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Saving Mothers' lives and uterus by intrauterine foley's catheter ballooning tamponade during post-partum hemorrhage

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Abstract
Introduction: Uterine balloon tamponade became more popular when first lines management is not effective to control postpartum hemorrhage due to atony.
Objective: The purpose of this study was to evaluate the success and outcome of intra uterine foley's catheter ballooning tamponade for the management of primary postpartum hemorrhage due to atony.
Methods: This study was conducted at Duhok Obstetrics Teaching Hospital in Duhok, Iraqi Kurdistan between April 2013 and March 2019 and reviewed retrospectively. The Kurdistan institutional ethics review board in Duhok approved the study design before the start of the study. All cases developed postpartum hemorrhage underwent intra uterine foley's catheter ballooning tamponade.
Results: Intra uterine foley's catheter ballooning tamponade placed in (110) cases, postpartum hemorrhage was controlled with a success rate of 100%, no patient needed an invasive procedure as well as laparotomy. There was no sepsis and no maternal deaths.
Conclusion: The early use of intra uterine foley's catheter ballooning tamponade for primary postpartum hemorrhage due to atony is a simple and a quick method for saving the life of mother along with conserving the uterus.

Keywords: Foley's catheter tamponade, postpartum hemorrhage, uterine tamponade

Introduction

Postpartum hemorrhage (PPH) is a leading and direct cause of maternal mortality (Foley *et al*. 2010) [1]. This emergency and dangerous condition can be a complication of cesarean and vaginal delivery (Khan *et al*. 2006) [2]. As most of maternal deaths have been unpreventable while hemorrhage is one of the preventable causes, all maternity hospital should have their protocol for identification and treatment of postpartum hemorrhage (The Joint Commission. 2010) [3].

Traditionally post partum hemorrhage has several definitions, American Collage of Obstetrician and Gynecologist redefine post -partum hemorrhages in 2017, as blood loss of more than 1000 ml or bleeding associated with signs and symptoms of hypovolemia within 24 hours of the vaginal or cesarean delivery (Committee on Practice Bulletins-Obstetrics. 2017) [4].

Normally after separation of placenta uterine bleeding is controlled by several mechanisms, disturbance in one of these mechanisms lead to bleeding, mechanical compression of the blood vessels which supply the placental bed by tonicity of the myometrium complemented by locally released hemostatic factors from deciduas, as well as platelets and circulating clotting factors [5]. The remaining cause of post partum hemorrhage is a disruption of vessels during genital trauma [6].

Uterine atony is a major cause of postpartum hemorrhage, there are several risk factors for uterine atony that should be identified during antenatal and intra partum periods however, uterine atony can be unpredictable and occur without risk factors. The rate of post partum hemorrhage is increasing due to (multiple gestations, obesity, vaginal birth after cesarean section, cesarean delivery, induction of labour and advanced maternal age) [5].

Recently uterine balloon tamponade has been used for the management of post partum hemorrhage [7]. After attempts of uterine rubbing and uterotonic agents prove to be unsuccessful and approaches including the exclusion of retained products and genital tract [8, 9]. This life saving intervention is an effective measure to prevent invasive procedures especially in low-resource settings where surgical facilities and blood bank may not be available [10].

There are many types of balloon tamponade were specifically and non-specifically designed for placement in the uterus for control of postpartum hemorrhage [11]. These balloons including the Foley catheter, Bakri balloon, condom catheter, Ruch balloon catheter and Sengstaken-Blakemore [9].

The early use of balloon tamponade is a method of decreasing bleeding in post partum hemorrhage while efforts taken for reversing uterine atony [12]. The mechanism of balloon tamponade is related to direct pressure against the uterine wall and compression of the uterine artery to reduces blood flow and facilitates clotting, another mechanism is a reduction in persistent capillary and venous bleeding from the endometrium and placental bed [13, 14, 15].

Most of the international guidelines recommend the use of uterine balloon tamponade for controlling bleeding after delivery among these (World Health Organization, the International Federation of Gynecology and Obstetrics and the Royal college of Obstetricians and Gynecologist) [16, 17].

