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Short Communication

Implementing uterine balloon tamponade (UBT) device for immediate postpartum hemorrhage management: Leveraging resource allocation and highlighting noteworthy experiences

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ABSTRACT

Background: The use of uterine balloon tamponade (UBT) devices for intrauterine packing and management of vaginal bleeding by uterine atony has shown promising results in improving the quality of care and reducing maternal mortality.
Objective: This report aims to provide an overview of progress made in implementing UBT devices in northern Cote d'Ivoire.
Material and methods: A four-year retrospective study was conducted in the North-East (163,645), North-Center (351,909), and North-West (57,983). In 2017, UBT was adopted by members of the healthcare system. Subsequently, 5 national and 32 regional trainers have been trained. The training session was a theoretical and practical program with a low simulator. UBT is a male condom tied to a urinary catheter, filled with liquid. Positive outcomes included stopping bleeding, avoiding the need for surgery, and preventing maternal deaths (MD). In 2018, 3,515 UBT devices were distributed. In 2019, monitoring tools and transmission circuits of the data were validated. In 2020, the collection of data and local manufacturing was launched.
Results: During the process, 978 health workers, mainly midwife (52.0%) and nurses (32.2%) out of the 1,295 assigned were trained. The number of trained individuals decreased from 209 in 2019 to 160 in 2020. A total of 1,715 UBT devices were locally manufactured, adding to the existing gift of 5,080 devices, with total availability of 6,795. The distribution of devices increased from 2017 to 2019 but decreased in 2020. Success rates increased from 87.3% in 2017 (365/418) to 95.0% in 2019 (556/585) and slightly decreased in 2020 to 98.0% (681/695). Adverse outcomes (144/2,193), included MD (35/2,193) and medical evacuation to the surgical center (109/2,193).
Conclusion: The implementation of UBT in northern Cote d'Ivoire successfully reduced maternal death rates caused by immediate post-partum hemorrhage (IPPH). However, to ensure sustainability, further improvements are needed, including increased monitoring, ongoing training, and device availability.

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1. Introduction

Implementation is the set of activities, methods, and procedures used to direct, execute or put into practice a plan.[1,2] This principle can be applied to the management of health services to improve the quality of care. Immediate post-partum hemorrhage (IPPH) refers to vaginal blood loss of at least 500 mL within 24 h after delivery. Severe post-partum hemorrhage is defined as abnormal blood loss of 1000 mL or more in the same time interval, with effects on maternal hemodynamics.[3–8] In Western countries, estimates of blood loss are based on the use of measuring bags, whereas in our resource-limited countries, the impact on maternal hemodynamics is given more consideration.[9,10]

Maternal mortality (MM) resulting from post-partum hemorrhages remains a major health problem in low- and middle-income countries (LMIC).[3–8,11–15] To address this issue and reduce MM, the World Health Organization (WHO) recommends new high-impact interventions,[6,7], such as the use of uterine balloon tamponade (UBT). This method is simple, effective and eliminates the need for surgical uterine compression sutures, ligation of the uterine artery, or hysterectomy.[11,12] In Cote d'Ivoire, maternal mortality ratios (MMR) have been consistently high and on the rise, increasing from 543 maternal deaths per 100,000 live births in 2005 to 614 in 2012, with IPPH as the leading cause (42.2%).[11–13,16] In response to this critical situation, a collaborative plan was developed with Harvard University (Massachusetts-USA), and technical and financial partners (United Nations Children's Emergency Fund-UNICEF, WHO), to implement the UBT device in the management of IPPH. The implementation process was initiated in the health regions of northern Cote d'Ivoire, which had high MMR.[11–13,16] This study presents on the process and tools for implementing the UBT device in an African sub-Saharan LMIC.

