EFFECTIVENESS OF FOLEYS INTRAUTERINE BALLOON TAMPONADE IN MANAGEMENT OF POSTPARTUM HAEMORRHAGE AND FACTORS ASSOCIATED WITH ITS FAILURE; A TERTIARY CARE EXPERIENCE

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ABSTRACT

OBJECTIVES

To evaluate the effectiveness and factors associated with the failure of intrauterine balloon tamponade (IUBT) in managing postpartum hemorrhage (PPH).

METHODOLOGY

We conducted a retrospective observational study including data from 160 patients aged 21-30 years at the Department of Obstetrics and Gynaecology, Lady Reading Hospital, Peshawar, managed for PPH with IUBT, after failed medical treatment from Jan 2020 to December 2021. Data were collected retrospectively in three months, from January to March 2022. IUBT was successful if, after 24 hours of insertion, no or less than 100ml bleeding occurred.

RESULTS

Among the patients managed by IUBT, the majority had uterine atony (81.25%), 17.5% had lower segment hemorrhage, and 1.25% of cases had a placental abruption. The mean estimated blood loss was 1263.7±398.7 ml. The procedure was successful in 89.3% of cases. Sixteen patients underwent a hysterectomy for failed IUBT. There were six maternal deaths, mainly due to acute renal failure and disseminated intravascular coagulation (DIC). Between the successful and unsuccessful cases of IUBT, there was a statistically significant difference in the gravidity, mode of delivery, gestations, booking, peripartum BP, pulse rate, hemoglobin, platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT), blood loss during the procedure, DIC, and intensive care unit admissions ($p<0.00$). The median hemoglobin, hematocrit, platelets count, and lymphocytes were significantly higher before IUBT insertion ($p<0.00$).

CONCLUSION

IUBT is an effective, easy-to-use, inexpensive, and safe tool in the management of PPH. Low hemoglobin, thrombocytopenia, high PT, aPTT, and DIC are associated with low success rates

KEYWORDS: *Postpartum Haemorrhage, Intrauterine Balloon Tamponade, Foleys Catheter*

INTRODUCTION

Postpartum hemorrhage (PPH) is the loss of blood, more than 500 mL during vaginal delivery and 1,000 mL during a cesarean section (C-section) within the first 24 hours.[1] In 2017, the American College of Obstetricians and Gynecologists redefined PPH as "cumulative blood loss more than or equal to 1,000 mL of blood loss accompanied by signs and symptoms of hypovolemia such as tachycardia, oliguria, or chest pain within 24 hours after the birth process regardless of route of delivery".[2] PPH is reported to occur in up to 10% of all births.[3] In low-middle income countries, the reported incidence is 6% in live births and is the leading cause of maternal mortality and morbidity globally.[4] There are various causes of PPH. Uterine atony is the most common cause, accounting for 70% of all hemorrhages in the United States. It results from insufficient uterine muscle contraction required to maintain hemostasis. Other documented causes include retained placenta, failed progress during the second stage of labor, genital tract lacerations, IVD, placenta previa, and morbidly adherent placenta.[5] The first-line management of PPH comprises bimanual uterine compression, massage, and pharmacological uterotonic agents.[6] The second-line conservative management options include uterine packing with gauze, IUBT, and compression sutures.[7] In case of continued PPH, surgical options such as uterine artery embolization, internal iliac artery ligation, and emergency

hysterectomy are resorted to. However, these procedures are associated with increased maternal morbidity and mortality. IUBT has been widely used in the management of PPH in recent years. It is recognized by WHO as a significantly effective method for managing PPH, especially in low-income countries.[8] It is also endorsed by RCOG in managing PPH due to uterine atony.[9] It stops uterine bleeding by applying pressure to the uterus. There is a variety of IUBT devices available globally, but due to their high cost and non-availability in developing countries, most setups use 2-way Foley catheters or condoms attached to Foley catheters. Local studies have shown it to be effective in controlling PPH.[10] We conducted this study to assess the efficacy of IUBT, using the 2-way Foley catheter to manage PPH in the tertiary setting.

