

Intrauterine Balloon Tamponade versus Gauze Packing for Treatment of Post-Partum Hemorrhage

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ABSTRACT

OBJECTIVE: To compare the efficacy and safety of uterine balloon tamponade with uterine gauze packing in terms of success rate and complication to arrest the massive postpartum haemorrhage in women not responding to medical treatment.

METHODOLOGY: This was a prospective comparative cross-sectional study conducted for six months from Jan to June 2019 at Liaquat University of Medical and Health Sciences. The sampling technique used was non-probability consecutive sampling. All the patients with PPH not responding to medical treatment after vaginal delivery were enrolled. Cases with genital tract trauma retained placenta and coagulation disorders were excluded. Patients were divided into two groups. Uterine balloon tamponade (UBT) was used in group A and group B intrauterine gauze packing (IP). A comparison of two groups in terms of success rate was analyzed on spss version 22.

RESULTS: A total of 103 patients were included; out of them, 50 underwent BT and 53 underwent uterine gauze packing; there was no remarkable difference among both groups according to age p-value of 0.502. Booked cases were higher in both groups, with a p-value of 0.513. The success rate was significantly higher in the balloon tamponade group at 96.0%, compared to the uterine gauze packing group at 84.9%, with a p-value of 0.048. Safety was more in BT Group 46(92.0%), and infection was common morbidity with uterine gauze packing group 13(24.5%) as compared to BT 4(8.0%) group, with a p-value of 0.001.

CONCLUSION: It was concluded that BT showed better efficacy and safety in managing postpartum haemorrhage after normal vaginal delivery.

KEYWORDS: Balloon tamponade, efficacy, Intra uterine packing, PPH

This article may be cited as: Naeem S, Memon FP, Najam H, Memon A. Intrauterine Balloon Tamponade versus Gauze Packing for Treatment of Post-Partum Hemorrhage. J Liaquat Uni Med Health Sci. 2022;21(03):185-9. doi: 10.22442/jlumhs.2021.00829. Epub 2021 May 07.

INTRODUCTION

As the world pursues to achieve the Sustainable Development Goal (SDG) 3, maternal health targets to lower the global maternal mortality ratio to less than 70 per 100,000 live births by 2030. A significant challenge will be to address the leading causes of maternal death¹. Postpartum haemorrhage (PPH) accounts for 30% of maternal deaths², which may occur in 1-5% of deliveries in developed and developing countries³. Most deaths occur soon after delivery, and almost 99% occur in low-wage countries⁴. PPH is defined as vaginal bleeding more than 500 ml after normal vaginal delivery or more than 1000 ml after cesarean section⁵. Another definition of PPH is that blood loss is sufficient to cause hypovolemia³. The well-known causes of PPH are uterine, placental, cervical, vaginal laceration and coagulation disorders⁴. Uterine atony is the most frequent cause of PPH⁶. Management for uterine atony is well-argued in international recommendations and follows a well-defined stepwise approach, including drugs and mechanical interventions followed

by surgery as a last resort¹.

In most cases, this life-threatening condition can be prevented if efforts are taken instantly to achieve hemostasis⁷. Uterine balloon tamponade (UBT) is one of the conservative interventions; its efficacy for severe haemorrhage is encouraging⁸. Uterine gauze packing is another conventional procedure. Although it is readily available and inexpensive for the management of PPH, its use was criticized because of the potential risk of postpartum infection, uterine trauma and ineffective packing⁹.

As both of these methods are the least invasive and readily available, it would be logical to use them when medical management is unresponsive and before proceeding to surgical interventions¹⁰.

Tamponade devices for managing bladder and oesophageal haemorrhage were first reported over 50 years ago¹¹, and in 1983, Goldrath introduced the use of Foley catheters as tamponade devices to halt postpartum hemorrhage⁶⁻¹². Since then, commercial UBT devices have become available for use in atonic postpartum haemorrhage; however, they are often uneconomical in constrained resource settings⁶. The overall success rate of UBT reported in the literature ranges from 70 to 100%¹³ and is a very effective

Received: 11-12-2020
Accepted: 04-05-2021
Published Online: 07-05-2021

method of treating severe PPH. Although uterine gauze packing appears to achieve similar effectiveness as uterine balloon tamponade, our study aims to detect the safety and efficacy of uterine balloon tamponade compared to uterine balloon tamponade gauze packing.

