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Original Research Article

To Evaluate the Effectiveness of Balloon Tamponade in Preventing Atonic Postpartum Hemorrhage in Comparison to Foley's Condom

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Abstract:

Background: One of the top five causes of maternal mortality in both developed and developing nations is primary postpartum hemorrhage (PPH). Various uterine taponade devices have been used successfully to treat PPH over the past 20 years. In order to reduce atonic postpartum hemorrhage, this study compares the effectiveness and safety of balloon tamponade and Foley's condom balloon tamponade (FC).

Methods:100 patients with atonic PPH were randomly divided into two groups for the prospective randomized control experiment. Group 1 (50 cases) received Foley's condom balloon management, while Group 2 (50 cases) received JH balloon tamponade management. Time of UBT implantation and time of bleeding cessation were used as outcome indicators. It was also documented if there were any negative effects or balloon slippage. To ascertain the long-term outcomes in terms of menses, uterine cavities, and pregnancies, the patients were followed up with at 6 months.

Results: In cases of JH balloon tamponade, the success rate was 92%, whereas in situations of FC balloon tamponade, it was 88% (p=0.74). B-Lynch sutures, uterine artery ligation, and sub-total hysterectomy were used in two of the six cases of failure in the FC group, while same procedures were used in all four cases of failure in the JH group (p=0.418). The mean time to make, insert, and inflate the catheter (3.01 vs. 3.12 mins; p=0.09) and the mean time to halt bleeding (7.08 vs. 6.91 mins; p=0.65) were comparable between the FC and JH groups. Only 1 patient in the JH group experienced JH balloon tamponade slippage compared to 10 patients out of 50 in the FC group (p=0.008). 38 patients in the FC group and 40 patients in the JH group reported no unfavorable long-term results during the 6-month follow-up. During that time, they experienced typical menstrual periods with no subsequent pain.

Conclusion: The success rates of JH balloon tamponade and Foley's condom balloon were both good and comparable (88% and 92%, respectively). Both balloon tamponades make the best use of the available resources and are simple to perform, even at peripheral health centers with limited resources and without wasting much time. Therefore, both types of balloons can be employed successfully in atonic PPH treatments instead of surgery.

Keywords: Atonic PPH, balloon tamponade, Foley's condom balloon.

Introduction

One of the main factors contributing to significant obstetric hemorrhage in obstetric settings is postpartum hemorrhage (PPH). Numerous consequences such as hypovolemic shock, renal failure, coagulopathy, and mortality result from the enormous blood loss. [1-4] Even though WHO and FIGO have standardized the care of PPH and advise using uterotonics followed by intrauterine balloon tamponade (UBT),3 the morbidity and mortality associated with atonic PPH are not adequately controlled, especially in countries with limited resources. [1] The main factor is the expensive expense of high-quality balloon tamponades, which prevents women from receiving sufficient care. As a result, hospitals with limited resources must rely on other, less expensive but more efficient adjustments and improvements. UBT uses a process that involves inflating a balloon inside the uterus to exert pressure on the blood vessels and reduce bleeding. It has been demonstrated that they have a high effectiveness rate of about 97.0%.;[5] Numerous balloon tamponades are available on the market, including the Sengstaken-Blakemore esophageal tube, the

Foley's condom balloon catheter, the Rusch balloon, and the Bakri balloon [1]. The majority of these devices are expensive but have the benefit of a drainage port via which the amount of blood loss can be determined. The Foley's condom balloon catheter [3], whose effectiveness has been well established, and the JH balloon [4], a more recent invention manufactured from readily available, inexpensively sterilized materials, are two examples of moderately priced adaptations.
The failure rate of JH balloon tamponade was determined to be only 3.61% in a study by Nalini et al. [4] In the resource-constrained environments of developed nations like our own, these adaptations are extremely important. They are straightforward, simple to manufacture, and effective.

Material and Methods

From April 2022 to March 2023, the prospective randomized control experiment was carried out in the Department of Obstetrics and Gynecology, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar. Patients with atonic PPH who couldn't be treated medically were included in the trial.

Patients with traumatic PPH, remaining placental and membrane fragments, clinical signs of chorioamnionitis, congenital uterine anomalies, retained bits of membrane, and suspicion of uterine rupture were excluded from the study.

During the study period, 100 suitable cases were included and randomly divided into two groups.

Foley's condom balloon was used to control Group 1 (50 cases), and JH balloon tamponade was used to manage Group 2 (50 cases).

