THE JOURNAL OF OBSTETRICS AND GYNECOLOGY OF INDIA

The Journal of Obstetrics and Gynecology of India (January–February 2016) 66(1):63–67
DOI 10.1007/s13224-015-0818-2

INSTRUMENTATION & TECHNIQUES

Use of an Innovative Condom Balloon Tamponade in Postpartum Haemorrhage: A Report

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Received: 20 September 2015 / Accepted: 29 October 2015 / Published online: 22 December 2015

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Introduction

In order to meet the Millennium Development Goals [1], we must achieve a reduction in the deaths due to postpartum haemorrhage (PPH) which is the major contributor in the developing countries [2]. As per WHO recommendations, the use of intrauterine balloon tamponade (UBT) is recommended for the treatment of PPH due to uterine atony if women do not respond to uterotonics [3]. FIGO also included uterine balloon tamponade as a recommended second-line intervention for the treatment of PPH [4]. The successful outcome of balloon tamponade is reported to be 80–100 % [5]. This high efficacy avoids surgery which is often delayed or may be unavailable thereby costing the women her life. Intrauterine balloon may also be used as a temporizing measure while awaiting transfer or to resuscitate her.

The commercially available uterine-specific devices are designed with an intrauterine drainage port but have a prohibitively high cost. Low resource settings have to rely on lower cost adaptations like condom balloon tamponade which is the most cost-effective second-line management option [6].

The condom balloon tamponade has two main disadvantages. First is not having a drainage port and therefore not letting the clinician assess the actual blood loss and second is that the thread or suture is used to tie the

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condom to the catheter which often causes leakage of saline.

To overcome these disadvantages, we have designed an innovative variation of condom balloon catheter and named it "**CG Balloon**" (CG is our state of Chhattisgarh in India).

It is prepared manually with all aseptic precautions as follows (Fig. 1):

(1) Collect a Foley's catheter of size 20–22, a packed condom, scissors, two 20-ml syringes and 500-ml bottle of saline in a tray.
(2) From the drainage tube of the catheter, cut two rings of approximately 1–2 mm width (Fig. 1a).
(3) Excise (not merely incise) the bulb of the catheter after inflating it with air (Fig. 1b).
(4) Unfold the condom over distal one-third of the catheter (Fig. 1c).
(5) Use these rings encircling twice only (like a rubber band in a ponytail) to secure the condom over catheter leaving 1.5–2 cm from both the ends of condom (Fig. 1d).
(6) Excise the tip of the Foley's catheter and condom together to facilitate drainage of blood (Fig. 1e). Wash the device with antiseptic solution.

We hereby present our experience of 15 cases of its use.

Case Series

In our series of 15 women, CG Balloon was used as a second-line intervention in 13 women who had atonic PPH not responding to medical means. The remaining two had other causes of haemorrhages detailed below. Women having retained placenta, uterine rupture, chorioamnionitis and known uterine anomaly were excluded. The blood loss calculation was done by pictorial blood loss assessment charts.

Women with atonic PPH were 13 and delivered between December 2014 and August 2015. The details are summarized in the Table 1. The mean age was 26.6 years, the mean gestational age was 37.2 weeks. Primi and para two women were five each and remaining three were para three. Ten (76.9 %) of them have delivered vaginally. Each of the delivery was conducted with active management of third stage of labour and as soon as atonic PPH was diagnosed, uterine massage started and uterotonic agents

