



Various Modifications of Condom Balloon Tamponade and their Method, Efficacy, Outcomes in Management of Atonic Postpartum Hemorrhage in Tertiary Care Centre- A Observational Study

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Abstract

Background: There are many types of uterine tamponades with uterine drainage port. Among them, the condom catheter seems to be an efficient, easy available and economic intervention for the treatment of PPH in low-resource countries. The aim of this study to evaluated the method, efficacy and outcomes of Atonic PPH with various types of Condom balloon tamponade.

Material & Methods: Our study was a prospective interventional study conducted at a tertiary care centre SMS medical college jaipur, India from January 2017 to October 2017. All patients who delivered vaginally and those who developed non-traumatic postpartum haemorrhage not responding to medical management were included in this study. These 30 cases were divided into 3 groups: Group I- managed by conventional CBT, Group II- managed by CBT with tip cut & Group III- managed by chattisgarh CBT i.e. CG-Balloon. All three groups were compared according to their time consumption, cost effectiveness, chances of slippage and leakage, deflation, blood loss, success rate, advantages and disadvantages etc.

Results: The age of the patients ranged from 18-40 years, with the mean age group of 20-30 years. PPH occurred mostly in women of 2-4 parity. In antenatal care the 63% of the women reported to have PPH were unbooked cases. Therefore, the fastest and easiest to assemble CBT was CBT with tipcut> CG-Balloon>Conv CBT. Out of 30 cases, 27 cases had successful tamponade and 69% of cases ie 23 cases needed continous oxytocin infusion for less than 12 hours.

Conclusion: We concluded that balloon tamponade method should become a familiar component of existing guidelines for the management of PPH, although not as an isolated form of therapy and modification of conventional CBT should be used as a second line of management in Atonic PPH.

Keywords: Uterine Tamponades, Conventional CBT, CG-Balloon, Atonic PPH.

Introduction

Obstetric hemorrhage is the single most significant cause of maternal mortality worldwide accounting for 25-30% of all maternal deaths.^{1,2} Postpartum hemorrhage (PPH) is one major cause of maternal deaths worldwide. Traditionally, postpartum hemorrhage has been defined as the

loss of 500 ml of blood or more after completion of the third stage of labour.³

The risk of maternal death from PPH in developing countries is approximately 1 per 1000 deliveries⁴. Uterine atony is the most common cause of PPH and accounts for 79% of all PPH^{5,6}. A delay in correction of hypovolemia and delay in

the control of bleeding are the main avoidable factors in most maternal deaths caused by hemorrhage.⁷ Whatever is the cause of PPH, death due to this should be preventable and successful outcome is largely dependent upon timely interference and use of rapidly effective method. Active management of the third stage of labor reduces uterine atony and is the mainstay of prevention of hemorrhage.⁸

Guidelines for the management of postpartum haemorrhage (PPH) involve a stepwise approach including the exclusion of retained products and genital tract trauma. Many times PPH does not respond to commonly used first line pharmacological measures like ergometrine, oxytocin, carboprost and misoprostol. Then, non surgical methods such as Bimanual compression, uterine packing, balloon tamponade are employed. Surgical interventions such as B-Lynch suture,^{9,10} ligation of uterine artery, ovarian artery, and internal iliac artery, and embolization are effective methods for controlling intractable hemorrhage. Hysterectomy is the procedure of last resort to save patient's life.^{11,12}

After failed medical treatment, and before proceeding to major surgical intervention and possible hysterectomy, attempting to compress the uterine sinuses and to stop bleeding via intrauterine tamponade is a reasonable option for management of PPH. Recently, uterine balloon tamponade has been added to this armamentarium in the management of PPH.¹³⁻¹⁵ World Health Organization, the International Federation of Gynecology and Obstetrics, and the Royal College of Obstetricians and Gynaecologists all recommend a uterine balloon tamponade (UBT) if uterotonics and uterine massage fail to control bleeding. FIGO also included uterine balloon tamponade as a recommended second-line intervention for the treatment of PPH.¹⁶

There are many types of uterine tamponades with uterine drainage port. Among them, the condom catheter seems to be an efficient, easy available and economic intervention for the treatment of PPH in low-resource countries.¹⁷ But, the success

rates of current UBT have been reported to be at the level of 84% i.e. 80-100%.¹⁸ Therefore, modification are needed to make uterine balloon tamponade more easy and effective.¹⁹ The aim of this study to evaluated the method, efficacy and outcomes of Atonic PPH with various types of Condom balloon tamponade.