Age, obstetric history, gestational age, start of labor, substance used to induce labor, length of labor, and high-risk conditions including multiple pregnancies, polyhydramnios, macrosomia, etc. were all noted in the patients' demographic information. Pallor, pulse, blood pressure, chest, CVS, and any varicose veins in the lower limbs were noticed during the clinical examination.

The necessary investigations, including complete blood counts, coagulation tests, thyroid levels, and HIV status, were carried out. The third stage of labor was being actively managed. Before inserting balloon, the uterovaginal canal was examined to rule out any instances of traumatic PPH.

Following doses of oxytocin was used before giving balloon tamponade -

1. 20 unit of oxytocin in 500ml of ringer lactate: - 40-60drops/min
2. 1 amp of methyl ergometrine IM (If not con-traindicated)
3. 250 micrograms of carboprost IM (If not con-traindicated)

After employing the aforementioned dose of uterotonic and continuously unbroken bimanual uterine compression for 5 minutes, supportive measures, the creation of a "JH Balloon" or "Foleys Condom balloon," and bimanual compression of the uterus were all initiated concurrently. If atonicity and bleeding persisted, we proceeded with uterine balloon tamponade using either the JH balloon or the Foley's balloon in accordance with random group allocation.

Prior to transferring the patient to the observation room, USG was performed to rule out the possibility of blood accumulating between the balloon wall and the uterine wall after the UBT had been applied. After the balloon was removed, all patients were kept under surveillance for 12 hours by having their pulse, blood pressure, and vaginal hemorrhage measured every 2 hours. Following balloon tamponade, broad spectrum antibiotics (ceftriaxone with sulbactam, metrogyl) were begun and maintained for 24 hours. Methyl ergometrine was administered intramuscularly 7 to 10 minutes before to balloon removal (if not contraindicated). Oxytocin drip (10 units in 500ml of ringer lactate) was started and sustained for two hours following balloon removal in patients for whom methyl ergometrine is contraindicated.

The continuation of bleeding after 15 minutes of tamponade was used to determine whether the balloon tamponade was successful or not. Surgery was used to control the current bleeding attack as part of the patients' continued therapy in accordance with hospital practice.

Time of UBT implantation and time of bleeding cessation were used as outcome indicators. Additionally, any negative effects or UBT slippage were observed. To ascertain the long-term outcomes in terms of menses, uterine cavities, and pregnancies, the patients were followed up with at 6 months.

The mean±SD was used to depict the quantitative data. Nominal and categorical data were both reported as percentages. Quantitative data was evaluated using the t-test, while categorical data was studied using the Chi-square test and non-parametric data was analyzed using the Mann Whitney test. The p-value's significance cutoff was set at <0.05. SPSS software version 21 was used for all of the analysis.

Results

The study group average age was 25.19 years, and 71% of the females were between the ages of 20 and 30. Age-related differences between study groups were not found ($p=0.55$). Out of the 100 respondents in the study, 54% had multiple paragraphs and 46% had a single paragraph ($p=0.55$). Pre-term birth, defined as birth before 37

weeks of gestation, was reported in 22% of instances, while term birth, defined as birth between 37 and 42 weeks, was recorded in 76% of cases (p=0.89). In 16% of the instances, labor had to be induced; however, in 84% of the cases, spontaneous labor took place (p=0.17).Anemia (81%) and PIH (14% each) were the most prevalent risk factors for atonic PPH in the current investigation, while history of LSCS and twin gestation were found in 9% and 5% of patients, respectively (p>0.05). In 80% of instances, vaginal birth occurred, while 20% of deliveries necessitated cesarean sections (p>0.05). The mean preoperative hemoglobin level in the FC and JH groups was comparable (7.90 vs 7.68 g/dL; p=0.49).The bulk of the patients in both groups was either illiterate or had only completed elementary school. None of them have any college experience. The modified Kuppuswamy scale was used to classify patients into different socioeconomic statuses. The majority of the patients, 54% in the JH group and 58% in the FC group, belonged to lower socioeconomic status. Patients in the FC group were 82% Hindu, 12% Muslim, 6% Christian, and 72% Hindu, 16% Muslim, 12% Christian in the JH group. In the study, the majority of patients (p=1) were from rural areas. According to tables 1 to 11, the study groups' baseline demographic parameters were comparable across all groups.

