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ORIGINAL ARTICLE

Efficacy of Balloon Tamponade in Postpartum Hemorrhage

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ABSTRACT

Aim: An estimated loss of more than 500 mL of blood after vaginal delivery and more than 1000 mL of blood following caesarean delivery from the birth canal within 24 hours is considered primary postpartum haemorrhage (PPH). Rightfully termed the "obstetrician's nightmare," primary postpartum haemorrhage remains a major contributor to maternal mortality and morbidity in underdeveloped countries like Pakistan, where it accounts for 21-31% of maternal deaths. As a result, investigating PPH management strategies is vital.

Objectives: To determine the efficacy of intrauterine balloon tamponade in the management of post-partum hemorrhage

Study Design: Descriptive study

Study Setting: Department of Obstetrics and Gynecology, Sheikh Zayed Medical from 21st May 2021 till 20th November 2021.

Methods: Total 126 women aged 18-35 years, parity 1-6 and 31-41 weeks of gestation, who develop atonic post-partum hemorrhage not responding to uterotonics following normal vaginal delivery or caesarean section were enrolled using non-probability consecutive sampling technique. Women having postpartum hemorrhage were treated with balloon tamponade to stop bleeding. Efficacy was noted after 06 hours of procedure. Data was entered and analyzed using SPSS 25.

Results: In this study total 126 patients were enrolled with mean age of 25.6±5.3 years. Mean gestational age was 38.2±3.2 weeks. Mean blood loss was 1032.1±379.6 ml. Mean parity was4.1±1.3. Most of patients had middle education i.e. 33.3%. Majority of patients belonged to middle socioeconomic status i.e. 47.6%. There were 41.3% patients who were booked and 2 had regular antenatal visits. Vaginal delivery was done in 55.6% patients. Balloon tamponade was effective in 81% patients.

Practical Implication: Since balloon tamponade is a relatively new procedure, there is little information about its efficacy compared to the more traditional method of uterovaginal packing in Pakistan.

Conclusion: Balloon tamponade is effective in stopping postpartum hemorrhage. The success rate (81%) of balloon tamponade in preventing PPH is high. It's convenient for use in situations with a higher risk of PPH.

Keywords: Postpartum Hemorrhage, Balloon Tamponade, Delivery, Efficacy, Blood Loss, Management

INTRODUCTION

Estimated blood loss greater than 500 mL during vaginal birth and 1000 mL following caesarean section is primary postpartum haemorrhage (PPH),[1] after caesarean delivery from the birth canal within 24 hours.[2] Rightfully termed the "obstetrician's nightmare," primary postpartum haemorrhage remains a major contributor to maternal mortality and morbidity in underdeveloped countries like Pakistan, where it accounts for 21-31% of maternal deaths.[3] The most prevalent cause of PPH is uterine atony, which accounts for 80% of all cases. Primary PPH can also be brought on by things like a uterine rupture, lower genital trauma, or a retained foetus.[4] Management of PPH involves step wise approach: uterine massage, utero tonic drugs (oxytocin and prostaglandins), exclusion of retained products & repair of genital tract trauma, uterine packing and balloon tamponade placement. If these attempts fail then surgical intervention is needed including external compression with uterine sutures, ligation of uterine artery and internal iliac artery and if failed then hysterectomy as a last resort.[4-7]

Intrauterine Balloon tamponade is being used in world with different methods using bakery balloon, folley's catheter and condomes. These gadgets are placed in utero and inflated with sterile fluid to produce temponade effect on uterine walls in order to stop bleeding. Bakery balloons are expensive and are not available in resource poor setup. Using cheap methods like condoms is a crucial step in the management of primary PPH to save lives of mothers in resource poor countries like Pakistan because most of the patients deliver at far off areas and most of them are received in tertiary care centers in irreversible state where they have already developed Disseminated Intravascular Coagulation (DIC) and it is more hazardous for them to proceede for surgery. Condomes are cheap, easily available and placement procedure is simple.

