Solution to Technical Difficulties of Uterine Balloon Tamponade Placement in Primary PPH Management: A Retrospective Case Series

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ABSTRACT

Objective: The aim of this study was to devise and enforce a simple yet effective method of condom placement for IUBT while dealing with all the technical difficulties in a poor resource setup to control primary PPH to save life of mother. **Methodology:** It is a retrospective case series study that is based on the hospital data obtained from Gynecology and Obstetrics Department of Sheikh Zayed Hospital, Rahim Yar Khan for a period of 8 months (July 2019 to Feb 2020). Patients with persistent primary PPH after medical management who were given intra-uterine balloon tamponade (IUBT) were included in this study after evaluation for possible risk factors of PPH. Sample size was kept 30 with power of test at 80% and level of significance at 5%. Statistical assessment of the variables was done and the data was analyzed with SPSS v.21.

Results: The 30 female patients, included in this study, had mean age of 30.3±6.06 years ranging from 17 to 39 years. Condom IUBT was successfully placed in 28(93.3%) patients by using 4 ring forceps applied on cervix and tied together with a gauze to keep the balloon in utero in order to control bleeding of PPH while in 2(6.66%) patients; it was unsuccessful due to inexperience of the operating staff. Out of these 28 patients with successful IUBT placement, condom based intra-uterine balloon tamponade was successful in controlling bleeding of PPH in 26(92.86%) patients while in 2(7.14%) patients, bleeding was not controlled and they underwent surgical interventions.

Conclusion: Condom based Intra-uterine balloon tamponade is a simple yet effective method to control bleeding in primary postpartum hemorrhage but needs positive re-enforcement in the form of awareness/training sessions for the healthcare staff.

Keywords: Catheter, Post-Partum Morbidity, Condom, Intra-Uterine Balloon Tamponade, Hemorrhage, Hysterectomy

INTRODUCTION

Post-partum hemorrhage (PPH) is one of the most critical obstetric emergencies around the world which leads to considerably higher rates of morbidity and mortality among the pregnant women. [1,2]

Available data shows that more than 1.5 million women encounter hemorrhagic complications during pregnancy or in their post-partum periods.[3] According to studies by WHO, around 38,000 maternal deaths occurred in 2017 due to hemorrhage including almost 90% out of these occurring in the countries having majority of population with low or medium levels of income (LMICs).[2,4] If we have a look at the data of high income countries (HICs), as per reports, PPH accounts for 7-12% of pregnancies including around 25.7% in Sub-Saharan Africa. [3,5] There are a number of etiologies and risk factors associated with PPH. Although these risk factors serve as a clue to remain vigilant about PPH but in reality not all the women with these risk factors necessarily encounter PPH. Some of these predisposing factors are, any previous history of PPH, neonate which is large for gestational age, presence of placenta previa or placenta accrete, hypertension or ischemic heart disease, high BMI as obesity, multiparity, bleeding diathesis, use of induction or augmentation methods, prolonged 1st stage of labour (more than 24 hours), delayed 2nd stage of labour, instrumental delivery, c-section, retained products of conception like placenta, any tears or lacerations. [6]

Regarding the treatment of PPH, studies show that the use of intra-uterine balloon tamponade (IUBT) is a very much efficient technique to save the patient from surgical interventions in order to treat persistent PPH. Some studies describe that around 75% of patients with PPH didn't need further treatment after the use of IUBT method.[7] There are a

number of treatment options being practiced at well-equipped hospital setups including immediate use of oxytocic drugs, intrauterine balloon tamponade method, embolization techniques and surgical interventions like hysterectomy.[5,8,9] Intrauterine balloon tamponade method is one of the very effective and low cost procedure to treat PPH in order to save the patient from surgical interventions.[10]

There are different types of balloon catheters used in clinics for IUBT method which include Roush Balloon, Sengstaken-Blakemore tube, Bakri balloon, condom, surgical gloves or Foley's catheters.[8] While placing intrauterine balloon tamponade, we come across technical difficulties because of unavailability of the proper equipment, operating table and other facilities which leads to failure of the procedure. By applying ring forceps on the cervix and tying them together makes this procedure successful and easier.

The aim of this study was to devise and enforce a simple yet effective method of condom placement for IUBT while dealing with all the technical difficulties in a poor resource setup to control primary PPH to save life of mother.We can train our doctors, birth attendants and mid-wives working at the peripheries so that the patient with primary PPH can be managed properly within the golden hour by them and time could be saved for shifting of the patient to tertiary care hospital for further management like blood transfusion or surgery.

MATERIAL AND METHODS

It is a descriptive type of cross-sectional study that is based on the hospital data obtained from Gynecology and Obstetrics Department of Sheikh Zayed Hospital, Rahim Yar Khan for a period of 8 months (July 2019 to Feb 2020). The data collection procedure was started after taking ethical permission from the Institutional Review Board of this institute and informed written consent was taken from the study subjects for their participation in this study. Sample size was kept 30 as per calculations while keeping the power of test at 80% with the level of significance at 5%. All patients with persistent primary PPH who underwent condom based intrauterine balloon tamponade (IUBT), after medical management, were included in this study regardless of number of previous deliveries, mode of delivery, site of delivery or cause of PPH.

All the patients having primary PPH due to cervical or vaginal tear, retained products of conception, intra-peritoneal bleeding and evidence of infection were kept excluded from the study. At the time of presentation, clinical examination of all the study subjects was completed and vital signs were recorded. Signs and symptoms of active hemorrhage and the degree of bleeding were evaluated along with their general state of health. Immediately, the amount of blood already lost due to bleeding was replaced by transfusion of whole blood, fresh frozen plasma and other solutions including crystalloids. Then the response to this medical treatment was examined by the degree of improvement in health state of the patient along with her vital signs including degree of paleness and her urine output.