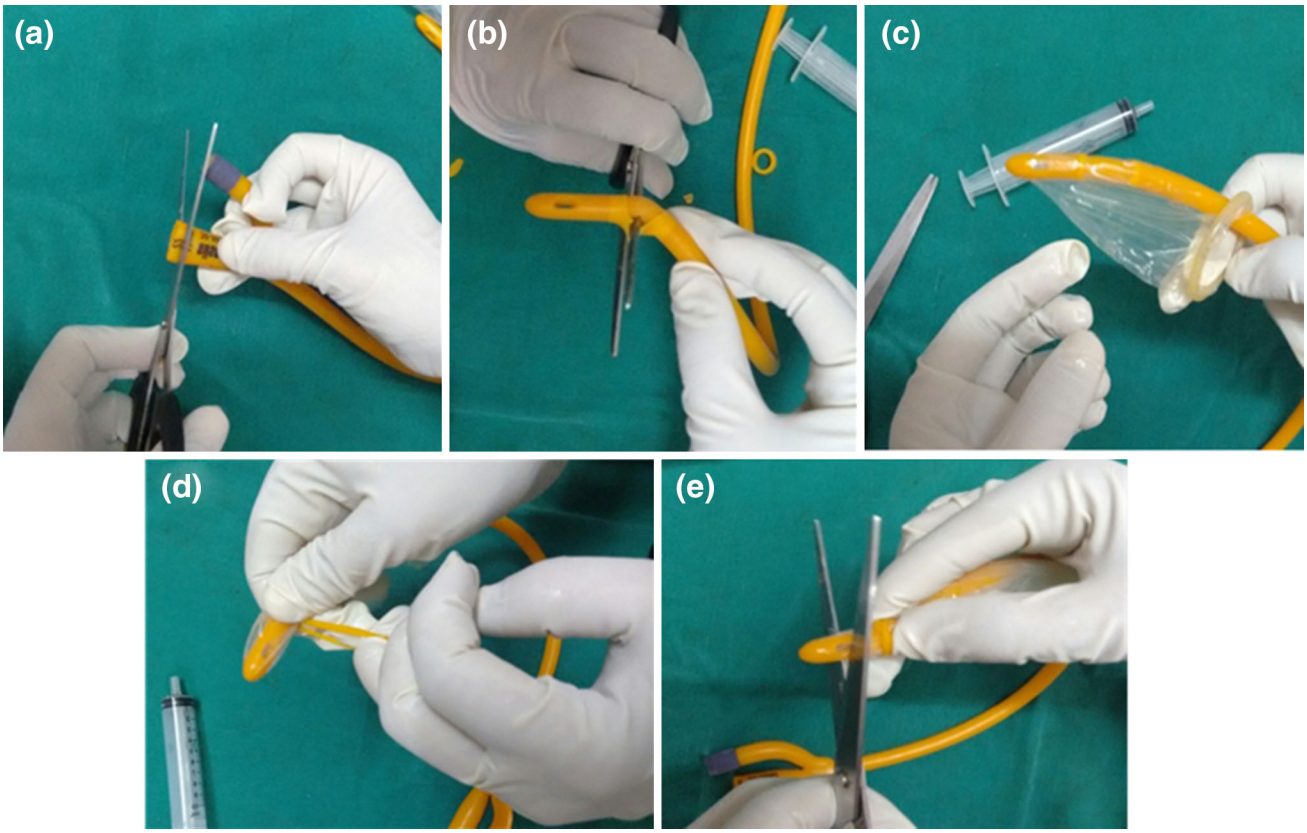

Fig. 1 Preparation of the CG Balloon—**a** cutting two rings from the drainage tube of Foley's catheter. **b** Excision of the bulb of catheter subsequent to inflation with 2–5 ml of air. **c** Rolling of condom over catheter. **d** Tying condom to catheter using the rings twice around both the ends of condom leaving 1.5–2 cm of condom on either end. **e** Excision of the tip of Foley's along with the blind end of condom together 0.5 cm away from the tied ring. Leaving both the rings with CG Balloon

namely oxytocin, methyl ergometrine (if not contraindicated) and carboprost were used along with the supportive measures including intravenous fluids and blood or blood products. The mean blood loss was 1611 ml (95 % confidence interval of 1458–1764 ml). The process of making of CG Balloon started simultaneously and introduced if the bleeding was not controlled by medical method, and the interval was inversely proportional to the severity of bleeding.

The mean time interval between the diagnosis of atonic PPH and introduction of CG Balloon was 19.6 min (95 % CI 15.06–24.3 min). The shortest interval was in caesarean sections. The longest time interval was 45 min where repair of the coincidental cervical tear had to be done before placement of balloon in a case where uterus was being atonic intermittently. The shortest interval was 8 min in a case of severe atonic PPH during caesarean section not responding to any uterotonic agent.

CG balloon was inserted into the uterine cavity holding it along two fingers after grasping the cervical lips with sponge holding forceps in case of vaginal delivery. During caesarean section, it was inserted directly and the catheter shaft was pushed through the cervical canal from above, the balloon was then inflated with 20–50 ml saline before quick suturing of uterine incision. Further inflation of balloon was done to ensure the arrest the bleeding followed by closure of the abdominal wall. The balloon was inflated with saline through the bulb inflation port of the catheter by syringes in the alternating repetitive manner until the balloon conforms to the shape of uterus and the uterine fundus become firmly palpable or bleeding was controlled (whatever is earlier). Constant assessment of uterine bleeding was done while inflating the device. If bleeding persisted, inflation was continued in 20 ml aliquots. We have set an arbitrary upper limit of 500 ml, although maximum tamponade volume needed in our series was 320 ml.

Control of PPH was achieved in 12 cases in the mean time of 12.6 min (95 % CI 9.28–16.09 min). In case of continuing alarming haemorrhage, surgical intervention was resorted to. This happened in one woman (case number 9 in the Table 1) where the bleeding did not stop and the drainage port of the CG Balloon has drained 300 ml of blood while she was being shifted to operation theatre. The laparotomy was performed followed by uterine compression suturing and devascularization. She ultimately succumbed to disseminated intravascular coagulopathy. This was the only case of failure of tamponade and death in our case series.