Balloon tamponade for PPH was the intended focus of this investigation. This technique was tried before any invasive procedures were attempted. In the past, tamponade was utilised to manage PPH using uterine packing; however, the invasive nature of inserting roller gauze packs has made uterine balloon tamponade the preferred method. The therapy of PPH involves the insertion of a condom catheter, a fluid-filled device that exerts a tamponade effect to halt bleeding. [8] A condom was rolled over a Foley's catheter and knotted with silk thread at two points 1 centimetre apart before being placed into the uterus and filled with N/S 300–400 ml using aseptic techniques.[9] A cotton string or umbilical clamp was used to secure the catheter to the patient's thigh. The bladder was remained plugged with the indwelling catheter until the condom tamponade was in place. The height of the fundus was noted on the abdomen. To keep the balloon in situ, 4 sponge holding forceps applied on cervix lips, 2 on anterior and 2 on posteriorlip, tied with roller gauze to keep the balloon in situ.[10-11] If bleeding continues, it will trickle through the introitus to soak the outside pad and undergarments.[12] In a study, successful balloon tamponade outcome has been reported as 90.4%.[13] In another study, successful balloon tamponade outcome has been reported as 80%.[14] In another study, successful balloon tamponade outcome has been reported as 75%.[15] Although balloon tamponade is being used in other part of world and few centers of Pakistan as well. But in our area this technique is still not in practice.

The purpose of this study is to use balloon tamponade in usual practice to arrest massive hemorrhage as Sheikh Zayed Hospital is situated in an area where we receive huge number of patients with primary PPH, who were severely compromised by the time they reach the Hospital and it, is not possible for us to immediately precede for surgical intervention. With the concept of every minute matters, we can implement balloon tamponade in usual practice to stop bleeding. As this is simple procedure to perform even primary health care workers can implement it before referring the patient to Sheikh Zayed Hospital, which will minimize blood loss and prevent irreversible shock. Thus, to add our part in reducing maternal mortality and morbidity and help in achieving sustainable development goals (SDG's)

MATERIALS AND METHODS

The study was done at Rahim Yar Khan's Sheikh Zayed Medical College and Hospital in the Department of Obstetrics and Gynaecology. Cross-sectional is the type of study design, and non-probability straight sampling is the type of sample method. The sample size is 126 which are calculated by 95% confidence level with 7% margin of error and taking expected efficacy as 80%.

Sample selection was done keeping in mind that women should be aged 18-35 years, parity 1-6 and 31-41 weeks of gestation, who develop atonic post-partum hemorrhage not responding to uterotonics following normal vaginal delivery or caesarean section. While, those who had Obstetric hemorrhage <31 weeks of gestation, traumatic PPH, allergy to latex and acute uterine infection were excluded. Data collection was started after taking approval from institutional ethics committee, 126 patients were selected from Gynecology Unit-I according to inclusion and exclusion criteria. After describing the purpose of the research to the patient, informed consent was obtained. A proforma was used to document demographic and epidemiological information. Women with postpartum haemorrhage who did not improve with uterotonics were evaluated for treatment with a condom and folley catheter balloon. A condom-lined sterile rubber catheter was inserted into the uterus using strict aseptic procedures. Balloon was placed on cervix and held in place using roller gauze and sponge-holding forceps. 300-400 ml of regular saline were used to inflate the condom. Meanwhile, the infusion of syntocinon began. The catheter condom was stored for up to six hours. When no active bleeding was detected through the cervix and the uterine fundus felt contracted after 6 hours, the balloon was slowly deflated at a rate of 50 ml/hour to half its volume in 2 hours.

If no further bleeding occurred during the next 30 minutes, the balloon was removed in the presence of a senior staff member. Condom temponade was abandoned and surgical intervention was pursued if bleeding persisted or the uterine fundus rose after it was placed. Balloon tamponade's effectiveness in stopping bleeding six hours after insertion was the primary measure of success. Age, foetal age, booking status, parity, route of delivery, and the success of balloon tamponade in preventing postpartum haemorrhage were all recorded on the accompanying proforma.

