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Original Article

Efficacy of Intrauterine Balloon Tamponade in the Management of Postpartum Hemorrhage when Uterotonic Agents Fail

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Abstract

Objective: To determine the efficacy of intrauterine balloon tamponade in the management of postpartum hemorrhage when uterotonic agents fail.

Methods: It was a descriptive case series study carried out in Obstetrics & Gynecology Department, Lady Aitchison Hospital, Lahore for 6 months.35 females were enrolled. Females underwent balloon tamponade by using condom. Then females kept under observation in ward for 15 minutes. If blood flow stopped within 15 minutes and no recurrence occurred after removing tamponade after 24 hours, then efficacy was labeled using SPSS 26.

Results: Mean age of patients was 26.4±3.81 years, there were 9(27%) nulliparous. The Mean gestational age was 38.22±0.68 weeks. In this study the efficacy of balloon tamponade achieved among 30(86%) females.

Conclusion: Intrauterine balloon tamponade is efficacious tool for postpartum hemorrhage management when uterotonic agents fail.

Keywords: Uterotonic, Efficacy, Intrauterine Balloon Tamponade, PPH

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Introduction

Worldwide primary cause of approximately one fourth of maternal deaths is PPH.[1] PPH rate has risen from 1.5% in 1999 to 4.1% in 2000. The options for management of PPH include uterotonics, intrauterine balloon tamponade, B-Lynch sutures, bilateral embolization of uterine arteries, or hysterectomy.[2] This uterine tamponade is a relatively easy and simple technique for the management of PPH. Management of PPH is improved with the implementation of intrauterine balloon tamponade and it can save maternal life especially in low resource areas.[3] Different kinds of balloon catheters including the Bakri balloon catheter, the Sengstaken-Blakemore tube, foley catheter the Roush balloon are in use for the uterine tamponade. Akhter et al, showed the intrauterine balloon tamponade is efficacious in 100% (n=23) patients in controlling PPH.[4] Dabelea et al, found that balloon tamponade was successful in 90% of the patients (18/20) presenting with PPH after delivery and had no response to medical treatment. Doumouchtsis et al., found that balloon tamponade is 81% (n=27) effective in controlling PPH after delivery.[5] Rationale of this research is to find out the efficacy of uterine balloon tamponade in PPH after normal vaginal delivery when uterotonic drugs failed to control bleeding.[6] Even if it is not successful it provides the time for other interventions to be done or to take the patient from local setup to tertiary care hospital. So, through this study we want to confirm that whether balloon tamponade is highly effective or we should search some other methods or drugs to control PPH.[7]

About 1.2% of deliveries are linked with PPH in the developing countries and about 3% of the patients die when this PPH occurs.8 Globally PPH occurs in around 8.7 million patients, so it is very important cause of death of mothers in pregnancy resulting in 44,000 to 86,000 deaths per year.[9] In poor regions of the world like in sub- Saharan Africa maternal mortality rate is about 0.4 women per 100,000 deliveries and in developed countries like in the England maternal mortality is 150 women per 100,000 deliveries. So maternal mortality is reduced greatly since the late 18th century in

the United Kingdom.[10] Worldwide rate of PPH is 10.8%. Among the developing countries the incidence of postpartum hemorrhage is highest in Africa that is (27.5%), and in Oceania, rate of PPH is lowest that is (7.2%). The rate of PPH in developed countries like in North America and Europe is 13%. The rate of PPH is higher for nulliparous patients i.e. 12.9% as compared to patients with subsequent pregnancies i.e. 10.0%. In patients with multiple pregnancies the rate of PPH is 32.4% as compared to patients with singleton pregnancy i.e. 10.6%. Globally the rate of severe postpartum hemorrhage in which loss of blood is more than 1 liter, is 2.8% and again highest rate of severe PPH is found in Africa i.e. 5.1%.[11]

Causes of postpartum hemorrhage are categorized as the "four Ts", that includes atonic uterus, retained placenta, trauma, and coagulopathy. The most common risk factors of PPH in normal vaginal deliveries are: 1) nulliparity; 2) multiparity; 3) multiple pregnancy; 4) after episiotomy; 5) pre-eclampsia; 6) prolonged labor and augmentation of labor; 7) retention of placenta; 8)assisted deliveries e.g., the use of forceps and vacuum and 9) Hispanic or Asian population.[12] Recent research was conducted on 50 cases of PPH, in which Bakri balloon was effective in 86% of the cases at University of Central Hospital in Helsinki, Finland.[12] So it was concluded that balloon tamponades are a better option to manage PPH. Moreover, it also provides the temporary time to take the patient to tertiary care setup from local centers or to do other interventions. It is recommended by the author to include Bakri Balloon in treatment protocol of PPH.[13]