In three cases of PPH after vaginal delivery, all primipara, the expulsion of the balloon was noticed during inflation process. This was tackled by deflating the balloon, reinserting it and packing of vagina followed by re inflation. Such expulsion was not common in multiparous women where vagina was packed with gauze pack subsequent to control of PPH. Packing prevented the condom catheter from slipping out. The catheter was then strapped

Table 1 Case details of women with atonic PPH managed by CG Balloon

Case	Mode of delivery	Cause of PPH	Other cause of bleeding	PPH volume	PPH to CG Balloon interval	CGB tamponade volume	CGB to haemostasis interval	Inflation deflation interval	Surgical intervention if required
1	Vaginal	Atonic	Cervical tear	1200	45	280 cc	12 min	12 h	Cervical tear repair
2	Vaginal	Atonic	–	1700	24	250 cc	05 min	12 h	No
3	Vaginal	Atonic	–	1200	20	300 cc	14 min	14 h	No
4	Vaginal	Atonic	–	1100	18	290 cc	18 min	12 h	No
5	LSCS (twins)	Atonic	–	1550	15	300 cc	10 min	12 h	No
6	Vaginal	Atonic	–	1700	17	320 cc	15 min	24 h	No
7	LSCS	Atonic	–	1600	20	250 cc	10 min	12 h	No
8	LSCS	Atonic	–	1800	10	150 cc	06 min	12 h	No
9	vaginal	Atonic	DIC	2000	20	250 cc	Haemostasis not achieved		Laprotomy
10	vaginal	Atonic	–	1750	22	200 cc	10 min	15 h	No
11	vaginal	Atonic	–	1800	15	270 cc	12 min	12 h	No
12	vaginal	Atonic	–	1650	17	170 cc	10 min	16 h	No
13	vaginal	Atonic	–	1900	13	165 cc	13 min	22 h	No
Mean	–	–	–	1611.58	19.69	245.76	12.69	14.38	–
95 % CI				1458.74–1764.42	15.06–24.31	214.84–276.67	9.28–16.09	12.1–16.59	

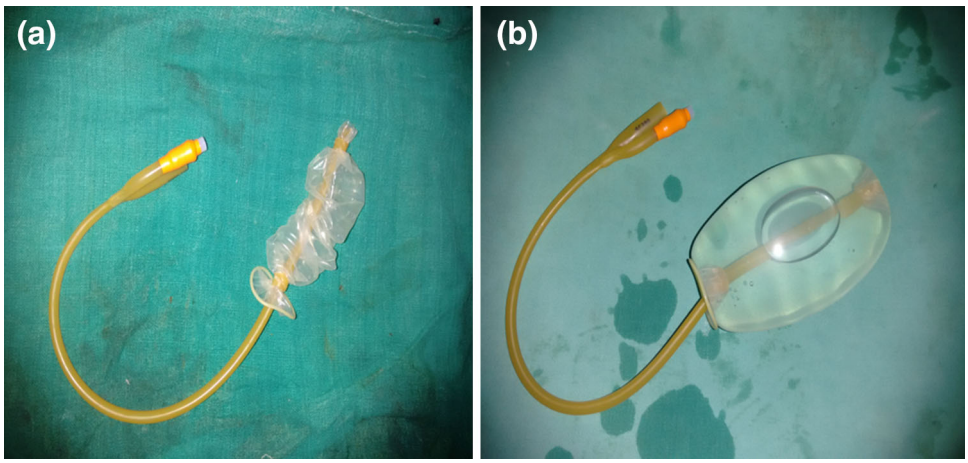

Fig. 2 CG Balloon **a** before inflation, **b** after inflation

to the thigh with a small piece of adhesive tape to prevent an accidental pull and inadvertent expulsion of balloon. It was connected to a urobag to measure the uterine bleeding. Bladder was catheterized. The fundus of the uterus was marked on the abdomen. Oxytocin drip started and broad-spectrum antibiotic coverage was given. The woman was monitored closely for bleeding, any rise in the fundal height and vital signs.

The mean blood loss after control of PPH was 35 ml in next 12 h. In some cases, it was seen only in the connecting tube. Though the authors cannot rule out blockage of the draining aperture but since it was without any change in the fundal height or deteriorating vital parameters, we did not attempt to test the patency.

The CG Balloon was kept in situ for at least 12–24 h and deflated at a convenient hour. Deflated condom catheter was left in situ for an hour of observation with an intention to reinflate the balloon again in case of recurrence of bleeding. It was not needed in any case, and the balloon was removed along with vaginal pack. CG Balloon closely resembles uterine-specific devices after inflation (Fig. 2a, b).