2. Materials and methods

2.1. Location and period of the study

Our study was conducted over four years, spanning from May 2017 to December 2020, in the northern region of Cote d'Ivoire, a country located in sub-Saharan West Africa. The choice of this region was due to its relatively high MMR. The MMR varies by region, from 67 to 203.7 in the southern regions, from 20.9 to 113.6 in the central regions, and from 83.7 to 153.7 in the northern regions, which included the North-East, Center-North, and North-West.[11,14] Before the introduction of the UBT system in the north of Cote d'Ivoire, there were 27 health districts, 16 reference maternity, and 247 first contact maternity. The healthcare practitioners in hospitals were predominantly composed of nurses (n = 939) and midwives (n = 286). Throughout the study period, there were a total of 77,094 vaginal deliveries, 76,277 live births (LB), and 173 maternal deaths recorded, representing a maternal mortality ratio of 226.8 per 100,000 LB (see Table 1).

2.2. Progression of UBT implementation

The implementation process commenced in May 2017 with a preparatory phase, during which the national authorities adopted the use of the UBT for managing IPPH. It followed the adoption by all stakeholders of a consensus to introduce the device into daily practices at all levels of the health system. The UBT device consists of a male condom tied to a urinary Foley catheter, filled with liquid, after failure to use uterotonic drugs. Key judgment criteria included assessing whether vaginal bleeding stopped or continued, if the device fell out, whether the patient needed to be evacuation to a reference center if surgery was required, or if there was any maternal death (MD).

The training session began, with the collaboration of a trainer's team of Massachusetts University. The training program aimed to train 5 national trainers (obstetricians or gynecologists of Felix Houphouet Boigny University) and 32 regional trainers. Skills were acquired via training sessions for obstetricians or gynecologists, general practitioners with obstetric skills, midwives, and nurses.

The training consisted of a theoretical program of 3 days, followed by practical sessions using low–fidelity simulators. Thereafter, a local UBT manufacturing program has been launched, with a large-scale extension of training in the various health districts. It was ultimately a question of arriving at fragmented formations on the various work sites, as well as the large-scale distribution of the UBT device. These training courses within the various health centers in the north were to be provided by regional trainers and trained health providers, to achieve cascading training.

This permitted better assessment of accomplishments and correction of shortcomings. In the presence of uterine atony, and after the failure of oxytocin and misoprostol, in a first-contact facility, the midwife had to insert the UBT device and prepare the patient for referral to a general or regional hospital if vaginal bleeding continues. During 2018, the implementation of the project enabled the acquisition and distribution of 5,000 UBT offered by the Kenyan republic, of which 3,515 devices were utilized for training sessions as well as in the management of IPPH in practice. During the same year, the monitoring and evaluation activities of the implementation process required the development of monitoring tools, in particular, notification by short message service (SMS), a monitoring sheet, and a monthly activity report sheet. In 2019, these monitoring tools as well as the data transmission circuit were validated. The data collected at the maternity facilities where IPPH was managed, were transmitted to the regional level, then forwarded by email to the National Mother and Child Health Program (NMCHP), where data were centralized. After each use of the UBT device, a notification was sent via SMS to the U-report server. From the year 2020, the NMCHP actively collected data on the use of UBT, in addition to local manufacturing of UBT devices by the national public pharmacy. This comprehensive approach aimed to strengthen the ongoing monitoring and evaluation of the implementation process.

2.3. Operational definitions

The Uterine Balloon Tamponade (UBT) consists of five elements: a 60 cc syringe, two condoms, two strings, a Foley urinary catheter N°16, and an adhesive strip. (Fig. 1). The recommended strategy for managing IPPH due to uterine atonia using UBT involves installing the device and filling

Table 1
Summary of the characteristics of health regions and their activities in 2014, the period preceding the implementation of UBT.

Data	North-Center	North-West	North-East
Number of health districts (n = 27)	11	7	9
Number of reference hospitals (n = 16)	8	4	4
Number of maternity (n = 247)	102	70	75
Number of functional operating rooms (n = 13)	6	3	4
Number of gynecologists (n = 13)	5	2	6
Number of physicians acting as gynecologists (n = 58)	14	0	44
Number of nurses (n = 286)	132	67	87
Number midwives (n = 939)	236	465	238
Number of women of reproductive age (n = 573,537)	351,909	57,983	163,645
Number of vaginal deliveries (n = 77,094)	47,617	10,564	18,913
Number of LB (n = 76,277)	47,074	10,445	18,758
Number of MD (n = 173)	91	47	35
Ratio of MD (226.8MD/100,000 LB)	193.3	449.5	186.6
Blood banks (n = 16)	10	3	3
Availability (%)			
Oxytocin	100	100	100
Misoprostol	25	25	25

