Journal of Women's Health Care
ISSN: 2167-0420

Tort et al., J Women's Health Care 2013, 2:4
DOI: 10.4172/2167-0420.1000135

Research Article Open Access

A Randomized Controlled Trial to Test the Effectiveness of Intrauterine Balloon Tamponade with Condom Catheter in Severe Postpartum Hemorrhage Management: A Feasibility Study in Benin

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Abstract

Background: In low-resource countries, Postpartum Hemorrhage (PPH) is the leading cause of maternal mortality. Thus, it is important to identify procedures that are adapted to their situation. The intrauterine balloon tamponade was recently incorporated into the strategy to manage uterine atony. There are many types of tamponades. Among them, the condom catheter seems to be an efficient and economic intervention for the treatment of PPH in low-resource countries. However, its effectiveness has not yet undergone rigorous evaluation. Our objective is to assess the feasibility of a Randomized Control Trial (RCT) that will test the efficacy of the intrauterine balloon tamponade with condom catheter in low-resource countries.

Methods: We carried out a pilot study of an individual randomized parallel-group controlled trial (CONDOM-PPH Trial) in three health facilities representing different levels in the health pyramid in Cotonou, Benin. Women presenting postpartum hemorrhage refractory to first-line treatments after a vaginal delivery were included. The main outcomes measures were the feasibility of recruitment, acceptability of the condom catheter by clinicians, its impact on organizing care, and its tolerance among women. Data collected from interviews with clinicians, field observations, a standardized questionnaire on the women's characteristics and their treatment at inclusion, and a weekly data-collection system on facility activities and inclusion monitoring. Analysis was performed using quantitative and qualitative methods.

Results: The condom catheter is generally well accepted by clinicians. Its assembly was considered fast and easy. No side effects were reported. Over a four-month period, ten women were randomized: five in the intervention group (condom catheter + misoprostol) and five in the control group (only misoprostol). The recruitment rate was 0.3% of vaginal deliveries.

Conclusion: By ensuring that measures are taken to increase staff motivation, implementing a RCT is feasible in this context despite a few technical difficulties related to randomization in an emergency situation.

Keywords: Postpartum hemorrhage; Low-resource countries; Uterine balloon tamponade; Pilot study

Introduction

In low-resource countries, Postpartum Hemorrhage (PPH) is the leading cause of maternal mortality, and more than 30% of maternal deaths are attributed to PPH [1]. The risk of maternal death from PPH in developing countries is approximately 1 per 1000 deliveries [2]. Uterine atony is the most common cause of PPH and accounts for 79% of all PPH [3,4]. The management of uterine atony is well known and based on international guidelines [5]. First-line treatment includes immediate uterine massage and administration of uterotonic drugs. The second-line treatment of uterine atony includes artery embolization and surgery interventions with artery ligation or hysterectomy.

Significant variations in PPH management between countries have been observed based on the availability of resources. Uterine artery embolization is often unavailable in developing countries. Artery ligation via laparotomy and hysterectomy are the most common invasive procedures, but these interventions have high case fatality rates due to limited capacity for surgery, obstetrics, and anesthesia [6,7]. Thus, it is important to identify second-line procedures that are less invasive and better adapted to the situation in low-resource countries.

The intrauterine balloon tamponade was recently incorporated into the strategy to manage uterine atony if bleeding is not stopped by pharmacological treatments [5,8]. There are many types of tamponades. Among them, the condom catheter seems to be an efficient and economic intervention for the treatment of PPH in low-resource countries [9-14]. A latex condom is inserted into the uterus by a Foley catheter and inflated with solute. The reported success rate is 96% in a systematic review of observational studies in low-resource

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Received October 14, 2013; **Accepted** November 16, 2013; **Published** November 22, 2013

Citation: Tort J, Hounkpatin B, Popowski T, Traore M, Bodin C, et al. (2013) A Randomized Controlled Trial to Test the Effectiveness of Intrauterine Balloon Tamponade with Condom Catheter in Severe Postpartum Hemorrhage Management: A Feasibility Study in Benin. J Women's Health Care 2: 135. doi:10.4172/2167-0420.1000135

countries, and this could reduce the risk of invasive procedures [9-11]. However, its effectiveness has not yet undergone rigorous evaluation, and, according to World Health Organization, research on this subject should be a priority [5].

