

COMPARISON OF EFFICACY AND SAFETY OF INTRAUTERINE BALLOON TAMPONADE VERSUS UTEROVAGINAL PACKING IN FEMALES PRESENTING WITH POSTPARTUM HEMORRHAGE AFTER NORMAL VAGINAL DELIVERY

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ABSTRACT

To compare the efficacy and safety of intrauterine balloon tamponade with uterovaginal roll gauze packing in patients presenting with primary postpartum hemorrhage after normal vaginal delivery. This randomized controlled trial, conducted at Department of Obstetrics and Gynecology, Lady Willingdon Hospital, Lahore, from December 2015 to November 2016. Two hundred and twelve patients presenting with primary postpartum hemorrhage who did not respond to medical treatment following normal vaginal delivery were included. They were randomly divided in two groups. The first group underwent balloon tamponade using condom and second group underwent intrauterine packing using roll gauze. Both interventions were removed after 24 hours. All females were kept under observation with antibiotic coverage in ward to prevent infection. If bleeding was stopped within 15 minutes and the patient remained hemodynamically stable, then efficacy was labeled and if no complications occur while applying or removing, safety was labeled. Mean age group of women using balloon tamponade and intrauterine packing was used was 28.25 ± 4.672 and 28.30 ± 4.613 years. The mean gestational age of patients using balloon tamponade and intrauterine packing was 38.57 ± 1.36 and 38.63 ± 0.62 years. Mean blood loss in patients using balloon tamponade and intrauterine packing was 600.28 ± 25.338 and 699.21 ± 70.176 ml. Efficacy of intrauterine packing was 94 (88.7%) and balloon tamponade was 104 (98.1%). Safety of intrauterine packing was 83 (78.3%) and that of balloon tamponade was 97 (91.5%). Thus, treatment of balloon tamponade was more effective and safer than intrauterine packing in female presenting with postpartum hemorrhage after normal vaginal delivery.

KEYWORDS

Efficacy, postpartum hemorrhage, safety, uterine balloon tamponade.

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INTRODUCTION

Postpartum Hemorrhage (PPH) results in critical blood loss and may present with hypovolemic shock. Critical care nursing practices are required to closely observe the patients with PPH, including documentation of vitals, vaginal bleeding, uterine size and tone. Uterine massage should be continued if there is frequent uterine atony.¹⁻³ PPH is the occurrence of severe bleeding exceeding 500 ml, after childbirth. It usually takes place within the first 24 hour, but can happen up to 6 weeks after delivery, during the puerperium period. This is the leading cause of death worldwide especially in low socioeconomic countries.¹

There are different causes for PPH in which uterine atony is the most common reason. Other causes are genital tract trauma, uterine rupture, retained placenta or part of placenta and coagulation disorders.^{2,3} Common consequences of PPH are hypovolemic shock, disseminated intravascular coagulopathies (DIC), renal and hepatic failure and adult respiratory syndrome (ARDS) which may end up in maternal death.¹ PPH can be classified as primary postpartum hemorrhage: excessive bleeding during third stage of labor or within 24 hours of delivery and secondary postpartum hemorrhage: excessive bleeding between 24 hours to six weeks of delivery. Among different treatments options for the management of PPH medical management (uterotonic agents) is always the first line, if not successful then we proceed to interventional methods. Depending upon parity and severity of PPH, we choose the best options.^{2,3}

In the modern technological age, different techniques have been introduced to manage PPH, if medical management failed. These include intrauterine balloon tamponade, uterine compression suturing, arterial embolization, and iliac artery ligation or uterine devascularization to treat PPH.¹ At present, there is no definitive method that favors the one to be more efficient than other for management of severe PPH. Not many studies have been conducted in randomized trials to prove which one is the best one technique. Among all, balloon tamponade is the least invasive and can be used to help the patient to fast recovery from severe PPH.¹ There is apprehension in use of uterine packing with risk of infection, perforation and cost effectiveness. Balloon tamponade is very effective in controlling PPH successfully after delivery in about 78 to 90%.^{5-8,10} Regarding uterine packing; various studies show that it is 86 to 89% effective in controlling PPH after delivery.^{9,11,12}

Even though literature has reported good results in control of PPH with both balloon tamponade and uterovaginal packing, no study exists comparing either of these methods being more efficacious and safer. Thus, we are conducting this study to confirm the more appropriate and efficacious method of controlling PPH which minimizes the incident of hysterectomy along with complications cause by bleeding diathesis.

