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5 April 2020

Elizabeth Maxwell

A Comparative Analysis of User Experience with Uterine Balloon Devices during Standardized Postpartum Hemorrhage Simulations

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GLOSSARY OF ABBREVIATIONS

ESM-UBT: Every Second Matters Uterine Balloon Tamponade

FDA: Food and Drug Administration

HMS: Harvard Medical School

MGH: Massachusetts General Hospital

MMR: Maternal Mortality Rate

PPH: Postpartum Hemorrhage

SD: Standard Deviation

SDG: Sustainable Development Goals

UBT: uterine balloon tamponade

US: United States

ABSTRACT

Background: Maternal mortality remains the greatest global health disparity with postpartum hemorrhage (PPH) the most common cause. Uterine balloon tamponade (UBT) devices offer a highly effective, point of care intervention that does not require complex equipment. However, there are many UBT devices on the market and few studies have compared them in clinical practice. Additionally, no studies have examined differences in user experience between devices. In cases of PPH, it is essential to have simple, easy to use equipment that can be deployed in minutes. Understanding how ease of use compares between devices is critical to informing PPH guidelines and practice.

Methods: User experience was assessed with five UBT devices by simulating emergency PPH clinical scenarios with a SynDaver pelvic model. The five devices tested encompassed a range of commercial, low-cost, and improvised devices, including: Ellavi balloon, Bakri balloon, Ebb balloon, Every Second Matters-UBT (ESM-UBT), and an improvised condom balloon. Participants placed and inflated each device in the SynDaver uterus during PPH simulations. Data collected included user subjective experiences reported via surveys and the time and number of attempts required for participants to achieve successful placement.

Results: Four key findings were drawn from this study. Firstly, Ellavi balloon was rated to be the simplest, easiest, and fastest device to use overall. Secondly, both Ellavi and the ESM-UBT, low-cost alternatives to expensive commercial devices, were found to be non-inferior with regard to ease of use and may be superior to Bakri balloon. Thirdly, the ESM-UBT was rated higher than the improvised balloon and was faster to assemble and inflate even without simulating one of the greatest differences between the devices, which is that the components for the improvised are often not readily available. Fourthly, the Ebb was fast to use but also more confusing for users with a higher rate of error. Finally, Bakri balloon was not as highly rated as expected given that it is the gold standard. It ranked fourth overall, just above the improvised device.

Conclusion: This study provides evidence that devices vary substantially in their user-friendliness and speed at which they can be assembled, placed, and inflated. Given the high cost of commercial

devices like Bakri balloon, which is approximately 100x the cost of Ellavi and ESM-UBT, and a climate of rising healthcare costs, these results suggest it may be time to consider adopting less expensive, easier to use devices that have recently come to market.

1 INTRODUCTION

Maternal mortality remains the greatest global health disparity with postpartum hemorrhage (PPH) the most common cause[1]. Hemorrhage accounts for approximately 27.1 percent of total maternal deaths[1], and more than 90% of these deaths occur in low- and middle-income countries where access to timely and appropriate treatment is limited[2]. Preventing and treating PPH is essential to meeting the Sustainable Development Goals' (SDGs) 2030 target to reduce the global maternity mortality ratio (MMR) to less than 70 per 100,000 live births[3].

Primary causes of PPH are uterine atony, uterine inversion, lacerations, retained placenta, retained products of conception and blood clots, and coagulation disorders[4]. Active management of the third stage of labor has been shown to reduce the incidence of PPH; yet, it still occurs in approximately 4% of all births[5]. Key interventions include uterotonic medications, tranexamic acid, uterine massage; and with refractory bleeding, uterine balloon tamponade (UBT), pelvic artery embolization, and surgical intervention may be necessary[4]. Rapid management is required for effective treatment, and in low-resource settings, access to timely medication or surgery is often unavailable. In these settings, UBT devices can be particularly lifesaving as they offer a highly effective, point of care intervention that does not require extensive training or complex equipment.

UBT devices arrest PPH from atonic uterus between 83% and 95% overall with nearly 100% survival among women with uncontrolled hemorrhage when a device is placed before the onset of advanced shock[6]. A recent systematic review and meta-analysis that compiled evidence on the safety, efficacy, and effectiveness of UBT devices showed an overall success rate of 85.9%[7]. This varied slightly with mode of delivery and cause of PPH but remained consistently high. Notably, one trial found that using a UBT device in places with surgical facilities was associated with higher morbidity and mortality due to delays in secondary PPH management (i.e. misoprostol, hysterectomy, etc.), yet it was limited by a small sample size and suboptimal observance to research protocol and primary PPH management guidelines[8]. Several other studies have shown that UBT devices avert hysterectomy and other operative procedures and are safe[9-13].