Postpartum haemorrhage is potentially lethal, and in most cases, simple methods are used to prevent a disaster. Intrauterine balloon placement appears to be an effective tool in the management of post-partum hemorrhage.

METHODOLOGY

This study was conducted in the Obstetrics & Gynaecology department at Liaquat university hospital Hyderabad after consent from the ethical review committee. It was a prospective Comparative cross-sectional study conducted from January to June 2019. The sampling technique used was non-probability consecutive sampling. The sample calculation was done using the Raosoft software and for "sample size calculation" by using the proportion (effectiveness of intrauterine balloon tamponade is 90%), with a 95% confidential interval and 5.8% of margin of error. All the patients admitted through an emergency with PPH aged between 20-35 years, parity > 5, who failed to respond to medical treatment were included. Patients with PPH due to genital tract trauma retained placenta, and PPH due to fibroids were excluded. Those who developed PPH after delivery were evaluated for the cause of PPH after written and informed consent. The procedure was explained, and patients were randomly divided into two groups based on inclusion and exclusion criteria.

After examination, vital signs, the sign of active haemorrhage and severity of bleeding was assessed, and baseline investigations of blood group, cross match, serum electrolyte and coagulation profile were done. Patients with PPH after failed medical treatment in whom uterine balloon tamponade was used were included in group A and women with PPH in whom uterine gauze packing was used were included in group B. In group A patients after aseptic measures, sterile rubber catheter fitted with a condom was introduced into uterus and condom was filled up with 250 – 500 ml of normal saline. BT was labelled "effective" in terms of not or less than 100 ml blood loss (assessed by inspection of the sanitary pad) after insertion, and it was kept for 24hrs. For group B patients, sterile gauze was approximately 2 meters long and 3cm wide, intrauterine packing was done with sponge holding forceps starting from fundus to cervix, vaginal packing was done to keep the uterine packing in place, and uterine packing was removed after 24 hours of insertion. IP and BT were labelled "effective" if there were no bleeding, the patient remained vitally stable, and no complications occurred. If the patient's condition deteriorates, both

procedures are stopped and preceded by the laparotomy. All data were entered in pre-designed Proforma and analyzed on SPSS version 22.0. Mean and standard deviation was calculated from age, parity, and gestational age blood loss. Frequencies and percentages were calculated from the mode of delivery, booked and un-booked cases and effectiveness-stratification through maternal age, parity gestational age and method of delivery. Post-stratification chi-square test was applied to see the difference by taking a P value < 0.05 was considered remarkable.

RESULTS

Out of 103 patients, 50 were selected for BT as group A, and 53 were chosen for uterine gauze packing as group B. Out of all 25(50.0%) patients of group A and 30(56.6%) patients of group B were with the age group of 25-30 years, while 25(50.0%) women of group A and 23(43.4%) of group B were found with the age group of 31-35 years. There was no significant difference between both groups according to the age p-value of 0.502. **Table I.**

Fifty cases were from rural areas, followed by 28 (56.0%) of group A and 22(44.0%) of group B, and 53 were from urban areas, 22(41.5%) of group A and 31 (58.5%) of group B, residency findings were insignificant among both groups, p-value 0.141. **Table I.** In this study, in group A, 34(68.0%) women had a parity of 5-7 and 16(32.0%) parity >7, while in group B, 38(71.7%) women were a parity of 5-7 and 15 (28.3%) were with parity of >7. Still, findings were insignificant according to the study groups, with a p-value of 0.683, **Table II.**

According to the booking status in group A, 27(54.0%) women were booked, and 23(46.0%) were un-booked; on the other hand, in group B, 32(60.4%) women were booked, and 21(39.6%) were un-booked, findings regarding booking status were statistically insignificant p-value 0.513. **Table II.**