Table 1: Age distribution of both groups

Age group (in yrs.)	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
≤20	13(26%)	8(16%)	21(21%)	0.55
21-25	15(30%)	19(38%)	34(34%)	
26-30	17(34%)	20(40%)	37(37%)	
31-35	4(8%)	3(6%)	7(7%)	
>35	1(2%)	0(0%)	1(1%)	

Table 2: Obstetrics History of both groups

Obstetrics History	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
Primi	25(50%)	21(42%)	46(46%)	0.55
Multi	25(50%)	19(58%)	54(54%)	

Table 3: Gestational Age of both groups

Gestational Age (in weeks)	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
<37	12(24%)	10(20%)	22(22%)	0.89
37-42	37(74%)	39(78%)	76(76%)	
>42	1(2%)	1(2%)	2(2%)	

Table 4: Onset of Labour in both groups

Onset of Labour	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
Induced	11(22%)	5(10%)	16(16%)	0.17
Spontaneous	39(78%)	4(8%)	84(84%)	

Table 5: Risk factors of both groups

Risk Factors	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
Anemia	43(86%)	38(76%)	81(81%)	0.31
PIH	7(14)	7(14%)	14(14%)	1
Previous LSCS	4(8%)	5(10%)	9(9%)	1
Twins	3(6%)	2(4%)	5(5%)	1
Obstructed Labour	2(4%)	2(4%	4(4%)	1
IUD	2(4)	2(4%	4(4%)	1
PROM	1(2%)	3(6%)	4(4%)	0.49
Placental abnormalities	2(4%)	1(2%)	3(3%)	1
NPOL	1(2%)	0(0%)	1(1%)	1
Shock	0(0%)	1(1%)	1(1%)	1
Oligohydramnios	1(2%)	0(0%)	1(1%)	1

Table 6: Mode of Delivery in both groups

Mode of delivery	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
LSCS	9(18%)	11(22%)	20(20%)	0.55
Vaginal	41(82%)	39(78%)	80(80%)	

Table 7: Preoperative Hemoglobin in both groups

	FC Group	JH Group	Total	p-value
Pre-op Hemoglobin in gm%	7.9±1.44	7.68±1.77	7.79±1.62	0.49

Table 8: Education status in both groups

Education	FC Group N (%)	JH Group N(%)	Total N (%)	p-value
Illiterate	20(40%)	15(30%)	35(35%)	0.557
Primary school	25(50%)	30(60%)	55(55%)	
Higher secondary	5(10%)	5(10%)	10(10%)	
College	0(0%)	0(0%)	0(0)	

Table 9: Socio-economical status in both groups

Socio-economical status	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
Lower	29(58%)	27(54%)	56(56%)	0.366
Upper lower	5(10%)	11(22%)	16(16%)	
Lower Middle	12(24%)	10(20%)	22(22%)	
Upper middle	4(8%)	2(4%)	6(6%)	
Upper	0(0%)	0(0%)	0(0%)	

Table 10: Religion of both groups

Religion	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
Hindu	41(82%)	36(72%)	77(77%)	0.447
Muslim	6(12%)	8(16%)	14(14%)	
Christian	3(6%)	6(12%)	9(9%)	

Table 11: Area of Resident in both groups

Religion	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
Rural	38(76%)	39(78%)	77(77%)	1.0
Urban	12(24%)	11(22%)	33(33%)	

In cases of JH balloon tamponade, the success rate was 92%, whereas in situations of FC balloon tamponade, it was 88% (p=0.74). B-Lynch sutures, uterine artery ligation, and sub-total hysterectomy were used in two of the six cases of failure in the FC group, while same procedures were used in all four cases of failure in the JH group (p=0.418).The mean time to make, insert, and inflate the catheter (3.01 vs. 3.12 minutes; p=0.09) and the mean time to halt bleeding (7.08 vs. 6.91 mins; p-0.65) were comparable between the FC and JH groups. In the FC group, 10 patients out of 50 experienced balloon tamponade slippage, compared to just 1 patient in the JH group (p=0.008) (table 12).

Table 12: Comparison of outcome in both groups

Variables	FC Group N (%)	JH Group N (%)	Total N (%)	p-value
Outcome • Failure • Success	 6(12%) 44(88%)	 4(8%) 46(92)	 10(10%) 90(90%)	0.74
Time of making, insertion and inflation of catheter FC(n=50), JH (n=50)	3.01±0.05	3.12±0.13	3.065±0.11	0.09
Time to stop bleeding FC (n=44), JH (46)	7.08±2.14	6.91±1.45	6.99±1.82	0.65
Slippage of balloon tamponade	10(20%)	1(2%)	11(11%)	0.008

38 patients in the FC group and 40 patients in the JH group reported no unfavorable long-term results during the 6-month follow-up. During that time, they experienced typical menstrual periods with no subsequent pain.