METHODOLOGY

The study was a retrospective review of medical records of patients who either developed or were admitted with primary PPH after an NVD, IVD, or CS after medical treatment failed at the Lady Reading Hospital, Peshawar, between January 2020 to December 2021. We excluded all patients with PPH due to retained products, genital tract lacerations, or missing data. In our department, PPH is managed according to RCOG guidelines. After initial resuscitation, the cause of PPH is explored, and in the case of uterine atony, pharmacological agents are given, and bimanual compression is done. If this management fails, balloon tamponade is applied by postgraduate trainees. After taking consent, under aseptic precautions, a sterile 2-way Foley catheter is introduced into the uterus and inflated with 50-100ml normal saline. Sometimes we use two Foley catheters in case of continuing bleeding, and vaginal packing is done once the catheter is inflated. Syntocinon infusion is given. The catheter is removed after 24 hours in the presence of a registrar. Blood loss is measured after pouring it into a graduated plastic jar from a kidney tray to collect blood. We reviewed the files of all patients with PPH and retrieved the data from January to March 2022. A structured proforma was used to gather data related to demographic and clinical characteristics, including maternal age, body mass index (BMI), MOD, induction of labor, gestational age, management of PPH, and efficacy of IUBT in controlling PPH, of all patients admitted to the Unit-A of the Obstetrics department during the defined study period. Balloon tamponade was considered effective if there was no bleeding or less than 100ml after 24 hours of its insertion. Data was entered and analyzed using SPSS package version 21 (IBM Corp.; Armonk, NY, USA). Quantitative variables like age, BMI, and gestational age were presented as mean ± standard deviation or median (IQR). Frequencies and percentages were calculated for qualitative data like MOD and the effectiveness of IUBT. For inferential statistics, continuous scale data were analyzed using Student's t-test, Man Whitney-u test, or Wilcoxon-sign rank test as appropriate. In addition, the categorical data were compared using the Chi-squared test or Fischer exact test as appropriate. A p-value < 0.05 will be considered statistically significant. The study was conducted after seeking approval from the institutional ethical review committee (ERC No. 267/ LRH/ MTI).

RESULT

Out of 15000 deliveries conducted in our ward during the study period, about 220 cases were complicated by PPH. A total of 160 patients were treated with IUBT (1.06%). Among them, 130 (81.25%) patients had uterine atony, 28 (17.5%) patients had lower segment hemorrhage, and two (1.25%) patients were complicated by placental abruption. The mean duration of IUBT in situ was 22.88 ±5.6 hours, and the mean blood loss was 1263.7±398.7 ml. It succeeded in arresting hemorrhage in 89.3% (143/160) of patients while 17 failed to respond (figure-1). Of these, 16/17 ended up in total abdominal hysterectomy, while one responded to conservative management. Among the ineffective cases, six (35.29%) had a large uterine size, three (17.64%) cases expelled the balloon, three (17.64%) had uterine leiomyoma, and 5 (29.41%) had DIC. There were six maternal deaths observed. The median age and BMI (IQR) were 23.5 (21-30) years and 26.4 (26-27) $kg/m^{2,}$ respectively. The mean gestational age was 39.17+1.219 weeks. The majority of patients were primigravida (52.5%). Most labours were induced, 93 (58.12%), and SVD was the most common mode of delivery performed in 80.6% of patients. To find factors for the failure of IUBT, we compared the successful group with the ineffective IUBT group (Table. I). There was no statistical difference in clinical characteristics other than gravidity, MOD, booking status, and multiple gestations ($p= 0.036$, $p< 0.00$, $p< 0.00$, $p< 0.00$). Among the women with effective IUBT, the majority were unbooked; 99 (69.23%), primigravida; 71 (49.6 %), had an NVD; 123 (86.01%), and underwent induction of labor; 82 (57.34%). Development of DIC and ICU admissions were significantly higher in patients with ineffective IUBT ($p< 0.00$). However, the hospital stay didn't differ significantly (Table. 1). For comparing the severity outcomes between the two groups, data were available for only 140 patients (Table. 2). There was a significantly higher total blood loss in the ineffective group ($p<0.00$). About 120 patients (83.9%) received a blood transfusion in the IUBT group, and all cases were in the ineffective IUBT

group (p<0.00). Peripartum BP, pulse rate, hemoglobin, hematocrit, platelets, prothrombin time (PT), and activated partial thromboplastin time (aPTT) statistically differed between the two groups (p<0.00). Preoperative hemoglobin and platelet counts were higher in the successful group (p<0.00), while PT and APTT were more elevated in the IUBT fail group (p<0.00). Pre and post-procedure laboratory test results showed that the level of median hemoglobin (p<0.00), hematocrit (p<0.00), platelets (p<0.001), and lymphocytes (p<0.001) were all significantly higher in the patients before IUBT whereas PT (p=0.29), PT (p<0.00), aPTT (<0.00), international normalization ratio (INR) (p<0.00), white blood cell (<0.00), and Neutrophil values (<0.00) were lower in patients before the procedure (Table. 3).

