

Efficacy of Balloon Tamponade in the Management Primary Postpartum Haemorrhage

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Abstract

Background: Postpartum Haemorrhage is the leading cause of maternal death all over the world. It remains a serious complication of childbirth in developed and developing countries.

Objective: To evaluate the success of uterine balloon tamponade in those patients suffering from postpartum Haemorrhage where medical treatment has failed.

Materials and Methods: This study was conducted in Gynae Department of Khyber Teaching Hospital, Peshawar from 1st January 2022 to 31st December 2022. Cross sectional is the type of study design and no probability sampling is the type of sampling method. All patients with primary postpartum Haemorrhage, in 15-45 years age range, who delivered vaginally after a full term pregnancy, were included. Those having history of caesarean section, uterine anomalies, preterm labor, morbidly adherent placentas, placental abruptions, placenta previas and retained products were excluded. All the patients where the cause of PPH was uterine atony were first managed with pharmacological treatment, which if failed then uterine balloon tamponade was inserted. Tamponade was removed after 24-48 hours. Failure in cessation of bleeding was followed by surgical management in the form of B lynch suture or hysterectomy. Data was collected in a predesigned Proforma.

Results: The mean age was 26.02±4.42 years. 9.72% women had past history of PPH. Majority of our study population was grand Multigravidas (61.57%) and the most prevalent age group was 26-35 years age group. 87% women responded to medical treatment and UBT was applied in the rest. The UBT success rate was 89.2% whereas it failed in 10.8% women where laprotomies were conducted. The higher response rate was noticed in grand Multigravidas (50%) and in 26-35 years age group (46%). It failed in three patients who had no history of PPH and was successful in those with coagulopathies.

Conclusion: The response rate to uterine balloon tamponade is higher in patients with postpartum Haemorrhage due to uterine atony. Before embarking on surgical procedures with many possible complications, uterine balloon tamponade should be used.

Keywords: Primary Postpartum Hemorrhage, Medical Management, Response Rate, Condom Catheter, Caesarean Section, Grand Multigravidas

Cite as: Qadir M, Efficacy of Balloon Tamponade in the Management Of Primary Postpartum Hemorrhage BMC J Med Sci 2024. 5(1): 79-82

Introduction:

Postpartum Haemorrhage is the leading cause of maternal death all over the world. 1 Postpartum Haemorrhage is blood loss of more than 500 ml following vaginal delivery and 1000 ml after caesarean section. 2 In developing countries, it is responsible for an annual mortality of 150,000 women per year.³ It remains a serious complication of childbirth in developed and developing countries. The most common cause of Postpartum Haemorrhage is uterine atony.⁴

As per WHO recommendations, the use of intrauterine balloon tamponade is recommended for the treatment of PPH due to uterine atony if women do not respond to uterotonics.⁵ FIGO also included uterine balloon tamponade as a recommended second line intervention for the treatment of postpartum Haemorrhage.⁶ The

successful outcome of balloon tamponade is 80-100%⁷. The idea of using a condom as balloon tamponade was first conceived in 2001 by Akhtar in Bangladesh to fulfill the need and to avoid the high cost of tamponade devices used at that time.⁸ Low resource settings have to rely on lower cost adaptations like condom balloon tamponade which is most effective second line management option.⁹

The placenta is a low pressure system, so it seems likely that when the placenta is the source of Haemorrhage, the direct pressure of the balloon, even well below systolic pressure will stop bleeding. When the bleeding is from an arterial source, the balloon's exerted pressure exceeds the arterial pressure and promotes the formation of clot, another possibility being the introduction of balloon in atonic uterus causes it to contract.¹⁰ The condom balloon tamponade has two

Authorship Contribution: ^{1,3,4}Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work, ²Final approval of the version to be published, Supervision, Active participation in active methodology

Funding Source: none
Conflict of Interest: none

Received: March 23, 2024
Accepted: May 5, 2024
Published: July 2, 2024

main disadvantages. First is not having a drainage port, making it difficult to assess the blood loss and second is thread or suture is used to tie condom to the catheter which often causes leakage of saline.¹¹

The aim of our study is to evaluate the success of uterine balloon tamponade in those patients suffering from postpartum haemorrhage where medical treatment has failed.