The patients who failed responding to medical management were given condom based IUBT with 4 ring forceps applied to the cervix in order to hold the balloon in situ. The patients who failed to respond effectively against IUBT method were proceeded towards surgical interventions including hysterectomy. All the data including age, number of childbirth (parity), mode of delivery, cause of PPH and the outcome of IUBT was collected on a predesigned questionnaire which was, later on, entered in and analyzed by using SPSS v.21. Mean and standard deviation of quantitative data was recorded while frequency and percentage was calculated for the qualitative data.

Operational Definitions:

• Primary Post-Partum Hemorrhage was demarcated as "the blood loss of more than 500ml from the genital region within first 24 hours subsequent to vaginal delivery" or "the loss of 1000ml of blood within first 24 hours subsequent to C-Section".

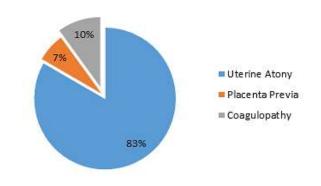
A salver was placed at the foot end of delivery table and the blood leaving the genital tract was measured after its collection in the salver.

• Intra-uterine balloon tamponade method was labeled successful if there was 0-100ml of blood loss following the intrauterine balloon tamponade placement for at least 48 hours.

Success of condom based intra-uterine balloon tamponade was noted by observing vaginal bleeding, vital signs of the patient, her urine output and abdominal girth measurements.

RESULTS

For the 30 patients included in this study, the mean age came out to be 30.30 ± 6.06 years ranging from 17 to 39 years. For most of the study subjects 11(36.7%), it was their first child birth. Out of them, 22(73.3%) women had spontaneous vaginal deliveries (SVDs) and 8(26.6\%) underwent C-section where 12 (40%) patients delivered at Sheikh Zayed Hospital and 18(60%) were referred from other health care centers. Causes of primary PPH in these patients are shown in figure.01 while the success ratio of condom placement by using 4 ring forceps and then, ultimate outcome of IUBT is shown in figure.02.



Cause of Primary PPH

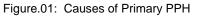




Figure 02: Outcome of Condom based IUBT

DISCUSSION

In this study, we shared our experience of treating primary PPH byusing condom based intra-uterine balloon tamponade method. We encountered a total of 30 study subjects meeting our inclusion criteria where 28 of them got successful placement of condom as IUBT and subsequently, 26 of them were treated successfully by using condom based Intra-uterine Balloon Tamponade method. Intra-uterine balloon tamponade (IUBT) method was introduced by WHO in 2012 in order to serve as an immediate and effective intervention for severe/uncontrolled primary post-partum hemorrhage not responding to oxytocics whereas proper training programs for IUBT placement or latest IUBT devices have not been introduced in the health care sector so far at mass level.[10,11]

Though condom based intra-uterine balloon tamponade method doesn't need any specialized kind of professional training but being a life saving method, it demands more spread of awareness among the health care staff particularly working at the center with very limited resources regarding blood transfusions or surgical interventions. In the recent years, an increasing trend towards the use of intra-uterine balloon tamponade (IUBT) to treat primary PPH has been observed worldwide. A number of balloon catheters are being used for this purpose, such as Bakri balloon, Sengstakene Blakemore balloon and even a condom or surgical gloves can serve the purpose.[9]

A study article from 2013 conducted at LMIC (mostly using condom-catheter devices) states that the bleeding of primary PPH was effectively controlled in 234/241 (97.1%) women by using IUBT method.[12] Most of the studies conducted on IUBT method at higher resource centers have implied the use of costly catheters like Bakri balloon.[13,14] But it is a proven fact that a similar tamponade effect can also be achieved by using some cheap and easily available alternatives like a condom or surgical gloves.[15,16]

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Intra-uterine balloon tamponade by using a condom is a very low price and cost effective method which can be used as an emergency treatment option. Three cases of primary post-partum hemorrhage (due to uterine atony) have been reported in a study which were successfully treated by using a condom for intra-uterine tamponade effect.[17] A meta-analysis was done in America in 2020, where a total of 4729 women were included, showed a success rate of 85.9% regarding use of intra-uterine balloon tamponade, including 86.8% success rate in placenta previa and 87% in uterine atony as compared to our study showing 92.86% overall success rate in uterine balloon tamponade.[18]

In our study, the study subjects, who received IUBT, showed a survival rate of 92.86% which is similar to the one resulting at 92.7% in one study [19] where, another study reported a survival rate of 94.5–97.4% in context of using a condom for IUBT effect in LMIC.[20,21]

The outcomes of these studies suggest that condom based IUBT can be used as a simple yet effective intervention for the control of primary PPH. As a result of our study, the authors also came at the same conclusion that condom based IUBT is an effective treatment for primary post-partum hemorrhage in health care centers with poor resources. Moreover, It is also an important corner to consider that such uncontrolled studies can areatly over-estimate the effectiveness of some interventions and that we would still regard IUBT method as an unproven technique due to lack of evidence from randomized control trials on a mass level.

CONCLUSION

This study has helped to devise and enforce a simple yet effective method of condom based IUBT placement using 4 ring forceps dealing with the all technical difficulties in a poor resource setup to control primary PPH to save life of mother. The study has shown the effectiveness of condom based IUBT thus eliminating the need of any further interventions like surgical procedures.

So, a wide-ranging registry for postpartum hemorrhage should be established in all the tertiary health institutions. This will benefit in further large-scale studies and authentication of these results. Moreover, a larger cross sectional study or may be a case-control study is required to confirm the findings of this research on a broader aspect.

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