Original Article

Double Balloon Catheter Tamponade in the Management of Primary Atonic Postpartum Hemorrhage: A Novel Technique in Low Resource Settings

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ABSTRACT

Background: Globally, postpartum hemorrhage is the most common cause of maternal death. The American College of Obstetricians and Gynecologists (ACOG) recommends the use of intrauterine balloon tamponade, which can be beneficial in reducing bleeding owing to uterine atony when uterotonics fail to generate persistent uterine contractions and provide sufficient control of hemorrhage after delivery.

Objectives: This study was conducted to assess the efficacy of the Novel double balloon catheter tamponade (NDBCT) in the management of atonic primary postpartum hemorrhage (PPH).

Patients and Methods: This was a prospective study carried out for one year from 01-02-2019 to 30-1-2020 comprised 22 patients diagnosed with atonic PPH following vaginal delivery refractory to the medical treatment. All cases were managed using the Novel double balloon catheter tamponade (NDBCT)

Results: After application of the NDBCT, bleeding stopped completely in 20 out of 22 cases (90.9%), while it decreased significantly in one case (4.5%), giving a total success rate (95.4%), while one case failed (4.5%). In addition, there was highly statistically significant improvement in the mean hemoglobin levels after the operation ($P < 0.001$).

Conclusions: The NDBCT is likely to be effective in most cases of PPH associated with vaginal delivery, without causing additional adverse events. Laparotomy with subsequent hysterectomy was avoided in such cases, and fertility was preserved.

Key Words: Double balloon catheter tamponade, postpartum hemorrhage, uterine atony.

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INTRODUCTION

Postpartum hemorrhage (PPH) remains one of the most common causes of maternal death and serious morbidity in both developed and developing nations[1]. Uterine atony is responsible for about 70–80 % of cases of PPH[2]. There are many risk factors for PPH such as high parity, multiple pregnancy, macrosomia, polyhydramnios, cesarean delivery, instrumental vaginal delivery, prolonged or precipitate labor, induction or augmentation of labor, placental abruption, uterine leiomyomas and malformations, maternal bleeding disorders, chorioamnionitis, placenta previa and abnormally adherent placenta, pre-eclampsia, amniotic fluid embolism, idiopathic (10%) and previous postpartum hemorrhage[3].

As soon as the PPH is diagnosed, treatment options should be applied step by step. If medical treatment fails, conservative methods or surgery are indicated[4]. ACOG guidelines 2006, and WHO guidelines 2017, recommended conservative treatment of PPH such as, balloon tamponade should be tried first. If these fail, more invasive procedures should be followed such as, uterine sutures then uterine, utero-ovarian and hypo gastric vessel ligation may be tried[4,5]. The tamponade is preferred because it protects patient's complications of surgical treatment such as, loss of fertility, infectious morbidity, urologic lesion and intensive care unit stay[4]. Different types of balloons are used, the Bakri balloon, Sengestaken -Blackmore gastric tube, Rush urologic balloon and Ebb balloons, although were effective, they are expensive and not readily available in emergency situation. Attempts to develop a cheaper catheter tamponade as intrauterine insertion of multiple Foley catheters, a condom adapted to Foley catheter were done, but results were inferior to Bakri balloon[5]. The available double balloons including Rush urologic balloon and Rush balloons, both were expensive. The aim of this study was to assess the efficacy of the Novel double balloon catheter tamponade in the management of primary atonic Postpartum hemorrhage (PPH) in low resource settings.

PATIENTS AND METHODS

This was a prospective study conducted at Mansoura University Hospital, department of Obstetrics & Gynecology, Mansoura University, Egypt, over a period

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of 1 year from 01-02-2019 to 30-1-2020. The ethical committee at Mansoura University approved the study (Code number: MS.02.509).

