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CLINICAL ARTICLE

Use of uterine balloon tamponade for control of postpartum hemorrhage by community-based health providers in South Sudan

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ABSTRACT

Objective: To determine whether use of uterine balloon tamponade (UBT) for management of uncontrolled postpartum hemorrhage (PPH) by community-based providers in a resource-limited setting could be feasible, effective, and safe. *Methods:* In rural South Sudan, community providers were trained and equipped with a simple UBT device consisting of a catheter, condom, and syringe. Snowball sampling identified cases of UBT use since training. Semi-structured interviews were conducted among community providers, referral facility providers, patients, and patient family members. Interview transcripts were analyzed using qualitative methods. *Results:* Thirteen cases were identified and 24 interviews related to community-based UBT use were conducted. Qualitative analysis revealed several major themes. Community providers applied UBT in appropriate clinical situations. UBT was effective for controlling PPH, even among severely ill patients. Referral was difficult and lengthy owing to the austere setting, but simple UBT appeared to mitigate these challenges. Communities had some initial fears, yet ultimately embraced UBT. Equipment and supplies were largely maintained. There was universal satisfaction with UBT among patients, family members, and providers. One death occurred among the 13 cases, although it was probably not attributable to PPH. *Conclusion:* Training and UBT device provision are simple, affordable, and effective for managing uncontrolled PPH in a resource-limited setting.

1. Introduction

Postpartum hemorrhage (PPH) is a leading cause of maternal mortality worldwide [1,2]. Approximately one-quarter of all maternal deaths are attributable to PPH, and the vast majority of these deaths occur in low-resource countries, outside of established health facilities [3,4]. Uterine balloon tamponade (UBT) is an effective technique for managing uncontrolled PPH in high-income countries, and several studies have also illustrated its usefulness among facility-based providers in resource-constrained areas [5,6]. However, little is known about the use and effectiveness of UBT for treating the larger burden of PPH among community-based providers in resource-constrained settings [7].

Uterine balloon tamponade involves placing a balloon within the uterine cavity and inflating it to achieve tamponade and arrest of bleeding. This approach can be used when PPH is uncontrolled by initial interventions such as uterine massage, administration of uterotonics, and manual uterine evacuation. Purpose-specific uterine balloons used in high-income countries for management of PPH can cost hundreds of US dollars each and are, therefore, prohibitively expensive for resource-limited settings [6,8]. Uterine balloon tamponade using a simple condom–catheter device, assembled at the point of care from readily available supplies, has been used as an inexpensive and effective alternative [9–11].

Beginning in 2010, in partnership with the Ministry of Health of the Republic of South Sudan, UBT training and device provision were included as part of a countrywide best-evidence package intervention for frontline health workers in South Sudan known as the Maternal, Newborn, and Child Survival (MNCS) initiative [12,13]. South Sudan has the worst maternal mortality in the world, and more than 90% of deliveries occur among community-based, unskilled birth attendants outside of health facilities [14,15]. Birth settings are so austere that a facility with an operating theater is frequently more than a half-day journey away. The MNCS initiative uses a best-evidence package of pictorial checklists, participatory training, and reusable equipment

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and commodities. To date, the program has trained and equipped more than 800 community-based health workers throughout South Sudan to identify, manage, and refer the leading causes of mortality among mothers, newborns, and children.

To determine whether introducing UBT for the management of PPH by community-based providers in a resource-limited setting could be safe and effective, a qualitative research study of UBT use among MNCS-trained providers in South Sudan was conducted.

2. Materials and methods

As part of the MNCS initiative, community-based providers were equipped with and trained in the use of a uterine condom balloon (UCB) for uncontrolled PPH (Fig. 1). Most trainees were non-literate, unskilled birth attendants such as traditional birth attendants and community midwives. Training included description, demonstration, and practice sessions with the UCB. In addition, each participant was provided with a pictorial PPH checklist (Fig. 2), which guided them through the initial PPH management steps, followed by UCB placement and referral to a health facility if bleeding continued. The UCB was simple and inexpensive (less than US $5 each); it consisted of a urinary catheter, a Luer lock valve, and a condom fastened with 2 cotton string ties to the distal end of the catheter. Upon placement within the uterine cavity, the uterine balloon was inflated with clean water via repeated use of a 60-mL syringe until tamponade occurred, as evidenced by bleeding cessation. Community-based providers were trained so that, once bleeding was arrested and with the balloon in place, they referred the patient to the nearest health facility and sent an accompanying laminated referral card (Fig. 3) that explained to the receiving provider the purpose of the balloon and provided instructions for its removal.

