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RESEARCH ARTICLE

To compare the role of JH balloon tamponade and Foley's condom balloon tamponade to control atonic postpartum haemorrhage

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ABSTRACT

Objectives: To compare the efficacy and safety of JH balloon tamponade and Foley's condom balloon tamponade (FC) to control atonic postpartum haemorrhage. **Methods:** The prospective randomized control trial was conducted on 100 patients of atonic PPH who were randomly assigned into two groups: Group 1 (50 cases): managed by Foley's condom balloon and Group 2 (50 cases): managed by JH balloon tamponade. The outcome measures were time of insertion of the UBT and time of stoppage of bleeding. Any side effects or slippage of the balloon was also noted. The patients were followed up at 6 months to determine the long term outcomes in terms of menses, uterine cavity and pregnancies. **Results:** Success rate was 92% in cases of JH balloon tamponade while it was 88% in cases of FC balloon tamponade respectively (p-0.74). In 6 cases of failure in FC group, 2 each were managed with B-Lynch sutures, uterine artery ligation and sub-total hysterectomy while the 4 cases of failure in JH group were managed by B-Lynch sutures and uterine artery ligation (p=0.418). Mean time to making, insertion and inflation of the catheter (3.01 vs 3.12 mins; p-0.09) and mean time to stop bleeding was comparable between the FC and JH groups (7.08 vs 6.91 mins; p-0.65). In FC group 10 patient out of 50 slippage of balloon tamponade occurred whereas only 1 patient in JH group slippage of JH balloon tamponade occurred (p=0.008). At 6 months follow up, 38 patients in FC group and 40 patients in JH group reported no adverse long term outcomes. They had normal menstrual cycles with no subsequent pain during that period. **Conclusion:** In conclusion, success rate of Foley's condom balloon and JH balloon tamponade was good and comparable (88% and 92% respectively). Both balloon tamponade utilizes the existing resources to their best and can be easily made even in resource poor peripheral health center without wastage of time. So both type of balloon can be successfully used in atonic PPH protocols before opting for surgical options.

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

Postpartum hemorrhage (PPH) is one of the major causes of massive obstetric hemorrhage in obstetric settings. The unprecedented blood loss leads to numerous complications like hypovolemia induced shock, renal dysfunction, coagulopathy and mortality [1-4]. Though the management of the PPH has been standardized by WHO and FIGO which recommends the use of uterotonics followed by intrauterine balloon tamponade (UBT) [3], the morbidity and mortality associated with atonic PPH fails to be controlled especially in resource poor settings [1]. The major cause being that women do not receive adequate care with high quality balloon tamponades [5] since they are costly. Thus, low resource hospitals have to rely on other adaptations and modifications which are cheap but effective.

UBT work on the mechanism of insufflation of a balloon in the uterine cavity to create a pressure effect for controlling the bleeding. They have been shown to present a high success rate of around 97.0% [5]. The market is flooded with a

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plethora of balloon tamponades including Sengstaken–Blakemore esophageal tube, Foley's condom balloon catheter, Rusch balloon, and Bakri balloon [1], most of which are costly but have an advantage of a drainage port through which one can assess the blood loss. Among the reasonably affordable adaptations are the Foley's condom balloon catheter whose efficiency has been well proven [3] and JH balloon (JH stands for Jharkhand) [4] which is a recent innovation developed from readymade cheap sterilized materials. In a study by Nalini et al, the failure rate of JH balloon tamponade was found to be only 3.61% [4]. These adaptations hold significant importance in the resource poor settings of the developed countries such as ours. They are simple, easy to make and have shown good effectiveness. However, no studies till date have evaluated and compared the efficacy of these two innovations. In present study, we thus aimed to compare the efficacy and safety of JH balloon tamponade and Foley's condom balloon tamponade (FC) to control atonic postpartum haemorrhage.

Methods

The prospective randomized control trial was conducted in the Department of Obstetrics & Gynaecology, Ranchi from April 2019 to September 2020. The study included patients of atonic PPH who could not be medically managed. Any patient with clinical evidence of chorioamnionitis, congenital anomaly of uterus, traumatic PPH, retained bits of placenta and membrane and suspicion of uterine rupture were excluded from the study.