However, commercial devices are expensive. Bakri balloons, the most commonly used UBT devices in the United States, and Ebb balloons cost over $400 each. Many facilities in low-resource settings cannot afford these prices therefore instead use improvised devices that consist of a condom secured to the end of a Foley catheter. These improvised UBTs are not standardized,

nor have they been rigorously tested, and the time required to find and assemble the components can delay treatment[14]. To fill the gap between prohibitively expensive and improvised devices, the Massachusetts General Hospital (MGH) Global Health Innovation Laboratory developed an ultra-low-cost (less than $5) Every Second Matters-UBT (ESM-UBT) that has been proven to be safe and effective and was recently approved by the United States Food and Drug Administration (FDA)[15-16]. Similarly, in 2017, PATH and Sinapi Biomedical released the Ellavi balloon that provided another low cost alternative[17].

Few studies have directly compared these devices. The only randomized control trial to date that compared Bakri balloon with condom catheter balloons did not show a significant difference in outcomes[18]. Interestingly, when pooled with observational studies, the overall success rate was actually higher among women treated with a condom UBT (90.4%, 95% CI 87.7 -92.8%) compared to Bakri (83.2%, 95% CI 80.5-85.8%)[7]. Though it is possible that this difference is simply because UBT devices are used earlier in low-income settings when they are the only option, compared to high-income settings where they may be reserved for more complex cases. Regardless, these data suggest that condom UBT devices are at least as efficacious as Bakri balloons. The Ebb and Ellavi have not yet been directly compared to other devices[19,20].

More research is needed to understand how these devices compare in clinical practice. For example, no studies have examined differences in user experience with each device. Most of the current data on provider experience is qualitative and only details thoughts on one specific balloon rather offering a comparative perspective. For example, one study that investigated provider experience with improvised devices found that the greatest challenge was finding all the necessary components in the midst of an emergency[14]. However, it is also important to understand how user experience may differ between devices. Are some easier to assemble, place, and inflate than others? Effective treatment for PPH should be initiated in minutes and, particularly in emergencies, having simple, easy-to-use equipment is essential. This study aims to fill this gap in research by comparing ease of use between commercial, improvised, and low-cost alternative UBT devices in simulated PPH scenarios to help better inform PPH guidelines and practice.

2 STUDENT ROLE

My role on this project was to recruit participants for the PPH simulations, lead the one-on-one training sessions and simulations, record and analyze all data collected during the simulations, and

write the final report. These steps were done with the assistance of Dr. Burke and the research assistants and fellows on his team.

3 METHODS

We simulated emergency PPH clinical scenarios to collect data on user experience with five types of UBT devices. Data collected included subjective experiences reported on surveys and time and number of attempts required for participants to achieve successful placement. The UBT devices encompassed a range of commercial, low-cost, and improvised devices and included the Ellavi, Bakri balloon, Ebb balloon, ESM-UBT, and an improvised condom balloon.

3.1 Participants

We recruited third- and fourth-year medical students from Harvard Medical School (HMS) to participate in the PPH simulations. Medical students were considered the most appropriate study population as they have basic clinical knowledge and experience with pelvic exams but have not been trained on any one particular UBT device that could bias the study results. Most OB/GYNs and midwives have received some training or have clinical experience with Bakri balloon, the most commonly used device in the United States (US). HMS was chosen as the optimal recruitment site given the established affiliation with MGH.

Eligibility criteria required that the participants be enrolled in the third or fourth year of medical school, successfully completed the core OB/GYN clinical clerkship, and conducted a minimum of ten pelvic exams. These criteria ensured that students had the minimal knowledge and clinical skills necessary to properly place UBT devices.

