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TO EVALUATE THE EFFICACY OF INTRAUTERINE FOLEY TAMPONADE AS A MANAGEMENT OF MASSIVE POSTPARTUM HEMORRHAGE (PPH).

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ABSTRACT **Purpose:** To evaluate the efficacy of intrauterine Foley tamponade as a management of massive postpartum hemorrhage (PPH). **Methods:** Prospective study including women who underwent intrauterine Foley tamponade for massive PPH between April 2018 and July 2019 was conducted. Massive PPH was defined as estimated blood loss exceeding 1,500 mL. Foley tamponade was inserted into uterus if women had PPH despite medical treatment after vaginal delivery or cesarean section. The balloon was inflated with sterile saline and removed after 12-24 hours. Failure was defined as needing another procedure for hemorrhage control. Demographic, obstetric and specific factors in regard to the Foley tamponade use were recorded. The successful rate of hemostasis by Foley tamponade was evaluated. **Results:** Among 138 women with PPH managed Foley tamponade insertion, 57 patients were diagnosed with massive PPH. The most common cause of massive PPH was placenta previa without accreta (54.4%), uterine atony (33.3%), placenta previa with accreta (10.5%) and placenta accreta (1.8%). The mean estimated blood loss was 2279.0 mL (range, 1,500-6,500 mL). The rate of successful control of massive PPH after Foley tamponade placement was 82.5%. From the cases of 57 patients, 10 patients needed additional procedures; five required uterine artery ligation and five underwent cesarean hysterectomy. No short-term complications or maternal death were observed after Foley tamponade insertion. **Conclusion:**Foley tamponade is an effective, simple and quick approach in the treatment of massive PPH and it is useful as complementary management for earning time for another procedure.

KEYWORDS : Foley Tamponade; Massive Postpartum Hemorrhage; Intrauterine Tamponade

INTRODUCTION

Postpartum hemorrhage (PPH) is a life-threatening complication in obstetrics and it is a major cause of maternal mortality worldwide.1 PPH has been traditionally defined as an estimated blood loss of more than 500 mL after vaginal delivery or over 1,000 mL after cesarean section. Particularly if woman has massive PPH which is defined as bleeding exceeding 1,500 mL during delivery, patient may be in danger with needing massive transfusion, critical care and increasing the risk of death.The main causes of PPH are uterine atony, genital tract laceration, abnormal placentation, retained placental products and coagulation abnormalities, The management of PPH differs depending on these etiologies. The primary treatments for PPH include treatment of uterine atony with uterotonic agents, bimanual uterine massage and blood product replacement. If these conservative managements fail, surgical interventions must be considered. Surgical methods consist of ligation of uterine artery, intrauterine compression sutures and hysterectomy. Postpartum hysterectomy causes increased blood loss, injury to other organs and irreversible loss of fertility. Therefore, other nonsurgical conservative methods such as uterine artery embolisation (UAE) or uterine balloon tamponade should be considered before hysterectomy.

Intrauterine balloon tamponade has been quite widely used as a second-line procedure in the management of PPH. This tool acts to stop uterine bleeding via increasing intrauterine pressure over systemic pressure around the placental bed or low segment in placenta previa. Different balloons have been used such as the Sengstaken-Blakemore tube, Foley, Rusch or Bakri balloon. The success rate for this technique has been reported by 60-90%.This study describes the use of Foley tamponade for managing massive PPH that bleeding more than 1,500 mL after delivery. The aim of this study was to evaluate the success rate of Foley tamponade in cases of massive PPH that were intractable to medical treatment.

Materials and methods

This study was a prospective review of patients diagnosed with massive PPH who failed conservative management with uterotonic agents and were subsequently treated with intrauterine balloon tamponade at our institute between April 2018 and July 2019.

Massive PPH was defined as >1,500 mL estimated blood loss after vaginal delivery or cesarean section. This was measured of the amount of bleeding before Foley tamponade insertion. The first standard managements for PPH such as uterine massage, bimanual compression, or medication with an intravenous infusion of Oxytocin (20-40 IU in 1,000 ml Ringer's lactate solution at a rate of 120 mL/hour) or an additional injection of intravenous Carboprost, rectal Misoprostol were applied to all patients. Close inspection of the cervix and vagina was performed routinely for distinguishing genital tract lacerations in women with profuse bleeding after vaginal delivery. Any patients with bleeding who need surgical procedure after vaginal delivery due to lower genital tract lacerations were excluded. If the bleeding continued despite of primary medical treatments, the Foley catheter (16 Fr) was applied.