The sample size calculation was based on the study of Darwish et al [1], who observed that time between starting insertion of balloon and stoppage of bleeding was 11.76 ± 7.23. Taking these values as reference and assuming difference of 35% in time, the minimum required sample size with 80% power of study and 5% level of significance is 49 patients in each study group. To reduce margin of error, total sample size taken is 100 (50 patients per group).

A total of 100 eligible cases were included during study period which were randomly assigned into two groups. Group 1 (50 cases): managed by Foley's condom balloon and Group 2 (50 cases): managed by JH balloon tamponade. The randomization technique was done by sealed envelope system which contained randomly generated treatment allocations slips. In this, I prepared ten sealed opaque envelopes assigning A and B in 5 envelopes each, where A represented FC Group and B represented JH Group. Once a patient consented to enter a trial, an envelope was opened and the patient was then offered the allocated treatment regimen. The total patients were randomized in a series of blocks of ten. Prior approval for this study was granted by "Institutional Ethics Committee, RIMS, Ranchi". The patients or their relatives were counseled and a willful, written informed consent was obtained from them with their signature.

The demographic details of the patients including age, obstetric history, duration of pregnancy, labor onset, labor inducing agent, labor duration, high risk factors like multiple pregnancy, polyhydramnios, macrosomia etc. were recorded. The clinical examination included pallor, pulse, blood pressure, chest, CVS, any varicose vein in lower limb noted. The relevant investigations were performed such as complete blood counts, coagulation tests, thyroid levels and HIV status. Active management of third stage of labor was being performed. Uterovaginal canal was explored to rule out cases of traumatic PPH before applying balloon.

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 contraindicated)
3. 250 micrograms of carboprost IM (If not contraindicated)

Bimanual compression of uterus, supportive measures and making of "JH Balloon" or "Foleys Condom balloon" was started simultaneously after using above dose of uterotonic and continuous uninterrupted bimanual uterine compression for 5 minutes. If atonicity and bleeding persisted, then we proceeded for uterine balloon tamponade by JH balloon or Foley's balloon as per randomized group allotment.

After applying UBT, we waited for 15 minutes to observe any bleeding through os, and then USG was done to rule out collection of blood between balloon wall and uterine wall before shifting the patient to observation room. All patients were kept under observation for 12 hours (after removal of balloon) by recording pulse, BP, and bleeding per vaginum 2 hourly. Broad spectrum antibiotics (ceftriaxone plus sulbactam, metrogyl) were started and continued till 24hrs following balloon tamponade. Before removing balloon methyl ergometrine was given intramuscular 7 to10 minutes before (if not contraindicated). In those patients whom methyl ergometrine is contraindicated, oxytocin drip (10 units in 500ml of ringer lactate) was started and continued for 2 hrs after removal of balloon.

The success and failure of the balloon tamponade was considered on the basis of continuing bleeding after 15 minutes of tamponade [1]. Further management of the patients according to the hospital protocol included surgical interventions to stop the current attack of bleeding. The outcome measures were time of insertion of the UBT and time of stoppage of bleeding. Any side effects or slippage of the UBT was also noted. The patients were followed up at 6 months to determine the long term outcomes in terms of menses, uterine cavity and pregnancies.

Statistical analysis: The quantitative data was represented as their mean ± SD. Categorical and nominal data was expressed in percentage. The t-test was used for analysing quantitative data, or else non parametric data was analyzed by Mann Whitney test and categorical data was analyzed by using Chi-square test. The significance threshold of p-value was set at <0.05. All analysis was carried out by using SPSS software version 21.

Results

Mean age of the study group was 25.19 years with 71% of the females between the age range of 20 to 30 years. No difference was observed between study groups in terms of age group (p-0.55). Out of the total 100 subjects in present study, 54% were multi-para and 46% were primi-para (p-0.55). Term delivery i.e. between 37 to 42 weeks was seen in 76% cases while pre-term delivery i.e. less than 37 weeks of gestation was observed in 22% cases (p-0.89). Induction of labor was required in 16% of cases while spontaneous labor occurred in 84% cases (p-0.17).

Most common risk factors of atonic PPH seen in present study were anemia (81%) and PIH (14% each) while history of LSCS and twin gestation was seen in 9% and 5% cases respectively (p>0.05). Vaginal delivery was seen in 80% cases while caesarean delivery was required in 20% cases (p>0.05). Mean preoperative hemoglobin level was comparable between the FC and JH groups (7.90 vs 7.68 g/dL; p-0.49).