Patients and Methods

Design and Setting

This study was conducted at Duhok obstetrics teaching hospital in Duhok, Iraqi Kurdistan from April 2013 to March 2019, which includes the period of ISIS occupation as well as the financial crisis in Iraqi Kurdistan, and reviewed retrospectively. The Kurdistan Duhok institutional ethics review board approved the study design before the start of the study, and written informed consent was obtained from all patients. All cases whether delivered vaginally or by Caesarean section, they were developed postpartum hemorrhage not responding to first line management who underwent intra uterine foley's catheter ballooning tamponade (IUFCBT) were included in this study.

Measures

The initial management of persistent primary postpartum hemorrhage includes:

- Resuscitative measures
1. intravenous fluid
2. Blood transfusion
3. Blood components
4. Correction of hypocalcemia and hyperkalemia.
- Placing a bladder catheter.
- Uterine massage and/or bimanual compression.
- When uterus did not contract after giving oxytoxic agents
1. 5 units of oxytocin slow intravenous route.
2. Intravenous infusion of 40 units oxytocine in 500 milliliters of ringer lactate.
3. One ampoule of methyl ergometrine intramuscular. (if not contraindicated)
4. 1000micrograms misoprostol rectally.
- Tranexamic acid is generally administered as an early intervention in the management of postpartum hemorrhage.

After using the above medications and bimanual uterine compression if bleeding persisted, we proceeded for the procedure. A coagulation profile was sent. The balloon should be inserted before coagulopathy develops since tamponade is less likely to be successful if clotting is impaired. However, it may be possible to correct coagulopathy concurrently with balloon insertion.

Procedure

The insertion procedure involves the following general steps, after counseling, and written consent was taken from patients relative then patient transfer to the theater, under epidural, spinal or general anesthesia

After vaginal delivery

- Put the patient in a lithotomic position.
- Cleanse the cervix and vagina with povidone-iodine.
- Visual inspection of the vagina and cervix to exclude any lacerations.
- Perform bimanual examination for any palpable hematoma.
- Perform a gentle digital examination of the uterine cavity to make sure it is empty and not ruptured.
- Grasp the anterior and posterior lip of the cervix with ring forceps and apply gentle traction to align the direction of the cervical canal to that of the uterine cavity.
- Use long forceps or manual to insert the catheter into the uterine cavity, as high in the uterine cavity as possible without exerting any force.
- Introduce yellow colored 3-4 Foley's catheter to the uterus, size 20 french, inflate all balloon with a volume of 50-60 milliliters of fluid (0.9 % sodium chloride) until significance resistance felt while injecting fluid and enough counter-pressure is exerted to stop bleeding or slows and usually one of balloon visible in the cervix lumen.
- An assistant is inflating the balloon while the operator holds the vaginal portion in position, which helps to keep the intrauterine portion from popping out.

After cesarean delivery

- Close the uterine incision and an assistant then inserts the balloon catheter from below and inflates it while the surgeon watches from above. This eliminates the risk of accidental needle perforation during uterine closure.

For all patients, the urinary catheter was left, tape balloon to the woman's inner thigh to maintain tension and strait to ensure drainage. Pack the vagina with sterile gauze to ensure the balloon stays in place providing additional compression of the lower uterine segment and avoid catheter from sliding, and finally, a pad put under the perineum area. If bleeding continues and sever this vaginal pack will usually become soaked with blood, but this did not happen in our study.

During the procedure, team of operation was ready for any other necessary approaches, if the bleeding did not stop within 15-20 minutes of tamponade application. All patients were observed in the operation theater for about one hour.

Any deterioration in patient vital signs, with an increase of uterine fundus by abdominal examination after marking the abdomen at level of the uterine fundus, as well as no obvious vaginal bleeding suggests that blood is accumulating within the uterine cavity above the balloon.