A condom balloon tamponade is another type of intrauterine tamponade, which is prepared by tying the male latex condom to the tip of Foleys catheter with the help of a string. It is a low-cost method particularly in resource poor settings, developed by Dr. Sayeba Akhter in 2001 in Bangladesh. Worldwide many health care providers have supported its use to control PPH.[14] According to a suggestion by the American College of Obstetricians and Gynecologists, balloon tamponade can be implemented successfully for the treatment of PPH due to atonic uterus. Other conservative surgical procedures like B-Lynch and bilateral uterine artery ligation can be used to avoid hysterectomy.[15] In context of above mentioned, the aim of this study is to determine the efficacy of intrauterine balloon tamponade in management of PPH when uterotonic agents fail.

Methods

This was a descriptive case series conducted at Obstetrics & Gynecology department, Lady Aitchison Hospital, Lahore for 6 months from 1st august 2020 to 31st January 2021. Sample size of 35 cases was calculated with 95% confidence level, 8% margin of error and taking expected percentage of efficacy i.e. 90%[14] with balloon tamponade in females presenting with massive PPH after delivery when uterotonic drugs failed to control bleeding.

$n = Z^2_{1-\alpha/s}.P(1-P)/d^2$

Z = Confidence Level=95%=1.96

P = Prevalence of Balloon tamponade =90%

d = Absolute precision=10% n= 35

Females of age18-40 years with Parity less than 5 Presenting after vaginal delivery at term (Gestationalage ≥37 weeks on LMP) were included in the study with non-probability, consecutive sampling technique. Multiple pregnancy (on USG), Females with perineal tear on clinical examination. Females having BP≥140/90 mmHg as pregnancy induced hypertension (PIH), preeclampsia (PIH with +1 proteinuria on dipstick method) or eclampsia (convulsions with PIH). Placental abnormality like accrete, previa (on medical record and history). 35 females with PPH who fulfill the inclusion and exclusion criteria and did not show response to medical treatment including 1. Oxytocin 5 I.U by slow I/V injection and 40 I.U in 500ml Hartmann's fluid at 125ml/hour 2. Ergometrin 0.5mg by slow intravenous or intramuscular injection. 3. Misoprostol 800µg sublingually, were included in the research from inpatient department. Informed consent was obtained from all the patients. All basic demographic details were taken. Then females underwent balloon tamponade by using condom. This was achieved by tying a male latex condom to the 3-4cm end of foley catheter and placing in the uterus. This condom filled with 500ml of normal saline until there was reduction of vaginal bleeding. The roll gauze was used to pack the vagina in order to prevent the condom catheter from falling out of uterus. Balloon tamponade was removed after 24 hours. Then females were kept under observation in labor room. If blood flow stopped within 15minutes and no recurrence of bleeding occurred after removal of tamponade, then efficacy was labeled. Patients, in whom bleeding did not stop, were managed as per hospital protocol. All this information recorded by using specially designed proforma.

Data was analyzed using SPSS version 26. Quantitative variables like age and gestational age were taken as mean and Standard Deviation. Qualitative variable like parity, efficacy was plotted as frequency and percentage. Data stratification was done for age, gestational age, and parity. Stratified groups were compared by using chi-square test taking p-value ≤ 0.05 as significant.

Results

The mean age was 26.4±3.81 years with minimum and

maximum ages of 20 & 36 years respectively.

There were 9(27%) nulliparous females, 11(31%) females had parity one, 8(23%) females had parity two, 4(11%) females had parity three and 3(8%) females had parity four. The mean gestational age was 38.22 ± 0.68 weeks with minimum and maximum 37 & 40 weeks respectively. Blood flow stopped among 30(86%) females and efficacy was achieved among 30(86%) females. (Figure I)

There were 29 females with age ≤ 30 years out of which efficacy was achieved in 25 cases, similarly 6 were > 30 years out of which efficacy was achieved in 5 cases. There was insignificant difference found between the efficacy with age i.e. p-value=0.634. (Table 1)

There were 20 females with nulliparity and primary parity in which efficacy was achieved in 18 cases, similarly the females having multiparity were 15 in which efficacy was achieved in 12 cases. Statistically significant difference found between the efficacy with parity i.e. p-value=0.004. (Table 2) According to the result of this study the females with gestational age37-38 weeks were 22 in which efficacy achieved in 19 cases, similarly the females with gestational age 39-40 weeks were 13 in which efficacy found in 11 cases. There was significant difference between the efficacy with gestational age i.e. p-value=0.261. (Table 3)

