



Original Article

Effectiveness of Balloon Tamponade with a Condom Catheter versus Using a Sengstaken-Blakemore Tube in Patients with Primary Postpartum Hemorrhage

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ABSTRACT

Balloon tamponade or Sengstaken-Blakemore tube, are gaining fame because of its low complications, low invasiveness, rapid approach, painless removal, and rapid identification of failed cases in primary postpartum hemorrhage. **Objective:** To compare the efficacy of balloon tamponade versus Sengstaken-Blakemore tube in patients with primary postpartum hemorrhage. **Methods:** This comparative/cross-sectional was conducted at the department of Obstetrics and Gynaecology at Bahawal Victoria Hospital, Bahawalpur from July 2023 to December 2023. A total of 64 patients (32 in each group) females aged between 18 and 40 years of parity 1-6, gravida 1-6, gestational age 31 to 41 weeks, with primary postpartum hemorrhage were recruited. Females in balloon tamponade group underwent balloon tamponade, and those in Sengstaken-Blakemore tube group underwent Sengstaken-Blakemore tube insertion and balloon removal after 24 hours. The effectiveness was labelled as yes where there was no blood loss for 24 hours after the removal of the pack or foleys. **Results:** The mean age was 31.05 ± 5.92 years. The effectiveness of the treatment was observed among 51 (79.7%) females. In balloon tamponade group, mean blood loss was 787.81 ± 265.11 ml and 791.34 ± 254.78 ml in Sengstaken-Blakemore tube group. In balloon tamponade group, 29 (90.6%) patients had effectiveness of treatment while 22 (68.8%) females in Sengstaken-Blakemore tube group reported effectiveness (p=0.030). **Conclusions:** Tamponade with a balloon attached to a condom catheter were more successfully in stop bleeding after delivery of primary PPH cases.

INTRODUCTION

A Postpartum Hemorrhage (PPH) is a condition characterized by the loss of more than 500 ml of blood after a vaginal birth or more than 1000 ml of blood after a cesarean delivery, accompanied by signs and symptoms of hemodynamic instability [1]. Around 5% of obstetrics patients may develop PPH, and 1% of vaginal births result in severe PPH, even if they are treated well [2]. PPH is the leading cause of maternal mortality in low-income countries, accounting for 150,000 fatalities per year, or 25% of maternal deaths globally [3]. Regional data describes 34% of maternal mortality attributable to PPH [4]. Local data reveals that PPH contributes to 27.2% maternal deaths [5]. While uterine atony is among the

leading causes of primary PPH, it is estimated that 20% of patients have no identifiable risk factors. Consequently, the caregiver needs to maintain constant vigilance [6]. Anemia, fatigue, postpartum depression, acute stress reactions, dilutional coagulopathy, Sheehan's syndrome, transfusion reaction, infection, and occult myocardial infarction are some of the potential complications of PPH that can reduce quality of life and even lead to maternal mortality [7]. The Sengstaken-Blakemore tube, the Bakri balloon, the Rusch balloon, the Foley catheters, and the condom catheters are only a few of the balloon devices that have been used successfully to manage primary PPH [8]. Uterine balloon tamponade represents a new tool in the

arsenal for the treatment of PPH. This is done prior to any invasive surgery. Uterine packing, or roller gauze, was once used to manage PPH. Uterine balloon tamponade has lately gained popularity as an alternative to roller gauze packs due to the latter's complexity and probable painful nature during insertion [9]. After medical managements failed, balloon catheter is probably the next logical option before resorting to surgical intervention and, potentially, a hysterectomy because it is the least invasive and the fastest technique. The benefits of this technique include the elimination of the need for a laparotomy, the quick and painless insertion with minimum anesthesia, the ability to have relatively untrained professionals do the procedure, and the prompt detection of failed instances [10]. A Sengstaken-Blakemore tube tamponade has been used in PPH, but the published data is scarce. To the best of our knowledge, not much data exists to assess the efficacy of balloon tamponade versus Sengstaken-Blakemore tube for treating PPH. A study found that when systematic administration of broad-spectrum antibiotics was done for preventative purposes in 88% of patients, the therapy with tamponade spared them from needing surgery, and in 71% of cases, the bleeding was brought under control [11]. The presence of an infection at the time of delivery is the one and only evident contraindication [11]. It was hypothesized that there is a difference in efficacy of balloon tamponade versus using Sengstaken-Blakemore tube in patients with PPH.

