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EFFICACY OF INTRAUTERINE BALLOON TAMPONADE IN THE MANAGEMENT OF POSTPARTUM HAEMORRHAGE WHEN UTEROTONIC AGENTS FAIL

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Abstract

Background: *Globally, the biggest cause of maternal mortality in postpartum period is postpartum haemorrhage (PPH). A prophylactic uterotonic drug should be administered to all women undergoing delivery. It is advised to continue administering uterotonic medicines as "first-line" treatment if prevention fails and PPH develops. One known method for avoiding more intrusive methods for PPH is intrauterine balloon tamponade. Because it is easy to use and less intrusive, it is extensively used. But varied data has been reported before and there was limited studies done in local population before. Therefore, this study was conducted to acquire data for local population to get updated findings about more effective and successful method of cessation of blood loss i.e. PPH.*

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

Study design: *Longitudinal study*

Methodology: *This longitudinal study was carried out at the Department of Obstetrics & Gynaecology, Lady Aitchison Hospital, Lahore from February to June, 2025. One hundred females were enrolled from post-delivery wards. Then females underwent balloon tamponade. The intrauterine balloon tamponade catheter was inserted and inflated. If bleeding stopped within fifteen minutes of the procedure, then efficacy was labelled. All the data was collected via proforma and analysed in SPSS.*

Results: *In this study, the median age of females was 27.00 (IQR: 6.00) years and most of them had age range 20-30 years (65%). The median gestational age at delivery was 40.00 (IQR: 100) weeks and mostly delivered after 39 weeks (85%). Out of 100 females, 88 (88%) females had spontaneous vaginal delivery while 12 (12%) females had induced labor. Out of 100 females, efficacy within 15 minutes was achieved in 90 (90%) females.*

Conclusion: *It has been concluded that intrauterine balloon tamponade is a useful and highly effective method to control blood loss in females with failed uterotonic agents.*

INTRODUCTION

Globally, the biggest cause of maternal mortality in postpartum period is postpartum haemorrhage (PPH). It is defined as a blood loss of 500 mL or more following delivery.[1] Primary PPH within the first 24 hours after birth carries a maternal mortality risk of 1 in 100,000 deliveries in the UK and is a significant

contributor to maternal death worldwide.[2] A prophylactic uterotonic drug should be administered to all women giving delivery, according to the World Health Organization.[3, 4] PPH is still a prevalent complication that accounts for 25% of maternal deaths all around the globe, despite the regular prescription of uterotonic agents for prophylaxis. It is advised to continue administering uterotonic medicines as "first-line" treatment if prevention fails and PPH develops. The optimal uterotonic medication for the "first-line" therapy of PPH, however, is still up for debate.[5]

Other uterotonics, like methylergonovine, carboprost or misoprostol, have been demonstrated to be effective as 2nd line uterotonics when oxytocin is insufficient to treat PPH. Nevertheless, there is insufficient data to determine which particular extra uterotonics work best.[6] One known method for avoiding more intrusive methods for PPH is intrauterine balloon tamponade. Because it is easy to use and less intrusive, it is extensively used.[7, 8] The first balloon system created especially to treat PPH was the Bakri tamponade, which showed impressive success rates.[2] Newer systems have been described, and more research on intrauterine balloon tamponade has been published.[9, 10]

Rationale of this study is to determine the efficacy of intrauterine balloon tamponade in the management of PPH when uterotonic agents fail. Literature showed that intrauterine balloon tamponade is an effective mode of controlling excessive bleeding after delivery and can be achieved in around 80% cases. But varied data has been reported before and there was limited studies done in local population before. Therefore, there was a need to conduct this study to acquire data for local population to get updated findings about more effective and successful method of cessation of blood loss i.e. PPH. Therefore, we planned this study to find the evidence for local population in order to improve our knowledge and practice, which will help to implement findings in local setting. That will help to reduce burden form obstetricians and hospital administration and early discharge of patients.