Table 1: Demographic and Clinical Characteristics of the Study Population, n=160

Variables	IUBT Successful Group (143)	IUBT Fail Group (17)	P-Value
Maternal age (years) Median (IQR)	24(21-30)	23(21-30)	0.86[a]
BMI (kg/m^2) Median (IQR)	26(25-28)	27(26-27)	0.42[a]
Gestational age (weeks) Mean ± SD	39.22+1.23	38.70+0.98	0.09[b]
Gravidity n(%) Primigravida Multigravida	71(49.6 %) 72(50.3 %)	13(76.4%) 04(23.5%)	0.03[c]
Multiple pregnancies n (%) Yes No	33(23.07%) 110(7.69%)	16 (94.12%) 01(5.88%)	<0.00[d]
Booking status n (%) Yes No	44(30.77%) 99(69.23%)	16(94%) 01(5.88%)	<0.00[c]
Mode of delivery n (%) NVD IVD	123(86.01%) 20(13.98%)	06(35.29%) 11(64.70%)	<0.00[c]
Induction of labour n (%) Yes No	82(57.34%) 61(42.65%)	11 (64.70%) 06(35.29%)	0.56[c]
Red blood cell transfusion Yes No	120(83.91%) 23(16.08%)	17(100%) 0(0%)	0.078[d]
DIC Yes No	0(0%) 143(100%)	05(29.41%) 12(70.58)	<0.00[d]
ICU admission Yes No	6(4.19%) 137(95.80%)	09(52.94%) 08(47.05%)	<0.00[c]
Hospital stays, days Median (IQR)	07(3-22)	10(3-30)	0.015[a]

Abbreviations: BMI; body mass index, NVD; normal vaginal delivery, IVD; instrumental vaginal delivery, DIC; disseminated intravascular coagulopathy, ICU; intensive care unit a; Man Whitney-u test, b; independent t-test, c; chi-square test, d; Fischer exact

Table 2: Comparison of Severity Outcomes between Uterine Balloon Tamponade Successful and Unsuccessful Groups n=140

Variables	IUBT Successful Group(n=123)	IUBT Fail Group (n=17)	P-Value
Preop Hemoglobin (g/dL)	11(8.1-13)	09(8.2-10.7)	<0.00
Preop platelet (10^3 /µL)	225.3(220-300)	225(221-227)	<0.00
Prothrombin time (sec)	13.5(12-20)	17.9(14-22)	<0.00
Partial thromboplastin time (sec)	27(21-41)	36(28-47)	<0.00
Estimated blood loss (ml)	1800(400-3500)	4000(1500-5500)	<0.00
Peripartum systolic BP (mmHg)	133(112-142)	112(100-125)	<0.00
Peripartum diastolic BP (mmHg)	69(56-71)	62(56-70)	0.001
Peripartum pulse rate /min	78(67-89)	89(72-100)	<0.00

Data are presented as median (IQR)

Table 3: Laboratory Test Results Before and After the Procedure of the Study Group (n=140)

Variables	Pre-Procedure	Post-Procedure	P-Value
Hemoglobin (g/dL)	10.8(8.1-13)	8.1(6.5-11)	<0.00
Hematocrit (%)	32(24-35)	25 (19-35)	<0.00
WBC (10^3µL)	12.95(8-16)	14.8(11-18)	<0.00
Partial thromboplastin time (sec)	27(21-47)	28(20-56)	<0.00
Prothrombin time (sec)	13.6(12-22)	13.9(12-23)	<0.00
INR	1.01(.96-1.06)	1.03(.96-1.09)	<0.00
Platelets (10^3µL)	225.25(220-300)	197.2 (165.6-225.3)	<0.00
Neutrophils (10^3µL)	9.95 (8.9-14)	14.9 (9-17)	<0.00
Lymphocytes (10^3µL)	1.66(1.2-2.1)	1.42 (1.01-1.91)	<0.00

Abbreviations: WBC, white blood cell; INR, international normalized ratio. Data are presented as median (IQR).