Material & Methods

Our study was a prospective interventional study conducted at a tertiary care centre SMS medical college jaipur, India from January 2017 to October 2017. All patients who delivered vaginally and those who developed non-traumatic postpartum haemorrhage not responding to medical management were included in this study.

30 cases of atonic PPH were studied. Initial management of atonic PPH included resuscitative measures, correction of hypovolemia with intravenous fluid/blood transfusion, uterotonics, uterine massage and/or bimanual compression.

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.

In the majority of cases the decision for condom tamponade was made when active continuous hemorrhage persisted despite of these initial conservative measures. These 30 cases were divided into 3 groups:

Group I- managed by conventional CBT

Group II- managed by CBT with tip cut

Group III- managed by chattisgarh CBT i.e. CG-Balloon

All three groups were compared according to there time consumption, cost effectiveness, chances of slippage and leakage, deflation, blood loss , success rate, advantages and disadvantages etc. Statistical analysis was done using simple measures like mean, median etc

Conventional CBT

With aseptic precautions, a condom was rolled over proximal one third of a foley catheter (no. 20) and tied with a cotton thread or vicryl/silk on two sites 1 cm apart (Figure 1). The cervix was

identified and the condom tamponade was introduced into the uterus manually. The condom was inflated with 100-500 ml warm saline with the help of a 50 ml syringe or iv set till bleeding

ceased. The catheter was tightened by an umbilical clamp or cotton string and taped to the thigh. Vagina was loosely packed.

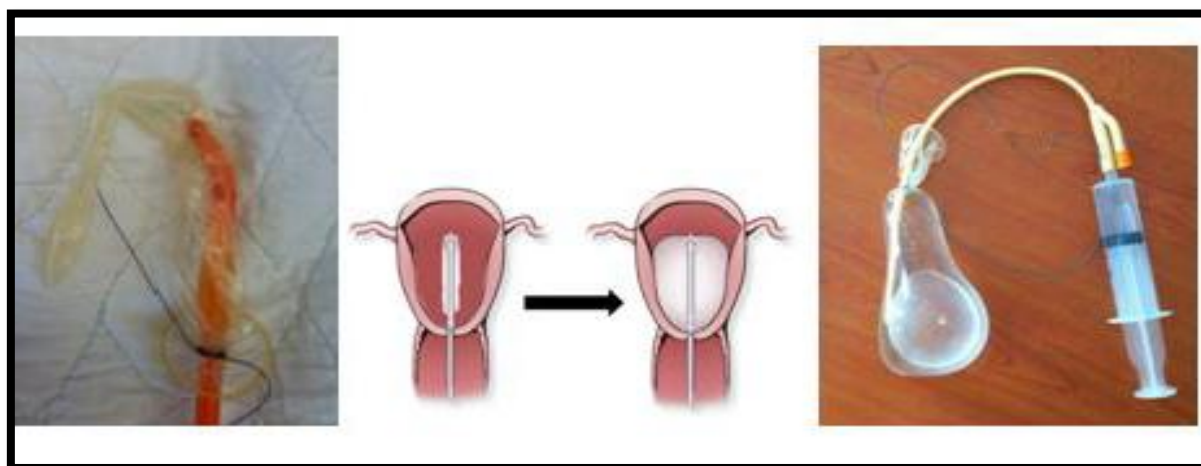


Figure 1 assembly and insertion of conventional CBT

CG-Balloon

It was named ‘CG Balloon’ as it was invented in chattisgarh India.¹⁹ It is prepared manually with all aseptic precautions as follows (Fig. 2). 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. From the drainage tube of the catheter, cut two rings of approximately 1–2 mm width (Fig. 2a). Excise (not merely incise) the bulb of the catheter after inflating it with air (Fig. 2b).

Unfold the condom over distal one-third of the catheter (Fig. 2c). 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.2d).

Excise the tip of the Foley’s catheter and condom together to facilitate drainage of blood ie uterine drainage port (Fig. 2e). Wash the device with antiseptic solution.