Extended Use of CG Balloon: Case 1

A 34-year-old unbooked para four woman delivered preterm in our institute on 3rd August 2015 had profuse bleeding with well-contracted uterus. Cervix was explored in labour room but did not reveal any obvious tear of cervical lips. She was shifted to operation theatre and was explored under anaesthesia. A partial thickness laceration of about an inch was felt digitally at 2 o'clock position in the upper part of cervix, not approachable for repair. We put CG Balloon in the cervix and the bleeding was controlled in 8 min with inflation of 120 cc saline (Fig. 3). The uterine bleeding drained at the outflow tract was 40 ml in 24 h when the Balloon was removed. She was discharged well after 2 days.

Case 2

A 24-year para three woman with 28-week pregnancy with bleeding placenta previa has undergone an emergency caesarean section on 6th August 2015. Uterus was well contracted after delivery of the baby and placenta, but there was significant oozing from the placental bed. CG Balloon was placed and bleeding could be controlled. Post-operative bleeding was minimal and was limited to the tubing of CG Balloon which was removed after 24 h. The woman made an uneventful recovery.

In our case series, the mean time taken in making, insertion and inflation of CG Balloon was 5–7 min. The 20-cc syringes worked best and if an assistant fills the other syringe while one is being used for inflation, tamponade can be reached real fast.

Once removed, the CG Balloon was always checked for the rings which were cut out of Foley's catheter and used to fasten the condom to catheter. Neither the upper nor the lower one ever slipped or misplaced.

Discussion

We follow the protocol of achieving haemostasis within one (golden) hour of beginning of PPH. In keeping up with the policy, we go in a stepwise approach in management in a time bound manner. In case of vaginal delivery and atonic PPH, the woman is managed by medical means for 5–30 min depending upon the severity of bleeding. In unresponsive cases, balloon tamponade is inserted while the woman is prepared to be shifted to operation theatre for

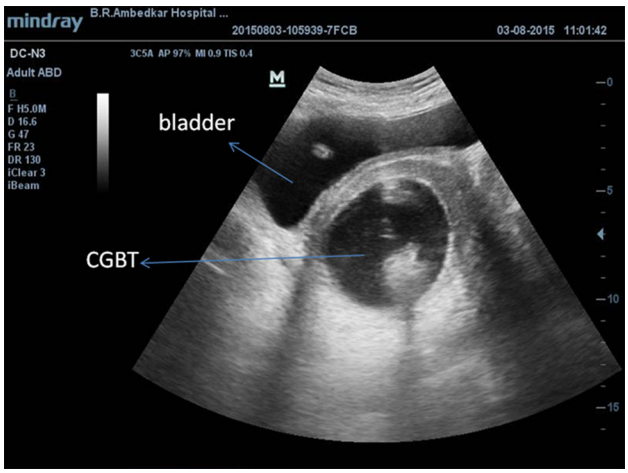

Fig. 3 Ultrasonography showing CG Balloon used as tamponade in a case of partial thickness anterior cervical laceration

any surgical intervention if needed. CG Balloon by virtue of having a drainage port helps in correct estimation of any ongoing uterine bleeding and taking timely decision.

The CG Balloon successfully overcomes both the disadvantages of conventional condom balloon tamponade namely the lack of drainage inherent to it and the procedure of tying the thread which sometimes leads to leakage of saline. In our device, a uniform protocol to use the rings around only twice gives a consistent leak-proof seal with optimal tightness. It has never slipped also. Even excising the bulb takes 20–30 s.

Filling with alternating syringes helped to optimize the tamponade volume and we did achieve tamponade with much lesser volume. The rapid filling method of conventional condom balloon does not necessarily result in an increase in successful outcomes, on the contrary it may result in the inadvertent "over-distension" of the uterus by inflating blindly [5].

Conclusion

The authors present the first-hand experience of 15 cases after using an innovation in condom balloon tamponade. It utilizes the existing resources to their best. It overcomes the major disadvantages of conventional condom balloon tamponade by having a drainage channel for assessing the uterine bleeding. It uses rings cut out of catheter only and not the thread to tie the condom to catheter which avoids loose/too tight knots as well as infection, saves time and is simple to use. CG Balloon is successful in 92.3 % cases as a second-line approach in atonic PPH protocols when first-line treatment fails and before more costly and risky surgery. It can also be used for extended indications for lower genital tract tears or placental bed oozing as it allows the drainage of uterine bleeding simultaneously.

We need larger trials to confirm the findings of this short series.

Compliance with Ethical Standard

Conflict of interest The authors declare that there is no conflict of interest.

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