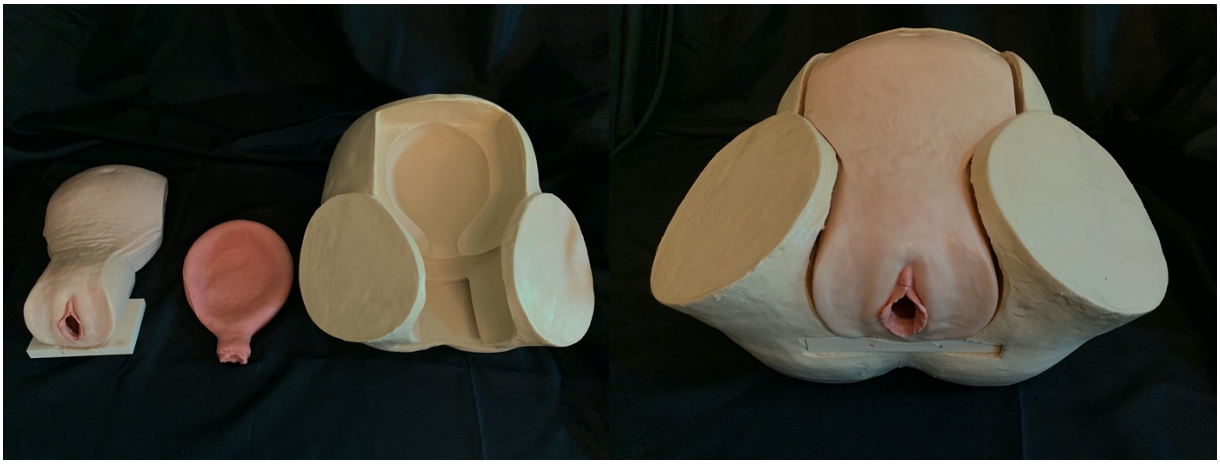
A total of 20 students were recruited via email for the study, in addition to three students for a pilot study that helped refine the simulation protocol. The sample size was calculated via an ANOVA two-way calculation. ANOVA is used for normally distributed data and, given that the central limit theorem suggests samples sizes of 30 units trend to approach a normal distribution, the experiments must have a minimum of 6 students (each student performing 5 experiments). However, we expanded the sample size to 20 to decrease uncertainty and increase the power and reliability of the study.

3.2 Materials

The PPH simulations were conducted using a SynDaver synthetic pelvis that was tissue engineered to realistically resemble a pelvis (vagina, cervix, and uterus) immediately postpartum (*Picture 1*). The five UBT devices tested were the Ellavi, Bakri, Ebb, ESM-UBT, and an improvised condom balloon (*Picture 2*). These five were chosen because they capture the range of available options from commonly used commercial devices to cost-effective alternatives and improvised condom balloons.

Each balloon was purchased from the manufacturing company or authorized third party seller. The improvised balloon was assembled using a method detailed in previous studies [21]. The components included an 18 French rubber catheter, condom balloon, string, 20cc syringe, and hemostat to occlude the catheter during inflation. The catheter type and syringe size were chosen based on materials most commonly found in low-resource facilities as described in in the literature[14]. Each commercial device was assembled, placed, and inflated per the instructions provided by the respective manufacturer; however, for those that had more than one inflation method, the option considered to be fastest and simplest was chosen. For example, Ebb balloon can be filled using an intravenous (IV) bag or a syringe, thus the IV method was chosen as it was clearly the fastest mode of inflation. Additionally, Ebb uses a duel balloon tamponade system, but only the uterine balloon was inflated for this study so that results could more easily be compared with the other devices. Similarly, Bakri was filled using what the manufacturer called the "rapid inflation method," as this was assumed be the fastest, simplest inflation method[22].

Picture 1: SynDaver Pelvic Model: *Left*: three Syndaver pieces separated, including the vaginal canal and abdomen, uterus, pelvic base; *Right*: fully assembled SynDaver model.



3.3 PPH Simulations

Prior to the simulation, participants received one-on-one training that provided an overview of PPH management guidelines and hands-on instruction on proper techniques for assembling, placing, and removing each device. Participants were also given time to practice with each device, ask questions, and receive feedback. This training opportunity aimed to align with standard practice as UBT devices are often distributed with short training sessions for clinical personnel. Additionally, medical students have limited to no prior training with UBT devices.

After the training, participants completed a total of five simulations, one for each UBT device. The order of devices was rotated for each participant to limit systematic bias. At the start of the simulations, devices were placed beside the SynDaver model with all unassembled components and required materials. For example, during the simulation with the ESM-UBT device, participants were given the ESM-UBT package that included condoms, O-rings, a 24 French silicone Foley catheter, one-way leur valve, catheter holder, an instruction card, and a basin of clean water. Participants were asked to assemble the UBT, insert it into the SynDaver uterus, and inflate with 500cc of normal saline from an IV bag or clean water from a basin. The volume of 500cc was chosen as that is the US FDA predicate requirement amount for UBTs.

During each simulation, an observer was present to ensure that the participants were using the devices correctly and to record the time and number of attempts required to achieve successful placement. The observer did not guide participants in any way during the simulations and only notified participants if they had incorrectly placed the device and needed to place it again.

