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Uterine balloon volume shifts using a free-flow uterine balloon in the management of refractory post partum haemorrhage

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Background. Uterine balloon tamponade (UBT) is used as part of the post partum haemorrhage (PPH) algorithm for the treatment of PPH.
Objectives. The free-flow Ellavi uterine balloon controls the pressure in the uterine balloon by adjusting the height of the supply bag above the patient and allows for expulsion of water from the balloon. The study quantified the volume shifts in the supply bag and assessed the optimal use of the Ellavi UBT by reducing the intrauterine pressure at regular intervals.
Methods. A prospective descriptive study of consecutive patients with refractory PPH was conducted. For group A, the supply bag was weighed every 30 minutes with a sensitive digital scale. Additionally, for group B the supply bag was lowered by 50% and the uterus gently massaged for 30 seconds.
Results. Thirteen patients were included in the study. The mean volume shifts was 23.5 mL for Group A and 132.7 mL for Group B. The difference in the means of groups A and B was borderline significant (p=0.06).
Conclusion. The study did find volume shifts in the free-flow system, which may be enhanced by lowering the supply bag halfway at regular intervals.
S Afr J Obstet Gynaecol 2024;30(1):e1525. https://doi.org/10.7196/SAJOG.2024.v30i1.1525

In South Africa, obstetric haemorrhage remains the third most common cause of maternal death and 75% of these deaths are potentially preventable.[1] The World Health Organization (WHO) recommends a set of interventions as a first-line treatment for women with post partum haemorrhage (PPH).[2] These include administration of uterotonics and tranexamic acid, uterine massage, suturing tears and excluding retained placental tissue. In most cases, these measures will resolve the PPH. However, a small proportion of women will require additional management. For women with refractory PPH, before proceeding to invasive surgical procedures, a reasonable approach is the administration of additional uterotonics, a second dose of tranexamic acid and uterine balloon tamponade (UBT).

UBT is used as part of the PPH algorithm. This method has a very important role in reducing deaths from PPH. Compared with other interventions used to treat PPH, UBT requires minimal resources and is simple enough to be performed by midwives and junior doctors. UBT works by filling the uterine cavity and applying pressure to the bleeding sinusoids in the placental implantation site.[3] If the pressure inside the uterus corresponds to the patient's systolic blood pressure, a tamponade effect is achieved. The free-flow Ellavi uterine balloon (*Sinapi Biomedical, SA*) makes it possible to control the pressure in the uterine balloon by adjusting the height of the supply bag above the patient. It also allows the expulsion of water from the balloon.[4] Feasibility case series were conducted using the Ellavi UBT at three levels of obstetric care.[5] Insertion of the uterine balloon proved to be easy and the pressure in the uterine balloons were controlled appropriately. The intraluminal uterine balloon pressure achieved when uterine balloons are used is uncertain. Georgiou[6] designed a study to determine the intraluminal pressure within the Bakri balloon when tamponade was achieved in the management of PPH. The intra-balloon pressures were measured on two patients. The two cases reported by Georgiou challenged the idea that the intraluminal pressure should exceed the systolic blood pressure. In both cases, the intraluminal pressure was lower than the systolic blood pressure. More cases need to be obtained to provide the reproducibility of these results; specifically, the linear relationship between the intraluminal pressure and balloon volume during the achievement of a positive tamponade test. The linear relationship of the intraluminal pressure during the attainment of a positive tamponade test may be the result of the inherent contractile ability of the myometrium.

Volume shifts from the intra-uterine balloon back into the supply bag have been observed by clinicians using the Ellavi UBT. These shifts have not been quantified. In addition, measures to facilitate expulsion of water by reducing the intrauterine pressure at regular intervals to optimise uterine contraction and retraction have not been previously investigated.

Methods

A prospective descriptive study using quantitative data was conducted. The study population included consecutive patients with refractory PPH at Tygerberg Hospital, managed in the Obstetric Critical Care Unit (OCCU).

Patients presenting with refractory PPH following the implementation of emergency resuscitative measures and with the Ellavi uterine balloon inserted were recruited. These patients were managed according to the departmental PPH management bundle.

The assessment began as soon as the patients arrived at the OCCU. For group A, the supply bag was weighed every 30 minutes with a sensitive digital scale, to measure the amount of fluid in the supply bag. This continued every 30 minutes for up to 24 hours following insertion of the balloon, or for a shorter period if the balloon was expelled. Additionally, for group B, the supply bag was lowered by 50% every 30 minutes and the uterus gently massaged for 30 seconds to allow the water to be expelled back to the supply bag, reducing the size of the balloon. The t-valves were closed when the supply bags were weighed.

To compare the weighted measurements between the groups, one-way analysis of variance (ANOVA) was used. The Levene's test was used to evaluate the homogeneity-of-variance assumption, and in one case where it was significant, the Welch test was performed instead of the ANOVA F-test.