The implementation of a Randomized Controlled Trial (RCT) to assess the effectiveness of the balloon tamponade in developing countries presents several issues, particularly the recruitment rate and the acceptability and tolerance of this intervention.

The objective of this pilot study in Benin is to assess the feasibility of a larger trial that will assess the efficacy of the intrauterine balloon tamponade as a non-pharmacological treatment of uterine atony in low-resource countries.

Materials and Method

Study design

We carried out a pilot study of an individual randomized parallel-group controlled trial (CONDOM-PPH Trial). A woman presenting uterine atony resistant to oxytocin was the unit of randomization.

Participants and settings

All women who gave birth in one of the three selected facilities between 18 October 2012 and 28 February 2013, who presented immediate postpartum hemorrhage refractory to first-line treatment (uterine massage and oxytocin) following a vaginal delivery and who gave their consent were included in the study and randomized. Women who delivered by cesarean section, presented a contraindication or known allergy to prostaglandins or latex, or presented clinical chorioamnionitis or primary hemorrhage caused by cervical-vaginal lacerations, a uterine rupture, or a placenta accreta were excluded.

Characteristic	A Teaching/ tertiary level	B Zone hospital	C Health center
Urban context (Cotonou city)	Yes	Yes	Yes
No. of maternity beds	135	30	34
No. of doctors covering maternity	10	3	1
No. of midwives	65	19	13
No. of deliveries (2012)	4500	3200	2000
Availability of basic services[a]	Yes	Yes	Yes
Availability of basic emergency obstetric services[b]	Yes	Yes	No
Availability of caesarean sections[c]	Yes	Yes	No
Availability of blood transfusion[c]	Yes	Yes	No
Availability of adult intensive care unit	Yes	Yes	No
Number of maternal deaths (2012) [d]	51	3	0
Overall rate of maternal letality/1000[e]	11.4	0.9	0

a. Reliable water supply, sanitation facilities, electricity, generator, refrigerator, telephone
b. Parenteral antibiotics, parenteral oxytocic drugs, parenteral anticonvulsants for pre-eclampsia and eclampsia, manual removal of placenta, removal of retained products (e.g., vacuum aspiration), assisted vaginal delivery (e.g., vacuum extraction, forceps)
c. Caesarean section and transfusion can be done in the facility 365 days/year, 24h/day
d. Source of information: registers of deliveries in the maternity units for year 2012
e. Number of maternal deaths among women giving birth in the facility during the same period

Table 1: Characteristics of participating hospitals.

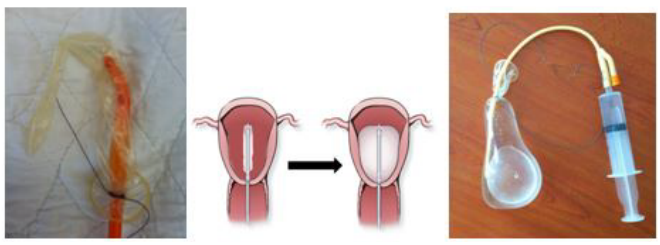

Figure 1: Assembly and insertion of the intrauterine balloon tamponade with condom catheter.

This multicentric pilot study was conducted in three public maternity units in the urban area of Cotonou (Benin). We chose three maternity units belonging to the same healthcare network. These centers' characteristics are summarized in Table 1. They represent the different levels of healthcare in Benin. The first healthcare level was represented by a peripheral facility that did not have an operating room and no obstetrician on duty at night. The intermediate level was represented by a zone hospital with an operating room and an obstetrician on duty continuously. The last level was represented by a university facility that has a maternal and neonatal intensive care unit, with an emergency team on-call 24 hours a day, including an anesthesiologist, an obstetrician-gynecologist, and two midwives.