Following vaginal delivery, 2 Foley catheters were inserted transvaginally. When the balloon was inserted during a cesarean section, the distal end of the catheter shaft was introduced into the uterine incision and passed through the cervix. After the balloon was inflated with approximately 50 mL of sterile saline solution, the lower segment incision was closed carefully in order to avoid damaging the balloon. Further filling was depending on the size and capacity of the uterus. Then, Betadine-soaked gauzes were packed into vagina to prevent slippage or prolapse of the balloon through the cervix. The distal end of the catheter was fixed to the patient's thigh and ultrasound visualization of balloon placement was confirmed after procedure. After Foley tamponade placement, the balloon drainage end was connected to a collecting bag to monitor blood loss. The balloon remained in place between 12 and 24 hours. Removal of the catheter was by either complete deflation after 24 hours or stepwise deflation by removing 50% of the fluid at 12 hours followed by complete deflation after 12 hours.

Foley tamponade was considered to be failed if the bleeding from drainage catheter was continued and more than 100 mL during 10 minutes, so further interventions such as UAE, compression sutures or hysterectomy were needed. Women were hospitalized either in postnatal ward or intensive care in the postpartum period depending on the level of PPH and maternal tolerance. All patients had a Foley catheter for urine output monitoring and prophylactic broad-spectrum antibiotics were used. We compared between Foley tamponade success group and failure group to identify factors associated with its failure, as well as determine if any complications were associated with its use.

Outcome measures were compared with Student's t-test and chi-square analysis, as well as Fisher's exact test and Wilcoxon's test when appropriate due to smaller sample size. A P value of 0.05 or below was considered statistically significant.

RESULTS

During the study period, 138 women who were diagnosed with PPH following either vaginal delivery or cesarean section were managed with Foley tamponade. A total of 57 (41.3%) of these women had massive PPH with an estimated blood loss exceeding 1,500 mL. All patients were diagnosed massive PPH and treated during hospital stay except one case. In one case, massive PPH was occurred 6 days after she was discharged from the hospital. She had cesarean section

because of twin pregnancy. The mean age of these women were 34.2 years and 28 (49.1%) were more than 35 years old. Of the women in whom the Foley tamponade was used for the management of massive PPH, twenty-three were nulliparous (40.4%) and three (5.3%) were multiple gestations (all were twin pregnancies). A total of 9 women (15.8%) delivered vaginally and 48 (84.2%) had a cesarean section. Out of 48 women with cesarean section, Foley tamponade was inserted during operation in 45 women, at recovery room in 2 women and at emergency room in one women who had massive bleeding after discharge from hospital. The mean gestational weeks at the time of delivery was 37.7 (range 34.28-40.71). Mean weight of newborn was 3,006.9 g and 4 babies were diagnosed with large for gestational age (Table 1).

Table 1: Baseline and Pregnancy-Associated Characteristics of Women with Foley Tamponade

Characteristic	N=57 (%)
Age, year (mean)	34.2 (range 25-41)
≥ 35	28 (49.1)
Parity	
0	23 (40.4)
1	24 (42.1)
≥2	10 (17.5)
Multiple gestations	3 (5.3)
Mode of delivery	
Vaginal delivery	9 (15.8)
Cesarean section	
Elective	34 (59.6)
Emergency	14 (24.6)
Gestational age, weeks (mean)	37.7 (range 34.28-40.71)
Birthweight, g (mean)	3,006.9 (range 1,790-3,990)
LGA	4 (7.0)
Blood loss, mL* (mean)	2,279.0 (range 1,500-6,500)
Indication for Foley balloon tamponade	
Uterine atony	19 (33.3)
Placenta previa without placenta accreta	31 (54.4)
Placenta previa with placenta accreta	6 (10.5)
Placenta accreta	1 (1.8)
Pain by FPS	3.7 (range 1-8)
ICU admission	20 (35.1)
Hemoglobin/Hematocrit, mg/dL/%	
Antepartum	11.2 (range 6.3-13.1)/33.5 (range 19.4-40.1)
Postpartum†	9.1 (range 5.9-12.3)/26.8 (range 16.5-36.3)
Day of postpartum admission, day (mean)	4.8 (range 2-12)
Maternal death	0

Values are presented as mean (range) or n (%).