Study population and inclusion/exclusion criteria

The study carried out for one year which involved (22) patients diagnosed with atonic PPH following vaginal deliveries, who were refractory to medical treatment according to the local hospital protocol. All cases were managed using the Novel Double Balloon Catheter tamponade (NDBCT). All women who have one or more of the following were not be eligible to participate in the study:

1. Genital tract lesions (trauma and lacerations).
2. Uterine malformations.
3. Abnormally adherent placenta (accreta, increta and percreta).
4. Maternal bleeding disorders (such as DIC).
5. Uterine inversion and uterine rupture.

The Novel Double Balloon catheter tamponade (NDBCT)

a. Equipments

We used silicon coated Foley Catheter- no.20, two bottles of normal saline 0.9%, 500 ml, infusion set, disposable plastic syringes 20 cm, 50 cm, sterile finger gloves, 3-way valves (Ultra medical product, Egypt), silk thread no. 1, and scissors.

b. Preparation of NDBCT

i. The upper uterine balloon was prepared as follow: A sterile finger glove was firmly tied around the tip of the silicon coated Foley catheter, using silk thread knot, below the draining ports of the catheter as well as above the limits of the Foley self-retaining balloon. The distal end of a 3-way valve was firmly tied using silk thread around the drainage port of the Foley catheter, to allow proper filling of the uterine balloon without saline leakage, the proximal end of the 3-way valve was connected to the infusion set connected to a bottle containing 500 ml warm saline, while a 20 ml or 50 ml syringe was connected to the side way of the 3- way valve and used for inflation of the uterine balloon (Figure 1). The manufacturer Foley self-retaining balloon was used as the lower vaginal balloon. Before insertion of the catheter, we checked for the proper integrity of both balloons by testing with saline injected to each balloon.

Fig. 1: A novel double balloon catheter tamponade.

ii. The technique of NDBCT: in the operating theater, we used minimal analgesia, the woman was placed in the lithotomy position with an indwelling urethral catheter. The anterior and posterior lips of the cervix were grasped with ring forceps and apply gentle traction to align the direction of the cervical canal to that of the uterine cavity. Then placing the distal empty balloon into the uterine cavity with another sponge forceps catheter. At least distal 3 cm of the catheter was inserted into the uterine cavity to assure proper placement. The upper balloon catheter was then inflated to 250-300 mL at first, followed by reassessment, depending on the size and capacity of the uterus based on the point of resistance during infusion. The further amount of injected saline 50 ml each time guided by the patients response until the bleeding was controlled and the uterine fundus was firmly palpable through the abdomen. Then, the proximal port of the 3-way valve was occluded. Lastly inflation of the lower (vaginal) balloon with another 80-120 mL compress the cervix as well as to avoid spontaneous expulsion of the NDBCT. Vaginal packing was not done.

Success of the procedure and care after procedure

All patients were observed in the operation theater for about one hour. The woman was cared in an area like High Dependency Unit or Intensive Care Unit. The urine flow, vital signs, fluid input/output chart, and fundal height were recorded every 15 minutes for the first 2 hours and every hour for the other 6 hours. Vaginal

blood loss was assessed. Temperature was checked every two hours. Oxytocin infusion was given for 4 hours, then discontinued unless there is a clinical indication to continue. Methylergometrine maleate was given every 8 hours except when contraindicated. The first eight cases were followed up by transabdominal scan to ensure of ideal NDBCT insertion immediately, then after 6 h, 12h and 24h and to diagnose or exclude blood collection behind the balloon (Figure 2). The HB and hematocrit values were measured after 3 hours to ensure that the patient need blood transfusion or not. Signs and symptoms of ongoing blood loss were monitored, such as pallor, dizziness, hypotension, tachycardia, confusion, uterine enlargement, abdominal pain, abdominal distension and oliguria. Blood transfusion and/or blood products were given, as needed, to correct prior deficits.