Materials and Methods:

This study was conducted in Gynae A unit of Khyber Teaching Hospital, Peshawar from 1st January 2022 to 31st December 2022. Cross sectional is the type of study design and nonprobability sampling is the type of sampling method. Ethical approval was taken from hospital ethical committee. All patients with primary postpartum haemorrhage, in 15-45 years age range, who delivered vaginally after a full term pregnancy were included. Those having history of caesarean

section, uterine anomalies, preterm labor, morbidly adherent placenta, placental abruptions, placenta previa and retained products were excluded. Postpartum haemorrhage was defined as loss of more than 500 ml of blood in first 24 hours after delivery. Term pregnancy means delivery after 37 completed weeks of gestation.

All the patients where the cause of PPH was uterine atony were first managed with pharmacological treatment. Initially oxytocin (10 units intravenously and then 80 units in ringer lactate infusion at rate of 100 ml/hour), misoprostol (800 micrograms per rectal) with continuous uterine massage, and bladder emptying was performed. Medical management succeeded in 188 patients, whereas in 28 patients, UBT was inserted.

The condom was attached to the inserting end of Foleys catheter and introduced to the uterus. Then it was filled with normal saline passing through the drip set. About 250 to 400 ml of fluid was filled or until bleeding stopped. The patient was observed for any bleeding or deterioration in vitals. Tamponade was removed after 24-48 hours. Failure in cessation of bleeding was followed by surgical management in the form of B Lynch suture or hysterectomy.

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

The mean age was 26.02 ± 4.42 years. 28 (12.96%) were primigravidas, 30 (13.88%) were multigravidas, 133 (61.57%) were grand multigravidas

and 25 (11.57%) were great grandmultigravidas. 39 (18.05%) were in 15-25 years age group, 142 (65.74%) were in 26-35 years age group, and 35 (16.2%) were in 36-40 years age group. 21 (9.72%) women and past history of PPH whereas 195 (90.2%) did not have any past history of PPH. Mean gestational age was 38.2 ± 3.2 weeks. Mean blood loss was 1032.1 ± 379.6 ml. Mean parity was 4.1 ± 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% pregnant patients who were booked and had regular antenatal visits.

Out of total 216 patients who suffered from PPH in the study period, 188 (89.2%) responded to medical treatment and only 28 (10.8%) patients where medical treatment failed were managed with uterine tamponade in which three cases failed.

In the 28 cases where balloon tamponade was used, 14 (50%) were grand multigravidas, 5 (17.85%) were multigravidas, 5 (17.85%) were primigravidas and 4 (14.28%) were great grand multigravidas. In 15-25 years age group, 8 (28.5%) women responded to UBT, in 26-35 years age group, 13 (46.4%) responded whereas it failed in one patient in this age group, and in 36-40 years age group, 7 (25%) responded to UBT and it failed in 2 patients. In those patients with history of PPH, UBT was successful in 12 (42.8%) and failed in no patient. In 16 (57.14%) patients where there was no history of PPH, it failed in three patients, and was successful in 16 (57.14%) women. Two of our patients where UBT applied and was successful suffered from thrombocytopenia.

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. Data stratification for effectiveness and educational status was not significant, p-value 0.804.