According to guidelines from the Ministry of Health in Benin, prevention and management of PPH is carried out as follows: Active Management of the Third Stage of Labor (AMTSL) - including an injection of oxytocin, early cord clamping, and controlled cord traction- is recommended to prevent uterine atony. In case of excessive bleeding, an examination of the uterus or artificial delivery, uterine massage, and urinary catheterization are conducted and an additional injection of oxytocin is administered. After this procedure, if bleeding persists, misoprostol is administered orally or intra-rectally to the woman. Maternal resuscitation is started while these procedures are being administered.

Intervention

Two treatment strategies were compared in this pilot study. The control group received standard treatment, or a dose of five 200-µg tablets of misoprostol alone, given sublingually or intra-rectally. The intervention group received the same dosage combined with the intrauterine balloon tamponade with condom catheter.

The clinician assembled the condom catheter at the time it was used. This is presented in Figure 1, and the assembly steps are described in Figure 2. Kits were packaged in Benin by a local supplier and made available in each delivery room. The kits contain the necessary materials for assembling a condom catheter. Each kit cost 21,78 USD. Lists the kits' contents. Blisters containing 200-µg tablets of misoprostol were also available in addition to the kits for the randomized women in the control group (Figure 3).

A condom was placed over a Foley catheter and secured with a suture. The catheter was introduced into the uterus, and the condom was inflated in increments of 250 mL of solute using a 50 mL syringe without exceeding 1000 mL. After each increment was added, if bleeding continued after five minutes, the clinician continued filling the condom until the maximum level was reached. If successful, compresses were placed on the vaginal fornix to prevent accidental removal of the condom catheter, and the Foley catheter was clamped. The condom catheter was then held in place for six to twelve hours. This corresponds to the minimum durations found in the literature [9]. Removal of the condom catheter began by emptying half of the solution initially injected. If bleeding resumed, the condom catheter was re-inflated and held in place for two more hours. Otherwise, it

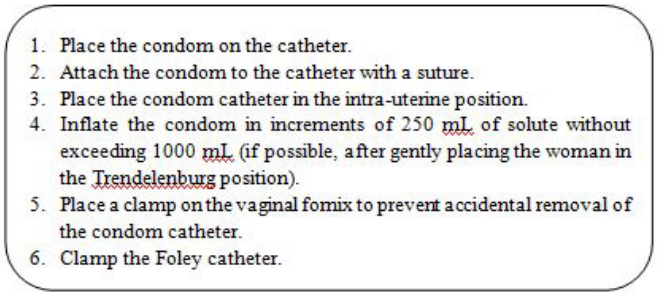

Figure 2: Steps to assemble the condom catheter device.

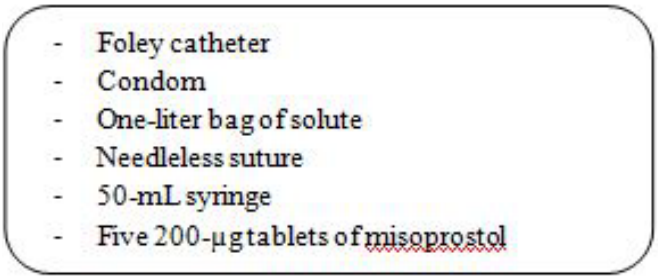

Figure 3: Contents of a kit.

was completely removed one hour later. A single dose of Cefazolin, an antibiotic prophylaxis, was recommended.

In the event of failure (continued bleeding 15 minutes after the condom was completely full), surgery was performed after removing the device.

In the control group, the treatment was considered a success if bleeding was under control 15 minutes after administration of the misoprostol. In the event of failure, surgery was performed.

Before the pilot study was launched, clinicians from the three participating centers (doctors and midwives) participated in a one-day training session on PPH management and assembling the new device. This training included PowerPoint presentations reviewing best clinical practices in PPH management and a practical workshop on device assembly. Following this, other training sessions took place in the centers so that clinicians could review the technique for assembling the condom catheter and so that new staff could be trained. A poster was also hung up in each delivery room to remind clinicians of the recommendations for PPH management.

Criteria for study feasibility

We have assessed the feasibility of the trial based on three main factors: recruitment of women in the trial, acceptability of the device among healthcare staff, and women's tolerance of the device.