Successfulness of the procedure

The successfulness of the intrauterine balloon is checked by the "tamponade test, if there is no bleeding or is minimal through the cervix or through the drainage channel of the balloon catheter. Then the test is positive (successful), the inflated balloon is left in place, and laparotomy can be avoided. A negative (unsuccessful) test is defined as bleeding not controlled with inflation of the balloon. Patients with a negative test should proceed to laparotomy and, possibly, compression sutures or hysterectomy.

Post procedure

The woman requires care in an area like High Dependency Unit

or Intensive Care Unit. Chart Observations for vital signs assessment. Fundal height must be firm on palpation, vaginal blood loss through the drainage bag and pads placed under the perineum. Temperature every two. A strict fluid balance chart must be kept with input/output recordings made at least hourly.
Monitor for signs and symptoms of ongoing blood loss, such as pallor, dizziness, hypotension, tachycardia, confusion, uterine enlargement, abdominal pain, abdominal distension and oliguria. Blood transfusion and/or blood products given, as needed, to correct prior deficits. Periodically flush the drainage port with sterile saline to ensure that it has not become occluded by blood and to remove clots.
All patients received intra operative antibiotic and continued for 24 hours after removal of catheter. Antibiotics administered intravenously (ampicillin or amoxicillin] 2g IV initial dose then 1g intravenously every 8 hours or 2 g cefazoline or ceftriaxone, initial dose then 1g IV every 8 hours, with two regimes metronidazole 500 mg IV every 12 hours). Oxytocine infusion given for 4 hours, then discontinued unless there is a clinical indication to continue it.
Intrauterine balloon tamponade if painful patient provided with analgesia, all received mechanical thromboprophylaxis in the form of above- knee graduated compression stockings as soon as12 to 24 hours after bleeding has been controlled, pharmacologic thromboprophylaxis was added, providing coagulation tests are normal.
The balloon catheter removed after 8-24 hours, if hemostasis has been achieved, the patient's vital signs are normal and stable, and any coagulopathy is corrected, all balloons were deflated at once. Then continue to observe the woman for any bleeding. Emergency surgical services and experienced staff should be readily available.
Documentation time and date of balloon insertion and removal to be documented in surgical record. All newborns were followed up by neonatologist. Patients was discharged on fourth day with a stable vital signs, and was found to be in a good state of health in her post intervention follow-up visit on tenth day.

Statistical analysis
Data were collected, tabulated and descriptive statistics for nominal variables were expressed as numbers and percentages (%).

Result
During the study period, from April 2013 to March 2019, there were 110 cases complicated by persistent primary postpartum hemorrhage due to atony, all cases were unresponsive to standard first-line measures then intrauterine foley's catheter ballooning tamponade (IUFCBT) was introduced within four hours after delivery.
Most of our patients had risk factors for developing post partum hemorrhage. No patient needed an invasive procedure as well as laparotomy. Bleeding was controlled successfully with a success rate of 100% within 15-20 minutes. The patients were followed up for up to 48hours. There was no sepsis, no organ failure, and no maternal deaths.

Characteristics of the patients
The characteristics of women selected for the intrauterine foley's catheter ballooning tamponade (IUFCBT) intervention are summarized in Table 1. Total numbers of post partum hemorrhage were 110 cases. The mean age of 110 patients was (19 to 44 years). Sixteen (14.5 %) cases were primigravida, ninety-four cases (85.4 %) were multigravida. Only seventy-five (68.1 %) cases had antenatal care (ANC) compared to thirty-five (31.8 %) who had no (ANC). Overall seventy-two 72 (65.4 %) cases delivered at the hospital and only thirty-eight (34.5 %) cases had home deliveries or referred from birth centers.

Table 1: Characteristics of women Selected for Intrauterine Foley's Catheter Ballooning Tamponade (IUFCBT) Intervention

Characteristics	Values
Total numbers of cases	110 cases
Age in years	(19-44) years
primigravida	16 (14.5 %)
Multigravida	94 (85.4 %)
Antenatal care	75(68.1 %)
No Antenatal care	35(31.8 %)
At hospital	72(65.4 %)
Referred cases	38 (34.5 %)

Mode of delivery
The mode of delivery among the studied women summarized in Table 2.
Eighty-eight cases were delivered vaginally (80%), sixty-six (60%) cases had spontaneous vaginal deliveries, while twenty-two (20%) cases were delivered by induction of labor. Among 110 cases twenty-two (20%) were delivered by cesarean section, seventeen (15%) cases were by elective cesarean section, while five cases (5.4%) were emergency cesarean section. Only one case (0.9%) was forceps delivery.