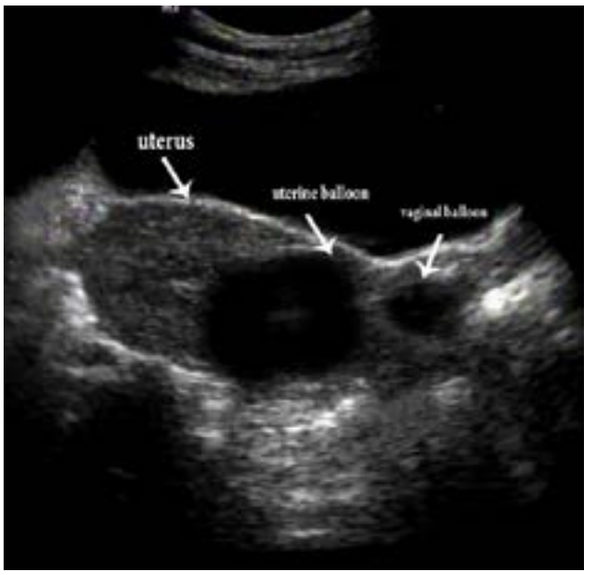

Fig. 2: Ultrasonographic appearance of NDBCT after intrauterine insertion

All patients received intra operative antibiotic and continued for 24 hours after removal of NDBCT. Antibiotics administered intravenously (ampicillin or amoxicillin] 2g IV initial dose then 1g intravenously every 8 hours. Analgesics were given if patients complain of pain, all received mechanical thromboprophylaxis in the form of above- knee graduated compression stockings as soon as 12 to 24 hours after bleeding has been controlled, pharmacologic thrombo-prophylaxis was added, provided that coagulation tests are normal.

The NDBCT was kept for 24-48 hours depending on the severity of blood loss. The timing of removal was determined by the availability of senior staff, in case of continuing bleeding. The balloons were deflated gradually at a rate of 40 mL for each balloon every hour. The NDBCT removed after 8-24 hours, if hemostasis had 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.

Outcomes

Primary outcomes: Control of bleeding after the use of the NDBCT, hemoglobin (g/dL) and hematocrit (%) levels before and after tamponade and recurrence of uterine bleeding

Secondary outcomes: number of red cells concentrate units, fresh frozen plasma units, whole blood (unit) and length of hospitalization (days).

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 15 for Windows® (SPSS Inc, Chicago, IL, USA). Qualitative data was presented as number and percent. Quantitative data was tested for normality by Kolmogrov-Smirnov test. Normally distributed data was presented as mean ± SD. Paired t-test was used for comparison within groups. $P < 0.05$ was considered to be statistically significant.

RESULTS

The mean age of the patients was 23.64 ± 3.58 ranging from 19 to 32 years and the mean body weight was 80 ± 10.89 ranging from 59 to 95 kg. Three patients were hypertensive, two were diabetic and two patients (9.1%) had a prior history of PPH. Further, the mean gestational age at time of delivery was 36.95 ± 3.58 weeks (32–40 weeks). Primigravida constituted (40.9%) of cases, followed by G 2 and G 3 which represented 27.3% for each. As presented in (Table 1).

Table 1: Demographic and Obstetric characteristics of studied cases

Age (years)							
Range	19 – 32						
Mean ± SD.	23.64 ± 3.58						
Body weight (kg)							
Range	59 – 95						
Mean ± SD	80 ± 10.89						
Gestational age at time of delivery (week)							
Range	32 – 40						
Mean ± SD	36.95 ± 2.30						
Gestational age at termination (weeks)					35-40		
No. of hypertensive patients					3 (13.6%)		
No. of diabetic patients					2 (9.1%)		
Previous history of PPH					2 (9.1%)		
Gravidity (no)							
1	9 (40.9%)	2	6 (27.3%)	3	6 (27.3%)	4	1 (4.5%)
History of Abortion (no)					2 (9.1%)		

Bleeding was stopped in 20 out of 22 cases (90.9%), while one case failed and another case bleeding decreased. The mean volume of saline solution used to inflate the uterine balloon was 436.36 ± 144.90 ml; if bleeding ceased, the balloon was maintained in place for a median of 27.75 ± 7.29 h. The mean volume of saline solution used to inflate the vaginal balloon was 107.27 ± 14.53 ml. as illustrated in (Table 2).