From February 23 to March 19, 2012, approximately 1 year after initial trainings, active field-based surveillance was conducted to identify and characterize use of the UCB among the nearly 100 MNCS-trained community-based providers in Eastern Equatoria, South Sudan. Snowball sampling was used to identify study participants, beginning at first- and second-level referral facilities in the study area and tracing cases, when possible, to the referring community-based providers, patients (if surviving), and immediate family members or birth observers of patients who had received UBT for the management of PPH.

Data were collected from participants via semi-structured interviews conducted by experienced researchers and facilitated by trained local translators. Informed verbal consent was obtained from all participants. The interviews were intentionally semi-structured in order to accommodate probing of emergent topics during each interview, including UBT-related experiences, challenges, perceptions, attitudes, outcomes, survival through time of interview, and recommendations for improvements in future UBT training and device design. Ethics approval for the study was obtained from the Partners Human Research Committee (Massachusetts General Hospital, Boston, MA, USA) and the Ministry of Health of the Republic of South Sudan.

Following the completion of field-based data collection, the research team used qualitative analytic methods to examine the data [16]. The digitally recorded interviews were transcribed verbatim, and a data codebook was established by author consensus through an iterative process. All data were coded using NVivo 10 (QSR International, Doncaster, VIC, Australia).

Two experienced clinical researchers independently coded the interview transcripts, reconciled any differences in coding, and identified themes that emerged from the interviews.

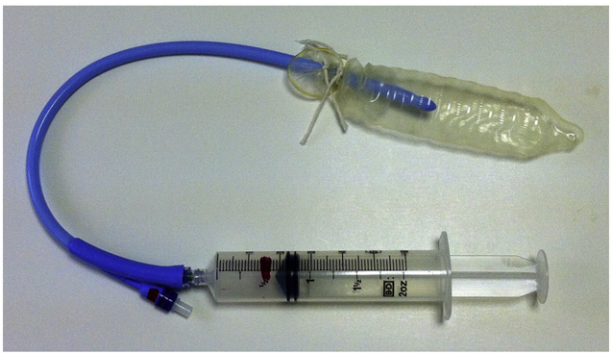

Fig. 1. Components of a simple uterine balloon. Condom, cotton string ties, catheter, Luer lock valve, and 60-mL syringe.

