

ORIGINAL ARTICLE

Intrauterine Balloon Tamponade Versus Guaze 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 term of success rate and complication to arrest the massive postpartum hemorrhage in women not responding to medical treatment.

METHODOLOGY: This was prospective comparative cross sectional study, conducted for six months from Jan to June 2019 at Liaquat University of Medical and Health Sciences. Sample 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 tamponed (UBT) was used in group A and in group B intrauterine gauze packing (IP) used. Comparison of two groups in term of success rate was analyzed on spss version 22.

RESULTS: Total 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 0.502. Booked cases were higher in both groups with p-value 0.513. Success rate was significantly higher in balloon tamponade group as 96.0% in contrast to uterine gauze packing group as 84.9%, p-value 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 compare to BT 4(8.0%) group, p-value 0.001.

CONCLUSION: It was concluded that BT showed better efficacy and safety in management of postpartum hemorrhage after normal vaginal delivery.

KEY WORDS: Balloon tamponade, efficacy, Intra uterine packing, PPH

INTRODUCTION

As the world pursues to achieve the Sustainable Development Goal (SDG) 3 maternal health targets to lower global maternal mortality ratio to less than 70 per 100,000 live births by 2030. A great challenge will be to address the main causes of maternal death¹. Postpartum hemorrhage (PPH) accounts for 30% of maternal deaths². It may occur in 1-5% of deliveries in developed as well as developing countries³. Majority 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 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 of the 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 hemorrhage is encouraging⁸. Uterine gauze packing which is another conservative procedure, although it is readily available and inexpensive measurement for management of PPH, its use was criticized because of potential risk of postpartum infection, uterine trauma and ineffective packing⁹.

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

Tamponade devices, for management of bladder and esophageal hemorrhage, 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 hemorrhage; however, they are often uneconomical in constrained resource settings⁶. Overall success rate of UBT reported in literature range from 70 to 100%¹³ and very effective method of treating severe PPH. Although uterine gauze packing appears to achieve similar effectiveness as uterine balloon tamponade, the goal of our study is to detect the safety and efficacy of uterine balloon tamponade, in comparison with uterine gauze packing.

Post-partum hemorrhage is potentially lethal event. In most of cases simple methods are used to prevent a disaster. Intra uterine balloon placement appears to be an effective tool in the management of post-partum hemorrhage.

METHODOLOGY

This study was conducted in department of the Obstetrics & Gynaecology at Liaquat university hospital Hyderabad after consent of ethical review committee. It was prospective Comparative cross sectional study conducted from January to June 2019. The sample 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 95% confidential interval and 5.8% of margin of error. All the patients admitted through emergency with PPH aged between 20-35 years, parity > 5 who failed to respond medical treatment were included. Patient with PPH due to genital tract trauma, retained placenta and PPH due to fibroids were excluded from. Those who developed PPH after delivery were evaluated for cause of PPH, after written and informed consent, procedure was explained and patients were randomly divided into two groups on basis of inclusion and exclusion criteria. After examination, vital signs, sign of active hemorrhage and severity of bleeding was assessed and base line investigations blood group, cross match, serum electrolyte and coagulation profile was done. Patients with PPH after failed medical treatment in whom uterine balloon tamponade 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 condom was introduced into uterus and condom was filled up with 250 – 500 ml of normal saline. BT was labeled “effective” in the terms of not or less than 100 ml blood loss (assessed by inspection of sanitary pad) after insertion, it was kept for 24hrs. For group B patients sterile gauze was used of approximately 2meter long and 3cm wide, intrauterine packing was done with sponge holding forcep starting from fundus to cervix, vaginal packing was done to keep the uterine packing in place, uterine packing was removed after 24 hours of insertion. IP and BT were labeled “effective” if there were no bleeding, patient remains vitally stable and no complications occurred. In case, if patient’s condition become deteriorate, both procedures were stopped and preceded to the laparotomy. All data was entered in pre designed Proforma and analyzed on SPSS version 22.0. Mean and standard deviation were calculated from age, parity, gestational age blood loss. Frequencies and percentages were calculated from mode of delivery, booked and un-booked cases and effectiveness. Stratification through maternal age, parity gestational age and mode of delivery. Post stratification chi square test was applied to see the difference by taking P value < 0.05 was considered remarkable.

RESULTS

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

In this study in group A 34(68.0%) women had parity 5-7 and 16(32.0%) parity >7, while in group B 38(71.7%) women were parity of 5-7 and 15(28.3%) were with parity of >7, but findings were insignificant according to study groups, p-value 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 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 gestational age of 34-38 weeks and 19(38.0%) were with gestational age of 39-42 weeks in group A, while in group B 37(69.8%) women were with gestational age of 34-38 weeks and 16(30.2%) were with 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 was significantly higher in BT group as 48(96.0%) in contrast to gauze packing group as 45(84.0%), p-value 0.047. Table IV.

Safety was more in BT group 46(92.0%) as compare 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)

Effectiveness	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		Total	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 use of BT as a non-surgical intervention in the management of PPH unresponsive to standard management¹. It is likely that, in the UK, a number of women with PPH are well managed with uterotonics and BT alone. According to the UKOSS study, 25% of women had BT before the use of another second-line therapy¹⁴.

In this study booking patients were more in both groups as in group A 54.0% women were booked and 46.0% were un-booked, on other hand in group B, 60.4% 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 25-30 years and 48(46.4%) were with age group of 31-35 years. Consistently in the study of Georgiou C 2009¹³ reported that PPH was commonly seen in 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 range of 18 – 42 years) Underwent BT of which 27 (46.5%) women had normal vaginal delivery and 31 (53.5%) women had cesarean section. While in this series 87(84.4%) women vaginally delivered and 16(15.5%) had instrumental delivery.

In this study success rate was significantly higher in BT group as 96.0% in contrast to gauze packing group as 84.9%, p-value 0.047, similar results are seen in 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. Tamponade test not only identifies the need of laparotomy, it also allows time to correct any consumptive coagulopathy. Many times it also serves as a therapeutic maneuver and avoids the need of surgical intervention at all. Ashraf N 2018¹⁸ reported safety of BT group was 97(91.51%) and IP group was 55(51.88%), efficacy of BT was 78(73.6%) and in IP was 63(59.4%). Likewise, Wei J 2020¹⁹ assigned 102 women in 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 post-partum hemorrhage with impaired coagulation managed by condom catheter. Another study conducted by Maher MA 2017²¹ also reported that only balloon was successful in attaining hemostasis in 87.5% of cases. Pala S et al²² also found success rate of 84.12% and suggested placement of intra uterine BT devices before proceeding to hysterectomy. One of the foremost methods of achieving a tamponade effect to control PPH was by uterine packing¹⁷. Nizam K 2010²³ examined that the efficacy of uterovaginal packing was high as (98.13%). our result shows less morbidity in balloon tamponade group as compare to uterine gauze packing (43% vs 92.5%). Gauchotte E 2017²⁴ scrutinized less morbidity and success rate of tamponade was 92.1% (35 of 38 women).

In this study safety was more in BT group 46(92.0%) and infection rate was higher in uterine gauze packing group, p-value 0.001. McQuivey RW 2018⁷ and Lohano R 2016¹⁵ reported found similar findings regarding balloon tamponade uses. Inconsistently Suarez S 2020²⁵ stated that over 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 hemorrhage from unsighted insertion. BT is a simple procedure which is readily available and can be easily performed by post graduates under supervision. 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 required to save mothers.

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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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