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CLINICAL ARTICLE

Provider experiences with uterine balloon tamponade for uncontrolled postpartum hemorrhage in health facilities in Kenya

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ABSTRACT

Objective: To understand provider perceptions and experiences following training in the use of a condom-catheter uterine balloon tamponade (UBT) as second-line treatment for uncontrolled postpartum hemorrhage (PPH) in health facilities in Kenya. **Methods:** As part of a qualitative study, interviews of facility-based providers who had managed PPH following comprehensive PPH training were conducted between February and April 2014. Facilities were purposively sampled to represent a range of experience with UBT, facility size, and geography. Interviews continued until thematic saturation was achieved. Interview transcripts were analyzed for themes. **Results:** Overall, 68 providers from 29 facilities were interviewed, of whom 31 reported experience with UBT placement (25 midwives, 2 clinical officers, 4 medical officers). Qualitative analysis revealed several major themes. Providers used UBT appropriately within the PPH algorithm, although the timing and clinical severity of patients varied. UBT was most commonly used when bleeding was unresponsive to uterotonics, hysterectomy was unavailable, and referral times long. Providers reported that bleeding was arrested following UBT use in all except one patient, who had a suspected coagulopathy. Most providers described UBT as technically easy to use, although three described initial balloon displacement. **Conclusion:** UBT has been readily accepted by providers at all levels of training and is being incorporated into the existing PPH management algorithm in Kenya. © 2015 International Federation of Gynecology and Obstetrics. Published by Elsevier Ireland Ltd. All rights reserved.

1. Introduction

Postpartum hemorrhage (PPH) remains the leading cause of maternal mortality worldwide [1]. The burden of PPH is most significant in Sub-Saharan Africa, where 33% of maternal deaths are attributed to PPH [2]. In Kenya, the maternal mortality ratio is estimated to be 488 maternal deaths per 100 000 live births [3], so the number of deaths due to PPH is high.

The 2012 WHO recommendations for second-line therapies for PPH uncontrolled by uterotonics include the use of mechanical interventions such as balloon tamponade, compression sutures, artery ligation, uterine artery embolization, and hysterectomy [4]. However, in resource-poor settings—where most of these measures are unavailable or unacceptable, and few professionals have the necessary level of training—a condom-catheter uterine balloon tamponade (UBT) represents a simple, minimally invasive, and rapid approach to stop bleeding as a primary endpoint or as a temporary measure until higher-level care is reached [5].

A systematic review of UBT use in resource-poor settings concluded that it can be effective in the management of uncontrolled PPH [6,7]. However, most cases in which UBT was used were in tertiary hospitals in Asia and Africa that had highly trained health professionals [6–9]. Thus—considering that most women in low-income countries deliver in peripheral facilities where access to surgery, blood, and advanced care is limited—the use of UBT at primary health facilities by lower-level providers could have a significant positive impact [10,11].

Few studies have investigated the feasibility of implementing UBT in peripheral facilities with lower-level health providers. Specifically, questions regarding the appropriate use of UBT within the PPH management pathway, a provider's ability to insert the balloon, and challenges to effective uptake remain unanswered. The aim of the present study was to address these questions by assessing providers' experience with PPH management following a comprehensive PPH training package including UBT use in Kenya.

2. Materials and methods

A qualitative study was conducted in the context of an ongoing research project examining the safety and effectiveness of UBT use in Kenya. A PPH package of training, commodities, and job aids/checklists

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(named Every Second Matters for Mothers and Babies–Uterine Balloon Tamponade [ESM-UBT]), incorporating current standards from WHO and the International Federation of Gynecology and Obstetrics, was developed by Massachusetts General Hospital in close collaboration with the Ministry of Health of Kenya and Kisumu Medical Education Trust, a Kenyan nongovernmental organization [4,12,13]. Trainees were instructed to use a UBT within the context of the established Kenyan national protocol for PPH, including active management of the third stage of labor (prophylactic oxytocin and/or misoprostol, fundal massage, and controlled cord traction) and basic PPH management (emptying the bladder, identifying and treating tears, manual removal of the placenta and retained products, and administering treatment uterotonics). These interventions, along with repeated doses of uterotonics and other resuscitation measures, were to occur before UBT placement—i.e. the UBT was to be used as a rescue device.

Prior ESM-UBT implementation targeted providers from facilities at all levels of the healthcare system. Most facilities in Kenya underwent training in 2013. For the present study, a two-step purposive sampling method was used to identify health providers for inclusion to ensure coverage of the domains salient to the research question. From February 1 to April 30, 2014, approximately 6–12 months after the initial facility training, health facilities representative of geographic regions, facility level and type, delivery volume, and UBT use were sampled. Specifically, facilities were included if deliveries were actively conducted, over 85% of the providers were trained in ESM-UBT, and cases of PPH had been managed since the training. Leaders of the included facilities were then asked to identify all health providers on duty at the time of a visit who had been trained in ESM-UBT, actively conducted deliveries, and had treated cases of PPH since undergoing ESM-UBT training. Health providers on duty who met these criteria were invited to participate in the present study. Providers were interviewed until theoretical saturation was achieved. Informed verbal consent was obtained from all participants. Ethical approval for this study was obtained from the Partners Healthcare Human Research Committee (Boston, MA, USA), Maseno University Ethics Review Committee (Maseno, Kenya), and the Ministry of Health of Kenya.