LB: live births; UBT: uterine balloon tamponade; MD: maternal deaths.

the balloon with 300 to 500 cc of water. Additionally, systematic administration of uterotonics (oxytocin, misoprostol), and antibiotic prophylaxis are recommended. When removing the UBT, it was recommended to gradually deflate the balloon by 60 cc after 12 to 24 h following the cessation of the vaginal bleeding. After 24 to 48 h, the balloon is gradually deflated while closely monitoring vaginal bleeding. If the bleeding stops, the UBT is completely removed. However, if the vaginal bleeding continues despite the UBT installation, surgery intervention is required, or the patient must be transferred to a reference center.

3. Results

3.1. Data collected within healthcare facilities in northern regions of the Cote d'Ivoire

We observed a decrease in maternity and reference hospitals from 188 in 2014, to 149 in 2020. However, the number of surgical operating rooms has increased from 13 in 2014 to 13 in 2020. In 2020, there were 16 new blood banks, and 71 new obstetrician-gynecologists and hospital practitioners who acted as gynecologists-obstetricians assigned to the region. Moreover, the number of midwives also increased significantly from 286 to 415. The maternal death ratio was 193, 450, and 187 per 100,000 live births in North-Center, West-Center, and East-Center, respectively. In total, health facilities in the North included 27 health districts with 1,295 healthcare providers. These comprised 70 doctors, of which 12 were physicians and 58 were obstetricians, as well as 286 midwives and 939 nurses. The health indicators of the northern regions both before and after the implementation of the UBT are summarized in Table 1.

3.2. Data on the UBT device implementation process in northern Cote d'Ivoire

In 2020, after 4 years of the introduction of the UBT system in the health regions of the northern Ivory Coast, 1,498 health professionals have assigned to it. This corresponded to an additional workforce of 495 health workers. The training concerned 978 health workers out of the 1,498 assigned to the northern health facilities (65.3%). This population was mainly dominated by midwives (52.0%) and nurses (32.2%). The number of hospital practitioners experienced a gradual increase in the first years of implementation, 2017 (n = 236) and 2018 (n = 373), followed by a significant decrease between 2019 (n = 209) and 2020 (n = 160). In addition, just over a third of trained care providers (36.9%) were assigned to other health centers for the need to mobilize workers in the public sector. During the implementation process, 1,715 UBT devices were locally manufactured by the national public pharmacy facility, in addition to the devices acquired through cooperation with the Republic of Kenya, resulting in a total availability of 6,795 UBTs. Out of these, 3,515 UBTs (51.7%) were distributed in the northern regions of Cote d'Ivoire, either for training purposes or for use in current medical practice. The distribution of UBTs showed an upward trend with 286 distributed in 2017, 1450 in 2018, and 1086 in 2019, followed by a decrease to 693 in 2020. The results of this study show that out of 82,830 deliveries, a total of 4,199 cases of IPPH were recorded, accounting for 5.1% of the cases. Uterine atonia was the main cause of IPPH (77.2%) of which 2,193 cases were treated with UBT (67.6%). The UBT treatment achieved a success rate of 93.4% (n = 2049), with 144 cases (6.6%) showing adverse outcomes. The use of UBT demonstrated a gradual increase from 418 cases in 2017 to 495 in 2018, 585 in 2019, and 695 in 2020 (see Tables 2 and 3).

