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ORIGINAL ARTICLE

Efficacy of Follys Catheter Intrauterine Balloon Temponade for the Control of Postpartum Hemorrhage

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ABSTRACT

Objective: This research aims to determine how well balloon temponade works as a treatment for postpartum bleeding.
Study Design: Retrospective Study
Place and Duration: Gynaecology and Obstetrics Department, Combined Military Hospital, Peshawar for the duration from February 2021 to January 2022.
Methods: Total 118 women had age 18-40 years were presented in this study. Patients who were diagnosed with, or who were admitted to the hospital for treatment of primary postpartum haemorrhage caused by uterine atony were included. Gestational age and parity among all females were recorded. Folly catheter intrauterine ballon tamponade was used and its effectiveness among all cases was assessed. SPSS 23.0 was used to analyze all data.
Results: Among 118 cases, 40 (33.9%) cases had age 18-25 years, 55 (46.6%) females had age 26-30 years and 23 (19.8%) cases had age >30years. 75 (63.6%) had BMI <25kg/m^2 and 43 (36.4%) had BMI >25kg/m^2. Mean gestational age of the females was 36.55±6.72 and mean parity was 3.11±6.9. Mean blood loss was 1208.5±227.9 ml. Mean pulse rate was 106.8±4.97 bpm. Mean systolic and diastolic blood pressure was 88.41±12.7 mmHg and 56.14±8.4 mmHg. Efficacy of balloon tamponade was found in 108 (91.5%) cases. Complications were found in 3 (3.5%) cases.
Conclusion: We conclude that follys intrauterine catheter balloon tamponade controls postpartum bleeding. There should be a low threshold for using balloon tamponade as it is effective, easy to use, easily available, has a low complication rate, and is an economical modality to control non-traumatic postpartum haemorrhage, especially in resource-limited settings, and sustain reproductive potential.
Keywords: Balloon Temponade, PostPartum Haemorrhage, Efficacy, Complications

INTRODUCTION

About 4.8 out of every 1,000 pregnancies experience placenta previa [1], which is linked to an increased risk of maternal death and severe complications for the mother, such as heavy bleeding, infection, organ damage, and the need for an emergency hysterectomy. Postpartum haemorrhage (PPH) can be caused by a number of different factors, including placenta previa, bleeding from the uterine lower flap, and invasive placentation [2-4]. Patients with placenta previa may undergo intraoperative treatment strategies such as bimanual uterine compression, implantation site compression with sutures, uterine arterial ligation, pelvic arterial embolization, or hysterectomy in order to prevent excessive bleeding.

Hysterectomy is associated with significant morbidity and mortality and results in the loss of fertility, while arterial ligation and compression suture have a poor success rate among untrained surgeons, and pelvic arterial embolization necessitates large medical expenses and specialised equipment. Therefore, in order to cure PPH and keep the uterus, various non-invasive treatments are required. When it comes to stopping blood loss following a caesarean section, Bakri pioneered the use of intrauterine balloon tamponade in 1992 [5]. In order to control bleeding from the lower uterine segment caused by placenta previa-accreta, balloon tamponade has been reported in several recent papers as being both safe and effective. Balloon tamponade is effective in preventing further bleeding in 80% of cases [6], but it cannot distinguish between placenta previa and other causes of PPH such as uterine atony, a retained placenta, a lacerated genital canal, or a ruptured uterus [7].

When uterotonics fail to stop postpartum bleeding, a balloon tamponade of the uterus has been reported as a low-cost but successful technique [8]. The bleeding venous sinuses in the placental bed are stopped by applying pressure on and sealing off the veins using this method. The development of a clot and the subsequent stopping of bleeding [9] are the inevitable outcomes. While a variety of commercial tamponade devices have been reported, these options are generally unavailable in remote areas or prohibitively expensive for the few that are accessible.[10]

UBT is a cost-effective, time-saving, and locally-implemented alternative to existing therapies for treating refractory PPH. In addition to decreasing in price, UBTs are now used by a wider range of medical professionals. [11] The data supporting UBT's effectiveness in the treatment of PPH is not yet conclusive, though. UBT is beneficial for the treatment of PPH in low-resource settings, according to a 2013 systematic review that looked at 13 observational studies including a total of 241 women. [12]Several balloon devices, such as the Sagstaken-Blakemore tube, Bakri balloon, Rusch balloon, Foley catheters, and Condom catheters, have been found to work effectively.

In a study comparing the effectiveness of many balloons, the authors found that the overall success rate was 84% (95% CI, 77.5%-88.8%)[13]. Although there have been accounts of both successes and failures with the use of balloons to treat obstetric haemorrhage, these reports often lack details such as the justifications for treatment, the procedures employed, the kind of balloon utilised, and the potential causes of complications. In low-resource contexts, the usage of condoms has been found to be five times more effective. [14] Given that this is the least intrusive and fastest method, it seems sense to try it first if medicinal therapy fails before moving on to surgical intervention and, ultimately, a hysterectomy. Avoiding a laparotomy, having the device inserted quickly and painlessly with only a local anaesthetic, having relatively untrained staff do the job, and being able to quickly pinpoint any unsuccessful cases are all benefits of this technique. [15]

MATERIAL AND METHODS

This retrospective study was conducted at the department of Gynaecology and Obstetrics, Combined Military Hospital, Peshawar for the duration from February 2021 to January 2022 and comprised of 118 females. After obtaining informed written consent, detailed demographics of enrolled cases age and BMI were recorded.