3.4 Data Analysis

Measured outcomes included the time to correct placement, number of attempts, and subjective user experience collected via surveys. Time to correct placement was defined as the time from the start of the simulation to correct placement of each UBT in the SynDaver uterus and instillation of 500cc of fluid. The observer used a stopwatch to record this time. Number of attempts was defined as the tries required to successfully insert and inflate the UBT in the correct position. To assess ease of use, participants were asked to complete a survey after placing each device that included a numbered grading scale from one [easy] to ten [difficult] across five variables: assembly, placement, inflation, removal, and overall use (*Appendix 1*). Participants were also asked to rank

the devices from easiest [1] to hardest [5] across each of these variables. Surveys were completed immediately after the end of each simulation for a particular device.

4 RESULTS

4.1 SUBJECTIVE USER EXPERIENCE

4.1.1 Results from Survey Data

There were four main findings drawn from analysis of the survey data (*Tables 1 and 2*). First, the Ellavi balloon was rated the easiest device to use overall by 19 of the 20 participants. The one participant who did not rank Ellavi first had difficulty filling the balloon due to a kink in the tubing that occurred during placement. However, all the participants ranked Ellavi number one as the easiest device to inflate and remove. Ellavi ranked slightly lower in terms of placement, 1.6 out of 5 on average (1 = easiest, 5 = hardest), as some found it more difficult to insert through the cervix. Second, the ESM-UBT ranked consistently higher than the improvised and Bakri balloons across all variables, except ease of assembly. On that variable, Bakri ranked higher at 3.1 compared to 3.4 and 4.7 for the ESM-UBT and improvised device respectively. This result was expected as Bakri balloon comes nearly fully assembled. Third, Bakri ranked lower than expected given that it is the gold standard used in most hospitals in the United States. On average, it ranked fourth for ease of use overall, just above the improvised condom balloon. Finally, on aggregate, the devices ranked from easiest to hardest in the following order: Ellavi, ESM-UBT, Ebb, Bakri and the improvised device. However, the ESM-UBT and Ebb scored similarly at a 2.8 and 2.9 respectively. The same was also true of Bakri and the improvised balloon, which ranked 3.9 and 4.4 respectively. These results were also reflected in participants' experiences as scored on the numbered grading scale for each individual device as shown in Table 1.

4.1.2 Themes in Participant Comments

Several themes also emerged from comments that participants reported on the survey. Multiple comments on the improvised balloon, for example, highlighted that inflating this device was more time consuming due to the smaller 20cc syringe, which required 25 syringe injections to reach the goal volume of 500cc. Comments included, "took longer to inflate because the syringe was only 20cc," "time to inflate made this more cumbersome," "took a lot of time to completely fill [20cc vs 60cc syringe]." The time required to assemble, place, and inflate this device took twice as long

on average than the ESM-UBT, which came equipped with a 60cc syringe. Participants also found it difficult to securely attach the condom balloon to the Foley catheter without also obstructing the lumen and to maneuver the hemostat during the inflation process. For example, one participant wrote, “had trouble tying the knot! Had to redo because it was too tight.”

Table 1: Subjective experience with assembling, placing, inflating, removing, and overall use of each UBT device; scale 1 (easiest) to 10 (hardest).

	Improvised Device			**ESM-UBT**			**Ellavi**			**Ebb**			**Bakri**		
	Average	Range	SD	Average	Range	SD	Average	Range	SD	Average	Range	SD	Average	Range	SD
Assembly	5.5	3-8	1.8	3.4	1-6	1.3	1.6	1-3	0.7	2.3	1-5	1.4	3.8	1-7	1.8
Placement	4.7	1-8	1.9	3.0	1-8	1.7	2.2	1-6	1.4	3.7	2-8	1.6	4.2	1-6	1.6
Inflation	6.8	3-10	1.9	4.2	1-8	1.8	1.8	1-10	2.0	3.2	2-7	1.5	6.5	2-10	2.1
Removal	3.7	1-10	2.1	2.7	1-5	1.2	1.2	1-2	0.4	4.8	1-10	2.6	3.8	1-8	2.0
Overall	5.5	3-8	1.4	3.5	3-5.5	1.0	2.1	1-8	1.7	4.0	3-9	1.9	4.9	2-8	1.8

Table 2: Average comparative ranking when participants asked to rank the easiest (1) to hardest (5) in terms of assembly, placement, inflation, removal, and use overall.