Ethical clearance

The study was approved by the Health Research Ethics Committee of the Stellenbosch University Faculty of Medicine and Health Sciences (ref. no. S20/02/033).

Results

A total of 13 patients were included in the study between June 2020 and November 2021. The mean age was 27 (range 17 - 36) years. The mean gravidity was 2 and parity 1. Five patients had a normal singleton vertex delivery (NVD), two had twin vaginal deliveries, three had an elective C-section and three had an emergency C-section.

Active management of the third stage of labour was performed in all patients with vaginal deliveries, using 10 IU of intramuscular oxytocin. All patients who delivered by C-section had a bolus of intravenous 1 - 3 IU oxytocin. Subsequently, all patients had intravenous oxytocin infusions. All the patients delivered complete placentas. The median birth weight of the 16 babies was 3 262 g (range 2 290 - 4 290 g). The estimated median blood loss by the time the physician placed the uterine balloon was 1.442 mL (range 800 - 3 000 mL). On initial assessment, 10 patients had atonic uteri and three had contracted uteri prior to insertion of the uterine balloon. Four patients had moderate to severe hypovolemic shock, with systolic blood pressure ranging from 44 - 84 mmHg. All patients had arrest of haemorrhage following insertion of the uterine balloon.

Nine patients required a transfusion of packed cells and 10 received fresh frozen plasma.

None of the uterine balloons in group A were expelled before 24 hours. Five patients in group B had spontaneous expulsion of the uterine balloon before 24 hours. In all 13 patients, the height of the supply bag was adjusted every 30 minutes according to their systolic blood pressure. When comparing the duration of the UBT in groups A and B (Table 1), the time was significantly longer in group A than in group B ($p<0.01$).

A total of 89 and 92 weight measurements were made in groups A and B, respectively. The mean volume differences of the highest minus the lowest volumes in the supply bags was 23.5 mL in group A and 132.7 mL in group B. The difference in the means of the groups was borderline significant (Welch test $p=0.06$). The medians in groups A and B were 19.0 mL and 88.9 mL, respectively.

Table 1. Duration of uterine balloon tamponade (UBT) in groups A and B

Effect	Level of factor	N	Duration of UBT in uterus (hours), mean (SD)
Total		13	18 (7.92)
Group	A	7	24 (0)
Group	B	6	11 (6.42)

P=0.02
SD = standard deviation.

Discussion

During the study period, 50 768 infants with a birth weight of 500 g or more were delivered in public health facilities in the Metro East. This study was undertaken to evaluate the differences in volume of the supply bags of the free-flow Ellavi uterine balloon for the emergency management of refractory PPH. The successful management of refractory PPH requires an expedited stepwise approach, in which the availability of resources and an efficient health system are essential. The study site complied with the necessary protocols and the possibility of emergency surgical intervention if required.

The overall success rate was 100% (13/13). This compares favourably with reported success rates of 83% and 86%.[7,8] The study supports the timely intervention with UBT in cases of refractory PPH. The use of uterine balloons should decrease the rate of surgical intervention in cases of PPH. This study should encourage clinicians across all levels of healthcare to attempt this non-surgical intervention before proceeding with surgical interventions.

The study revealed that water is expelled from the uterine balloon back to the supply bag in the free-flow system. A comparison of the highest and lowest volumes confirmed that more water was expelled in group B ($p=0.06$).

The uterine balloon remained significantly longer in the uterus in group A than in group B (Table 1, $p=0.02$), supporting the assumption that contractility was enhanced in group B.

Conclusion

The study found volume shifts in the free-flow uterine balloons, which may be enhanced by reducing the pressure in the uterine balloon by 50%. This suggests that lowering the supply bag halfway at regular intervals enhances the physiological process of contraction and retraction of the myometrium—an essential process to arrest PPH. Further research is warranted regarding free-flow and pressure-controlled uterine balloons compared to fixed-volume devices.

Declaration. Tasleem Hassim and Gerhard Theron have no financial or non-financial interests that could inappropriately influence the conduct of this research. They did not receive any remuneration from Sinapi Biomedical (Pty) Ltd or hold any appointments in the company.

Acknowledgements. The authors acknowledge the dedication and assistance of the medical and nursing personnel in the Obstetric Critical Care Unit and the patients who gave consent for the weight measurements. The authors want to thank Sinapi Biomedical for supplying the Ellavi UBT devices used in the study free of charge.

Author contributions. The article is the original work of all four authors. TH prepared the research protocol and collected, analysed, and interpreted the data. GT and EL supervised the study and critically reviewed the manuscript. MK was involved with the data analysis.

Funding. None.

Conflicts of interest. None of the authors have any conflicts of interest to declare.

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Accepted 7 April 2024.