The feasibility of recruiting women in the trial was assessed using the number of eligible women actually identified by the clinicians and the possibility of randomizing them in an emergency situation. Therefore, we assessed: (1) the rate of women diagnosed with PPH who were resistant to oxytocin, (2) the rate of randomized women among eligible women, and (3) the reasons why eligible women were not randomized. We implemented a weekly data collection system to identify eligible women that were filled out by the study coordinator. The collected data dealt with the number of: deliveries, cases of PPH, women who meet the inclusion criteria, women presenting at least one exclusion criterion, and errors in treatment allocation. Issues related to treatment allocation allowed us to evaluate proper administration of treatments allocated through randomization. The reasons for missed randomizations were investigated later by interviewing healthcare staff. In addition, a standardized observation notebook was filled out for each eligible woman, whether she was randomized or not.

Acceptability among healthcare staff regarding the insertion of the intrauterine balloon tamponade with condom catheter was evaluated in two stages. First, participants were observed during the initial training sessions by the instructors, and a debriefing was organized with the instructors at the end of the training to identify the main problems that participants encountered. Then, two members of the research team made several visits to each center after the start of the study to interview healthcare staff and the study's local leaders. A specific questionnaire was developed to guide the individual interviews and analyze the reactions of various factors involved in the study. A series of closed questions aided in documenting actors' perceptions about: (i) the feasibility of assembling the condom catheter; (ii) its acceptability and possible limitations; and (iii) the potential impact on the organization of care and the outcome for women.

Women's tolerance of the condom catheter was assessed based on possible treatment side effects. We specifically noted possible known side effects related to the administration of misoprostol: nausea, vomiting, diarrhea, abdominal pain, headache, chills, and fever; and those likely related to the intrauterine balloon tamponade: abdominal pain; fever, allergic reaction to latex, foul-smelling vaginal discharge, and pruritus. Other side effects could be recorded with this data collection system. In addition, a procedure for mandatory reporting of serious adverse events was implemented. It dealt with events that could cause re-hospitalization, a life-threatening situation, or maternal death. Clinical tests and diagnostic exams were analyzed to identify what caused the event. An independent Data Security and Monitoring Board (DSMB) were created to assess the condom catheter's imputability relative to serious adverse events.

These data were collected using a specific questionnaire directed at clinicians and the study coordinator, who telephoned each included woman 15 days after she was discharged from the hospital.

Outcome for the main trial

The primary outcome under consideration is the recourse to surgery interventions: uterine artery ligation via laparotomy and/or hysterectomy.

Secondary outcomes are:

- Uterine artery ligation via laparotomy

- Hysterectomy

- An estimated volume of blood loss >1000 mL

- Blood transfusion

- Maternal death

The primary and secondary outcomes were measured at the hospital. A data collection system was set up in all participating hospitals. For each woman with uterine atony refractory to oxytocin, the clinician completed a standard questionnaire that included information on maternal characteristics, prenatal care, labor and delivery, PPH management, and the mother's vital signs at the time of hospital discharge. The clinician responsible for the inclusion was paid

for each case included in the study (9.82 USD per woman). The study coordinator checked these data regularly throughout the study and transmitted them to the data manager for quality control and storage in a secure location.

The DSMB was created to perform blind interim testing if the trial is deemed feasible and implemented.

Calculating the necessary number of subjects

Knowing how many subjects are needed for an efficacy trial is critical when determining the feasibility of recruitment using the recruitment rate observed in the pilot study. This calculation is based on a conservative estimation of the expected efficacy (75%) of the condom catheter using rates reported in the literature [9]. Based on this assumption, we expect a decrease in the rate of the primary outcome of 25% in the control group to a rate of 6% in the experimental group [15]. Taking into account an alpha risk of 5% and a power of 80% for a bilateral formulation, we needed to include 51 women in each group, or a total of 102 women who presented hemorrhage refractory to oxytocin. In order to compensate for those lost to follow-up, we will increase the number of necessary subjects by 10%. Hence, we will include a total of 112 women. In this pilot study, we have included a limited number of women because we want to determine the trial's feasibility and not the efficacy of the condom catheter.