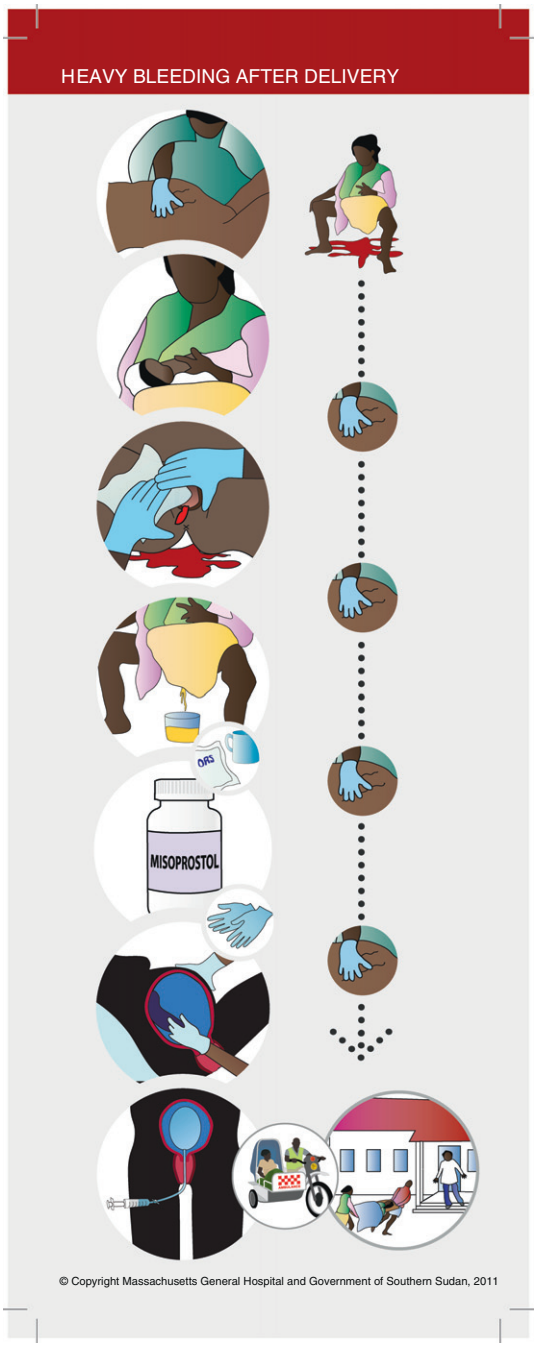

Fig. 2. Checklist for the management and referral of postpartum hemorrhage (PPH), including the placement of a uterine condom balloon for uncontrolled PPH. One of 9 pictorial checklists in the Maternal, Newborn, and Child Survival training program.