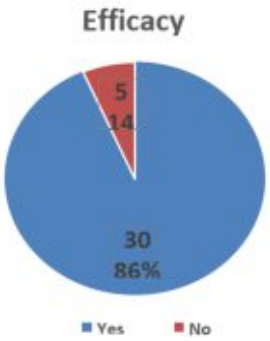

Figure I: *Achievement of efficacy*

Table 1: *Comparison of efficacy with age*

		Efficacy		Total	p-value
		Yes	No		
Age (years)	≤ 30	25	4	29	0.634
	>30	5	1	6	
Total		30	5	35	

Table 2: *Comparison of efficacy with parity*

		Efficacy		Total	p-value
		Yes	No		
Parity	Nulliparous & Primary	18	2	20	0.004
	Multiple	12	3	15	
	Total	30	5	35	

Table 3: *Comparison of efficacy with gestational age*

		Efficacy		Total	p-value
		Yes	No		
Gestational age (weeks)	37-38	19	3	22	0.261
	39-40	11	2	13	
Total		30	5	35	

Discussion

Depending upon the mode of delivery and cause of PPH different techniques are devised to manage PPH. Second line option to manage PPH is Intrauterine balloon tamponade that is used quite frequently now a days.[17] This research showed that incidence of PPH increases with increased parity whereas the age of patient and gestational age has no effect on PPH. In this study the intrauterine balloon tamponade in management of patients presenting with PPH when uterotonic agents failed to arrest bleeding showed efficacy in 86% females.

Different studies showed that the Intrauterine balloon tamponade is successful in 60-90% of the cases. In agreement with these researches, intrauterine balloon tamponade is effective to control PPH.[18] According to a report by a case series[19] intrauterine balloon tamponade was successful in 90% of their patients (18 out of 23cases) who did not show response to the medical management. Hysterectomy was done in two cases. The success rate was 100% (11/11 cases) for PPH due to atonic uterus. The catheter cannot be placed in three cases due to some technical difficulties. The success rate was 80% in hemorrhage due to retained placenta.(4/5; failure with placenta percreta).

Akhter et al, reported that balloon tamponade is efficacious in 100% (n=23) cases in controlling PPH20. Dabeleaet al., found that with balloon tamponade, PPH was controlled in 18 of 20 (90%) cases presenting with PPH after delivery and had no response to medical treatment.[13] Doumouchtsis et al., found that balloon tamponade is81% (n=27) effective in controlling PPH after delivery.(14)Kong and To found that balloon tamponade is 78.9% (15/19 cases) effective in controlling PPH after delivery.[21]

A study by Sahithi Tirumuru et al[22] concluded that the tamponade was successful in 87% of the patients. Balloon tamponade was done in Fifty-eight patients (mean age, 30 years; range, 18 - 42) of which 31 (53.5%) patients delivered by cesarean deliveries and 27(46.5%) women had vaginal delivery. This study showed that the intrauterine balloon exerts "inward-to-outward pressure "on the wall of uterus that is greater than the systemic arterial pressure, in this way it prevents continuous bleeding.[23] One study by Rajni Lohano et al[24]

showed that the mean estimated blood loss in the patients was 1155.8±350.6 ml. Whereas mean systolic blood pressure was 90.96±18.1 mmHg, diastolic blood pressure was 55±7.5 mmHg and mean pulse was 108.3± 10.89 bpm. Efficacy of intrauterine balloon tamponade was achieved in 126(90.4%) cases. Research by Hee Young Cho et al[25] demonstrated that intrauterine tamponade was successful in 75% (48/64) patients of placenta previa. Intrauterine balloon tamponade isa non-invasive and simple procedure that can preserve the uterus in PPH after cesarean delivery due to low lying placenta.

Another study by Khaldoun Khamaiseh[26] showed that the balloon tamponade can be used as alternative to other conservative surgical techniques to manage PPH. So all these studies show that balloon tamponade is very effective second line management to control PPH. This tamponade effect is achieved by using condom catheter which is very easy and simple procedure. It is readily available and can be used effectively in resource poor settings. Cesarean hysterectomy can be avoided in many cases. In this way it helps to preserve the fertility. So balloon tamponade is very effective in reducing maternal mortality and morbidity related to PPH.

Conclusion

According to this study the intrauterine balloon tamponade is efficacious tool to manage PPH when uterotonic agents failed to arrest bleeding.

Ethical Approval: The IRB/EC approved this study via letter no. 287-88/CE/TD Dated July 30, 2024.

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Authors' Contribution

MM: Conceptualization of the project

HM, MA: Design of the work.

SI, SG: Data acquisition, analysis, or interpretation.

HM, SI, SG: Draft the work.

MM, MA: Critical review of important intellectual content.

All authors approve the version to be published.

All authors agree to be accountable for all aspects of the work.

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