Data was entered and analyzed by using SPSS v25.0. Quantitative variables i.e. age, gestational age, blood loss and parity are presented with Mean±S.D, while qualitative variables i.e. education status, socio-economic status, booking status, mode of delivery and outcome (efficacy) are presented with frequency and percentages. Data is stratified for age, gestational age, parity, education status. Post-stratification, Chi-square test is applied. A p-value ≤0.05 is considered significant.

RESULTS

In our study total 126 patients were enrolled with mean age of 25.6±5.3 years. Mean gestational age was 38.2±3.2 weeks. Table 2 Mean blood loss was 1032.1±379.6 ml. Mean parity was 4.1±1.3 as shown in table 1. Table 2 shows most of patients had middle education i.e. 33.3%, majority of patients belonged to middle socioeconomic status i.e. 47.6%, there were 41.3% pregnant patients who were booked and had regular antenatal visits, vaginal delivery was done in 55.6% patients.

Table 1: Age, gestational age, blood loss during PPH, parity of sampled population

Variables	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	126	18	35	25.62	5.368
Gestational Age (weeks)	126	31	41	38.25	3.281
Blood loss(ml)	126	500	1800	1032.1 4	379.612
Parity	126	1	8	4.112	1.326

Table 3 shows balloon tamponade was effective in 81% patients. Table 4 shows data stratification for effectiveness and age groups was significant, p-value<0.001, data stratification for effectiveness and gestational age was not significant, p-value 0.480, data stratification for effectiveness and parity was significant, p-value 0.015. Table 5 Data stratification for effectiveness and educational status was not significant, p-value0.804.

Table 2: Educational status of sampled population

Variables	Characterstics	Frequency	Percent
Educational status	Illiterate	18	14.3
	Middle	42	33.3
	Up to matric	30	23.8
	Inter and above	36	28.6
	Total	126	100.0
Socioeconomic status	Low (less than 20thousand/month)	30	23.8
	Middle (20-50 thousand/month)	60	47.6
	High (more than 50thousand/month)	36	28.6
	Total	126	100.0
Booking status	Booked case	52	41.3
	Unbooked	case 74	58.7
	Total	126	100.0
Mode of delivery	Vaginal delivery	70	55.6
	C-section	56	44.4

Table 3: Frequency of effective treatment

Variables	Characterstics	Frequency	Percent
Efficacy	Yes	102	81.0
	No	24	19.0
	Total	126	100.0

Table 4: Data stratification for frequency of effectiveness and age groups

Variables			Efficacy		Total
			Yes	No	
Age groups	18-26 years	Count	70	6	76
		% within Agegroups	92.1%	7.9%	100.0%
	27-35 years	Count	32	18	50
		% within Agegroups	64.0%	36.0%	100.0%
Gestational age	31-36 weeks	Count	42	8	50 %
		within Gestationalage	84.0%	16.0%	100.0%
	37-41 weeks	Count	60	16	76 %
		within Gestationalage	78.9%	21.1%	100.0%
Parity	Primigravida	Count	34	2	36 %
		within Parity	94.4%	5.6%	100.0%
	Multigravida	Count	68	22	90 %
		within Parity	75.6%	24.4%	100.0%

Table 5: Data stratification for frequency of effectiveness and educational status

			Efficacy		Total
			Yes	No	
Education status	Illiterate	Count	16	2	18 %
		within Education status	88.9%	11.1%	100.0%
	Middle	Count	34	8	42 %
		within Education status	81.0%	19.0%	100.0%
	Up to matric	Count	24	6	30 %
		within Education status	80.0%	20.0%	100.0%
	Inter and above	Count	28	8	36%
		within Education status	77.8%	22.2%	100.0%

DISCUSSION

More than 30 percent of maternal fatalities are attributed to PPH, although this number can be lowered with better screening, diagnosis, and treatment.[16] In the early stages of PPH, uterotonic medications and bimanual compression are the mainstays of therapy. Compressive suturing of the uterus, occlusion of the internal iliac artery, or embolisation of the pelvic arteries are the options for secondary care. Due to the need for the caesarean section incision to be closed before pelvic arterial embolisation can be performed, this procedure cannot be done immediately in the operating room. Therefore, caesarean hysterectomy must be done to prevent maternal death if heavy bleeding persists.[17] Intrauterine tamponade, on the other hand, can be utilised right away during surgery to boost the likelihood of sustaining fertility. Our group was studied to see if balloon temponade would be effective in

preventing PPH.