As shown in Table 1, the leading cause of PPH was placenta previa without accreta in 31 cases (54.4%), followed by uterine atony in 19 cases (33.3%), placenta previa with accreta in 6 cases (10.5%) and placenta accreta in 1 case (1.8%). The mean estimated blood loss was 2,279 mL (range 1,500-6,500 mL) before insertion of a Foley tamponade, and 20 patients had a massive bleeding more than 2,500 mL. None of the patients had the Foley tamponade ruptured during and after inflation. The balloon was left in situ for 17.1 hours on average (range 0.2-36.1 hours). In 14 cases the balloon was in place less than 12 hours and in 9 cases more than 24 hours. Twenty patients were admitted to the intensive care unit for close monitoring.

The Foley tamponade was effective in 82.5% of the included women. In 57 cases, 47 women were successfully managed with Foley tamponade and no further surgical interventions or UAE were needed. Ten of the 57 cases required additional treatment after failure of Foley tamponade management (Table 2). Two women who delivered vaginally and three who delivered by cesarean section underwent UAE; five women who delivered by cesarean section underwent postpartum hysterectomy. In three cases of five patients with postpartum hysterectomy were diagnosed placenta accreta pathologically and in one case with UAE was suspected placenta accreta at the operation room.

Table 2 Additional Procedures Used in Eleven Cases with Foley tamponade Tamponade Failure

Case	Cause of PPH	Mode of delivery	Gestational weeks/ Age(yrs)	Risk factors	Procedure	Blood loss, mL	Transfusion, units
1	Placenta previa+accreta	Elective CS	37.71	Placenta previa	Hysterectomy	7,000	6 PRCs, 5 APF, 6 FFP, cryo
2	Placenta previa	Elective CS	37.57	Placenta previa	Hysterectomy	3,000	6 PRCs, 1 APF, 5 FFP, cryo
3	Chorioamnionitis	Elective CS	37.14	Multiple pregnancy, Placenta previa	UAE	3,100	11 PRCs, 3 APF, 8 FFP, cryo
4	Placenta previa+accreta	Elective CS	37.86	Placenta previa, two prior CS	Hysterectomy	3,700	14 PRCs, 4 FFP, 12 FFP, cryo
5	Placenta previa+accreta	Elective CS	38.14	two prior cesarean, placenta previa	UAE	3,800	10 PRCs, 5 FFP
6	Placenta previa+accreta	Elective CS	37.71	Placenta previa	Hysterectomy	7,000	6 PRCs, 5 APF, 6 FFP, cryo
7	Chorioamnionitis	VD	37.98		UAE	3,100	14 PRCs, 5 APF, 8 FFP, cryo
8	Uterine atony	VD	40.14	Large fetus	UAE	2,800	26 PRCs, 6 FFP, 16 FFP, cryo
9	Placenta previa	Emergency CS	39.14	Placenta previa	UAE	2,300	13 PRCs, 3 FFP, 12 FFP, cryo
10	Uterine atony	Elective CS	38.28	Placenta previa	Hysterectomy	2,500	10 PRCs, 2 APF, 12 FFP, cryo

Abbreviations: VD, vaginal delivery; CS, cesarean section; UAE, uterine artery embolization; PRC, packed blood cell; FFP, fresh frozen plasma; FFP, cryo, Platelet concentrate.

Maternal demographics showed no significant differences between success group and failures, with maternal age, gestational age, delivery mode and infants with large for gestational age (Table 3). The cause of massive PPH was not predictive of failure. There was no difference in volume of balloon inflation between two groups. Outcomes in the failure group were notable for longer length of hospitalization, higher likelihood of ICU admission, and higher transfusion rate. The drained blood loss after foley balloon insertion and average blood loss per 1 hour were heavier in the failure group compared to those of success group.

Table 3:Maternal Demographics and Outcomes between Success and Failure Group with Foley tamponade

	Success (n=47)	Failure (n=10)	*P* value
Maternal age, yr	33.9 (range, 25-41)	35.3 (range, 31-39)	0.32
AMA	22 (46.8)	6 (60.0)	0.50
GA, wks	37.6 (range, 34.2-40.7)	37.9 (range, 37.1-40.1)	0.54
Delivery mode			0.65
Vaginal delivery	7(14.9)	2 (20.0)	
Cesarean section	40 (85.1)	8 (80.0)	
LGA	4(8.5)	1(11.1)	0.17
Cause of PPH			0.25
Uterine atony	15 (31.9)	4 (40.0)	
Placenta previa without accreta	28 (59.6)	3 (30.0)	
Placenta previa with accreta	3 (6.4)	3 (30.0)	
Placenta accreta	1 (2.1)	1 (10.0)	
Blood loss*	2184.1 (range, 1500-6500)	2725.0 (range, 1900-3800)	<0.01
Length of hospitalization	4.3	7.2	<0.01
ICU admissions	10 (21.3)	10 (100.0)	<0.01
Transfusion	40 (85.1)	10 (100.0)	0.19
Hemoglobin, decreased	2.1 (range, -1.7-4.9)	2.2 (range, -0.7-4.7)	0.92
Hct, decreased	6.8 (range, -3.5-16.4)	7.6 (range, -2.6-14.1)	0.62

Values are presented as mean (range) or n (%).