Table 2: The mode of delivery among the studied women

Mode of delivery	Values
Vaginal delivery	88 (80%)
Spontaneous	66 (60%)
Induction	22 (20%),
Cesarean Section	22 (20%)
Elective	17 (15%)
Emergency	5 (5.4%)
Forceps delivery	1 (0.9%)

Predisposing Factors for post partum hemorrhage
The predisposing factors for PPH among the studied women summarized in Table 3. Twenty (18.1%) cases had a history of prior cesarean section, while 11cases (10%) of women had a history of abruption placenta, only twelve (10.9%) cases had history of twine pregnancy. Fifteen (13.6%) of women had prolonged labour. Two (1.8%) cases had placental retention, both underwent manual removal of the placenta. Among 110 cases only five (4.5%) cases were intra uterine demise (IUD).Two (1.8%) cases had a history 0f fibroid. Eight (7.2%) cases with a history of Preeclampsia. One (0.9%) cases had eclampsia, and one (0.9%) case had HELLP syndrome. Two (1.8%) cases were preterm pre-labor rupture of membrane (PPROM). Six (5.4%) cases were macrocosmic babies. Fifteen (13.6%) cases had anemia during pregnancy. Among 110 cases only twelve (10.9%) cases predisposing factor Unknown.

Table 3: Predisposing Factors for Post partum hemorrhage (PPH)

Predisposing Factors for PPH	Value S
Previous cesarean section	20 (18.1%)
Abruption placenta	11 (10%)
Twine pregnancy	12 (10.7%)
Prolonged labor	15 (13.6%)
placental retention	2 (1.8%)
IUD	5 (4.5%)
Fibroid	2 (1.8%)
Preeclampsia	8 (7.2%)
Eclampsia	1 (0.9%)
HELLP syndrome	1 (0.9%)
PPROM	2 (1.8%)
Macrosomia	6 (5.4%)
Anemia during pregnancy	15 (13.6%)
Unknown	12 (10.9%)

Characteristics of the newborns at delivery

The characteristics of newborns at delivery are summarized in Table 4. Total numbers of new born babies were 122 babies. The gender of the babies was seventy–two (59%) babies were males and forty (32.7%) were females. The gestational age at delivery was between (27-41weeks), twelve (9.8%) newborns were between 27-34weeks, while twenty (16 %) babies were between 35-37weeks and ninety (73.7%) were between 38-41weeks. The weight of babies at birth was, fourteen (11.4 %) babies were between 900gm-2.5kg and sixty-five (53.2 %) were 2.6-3.5kg, while forty- three (35.2 %) were between 3.6-4.4kg.

Table 4: Characteristics of the newborns at delivery

Characteristics	Values
Total numbers of newborn	122 babies
Gender	Male and female
male	72 (59%)
female	40 (32.7%)
Gestational ages	(27-41) weeks
27-34weeks	12 (9.8%)
35-37weeks	20 (16%)
38-41weeks	90 (73.7%)
Birth weight	900gm-4.4kg
900gm -2.5kg	14 (11.4 %)
2.6-3.5kg	65 (53.2 %)
3.6-4.4kg	43 (35.2 %)

Maternal complications

Complications among the studied women summarized in Table 5. Maternal fever affected were nine (8.1%) cases, abdominal pain requiring additional analgesia in thirty (27.2%) cases, massive blood transfusion in forty cases (36.3%), admission to the intensive care unit in eight cases (7.2%), no case of sepsis, no cases underwent hysterectomy and no maternal death.