METHODOLOGY

This longitudinal study was conducted at Lady Aitchison Hospital, Lahore, Pakistan from February to June, 2025. With WHO calculator, the calculated sample size (n) was 100 by keeping 95% confidence level, 8% margin of error with reported efficacy of balloon tamponade as 80% for management of PPH after delivery.[11] All the females who followed the criteria mentioned below were enrolled by using consecutive sampling technique (type of non-probability sampling technique). Females fall in age range 18-40 years, delivered at gestational age ≥37 weeks, developed PPH were included the study. PPH was defined as blood loss of more than 500 ml within 24 hours of vaginal delivery. Blood loss was assessed by using sanitary pads, where weight of dry pad was noted and net weight of blood was noted by taking the difference in weight of wet and dry pads considering 1gm = 1ml. Females with post-abortion obstetric haemorrhage, traumatic conditions, and pre-partum and already enrolled in another trial or already taken uterine tamponade were excluded. All the females were enrolled from post-delivery wards. Informed consent was taken and demographics like name, age, parity, BMI, gestational age at delivery, booking status, mode of delivery, h/o maternal anemia, h/o gestational hypertension, gestational diabetes, total blood loss and uterotonic used were noted. Then females underwent balloon tamponade. Females were given a capsule azithromycin 500 mg and amoxicillin / clavulanate 500 mg for oral intake with simple water. The intrauterine balloon tamponade catheter was then placed. The uterine balloon was gradually and carefully inflated until the uterine cavity was filled and slightly enlarged. The balloon's pressure, volume of saline infused, and time to maximum inflation were all recorded either throughout the inflation process or at the final inflation, depending on the clinical circumstances. Multiple pressure readings were also recorded. If bleeding stopped within 15 minutes of balloon

tamponade, then efficacy were labelled. All this information were recorded in proforma. In females where bleeding will not respond to balloon tamponade, other measures were adopted as per standard guidelines and females were efficiency managed.

Data entry and analysis was done by SPSS v. 25. Normality was tested by applying Shapiro-Wilk test. Mean ± Standard deviation was used for quantitative data like age, BMI, gestational age at delivery, blood loss, time to achieve maximum inflation, pressure within the balloon, and volume of infused saline. Qualitative data was presented in the form of frequency and percentage like parity, booking status, mode of delivery, anemia, hypertension, diabetes, uterotonic used and efficacy. Data was stratified for age, BMI, parity, gestational age at delivery, blood loss, booking status, mode of delivery, anemia, hypertension, diabetes, time to achieve maximum inflation, pressure within the balloon, and volume of infused saline and uterotonic used. Post-stratification, stratified groups were compared for efficacy by using chi-square. P-value of ≤ 0.05 were established as significant.

RESULTS

In this study, we enrolled 100 females with PPH with failed uterotonic agents to control haemorrhage. The median age of females was 27.00 (IQR: 6.00) years and most of them had age range 20-30 years (65%). There were 35 (35%) overweight and 57 (57%) obese females. The median gestational age at delivery was 40.00 (IQR: 100) weeks and mostly delivered after 39 weeks (85%). There were 19 (19%) primigravida, 50 (50%) were Parity 1-2 and 31 (31%) were Parity 3-4. Out of 100 females, 73 (73%) had antenatal booking. Among all females, 16 (16%) had anemia during pregnancy, 12 (12%) had gestational diabetes, 19 (19%) had gestational hypertension while 53 (53%) had no medical history during pregnancy. Out of 100 females, 88 (88%) females had spontaneous vaginal delivery while 12 (12%) females had induced labor. Table I

The median volume observed for blood loss was 1000.00 (IQR: 350.00) ml and median time for inflation of balloon was 17.00 (IQR: 5.00) seconds. The median volume of saline infused in the balloon was 364.50 (IQR: 84.00) cm^3 and median pressure within the balloon was 81.00 (IQR: 10.00) mmHg. Table II

Out of 100 females, efficacy within 15 minutes was achieved in 90 (90%) females. Figure 1