	Improvised Device			**ESM-UBT**			**Ellavi**			**Ebb**			**Bakri**		
	Average	Range	SD	Average	Range	SD	Average	Range	SD	Average	Range	SD	Average	Range	SD
Assembly	4.7	3-5	0.7	3.4	2-4	0.7	1.2	1-3	0.6	2.6	1-5	0.9	3.1	1-5	1.2
Placement	3.6	1-5	1.4	2.3	1-4	1.2	1.6	1-5	1.0	2.9	1-5	1.4	3.6	2-5	1.1
Inflation	4.4	1-5	1.0	3.2	2-5	0.9	1.0	1-1	0.0	2.3	1-4	0.6	3.8	2-5	0.9
Removal	3.2	1-5	1.1	2.4	1-4	0.7	1.0	1-1	0.0	4.0	2-5	1.1	3.3	1-5	1.2
Overall	4.4	2-5	1.0	2.8	1-4	1.0	1.2	1-4	0.7	2.9	2-4	1.0	3.9	2-5	0.9

In comparison, participants found the ESM-UBT easier to use due to simple modifications that addressed these challenges. For example, participants reported that it was "easier to inflate with the Leur lock" by negating the need for a hemostat. They also found that "the O-ring secured the condom better [to the catheter] than the string" provided for the improvised device. Finally, the 24 French silicone Foley catheter was "very easy to place given the rigid tubing… and wider lumen" than the 18 French rubber Foley catheter used for the improvised balloon. The biggest complaint with the ESM-UBT was that the Leur lock slipped out for three participants.

With regard to the Ebb balloon, many commented on feeling intimidated and confused by the multiple separate lumens corresponding to irrigation, drainage, and inflation of the duel uterine and vaginal balloons. One participant wrote, "Very confusing. Visually intimidating to the user. There were way too many ports. If I were stressed in an emergency, I would struggle to figure out which port to use." Four other participants wrote similar comments. Additionally, while placing this device, some had difficulty with the adjustable handle, which often slipped during insertion despite attempts to lock it in place. Finally, this device took longer to deflate, often because the uterine balloon would twist and obstruct flow.

One of the greatest complaints with Bakri balloon was the significant force required to inflate it. Twelve of the participants commented on this saying: "required a lot of force to inflate," "took more strength to press down on the syringe than others," "[the] most difficult part was just inflating the [uterine] balloon – it was more difficult than expected." This was likely in part due to the long, high-resistance IV tubing and stiff silicone balloon. Some also found it challenging to insert Bakri through the cervix as the tubing was not as stiff as other devices. One participant wrote, "more difficult to insert due to floppier tube," a comment echoed by two others.

Finally, for the Ellavi, twelve participants wrote that the device was fast and simple to use. Comments included: "super simple and fast," "easiest to inflate and deflate," "simple design made it easier to use! Probably my favorite!" Some reported difficulty with placement making comments like, "had difficulty placing through the cervix." But this was variable as another participant also commented that it was "easy to place because the tubing was firm and not as flexible as a Foley." Overall, participants preferred the Ellavi balloon with nearly every participant verbally commenting that it was the easiest and simplest device, likely due to its gravity-dependent, passive inflation and deflation method that required little manual labor.

4.2 QUANTITATIVE COMPARISON

4.2.1. Time to Correct Placement

The average time required to assemble, place, and inflate each device varied substantially. The Ellavi and Ebb were the fastest to use, taking on average 2 minutes 13 seconds and 2 minutes 30 seconds respectively. This was likely because neither device required syringes for inflation. Ellavi is filled by a passive, gravity-dependent system and Ebb is inflated by squeezing an IV bag. Interestingly, the ESM-UBT was the third fastest despite requiring assembly, unlike Bakri which is packaged nearly fully assembled. This was likely in part attributed to the manual force required to fill Bakri, which has a stiff silicone uterine balloon compared to the thin, flexible condom balloon provided with the ESM-UBT. Additionally, the "rapid inflation method" for Bakri requires using both a syringe and an IV bag (the fluid reservoir), which is attached to long, narrow tubing likely to have high resistance. However, the time difference between the ESM-UBT and Bakri was only 1 minute 11 seconds, which may not be clinically significant. Finally, the improvised balloon was the slowest device to use overall, taking on average 4 minutes 11 seconds longer than Bakri and 5 minutes 22 seconds longer than the ESM-UBT. This finding is primarily due to differences in inflation time as it only took 32 seconds longer on average to assemble the improvised balloon compared to the ESM-UBT. As participants noted in their comments, the smaller 20cc syringe likely played a key role in these time differences. Finally, the difference between the fastest device (Ellavi) and slowest device (improvised balloon) was on average 8 minutes 9 seconds. While the clinical significance of this time difference likely depends on the PPH scenario, in many cases these minutes would undoubtably be critical.

4.2.2. Number of Attempts to Correct Placement

Devices also varied in the number of attempts needed for participants to correctly place them in the SynDaver uterus. The term "misplaced" was defined to mean that the participant had inflated the device and mistakenly thought it was in the correct location. In this scenario, they were asked to drain, remove, and replace the device in the correct location, and this was counted as one "attempt." If participants caught their mistake and corrected it during the inflation process, this was not counted as a separate attempt.