No cases of hypoxic encephalopathy or death were encountered and no complications were observed due to insertion of Foley tamponade such as uterine rupture, endometritis and uterine incision dehiscence.

DISCUSSION

The incidence of PPH is steadily rising in association with an increased incidence of cesarean section with abnormal placentation, increased rates of maternal obesity and rising frequency of multiple pregnancies by artificial reproductive technologies.10 PPH is a significant cause of maternal morbidity and mortality. Especially if massive, women suffer from acute renal necrosis, irreversible hypovolemic shock, disseminated intravascular coagulation, Sheehan's syndrome until the death of the patient and death as well as severe anemia with the need for massive transfusion.Because late diagnosis and delayed management contribute to increased maternal morbidity when women had a massive PPH, rapid decision and interventions are essential. As a treatment for PPH, intrauterine balloon tamponade does not require either a highly technological facility or technical skill so that it can be rapidly applied for hemostasis. This procedure is the least invasive and lower-cost approach and it can preserve fertility by preventing hysterectomy.

The overall success rate of Foley tamponade in our study was 82.5% which is comparable to previous studies. In agreement with other studies, intrauterine balloon tamponade is effective for PPH even if massive bleeding during delivery.

In our study, both total drained blood loss and blood loss per hour after Foley insertion were significant higher in failure group compared of those in success group, suggesting that another procedure such as Uterine artery ligation,Internal Iliac artery ligation or hysterectomy should be considered when bleeding passed through drainage tube was over 400 mL within 1 hour. As continued bleeding after Foley Tamponade represent foley tamponade management failure, the Foley tamponade can make a rapid decision for another procedures such as surgical procedure when persisting bleeding was observed by connected tube.

The Foley catheter cost is cheaper,readily available and is equipped with a drainage port for ongoing blood loss.

Among the 57 cases examined, ten required additional treatment after Foley tamponade. In five failed cases in the cesarean section group who later underwent hysterectomy, three had placenta previa with accreta. In one cases with cesarean section who had a successful Foley tamponade catheter placement during cesarean section for PPH due to placenta previa, massive rebleeding was noted in the recovery room caused by complete displacement of the balloon into the vaginal cavity. At the time of balloon placement, the cervix was dilated to 1 cm but firm; therefore, vaginal gauze packing was not performed. However, results of a pelvic exam following balloon displacement showed that the cervix was dilated to 5-6 cm and 50% effaced. This finding led us to believe that the inflated balloon functioned as a transcervical catheter that mechanically dilated the cervix and a lack of balloon support (vaginal packing) contributed to balloon expulsion. Thus, we strongly recommend vaginal packing for balloon support and checking the balloon position by ultrasound at the end of surgery to prevent treatment failure due to balloon displacement.

Among PPH patients, we analyzed women with estimated blood loss more than 1,500 mL. Our study also had homogeneity. All procedures had record of causes of PPH, inflation volume of balloon, time of insertion and removal . In addition, women who underwent UAE or surgical procedure without trying to insert Foley tamponade were excluded in this study. It may affect to be overestimated the success rate of Foley tamponade in massive PPH. However, Foley tamponade could reduce heavy bleeding pending the arrangement of other procedures and this also regard efficiency of Foley tamponade to control massive PPH.

CONCLUSION

Intrauterine Foley tamponade is an effective tool with a comparable success rate to other treatment modalities for managing massive PPH when standard uterotonic agents fail. Considering its merits over other balloon catheters as well as its cost-effectiveness and lower invasiveness compared to uterine artery ligation and hysterectomy, uterine balloon tamponade using the Foley tamponade catheter deserves to be the first choice among second-line therapies for patients with massive PPH who are unresponsive to uterotonic agents. In patients who were delivered by cesarean section for placenta previa/accreta, intrauterine Foley tamponade combined with hemostatic compression sutures could further enhance success rates and preserve fertility. Foley tamponade tamponade can be also used not only in tertiary centers but also in limited-resource centers, and it may be able to earn time to prepare another procedure with preventing massive bleeding or refer.

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