About 31(62.0%) women were with a gestational age of 34-38 weeks, and 19(38.0%) were with a gestational age of 39-42 weeks in group A, while in group B, 37(69.8%) women were with a gestational age of 34-38 weeks and 16(30.2%) were with a gestational age of 39-42 weeks, findings were statistically insignificant p-value 0.403, **Table III.**

About 48(96.0%) women were vaginally delivered, and 2(4.0%) had instrumental delivery in group A out of 50 women, while in group B, 39 (73.6%) delivered vaginally and 14(26.4%) had instrumental delivery, p-value 0.001. **Table III.**

Success rate and efficacy were significantly higher in the BT group at 48(96.0%) in contrast to the gauze packing group at 45(84.0%), with a p-value of 0.047. **Table IV.**

Safety was more in BT group 46(92.0%) compared to uterine gauze packing 38(51.9%) cases. Infection was

common morbidity with IP group 13(24.5%) as compare to BT 4(8.0%) group, p-value 0.001.

Table IV.
TABLE I: AGE GROUPS, RESIDENCE, OF THE PATIENTS (n=103)

Age groups	Study groups		Total	P-value
	Group A	Group B		
25-30 years	25(50.0%)	30(56.6%)	55(53.4%)	
31-35 years	25(50.0%)	23(43.4%)	48(46.4%)	0.502
Total	50(100.0%)	53(100.0%)	103(100.0%)	

Residence	Study groups		Total	P-value
	Group A	Group B		
Rural	28(56.0%)	22(41.5%)	50(48.5%)	
Urban	22(44.0%)	31(58.5%)	53(51.5%)	0.141
Total	50(100.0%)	53(100.0%)	103(100.0%)	

TABLE II: PARITY, BOOKING STATUS OF THE PATIENTS (n=103)

Parity	Study groups		Total	P-value
	Group A	Group B		
5-7	34(68.0%)	38(71.7%)	72(69.9%)	
>7	16(32.0%)	15(28.3%)	31(30.1%)	0.683
Total	50(100.0%)	53(100.0%)	103 (100.0%)	

Booking status	Study groups		Total	P-value
	Group A	Group B		
Booked	27(54.0%)	32(60.4%)	59(57.3%)	
Un-booked	23(46.0%)	21(39.6%)	44(42.7%)	0.513
Total	50(100.0%)	53(100.0%)	103 (100.0%)	

TABLE III: GESTATIONAL AGE OF THE PATIENTS (n=103)

Gestational age	Study groups		Total	P-value
	Group A	Group B		
34-38 weeks	31(62.0%)	37(69.8%)	68(66.0%)	
39-42 weeks	19(38.0%)	16(30.2%)	35(34.0%)	0.403
Total	50(100.0%)	53(100.0%)	103 (100.0%)	

Mode of delivery	Study groups		Total	P-value
	Group A	Group B		
Vaginal	48(96.0%)	14(26.4%)	62(60.2%)	
Instrumental	2(4.0%)	39(73.6%)	41(39.8%)	0.001
Total	50(100.0%)	53(100.0%)	103 (100.0%)	

TABLE IV: EFFECTIVENESS OF BALLOON, SAFETY (n=103)

Effective-ness	Study groups		Total	P-value
	Group A	Group B		
Successful	48(96.0%)	45(84.9%)	93(90.3%)	
Failure	2(4.0%)	8(15.1%)	10(9.7%)	0.027
Total	50(100.0%)	53(100.0%)	103(100.0%)	

Safety	Study groups		P-value
	Group A	Group B	
Safety	46(92.0%)	40(75.5%)	
Infection	4(8.0%)	13(24.5%)	0.001
Total	50(100.0%)	53(100.0%)	

DISCUSSION

Uncontrolled PPH is the most common cause of maternal mortality and morbidity universally. World Health Organization recommends using BT as a non-surgical intervention in managing PPH unresponsive to standard management¹. It is likely that, in the UK, several women with PPH are well managed with uterotonics and BT alone. According to the UKOSS study, 25% of women had BT before using another second-line therapy¹⁴.