The current study was planned with the objective of comparing the efficacy of balloon tamponade with a condom catheter versus using a Sengstaken-Blakemore tube for the control of PPH among patients admitted to the Gynecology and Obstetrics Department Bahawal Victoria Hospital Bahawalpur.

METHODS

This comparative/cross-sectional study was carried out at the Gynecology and Obstetrics Department, Bahawal Victoria Hospital, Bahawalpur, Pakistan, from July 2023 to December 2023. The study had approval from the institutional ethical committee prior to its execution (Letter Number: 2363/DME/QAMC Bahawalpur, Dated: 15-03-2023). The sample size was calculated as 64 (32 in each group) by keeping the confidence level equal to 95% with 80% power and the anticipated prevalence of efficacy with balloon tamponade as 94.1% and with Sengstaken Blakemore tube as 68.2% [11]. Sample selection was made through simple random sampling approach. The inclusion criteria were females aged between 18-40 years of parity 1-6, gravida 1-6, gestational age 31 to 41 weeks, with primary PPH. The exclusion criteria were critically ill patients, those with documented end-organ liver or renal failure (assessed by a medical record), or those with a documented bleeding

disorder history, i.e., factor deficiencies (assessed by a medical record). Those with secondary PPH, due to trauma or retained products of the placenta, or those with chorioamnitis were also excluded. PPH was labelled when more than 500 ml of blood was lost within 24 hours of vaginal birth or more than 1000 ml after cesarean delivery. The amount of blood lost during delivery was recorded by taking samples from a tray at the base of the table. The contents of the tray were dumped into a cylindrical plastic basin marked out in increments from 100 ml to one liter. Study participants or authorized guardians were asked for informed and written consent after we explained the objectives and safety aspects of this research. Data secrecy was also assured to all the study participants. At the time of enrollment, detailed clinical and demographic information was collected in the form of age, gravida, parity, duration of gestation at delivery, mode of delivery, previous uterine scar, position of the placenta, estimated blood loss and need for transfusion of blood products. Cases were divided into two equal groups by a simple lottery method. In balloon tamponade group, females underwent balloon tamponade, and those in Sengstaken-Blakemore group underwent Sengstaken-Blakemore tube insertion and balloon removal after 24 hours. Standard surgical procedures were adopted. The effectiveness was labelled as yes, where there was no blood loss for 24 hours after the removal of the pack or Foleys. Effectiveness was labelled as failed if there was more than 100 ml of blood loss within 10 minutes after the removal of the balloon tamponade or Sengstaken-Blakemore tube. A specifically pre-designed proforma was created for data collection. The data were entered and analyzed through SPSS-26.0. Chi-square test was used to compare the two groups in terms of effectiveness and a p-value of <0.05 considered as significant.

RESULTS

In table 1, the mean age was 31.05 ± 5.92 years (ranging between 18-34 years). There were 36 (56.2%) females who were aged between 31-40 years of age. The mean gestation age was 37.43 ± 2.68 weeks, ranging between 31-41 weeks. Most of the females, 34 (53.1%) had gravidity >3. Parity status was ≤ 3 in 51 (79.7%) females. Mode of delivery was normal vaginal delivery in 37 (57.8%) females. Previous uterine scar was present in 17 (26.6%) females. In frequency distribution, various study characteristics among females of both study groups. Overall, effectiveness of the treatment was observed among 51 (79.7%) females. In balloon tamponade group, mean blood loss was 787.81 ± 265.11 ml and 791.34 ± 254.78 ml in Sengstaken-Blakemore tube group.