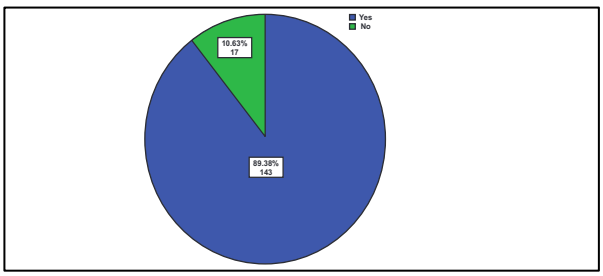

Figure 1: Efficacy of Uterine Balloon Tamponade

DISCUSSION

This study revealed that Foleys IUBT is an effective mode of managing patients with PPH, with an efficacy of 89.3%. Of the failed, 16 were executed by hysterectomy, while one was controlled with further conservative measures. There were six maternal deaths from PPH, secondary to acute renal failure and DIC. Patients with low hemoglobin, thrombocytopenia, and DIC at the time of insertion were associated with a low success rate of IUBT. A study by Cho HY et al. also showed that prior cesarean section history, anterior placentation**,** low platelet count, and DIC at the time of IUBT insertion were associated with a high risk of failed treatment.[11] PPH is an obstetric emergency with a high mortality rate of approximately 25% in the developing world and 34% in Pakistan.[12] There are various modalities available for the management of PPH. Balloon tamponade is a simple and effective therapeutic tool, first introduced in 2001 for managing PPH due to placenta previa. It works by applying pressure against the uterine wall and decreasing the capillary and venous bleeding from uterus layers, hence managing PPH.[13] A meta-synthesis of qualitative studies by Kenneth Finlayson et al., including 89 studies conducted in Africa's low- and middle-income countries, found IUBT effective, cheap, convenient, and user-friendly in the management of PPH. However, they suggested regular, hands-on training and emphasized community involvement for successful implementation.[14] Another systematic review by Frances J Kellie et al., including nine trials on 944 women conducted in various countries, including Pakistan, concluded that there was no sufficient evidence to recommend IUBT as an effective and safe management tool for PPH.[15] A study by Alkis et al. evaluating the efficacy of IUBT in PPH revealed an overall efficacy of 91.4%, and only four patients failed to respond.[16] Similar efficacy of 93.26% was observed in another study by Guo et al., who examined the effect of combined IUBT, vaginal tamponade, and abdominal compression for managing PPH in 98 patients.[17] Local studies have also proved it to be an effective method of controlling PPH.[18] A study by Rathore AM et al. reported that a condom catheter balloon was successful in 94% of cases of PPH. They filled the condom catheter balloon with 409 mL of fluid, and the average time taken to control PPH was 6.2 min. The mean duration of stay in situ was 27.5 h, and the average amount of blood loss was 1330 ml. About 28% developed infective morbidity.[19] In our study, most deliveries were NVDs; 129 (80.6%). We used 50-100 ml of fluid for insufflation of the balloon and mostly used two Foley catheters to achieve adequate hemostasis. The mean duration of IUBT in situ was 22.88 ± 5.6 hours. Furthermore, in line with the findings of a study by Gulten Ozgen et al our study showed a reduction in the median Hb and HCT post-procedure from 10.5 (8.2-12.5) to 8.1(6.5-10.4) and 32 (24-35) to 27 (19-35) respectively.[20] In line with the findings of a study by Pala et al., who compared the IUBT and cesarean hysterectomy in the treatment of patients with morbidly adherent placenta and revealed a significantly lower amount of packed cell volume of 2.7 U in IUBT versus 5.7 U in the hysterectomy group, our study showed 83.9% received a blood transfusion in the IUBT group and all 100% in the ineffective IUBT group ($p<0.00$).[21]

LIMITATIONS

The study's limitations included its retrospective design, small sample size, and inability to address infective morbidity. However, it is the only study done in this hospital addressing the effectiveness and factors associated with the low success rate of IUBT in controlling PPH.

CONCLUSION

The current study reveals that IUBT using a Foleys catheter is an effective, safe, cheap, fertility-sparing, and simple way the management of PPH. Its use should be encouraged, especially in low-resource settings. However, certain factors identified in the study may be associated with the failure of IUBT; hence further management options must be anticipated in such patients.