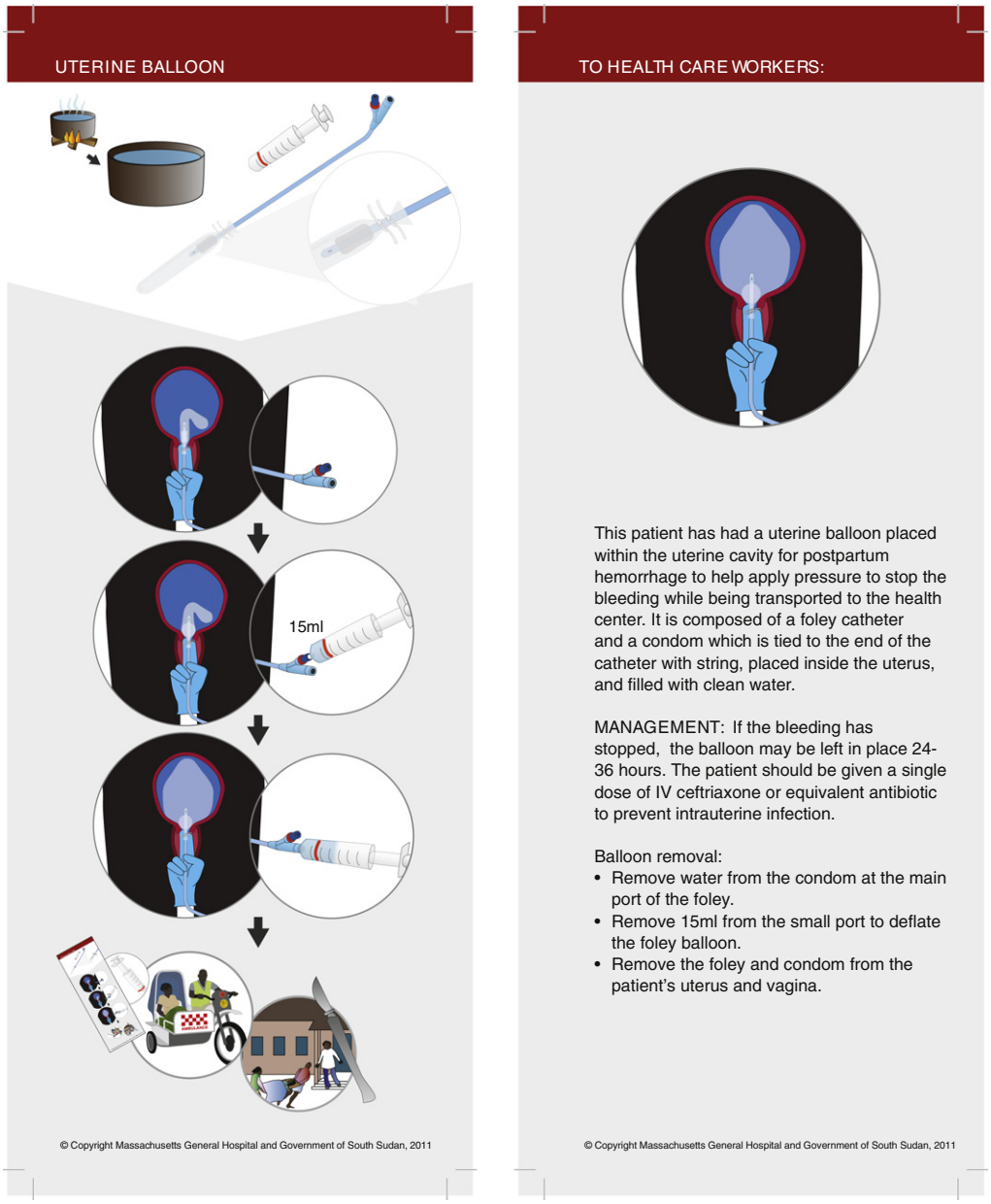

Fig. 3. Uterine balloon referral card. The double-sided, laminated card accompanies the patient to the health facility and instructs the receiving provider on the purpose, management, and removal of the uterine balloon.

3. Results

There were 24 semi-structured interviews pertaining to 13 identified cases of UCB use for uncontrolled PPH in Eastern Equatoria since MNCS training occurred. Interviewees were community-based birth attendants (n = 13), receiving facility-based providers (n = 3), patients (n = 3), patient relatives (n = 3), and other community members familiar with the cases (n = 2) (Supplementary Material S1). Qualitative analysis of the 24 interviews revealed several major themes related to UCB use by community-based providers (Box 1).

All 13 cases of PPH were identified by the community provider as uncontrolled with an indication for UCB. Although the patients receiving UCB were frequently severely ill at the time of balloon placement, 12 (92.3%) of 13 survived. The cause of death of the patient who died was probably not attributable to PPH. In this case, bleeding was quickly controlled by the UCB without complication. However, beginning postpartum, the patient showed apparent signs and symptoms of eclampsia, including headaches, seizures, unconsciousness, and eventually death. All survivors were confirmed as still alive at the time of interview (average follow-up time, 6.6 months [range 1–15 months]), and some had even had subsequent pregnancies.

Historically, communities seemed to be accustomed to mothers with PPH dying. For example, one of the providers explained that, when a mother developed PPH, the community and family members usually became resigned and acquiescent to her fate. Beyond uterine massage and removal of blood clots and placental remnants, the only reported intervention that community-based providers used for uncontrolled PPH was simply pouring more soil and ash onto the ground to help absorb the blood. However, providers felt that the UCB had significantly expanded their management options.

The UCB was applied to critically ill patients and only after initial steps on the PPH checklist failed to control the hemorrhage. Most patients receiving UCB were severely hemorrhaging (although not usually quantified) and often unconscious. Twelve of the 13 UCBs were placed at home, which is reflective of where women give birth in South Sudan.

Box 1
Key themes and illustrative respondent statements regarding community-level use of uterine balloon tamponade in South Sudan.