In both the groups, majority of the patient were illiterate or has taken primary schooling. None of them has attended college. According to modified Kuppuswamy scale patients were divided in various socioeconomic status. Majority of the patients belonged to lower socio-economic status accounting for 58% in FC group and 54% in JH group. In FC group, 82% of patient were Hindu,12% were Muslim, 6% were Christian and in JH group, 72% of patient were Hindu,16% were Muslim, 12% were Christian. The maximum number of patients in the study came from rural background (p=1). The baseline demographic characteristics were comparable among the study groups as shown in table 1.

Table 1: Demographic characteristics of the study groups

Baseline parameters	Group		Total	P value
	FC	JH		
Age(in years)				
≤ 20 years	13(26%)	8(16%)	21(21%)	
21-25 years	15(30%)	19(38%)	34(34%)	
26-30 years	17(34%)	20(40%)	37(37%)	
31-35 years	4(8%)	3(6%)	7(7%)	
> 35 years	1(2%)	0(0%)	1(1%)	0.55
Obstetric history				
Primi	25(50%)	21(42%)	46(46%)	
Multi	25(50%)	29(58%)	54(54%)	0.55
Gestation age				
< 37 weeks	12(24%)	10(20%)	22(22%)	
37-42 weeks	37(74%)	39(78%)	76(76%)	
> 42 weeks	1(2%)	1(2%)	2(2%)	0.89
Onset of labour				
Induced	11(22%)	5(10%)	16(16%)	
Spontaneous	39(78%)	45(90%)	84(84%)	0.17
Risk factors				
Anemia	43(86%)	38(76%)	81(81%)	0.31
PIH	7(14%)	7(14%)	14(14%)	1
Prev. 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(2%)	1(1%)	1
Oligohydramnios	1(2%)	0(0%)	1(1%)	1
Mode of Delivery				
LSCS	9(18%)	11(22%)	20(20%)	
Vaginal	41(82%)	39(78%)	80(80%)	0.55
Pre-op Hemoglobin (gm%)	7.9 ± 1.44	7.68 ± 1.77	7.79 ± 1.62	0.49
Education				
Illiterate	20(40%)	15(30%)	35(35%)	
Primary School(Ps)	25(50%)	30(60%)	55(55%)	
Higher Secondary(Hs)	5(10%)	5(10%)	10(10%)	
College	0(0%)	0(0%)	0(0%)	0.557
Social economic status				
Lower	29(58%)	27(54%)	56(56%)	
Upper Lower	5(10%)	11(22%)	16(16%)	
Lower Middle	12(24%)	10(20%)	22(22%)	0.366
Upper Middle	4(8%)	2(4%)	6(6%)	
Upper	0(0%)	0(0%)	0(0%)	
Religion				
Hindu	41(82%)	36(72%)	77(77%)	
Muslim	6(12%)	8(16%)	14(14%)	0.447
Christian	3(6%)	6(12%)	9(9%)	
Area of residence				
Rural	38(76%)	39(78%)	77(77%)	1
Urban	12(24%)	11(22%)	23(23%)	

Success rate was 92% in cases of JH balloon tamponade while it was 88% in cases of FC balloon tamponade respectively (p-0.74). In 6 cases of failure in FC group, 2 each were managed with B-Lynch sutures, uterine artery

ligation and sub-total hysterectomy while the 4 cases of failure in JH group were managed by B-Lynch sutures and uterine artery ligation (p=0.418).

Mean time to making, insertion and inflation of the catheter (3.01 vs 3.12 mins; p-0.09) and mean time to stop bleeding was comparable between the FC and JH groups (7.08 vs 6.91 mins; p-0.65). In FC group 10 patient out of 50 slippage of balloon tamponade occurred whereas only 1 patient in JH group slippage of JH Balloon Tamponade occurred (p=0.008) (table 2).

Table 2: Comparison of outcome between the study groups

Variables		Group		Total	P value
		FC	JH		
Outcome	Failure	6(12%)	4(8%)	10(10%)	0.74
	Success	44(88%)	46(92%)	90(90%)	
Time in 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(n=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

At 6 months follow up, 38 patients in FC group and 40 patients in JH group reported no adverse long term outcomes. They had normal menstrual cycles with no subsequent pain during that period.