Table No. 1: Demographic Characteristics Of Patients Presenting With Pph (N=216)

| AGE GROUP | FREQUENCY | PERCENTAGE |
|--------------------------|-----------|------------|
| 15-25 YEARS | 39 | 18.05% |
| 26-35 YEARS | 142 | 65.74% |
| 36-40 YEARS | 35 | 16.2% |
| GRAVIDITY | | |
| PRIMIGRAVIDAS | 28 | 12.96% |
| MULTIGRAVIDAS | 30 | 13.88% |
| GRAND MULTIGRAVIDAS | 133 | 61.57% |
| GREAT GRANDMULTIGRAVIDAS | 25 | 11.57% |
| HISTORY OF PPH | | |
| YES | 21 | 9.72% |
| NO | 195 | 90.2% |

Discussion:

| | RESPONDERS | | NONRESPONDERS | |
|-----------------------------|------------|------------|---------------|------------|
| AGE GROUP | FREQUENCY | PERCENTAGE | FREQUENCY | PERCENTAGE |
| 15-25YEARS | 8 | 28.5% | - | - |
| 26-35YEARS | 13 | 46.4% | 1 | 3.5% |
| 36-40YEARS | 7 | 25% | 2 | 7% |
| HISTORY OF PPH | 12 | 42.8% | - | - |
| NO HISTORY OF PPH | 16 | 57.14% | 3 | 10.7% |
| HISTORY OF THROMBOCYTOPENIA | 2 | 7% | - | - |

Postpartum haemorrhage if not attended can kill a healthy woman within 2 hours. About 1 in 200 women can develop massive postpartum haemorrhage, which can lead to hypotension and shock. 10.10% of these women will need surgical procedures to save their lives and UBT is a method which is simple to apply and can handle the PPH in an efficient manner.¹²

The mean age of our patients was 26.02+4.42 years, which is close to 27.04+5.42 years which is the mean age observed by Begum Z in her study conducted at Saidu Medical College in 2020.¹² Likewise 26.82+6.36 years mean age was noticed by Akhtar S et al in their study.^{13,14} The cohort study done by Wang Y et al in 2023 observed most of their study population (69.89%) belonged to 25-35 year age group.²⁰

Grand multigravidas was the most vulnerable age group in our study, which showed most effectiveness to UBT. Likewise, grand multigravidas were the commonest group showing maximum effectiveness to UBT in research done by Georgiou C.¹⁵ In 50% of grand multigravidas, UBT was successful in our set up. On the contrary, UBT was successful in 64.52% primigravidas in another research study.²⁰

We analyzed that there were 28 cases which did not respond to medical treatment and we had to place UBT, where it got successful in 25 cases, making the success rate 89.2%. The success rate was higher i.e., 95% and it was 100% in another study done by Sayeba AF et al.¹⁶ Rathore AM et al observed that the success rate of UBT was 94% with bleeding controlled in 6 minutes.¹⁷

On the other hand, Majumdar A et al concluded that the UBT is not very successful in controlling postpartum haemorrhage and they had to proceed to surgical measures to save life of the patient. They reported success rate of 59%, with seven patients resorted to surgical measures to control their PPH.¹⁸ In two of our cases with thrombocytopenia, UBT was successful in controlling PPH. Bagga R et al also reported in their study that UBT is useful in patients with impaired coagulation in their case series, which focused at controlling PPH in women with coagulation disorders.¹⁹

Wang Y et al in their study in 2023 collected a cohort of 279 women with PPH who failed to respond to first line conservative measures. Balloon tamponade technique was used and it was observed that it had hemostasis success rate of 88.89%.²⁰

The balloon catheter is a very cost-effective and quick method requiring less expertise for insertion of balloon and has low failure rate. Its use should be encouraged in low resource settings after medical treatment doesn't work or to save time while referring the patient to a better health facility.