Table 2: Outcomes of NDBCT of studied cases

Success rate of balloon	
Bleeding stopped (No, %)	20 (90.9%)
Bleeding decreased (No, %)	1 (4.5%)
Failed case (No, %)	1 (4.5%)
Duration between NDBCT insertion and vaginal delivery (hours)	
Range	5 – 15
Mean ± SD	9.18 ± 2.94
Amount of the infused saline in the uterine balloon	
Range	250-700 ml
Mean ± SD	436.36 ± 144.90
Amount of the infused saline in the vaginal balloon	
Range	90-140
Mean ± SD	107.27 ± 14.53
Duration of balloon maintained in place before deflation (hours)	
Range	0.5 – 36
Mean ± SD	27.75 ± 7.29

Before NDBCT After NDBCT T P There was highly statistically significant improvement hemoglobin (HB) level after the operation ($P < 0.001$), while there were no significant differences regarding hematocrit (Ht) value ($P > 0.05$). As shown in Table 3.

Table 3: Hemoglobin and Hematocrits of the studied cases

		Before NDBCT	After NDBCT	T	*P*
HB level (gm/dl)	Range	7.3 – 11.6	8.8 – 12.5	10.594	< 0.001*
	Mean ± SD	9.25 ± 0.98	10.2 ± 0.95		
Ht %	Range	23.6 – 33.2	20.2 – 37.2	2.065	0.051
	Mean ± SD	28.07 ± 3.14	29.42 ± 3.65		

Maternal fever, Abdominal pain and admission to the intensive care unit represented the most complications of the NMDBC that the studied cases encountered (5 (22.7%), 8 (36.4%) and 7 (31.8%) respectively). Whereas none of the cases died after the procedure. As shown in (Table 4).

Table 4: Complications of the NMDBC in cases

Maternal fever	5 (22.7%)
Abdominal pain	8 (36.4%)
Massive blood transfusion	1 (4.5%)
Sepsis	1 (4.5%)
Sepsis and DIC	1 (4.5%)
Admission to the intensive care unit	7 (31.8%)
Hysterectomy	1 (4.5%)
Maternal death	0 (0%)
Balloon spontaneous rupture	0 (0%)

DISCUSSION

The results of the present study reported that, bleeding was stopped in 20 out of 22 cases (90.9%), it was decreased significantly in one case (4.5%), giving a total success rate (95.4%), while one case failed (4.5%). This high success rate of NDBCT compares favorably with other reports[5,6,7] Although the mechanisms of action of balloon tamponade has long been not well understood, it has been speculated that the uterine wall compliance with the inflated intrauterine balloon and good fitness of the balloon- uterine interface, exerting in inward-to-outward pressure "that is greater than the systemic arterial pressure" to prevent continual bleeding[5,8,9]. However, another study reported that the systolic blood pressure was higher than the intraluminal pressure of the Bakri balloon when a positive 'tamponade test'[9].

Yorifuji and his colleagues measured the stiffness of the uterine corpus and cervix by radiation force impulse elastography before and after Bakri Balloon Tampnade (BBT). Uterine stiffness increased immediately after insertion of the balloon, suggesting that the balloon induced- uterine contractions. Other mechanisms of action had been proposed, include: hydrostatic pressure effect on the uterine arteries, reduce blood flow and facilitates compression. Endometrial contact, vascular compression via myometrial stretch and myometrial activity secondary to myometrial stretching stimulate uterine muscle fibers that form a figure of eight, result in uterine contraction and placenta bed vasculature hemostasis after delivery. Also, reduction in the persistent capillary and venous bleeding from the endometrium and placental bed[10].

