive	-
Perceptions that influence adaptation	Life saving device		Deductive	"Conditions such as placenta previa covering the cervix, which causes bleeding, are extremely harmful for patients, and their bleeding cannot be easily controlled. In such cases, healthcare providers have been able to save several patients and immediately stop bleeding within 5 minutes by using this device." (Registrar, Chittagong Medical College Hospital)
	Simply adaptable		Deductive	-
Recommendation made by healthcare providers	Refresher training		Deductive	"Since most master trainers here are doctors, they may not be able to provide hands-on training to everyone. However, our representative attended the training and then passed on the knowledge to us during unit-wise training sessions. This included the methodology of S-Condom-UBT and its application to relevant patient cases." (Assistant Registrar, Chittagong Medical College and Hospital) "The provision of an annual refresher training facility makes it easy to use for all healthcare professionals. New doctors joining each year, their learning benefits from observing experienced practitioners; organizing

Theme	Sub-theme 1	Sub-theme 2	Type	Quotations
				training sessions through an institution ensures effectiveness and fruitful outcomes." (Registrar, Chittagong Medical College Hospital)
	Peripheral deployment with comprehensive training		Deductive	-
	Enhance device availability		Deductive	"If we want to spread this device, keep in mind that the majority of people in the medical field come from lower-income backgrounds. It's not just from tertiary hospitals, but even from peripheral areas where doctors are available. Also, birth attendants should also be equipped to utilize it during home deliveries." (Assistant Registrar, Chittagong Medical College Hospital)
	Affordable pricing		Deductive	"If the price is affordable and there's potential for increased supply from the government, it would be advantageous collaboration if possible. Additionally, obtaining it at a reasonable price would receive a positive response, given the excellent quality of the device and its performance." (Registrar, Chittagong Medical College Hospital)
	Improvement of the package		Inductive	-

Integration of quantitative and qualitative findings

The convergence of quantitative and qualitative findings strengthens the evidence for S-Condom-UBT as a feasible and acceptable intervention. The rapid time to bleeding control (3.31 minutes) observed quantitatively aligns with providers' qualitative emphasis on time-efficiency and the device's ready-to-use nature. The 100% success rate supports providers' perceptions of the device as life-saving, with one registrar noting successful control within 5 minutes even in complex cases such as placenta previa.

The high patient satisfaction (98.6%) and minimal pain scores (VAS mean 1.2) complement providers' observations that the device causes minimal discomfort and is well-tolerated. The low rate of adverse events (1.4% fever, no other complications) corroborates providers' reports of no side effects or infections. The qualitative emphasis on reduced manpower requirements and elimination of emergency assembly time provides the operational explanation for the quantitative efficiency outcomes. Together, these findings provide comprehensive evidence that the S-Condom-UBT is not only clinically effective but also acceptable to both patients and providers, supporting its potential for broader implementation in resource-limited settings.

Discussion

This mixed-methods study evaluated the feasibility, acceptability, and adaptation of S-Condom-UBT for managing atraumatic PPH in a tertiary care facility in Bangladesh. Our findings demonstrate that S-Condom-UBT is a highly feasible intervention with a 100% success rate in controlling bleeding, rapid time to hemostasis (mean 3.31 minutes), and high patient satisfaction (98.6% satisfied or very satisfied). Healthcare providers perceived the device as practical, time-efficient, and adaptable to low-resource settings.

The 100% success rate in controlling bleeding within 15 minutes is consistent with previous studies. Garg and Yadav (2022) reported bleeding control in 89 of 94 patients (94.7%) within 10 minutes using condom balloon tamponade (17, 22–24). The 100% success rate in our study also compares favorably with Bakri balloon success rates of 71–100% reported across various studies (25), suggesting the S-Condom-UBT is at least as effective as commercial devices costing 50–80 times more.

The mean time to bleeding control (3.31 minutes) is notably rapid, likely attributable to the preassembled, ready-to-use design eliminating preparation time. This is clinically significant as every minute of delay in controlling PPH increases the risk of maternal death (3). Providers qualitatively confirmed this benefit, with one assistant registrar noting: *"By using manual UBT catheter, it took 10 minutes to prepare and then install... But now through this device, it doesn't take as much time."* The mean fluid volume required for inflation (240 mL) was lower than reported by Tort et al. (443 mL) and Thapa et al. (425 mL) (23, 26). This difference may reflect earlier intervention in our setting, differences in patient characteristics, or the device's efficient design. Notably, all patients achieved hemostasis within the 200–500 mL target range, confirming the device's adaptability across varying clinical presentations.