The Ebb balloon was misplaced most frequently. Five of the twenty participants initially misplaced this device, and one participant needed three attempts to achieve correct placement.

Table 3: Average time required to correctly assemble, place, and inflate each UBT

Device	Average Time to Assemble, Place, and Inflate		SD
	Minutes	Seconds	
Improvised	10	22	1.76
ESM-UBT	5	6	0.91
Ellavi	2	12	0.86
Ebb	2	31	0.59
Bakri	6	10	1.43

Table 4: Average time required to assemble improvised condom balloon versus ESM-UBT

Device	Average Time to Assemble		SD
	Minutes	Seconds	
Improvised	1	28	0.28
ESM-UBT	0	56	0.28

Table 5: Number of attempts per device

Device	Number of Attempts		
	Average	Number of times misplaced	SD
Improvised	1	0	0.0
ESM-UBT	1.05	1	0.22
Ellavi	1.15	3	0.37
Ebb	1.30	5	0.57
Bakri	1.10	2	0.31

Ellavi was misplaced by three participants, Bakri by two, ESM-UBT by one, and the improvised device was never misplaced. All of these participants correctly placed the device on their second attempt. Notably, while the improvised device was never misplaced as defined here, several participants tied the condom balloon either too tightly, cutting off the catheter lumen, or too loosely and had to remove and reassemble it before inflation. Additionally, on three occasions the string came loose during the removal of the improvised device, water spontaneously emptied into the vaginal canal, the condom balloons had to be manually extracted from the uterus. However, it is important to note that misplaced devices were most commonly found anterior to the uterus, which is not anatomically possible, and may represent a limitation to the SynDaver model.

5 DISCUSSION

5.1 Summary of key findings

The conclusion drawn from this study are summarized in five main findings:

1. Ellavi balloon is rated the simplest, easiest, and fastest device
2. Ellavi and ESM-UBT, low-cost alternatives to expensive commercial devices, are non-inferior with regard to ease of use and may be superior to Bakri balloon
3. EMS-UBT is rated higher than the improvised balloon and is faster to assemble and inflate even without simulating one of the greatest differences between the devices, which is that the components for the improvised are often not readily available
4. The Ebb duel balloon tamponade system is fast to use, but also more confusing and has a higher rate of user error
5. Bakri balloon was not as highly rated as expected given that it is the gold standard

5.2 Clinical implications of findings

Time matters greatly in cases of PPH, where women can progress to advanced shock in minutes. Having a UBT device that is simple to use and fast in these emergency cases is critical. This study found that the ease of use and speed at which five different UBT devices were assembled, placed, and inflated varied substantially, even in a controlled setting where all device components were readily available, stress was lower, and active bleeding did not impede placement.

Ellavi emerged as the simplest, easiest, and fastest device to use overall, likely due to its passive gravity-dependent mode of inflation and deflation. Ellavi is a relatively new device to the

market and achieved Conformitè Europëenne (CE) marking in June 2019, signifying that it met European regulatory requirements[23]. No large, multicenter studies have yet evaluated the safety, efficacy, and effectiveness of Ellavi, but smaller case series have shown promising results[20]. Ellavi comes pre-assembled and fills by a free-flow system between the bag and uterine balloon. This allows for gravity-dependent inflation and for water to be pushed back into the bag as the uterus contracts, providing a visual indication of improved uterine contractility[23]. This method is unique and requires less manual labor compared to other devices, which is likely the reason participants ranked it favorably as the most user-friendly. Given that this balloon is easy to use and inexpensive ($20), it offers a promising alternative to more expensive commercial devices, especially in places with few resources or rising healthcare costs. This device has not yet been FDA approved for use in the US, but these findings suggest that seeking such approval may be beneficial. However, more studies are still needed to understand how its safety and efficacy profile compare to other devices.

Similarly, we found that ESM-UBT, another low-cost alternative, was non-inferior and may be superior to Bakri balloon with respect to ease of use. The ESM-UBT was first released in 2012 and has been shown to be safe and effective. It is also now used in over 20 countries and was approved by the US FDA in December 2019. However, given that ESM-UBT is a condom balloon device that requires assembly, we hypothesized that it may be more cumbersome to use than Bakri, which comes fully assembled and is the gold standard in the US. Yet, we found that most participants preferred the ESM-UBT to Bakri and ranked it easier to use overall as well as easier to place, inflate, and remove. ESM-UBT was ranked slightly lower with respect to ease of assembly; however, the average time to assemble, place, and inflate the ESM-UBT was still faster than Bakri balloon. This may be explained in part by Bakri's stiffer, silicone uterine balloon that participants reported took greater force to inflate. Regardless, these results suggest this low-cost alternative to Bakri is easier to use.