In this study, booking patients were more in both groups as in group A, 54.0% of women were booked, and 46.0% were un-booked; on the other hand, in group B, 60.4% of women were booked, and 39.6% were un-booked. While in the study of Lohano R 2016¹⁵ reported that 40(28.8%) cases had been booked compared to 80(57.7%) who were un-booked. In this study, 55(53.4%) patients had age ranges of 25-30 years and 48(46.4%) with age groups of 31-35 years. Georgiou C 2009¹³ reported that PPH was commonly seen in the age group 21-25 years (40.54%). Regarding parity, the maximum number of women in the case was primigravida and second gravida (45.94%). These findings are comparable to this study.

Another study conducted by Tirumuru, S 2013¹⁶ also reported that in their study, 58 women (mean age was 30 years with a range of 18 – 42 years) Underwent BT, of which 27 (46.5%) women had a normal vaginal delivery and 31 (53.5%) women had a cesarean section. While in this series, 87(84.4%) women were vaginally delivered, and 16(15.5%) had instrumental delivery.

In this study success rate was significantly higher in the BT group at 96.0%, in contrast to the gauze packing group at 84.9%, with a p-value of 0.047; similar results are seen in a study conducted by Zafar S A 2017¹⁷ reported that use of the balloon tamponade in all selected 80 patients and was successful in 73 patients. The tamponade test identifies the need for laparotomy and allows time to

correct any consumptive coagulopathy. It often also serves as a therapeutic manoeuvre and avoids the need for surgical intervention. Ashraf N 2018¹⁸ reported safety of the BT group was 97(91.51%), and IP group was 55(51.88%), the efficacy of BT was 78 (73.6%), and IP was 63(59.4%). Likewise, Wei J 2020¹⁹ assigned 102 women in the BT group and 102 women gauze group (93.1% vs 91.2%, P=80); there was no difference in the success rate. Bagga R, 2007²⁰ reported two cases of postpartum haemorrhage with impaired coagulation managed by condom catheter. Another study by Maher MA 2017²¹ also reported that only a balloon successfully attained hemostasis in 87.5% of cases. Pala S et al. ²² also found a success rate of 84.12% and suggested placement of intrauterine BT devices before proceeding to hysterectomy. One of the main methods of achieving a tamponade effect to control PPH was uterine packing¹⁷. Nizam K 2010²³ examined the efficacy of uterovaginal packing as high as (98.13%). Our result shows less morbidity in the balloon tamponade group compared to uterine gauze packing (43% vs 92.5%). Gauchotte E 2017²⁴ scrutinized less morbidity, and the success rate of tamponade was 92.1% (35 of 38 women).

In this study, safety was more in BT group 46(92.0%), and the infection rate was higher in the uterine gauze packing group, with a p-value of 0.001. McQuivey RW 2018⁷ and Lohano R 2016¹⁵ reported similar findings regarding balloon tamponade use. Inconsistently Suarez S 2020²⁵ stated that all frequency of complications attributed to BT was low (<6.5%). In present-day obstetrics, uterine packing has been replaced by balloon catheters due to the possibility of uterine injury, infection and concealed haemorrhage from unsighted insertion. BT is a simple procedure which is readily available and can be easily performed by postgraduates under supervision, and it is economical with less morbidity and immediate results.

CONCLUSION

It was concluded that BT appears to have considerable potential as an effective treatment for PPH. Further studies on Uterine BT are requiring saving mothers.

Ethical permission: Liaquat University of Medical & Health Sciences Thesis approval letter No. LUMHS/CE/PG/557, Dated; 20-07-2020.

Conflict of Interest: There is no any potential conflict of interest in this research, its publication and its authorship

Financial Disclosure / Grant Approval: No funding agency was used for this research.

Data Sharing Statement: The data supporting this study's findings are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

AUTHOR CONTRIBUTIONS

Naeem S: Data collection, results writing
Memon FP: Abstract & introduction writing
Najam H: Discussion Writing
Memon A: Reference collection

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