



ROLE OF INNOVATIVE BALLOON TAMPONADE IN ATONIC POST PARTUM HAEMORRHAGE

Obstetrics & Gynaecology

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ABSTRACT

Introduction: Postpartum hemorrhage is the major cause of maternal deaths, especially in the developing world. Uterine atony is the most common cause of PPH and when the hemorrhage is not controlled with medical management then Intrauterine balloon tamponade is one method that proves very effective and reduces the need for further surgical interventions. **Aims & Objectives:** To evaluate the effectiveness of balloon tamponade in the management of atonic PPH. **Materials & Methods:** This prospective study was conducted in the Department of Obstetrics & Gynaecology at Government Medical College and Rajendra Hospital, Patiala. We included 50 cases of atonic PPH in the study where medical management failed. Uterine tamponade was achieved by an innovative condom balloon catheter. **Results:** The success rate of balloon tamponade in controlling bleeding came out to be 94%. **Conclusions:** We concluded that Uterine balloon tamponade is effective, non-invasive, simple to use, easily available, and cost-effective method for the management of PPH. If we are unable to control bleeding with this method, it provides a temporary tamponade effect to gain time for surgical procedures or referral to a higher center if facilities are not available.

KEYWORDS

Uterine Balloon Tamponade (UBT), Postpartum Hemorrhage, Foley's catheter

INTRODUCTION

Postpartum hemorrhage (PPH) is responsible for around 25% of maternal mortality worldwide reaching as high as 60% in some countries. PPH can also be a cause of long-term severe morbidity, which includes organ failure, shock, edema, compartment syndrome, transfusion complications, thrombosis, ARDS, sepsis, anemia, and Sheehan's syndrome.^[1]

Conventionally PPH has been defined as blood loss of more than 500 ml in vaginal delivery and 1000 ml in a cesarean section.^[2] Historically, a decrease in hematocrit of 10% had been proposed as an alternative marker to define postpartum hemorrhage but according to ACOG, PPH is defined as blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process.^[3] The Royal College of Obstetricians and Gynecologists (RCOG) defines PPH according to the volume of blood lost: minor (between 500 and 1000 ml) and major (>1000 ml).^[4] Blood loss during the first 24 hours after delivery is known as primary PPH and blood loss after 24 hours and up to six weeks is termed as late or secondary PPH. The most common cause of PPH is uterine atony followed by the traumatic uterus, retained tissue, and blood coagulopathy.^[5]

The main factors in most maternal deaths caused by hemorrhage are when there is a delay in the correction of hypovolemia and a delay in the control of bleeding and both of these can be avoided.^[6]

Timely diagnosis of PPH and establishing the etiology of hemorrhage are essential to reduce maternal mortality and morbidity. Treatment is according to etiology and includes a range of medical methods and surgical procedures. Treatment for atony is recommended by various international bodies and follows a well-defined stepwise approach, first the medical management, then mechanical interventions, and finally surgery as a last resort. Oxytocin infusion and simultaneous uterine massage are the first-line management. If medical treatment fails then uterine conservation methods are resorted to which include balloon tamponade, uterine artery embolization, compression sutures, and stepwise devascularization.

Access to these key interventions is not available at all centers. And in cases where bleeding persists, the woman is at grave risk of losing her life unless she can be transported to a well-equipped health facility. Obstetric surgical capabilities and emergency transportation are limited in low-resource settings, thus there is a need for the provision of effective treatments at the point of care.^[7,8]

WHO has recommended the use of the uterine balloon tamponade (UBT) as a nonsurgical intervention for the treatment of uterine atony when bleeding could not be controlled by uterotonic drugs.^[9]

WHO and FIGO in 2012 Guidelines, recommended the use of intrauterine balloon tamponade for the treatment of PPH. This procedure potentially can avoid surgery and is appropriate while awaiting the transfer of the patient to a higher-level facility.^[10,11]