ESM-UBT was also found superior to improvised device, even under ideal circumstances when all device components were readily available. A large benefit to ESM-UBT is that it can be pulled off the shelf and ready to use, whereas the greatest reported delay with improvised devices is the time required to gather all the necessary components. For example, one study described how providers found it challenging to get male condoms in a maternity ward, and it could take up to 40 minutes to gather supplies[13]. However, this study showed that even when eliminating this difference, using ESM-UBT was still twice as fast and participants found it easier to use. As

described previously, this was likely attributed in large part to the larger 60cc syringe provided in the ESM-UBT package compared to the 20cc syringe used with the improvised device. The ESM-UBT needed 8.25 syringe injections to reach 500cc compared to the 25 injections required for the improvised device. However, participants also reported that the O-ring, one-way Luer lock valve, and the wider and stiffer 24 French silicone catheter also made the ESM-UBT device easier to assemble and inflate. These results suggest that facilities currently relying on improvised devices may benefit from adopting the ESM-UBT.

Additionally, although the Ebb could be inflated nearly as quickly as Ellavi in our tests, most participants found it to be a complicated device. The Ebb has four separate ports: (1) inflation/deflation for the uterine balloon, (2) inflation/deflation for the vaginal balloon, (3) drainage, (4) irrigation. Although each port is labeled, participants found this confusing and felt they would have more difficulty figuring out how to use this device is an emergency situation. This device was also misplaced on the first try by a quarter of the participants. The reason for this is unclear but the relatively heavy terminal handle and lumens may have contributed by pulling downward on the device during inflation. Additionally, the handle for the vaginal balloon did not easily lock and often slid during placement, which may have made device placement more challenging. Finally, the Ebb tubing and vaginal balloon handle is bulky, which may be made it more difficult for participants to manually confirm that the balloon was correctly places through the cervix. Overall, this suggests that while the Ebb can be quickly inflated and has some advantages to the other devices (e.g. larger 750cc uterine balloon, vaginal balloon, etc.), it may be more challenging and confusing for users during an emergency when a simple, straight-forward device is preferable.

Finally, the Bakri balloon did not score as highly as expected given that it is the gold standard and most commonly used device in the US. Bakri scored second to last in ease of use overall, just above the improvised balloon. The greatest complaint with the Bakri was the manual force required to overcome the resistance of the stiff uterine balloon. Given the high cost of Bakri and a climate of rising healthcare costs, these results suggest it may be time to reconsider Bakri as a gold standard as less expensive devices come to market.

5.3 Limitations of this study

There were several limitations to this study. Firstly, medical students were chosen as the study population because they have no prior training on a particular device that could bias the results; however, OB/GYNs and midwives would have been the ideal participants as they use these devices most commonly in clinical practice. Understanding their perspective on how the devices compare would be optimal and assuming medical students' perspective is similar may not be accurate given that students do not have the same level of experience and skill.

Secondly, these experiments were conducted in a controlled simulation setting, which cannot fully reflect a real PPH scenario. In this artificial environment, certain real-life differences between the devices could not be simulated. For example, all device components were readily available, which is often not the case as previously described with the improvised balloon. Similarly, Ellavi requires an IV pole or second operator and Ebb an IV bag or syringe for inflation, which may not be available in some settings. Differences in availability of materials would undoubtably affect ease of use. The ESM-UBT and Bakri were the only two devices that came fully equipped with all necessary components. Additionally, in a real PPH scenario, stress levels would be high and ongoing bleeding would likely make device placement more challenging. However, despite these limitations, this study showed that even under ideal circumstances there are clear differences between devices that would likely only be enhanced in a PPH emergent situation.

Thirdly, we recorded the duration of time required to assemble, place, and inflate the devices as a quantitative proxy for ease of use; however, the clinical significance of small differences in time is unclear. For example, the average time difference between Bakri and ESM-UBT was 1 minute 11 seconds, which is unlikely to significantly affect clinical outcomes. However, it is more likely that the 8 minute 11 second difference between the Ellavi and improvised device would matter clinically. Ultimately, the clinical impact of duration of time between when PPH is recognized to device insertion and instillation depends on the clinical scenario (i.e. how fast and how much the patient is hemorrhaging). However, this study assumed that faster devices would undoubtably be optimal.