Randomization

Randomization was stratified by health center and balanced by blocks of four. For each center, the randomization results were recorded in a notebook. The study coordinator kept the three notebooks.

To randomize a woman, the clinician called the study coordinator. The identities of the woman and clinician in charge of treatment were noted in the notebook. The study coordinator was supposed to be reachable 24 hours a day.

Blinding

The clinicians, the study coordinator, and the women were not blinded with respect to randomization. Neither the clinicians nor the study coordinator were involved in the assessment of the outcome. Access to the clinical database was restricted to the data manager until the end of the study.

Analysis

The data collected each week by the study coordinator were analyzed by calculating the recruitment rate of women for the study and comparing it with the expected rate. The expected rate of cases of PPH resistant to oxytocin is 0.3% of vaginal deliveries. Thus, among the women exposed to preventive treatment for uterine atony (AMTLS), 3% will present PPH, among whom 10% will be resistant to first-line treatment [15]. The potential recruitment rate was calculated by dividing the number of eligible women by the number of vaginal deliveries. The actual recruitment rate is the number of eligible and randomized women divided by the number of deliveries.

We have compared the characteristics and treatment of eligible randomized and non-randomized women, based on standardized questionnaires, using non-parametric tests, given the low numbers. The standardized questionnaires for eligible and non-randomized women were filled out by the study coordinator and the clinicians, respectively, using information contained in the medical records and delivery registers. For the randomized women, we have calculated the rate of missing data for essential variables: age of the women, obstetric history, how labor started and its duration, prevention of PPH, the estimated volume of blood loss, the cause of PPH as well as pharmacological and surgical treatment of PPH.

Data collected from the semi-directed interviews with clinicians and the observation notes collected in the field were analyzed using a qualitative approach to study professionals' perceptions and how the organization of healthcare services in adapted when introducing the condom catheter, which had never been used in the three participating centers.

Data on side effects underwent detailed qualitative analysis to detect the onset of anything untoward during the observation period that would be defined as an adverse event.

Ethical aspects

The protocol for this feasibility trial was approved by the Ethics Committee of Benin. The women were informed before the inclusion, and the midwife caring for them when PPH was diagnosed obtained their verbal consent. Whenever possible, the women were informed about this study during prenatal consultations in the centers. In case of severe hemorrhage requiring emergency care that made it impossible to inform the woman and obtain her consent, consent was obtained from the women's present family members. Once the women's condition was stabilized, she was given the information sheet, and her written consent was obtained. This specific procedure, adapted to emergency situations, was validated by the Ethics Committee of Benin. The woman received a copy of the consent form, and the study coordinator received and logged in a copy.

Results

Figure 4 presents the flow of women. Some 3279 vaginal deliveries were reported in the three participating centers during the study period. Some 35 women diagnosed with PPH were reported; among these, it was stopped by the first-line treatment for only one of them. Among the remaining 34 women, 17 were excluded due to unsutured cervical-vaginal lesions. Among the 17 women eligible to participate in the study, 10 (58%) were randomized and 7 (42 %) were not. Among the 10 randomized women, 5 women were randomized in the intervention group and the 5 others in the control group. As for the non-randomized eligible women, in three cases, the study was not understood; in one case, a problem with the telephone network prevented one woman's inclusion; in one case, the clinicians were not able to include a woman due to the emergency situation; in another case, the randomization process was not understood, and in the last case, the staff was not trained.

There was a protocol violation for one woman. The condom catheter was inserted in one woman from the control group.

The observed prevalence of hemorrhage refractory to oxytocin compared to the number of vaginal deliveries is 1.0% (34/3279) and higher than the expected rate (0.3%). By contrast, the prevalence of diagnosed PPH after a vaginal delivery reached 1.1% (35/3279) and is below the expected prevalence (3%).

The women were included from 18 October 2012 to 28 February 2013 and received follow-up until 14 March. The actual recruitment rate is 0.3% (10/3279) and, therefore, is equal to the expected recruitment rate (0.3%).

