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Original Research Article

Comparing the Effectiveness of JH Balloon Tamponade and Foley's Condom Balloon Tamponade in Preventing Atonic Postpartum Hemorrhage: A Study from NSCB Medical College, Jabalpur

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Abstract

Background: Postpartum hemorrhage (PPH) is one of the major causes of massive obstetric hemorrhage in obstetric settings. World Health Organization (WHO) and the Federation of Gynecology and Obstetrics (FIGO) recommend using uterotonics followed by intrauterine balloon tamponade to manage PPH.

Aim and Objectives: This study evaluates the efficacy and safety of two methods for controlling atonic postpartum hemorrhage: the JH balloon tamponade and the Foley's condom balloon tamponade (FC).

Materials and Methods: One hundred patients with atonic PPH were split into two groups for the prospective randomized control trial: Group 1 (n=50) was treated with Foley's condom balloon management, and Group 2 (n=50) was treated with JH balloon tamponade. The outcome metrics were the time to inject the UBT and the time to halt bleeding. The balloon's slipperiness and other unwanted consequences were also recorded. Long-term effects on menstruation, the uterine cavity, and pregnancy were assessed by following the patients for six months.

Results: The success rate of JH balloon tamponade was 92% (p=0.74), while the success rate of FC balloon tamponade was 88% (p=0.74). Four of the four failures in the JH group were treated with B-Lynch sutures and uterine artery ligation (p=0.418), while two of the six failures in the FC group were treated with each of these procedures (p=0.418). Mean times to make, insert, and inflate the catheter (3.01 vs. 3.12 minutes; p=0.09) and to halt bleeding (7.08 vs. 6.91 minutes; p=0.65) were similar between the FC and JH groups. Slippage of balloon tamponade occurred in 1 patient in the JH group compared to 10 patients in the FC group (p=0.008). No long-term complications were reported by patients in either the FC or JH groups after six months of follow-up. During their regular menstrual periods, they experienced no discomfort.

Conclusion: The success rates of the Foley's condom balloon and the JH balloon tamponade were high and similar to 92%. Both balloon tamponade methods efficiently use available

resources and may be made quickly and easily even at a health center with limited means located in a rural area. Therefore, both balloon types can be employed effectively in atonic PPH treatments as a non-invasive alternative to surgical interventions.

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

Introduction

One of the leading causes of severe obstetric bleeding is postpartum hemorrhage (PPH). Hypovolemic shock, renal failure, coagulopathy, and death are only a few side effects of massive blood loss. [1, 2]

Despite WHO and FIGO's standardized care of PPH (uterotonics followed by intrauterine balloon tamponade [UBT]) [3], atonic PPH remains a leading cause of maternal mortality, especially in low-resource countries. [1, 4]

The primary reason is the expensive expense of high-quality balloon tamponades [5], which means many women cannot access this life-saving treatment. Therefore, low-resource hospitals must rely on alternative, low-cost alterations and adaptations.

UBT uses the pressure force created by inflating a balloon inside the uterine cavity to stop bleeding. Their shown efficacy is relatively high, at roughly 97.0%. [5] Numerous balloon tamponades are available, such as the Sengstaken-Blakemore esophageal tube, the Foley's condom balloon catheter, the Rusch balloon, and the Bakri balloon. [1] These tamponades can be expensive, but they all share the same benefit of a drainage port that allows the patient's blood loss to be monitored.

Foley's condom balloon catheter, one of the more inexpensive adaptations with demonstrated efficacy, is one example. [3] and the recently created JH balloon (JH stands for Jharkhand) [4], which uses readily available, inexpensive, and sterile materials. The success rate of JH balloon tamponade was just 3.61 percent, according to research by Nalini et al. [4] These modifications are particularly crucial in the resource-limited environments of developed nations like ours. They're straightforward, quick to whip up, and have proven beneficial. However, no studies have compared the effectiveness of these two improvements yet. Therefore, this study aimed to evaluate the two methods of balloon tamponade commonly used to stop atonic postpartum hemorrhage: the JH balloon and the Foley's condom.

Materials and Methods

From April 2019 through September 2020, researchers in Jabalpur's Department of Obstetrics and Gynaecology conducted the prospective randomized control experiment. Patients with atonic PPH who were medically unmanageable were included in the trial. Participants were omitted if they had any of the following conditions: chorioamnionitis, uterine abnormality, traumatic PPH, retained placenta or membranes, or suspicion of uterine rupture.

Darwish et al. [1] found that the median time from the beginning of balloon insertion to the end of bleeding, a key variable in determining sample size, was 11.76 7.23 minutes. Using these parameters and supposing a time difference of 35%, we find that 49 patients per group are needed to achieve 80% power and a 5% significance level. One hundred people (fifty from each group) were surveyed to keep the error rate down.