The S-Condom-UBT demonstrated an excellent safety profile, with only one patient (1.4%) developing transient fever during hospitalization and no adverse events reported at 2- or 6-week follow-up. This contrasts with Ramanathan et al., who found 1.3% mild infections at six weeks despite prophylactic antibiotics (14). The absence of infections in our study may reflect the device's sterile, prepackaged ethylene oxide sterilization and standardized antibiotic protocol.

The mean catheter duration (24.78 hours) aligns with Akhter et al.'s recommendation of 24–48 hours (17) and Condous et al.'s finding of 26.14 hours (27). The shorter catheter duration for vaginal deliveries

(23.32 hours) compared to cesarean sections (26.96 hours) likely reflects differences in uterine contractility and surgical recovery. Only 4% required ICU admission, consistent with Deepika's finding of 5.1% in India (28). The mean hospital stay (6.07 days) was under 7 days in 91.4% of patients, similar to Aggarwal et al.'s finding (19). This shorter stay has important implications for resource utilization and healthcare costs.

Patient acceptability: The high satisfaction rate (87.1% satisfied, 11.4% very satisfied) indicates strong patient acceptability. No patients reported adverse effects requiring device removal, and zero complaints at 2- and 6-week follow-up suggest excellent tolerance. This contrasts with Ramanathan et al. who found 1.3% mild infections at six weeks despite prophylactic antibiotics (14). The absence of infections in our study may reflect the device's sterile, prepackaged design and standardized antibiotic protocol.

Provider acceptability: Healthcare providers universally perceived S-Condom-UBT favorably, citing its secure locking mechanism, high-capacity fluid intake, sterility, prevention of displacement, and minimal blood loss. The elimination of manual preparation was particularly valued, as improvisation could delay treatment by 15–20 minutes during emergencies. This aligns with Natarajan et al.'s finding that 87% of UBT insertions in Sierra Leone were performed by lower-level practitioners after minimal training (16). Our qualitative findings extend this by identifying specific design features (secure locking, one-way valve, preassembly) that enhance usability. Providers identified several facilitators for adaptation: the device's life-saving potential, simplicity, and adaptability to low-resource settings. Barriers included occasional resistance during fluid insertion and early leakage issues, which were subsequently resolved through manufacturer collaboration. This highlights the importance of ongoing quality assurance and responsive supply chains.

Recommendations for broader implementation included: (1) annual refresher training to maintain competency, especially for new staff; (2) peripheral deployment with comprehensive training to improve access in underserved areas; (3) enhanced device availability through government supply chains; (4) affordable pricing considering economic constraints; and (5) package improvement including a 50-cc syringe and quality assurance protocols.

These recommendations align with the WHO's emphasis on strengthening health systems for PPH management (13). The training model used in this study, where master trainers passed knowledge to unit-level staff, proved effective and could be replicated nationally. The shift from manual assembly to preassembled devices reduced provider stress during emergencies, enabling faster response and potentially better outcomes. S-Condom-UBT offers several advantages over commercial devices like the Bakri balloon. At less than 5 USD compared to 250–400 USD, it is dramatically more affordable (20). The 100% success rate in our study compares favorably with Bakri balloon success rates of 71–100% reported in various studies (25). The prepackaged, preassembled design addresses sterility and time concerns associated with improvised devices, while maintaining the low cost that makes it accessible in resource-limited settings.

Strengths and Limitations

Strength: This is the first mixed-methods study to comprehensively evaluate feasibility, acceptability, and adaptation of a prepackaged condom UBT device in Bangladesh. The inclusion of both quantitative clinical outcomes and qualitative provider perspectives provides complementary quantitative and qualitative evidence. The involvement of providers at all levels (registrar to trainee) enhances generalizability. The 2- and 6-week follow-up provides important data on long-term safety.