The patient was examined, their vitals were taken, and they were given a broad assessment of the severity of the bleeding based on their current state. Plasma expanders, blood

transfusions, and crystalloids were all used to make up for the blood loss. The patient's vital signs, skin colour, and urine output were used to gauge the reaction. The following tests were performed as part of the first assessment: complete blood count (CBC), urea, creatinine, electrolytes, and coagulation profile; blood group and cross-match; and blood type.

Bimanual massage and compression, as well as the medications oxytocin, syntometrine, and prostaglandins, were used to treat primary PPH caused by uterine atony. Balloon tamponade for PPH control was explored by postgraduate trainees after initial medicinal care failed but before surgical surgery (R4). The patient gave her informed permission over the phone, and then an aseptically prepared sterile rubber catheter with a condom on the end was inserted into the uterus. A volume of 250-500 ml of normal saline was used to inflate the condom. Once the condom had been inserted into the uterine cavity, vaginal packing was performed to secure it there. In the meanwhile, the infusion of syntocinon began. The catheter condom was stored for up to 24 hours. If the uterine fundus felt contracted after 6 to 8 hours and no active bleeding was identified through the cervix, the balloon was gradually deflated at a rate of 20 ml/hr to half its volume at 12 hours, and when no further bleeding occurred for another 30 minutes, it was removed in the presence of a senior staff member with more than 5 years of experience. The primary efficacy measure was the duration of time until balloon tamponade successfully stopped bleeding, which was measured after 24 hours.

Primary PPH was defined as bleeding from the genital tract of more than 500ml within the first 24 hours after vaginal birth or more than 1000ml following CS. To determine the amount of blood lost during delivery, a tray was set at the end of the table where the mother was lying. The contents of the tray were dumped into a plastic cylinder basin marked off in increments from 100 millilitres all the way up to a thousand millilitres. After 48 hours, balloon tamponade was considered successful if there was no bleeding or if the haemorrhage was less than 100 ml.

The data was analysed with SPSS 23.0. Age, gestational age, parity, blood loss, systolic blood pressure, diastolic blood pressure, and pulse rate were provided as means with standard deviations. Quantitative variables including mode of delivery, booked/unbooked cases, and efficacy were converted to frequencies and percentages. Using stratification, we were able to regulate for confounding factors such maternal age, gestational age, parity, and method of delivery. When comparing groups after stratification, we used a chi-square test and considered the result significant if the p-value was less than 0.05.

RESULTS

Among 118 cases, 40 (33.9%) cases had age 18-25 years, 55 (46.6%) females had age 26-30 years and 23 (19.8%) cases had age >30years.(figure 1)

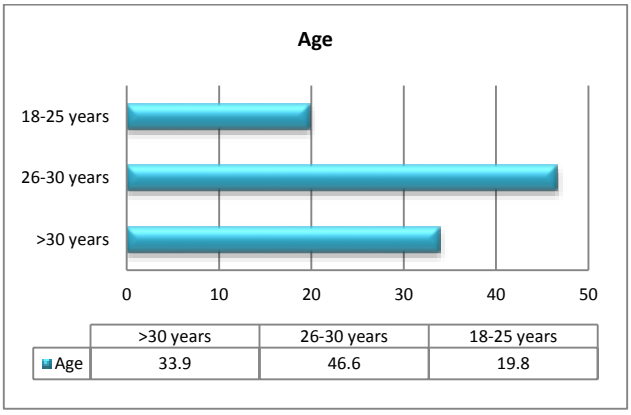

Figure-1: Age of included cases

We found that majority of the cases were from rural areas and were not educated. 75 (63.6%) had BMI <25kg/m^2 and 43 (36.4%) had BMI >25kg/m^2. Mean gestational age of the females was 36.55±6.72 and mean parity was 3.11±6.9. Mean blood loss was 1208.5±227.9 ml. Mean pulse rate was 106.8±4.97 bpm. Mean systolic and diastolic blood pressure was 88.41±12.7 mmHg and 56.14±8.4 mmHg.(table 1)

Table-1: Characteristics of enrolled cases

Variables	Frequency	Percentage
BMI		
<25kg/m^2	75	63.6
>25kg/m^2	43	36.4
Residence		
Rural	80	67.8
Urban	38	32.2
Education status		
Educated	55	46.6
Non-educated	63	53.4
Mean Blood loss (ml)	1208.5±227.9	
Mean Heart Beat (bpm)	106.8±4.97	
Blood Pressure		
Systolic (mmHg)	88.41±12.7	
Diastolic (mmHg)	56.14±8.4	

