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Research Article

BALLOON TAMPONADE: A CRUSADER AGAINST POSTPARTUM HEMORRHAGE

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ABSTRACT

This study was aimed to evaluate the effectiveness of uterine balloon tamponade with condom catheter in the management of postpartum haemorrhage (PPH) not responding to standard therapy. This prospective study was done over a period of three years in 301 patients and condom balloon tamponade was found highly effective in the management of postpartum hemorrhage approaching to success rate of 95.6%.

Mean age of 301 women was 25.2 years and average gestation age was 37.12±3.31 weeks. Most common cause of PPH was uterine atony (80.7%) and average blood loss was 1450 ml. Mean volume of fluid required to inflate balloon was 379.93 ml. Average time taken to arrest bleeding was 7.2 minutes and catheter removal was done with mean duration of 25.37 hours and no further complication was observed. To conclude, it is a simple, low cost, easily available alternative to manage PPH especially in resource poor developing countries.

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INTRODUCTION

Despite advances in medical treatment obstetric hemorrhage remains a significant contributor to worldwide maternal morbidity and mortality (Lalonde et al, 2006; WHO 2005). More than 30% of maternal deaths are attributed to postpartum hemorrhage (PPH) (Khan KS, 2006). Ninety nine percent of all maternal deaths occur in poor resource settings (WHO 2010)⁴. However death from PPH can largely be avoided through proper prevention, diagnosis and management (Karoshi M, 2009; RCOG, 2009). Most cases of primary PPH are caused by uterine atony often a result of prolonged labor, pre-eclampsia, a history of PPH in previous pregnancy. Although active management of the third stage of labour can prevent up to 60% of PPH cases (WHO, 2006).

Postpartum haemorrhage involve a stepwise approach which after exclusion of retained products and genital tract trauma involves uterine massage and various uterotonic agents such as oxytocin, ergometrine, misoprostol and prostaglandin F_{2α} (PGF_{2α}) (RCOG, 2008). If these attempts prove unsuccessful, operative therapy must be considered, including laparotomy for systemic devascularization, uterine compression sutures or hysterectomy. Since 1983, when Goldrath MH⁹, 1983, published evidence that insufflating a Foley catheter in the uterus could achieve tamponade, various case series and studies have suggested use of different uterine balloon tamponade

(UBT) devices in treating PPH. Condous GS et al, (2003) also evaluated tamponade test in the management of massive PPH in 16 patients and success was met in 14 (87.5%) of them. Two (12.5%) gave negative tamponade test and hence underwent laparotomy. This diagnostic test rapidly identified patients with PPH who required laparotomy-. Doumouchsis et al (2007) conducted a systemic review of conservative, non surgical treatment options for PPH and found that the reported 84% success rate of UBT does not significantly vary from surgical treatment outcome.

As per WHO recommendations, the use of balloon tamponade is recommended for the treatment of PPH due to uterine atony if women do not respond to uterotonic. WHO, FIGO, ACOG, ICM recognize balloon tamponade as a method that could significantly improve the management of intractable PPH, especially in low resource areas where blood transfusions are not available and surgical interventions are not an option. Intrauterine balloon tamponade may also be used as a temporizing measure while awaiting transfer or to resuscitate the patient.

Commercially available catheters like Sengstaken Blackmore tube, Rusch urological catheter and Bakri balloon which are commonly used but have a prohibitory high cost while condom catheter is a cheap and easily available alternative to catheter which can act as boon in low resource settings. So, this

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prospective study was planned to evaluate the effectiveness of condom catheter tamponade in atonic PPH after failure of medical management.

MATERIALS AND METHODS

Location and duration of study

This study was a prospective observational study carried out at G.S.V.M. Medical College, Kanpur over a period of three years between January 2013 to February 2016. All patients who delivered either vaginally or by caesarean section and developed PPH unresponsive to medical treatment and those patients who were high risk to develop PPH were included in the study. Women having retained placenta, uterine rupture, chorioamnionitis and known uterine anomaly were excluded. The blood loss calculation was done by visual method including use of calibrated mops and suction apparatus.

Procedure of catheter placement

Condom tied at distal end of a sterile Foley’s catheter (14Fr) with silk thread. This condom-catheter assembly was inserted into the uterine cavity with a sponge holding forceps. At least 15 cm of the catheter was inserted in uterine cavity to assure proper placement. After insertion catheter bulb was inflated with 30 ml of normal saline, followed by retrograde filling of normal saline by an infusion set into the condom via catheter until the uterine fundus becomes firmly palpable or bleeding was controlled (whatever is earlier). Outer end of Foley’s catheter was clamped and tied with silk thread. Meanwhile a clenched fist was kept in vagina to prevent slippage of inflated condom. When condom was inflated to about 200 ml vaginal hand was removed. We routinely used sterile gauze packing to prevent slippage of condom catheter.