Limitation: The sample size (70 patients) was limited by the feasibility constraints of the study setting; however, the precision achieved ($\pm 5.2\%$ around the primary outcome) was acceptable for this exploratory feasibility study. The study was conducted at a single tertiary care center, which limits generalizability to other settings such as primary or secondary health facilities. Furthermore, women with advanced hypovolemic shock were excluded, potentially introducing selection bias and limiting applicability to the most severe PPH cases. Visual estimation of blood loss may have introduced measurement error. Telephone follow-up may have introduced information bias, though trained physicians conducted calls to minimize this. The absence of a comparison group limits causal inference. While no major adverse events occurred, the sample size may not detect rare complications. The occupation subgroup comparison should be interpreted with caution due to the very small number of participants in the "Others" category ($n = 2$). Preparation time prior to device insertion was not quantitatively compared with control UBT; therefore, the time-saving effect of pre-assembly could not be directly estimated. Patient satisfaction assessed before discharge may have been influenced by courtesy and social-desirability bias. Provider interviews were conducted among users from a single institution and may therefore overrepresent favorable experiences.

Implications for Policy and Practice

The findings have important implications for PPH management in Bangladesh and similar resource-limited settings. The high success rate, rapid bleeding control, favorable safety profile, and low cost of S-Condom-UBT support its consideration for broader integration into PPH management programs. While condom UBT is already recommended as a second-line intervention in Bangladesh, clearer guidance on standardized device specifications, procurement, quality assurance, and monitoring may facilitate consistent implementation. The high success rate suggests that universal access to this device could significantly reduce PPH-related mortality, helping Bangladesh achieve SDG target 3.1 (reducing maternal mortality ratio to 70 per 100,000 live births) (29). Further multicenter implementation studies, particularly in secondary-level facilities, are warranted to assess feasibility, safety, and effectiveness across diverse settings.

At the facility level, S-Condom-UBT should be readily accessible in labor wards, operating theaters, and emergency obstetric care units as part of comprehensive PPH preparedness. Its preassembled design may facilitate rapid deployment during obstetric emergencies and reduce the need for device preparation or improvisation. Scale-up should be accompanied by standardized hands-on training,

competency assessment, refresher training, and inclusion of obstetricians, medical officers, nurses, and midwives.

The implementation experience also highlights the importance of strengthening supply-chain and quality-assurance systems. Practical improvements, including provision of an appropriately sized syringe and clear illustrated instructions with the device, as well as mechanisms for reporting and addressing device-related concerns, could further improve usability and reliability. Together, these measures could support safe and sustainable integration of S-Condom-UBT into routine PPH care.

Future research directions

Future studies should: (1) conduct a randomized controlled trial comparing S-Condom-UBT with commercial devices and conventional condom UBT; (2) evaluate implementation in primary and secondary health facilities; (3) assess cost-effectiveness and health economic impact; (4) explore factors affecting long-term outcomes including fertility and future pregnancy outcomes; and (5) develop and validate training programs for scale-up.

Conclusion

S-Condom-UBT is a feasible, acceptable, and adaptable intervention for managing atraumatic PPH in resource-limited settings. Its 100% success rate, rapid time to hemostasis, high patient satisfaction, and favorable provider perceptions support its integration into routine practice. The device's preassembled, sterilized, low-cost design addresses the limitations of both commercial devices and improvised methods. Policy makers should consider nationwide deployment with comprehensive training to reduce PPH-related maternal mortality and help achieve SDG targets in Bangladesh and similar contexts.

Abbreviations

AMTSL: Active Management of Third Stage of Labor; ANOVA: Analysis of Variance; BDT: Bangladeshi Taka; CI: Confidence Interval; CMCH: Chittagong Medical College Hospital; CRF: Case Report Form; ERC: Ethical Review Committee; FFP: Fresh Frozen Plasma; FIGO: International Federation of Gynecology and Obstetrics; GDG: Guideline Development Group; icddr,b: International Centre for Diarrhoeal Disease Research, Bangladesh; ICU: Intensive Care Unit; IDI: In-Depth Interview; LSCS: Lower Segment Cesarean Section; MBBS: Bachelor of Medicine, Bachelor of Surgery; NIPORT: National Institute of Population Research and Training; PPH: Postpartum Hemorrhage; PRBC: Packed Red Blood Cells; SD: Standard Deviation; SDG: Sustainable Development Goal; STROBE: Strengthening the Reporting of Observational Studies in Epidemiology; UBT: Uterine Balloon Tamponade; VAS: Visual Analog Scale; VD: Vaginal Delivery; WHO: World Health Organization.