Discussion

PPH is of a significant concern among pregnancies of any age group. The age distribution in the present study and other previous studies reflects that in developing countries, young pregnancies in the age group of 20-30 years are relatively more as compared to western countries [2-4]. This is of significance because at a young age, they have multiple children at regular intervals making them moderately anemic. In our study, 81% of the women were anemic which was a major risk factor of PPH, adding to the requirement of blood products. This has been consistently observed in previous Indian studies [3].

The mode of delivery and the management of PPH goes hand in hand. At one end, post-caesarean deliveries, the decision to manage PPH by B-lynch suture or sub-total hysterectomy is easy but after vaginal delivery, the decision for surgery is time-consuming and thereby the use of UBT has increased [4]. Presently, in our study and other previous study [6], vaginal delivery is a predominant mode of delivery (80% cases).

The time of making the balloon catheter is a critical event after the decision of the use of UBT is taken. Both equipment took an average of slightly over 3 minutes for its making and inflation which was more than the conventional (1.8 minutes) and CG balloon catheter (1.2 minutes) used in the study by Xess et al [2]. The difference may be because their study did not take into account the time of inflation and calculated only the time to assemble. The time taken to make JH balloon was less than it took in the pioneer study, that is, 5.2 minutes [4].

Since PPH is accompanied with massive bleeding at times which may lead to coagulation abnormality and DIC, it is important to stop it in the minimal possible time. In our study, the time to stop bleeding was comparable between the FC and JH groups (7.08 vs 6.91 mins; p-0.65); which was within 10 minutes as seen in other comparative studies [1,3]. Though statistically the time to stop bleeding was comparable, the actual numbers favored JH balloon in place of FC catheter which may be because the soft material of the condom which may require more time to produce the adequate compression [1,4]. To further validate, Nalini et al, reported a mean time of 8.4 minutes to control bleeding [4].

The success of both the balloons was comparable to each other with only 8% and 12% failures in JH balloon and Foley's condom balloon catheter (p>0.05). At one end, the studies have shown a success range of 86-100% for Foley's condom catheter [1, 8]. In Darwish et al [1], condom loaded Foley's catheter (CLFC) showed a 15% failure rate which was higher than our study and in Burke et al [5], and Lohano et al [5], the effectivity was 95% and 90.4% respectively which was slightly more than our study. This may be attributable to a small sample size in the former study (33 cases in each group) and larger sample size in the latter studies (201 and 139 cases respectively). On the other end, the success of JH balloon was comparable to the pioneer study of Nalini N et al, where 92% achieved control of PPH [4]. Interestingly, we also found that the success rate of JH balloon (92%) was comparable to the Bakri balloon catheter (91%) which is one of the standard UBT in developed countries [1].

The slippage of balloon tamponade was significantly more with FC as compared to JH group (10 cases vs 1 case, p=0.008). This may be due to the use of latex gloves in JH balloon which are more durable, easy to handle and acquire a more "pyriform shape" than condoms [4].

All the cases who failed with the UBT were managed with B-lynch sutures, artery ligation or surgery. This remains a standard procedure of management of such cases [1-3]. Overall there were no side effects or mortality in our study indicating a successful management of PPH with the use of these adaptations for resource poor settings. Safety of these balloon catheters remains ensured as they are disposable

devices with single use, thereby preventing any infection from reuse.

The present study holds strength in following up the patients for 6 months to record any complications of balloon tamponade on fertility, menses and pregnancy. Also the randomization in the study ensured an appropriate comparison of the intervention without creating a confounding bias. The study suffered from the limitation of not assessing the cost-effectiveness as it is a matter of interest to the middle class and lower class of society. The sample size of the study was relatively small which may dilute the results of some parameters. The accurate estimation and comparison of the blood loss was not done. Lastly, the control population was not taken and thus we cannot be certain if those women would have a different outcome without the use of UBT.

Conclusion

In conclusion, success rate of Foley's condom balloon and JH balloon tamponade was good and comparable (88% and 92% respectively). Both balloon tamponade utilizes the existing resources to their best and can be easily made even in resource poor peripheral health center without wastage of time. So both type of balloon can be successfully used in atonic PPH protocols before opting for surgical options. Also uterine balloon tamponade gives time to arrange for blood transfusion/laparotomy and also to transfer the patient to tertiary referral center (if required) for further management. However we need larger trials to confirm the findings of this short series.

Conflict of interest: None. **Disclaimer:** Nil.

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