Table 1: Distribution of the Study Characteristics in Both Groups (N=64)

Study Variables		Total N (%)	Balloon Tamponade (n=32) N (%)	Sengstaken-Blakemore Tube (n=32) N (%)	p-Value
Age (Years)	18-30	28 (43.8%)	15 (46.9%)	13 (40.6%)	0.614
	31-40	36 (56.2%)	17 (53.1%)	19 (59.4%)	
Gestational Age (Weeks)	31-36	22 (34.4%)	12 (37.5%)	10 (31.3%)	0.598
	37-41	42 (65.6%)	20 (62.5%)	22 (68.8%)	
Gravida	≤3	30 (46.9%)	17 (53.1%)	13 (40.6%)	0.316
	>3	34 (53.1%)	15 (46.9%)	19 (59.4%)	
Parity	≤3	51 (79.7%)	26 (81.3%)	25 (78.1%)	0.756
	>3	13 (20.3%)	6 (18.8%)	7 (21.9%)	
Mode of Delivery	Cesarean Section	27 (42.2%)	14 (43.8%)	13 (40.6%)	0.800
	Vaginal	37 (57.8%)	18 (56.3%)	19 (59.4%)	
Previous Uterine Scar	Yes	17 (26.6%)	9 (28.1%)	8 (25.0%)	0.777
	No	47 (73.4%)	23 (71.9%)	24 (75.0%)	
Blood Transfusion Required	Yes	15 (23.4%)	7 (21.9%)	8 (25.0%)	0.767
	No	49 (76.6%)	25 (78.1%)	24 (75.0%)	

In table 2, details about the stratification of various confounding factors were compared with respect to effectiveness in both study group, insignificant results were observed in all categories (p>0.05).

Table 2: Stratification of Effectiveness of Treatments between Two Groups According to Study Variables (N=64)

Study Variables		Effectiveness	Total N (%)	Group-A (n=32) N (%)	Group-B (n=32) N (%)	p-Value
Age (Years)	18-30	Yes	20 (71.4%)	12 (80%)	8 (61.5%)	0.281
		No	8 (28.6%)	3 (20%)	5 (38.5%)	
	31-40	Yes	31 (86.1%)	17 (100%)	14 (73.7%)	0.053
		No	5 (13.9%)	-	5 (26.3%)	
Gestational Age (Weeks)	31-36	Yes	14 (63.6%)	10 (83.3%)	4 (40%)	0.055
		No	8 (36.4%)	2 (16.7%)	6 (60%)	
	37-41	Yes	37 (88.1%)	19 (95%)	18 (81.8%)	0.188
		No	5 (11.9%)	1 (5%)	4 (18.2%)	
Gravida	≤3	Yes	22 (73.3%)	14 (82.4%)	8 (61.5%)	0.201
		No	8 (26.7%)	3 (17.6%)	5 (38.5%)	
	>3	Yes	29 (85.3%)	15 (100%)	14 (73.7%)	0.051
		No	5 (14.7%)	-	5 (26.3%)	
Parity	≤3	Yes	42 (82.4%)	23 (88.5%)	19 (76%)	0.243
		No	9 (17.6%)	3 (11.5%)	6 (24%)	
	>3	Yes	9 (69.2%)	6 (100%)	3 (42.9%)	0.056
		No	4 (30.8%)	-	4 (57.1%)	

Mode of Delivery	Cesarean Section	Yes	20 (74.1%)	11 (78.6%)	9 (69.2%)	0.580
		No	7 (25.9%)	3 (21.4)	4 (30.8%)	
	Vaginal	Yes	31 (83.3%)	18 (100%)	13 (68.4%)	0.059
		No	6 (16.2%)	-	6 (31.6%)	
Previous Uterine Scar	Yes	Yes	11 (64.7%)	7 (77.8%)	4 (50%)	0.232
		No	6 (35.3%)	2 (22.2%)	4 (50%)	
	No	Yes	40 (85.1%)	22 (95.7%)	18 (75%)	0.057
		No	7 (14.9%)	1 (4.3%)	6 (25%)	
Blood Transfusion Required	Yes	Yes	9 (60%)	4 (57.1%)	5 (62.5%)	0.833
		No	6 (40%)	3 (42.9%)	3 (37.5%)	
	No	Yes	42 (85.7%)	25 (100%)	17 (70.8%)	0.054
		No	7 (14.3%)	-	7 (29.2%)	

In figure 1, balloon tamponade group, 29 (90.6%) patients had effectiveness of treatment while 22 (68.8%) females in Sengstaken-Blakemore tube group reported effectiveness (p=0.030).