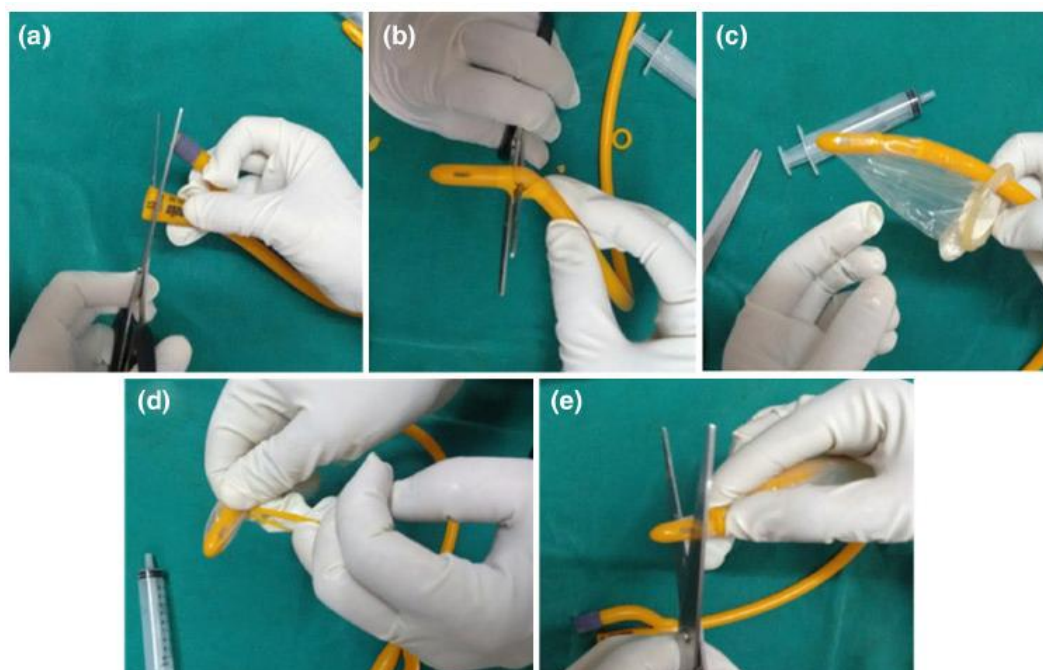


Figure 2: Assembly of CG-Balloon

CBT with tip cut

Under all aseptic precautions, the tip of foleys catheter is cut approximately of 1cm. Then assembly is started with rolling a condom over foley's catheter as in conventional CBT. This is followed by a different method of tying and is done by cutting 2 rings of approx. 1 mm width from the drainage port of foley's catheter. 1st of

these rings is used to tie the condom to the catheter. The method of device placement and insufflation is similar to conventional CBT. Another ring is used to occlude the distal end of balloon once balloon inflation is done and hemostasis is achieved. Vaginal packing used according to clinician need.



Figure 3: Assembly of CBT with tipcut

Results

During the study period of 10 months there were 30 cases of obstetric hemorrhage due to atonic PPH in women who delivered vaginally with estimated blood loss more than 500ml which didn't responded to medical management. The age of the patients ranged from 18-40 years, with the mean age group of 20-30 years. PPH occurred mostly in women of 2-4 parity. In antenatal care the 63% of the women reported to have PPH were unbooked cases (table 1). In 54% of cases time taken to assemble CBT was <1 minute with mean of 1min 26sec. Therefore, the fastest and easiest to assemble CBT was CBT with tipcut > CG-Balloon > Conv CBT (table 2). In 27 patients

(81%), condom catheter balloon successfully controlled bleeding and no additional intervention was required at the time of deflation. The mean time taken to arrest bleeding after the application of the condom catheter balloon tamponade was 6.66 minutes.

The present study showed that the 69% of cases, volume of saline used to create tamponade was 300-500ml. The mean volume of fluid used to create tamponade was 350 ml (graph 1).

Out of 30 cases, 27 cases had successful tamponade. Out of which, 3 cases required tamponade for less than 15 hours, 20 cases ie 60% required tamponade of 15-25 hours, 3 cases required tamponade for 26-36 hours and one case

required tamponade more than 36 hours that was with conventional CBT. The mean duration of tamponade required in situ came out to be 22.56 hours (graph 2).