The commercially available uterine tamponade devices are designed with an intrauterine drainage port to assess ongoing hemorrhage but have a very high cost. Thus, developing countries have to rely on lower-cost adaptations like condom balloon tamponade which is the most cost-effective management option. The condom balloon tamponade has two main disadvantages. First, it's not having a drainage port and therefore actual blood loss can't be assessed. The other disadvantage is that the thread or suture is used to tie the condom to the catheter and it can cause leakage of saline, thus compromising effectiveness. Thus, to address these shortcomings, Dr. Nalini Mishra has designed an innovative variation of a condom balloon catheter and named it "CG Balloon" (state of Chhattisgarh in India). CG Balloon has high efficacy and low cost. Moreover, it has a drainage port to assess ongoing hemorrhage, and rubber rings are used instead of sutures to tie the condom to the catheter which quite effectively prevents leakage of saline.^[12]

The study was done to see the effectiveness of this innovative uterine balloon tamponade in PPH due to uterine atony.

AIMS & OBJECTIVES

To evaluate the efficacy of innovative Balloon Tamponade for control of Postpartum hemorrhage (PPH).

MATERIAL & METHODS

This prospective study was conducted in the Department of Obstetrics and Gynaecology, Government Medical College, and Rajindra Hospital Patiala. 50 cases of Atonic PPH following delivery after 28 weeks of gestation, where pharmacological methods proved ineffective were included in the study. Second-line therapy in the form of Balloon Tamponade (BT) was used in the management of intractable PPH.

Inclusion Criteria

- All cases of Atonic PPH not responding to pharmacological methods.

Exclusion Criteria

- Traumatic PPH
- Untreated uterine anomaly
- Uterine infections
- Suspicion of uterine rupture.
- Disseminated intravascular coagulation
- Retained placenta tissue
- History of allergy to Latex / Rubber.

Fig.1 shows the materials required to prepare BT. Fig. 2 shows the prepared BT with the drainage port for assessment of ongoing bleeding.



Fig.1: Materials needed for innovative balloon tamponade



Fig.2: Showing prepared BT with drainage port

Inserting of Balloon Tamponade (After Vaginal Delivery)

- 1) The cervix was exposed with Sims's speculum (preferably two).
- 2) Two sponge-holding forceps were used to hold the anterior and posterior lips of the cervix.
- 3) Third sponge holding forceps were used to introduce the prepared condom high up into the uterus.
- 4) To prevent slippage of Balloon Tamponade, the vagina was packed with sterile roll gauze.
- 5) The condom was then inflated with normal saline through the bulb port till further bleeding stopped and effective tamponade was created. (Up to max. of 500 ml of Normal saline)
- 6) Urobag was attached to the drainage port to assess the effectiveness of tamponade, as through this real-time assessment of blood loss could be there

Inserting of Balloon Tamponade (After Caesarean Delivery)

During Caesarean delivery, the prepared balloon tamponade was inserted directly through the uterine incision and the lower end of the balloon tamponade was pushed through the cervical canal into the vagina and brought out through the vulva. The condom end of the Balloon Tamponade was pushed towards the fundus. The Assistant was asked to pack the vagina tightly with sterile gauze to keep the Balloon Tamponade in place.

The uterus was closed in layers to avoid puncture of condom balloon tamponade and saline was instilled through the bulb inflation port of the Foley's Catheter by 20 cc syringes in the alternating repetitive manner by the assistant until the bleeding stopped. The effectiveness of Balloon Tamponade was seen by the operating surgeon before closing the abdominal wall.

The patient was observed closely for vitals and any further fall in BP. If the bleeding was not controlled within a maximum of 15 min. of insertion of Balloon Tamponade or vitals deteriorate further then other methods for control of PPH were opted for. Blood Transfusions were given as per the estimated blood loss and resuscitative measures were continued along with an oxytocin drip. After 12-24 hrs. The balloon was gradually deflated, at a rate of 100ml /hour, and the patient was observed for any bleeding and deterioration of vitals. After complete deflation of the catheter patient was further observed for 1hr for any

bleeding per vaginum and atonicity and if no bleeding was observed then Balloon Tamponade along with vaginal packing was removed. The study was analyzed using IBM SPSS-22 version (statistical package for social science). Descriptive statistics were used to analyze the results. Mean, median, standard deviation, and percentages were calculated.