Efficacy of balloon tamponade was found in 108 (91.5%) cases and 10 (8.5%) cases were non effective.(table 2)

Table-2: Post-treatment frequency of efficacy

Variables	Frequency	Percentage
Effectiveness		
Yes	108	91.5
No	10	8.5

Complications were found in 3 (3.5%) cases.(fig 2)

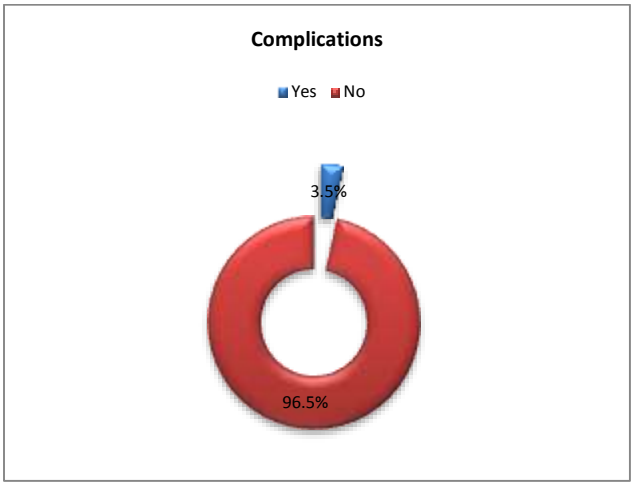

Figure-2: Post-treatment frequency of complications

DISCUSSION

In underdeveloped nations, PPH is a key contributor to maternal mortality rates and female mortality overall. The Central Statistical Office of Poland reported 540 maternal peripartum fatalities in 2006. Of them, 34.7 were attributable to PPH. [16] Modern obstetrics should focus primarily on postpartum care. The World Health Organization (WHO), the American College of Obstetricians and Gynecologists (ACOG), and the Polish Gynecological Society have all put out guidelines for the management of PPH (PGS). Balloon uterine tamponade is a relatively new addition to the arsenal for controlling preterm labour when standard methods (uterotonics, etc.) fail. Some examples of balloon catheters are the Bakri, Foley, Sengstaken-Blakemore, Rusch, and the condom catheter. [17]

For severe cases of PPH, a balloon catheter intrauterine tamponade is another treatment option. Using this method to treat individuals with severe PPH has been the subject of a published research. Even though the catheter was successfully placed in 90% of the instances, the tamponade was unsuccessful and a hysterectomy was necessary in 10% of the cases. [18]

In current study 118 females had age 18-40 years presented with postpartum hemorrhage. Among 118 cases, 40 (33.9%) cases had age 18-25 years, 55 (46.6%) females had age 26-30 years and 23 (19.8%) cases had age >30years. These results were comparable to the previous researches.[19,20] We found that majority of the cases were from rural areas and were not educated. 75 (63.6%) had BMI <25kg/m^2 and 43 (36.4%) had BMI >25kg/m^2. Mean gestational age of the females was 36.55±6.72 and mean parity was 3.11±6.9. Mean blood loss was 1208.5±227.9 ml. Mean pulse rate was 106.8±4.97 bpm. Mean systolic and diastolic blood pressure was 88.41±12.7 mmHg and 56.14±8.4 mmHg.[16-20] Uterotonic medicines and bimanual compression are the first-line therapy for PPH. Compressive suturing of the uterus, ligation of the internal iliac artery, or embolization of the pelvic arteries constitute secondary therapies. In contrast, pelvic arterial embolization necessitates a radiology intervention suite and cannot be conducted expeditiously in the operating room since the caesarean section incision must first be closed. If severe bleeding persists, a caesarean hysterectomy is the only option to ensure the mother's safety [21,22]. Intrauterine tamponade, on the other hand, may be administered in the operating room almost immediately, and it has a higher success rate in sustaining fertility.

In current study, efficacy of balloon tamponade was found in 108 (91.5%) cases and 10 (8.5%) cases were non effective. Due to the increased risk of surgical intervention or angiographic embolization, uterine tamponade may be necessary in PPH coupled with disordered coagulation. Some methods, including the Sengstaken-Blakemore tube, rolled gauze, and most recently the condom catheter, have been reported to be effective for tamponade. [23] Previous studies have reported the benefit of balloon tamponade for massive PPH regardless of cause and suggested that balloon tamponade should be part of all protocols in the management of PPH.[24] More recently, Laas et al. [25] reported an 86% global success rate of uterine balloon tamponade in a before-and-after study to evaluate its utility for PPH management.

In our study,complications were found in 3 (3.5%) cases. Balloon catheterization has been shown to have a number of drawbacks, including occlusion by uterine myoma, accidental catheter injury, and incompatibility with other therapies, according to a prior research [26].

CONCLUSION

We conclude that follys intrauterine catheter balloon tamponade controls postpartum bleeding. There should be a low threshold for using balloon tamponade as it is effective, easy to use,easily available, has a low complication rate, and is an economical modality to control non-traumatic postpartum haemorrhage, especially in resource-limited settings, and sustain reproductive potential.

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