During the trial, 100 patients who met the criteria were included and split evenly between two groups. Foley's condom balloon was used to handle the first group

of 50 patients, while JH balloon tamponade was used to control the second group of 50 cases. The randomization procedure utilized a sealed envelope system with treatment allocation slips created randomly. Here, we made ten hermetically sealed, opaque envelopes and randomly assigned each letter, A through JH, to five envelopes. A patient's allocated treatment regimen was revealed after they gave their informed agreement to participate in a trial. Ten-person blocks were used to assign all of the patients randomly.

The "Institutional Ethics Committee" has already approved this study. Patients or their legal guardians were counseled, and their signatures on a written informed consent form were acquired.

High-risk factors such as multiple pregnancies, polyhydramnios, macrosomia, etc., and demographic characteristics such as age, obstetric history, pregnancy duration, labor commencement, labor-inducing agent, duration of labor, and other details were noted. Pallor, pulse, blood pressure, chest, central nervous system, and lower limb varicosities were recorded throughout the clinical examination. Complete blood count, coagulation, thyroid, and HIV testing were all carried out, among other pertinent diagnostics. Third-stage labor management was being actively administered. Before balloon insertion, the uterovaginal canal was examined to rule out traumatic PPH.

Following doses of oxytocin were 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 contraindicated)
3. 250 micrograms of carboprost IM (If not contraindicated)

After utilizing the amount mentioned earlier of uterotonic and maintaining uninterrupted bimanual uterine compression for 5 minutes, the patient began receiving supportive care and making a "JH Balloon" or "Foleys Condom balloon." Depending on the patient's random assignment, uterine balloon tamponade was performed using a JH balloon or a Foley balloon. We waited 15 minutes after applying UBT to check for bleeding through the os. Then we completed a USG to rule out blood collection between the balloon and uterine walls before moving the patient to the observation room.

After removing the balloon, all patients were monitored for 12 hours by taking their pulse, blood pressure, and vaginal bleeding rates every two hours. After balloon tamponade, a broad-spectrum antibiotic regimen of ceftriaxone plus sulbactam and metrogyl was initiated and maintained for 24 hours. Methyl ergometrine was injected intramuscularly 7-10 minutes before balloon deflation (unless contraindicated). Patients for whom methyl ergometrine is contraindicated underwent a 2-hour oxytocin infusion after removing the balloon (10 units in 500 ml of ringer lactate).

Balloon tamponade was judged successful or unsuccessful based on whether or not bleeding persisted after 15 minutes of tamponade. [1] Surgical measures to stop the current episode of bleeding were part of the subsequent therapy of the patients as per hospital protocol. The outcome metrics were the time to inject the UBT and the time to halt bleeding. The UBT's slippage and any adverse effects were also recorded. Long-term effects on menstruation, the uterine cavity, and pregnancy were assessed by following the patients for six months.

Statistical analysis:

Statistics were summarised as means and standard deviations. Percentages were used to represent categorical and nominal data. When assessing numerical data, we utilized the t-test; when dealing with non-parametric data, we used the Mann-Whitney test; and when dealing with categorical data, we used the Chi-square

test. The p-value cutoff for significance was determined to be.05.

Results

The average age of the participants was 25.19, and 71 percent of the women were in their 20s and 30s. There was no significant difference in age between the study groups (p=0.55). Five-and-a-half percent of the study's subjects were multi-para, and nearly half were primipara (p = 0.55). In 76% of deliveries, the gestational age was at least 37 weeks; in 22%, the gestational age was less than 37 weeks (p=0.89). Only 16% of births required induction, while 84% were natural (p=0.17).

Anaemia (81%), pulmonary hypertension (14%), and a history of LSCS (9%) or twin gestation (5%; p>0.05) were the most common risk factors for atonic PPH in the current investigation. Eighty percent of births occurred naturally, while twenty percent required surgical intervention. The FC and JH groups had similar preoperative mean hemoglobin levels (7.90 vs. 7.68 g/dL; p=0.49).

The vast majority of patients in both cohorts had only completed elementary school. No one has gone to university. Patients were classified by their socioeconomic status using the modified Kuppuswamy scale. Most patients were from lower socioeconomic backgrounds (58% in FC and 54% in JH) in both the FC and JH groups. Patients' religious affiliations were as follows: 82% Hindu, 12% Muslim, and 6% Christian in the FC group; 72% Hindu, 16% Muslim, and 12% Christian in the JH group. The majority of study participants were of rural origin (p=1.00). As can be seen in Table 1, there were no significant differences in baseline demographics between the research groups.

JH balloon tamponade had a 92% success rate, while FC balloon tamponade only had an 88% success rate (p=0.74). B-Lynch sutures were used to repair the uterine artery in two of the six FC group failure cases.

