Research Article

E cacy and Safety of Intrauterine Balloon Tamponade VersusUterovaginal Roll Gauze Packing in Patient Presenting with Primary Postpartum Hemorrhage after Normal Vaginal Delivery

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Abstract

Objective: To compare the e ectiveness and safety profile of intrauterine balloon tamponade with uterovaginal roll gauze packing among patient of primary postpartum hemorrhage after normal vaginal delivery.

Methods: In this Randomized controlled trial,212 patients of age range 20 to 40 years who presented with postpartum hemorrhage after a normal vaginal delivery (NVD) those who did not responded to medical treatment were included. Cases of PPH due to perineal, cervical or vaginal tear, episiotomy, retained placenta, coagulation disorder, secondary PPH and PPH with normal vaginal delivery after previous cesarean section were excluded from this study. Subjects were randomly assigned to either intrauterine balloon tamponadeor uterovaginal roll gauze packing. Intrauterine packing (IP) was removed after 24 hours and balloon tamponade after 24 hours of insertion. Antibiotic coverage was also given to prevent intrauterine infection. All females were kept under observation in ward. E ectiveness was labeled if bleeding was stopped within 15 minutes after uterovaginal packing or balloon tamponade (BT) and patient remain hemodynamically stable and if no complications occur after applying or removing balloon tamponade or intrauterine packing safety was labeled. Data was analyzed by SPSS version 20.2.Frequencies and percentage of complications were calculated along with rate of successful cessation of bleeding were calculated.

Result: Mean age group of woman in whom balloon tamponade and intrauterine packing was used was 29.22+6.52 and 29.05+ 6.802 years. Mean gestational age of woman in BT and IP group and was 39.95+1.304 and 38.98+ 1.428 years. Mean blood loss in woman in BT and IP group was 600.28+ 25..338 and 669.21+70.176 ml. E cacy of group BT was 78(73.6%) and in IP was 63(59.4%).Safety of BT group was 97(91.51%) and IP group was55(51.88%). Treatment of balloon tamponade was more e ective and safe than intrauterine packing in female presented with PPH after normal vaginal delivery ($p < .05$).

Conclusion: This study concluded that balloon tamponade is an e ective and safe method than intrauterine packing for the management of PPH after normal vaginal delivery.

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Introduction

Postpartum Hemorrhage (PPH) is an excessive blood loss of more than 500 ml in normal virginal birth of child from genital tract from time of delivery of the baby till the completion of puerperium i.e, 42 days after delivery. This is big reason of death worldwide and especially in low income countries.[1]

The most common cause of PPH is uterine atony among other causes that include genital tract trauma, uterine rupture, retained placenta or part of placenta and coagulation disorders.[2] Common consequences of PPH are disseminated intravascular coagulopathy (DIC), hypovolemic shock, adult respiratory syndrome (ARDS) and hepatic and renal and hepatic failure which may end up in maternal death.[3]

For the management of PPH di erent treatments of PPH are available, first we go for medical uterotonic agents and if not successful then we proceed to interventional methods. Depending upon parity of patient and severity of PPH we choose the best options.

After failure of medical treatment we can try uterine packing, there is apprehension in use of uterine packing – risk of infection, perforation. It is very cheap and the best for low resource hospital like ours.

Methods

Randomized controlled trial conducted in Department of Obstetrics & Gynaecology of a Tertiary Care Hospital, Lahore for One year.

Sample size of 212 cases. About 106 in each group is calculated by using 90% confidence level, 8% margin of error and by taking expected percentage of e cacy with uterovaginal packing and intrauterine balloon tamponade as 89.14% and 81% respectively.

Confidence level in percentage (1 –a) =90
P_1 = 89/14%.[11]
P_2 = 81%.[7]
Absolute precision=8%

$$n = Z_1^2 - a/2\ P_1\ (1\text{-}P_1) + P_2(1\text{-}P_2)$$

$$a^2$$

The Sample Technique was purposive sampling technique and selection criteria was 20 – 40 years of age, presented with primary PPH after vaginal delivery at term (i.e.> 37 weeks) unresponsive to medical treatment.

The Exclusion Criteria includes the females with PPH due to perineal, cervical or vaginal tear, episotomy, 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.

Postpartum Hemorrhage (PPH) was defined as excessive bleeding from genital tract from the time of delivery of the baby till the completion of the puerperium i.e. 42 days after delivery

The Primary PPH excessive blood loss from genital tract occurring during third stage of labor and within first 24 hours after parturition.

Estimation of Blood loss done by counting saturated pads or by weighing of sponges used to absorb blood 1ml of blood weighs-approx. 1 blood clots removed from uterine cavity kept in kidney tray which is , full kidney tray-approx 500 ml of blood drop in hematocrit of patient

E ectiveness measured if there were no bleeding within 15mins after applying/removing balloon tamponade or uterovaginal packing and patient remain hemodynamically stable.

The safety was defined if no complications occur after applying or removing balloon tamponade or intrauterine packing.

Patients were kept under close observation after both procedure and if patient does not occur fever (>99 degree oF), tachycardia (> 100/min or after procedure then labeled as safety.

The Procedure used to pack uterus by roll guaze and vagina by epipad to apply pressure and prevent blood loss for 24 hours.

Balloon tamponade - procedure used to apply compression in uterine cavity with condom catheter for pressure and prevent blood loss and kept in situ for 24hours.

After taking approval from hospital ethical committee, 212 females with prima ry PPH were included in

the study form labor room in Department of Obstetrics & Gynaecology, of a Tertiary Care Hospital, Lahore.