1. **Providers applied the uterine condom balloon (UCB) in appropriate clinical situations**
   - Patients receiving the UCB were usually severely hemorrhaging and had altered mental status or were unconscious (i.e. severe hemorrhagic shock):
     - *"One person [said], 'I believe she is dead.' Even the driver thought she was dead. I said, 'No, she is not dead.' Then I felt a pulse in the hand, it was still beating. Then I [said], 'You bring for me more water so that I [can] put in this balloon.'"*
   - Community providers attempted other postpartum hemorrhage (PPH) treatments prior to placing the UCB.
   - The pictorial checklist was a useful reminder of the steps in PPH management.
2. **The UCB was effective in controlling PPH**
   - Bleeding stopped rapidly after the uterine balloon inflated:
     - *"The woman…was in bad condition, and when she put this [uterine balloon in], it stopped bleeding. So she sent the woman to the hospital…and the woman is now alive. The woman is not dead."*
   - No recurrent bleeding or displacement of the device was reported, even during transport.
   - Those patients who were conscious during UCB placement tolerated it well and reported no pain from the UCB.
3. **The referral process was dif cult and lengthy owing to the austere setting, but the UCB appeared to overcome these challenges**
   - Time from UCB placement to arrival at a health facility ranged from half an hour to half a day.
   - Transportation was by non-governmental organization vehicle, passing car or motorcycle, or foot.
   - There was no recurrence of bleeding during transportation.
   - All referrals were initially referred to the nearest health facilities, none of which had surgical capacity.
4. **The community was initially fearful but accepting**
   - Some in the community had initial concerns with the UCB because it was new and used a condom, and they feared it might cause infertility or remain permanently:
     - *"People do not know [if] it is good or it is not, because [the uterine balloon] had not been there."*
     - *"They were thinking that the balloons will block the uterus, and inside the womb, the mother will not bear any childs anymore. It will block."*
     - *"People were afraid, they say that, 'You're going to put that thing? Is it not going to kill this mother?'"*
   - Communities' respect and trust of trained providers allowed acceptance of the UCB.
   - Once the community saw the impact of the UCB, they were no longer fearful but considered it good:
     - *"They have seen that this thing is good now because they have seen people recover."*
     - *"They have seen a person who has been helped by uterus condom and they have seen the mother is alive. So they are now agree on it, they are not refusing they say that it is good because it is helping their lives."*
   - The UCB is now changing how the community sees PPH, which was considered a feared contagious disease called "yab-yab:"
     - A community member explained, *"Somebody who had delivered and after delivered they bleed a lot she cannot go where a person on labor is."*
     - A mother who had PPH shared, *"[If] they bring [me] to the place where a lot of women give birth…it could then affect other mothers and cause PPH in other mothers."*
   - Using the term "balloon" is preferable to "condom" in many communities:
     - *"Yes, it's not a problem so long as people will continue calling it a balloon, it will not be a problem."*
5. **Equipment and supplies were available despite the resource-limited setting**
   - Providers reported no failures of the UCB device or its components.
   - Providers usually received catheters and syringes back from the referral facility and were boiling and reusing them; some health facilities had replacements available.
   - Condoms were usually available at health facilities and pharmacies.
   - Uterotonics were not available to community providers and were only rarely available in health facilities.
6. **Universal satisfaction with the UCB**
   - All providers, patients, and community members thought that the UCB was good, useful, and could save maternal lives. Providers stated:
     - *"All people really like it…Even the doctor, he commented that this is the first time to see this kind of thing…The midwives, they are really so happy about the uterine balloon because, medically, PPH is the leading cause of maternal death in our area."*
     - *"It's so good! It's so good, really. These lives of the mothers that the uterine balloon has saved…if it was not for the uterine balloon, they would have died."*
     - *"…it was helpful so much for this lady. Because since we tried other possible ways to arrest this bleeding and it would not help, now when [the balloon] was put, at last it stop the bleeding. It was so useful for the life of that lady."*
     - "*If the uterine balloon was not inserted, she wouldn't live because the bleeding would be continuously, and she would go into anemia and end up…dying."*
7. **Other suggestions for improvement**
   - Respondents reported universal satisfaction with the UCB and most had no suggestions for improvements to the device.
   - Many providers requested additional or refresher training for themselves:
     - *"[The uterine balloon] is good, and also it need even to be trained again and again and give them encouragement so that even though they don't come across those patients [with PPH regularly], they will not forget."*
   - Some providers requested also making uterotonics available for treatment of PPH.
   - There was widespread desire for training for other healthcare providers and public education of community members.

In all instances, despite little education or medical background, the community-based unskilled birth attendants placed the UCB without reported difficulty, complication, or patient discomfort. Once the balloon was inflated within the uterus, bleeding was arrested and there was neither bleeding recurrence nor inadvertent balloon displacement, even during lengthy transport over difficult terrain.

The identified cases reflected the large challenges of referral and transport common in Sub-Saharan Africa. In South Sudan, even first-level referral facilities can be hours away along dirt roads that are, at times, impassable; furthermore, transportation can be expensive, requiring the sale of a valuable family asset such as a cow. Almost no transport occurs after dark because of safety concerns. Within the present study, transportation of patients after UCB placement at home was achieved by private motorcycle, passing vehicle, non-governmental organization vehicle, and even on foot. The time between placing the UCB and the patient arriving at the referral facility ranged from less than 1 hour to 6 hours. Providers who cared for patients on arrival at the referral facility were typically midwives or nurses. None of the referral facilities had surgical capabilities. However, although MNCS trainees were instructed to refer all patients immediately upon UCB placement, 5 (38.5%) women were not referred. The non-referred patients included the woman who died; the other 4 were managed to full recovery within the community. In 4 (80.0%) of the cases of non-referral, the reported reason was lack of available transportation.