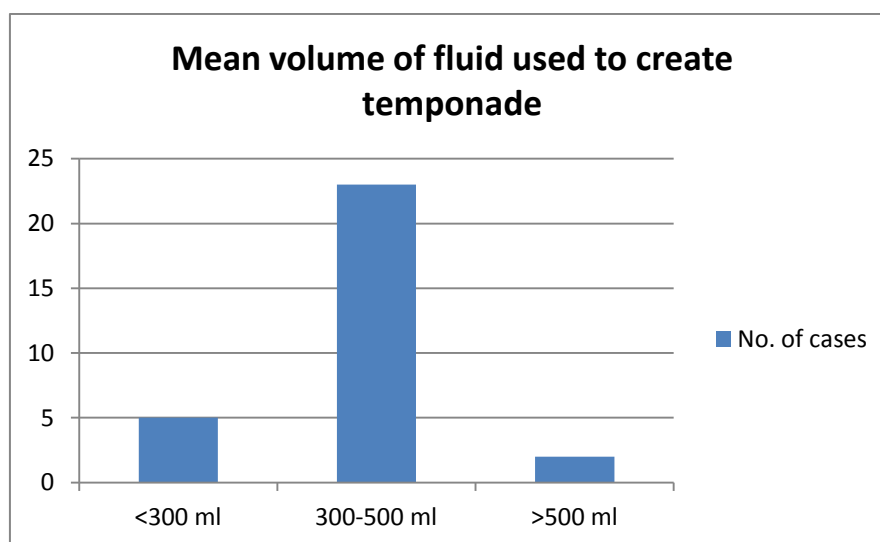
Our study showed that the 69% of cases ie 23 cases needed continuous oxytocin infusion for less than 12 hours. Only 3 cases ie 9% cases needed oxytocin infusion FOR 12-24 hours. And only 2 cases i.e. 6% needed infusion more than 24 hours. CG-Balloon CBT needed oxytocin infusion for max upto 12 hour as it had uterine drainage port (table 4).

Table 1: Profile of patients

AGE GROUP	NO. OF CASES (N=30)
<20 YEARS	4
20-30YEARS	14
30-40YEARS	9
>40YEARS	3
Parity	
1	9 (27%)
2-4	16 (48%)
>4	5 (15%)
Anticare natal visits	
BOOKED	9 (27%)
UNBOOKED	21 (63%)

Table 2: The mean time taken to Assemble condom catheter balloon tamponade

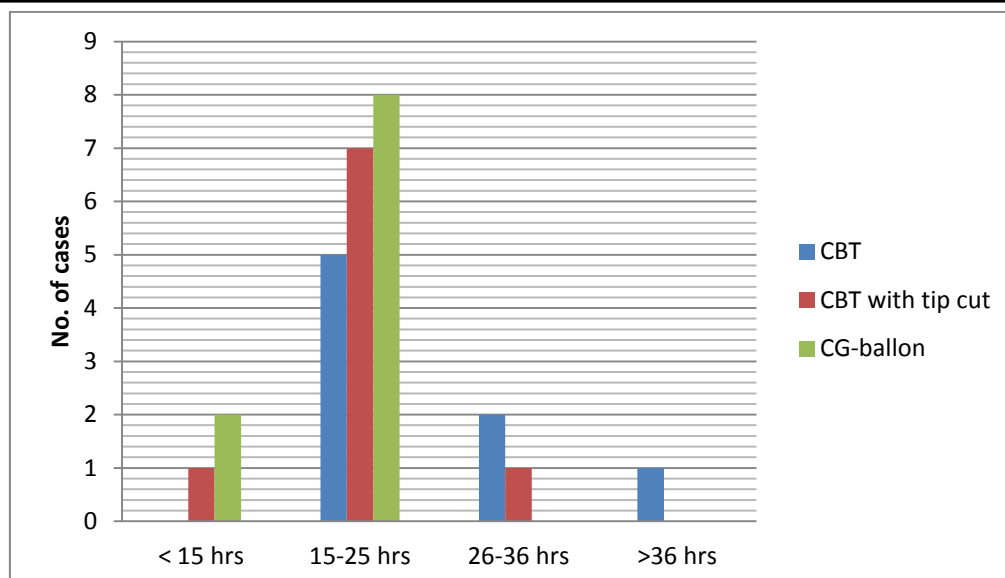
MEAN TIME	Conv. CBT	CBT with tip cut	CG-BALLOON	TOTAL
<1MIN	5	7	6	18 (54%)
2-3MIN	3	3	3	9 (27%)
>3MIN	2	0	1	3 (9%)
TOTAL	10	10	10	30