MATERIALS AND METHODS

This was a randomized controlled trial conducted among 212 cases that presented at Department of Obstetrics and Gynecology, Unit-1, Lady Willingdon Hospital, Lahore, Pakistan from December 2015 to November 2016. Ethical approval was taken from the Institutional Review Committee (Reference No. 44/RC/KEMU 19/01/2015). These patients were enrolled after getting written informed consent. Probability, sampling technique with lottery randomization, a sample size of 212 was estimated with 106 cases in each group. The efficacy of uterovaginal packing and intrauterine balloon tamponade was 89.1% and 81.0% respectively. For this study, to ensure the margin of error of 8.0% and confidence level of 90.0%, this statistic was calculated.

Inclusion criteria

- Age 20-40 years.
- Presented with primary PPH after vaginal delivery at term (i.e. ≥ 37 weeks).
- Unresponsive to medical treatment.

Exclusion criteria

- Female with PPH due to perineal, cervical or vaginal tear, episiotomy.
- Presented PPH due to retained product of placenta.
- Presented with normal vaginal delivery after one previous cesarean section.
- Patient with coagulation disorder.
- Patient with secondary PPH.

Demographic information including name, age, parity, gestational age, education, economic status, and contact no, amount of blood loss and hemodynamic status was documented. All the females were randomly divided in two groups by using lottery method. Group A females underwent balloon tamponade by using condom whereas group B females underwent uterovaginal packing by using roll gauze. Both were removed after 24 hours of insertion. All patients were kept under observation with antibiotic coverage to prevent infection. If bleeding was stopped within 15 minutes of tamponade or packing, then efficacy

was labeled (as per operational definition) and if no infection, fever, perforation and need of laparotomy was seen, safety was labeled. Data was entered and analyzed through SPSS version 20. Quantitative variables like age, gestational age and blood loss are presented as mean and standard deviation. Qualitative variables like parity and efficacy are presented as frequency and percentage. Chi-square test applied to compare efficacy in both groups. P-value <0.05 was taken as significant. Data were stratified for age (20-40 years). Stratified groups also be compared by using chi-square test taking p-value <0.05 as significant.

RESULTS

There was a total of 212 patients in our study. They were divided into two groups, Group A

where balloon tamponade was applied and Group B where uterovaginal packing was applied. Descriptive statistics of quantitative variable presented in Table 1, reveals that the mean age of the patient in Group A and Group B was 28.25 years and 28.20 years with standard deviation (SD) 4.672 and 4.613 respectively. The mean gestational age of Group A and Group B was 38.57 and 38.63 weeks with SD of 1.36 and 0.62. Likewise, blood loss in Group A and Group B was 600.28 ml and 699.29 ml with SD of 25.338 and 70.176 respectively. Among all quantitative variables, blood loss in Group A was significantly lower compared to Group B with mean blood loss of 600.2 ml and P-value = 0.029.

Table 2 presents a comparison of qualitative variables between the two groups. It indicates

Table 1: Descriptive statistics of quantitative variables in both groups

	Groups	n	Mean	SD	P value
Age (years)	Group A	106	28.25	4.672	0.929
	Group B	106	28.30	4.613	
Gestational Age (weeks)	Group A	106	38.57	1.36	0.69
	Group B	106	38.63	0.62	
Blood loss (ml)	Group A	106	600.28	25.338	0.029
	Group B	106	699.21	70.176	