Declarations

Clinical trial number: Not Applicable

Ethics approval and consent to participate

The study was approved by the Ethical Review Committee (ERC) of International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) (PR-22008) and Institutional Review Board (IRB) of Chittagong Medical College Hospital, Chattogram, Bangladesh. Informed written consent was obtained from all participants. An independent Data Safety Monitoring Board oversaw the research and reported no adverse events. All data were anonymized and stored securely. All procedures were performed in accordance with the Declaration of Helsinki. Written and verbal informed consent was obtained from all respondents before any data collection.

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Competing interests

The authors declare no competing interests.

Data sharing statement

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request, subject to institutional data sharing policies and ethical approvals.

Author contributions

TK, SA, MZN, and QN conceptualized the study and designed the methodology, with TK and MZN leading the formal analysis, and writing of the original draft, while SA, ST, SA, SC and QN provided supervision and critical review. SA & QN supervised the research process and participated in reviewing and editing the manuscript. All authors read and approved the final version of the manuscript.

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Use of Artificial Intelligence

AI-assisted tools were used exclusively for language editing and structural refinement. No AI was used for data analysis or interpretation. The authors conducted all analyses and take full responsibility for the

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Figures

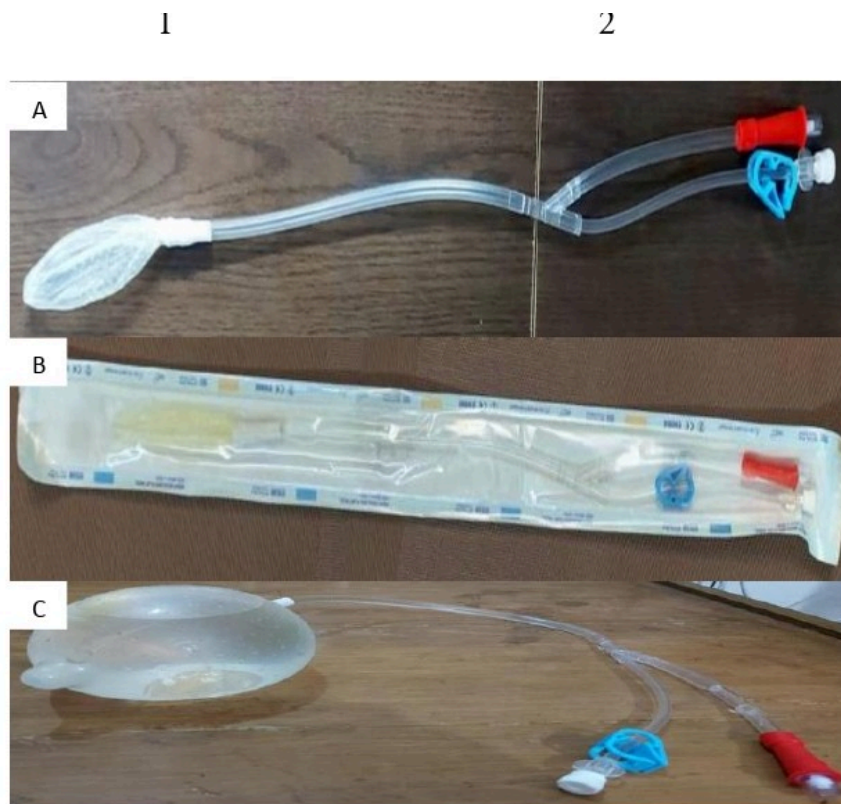


Figure 1: S-Condom-UBT structure; A.1) Male condom is fitted with a catheter/tube, A.2) One-way valve through which saline can be pushed and not get returned (No need of additional tying), A.3) Another valve to drain saline; B) Prepackaged, preassembled S-Condom-UBT; C) S-Condom-UBT after inflation with saline

Figure 1

See image above for figure legend.