Graph 1: The mean volume of fluid used to create tamponade

Table 3: Comparison of Different Modification of CBT

	Conv. CBT	CBT with tip cut	CG-BALLOON
COST	>200-300RS when vicryl/silk used	100rs	100rs
TIME CONSUMPTION	Time consuming 2min22sec	Quick 52secs	Quick 1min04secs
METHOD	EASY	EASIEST	EASY
CHANCES OF LEAKAGE	HIGHER, due to slippage of knots	LOW	LOW
CHANCES OF LUMEN OCCLUSION	HIGHER, due to tight knot	LOW	LOW
UTERINE DRAINAGE PORT	ABSENT	ABSENT	PRESENT
NO. OF ATTEMPTS	More than one needed	Usually single	Usually single
CHANCES OF EXPLUSION	MORE, tight vaginal packing is must	LESSER, less need of vaginal packing	NIL, usually no need of vaginal packing
SUCCESS RATE	80%	90%	100%
DEFLATION	DIFFICULT, as clamp or thread is used	EASY	EASY



Graph 2: Duration of tamponade required

Table 4: Need of Oxytocin Infusion

20 IU	Conv. CBT	CBT with tip cut	CG-BALLOON
<12 hours	5	8	10
12-24hours	2	1	0
>24 hours	2	0	0

Discussion

In our study, in 27 out of 30 patients (81%), condom catheter balloon successfully controlled bleeding and no additional intervention was required. Tindell K et al conducted a systemic analysis to evaluate the effectiveness of various types of uterine balloon tamponade in the management of PPH in resource poor settings.¹⁷ In these studies, uterine balloon tamponade successfully treated intractable PPH in 234 out of 241 women. Akhter S et al evaluated the efficacy of hydrostatic condom catheter to control PPH due to atonicity and morbid placental adhesions in 23 patients. In all 23 cases bleeding was successfully controlled.¹⁸

CBT is the easiest and cost effective tamponade method for control of PPH with least training required. The mean time were taken to assemble the appartus was 1min 26sec and the fastest to assemble was CBT with tipcut and CG Balloon. In our study the mean time taken to arrest bleeding after the application of the balloon tamponade was 6.66 ± 1.98 minutes which was comparable to the study by Rathore AM et al (6.06 minutes).²⁰ And

the most effective modification was CG-balloon which stopped bleeding in 1-5 mins.¹⁹ While waiting for arrest of haemorrhage, simultaneous arrangements can be done to proceed to surgical measures. So waiting for 10 - 15 minutes for the haemorrhage to stop while patient and operation theatre are prepared for laparotomy can be justified, when weighed against the radical procedures like hysterectomy. Hence guarded wait can prevent radical procedures, more importantly so in primiparous women, and the much valuable uteri can be salvaged. Average blood loss in this study was 1.65 litres which was comparable to the study by Rathore AM.²⁰

In our study the condom catheter tamponade was placed in situ for a mean duration of 22.56 ± 3.84 hours. 60% of cases required tamponade for 15-25 hours. 100% of CG-balloon were removed within 24 hours with mean of 18 hours . It was due to easy contractability of uterus due to uterine port. In the study by Rathore AM²⁰ and Nalini M¹⁹ duration of tamponade was between 24 to 28 hours and 12-24 hours respectively.

Few technical difficulty were encountered leading to expulsion of tamponade. There was 6% leakage, 9% slippage, 6% occlusion of lumen and total 9% of failure of CBT. And 90% problem were encountered in conventional CBT.

Conclusion

We concluded that balloon tamponade method should become a familiar component of existing guidelines for the management of PPH, although not as an isolated form of therapy and modification of conventional CBT should be used as a second line of management in Atonic PPH.

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