*Group A: Balloon tamponade, Group B: Uterovaginal packing

Table 2: Comparison of qualitative variables in both study groups

		Group A (%)	Group B (%)	Total	P value
Fever	Yes	29 (27.4)	33 (31.1)	62 (29.2)	0.546
	No	77 (72.6)	73 (68.9)	105 (70.8)	
Perforation	Yes	1 (0.9)	9 (8.5)	10 (4.7)	0.010
	No	105 (99.1)	97 (91.5)	202 (95.3)	
Hysterectomy	Yes	1 (0.9)	5 (4.72)	6 (2.8)	2.74
	No	105 (99.1)	101 (95.3)	206 (97.2)	
Total		106 (100.0)	106 (100.0)	212 (100.0)	

*Group A: Balloon tamponade, Group B: Uterovaginal packing

Table 3: Comparison of safety in both study groups

		Group-A	Group-B	Total	P-value
Safety	Yes	97 91.5%	83 78.3%	180 84.9%	0.007
	No	9 8.5%	23 21.7%	32 15.1%	
Total		106 100.0%	106 100.0%	212 100.0%	

*Group A: Balloon tamponade, Group B: Uterovaginal packing

Table 4: Comparison of efficacy in both study groups

		Group A n (%)	Group B n (%)	Total n (%)	P value
Efficacy	Yes	104 (98.1%)	94 (88.7%)	198 (93.4%)	0.006
	No	2 (1.9%)	12 (11.3%)	14 (6.6%)	
Total		106 (100.0%)	106 (100.0%)	212 (100.0%)	

*Group A: Balloon tamponade, Group B: Uterovaginal packing

that perforation was significantly lower in group A patients than in Group B. Although incidence of fever and hysterectomy was lower in Group A patients, it did not show clinical significance when Chi-square test was applied.

In Table 2 and 3, Chi-square test was applied to compare the efficacy and safety of balloon tamponade and uterovaginal packing, it shows that use of balloon tamponade was more efficient and much safer than that of using uterovaginal packing with p-value of 0.006 and 0.007, respectively.

DISCUSSION

This randomized control trial had been conducted in 212 patients who had presented with PPH. They were divided in two groups, Group A and Group B each consisting of 106 patients. Group A received treatment with balloon tamponade using condom, while Group B underwent uterovaginal packing using gauze roll. The study had revealed that both treatment groups had an average age of 28.25±4.67 years, matching the age ranges observed in other relevant studies.^{1,6,10} Balloon tamponade or uterovaginal packing were applied as treatment method for severe PPH, especially when medical therapy had been ineffective in managing uterine atony.^{2,3} For medical management of PPH, rectal administration of misoprostol had appeared to be an effective, which could have been an alternative to parenteral prostaglandin and minimize the needs for invasive treatment.⁴

Balloon tamponade is a simple, readily available, effective and safe procedure for the management of PPH but does not exclude the use of other treatment modalities if required. Even if it failed, it might provide tamponade effect and buy time for other interventions like hysterectomy.⁵ In this study, use of balloon tamponade was more effective than uterovaginal packing in cessation of blood loss (98.0% versus 88.0%). Whereas in other various

other studies it shows that balloon tamponade was effective in (90.0%, 80.0%, 79.0% and 90.0%).^{6-8,10} Similarly uterovaginal packing was effective in (89.0%, 86.0% and 82.0%).^{9,11,12}

The positioning of balloon tamponade and uterovaginal packing carries the potential of serious complications such as fever, perforation and even hysterectomy. Our research findings indicate that the occurrence of fever, perforation and hysterectomy in Group A and Group B are (29.0%, 1.0%, 1.0% versus 33.0%, 9.0%, 5.0%), respectively. The overall safety comparison between both groups shows that Group A had a safety rate of 91.0% whereas Group B had a safety rate of 84.0%. When comparing our study with other research, it is evident that the risk of fever and infection was 18.0% and 6.0%, respectively, with hysterectomy required in 7.0% of patients.^{9,11,12}

The result of this study demonstrates that balloon tamponade is a safe and efficient method for stopping bleeding. In our setup, where resources are limited, balloon tamponade plays a crucial role in emergency obstetric. This uncomplicated technique proves to be cost-effective, rapid, and easily learnable, making it particularly suitable for trainee residents and junior obstetricians who are often the initial responders in such urgent situations.

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