Table 1: Demographic characteristics of the study groups

Baseline parameters		Group		Total
		FC	JH	
Age (years)	<20	13	8	21
	21-25	15	19	34
	26-30	17	20	37
	31-35	4	3	7
	>35	1	0	1
Obstetric history	Primi	25	21	46
	Multi	25	29	54
Gestational age (weeks)	<37	12	10	22
	37-42	37	39	76
	>42	1	1	2
Onset of labor	Induced	11	5	16
	Spontaneous	39	45	84
Risk factors	Anemia	43	38	81
	PIH	7	7	14
	Previous LSCS	4	5	9
	Twins	3	2	5
	Obstructed labor	2	2	4
	IUD	2	2	4
	PROM	1	3	4
	Placental abnormalities	2	1	3

Table 2: Comparison of outcome between the study groups

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

No long-term complications were reported by patients in either the FC or JH groups after six months of follow-up. During that time, they experienced pain-free menstrual periods.

Discussion

PPH is a major worry in any age group's pregnancy. This and other studies that have looked at age distributions have found that in developing countries, there are disproportionately more births to women in their twenties and thirties than in the West. [2-4] They are somewhat anaemic because they start having children early and have them at regular intervals. Eighty-one percent of the women in our research had anemia, a key risk factor for PPH that increases the demand for blood products. Previous research in India has repeatedly found this to be the case.

PPH management and distribution methods are intertwined. Managing PPH with a B-lynch suture or sub-total hysterectomy is a simple choice for mothers who have just undergone a cesarean section, but this is not the case for those who have given birth vaginally, leading to an increase in the usage of UBT. [4]

Our study and another recent one [6] found that vaginal births are currently the most common. After deciding to employ UBT, a pivotal moment occurs during creation of the balloon catheter. Making and inflating each device took an average of just over 3 minutes, longer than the standard balloon catheter (1.8 minutes) and CG balloon catheter (1.2 minutes) employed in the Xess et al. trial. [2] It's possible that inflation wasn't factored into their study's calculations for how long it would take to put everything together.

Making a balloon out of JH required less than the 5.2 minutes used in the original investigation. [4] Massive bleeding can occur with PPH, leading to coagulation abnormalities and DIC if it is not stopped as soon as feasible. Similarly to prior comparative studies, we found that the time to stop the bleeding was similar between our study's FC and JH groups (7.08 vs. 6.91 mins; p=0.65). [1, 3] The two methods took roughly the same time to stop the bleeding, but the exact numbers favored the JH balloon over the FC catheter. This may be due to the soft material of the condom, which may take longer to provide the appropriate compression needed to stop the bleeding. [1, 4] Nalini et al. revealed a mean time to stop bleeding of 8.4 minutes, lending further credence to the findings.[4]

Failure rates were similar for the JH balloon and the Foley's condom balloon catheter, at 8% and 12%, respectively (p>0.05). Foley's condom catheter has been demonstrated to work between 86% and 100% of the time in tests. [1] Condom-loaded Foley's catheter (CLFC) failure rates were greater in Darwish et al. 1 (15%) than in our study and Burke et al.[5] and Lohano et al. [6] 95% and 90.4% were somewhat higher than in ours. This may be because the sample sizes in the first trial (with 33 cases in each group) were much less than those in the second and third investigations (with 201 and 139 cases, respectively). In contrast, 92% of patients with PPH 4 could maintain their normal blood pressure after receiving

a JH balloon, similar to the results of the pioneering study by Nalini N et al. [4] Interestingly, we also discovered that the JH balloon's success rate (92%), like that of the Bakri balloon catheter (91%), a typical UBT in industrialized countries, was comparable to theirs.[1]

Balloon tamponade slippage was more common in the FC group (10 cases vs. 1 case, p=0.008). It's possible that latex gloves, used in JH balloons because they're stronger, last longer, and are easier to work with/acquire a more "pyriform shape" than condoms, are to blame for this.[4] When the UBT was unsuccessful, B-lynch sutures, artery ligation, or surgery were used to treat the patients. This method of handling such circumstances has become common practice.[1-3]

Our results show that PPH may be successfully managed with these modifications for low-resource settings, with no adverse effects and no deaths. Because they are single-use disposables, there is no risk of infection from using a balloon catheter more than once. The current study's strength lies in its ability to record the effects of balloon tamponade on fertility, menstruation, and pregnancy by tracking patients for six months. Furthermore, the randomization in the study prevented any confounding bias from influencing the results of comparing the interventions. The study did not evaluate cost-effectiveness, which is of interest to the middle and lower classes. Results for some parameters may be skewed because of the short sample size. No proper assessment or comparison of blood loss was made. Finally, because no comparison group was used, we cannot say whether the outcomes for these women would have been different if UBT had not been used.

Conclusion

There was little difference between the success rates of Foley's condom balloon and JH balloon tamponade (88% for Foley and 92% for JH). Both balloon tamponade methods efficiently use available resources and may be made quickly and easily even at a health center with limited means located in a rural area. Therefore, both balloon types can be employed effectively in atonic PPH treatments as a non-invasive alternative to surgical interventions. In addition, tamponading the uterus with a balloon provides enough breathing room to transport the patient to a tertiary referral center, perform a laparotomy, or both. However, further extensive testing is required to confirm the results of this small sample.

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