For the randomized women, the observation notebook was filled out quite satisfactorily, and there was no missing data for the selected variables. We did not observe a significant difference relative

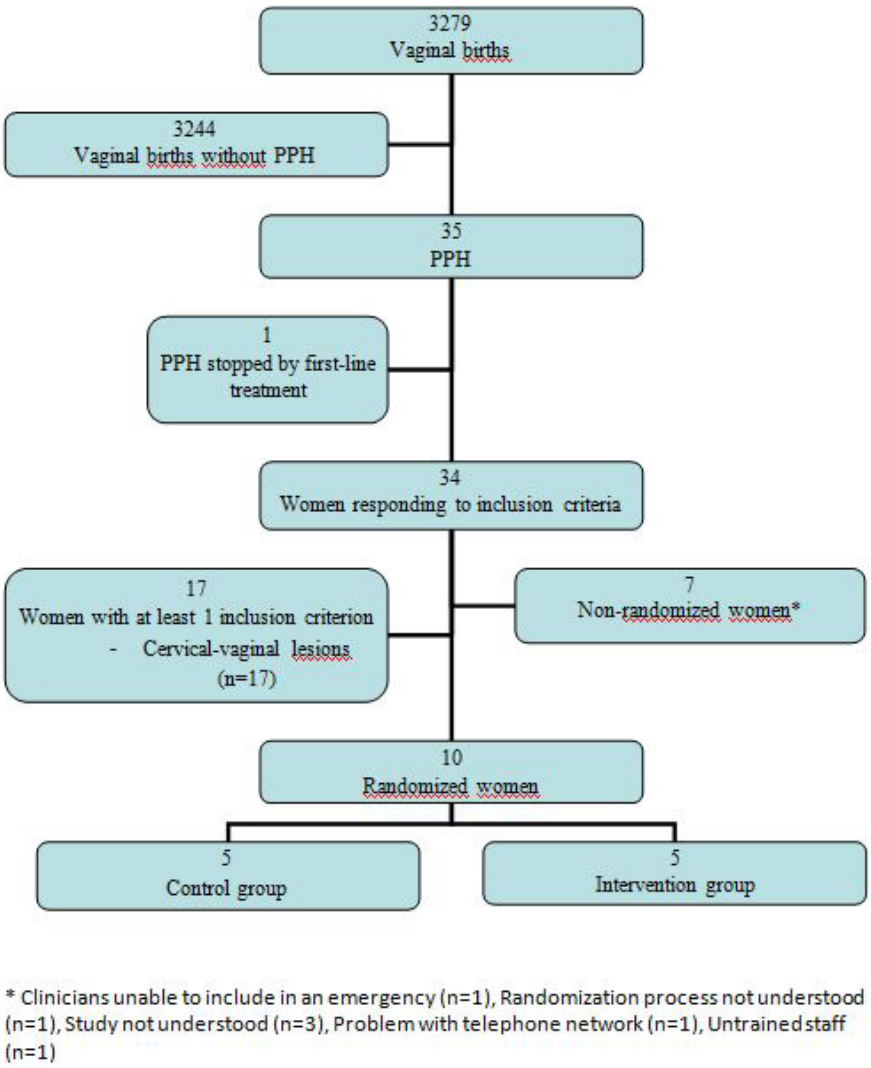

Figure 4: Flow chart.

to the characteristics or care of eligible women between the group of randomized women and the group of non-randomized women (Table 2).

The average time during which the condom catheter was left in place was 9 hours 11 minutes, and the average fill volume was 443.3 mL (Table 2).

In total, 85 healthcare staff received training (33 doctors and 52 midwives) before the study began and were observed during practical workshops. Some 19 persons were interviewed two and three-and-one-half months after the training (3, 10, and 6 in centers A, B, and C, respectively). The balloon was widely accepted by all persons. Assembly did not pose any problems, and the various parts were assembled in an average of five minutes. However, the main problem brought up by healthcare staff was the additional workload related to the randomization process, and data collection was also a frequently mentioned problem among clinicians (Table 3).