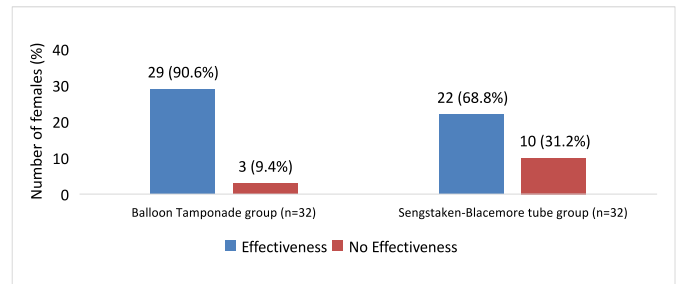


Figure 1: Effectiveness of Treatment in Both Study Groups (N=64)

DISCUSSION

In the present study, balloon tamponade group revealed effectiveness in 90.6% cases versus 68.8% cases in Sengstaken-Blakemore tube and the difference was statistically significant favoring balloon tamponade group (p=0.030). Dabelea et al., utilized intrauterine balloon tamponade in 23 patients with PPH who did not respond to medical therapy, reporting a 100% success rate for cases attributed to uterine atony and an 80% success rate for bleeding associated with retained placenta [12]. Similarly, Kucukbas et al., applied balloon tamponade in four PPH cases unresponsive to medical treatment, achieving successful hemostasis in all instances (one placental abruption, two cases of uterine atony, and one placenta previa)[13]. Another study treated 94 cases diagnosed with PPH who were unresponsive to medical therapy using balloon tamponade, resulting in an 84% success rate in achieving hemostasis for these patients. Another study provided that in 94% cases, condom catheter balloon stopped bleeding [14]. These findings exhibit that the balloon tamponade is an effective adjuvant in the treatment of severe PPH, particularly when the condition is

caused by uterine atony and medicinal therapy is unsuccessful. A study done by Cho *et al.*, from Korea reported that Sengstaken-Blakemore tube was successful in 83.3% of PPH cases [15]. Sengstaken-Blakemore tube may be bent without breaking, and it is soft, non-traumatic consistency means that lengthy forceps are unnecessary for insertion. This makes implantation into the uterus safer by lowering the possibility of perforation. In contrast to using gauze as a tamponade, the failure of this approach to halt the bleeding is readily apparent. Sengstaken-Blakemore tubes are preferred once because they are disposable [16]. The use of a balloon catheter for postpartum bleeding is thought to be inappropriate in the presence of an infection contracted during delivery. A tamponade performed with a Sengstaken-Blakemore tube is not only easier to do but also less intrusive. It needs to be done before any surgical treatments are carried out. The World Health Organization (WHO), the American College of Obstetricians and Gynecologists (ACOG), and the Polish Gynecological Society have each established their own PPH treatment algorithms [17, 18]. Uterine balloon tamponade is a relatively new option for treating PPH, while The Bakri, Foley, Sengstaken-Blakemore, Rusch, and condom catheters are only a few examples of the many balloon options [19, 20]. Being a single center study conducted on a relatively small sample size were some of the limitations of this study.

CONCLUSIONS

Tamponade with a balloon attached to a condom catheter were more successfully in stop bleeding after delivery of primary PPH cases.

Authors Contribution

Conceptualization: SUN, MUR, NB

Methodology: SUN, AJ, NB

Formal analysis: AJ, MUR

Writing, review and editing: SUN, AJ, MUR, NB

All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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