OBSERVATIONS

The present prospective study was conducted in the Department of Obstetrics & Gynaecology, GMC, and Rajendra Hospital, Patiala. 50 subjects who had atonic primary postpartum hemorrhage (PPH) following delivery after 28 weeks of gestation and did not respond to medical management were enrolled in the study. The mean age of the study subjects recruited was 29.16 ± 5.16 years. Among 50 subjects, only 4 (8%) subjects were booked (had an antenatal checkup at least 3 visits) while the rest 46 (92%) were unbooked. The majority of the study subjects recruited were multipara i.e., 42 (84%) and 8 (16%) subjects were primiparas.

In the present study, the maximum number of study subjects delivered at the gestational age of 36-39th weeks i.e., 58% followed by 24% at 32-35th weeks, 14% delivered at >40 weeks, and 4% delivered at 28-31st weeks.

The majority of subjects 36 (72%) in our study, underwent cesarean section, and 14 (28%) subjects delivered vaginally. Many of the study subjects had the presence of risk factors for PPH in current pregnancy in the form of placenta previa (20%), Abruptio placentae (24%), Hypertensive disorders (24%), anemia (18%), Hepatitis (16%), IHCP (12%), twins (6%), polyhydramnios (2%), PPRM (2%), fetal macrosomia (4%) and associated fibroid uterus (4%). Only 10% of subjects had no risk factor.

Out of 50 subjects, BT was successful in 47 subjects (94%) without requiring further intervention. In 3(6%) cases tamponade failed to control hemorrhage thus stepwise devascularization was carried out but it also failed to control bleeding so peripartum hysterectomy had to be done as a life-saving procedure. (Fig.3)

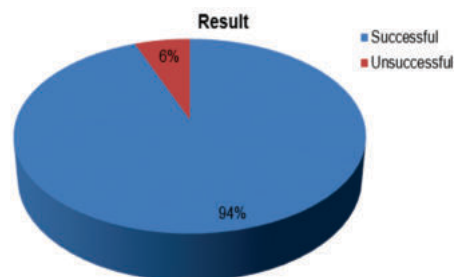


Fig. 3: Showing success rate of balloon tamponade

In the majority of subjects in our study, bleeding was controlled within 10 minutes of the creation of balloon tamponade. The average time taken to control PPH was 7.79 ± 1.99 minutes and with a range of 5-10 minutes. (Fig.4)

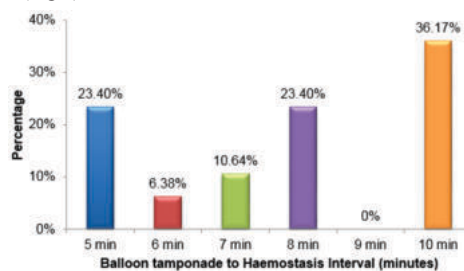


Fig. 4: Showing time taken to achieve hemostasis

The mean amount of saline required for uterine balloon tamponade was 211.60 mL, with a range of 110–410 mL (SD: 70.59). Majority 24(51.06%) of subjects needed 150-200ml of fluid for successful tamponade. Inflation of the balloon tamponade was stopped when there was resistance to more saline or when bleeding ceased.

The uterine balloon tamponade was kept from 12 hours to a maximum of 48 hours. In most (68.09%), cases, it was removed between 12-24

hours. In 15 cases (31.91%) duration of placement was >24 hours. The deflation of the balloon was done under close observation in a stepwise manner (50 ml every half hour), preferably in the daytime. After the balloon was completely deflated, the patient was observed for vitals and any fresh bleeding. If no further bleeding was observed, the vaginal packing was removed followed by the removal of balloon tamponade. This precaution was taken to address the need in case reinflation was required because of fresh bleeding. Where deflation was required during late hours in the evening, it was deferred to the following morning. None of our patients required reinflation of the balloon after deflation.