In the intervention group, chills were reported for one woman and vomiting for another after inclusion; this did not require stopping the treatment. Two women from the control group experienced chills. These events were classified as non-serious and possibly related to the use of misoprostol. Insertion of the condom catheter did not cause any pain in the five women concerned. In addition, no woman in the study was re-hospitalized following her initial treatment. No maternal deaths due to uterine atony or serious sequelae were recorded during the study period, and there was no recourse to surgical treatment (data not shown).

In the intervention group, 60% (3/5) of women received prophylactic antibiotic for the introduction of the device including ampicillin and gentamicin (data not shown). None of the women received a single dose of cefazolin as proposed in the initial protocol [15].

Discussion

Results from our multicenter pilot study show that the condom catheter is generally accepted by the healthcare teams and well tolerated by women. The recruitment rate is equivalent to what was expected, based on data from the literature [15]. However, PPH seems to have been under-diagnosed and problems were encountered in the

	Randomized n=10	Should have been randomized n=7	P value*
Age (years) Mean (SD)	27.2 (6.1)	26.0 (6.3)	NS
Parity (including current pregnancy) *I (n, %)* *II (n, %)* *>=III (n, %)*	2 (20.0) 2(20.0) 6(60.0)	1 (14.3) 3 (42.9) 3 (42.9)	NS
Delivery term (weeks' amenorrhea) *Mean (SD)*	39.0 (1.2)	38,1 (2.6) *(n=6)*	NS
No history of PPH *(n, %)*	10 (100,0)	7 (100.0)	NS
Spontaneous labor *(n, %)*			
Induced labor *(n, %)*	10 (100,0)	4 (66,7) (n=6)	NS
Preventive injection of oxytocin *(n, %)*	6 (60.0)	*7 (100,0)*	NS
Controlled cord traction *(n, %)*	10 (100.0)	6 (85,7)	NS
Estimated volume of blood loss at inclusion (mL) *Mean (SD)*	650 (259.3)	-	
Total estimated volume of blood loss (mL) *Mean (SD)*	800 (332.5)	533.4 (152.8) (n=3)	NS
Time between insertion and removal of condom catheter (hours: minutes) *Mean (SD)*	9:11 (10:04)	-	
Fill volume of condom catheter (mL) *Mean (SD)*	443.4 (234.7) (n=5)	-	

* Mann-Whitney test for continuous variables and Fisher exact test result for qualitative variables
SD=Standard Deviation

Table 2: Demographic and clinical characteristics of randomized women and those women who should have been randomized.

Barriers
Acceptability of device
• Inconsistent availability of materials necessary for assembling the device
Organization of care following introduction of the research protocol
• Study coordinator outside of facility
• Additional workload due to the study: call for randomization, data collection
Facilitators
Acceptability of device
• Condom catheter easy to assemble
• Supply kits available in delivery room
• Payment for the clinician for an inclusion
Organization of care following introduction of the research protocol
• Study coordinator in charge of randomization reachable 24 hours/day
• Telephone available in delivery room
• Communication costs covered by the project

* Barriers and facilitators that were the most frequently mentioned by the interviewed staff and local researchers in Benin.

Table 3: Identified barriers to the implementation of the study protocol BARRIERS.

randomization of women since more than 40% of eligible women were not included.

To our knowledge, this is the first pilot study that could assess the feasibility of a broader RCT that will test the efficacy of the condom catheter in a low-resource setting. Currently, all published studies on this topic are observational studies.

The maternity units that were included represent the different levels of the health pyramid in Benin and are representative of the range of technical platforms for obstetric care in this country.

The actual recruitment rate is equivalent to the expected rate based on data from the literature (approximately 0.3%) [15]. However, PPH is generally under-diagnosed. Estimating blood loss was subjective in the three health centers, and this method can lead to a lower estimation of PPH [16]. We could have introduced a collection bag in the main trial to objectively quantify blood loss. However, this practice is not common in Benin, and its introduction would be difficult to implement in the context of our study.