Finally, the inflation method chosen for Bakri may have unfairly disadvantaged the device. The "rapid inflation method," as termed by the manufacturer, may not have been the simplest and fastest inflation method as expected. In the pilot study, participants were asked to inflate Bakri using only a syringe with clean water rather than an IV bag per the "rapid inflation method," and the average time to insert and inflate it was 58 seconds faster than that reported in this study.

Additionally, two of these participants ranked Bakri second after Ellavi as the easiest device to use overall. Given the small sample size of the pilot study, it is difficult to interpret the significance of these differences. However, it became clear during the study that the manual force required to fill the syringe due to the long, high-resistance IV tubing was challenging for participants and likely affected their rating of the device. Additionally, the "rapid inflation method" requires some assembly.

5.4 Conclusions

The Ellavi balloon was the simplest, fastest, and most user-friendly device of the five tested in this study. The ESM-UBT also scored consistently high and rated higher than Bakri and the improved device. This evidence suggests that these two low-cost alternatives are not only safe effective, but also easier to use than more expensive commercial devices. The Ebb balloon, on the other hand, was fast to inflate but was more complicated with a higher rate of error. Finally, Bakri balloon did not score highly despite being the gold standard. This study provides evidence that devices vary substantially in their user-friendliness and speed at which they can be assembled, placed, and inflated.

5.5 Suggestions for future work

This work could be expanded to incorporate midwives and OB/GYNs as study participants as they have the experience and skill to better discern meaningful differences between devices and their impact in obstetrical emergencies. Additionally, other devices, such as the suction balloon tamponade device, could also be included to provide a broader comparative analysis. This work should also be expanded to incorporate other device properties that are clinically relevant. For example, anecdotal evidence suggests that one challenge clinically with these devices is that are sometimes expelled from the uterus, and it is possible that devices also differ in how securely they remain in the uterus. The SynDaver model is a unique tool that could be used to explore some of these biomechanical differences to understand how other important device properties compare.

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APPENDIX 1: Survey Instrument

Questionnaire:

Thank you for participating in this study. Before we start, we need to know some information about you.

1) Are you enrolled in the third or fourth year of medical school?
   a. Yes
   b. No

2) Did you successfully complete or are currently enrolled in the HMS OB/GYN Clerkship?
   a. Yes
   b. No

3) Approximately how many pelvic exams have you previously done? _____

4) Before this session, did you know what a uterine balloon tamponade was?
   a. Yes
   b. No

5) Have you ever been trained to insert a uterine balloon tamponade device before?
   a. Yes. When _____
   b. No

Using the scale below, choose a number between 1 and 10 (1 is easy and 10 is difficult) to rate how difficult it was to use each UBT.

Improvised UBT:

How difficult was it to assemble this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to place this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to inflate this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to remove this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to use this UBT overall?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

Comments:

ESM-UBT:

How difficult was it to assemble this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to place this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to inflate this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to remove this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to use this UBT overall?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

Comments:

Ellavi Balloon:

How difficult was it to assemble this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to place this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to inflate this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to remove this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to use this UBT overall?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

Comments:

Ebb Balloon:

How difficult was it to assemble this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to place this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to inflate this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to remove this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to use this UBT overall?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

Comments:

Bakri Balloon:

How difficult was it to assemble this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to place this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to inflate this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to remove this UBT?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

How difficult was it to use this UBT overall?

1	2	3	4	5	6	7	8	9	10
very easy				moderate					very hard

Comments:

Please rank the above 5 UBTs in order of difficulty (1 is easiest, 5 is most difficult). If you feel that two or more UBTs were the same, please give them the same rank order.

Ease of Assembly:

1. _____
2. _____
3. _____
4. _____
5. _____

Ease of Inflation:

1. _____
2. _____
3. _____
4. _____
5. _____

Ease of Placement:

1. _____
2. _____
3. _____
4. _____
5. _____

Ease of Removal

1. _____
2. _____
3. _____
4. _____
5. _____

Ease of Use Overall

1. _____
2. _____
3. _____
4. _____
5. _____

APPENDIX 2: Data Collection Form

UBT	Time to Assemble		Time to Correctly Place		Total Time to Assemble and Place		Time to Remove		Time to Place Again (if needed)		Time to Remove Again (if needed)		Time Overall		Number of Attempts
	Min	Seconds	Min	Seconds	Min	Seconds	Min	Seconds	Min	Seconds	Min	Seconds	Min	Seconds	
Improvised UBT															
ESM-UBT															
Ellavi															
Ebb															
Bakri															

Notes:

1) **Improvised UBT:**

2) **ESM-UBT:**

3) **Ellavi:**

4) **Ebb:**

5) **Bakri:**