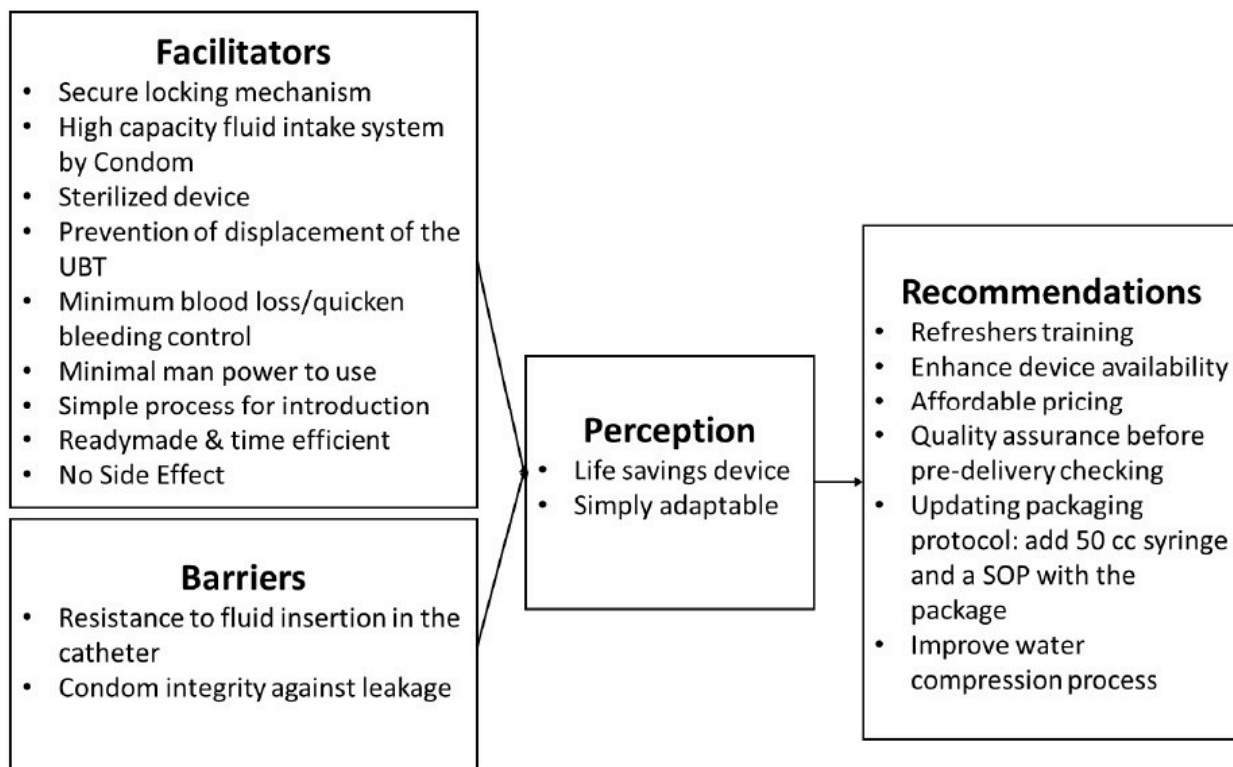


Figure 2: Framework to explore the acceptability and adaptation of S-condom device among Health Service Providers

Figure 2

See image above for figure legend.