In addition, in our study, the first-line treatment seems less effective than what was expected. This situation could be explained by the fact that the diagnosed PPH cases were probably more serious and less sensitive to oxytocin. It is possible that initial treatment steps were not carried out. Lastly, since refrigerated storage of oxytocin is not optimal in Benin, the actual effectiveness of the oxytocin may have been reduced.

In order to recruit the 112 women necessary for the efficacy trial, a population of 34,000 vaginal deliveries would need to be targeted. Reaching this number would therefore require recruiting from other centers to include 112 women over an acceptable time period of approximately two years. Given the number of vaginal deliveries recorded during the period of our study, we should include more centers.

Over 40% of the eligible women were not randomized. In most cases, problems in understanding the study and the randomization process were also encountered. This concept was unfamiliar to the clinicians. The randomization process was explained during the initial and supplementary training sessions. We also noted that inclusion of a woman during an emergency such as PPH management is a complex procedure to implement.

To facilitate inclusion, we provided staff with a cell phone. Communication costs were covered by the project, and teams could call the study coordinator from their centers day or night. A cluster randomization where the intervention unit would be the hospital could allow for getting around the problem of randomization during an emergency.

In our study, the randomized and non-randomized eligible women were comparable, demonstrating that no selection bias should be considered.

Problems were encountered in the availability of misoprostol and the necessary materials for assembling the condom catheter in the centers. In fact, inconsistent availability of materials and medicines is a constant problem in West Africa [17]. Therefore, kits were packaged by a local supplier in Benin and made available in each delivery room. These kits helped promote acceptance of the condom catheter.

The teams found assembling the condom catheter to be quick and easy, consistent with the literature [14,18]. Some staff was hesitant about changes caused by introducing the intrauterine balloon tamponade with condom catheter. Moreover, the center's staff did not always perceive data collection and verification conducted by a study coordinator who was not on staff in a positive light. Therefore, involving the facilities' directors and disseminating memos was important to motivate the teams and ensure the trial ran smoothly.

The clinician's added workload caused by the randomization process and data collection during inclusion of a woman was also problematic at the beginning of the study. The help provided by the study coordinator in filling out the observation notebook and payment received for an inclusion might have motivated staff members. No pain or infection was reported after using the condom catheter. However, only six cases were analyzed, therefore, the scope of our study was insufficient to provide a rigorous assessment of tolerance of the condom catheter. One systematic review presenting eight studies including 193 cases of PPH treated with the condom catheter reported no cases of infection [9].

The study protocol included several measures to increase tolerance of the device. The balloon was inflated gradually in increments of 250 mL until bleeding was arrested. Average fill volume in our study was 443.3 mL, which corresponds to data in the literature [9]. If successful, the balloon was then left in place for 6 to 12 hours. The average time in our study was 9 hours 11 minutes, which was relatively low compared to data in the literature [9].

Our recommendations for antibiotic prophylaxis (single-dose injection of Cefazolin) were not followed, but 60% of women received ampicillin and gentamicin. Cefazoline was probably not tailored to the context of Benin. But we believe it will be important to reduce the duration of the tamponade to six hours in the future trial to limit the risk of infection.

Conclusion

This pilot study in three health facilities in Benin representing three different levels in the health pyramid shows that the intrauterine balloon tamponade with condom catheter is generally accepted by healthcare staff and the use of this device is well tolerated by women in low-resource countries. Even though diagnosis of PPH appears to be under-estimated and randomization of women presents some technical problems in the context of obstetric emergencies, the recruitment rate is similar to what was expected. However, our results have shown that in order to include the number of subjects needed for an efficacy trial over an acceptable time period, more health centers must be included. In the context of a low-resource setting, we should also provide the teams with kits of the necessary materials for assembling the condom catheter in order to compensate for the inconsistent availability of materials. The duration of tamponade insertion should be short to limit the risk of infection. Lastly, leadership from the heads of facilities and payment for clinicians are essential to motivating the teams.

Ethical Approval

This pilot study was approved by the Ethics Committee of Benin and the Ministry of Health of Benin.

Acknowledgment

The authors thank the heads of the maternity units, the investigators, and all the women who participated in the survey.

Funding

Funding for this research was provided by the Inter-Institute Agency of Research for Development (AIRD).

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