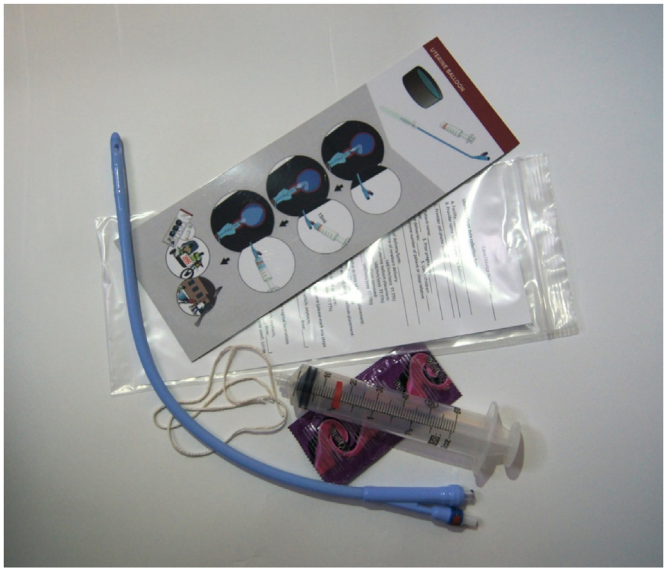

Fig. 1. Elements making up the uterine balloon tamponade (UBT) device.

3.3. UBT use impact on IPPH management

During the four years of UBT implementation, we recorded a total of 82,830 deliveries, including 4,199 cases of IPPH, accounting for 5.1% of deliveries. Out of these IPPH cases, uterine atony was treated with UBT in 67.6% of cases, corresponding to 2,193 cases. The main positive outcome of the use of the device showed effectiveness in stopping vaginal bleeding in 93.4% (n = 2,049), with a low failure rate of 6.6%. The overall success rate of UBT was remarkably high at 93.4%. The success rates of UBT utilization showed an increasing trend over the years, with rates rising from 87.3% in 2017 (365/418) to 90.0% in 2018 (447/495), further increasing to 95.0% in 2019 (556/585) and finally reaching 98.0% in 2020 (681/695). (see Table 2). However, there were 144 cases (6.6% of 2,193) where the UBT device failed to achieve its intended purpose or

Table 2
Synopsis of the implementation of UBT and main results of using UBT per year.

UBT data	2017	2018	2019	2020
Number of care providers assigned to health facilities (n = 1,498)	1,003	1,008	1,027	1,498
Physicians (n = 95)	33	65	75	95
Midwives (n = 917)	645	577	610	917
Nurses (n = 486)	235	301	342	486
Number of care providers trained (n = 978)	236	373	209	160
Physicians (n = 154)	23	65	35	31
Nurses (n = 315)	78	107	76	54
Midwives (n = 509)	135	201	98	75
Trained care providers assigned to another health facility (n = 361)	87	121	98	55
Number of functional operating rooms (n = 17)	8	12	15	17
Local UBT manufacturing (n = 1,715)	0	0	0	1,715
Number of women of reproductive age (n = 596,824)	143,306	147,554	152,979	152,985
Number of UBT distributed (n = 3,515)	286	1,450	1086	693
Number of deliveries (n = 82,830)	19,125	18,096	23,038	22,571
Number of PPH recorded in the North (n = 4,199)	830	858	1,122	1,389
PPH by uterine atony (n = 3,243)	540	662	854	1,187
PPH supported using the UBT device (n = 2,039)	418	441	485	695
Success: Stop vaginal bleeding and No transfer of patient (n = 1,941)	376	413	474	678
Success rate (%)	87.3	90.0	95.0	98.0
Failure: Maternal Death and medical transfer (n = 190)	84	56	32	18

PPH: post-partum hemorrhage; UBT: uterine balloon tamponade.

Table 3
Summary of the activities of health regions after implementation of UBT.

Data	North West				North East				North Center			
	2017	2018	2019	2020	2017	2018	2019	2020	2017	2018	2019	2020
Number of deliveries (n = 82,830)	2,556	2,154	4,567	3,256	4,245	4,499	5,857	6,049	12,324	11,443	12,614	13,266
Number of PPH(n = 4,199)	221	248	288	309	344	256	289	254	265	354	545	826
Uterine atony (n = 3,243)	132	194	239	265	187	181	237	133	221	287	378	789
Use of UBT (n = 2,193)	98	133	187	165	123	97	189	98	197	265	209	432
Favorable use (n = 2,049)	68	111	176	159	109	78	178	95	188	258	202	427
Success rate (%)	69.4	83.4	94.1	96.4	88.6	80.0	94.2	96.9	95.4	97.3	96.6	98.8
Maternal Death (n = 35)	6	4	2	1	4	3	2	1	6	4	1	1
Transferred patient (n = 109)	16	12	6	4	16	9	7	3	2	23	9	2