Informed consent was obtained from each female using their data for study purpose. Demographic information including name, age, parity, gestational age, education, economic status, and contact no, amount of blood loss and hemodynamic status of the patient documented. All the females were randomly divided in to two groups by using lottery method. In group A 106 subjects under went balloon tamponade by using condom. In group B, 106 subjects under went uterovaginal packing by using roll guaze and epipad. Both of them were removed after 24 hours of insertion. Antibiotic cover was also given to prevent intrauterine infection. Then females were kept under observation in ward. If blood loss stopped within 15 minutes and no recurrence of bleeding occured after removal of tamponade or packing roll guaze and epiapd, then e cacy were labeled (as per operational definition) and if no infection, fever then safety was labeled. All this information was recorded by using specially designed Performa.

Data entered and analyzed through SPSS version 20.0. Numerical variables like age, gestational age and blood loss was presented as mean + SD. Nominal variable like parity and e cacy of BT and IP was presented as frequency and percentage. Chi-square test was used to assess the e cacy between the two groups with P-value < 0.05 was as significant.

Results

In Group A balloon tamponade (BT) mean age was29.05+ 6.802 and in uterovaginal packing (IP) group was 29.22+ 6.52 years; The minimum age was 15 years and maximum age was 40 years both group showed insignificant variation with respect to age.

The mean gestational age in balloon tamponade group was39.95+1.304 weeks and in uterovaginal packing group was 38.98+ 1.428 weeks; although minimum gestational age was 36 weeks and maximum gestational age was 42 weeks. The mean parity in balloon tamponade group was 2.02+ 1.244 and intrauterine packing group was 2.12+ 1.263. Both group showed insignificant variation with respect to parity. (Table 1).

Table 1: *Obstetrics Parameter Among Groups*

Variables	Group BT n= 106	Group IP n= 106	P value
	Mean ± SD	Mean ± SD	
Age	29.05± 6.802	29.22± 6.52	P > .05
Parity	2.02± 1.244	2.12± 1.263	P > .05
Gestational age	39.95±1.304	38.98± 1.428	P > .05
Blood Loss	600.28 ±25.33	699.21±70.176	P > .05

The mean blood loss in balloon tamponade group was 600.28 + 25.338 and Uterovaginal Packing group was 699.21+70.176, All groups showed significant variation with respect to mean bleed loss.

In the balloon tamponade group, treatment was e ective in 82(77.4%) patients while inuterovaginal Packing group, treatment was e ective in 63(59.4%), (P-value <0.05). (Table 2). Safety were more in balloon tamponade group 97 (91.5%) cases as compare to uterovaginal packing group 55 (51.9%) cases, the di erence was statistically significant as p-value <0.05. (Table 2)

Fever was found to be common morbidity in patients with uterovaginal packing group as 98(92.5%), as compare to balloon tamponade group 46 (43.4%) cases.Perforation was found to be common morbidity in patients with uterovaginal packing group as 46 (43.3%) cases and in Balloon tamponade group 30 (28.3%) cases had tamponade with statistically insignificant di erence (P-value <0.05). (Table 2)

Table 2: *E cacy and Safety Among Two Groups*

Variables	Group BT n= 106	Group IP n= 106	P value
	Frequency (%)	Frequency (%)	
E cacy	82(77.4%)	63(59.4%)	X^2 = 7.878 P = 0.005
Safety	97 (91.5%)	55 (51.9%)	X^2 = 41.005 P = 0.000
Fever	46 (43.4%)	98(92.5%),	X^2= 58.542 P = 0.000
Perforation	30 (28.3%)	46 (43.3%)	X^2 = 5.251 P = 0.022

Discussion

The present study provides evidence that both treatment groups were younger as 29.17 + 5.542. years. Gray A et al found that balloon tamponade and uterovaginal packing group patients were younger as 27.17 + 3.542 year.4Dabelea V et al demonstrated that both treatment groups were more commonly found in younger age group (28 + 5.2) year.[5] Lohano R et al examined that both treatment group patients were found to be younger as 34.0+ 8.06

Present study reported that balloon tamponade is an e ective and method in treatment PPH as compared to uterovaginal packing group (77% vs.59%) and also its with a better safety profile.

Nizam et al examined that the e cacy of uterovaginal packing was high as (98.13%).7 Study conducted by Ali T at al showed that uterovaginal packing e cacy was high as 86%.8In an another clinical tiral by Shuja S et al showed 82.1% e cacy of uterovaginal packing for bleeding.[9] O'Brien Pet al in his study found out uterovaginal packing is a safe and e ective technique in the control of intractable hemorrhage as (79.4%).10Nizam et al also reported that uterovaginal packing is an e ective and safe technique.[11]

Our results showed less morbidity in Balloon Tamponade group as compared to intrauterine packing group as (55 vs. 97 cases). O'Brien P et a al scrutinized less morbidity in Balloon tamponade group as compared to intrauterine packing group as (34 vs. 55 cases).10Nizam et al examined that high morbidity in balloon tamponade group as compared to intrauterine packing group as (34 vs. 55 cases) due to di erent environmental factors and sampling frame. This study showed contradictory results in reduce postoperative outcome.[11]

Conclusion

This study concluded that balloon tamponade is an e ective and safe technique for cessation of the PPH. In our setup, with limited and overburdened resources, balloon tamponade plays an important role in emergency obstetrics and saves live. Balloon tamponade procedure is simple, can be learned easily, especially by trainee residents and junior obstetricians, who are usually the one who encounter and manage PPH acute emergency.

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Conflict of Interest: None
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