Data was controlled for effect modifiers including age, BMI, gestational age, parity and maternal history. Among females aged 20-30 years, efficacy was achieved in 58 (89.2%) females while among females aged 31-40 years, efficacy was achieved in 32 (91.4%) females. Age has no impact on the efficacy of intrauterine balloon tamponade ($p>0.05$). Among females with normal BMI, efficacy was achieved in 8 (100%) females, among overweight females, efficacy was achieved in 32 (91.4%) females and among obese females, efficacy was achieved in 50 (87.7%) females. BMI has no impact on the efficacy of intrauterine balloon tamponade ($p>0.05$). Efficacy was achieved in 16 (84.2%) primigravida, in 50 (100%) females who had parity 1-2 and in 24 (77.4%) females who had parity 3-4 and efficacy was significant better in females with parity 1-2 than primigravida females and females with higher parity. The females who delivered at 37-38 weeks, efficacy was achieved in 12 (80.0%) females and females who delivered at 39-40 weeks, efficacy was achieved in 78 (91.8%) females ($p>0.05$). In booked females, efficacy was achieved in 63 (86.3%) and in unbooked females, efficacy was achieved in 27 (100%) females ($p<0.05$). The females who had spontaneous vaginal delivery, efficacy was achieved in 78 (88.6%) females while among females who had induced labor, efficacy was achieved in 12 (100%) females ($p>0.05$). Among anemia and females with gestational diabetes, efficacy was achieved in 100% cases, while among females with gestational hypertension, efficacy was achieved in 16 (84.2%) females ($p>0.05$). Table III

Table I: Demographic and clinical profile of females (n = 100)

	Statistic
Age	27.00 (IQR: 6.00)
Age: 20–30 years	65 (65%)
Age: 31–40 years	35 (35%)
BMI	30.00 (IQR: 2.00)
Normal	8 (8%)
Overweight	35 (35%)
Obese	57 (57%)
Gestational age	40.00 (IQR: 100)
37–38 weeks	15 (15%)
39–40 weeks	85 (85%)
Parity	
Primigravida	19 (19%)
Parity 1–2	50 (50%)
Parity 3–4	31 (31%)
Booking status	
Booked	73 (73%)
Unbooked	27 (27%)
History of	
Anemia	16 (16%)
Gestational diabetes	12 (12%)
Gestational hypertension	19 (19%)
None	53 (53%)
Mode of delivery	
Spontaneous Vaginal delivery	88 (88%)
Induced labor	12 (12%)

Table II: Parameters of intrauterine balloon tamponade used (n = 100)

Parameters	Outcomes
Volume of blood loss	1000.00 (IQR: 350.00)
Time to achieve maximum inflation	17.00 (IQR: 5.00)
Volume of infused saline	364.50 (IQR: 84.00)
Pressure within the balloon	81.00 (IQR: 10.00)

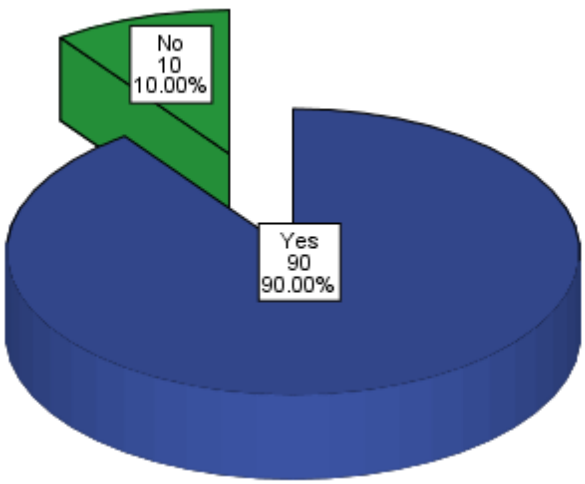

Figure 1: Efficacy of intra uterine balloon tamponade in the management of PPH (n = 100)

Table III: Association of efficacy achieved with intra uterine balloon tamponade when controlled for effect modifiers