PPH: post-partum hemorrhage; UBT: uterine balloon tamponade.

resulted in adverse outcomes. Among these, there were 35 maternal deaths (1.6% of 2,193 cases) and 109 cases (75.7% of 2,193 cases) where patients required evacuation to another medical center for surgical intervention (see Tables 2 and 3). By comparing the maternal death rates attributed to post-partum hemorrhage (PPH) before and after the introduction of the UBT, we observed a significant decline in mortality rates. The implementation of UBT has proven effective in reducing maternal deaths caused by PPH (Fig. 2).

4. Discussion

Postpartum hemorrhage remains a significant cause of maternal mortality worldwide, especially in LMIC.[2–8,14] The introduction of the UBT device in the management of IPPH[7] has been perceived by healthcare providers as an easy-to-use, accessible, and effective method for saving lives in cases of IPPH due to uterine atony. This has led to a significant number of midwives and nurses (84.2%) being trained in its use. Additionally, the distribution of the UBT device increased notably during the first two months after its introduction.

Despite the positive aspects of the UBT implementation, several obstacles persist in its adoption and optimal use.[7,14,15] To reduce MMR, the WHO recommended the use of UBT in managing Hemorrhage due to Uterine Atony in LMIC in 2020.[6,7,14,15] The process of implementing the UBT system in the northern regions of Cote d'Ivoire spanned four years (2017 to 2020), and in this communication, we report the various stages of this process. It is noteworthy that research on the implementation of the UBT device is limited in the literature. Most studies[15–19] have been conducted in contexts where significant challenges exist for the sustainable implementation of this method, thus providing opportunities for learning and improving screening systems and approaches. Sharing experiences and best practices will contribute to our collective capacity to overcome the many challenges and ensure the long-term sustainability of the implemented programs.[20,21]

During the UBT implementation process, midwives, nurses, and doctors were significantly represented among the trained practitioners, as observed by Adegoke et al.[12] The training of healthcare professionals is a crucial factor in facilitating the adoption of innovative methods like the UBT device, whether it is through basic medical training or continuing education.[18] Interventions based on simulation and refresher courses have a greater impact on skill retention and the utilization of new medical methods.[19] The training process has played a pivotal role in strengthening and sustaining the activity, with plans to expand it nationally to address the high MMR and address the lack of medical resources.

This educational strategy, based on low-cost simulation and training, has consistently proven effective in managing PPH in low-resource environments,[20,21], as well as in handling other emergencies.[22] As the UBT device is provided free of charge, its immediate impact is expected to be an increase in its utilization and a reduction in avoidable maternal deaths due to hemorrhage. Throughout our study, we indeed witnessed a notable increase in the use of the UBT device over the four-year implementation period.

The local production of the UBT device initiated through the public pharmacy in collaboration with UNICEF, was aimed at ensuring a continuous supply of the device. The engagement of all stakeholders in the fight against maternal mortality played a crucial role in achieving these successes. One of the contributing factors to the increased use of UBT was its accessibility as a free-of-charge method. Moreover, in certain regions, UBT was often the only available option to manage IPPH, even though the technique is considered a second-line treatment and recommended for health centers equipped with a surgical unit, as advised by WHO.[6,7]

The use of UBT has demonstrated significant outcomes in certain cases, including the cessation of vaginal bleeding, reduction in medical evacuations, surgical interventions, and maternal deaths. Despite these positive results, hemorrhagic shock remains the leading cause of maternal mortality worldwide, accounting for up to 130,000 deaths annually.[21,22] This could explain the relatively low utilization of the UBT device (6.6%) in some regions, as medical practitioners tend to apply the precautionary principle when making medical decisions.[6,7,14] Concerns