Since obesity is considered to be a risk factor for multiple health issues, overweight and obese individuals are suggested to have higher incidence and morbidity regarding thyroid disorders. This study was conducted to ascertain if any correlation exists between thyroid disorders and body mass index.⁶ Total participants included in this study were 200, out of which 149 (74.5%) were female and 51 were male. Thyroid disorders were seen predominantly in females similar to the studies by Meng et al⁷ and Archana et al.⁸ Our study showed a significant overall correlation between thyroid disorders and BMI according to Chi-square tests with $p=0.005$. Our study showed that Pearson's correlation between BMI and the euthyroid group was insignificant and association was negligible. This is in similarity with the studies by Manji et al, and Figueroa et al, that showed no relation between BMI and thyroid function in euthyroid subjects.^{9,10}

We found that, out of total hypothyroid subjects ($n=53$), 43 are overweight or obese. Thus, the majority of hypothyroid individuals had increased BMI. This is similar to another study conducted by Makwane et al where a higher frequency of hypothyroid subjects was found in obese group as compared to other groups.¹¹ Previous studies suggest that hypothyroidism is more frequently observed in obese individuals. Obesity is considered as a risk factor for hypothyroidism in particular.¹²⁻¹⁵ However, other studies reported no definite association between an increased risk of hypothyroidism and obesity.^{16,17} Our study gives a positive and significant correlation between BMI and the hypothyroid group. Different prevalence rates of hypothyroidism in obese individuals in these studies may be due to the differences in race, variation in body fat type, and conditions under which the studies were conducted.¹¹

On the other hand, many previous studies consider thyroidal illness to be a reason for altered metabolic rate leading to gain or loss of body weight. Longitudinal studies done by Fox et al., show that weight gain is caused by increased TSH¹⁸ and Wolters et al. in their study showed that weight loss is a result of reduced TSH.¹⁹ In our study Pearson's correlation showed a negative correlation between BMI and hyperthyroid group. We also compared levels of T_3 , FT_4 and TSH separately with BMI. Among these, T_3 and FT_4 showed negative association with BMI. It is in contrast to the study by Makwane et al., where they failed to find significant association between thyroid hormones and BMI in their study subjects.¹¹ Pergola et al, and Reinehr et al showed that raise in TSH and FT_3 can be seen in individuals with high BMI. They suggested no relation between FT_4 and obesity.^{20,21} Alevizaki et al, and Roef et al, in their research studied relation of FT_3 and BMI and gave the results that in healthy euthyroid adults FT_3 has positive association with BMI.^{22,23} This is contradictory to

our study, which shows a significant negative correlation between T₃ and BMI.

Our study showed the significant positive correlation of TSH with BMI and negative correlation of BMI with both FT₄ and T₃. Knudsen N et al., have suggested a positive correlation between BMI with TSH, and a negative association between BMI and FT₄. According to their results, no correlation of BMI was seen with serum free T₃.²⁴ Similar results were given by Nyrnes et al, in the fifth Tromso study. They concluded that there is positive correlation between TSH within the normal range and BMI.²⁵ Michalaki et al. reported that obese individuals had higher levels of T₃, T₄, and TSH than control group individuals.²⁶ Makwane et al showed significantly higher TSH level in overweight and obese subjects than normal subjects and reported no difference in the total T₃ or total T₄ levels with BMI in his control and study groups.¹¹ Similarly, Muscogiuri G et al., have concluded that higher TSH values are documented in overweight and obese subjects.²⁷ Another study of 87 morbidly obese female subjects found that they had higher TSH levels than those with moderate obesity. Thus, TSH had positive correlation with BMI. Individuals having higher BMI also had lower FT₄ values, while no relationship could be established between BMI and FT₃.²⁸ Other studies by Buscemi et al., and Manji et al, differ from the these results and that show no significant relationship between BMI and TSH as well as BMI and FT₄.^{9,29} Bastemir et al, in their research showed positive correlation between the serum TSH levels in participants with high BMI and normal thyroid function. They also gave the conclusion that BMI and the class of obesity were positively correlated.³⁰

Conclusion:

Use of condom tamponade can effectively help in reducing both maternal mortality and morbidity associate with postpartum haemorrhage. Our study showed a high reponse rate to Condom tamponade hence encouraging its use before embarking on more invasive surgical procedures with more side effects. 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 situation.

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