Interviewees described some initial trepidation by family and community members when informed of the intention to use the UCB. Some feared the UCB simply because it was new and unknown. Part of the initial community trepidation was concern over the use of a condom, which is socially stigmatized in some rural communities in South Sudan and thought to be used only by men. Some community members were also afraid that the UCB might cause infertility in the mother or remain permanently inside the mother's abdomen.

Nevertheless, providers related that any community fears were mitigated by simple explanation of the purpose and use of the UCB. The respect the community held for a trained provider also helped allay initial worries. Several providers recommended referring to the UCB as a "balloon," thereby eliminating the word "condom."

An important community perception discovered in the interviews was the common fear and misunderstanding of PPH itself. Although there was great awareness of the problem of PPH, the majority of community members were uncertain of its cause, referring to the condition locally as "yab-yab," or a presumed contagious disease in which a mother with PPH can pass the lethal condition to other pregnant women. However, as the effectiveness of UCB in controlling PPH was witnessed by the community, interviewees stated that traditional beliefs and stigma related to PPH were improving.

Another important theme was that the simple and affordable UCB device appeared to function without difficulty and without failure of any of its component parts. Furthermore, because of limited supply lines in South Sudan, the catheter and syringe were typically returned after use to the community-based provider to be boiled and reused—per instructions on the referral card. Additional condoms could be obtained at health facilities and pharmacies. Facilities could also sometimes provide replacement catheters, 1-way valves, and syringes. However, despite these sources of supplies, several of the providers reported currently needing some replacement parts for their device.

All providers in the study reported being satisfied and pleased with the UCB device and training. Because PPH is the leading cause of maternal mortality in the area, providers stated that they were excited to have a treatment option for the management of otherwise uncontrolled PPH. They felt that the uterine balloon saved lives and that their patients would have died were it not for the device.

Nevertheless, despite the unanimous satisfaction, a small number of providers did have suggestions for improvement. For example, one of the providers asked whether the UCB design might be further simplified by having the balloon pre-attached to the catheter. Several community-based providers requested additional or refresher training for themselves and first-time training for facility-based providers. Interviewees also recommended education campaigns to address any community fears about the UCB device. Finally, several providers requested extra UCB devices and access to oral or intravenous uterotonics (e.g. misoprostol).

4. Discussion

Postpartum hemorrhage is the leading cause of maternal mortality worldwide and it is particularly devastating among the still-large number of deliveries occurring outside health facilities in resource-limited settings [1]. While the overarching goal of governments and the international community is to encourage facility-based deliveries by skilled birth attendants, many low-resource countries currently lack this capacity and report a large majority of deliveries occurring at home by unskilled birth attendants.

Options for management of uncontrolled PPH are limited in the community, where surgical interventions and transfusions are too far away to affect survival. Pharmacologic treatment with the uterotonic misoprostol is available in some countries [17]. Anti-shock garments have also been used to control hypovolemic shock and obstetric hemorrhage [18]. However, UBT is the only current community-level option for PPH source control, addressing the bleeding at its origin. Furthermore, a simple UCB comprising a condom, urinary catheter, and syringe is both affordable and scalable.

The present findings indicate that the UCB can be effectively and safely deployed by non-physicians in the community. Providers in the study were largely non-literate, unskilled birth attendants who received minimal training (less than 1 day) in UCB use. In the 13 identified cases, UBT was appropriately placed among very ill patients with significant hemorrhage, bleeding was quickly arrested, and all but 1 of the patients made a full recovery—with the single death probably not attributable to PPH. Moreover, there were no reported complications such as recurrent bleeding, UCB displacement, or serious infection. The UCB device was well received by the community providers and the receiving facility providers. There were a few initial community fears, which were readily assuaged with education, and the community also became supportive of the UCB.

Although the present qualitative study is encouraging, additional research is still needed. Such research should include more systematic methods and examine questions related to the ideal device, initial and refresher training curricula, and implementation.

The present study had limitations. It used snowball sampling among a diversity of health cadres and supervisors in an attempt to identify all instances of UBT in the study region. However, it is likely that other cases of UBT occurred in the area and were not captured in the study. Limited reporting streams, a dearth of medical records, difficulty traversing the area, and lack of access to basic communications in South Sudan constrained the detection of all cases of UBT in the region. Furthermore, only individuals associated with actual use of UBT were surveyed; providers who never had an opportunity to use UBT and those who elected not to use UBT were not targets of the study. Among study participants, social desirability bias could also have been a factor if respondents answered in a manner they thought was desired by the researchers. However, interviewers sought to minimize this bias through specific instruction while explaining the purpose and confidential nature of the study.