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REFERENCES

1. Spreu A, Abgottspon F, Baumann MU, Kettenbach J, Surbek D. Efficacy of pelvic artery embolisation for severe postpartum hemorrhage. Archives of gynecology and obstetrics. 2017 Dec;296:1117-24.
2. Hemorrhage P. Practice bulletin no. 183. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2017;130:e168-81.
3. Gülmezoglu AM, editor. WHO guidelines for the management of postpartum haemorrhage and retained placenta. World Health Organization; 2009.
4. Andrikopoulou M, D'Alton ME. Postpartum hemorrhage: early identification challenges. InSeminars in perinatology 2019 Feb 1 (Vol. 43, No. 1, pp. 11-17). WB Saunders.
5. Winter J. Hospital Episode Statistics NHS Maternity Statistics–England, 2013-14. London: HSCIC. 2015.
6. Gallos ID, Papadopoulou A, Man R, Athanasopoulos N, Tobias A, Price MJ, Williams MJ, Diaz V, Pasquale J, Chamillard M, Widmer M. Uterotonic agents for preventing postpartum haemorrhage: a network meta-analysis. Cochrane Database of

Systematic Reviews. 2018(12).
7. Rossi AC, Lee RH, Chmait RH. Emergency postpartum hysterectomy for uncontrolled postpartum bleeding: a systematic review. Obstetrics & Gynecology. 2010 Mar 1;115(3):637-44.
8. Georgiou C. Balloon tamponade in the management of postpartum hemorrhage: a review. BJOG 2009; 116(6): 748-757.
9. Prevention and management of postpartum hemorrhage. Green-top guidelines No 52. BJOG 2017; 124(5):e106-e149.
10. Tabassum S, Siddique S. Efficacy of balloon tamponade in control of primary postpartum hemorrhage (PPH). The Profess Medical J. 2020; 10;27(04):717-720.
11. Cho HY, Park YW, Kim YH, Jung I, Kwon JY. Efficacy of Intrauterine Bakri Balloon Tamponade in Cesarean Section for Placenta Previa Patients. PLoS ONE. 2015; 10(8): e0134282.
12. Bibi S, Danish N, Fawad A, Jamil M. An Audit of Primary Postpartum hemorrhage. Ayub Med Coll Abbottabad 2007; 19: 102-106.
13. Bakri YN. Uterine tamponade drain for hemorrhage secondary to placenta previa-accreata. Int Gynecol Obstet 1992; 37(4):302-303.
14. Finlayson K, Vogel JP, Althabe F, Widmer M, Oladapo OT. healthcare providers' experiences of using uterine balloon tamponade (UBT) devices for the treatment of postpartum hemorrhage, A meta-synthesis of qualitative studies. PLoS One. 2021 ;16(3):e0248656.
15. Kellie FJ, Wandabwa JN, Mousa HA, Weeks AD. Mechanical and surgical interventions for treating primary postpartum hemorrhage, Cochrane Database Syst Rev. 2020 7(7): CD013663.
16. Alkış İ, Karaman E, Han A, Ark HC, Büyükkaya B. The fertility-sparing management of postpartum hemorrhage: A series of 47 cases of Bakri balloon tamponade. Taiwan J Obstet Gynecol 2015; 54(3):232-235.
17. Guo Y, Hua R, Bian S, Xie X, Ma J, Cai Y, et al. Intrauterine Bakri balloon and vaginal tamponade combined with abdominal compression for the management of postpartum hemorrhage. J Obstet Gynecol 2018; 40(5):561-565.
18. Tahir N, Fatima S, Jahangeer MH, Adil M, Khan S. Intrauterine balloon tamponade-a novel technique to prevent and manage placental site hemorrhage. PAFMJ. 2018 ;68(2):280-284
19. Rathore AM, Gupta S, Manaktala U, Gupta S, Dubey C, Khan M. Uterine tamponade using condom catheter balloon in the management of non-traumatic postpartum hemorrhage. J Obstet Gynaecol Res 2012; 38: 1162-1167.
20. Ozgen G, Aydin GA. Effectiveness of Intrauterine Bakri Balloon Tamponade for Placenta Previa and Placenta Accreta Spectrum. JCPSP. 2020;30(7):707-712.
21. Pala Ş, Atılgan R, Başpınar M, Kavak EÇ, Yavuzkır Ş, Akyol A, et al. Comparison of results of Bakri balloon tamponade and Caesarean hysterectomy in the management of placenta accreta and increta: A retrospective study. J Obstet Gynaecol 2018; 38(2):194-199.

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