Participants then underwent semi-structured interviews regarding provider management of PPH since ESM-UBT implementation at the selected study facilities. Their responses were documented using a standard interview guide. Interviews began by collecting general data from the provider, including the number of monthly deliveries and number of PPH cases managed since training. Participants were then asked, “Since the training, please describe the specifics of the most recent case of PPH you managed.” Specific probes concerning the details of management of up to the most recent three cases of PPH were asked to understand whether PPH management was performed in accordance with training and whether UBT was used appropriately within the training algorithm. Providers who had used the UBT were asked about their experiences related to the training as well as in implementing the ESM-UBT package.

All interviews were voice-recorded and transcribed. Two researchers (A.N. and J.C.) independently analyzed the data using NVivo10 software (QSR International, Doncaster, VIC, Australia). After first-pass independent analysis and code development, both researchers agreed on major codes. Following review of the interview data, provider comments were organized into three broad domains: management of PPH since ESM-UBT training, experiences with the ESM-UBT device, and challenges to the uptake of the ESM-UBT training package and device. Within each domain, themes that elucidated participant perspectives were developed.

3. Results

Overall, 68 providers from 29 facilities in six counties in Kenya were interviewed, of whom 31 reported experience with UBT placement since training. Most of the health facilities were lower-level facilities (Table 1). Among the 68 interviewed providers, 58 (85%) were nurse-

Table 1
Characteristics of sampled health facilities (n = 29).

Characteristic	No. (%)
Lower-level facilities	19 (66)
Health center	7 (24)
Dispensary/Medical clinic	10 (21)
Maternity home	2 (7)
Higher-level facilities	10 (34)
Private hospital	4 (14)
Subdistrict government hospital	2 (7)
District government hospital	2 (7)
Provincial general government hospital	2 (7)
Facility ownership	
Private	15 (52)
Kenya Ministry of Health	11 (38)
Faith based	3 (10)
Use of uterine balloon tamponade	
Yes	21 (72)
No	8 (28)

midwives, 5 (7%) were clinical officers, and 5 (7%) were medical officers. Among the 31 providers who had used a UBT for uncontrolled PPH, 25 (81%) were nurse-midwives, 2 (6%) were clinical officers, and 4 (13%) were medical officers. The major themes from the qualitative interviews are reported in [Supplementary Material S1](#).

Interviewed providers reported that, in the period subsequent to the ESM-UBT training, PPH unresponsive to uterotonics was a rare occurrence. Of the PPH cases discussed in the 68 interviews, providers most commonly diagnosed PPH as a result of uterine atony, followed by tears and retained tissue. Providers reported that most of the PPH cases that they had managed resolved with uterotonics or cause-specific management of PPH (i.e. repairing a tear or evacuating the uterus). In cases of PPH for which a UBT was not used because bleeding was minimal or resolved with treatment uterotonics, nearly all providers indicated that they would have used the balloon if the bleeding had continued.

In 30 of the 31 cases of UBT use described, providers reported using the device within the PPH management algorithm as a second-line treatment following assessment of addressable causes of PPH and administration of multiple doses of uterotonics. However, providers reported variation in both the timing and clinical condition of the patient when UBT was utilized. The balloon was inserted in patients with a wide range of clinical severity, from those who were clinically stable to those who displayed signs and symptoms of severe shock. A common theme was that providers placed the UBT when they perceived that patients were clinically deteriorating, as opposed to waiting for a set amount of time to elapse or following a specified quantity of blood loss. Providers who had successful first-time experiences with the UBT reported their inclination to repeat its use, often earlier in the PPH management algorithm (e.g. concurrent with uterotonics) as a means of minimizing blood loss.

Following insertion of the balloon, 30 providers reported that bleeding was arrested; the one provider who stated that bleeding continued described a patient who was thought to have disseminated intravascular coagulopathy and died during the transfer process. Five providers reported using the balloon in situations when they perceived that the woman's death was imminent, such as unconscious women in very remote facilities, no access to blood or surgery, and excessive bleeding after exhaustion of all treatment options (e.g. maximum uterotonic use).

The UBT device was accepted and used by a range of providers, most of whom reported that it was intuitive and easy to use, even by inexperienced providers. Despite some providers expressing concern that the device would be challenging to insert without assistance—e.g. when alone during night duty—this did not affect its use in any described case of PPH.