The present study strongly supports the conclusion that UBT is a safe, affordable, and effective intervention that can be successfully implemented among community-based, unskilled birth attendants in resource-limited settings. This can be a useful approach to addressing uncontrolled PPH at the community level—the most common reason and location women die from pregnancy-related causes in the world.

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ijgo.2013.02.017.

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Conflict of interest

The authors have no conflicts of interest.

References

[1] World Health Organization, UNICEF, UNFPA, The World Bank. Trends in maternal mortality: 1990 to 2008. http://whqlibdoc.who.int/publications/2010/9789241500265_eng.pdf . Published 2010. Accessed January 25, 2013.
[2] Khan KS, Wojdyla D, Say L, Gülmezoglu AM, Van Look PF. WHO analysis of causes of maternal death: a systematic review. Lancet 2006;367(9516):1066–74.
[3] Karoshi M, Keith L. Challenges in managing postpartum hemorrhage in resource-poor countries. Clin Obstet Gynecol 2009;52(2):285–98.
[4] Walraven G, Wanyonyi S, Stones W. Management of post-partum hemorrhage in low-income countries. Best Pract Res Clin Obstet Gynaecol 2008;22(6):1013–23.
[5] Doumouchtsis SK, Papageorghiou AT, Arulkumaran S. Systematic review of conservative management of postpartum hemorrhage: what to do when medical treatment fails. Obstet Gynecol Surv 2007;62(8):540–7.
[6] Georgiou C. Balloon tamponade in the management of postpartum haemorrhage: a review. BJOG 2009;116(6):748–57.
[7] Tindell K, Garfinkel R, Abu-Haydar E, Ahn R, Burke TF, Conn K, et al. Uterine balloon tamponade for the treatment of postpartum haemorrhage in resource-poor settings: a systematic review. BJOG 2013;120(1):5–14.
[8] Japaraj RP, Raman S. Sengstaken-Blakemore tube to control massive postpartum haemorrhage. Med J Malaysia 2003;58(4):604–7.
[9] Akhter S, Begum MR, Kabir Z, Rashid M, Laila TR, Zabeen F. Use of a condom to control massive postpartum hemorrhage. MedGenMed 2003;5(3):38.
[10] Airede LR, Nnadi DC. The use of the condom-catheter for the treatment of postpartum haemorrhage - the Sokoto experience. Trop Doct 2008;38(2):84–6.
[11] Rather SY, Qadir A, Parveen S, Jabeen F. Use of condom to control intractable PPH. JK Sci 2010;12(3):127–9.
[12] Nelson BD, Ahn R, Fehling M, Eckardt MJ, Conn KL, El-Bashir A, et al. Evaluation of a novel training package among frontline maternal, newborn, and child health workers in South Sudan. Int J Gynecol Obstet 2012;119(2):130–5.
[13] Nelson BD, Fehling M, Eckardt MJ, Ahn R, Tiernan M, Purcell G, et al. Maternal, Newborn, and Child Survival (MNCS): An innovative training package for building frontline health worker capacity in South Sudan. S Sudan Med J 2011;4(4):80–2.
[14] Sudanese Government of National Unity, Government of Southern Sudan. 2006 Sudan Household Survey. http://ssnbs.org/storage/SHHS%20Published%20report.pdf . Published 2006. Accessed January 25, 2013.
[15] Government of South Sudan, Ministry of Health. Health Sector Development Plan 2011–2015: Transforming the Health System for Improved Services and Better Coverage. http://www.gunneweg-imprint-consultants.nl/wp-content/uploads/2011/10/HSSDPL2010-2015-SOUTH-SUDAN.pdf. Published March 1, 2011. Accessed January 25, 2013.
[16] Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. Health Serv Res 2007;42(4):1758–72.
[17] Sheldon WR, Blum J, Durocher J, Winikoff B. Misoprostol for the prevention and treatment of postpartum hemorrhage. Expert Opin Investig Drugs 2012;21(2):235–50.
[18] Miller S, Martin HB, Morris JL. Anti-shock garment in postpartum haemorrhage. Best Pract Res Clin Obstet Gynaecol 2008;22(6):1057–74.