29 (61.7%) subjects required 4 or more than 4 units of PRBC, and each subject on average required 3.57 ± 1.78 units of PRBCs. 14 (29.79%) subjects required less than 4 units of PRBC

DISCUSSION

The present prospective study was done on 50 patients who had atonic primary postpartum hemorrhage (PPH) following delivery after 28 weeks of gestation and did not respond to medical management.

UBT is recognized by the WHO, FIGO, ACOG, RCOG, and ICM as a second-line treatment for PPH due to uterine atony when bimanual compression & uterotonic drugs are ineffective to control bleeding, precluding the need for surgical intervention.^[10,11, 13, 14, 15] In cases of failure, it provides a temporary tamponade effect & time to prepare for other interventions. This technique for achieving hemostasis is cheap, easy to perform, and takes less time. Moreover, it does not need special training, no anesthesia is required, is less traumatic, and acts immediately. The mechanism of action of the tamponade in stopping the bleeding is by creating an intrauterine pressure that is greater than the systemic arterial pressure. The success rate of balloon tamponade in the present study was 94% which is comparable to studies by other authors, Gurung et al (2014),^[16] Hasabe et al (2016)^[6] and Natu N et al (2019)^[17]. (Table No.1)

Table No. 1: Comparing success rate of balloon tamponade

Author and year of study	No. of study subjects	Success Rate
Tirumuru et al (2013) [18]	58	87%
Gurung et al (2014) [15]	08	100%
Hasabe et al (2016) [6]	36	94.44%
Parpillewar and Fusey (2017) [17]	23	78.2%
Natu N et al (2019) [16]	21	90.4%
Present Study (2019)	50	94%

The results of the present study showed that 16% were Primipara and a large proportion of the subjects were multipara (84%). It was seen that occurrence of PPH increased with increasing parity Parpillewar MB et al (2017)^[18] reported 78.2% as the proportion of multiparous women, However, Tirumuru S et al (2013)^[19] reported the proportion of multiparous women to be 48.2% which is lower than the findings of our study. Sudha et al (2017)^[20] in their prospective observational study reported only 8.24% as the proportion of multiparous women which is different than the findings noted in our study.

The majority of the studies in the literature reported vaginal delivery in subjects who underwent uterine balloon tamponade for control of atonic PPH. But in our study majority of subjects were delivered by the abdominal route which is comparable to a prospective observational study conducted by Kandeel et al in 2015^[21].

In our study mean fluid required to achieve hemostasis was 211.60 ml with a range of 110ml-410ml. Other authors have reported more amount of fluid required as Hasabe et al (2016)^[6] required an average of 350 ml of saline.

In our study, the balloon was deflated after a minimum of 12 hours before removal and up to 48 hours in some cases. The mean time of deflation of balloon tamponade was 30.26 ± 12.07 hours which is comparable to a prospective descriptive study conducted by Parpillewar and Fusey et al in 2017^[18] on 23 subjects as 30.1 hours. A retrospective study conducted by Tirumuru et al (2013)^[19] on 58 subjects reported the duration of deflation as 29 hours and which also is the same as in our study. (Table No. 2)

Table No. 2: Showing comparison of time of deflation of balloon after control of PPH

Author and year of study	No. of subjects	Mean time of Balloon deflation
Tirumuru et al (2013) [18]	58	29 hours
Hasabe et al (2016) [6]	36	24-72 hours
Parpillewar and Fusey (2017) [17]	23	30.1 hours
Present Study (2019)	50	30.26 hours

CONCLUSION

We concluded that Balloon tamponade is an effective means of controlling atonic PPH following delivery of the placenta with a success rate of 94%. It is a minimally invasive, simple to use, easily available, cost-effective, and conservative second-line method of PPH management not responding to uterotonic drugs. This method avoids the need for invasive surgical procedures. Many hysterectomies in young patients can be saved with this simple technique. In cases of failure, it provides a temporary tamponade effect, and time is gained to prepare for surgical interventions. If working at the periphery, time is gained to shift the patient to the nearest referral center after giving prior information. Hence it is an invaluable tool, especially in developing countries like ours and we can save many preventable maternal deaths with this simple technique.

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