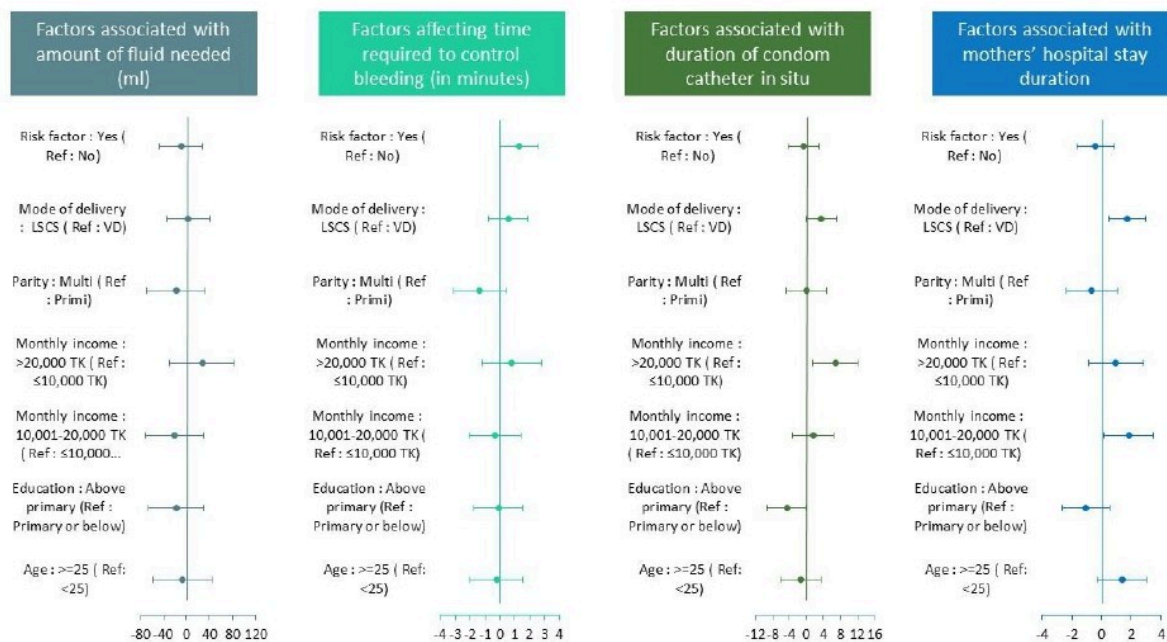


Figure 3: Forest plot of factors associated with amount of fluid needed (ml), time required to control bleeding (in min), duration of condom catheter in situ and mother's hospital stay duration

Figure 3

See image above for figure legend.

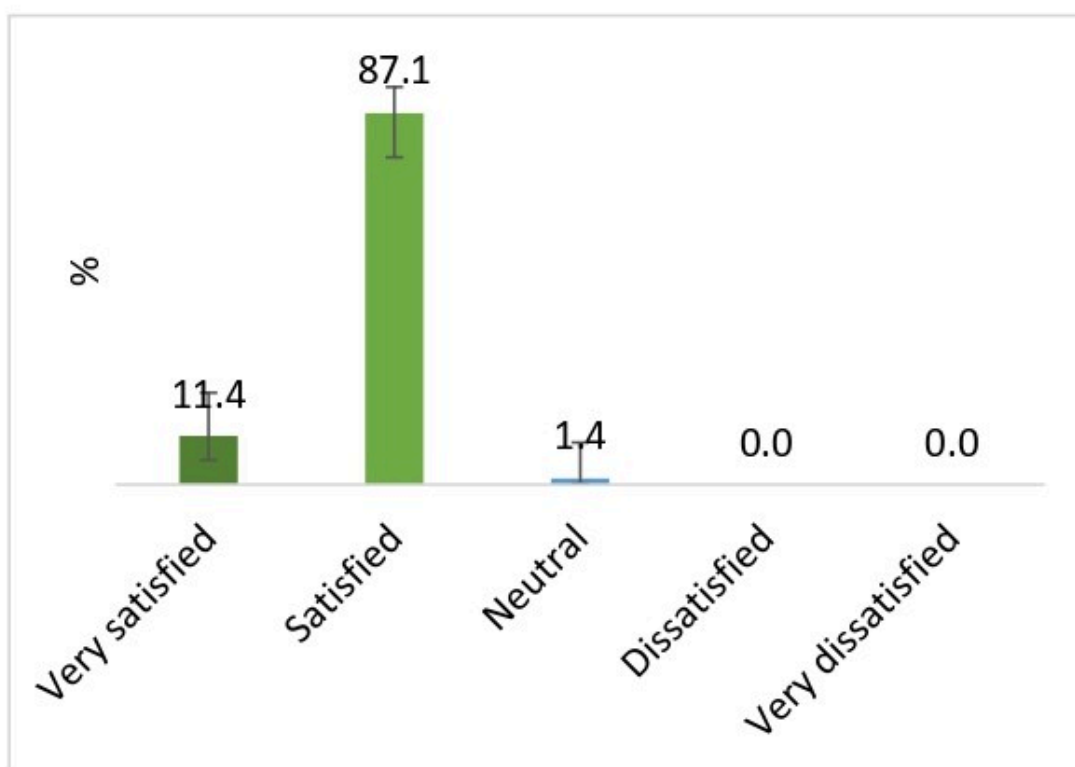


Figure 4: Mother's satisfaction levels with S-Condom UBT use

Figure 4

See image above for figure legend.

Supplementary Files

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