		Efficacy achieved within 15 minutes		p-value
		Yes n = 90	No n = 10	
Age, years	20-30	58 (89.2%)	7 (10.8%)	0.727
	>30	32 (91.4%)	3 (8.6%)	
BMI	Normal	8 (100%)	0 (0%)	0.523
	Overweight	32 (91.4%)	3 (8.6%)	
	Obese	50 (87.7%)	7 (12.3%)	
Parity	Primigravida	16 (84.2%)	3 (15.8%)	0.003
	Parity 1-2	50 (100%)	0 (0.0%)	
	Parity 3-4	24 (77.4%)	7 (22.6%)	
Gestational age	37-38	12 (80.0%)	3 (20.0%)	0.161
	39-40	78 (91.8%)	7 (8.2%)	
Booking status	Booked	63 (86.3%)	10 (13.7%)	0.043
	Unbooked	27 (100%)	0 (0%)	
Mode of delivery	Spontaneous Vaginal delivery	78 (88.6%)	10 (11.4%)	0.218
	Induced labor	12 (100%)	0 (0.0%)	
History of	Anemia	16 (100%)	0 (0%)	0.219
	Gestational diabetes	12 (100%)	0 (0%)	
	Gestational hypertension	16 (84.2%)	3 (15.8%)	
	None	46 (86.8%)	7 (13.2%)	

DISCUSSION

In this study, we observed the efficacy of intra-uterine balloon tamponade in 90 (90%) females in whom uterotonic agents failed to control the excessive bleeding. A preventive uterotonic drug should be administered to all women giving delivery, according to the WHO. PPH continues to be a prevalent complication that accounts for 25% of all maternal deaths worldwide, despite the regular use of a uterotonic drug for prophylaxis. Further uterotonic agent delivery as "first-line" treatment is advised when prophylaxis fails and PPH develops.[1, 12]

As a first-line treatment, oxytocin is typically administered. Although intramuscular and intrauterine dosage are feasible, intravenous treatment is the recommended mode of delivery. Second-line therapy must be started when oxytocin is unable to provide sufficient uterine tone. There are many other uterotonic agents available now. The selection of a second-line medication is based on both its contraindications and side-effect profile. Prostaglandins are very powerful uterotonic drugs. There are prostaglandin compositions that are both synthetic and natural. Prostaglandin F2α can be administered intrauterinally and intramuscularly to manage atony.[13, 14] In this regard, Munir et al., found that among the females in whom uterotonic medications failed, balloon tamponade was effective in limiting PPH in 30 cases (86%).[15]

In a study, Dalmedico et al. discovered that when uterotonic medicines fail to control PPH, intrauterine balloon tamponade is effective in 80% of instances.[11] According to a recent meta-analysis, intrauterine balloon tamponade was effective in treating PPH in 85.9% of cases when uterotonic treatments were ineffective.[16] However, a Pakistani study found that intrauterine balloon tamponade was effective in treating PPH in 95.6% of instances.[17] Doumouchtsis et al. report that intrauterine balloon tamponade was successful in 90% of their patients involving unsuccessful uterotonic

medications, with 80% of those instances involving retained placentas.[18]

According to Akhter et al., balloon tamponade is 100% effective in controlling the PPH.[19] As we observed in our study, Dabelea et al. aslso discovered that balloon tamponade successfully stopped the bleeding in 90% of cases.[20] In another study, Doumouchtsis et al., found again that Balloon tamponade is 81% successful in reducing PPH following delivery.[21] Kong and To discovered that balloon tamponade is 78.9% successful in reducing excessive bleeding following childbirth.[22] Akhtar et al. recently reported that balloon tamponade was effective in 88.8% of women. There was no discernible difference (P value > 0.05) when women were examined for maternal age, gestational age, and parity status.[23] We also sobered and insignificant relationship of efficacy of balloon tamponade with age and gestational age while with parity the association was significant.

The highest prevalence of efficacy (92.1%) was found by Gauchotte et al. in females with PPH when medical treatment failed to stop the bleeding.[24] According to all of these trials, balloon tamponade is a very successful second-line treatment for PPH. Condom catheters are used to create this tamponade effect, which is a pretty straight forward process. It is easily accessible and useful in environments with little resources. In many situations, a cesarean hysterectomy can be avoided. It aids in maintaining fertility in this way. Therefore, balloon tamponade is highly successful in lowering PPH-related morbidity and maternal death.[15, 25]

CONCLUSION

It is concluded that intra-uterine balloon tamponade is a useful and highly effective method to control blood loss in females with failed uterotonic agents. Now we have achieved an evidence in favour of intra-uterine balloon tamponade that is an effective and successful method of cessation of blood loss. Now, in future, we will implement the application of intra-uterine balloon tamponade to control excessive blood loss after delivery to prevent any complication or hazardous consequences of excessive blood loss or PPH.

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