Seven providers from hospitals with surgical capabilities described UBT as an alternative to hysterectomy. In two cases, providers reported

the use of UBT instead of hysterectomy in situations when the anesthesiologist declined hysterectomy because of the patient's deteriorating clinical condition and/or lack of blood. Two providers described the use of UBT in bleeding mothers who declined blood transfusion because of religious objections. Further, two providers described using the UBT in young women who desired fertility preservation and who would have otherwise received a hysterectomy.

In terms of technical difficulties associated with UBT use, three providers experienced challenges with balloon displacement, either in the facility or on route to a referral facility. In two of these cases, the balloon was rapidly replaced and the bleeding stopped. Although the precise etiology and circumstances of displacement were unclear, providers hypothesized that excessive blood flow and voluntary pushing by the patient were contributing factors.

Although initial UBT training recommends that peripheral facilities refer patients to higher levels of care following UBT placement, 27 of the 31 providers opted against referral when UBT placement resulted in bleeding cessation. Of the providers who did transfer patients, the most common reason was the requirement of a blood transfusion. Only one provider transferred a patient (who ultimately died from disseminated intravascular coagulation) because of persistent bleeding. Another theme that emerged among providers in lower-level facilities was the utility of the balloon in situations when poor road infrastructure, limited access to vehicles, and long referral distances created significant barriers to timely interfacility transfer.

Provider comments identified institution-, training-, and patient-related challenges to the uptake of the ESM-UBT training package. For example, facilities with very low delivery volumes were described as unlikely to encounter cases of uncontrolled PPH frequently enough to maintain competency. Furthermore, ESM-UBT was instituted within the facilities mainly by training sessions, word of mouth, and on-the-job training. The duration and extent of training varied from half-day standardized training with extensive practical skills development to more informal training conducted by the person who attended the initial training. High staff turnover and the need for frequent retraining also emerged as a challenge to ensuring that all members of the facility were trained on ESM-UBT.

Although most providers stated that they were confident in their ability to use the balloon, four providers who did not have hands-on practice during their training expressed uncertainty regarding their ability to use the balloon and their inclination to rapidly refer patients during a PPH emergency.

With regard to experiences of the patients, three providers noted that their patients expressed discomfort, described as "heaviness within the uterus," following insertion of the balloon. Further, three providers discussed their experiences with patients or family members—particularly in Garissa County, a conservative Islamic region of Kenya—who were uncomfortable being treated with a device that used a condom. Nevertheless, no patients refused treatment after providers had explained the utility of UBT. Finally, although providers reported that patient follow-up was inconsistent, no providers were aware of patient complications due to UBT use.

4. Discussion

The present study shows that ESM-UBT is readily accepted by providers at all levels of training and can be incorporated into an existing PPH management algorithm subsequent to focused didactic and hands-on training. Although the use of UBT has been most extensively described in higher-level facilities among highly trained health professionals, the present results support the use of UBT by providers with significantly less training in peripheral facilities [6]. Of those interviewed, most providers (81%) who had experience in UBT insertion were nurse-midwives. With adequate training, these providers could identify appropriate indications for UBT use and easily insert the device. These

findings are consistent with studies examining the use of UBT among frontline health workers in South Sudan [11].

With the exception of one maternal death, which was probably due to disseminated intravascular coagulation, providers described that bleeding resolved following the use of UBT in all cases. Although referral to higher-level facilities is recommended following UBT use, most providers from lower-level facilities stated that the device arrested the uncontrolled bleeding and was thus an endpoint therapy, decreasing the need for referral. In higher-level facilities, the use of UBT could represent a less invasive and more rapid approach to bleeding cessation, consequently averting emergency hysterectomies and other operative interventions [14].

In Kenya, ESM-UBT has recently been incorporated into the national guidelines as a second-line treatment for PPH, subsequently being introduced into some pre-service training curricula. However, ensuring universal awareness and competence in the use of UBT at all levels of health provision will probably require a combination of pre-service training, in-service/refresher training, and incorporation into facility protocols. Ideally, such training would include a supervised practical component to increase provider confidence in using the UBT for the first time.

The present study had several limitations. Although a diverse sample of providers was purposefully included, practices at each of the facilities involved might not necessarily reflect those at other health facilities in Kenya. Furthermore, the interview-based findings were grounded solely on provider recollection, which could be potentially affected by either social desirability or recollection bias.

Although it is becoming increasingly clear that ESM-UBT can help to improve and save lives, optimal impact will require crosscutting buy-in from all sectors of the health system, as well as incorporation of UBT into existing PPH guidelines and professional training. Country-specific information on the location of most deliveries and cases of severe PPH could help to identify facilities and providers that should be prioritized for training. Well designed studies are needed to better elucidate the barriers to effective implementation and to quantify the effect of UBT on PPH-related morbidity and mortality.

In conclusion, ESM-UBT represents a promising second-line treatment for uncontrolled PPH in resource-limited settings. It deserves future consideration by maternal health stakeholders worldwide.

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.ijgo.2015.05.020>.

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Conflict of interest

The authors have no conflict of interest.

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