In our study total 126 patients were enrolled with mean age of 25.6±5.3 years which contrasts with the mean age of 28.8 years that Jaleel et al.'s study found and 26.4±4.2 years found by Lohano et al. (2016).[13,19] Mean gestational age was 38.2±3.2 weeks which is in line with the findings of Kadioglu et al., who found that the average duration of pregnancy was 37.9±3 weeks and also matched with findings of Lohano et al. (2016), to be 37.81±1.67 years.[13,20] Mean blood loss was 1032.1±379.6 ml which was similar to study of Dawood et al. (2022) who reported that the average amount of blood lost was 1208.5±227.9 ml and also related with findings of Lohano et al. an average of 1155.8 ±350.6 ml of blood was lost per patient.[13,21] In our study mean parity was 4.1±1.3 which was comparable to findings of Lohano et al. (2016) 3.41±1.3.[13]

Mostof patients had middle education i.e. 33.3%. Majority of patients belonged to middle socioeconomic status i.e. 47.6%. Balloon tamponade was effective in 81% patients this finding was a little bit smaller from findings of Lohano et al. (2016), 126 out of 136 (90.4%) patients had successful balloon tamponade.[13] Anoter study found that there was a 100% success rate (11/11 instances) for uterine atony-related haemorrhage. In three instances, unsuccessful placement was caused by technological issues. Bleeding caused by a retained placenta had an 80% success rate (4/5; placenta percreta was a failure). In two of three cases of amniotic fluid embolus and one case of dilatation and curettage for postpartum septic shock, the catheter was successful in stopping vaginal bleeding. The stated success rate of balloon tamponade is 90%.[14] Cho et al. (2015) reported that 46.7% patients had placenta previa totalis, and 50 (78.1%) experienced postpartum haemorrhage from the lower uterine segment, requiring uterine balloon tamponade following caesarean surgery. Patients with placenta previa had a success rate of 75% (48/64) overall which was quite low from results of our study.[15]

The success rate of a catheter balloon for stopping bleeding was 94%, according to research by Rathore et al. (2016)[16], the average length of time spent on hemostasis management was 6.2 minutes, and the mean amount of fluid needed to fill the condom catheter balloon was 409 mL. The average amount of blood loss recorded in that study was also highly consistent with our own findings.[16] In terms of effectiveness, our results are in line with those of Dabelea et al.[17] According to the aforementioned research14, barriers to placement ended up being the primary cause of unsuccessful cases. According to the study's conclusion, balloon tamponade is superior to medical care for severe PPH, especially in the event of uterine atony.[17]

Balloon tamponade was effective in 81% of cases in our study. In 19% of cases, it was ineffective, prompting patients to have B-lynchsuture, uterine artery ligation, internal iliac ligation, or hysterectomy as a surgical option. Balloon tamponade has been shown to be successful in reducing obstetric haemorrhage, with study by Suarez et al. (2015) who described success rate to be 85.9% and another finding a 14.1% failure rate.[18]

In terms of drawbacks, it would have been helpful to compare the effectiveness of balloon tamponade to that of other conservative treatments used at our centre, such as uterovaginal packing. More randomised, controlled trials evaluating different approaches to PPH therapy are needed.

CONCLUSION

It has been shown that balloon tamponade has a good efficacy (81%) in reducing PPH. To better understand the factors impacting the outcome, more studies with larger sample sizes are needed. Balloon tamponade is a viable approach due to its ease of use in high-risk PPH situations.

Credit Authorship Contribution Statement: SY Study conception and Principal Investigator; NN Conducted experiment and data curation; SY, NN Data analysis and data interpretation; SY Data validation, SY, NN Manuscript writing, reviewing and editing; SY Final approval of the version to be published.

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