Discussion

PPH is a serious problem for expectant mothers of all ages. The age distribution in this study and other earlier studies shows that young pregnancies in the age range of 20 to 30 years are substantially more common in developing countries than in western countries. [2-4]This is significant because they have several children at regular intervals when they are young, which causes them to be mildly anemic. In our study, 81% of the women were anemic, which increased the need for blood products and was a significant risk factor for PPH. Previous Indian research has consistently noted this. [3]PPH management and delivery strategy go hand in hand. The decision to treat PPH by B-lynch suture or sub-total hysterectomy after cesarean deliveries is straightforward on the one hand, but following vaginal deliveries, the decision to undergo surgery is time-consuming, leading to an increase in the usage of UBT.4 Currently, vaginal delivery is the

most common mode of delivery (80% of cases) in both our study and other prior studies [6,7]. After deciding to employ UBT, the moment of constructing the balloon catheter is a crucial event. Both pieces of equipment required longer to make and inflate on average than the conventional (1.8 minutes) and CG balloon catheter (1.2 minutes) catheters used in the investigation by Xess et al. [2] Their study just calculated the time to assemble and did not account for inflation, which may be the reason for the discrepancy. JH balloon was created in 5.2 minutes as opposed to the pioneer study 10.5 minutes. [4]PPH must be stopped as soon as possible since it can occasionally be followed by significant bleeding, which can cause coagulation abnormalities and DIC. According to prior comparative studies, the time to halt bleeding in our study was less than 10 minutes (7.08 vs 6.91 min; p=0.65) and comparable across the FC and JH groups. [1,3]

Although statistically the time to stop bleeding was comparable, the JH balloon outperformed the FC catheter in terms of actual statistics. This may be due to the condom's soft material, which may take longer to achieve the necessary compression. [1,4] Nalini et al. reported a mean time of 8.4 minutes to control bleeding to further validate. [4]

Only 8% and 12% of the JH balloon and the condom balloon catheter, respectively, experienced failures, making both balloons equally successful (p>0.05). The investigations have revealed a success rate range for Foley's condom catheter of 86–100% at one end.1,8 Condom loaded Foley's catheters (CLFC) had a failure rate of 15% in Darwish et al. [1] and 95% and 90.4% in Burke et al. [5] and Lohano et al. [5], respectively, which was slightly higher than in our study. This may be due to the older study small sample size (33 instances in each group) and the latter studies' larger sample sizes (201 and 139 cases, respectively). On the other hand, JH balloon's success was comparable to that of the groundbreaking trial by Nalini N et al, where 92% of PPH cases were successfully controlled. [4] Interestingly, we also discovered that the JH balloon's success rate (92%) was close to that of the Bakri balloon catheter, one of the common UBTs in industrialized nations (91%). [1]With FC, there were considerably more cases of balloon tamponade slippage (10 cases vs. 1 case, p=0.008) than in the JH group. This might be as a result of JH balloon using latex gloves, which are more robust, manageable, and take on a more "pyriform shape" than condoms. [4]

All of the UBT failure instances were handled surgically, with B-lynch sutures, or both. This continues to be the accepted practice for handling such issues. [1-3]Overall, the lack of side effects or mortality in our study indicates that these adaptations for resource-constrained settings are helpful in managing PPH. Due to the fact that these balloon catheters are single-use disposables, any infection from reusing them is prevented.

The strength of the current study is the 6-month follow-up of the patients to track any negative effects of balloon tamponade on menstruation, fertility, or pregnancy. Additionally, the study's randomization ensured an accurate comparison of the treatments without introducing confounding bias. Due to the fact that the cost-effectiveness is a topic that the middle class and lower classes of society find interesting, the study was limited in that it did not evaluate it. The study's sample size was quite tiny, which might have tainted the findings for some factors. It was not done to accurately estimate and compare the blood loss. Last but not least, because the control group wasn't included, we can't say for sure whether the results for those ladies would have been different if UBT hadn't been used.

Conclusion

The success rates of JH balloon tamponade and Foley's condom balloon were both good and comparable (88% and 92%, respectively). Both balloon tamponades make the best use of the available resources and are simple to perform, even at peripheral health centers with limited resources and without wasting much time. Therefore, both types of balloons can be employed successfully in atonic PPH treatments instead of surgery. Additionally, uterine balloon tamponade enables time to schedule a laparotomy or blood transfusion as well as to transfer the patient to a tertiary referral hospital (if necessary) for additional therapy. To verify the results of this little series, we will require larger trials.

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