Table 5: Maternal Complications

Complications	Values
Maternal fever	9 (8.1%)
Abdominal pain	30 (27.2%)
Massive blood transfusion	40 (36.3%)
intensive care unit	8 (7.2%)
Sepsis	0 (0%)
Hysterectomy	0 (0%)
Maternal death	0 (0%)

Comment

Principal findings

Our study confirmed that intra uterine Foley's catheter ballooning tamponade has a success rate of (100%) to treat post partum hemorrhage resulting from uterine atony after vaginal delivery as well as after cesarean delivery. Intrauterine balloons tamponade appears to be a successful procedure in (84.0%), from a systematic review evaluating the success rates of uterine balloon tamponade in the treatment of major postpartum hemorrhage [8].

A study also reported (100%) success rate of intra uterine balloon tamponade for women with post –partum hemorrhage when blood loss was less than 1000 milliliters [18]. in a case series report, patients with postpartum hemorrhage unresponsive to medical therapy managed with intrauterine balloon tamponade, for hemorrhage due to uterine atony, the success rate of uterine balloon tamponade was (100%) [19]. Areport from a retrospective study showed that, the overall success rate of uterine balloon tamponade was (80%) in patients with postpartum hemorrhage [20].

In our study, vaginal delivery was the most common mode of delivery and the uterine atony was the most common cause of post-partum hemorrhage, all cases treated by intra uterine Foley's catheter ballooning tamponade, no other interventions were required and no maternal death was reported. There is conflicting evidence about the efficacy of uterine balloon tamponade to reduce invasive procedures or maternal deaths among women with massive post-partum hemorrhage due to uterine atony. A review was carried out and reported on massive post partum hemorrhage, uterine atony was the most common cause of massive post partum hemorrhage. Cesarean delivery was the most common mode of delivery, no maternal deaths were reported [21].

One randomized controlled trial showed, no maternal deaths and low maternal morbidities [22]. whereas another randomized controlled trials suggested that the case fatality rate was higher in the tamponade group than in the control group [23]. Evidence from one large non-randomized study showed that early use of uterine balloon tamponade for the management of post –partum hemorrhage is effective in decreasing post –partum hemorrhage associated invasive procedures after vaginal delivery [24].

One randomized controlled trials reported that placement of uterine balloon tamponade did not improve maternal outcomes and was associated with an increase in the combined incidence of post partum hemorrhage-related surgery and maternal death [25].

The principal outcomes of our study indicate lack of agreement with some previous studies on the efficacy and effectiveness of uterine balloon tamponade, however several studies reporting high success rates of uterine balloon tamponade in the treatment

of severe post-partum hemorrhage, to overcome the weaknesses of this effectiveness need further studies for optimizing performance that can lead to further maternal improvement.

Strengths and limitations

The major strengths of our study include. First, we only included intra uterine foley's catheter ballooning tamponade for persistent primary postpartum hemorrhage due to atony after all types of deliveries. Second, to evaluate the safety and success rates of intra uterine foley's catheter ballooning tamponade for the management of persistent primary postpartum hemorrhage due to atony.

There are two major limitations in this study that must be considered. The first, insufficient sample size. Second, the limited number of randomized controlled trial non-randomized studies that assessed efficacy and safety of uterine ballooning tamponade for managing post –partum hemorrhage due to uterine atony, however, the best available evidence suggests that uterine ballooning tamponade appears to be safe in the management of post-partum hemorrhage. There is need for further researches and evaluation for optimizing the management of post –partum hemorrhage.

Conclusion

Postpartum hemorrhage remains a leading cause of direct maternal death. It is mandatory and vital steps that, all maternity hospital should have their protocols for the prevention and rapid treatment of PPH as well as appropriate training for improving women health during childbirth. The early use of intra uterine foley's catheter ballooning tamponade (IUFCBT) to arrest bleeding in primary post partum hemorrhage is a simple, inexpensive, quick and safe method of conserving the uterus along with saving the life of the mother especially in a low-resource setting. We recommend the use of this easy and economic intra uterine foley's catheter ballooning tamponade in all cases when basics and first lines management is not effective to control the bleeding in post-partum hemorrhage.

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