Advantages of the NDBCT

One of the major advantages of the NDBCT, is the presence of a short shaft in the uterine Balloon, this allows a better fit between the uterine balloon after inflation and the uterine fundus, and the shape of the uterine cavity in general. However, 'over-inflating' the uterine balloon to prevent migration, may cause other problems, as distension of the uterus causes significant pain. Other advantages of the NDBCT, is the addition of the vaginal balloon as it

helps to maintain the uterine balloon in place, and negates the need for the vaginal pack. The use of vaginal packing may obscure any continuing bleeding leading to a delayed diagnosis of ineffective tamponade. It is well known that vaginal packing was used with many other tamponades, as early publications involving the Bakri balloon, a Sheffield guideline for the use of the Sengstacken–Blakemore tube, and with use of Foley catheter, and condom. However, the vaginal pack may only be necessary in cases of PPH involving a dilated cervix, as the balloon when expanded to fit the least resistant space.

The NDBCT is consider to be the cheapest balloon in comparison to other balloons such as Bakri and Rush balloon. Additionally, the novel double balloon is simple to prepare, inexpensive, easy to learn, it can be inserted quickly and it does not exclude the use of other procedures if necessary, it protects the patient's complications of surgical treatment, such as loss of fertility, infectious morbidity, urologic complications, and intensive care unit stay[4].

Comparison with another uterine tamponade

The Bakri balloon achieve success rate in management of PPH due to uterine atony but fortunately is expensive and not available[11]. Comparing with other fertility-preserving techniques for the management of PPH as pelvic arterial embolization and uterine compression sutures. Embolization has a success rate as high as 85-95%, but it is not readily available in most maternity units and the patient may thus require transfer to a tertiary hospital. In addition, placement of uterine compression sutures requires surgical skills. Both of these procedures carry a risk of complications as reported by previously[12].

Silicon type is more preferable to the ordinary rubber Foley catheter because its more firmness that enhance its application and insertion into the uterus. We decided to use the glove finger to act as a uterine balloon because its easy availability, expandability and its more firmness, compliance and fitness with the balloon-uterine interface if compared to the usage of a condom. It is worthy to be mentioned that balloons never ruptured in any case because of the optimization of the infusion volumes of the balloons in *vitro*.

Similar to the Rusch balloon and the condom catheter, the NDBCT don't have drainage port, as there is no continuity of the inner channel with the uterine cavity, so careful follow up for the vital signs and fundal level is mandatory to avoid concealed intrauterine bleeding. It can be suggested that the use of this novel double balloon earlier in the course of PPH would reduce a subsequent reduction in expensive operative therapies and blood transfusions and improve maternal outcomes. Even if unsuccessful, it will not result in significant delay as insertion is easily achieved. Furthermore, it may also reduce continuing bleeding prior to transfer to the operating theatre or while preparing for a laparotomy. The early use will allow time resuscitation of the women, obtaining cross-matched blood and arrival of senior help and may result in less maternal morbidity secondary to reduced blood loss.

Limitations

Certain limitations of this study must also be addressed. First, insufficient sample size. Second, we only included double intra uterine ballooning tamponade for persistent PPH due to atony after vaginal deliveries only. Finally, NDBCT cannot be used in life-threatening situations with massive bleeding that is not responding to any conservative management, and emergency postpartum hysterectomy in these cases may be needed.

CONCLUSION

In conclusion, our study showed that double catheter balloon is simple, easy to use, effective, inexpensive, and safe for treating PPH before more aggressive surgery. It does not require any special trained staff and is inserted quickly without any major complications; junior residents can easily learn and perform the test while waiting for help. The early use of double balloon catheter to arrest bleeding in, so laparotomy and hysterectomy can be avoided in many cases so fertility is preserved. We advise its widespread use in all obstetric units for PPH cases that do not respond to standard management, when basics and first lines management is not effective to control the bleeding in PPH.

RECOMMENDATIONS

According to the findings of the present study, the following recommendations are suggested: Utilization of double intrauterine balloon tamponade as an alternative modality for PPH management and further studies are needed in the future on large sample size.

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CONFLICT OF INTERESTS

There are no conflicts of Interest.

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