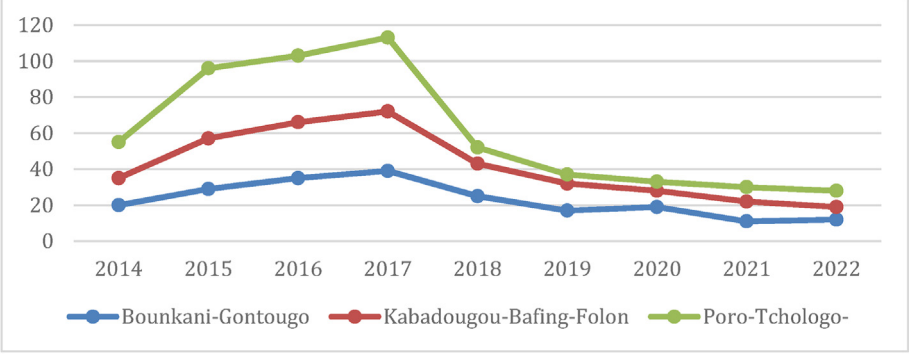

Fig. 2. Evolution of maternal death ratios caused by hemorrhage from 2014 to 2022
Note:Northeast: Boukani-Gontougo; Northcenter: Poro-Tchologo; Northwest: Kabadogou-Bafing-Folon

about the risk of bleeding resumption, lack of blood products, operating rooms, and resuscitation units have been cited as reasons for not using the device in cases of uterine atony by some practitioners.[6,7,14]

In this study, the use of the UBT device has resulted in a significant reduction in maternal deaths, attributed to its simplicity and free-of-charge nature, which has encouraged widespread adoption despite occasional stock-outs. The recent initiation of local production is a commendable effort in the ongoing struggle to reduce maternal mortality. To further enhance the positive impact of UBT, it is crucial to establish a robust monitoring and evaluation strategy for activities. This monitoring should be conducted at all levels of the healthcare system, employing simple, reproducible, and reliable tools. Regular data compilation and analysis will enable prompt access and ensure consistency in data collection.

The continuous involvement of local health authorities and trained healthcare providers is vital, particularly for providing ongoing coaching and support to new health workers assigned to these regions. Regular and frequent medical training and activity monitoring are essential to promote sustained utilization of UBT and to address barriers to its acceptance and use. This could help improve its overall use and efficiency, as some users have expressed concerns about its efficacy in managing PPH or its availability in certain districts.

Furthermore, the issue of trained health workers being transferred without being replaced by adequately trained colleagues underscores the need for continuous medical education and training. When trained health providers are redeployed to other health centers and regions without replacements, it necessitates the introduction of UBT training programs and the need for ongoing training on-site and in basic medical education curricula. In our country, some health workers may refuse assignments to regions far from the capital, leading to an imbalance in local human resources.[11–13,20,21]

Additionally, some health professionals reported not using the UBT due to concerns about the risk of bleeding resumption, unavailability of blood products, or lack of access to surgical operating rooms. Ensuring a consistent and reliable supply of the UBT device is crucial to overcome such disruptions and foster its widespread implementation effectively.

5. Conclusion

The study conducted on the implementation process of the UBT device in the North of Cote d'Ivoire demonstrates that introducing and achieving optimal adoption of new interventions is a complex endeavor. Nevertheless, this process can be regarded as a successful undertaking. The outcomes have shown a significant increase in the number of proficiently trained healthcare providers and successful utilization of the device. The primary advantages derived from this initiative include a notable reduction in medical emergency referrals, maternal mortality attributed to postpartum hemorrhage, and the need for surgical interventions. However, to ensure the long-term sustainability of the project, certain improvements need to be addressed. This includes implementing more robust monitoring and evaluation mechanisms, providing continuous training for new healthcare workers, and ensuring a steady supply of the UBT device.

Author contributions

DBM, PG, AH, EA, KVK, BA, and SK have made substantial contributions to the conception or design of the work; the acquisition, analysis, and interpretation of data for the work.

All authors have been involved in drafting the work and revising it critically for important intellectual content. They have also read and approved the final version of the manuscript to be published; and have agreed to be accountable for all aspects of the work, ensuring that any questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors have given consent for manuscript publication.

Ethical approval

The study obtained legal authorizations from the National Ethics Committee for Health Sciences and Life in Côte d'Ivoire (IRB N° 000111917) before commencing the research.

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Declaration of competing interest

The authors declare that they have no conflict of interest associated with this publication.

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