Constant assessment of uterine bleeding was done while inflating. If bleeding persisted inflation was continued in 20 ml aliquots. We have set arbitrary limit of 500ml. Bleeding was observed for next 15 minutes. If bleeding stopped, tamponade was continued till next 12 – 24 hours. In some patients with very severe anemia and coagulopathy it was kept up to 48 hours. Uterine contractility was maintained by oxytocin drip (20 U in 500 ml normal saline) for 6- 24 hours depending upon the case. Broad spectrum prophylactic antibiotics were administered intravenously as long as condom catheter was in situ. The balloon was deflated slowly (at the rate of 15-20 ml per minute) but not removed until next 30 minutes. Oxytocin infusion was continued during deflation. If the patient did not bleed for next 30 minutes, the catheter balloon assembly was removed.

Insertion at cesarean section

If balloon tamponade was followed after caesarean delivery, the catheter was inserted through the uterine insertion (pushing the tip to the fund us and the drainage port through the cervix into the vagina) or transvaginally and inflated after the uterine incision was closed.

Failed catheter placement

Failed catheter placement was defined as either the inability of the operator to insert the catheter inside the uterine cavity or the inability to inflate the balloon after intrauterine insertion.

Statistical analysis

Data analysis was done using simple measure like mean, standard deviation (SD) etc.

RESULTS

In this study period 11876 deliveries took place of which 498 (4.2%) were complicated by postpartum hemorrhage. Balloon tamponade was attempted in 301 patients but placement was unsuccessful in 5 patients and proper placement was achieved in 296 patients (98.3%) and tamponade was failed in 8 patients. Ultimately, baloontamponade was successful in 288 patients (95.6%). (Table 1).

Table 1 Outcome of Procedure (N=301)

Success rate	288(95.6%)
Failure	
Failure of catheter placement	5(1.6%)
Failed balloon tamponade	8(2.6%)

Majority of patients were in age group of 20 – 30 years (67.4%) and mean age was 25.2 years. 68.4% women had parity more than 3 and estimated gestational age was between 32 to 41 weeks with maximum (62.8%) women had gestation age >37 weeks. Majority of patients (70.1%) were unbooked in which 54.9% were referred from remote areas either in advance labour or immediate after delivery. 176 (58.5%) were delivered vaginally and rest by caesarean section. (Table 2).

Table 2 Profile of patients (n= 301)

Age		Mean
<20 yrs	32 (10.6%)	
20-30 yrs	203 (67.4%)	25.2
>30 yrs	66 (21.9%)	
Parity		
G ₁	43 (14.2%)	
G ₂	52 (17.2%)	
G ₃	110 (36.5%)	3.2±1.1
≥G ₄	96 (31.9%)	
Gest. Age		
<34 weeks	26 (8.6%)	
34 – 37 weeks	86 (28.5%)	37.12% ± 3.31
>37 weeks	189 (62.3%)	
Booking status		
Booked	90 (29.9%)	
Unbooked	211 (70.1%)	
Referred	116 (54.9%)	
Mode of Delivery		
Vaginal	176 (58.5%)	
Caesarean	125 (41.5%)	

All patients were anemic in which 71.1% had severe anemia (Hb< 7 gm). Average amount of blood loss was 1450 ml. Average whole blood / packed cell transfusion received by the patients in the study was 3.02 units (range 1 – 6) 1.21 units FFP (range 0-8) and 1.01 units of platelets (range 0-8) (Table 3).

Table 3 Clinical Condition of Patients (n=301)

Anaemia Severe	301 (71.09%)
Mean systemic BP	92 ± 10
Any amount of blood loss	1450 ml
Any blood transfusion	3.02 units
FFP	1.21 units
Platelets	1.01 units

Atonicity was the major cause found in 80.7% patients followed by placental site bleeding (17.9%) (Table 4).

Table 4 Causes of PPH (N = 301)

Atonic	243 (80.7%)
prolonged	91 (30.2%)
Obstructed	53 (17.6%)
Grand multigravida	88 (29.2%)
Twin	07 (2.3%)
Polyamnios	04 (1.3%)
PlacentalSite bleeding	54 (17.9%)
Coagulopathy	4(1.33%)

Bleeding was controlled in 288 patients. In rest 8 patients, PPH was not controlled. B-Lynch sutures were applied and systemic devascularisation was done. But inspiteof all efforts, 4 patients landed up in hysterectomy having multiple risk factors and there was no maternal death. Mean volume of fluid used to create tamponade was 379.93 ml (Table 5)

Table 5 Amount of Fluid Required To Inflate Condom Catheter (N=296)

	Mean
<200 ml	5 (1.6%)
200 – 300	48(16.2%)
300 – 400	112 (37.8%)
>400	131 (44.2%)

Bleeding was controlled in 86.1% cases within 10 minutes and mean time taken to arrest bleeding after condom catheter balloon tamponade was 7.2 minutes (Table 6). On average the condom catheter tamponade was placed in situ for 25.37 hours (Table 7).

Table 6 Mean time taken to arrest Bleeding After Application of Condom Catheter (N=296)

	Mean
<5 min	63 (21.2%)
6 – 10 min	192 (64.9%)
10 – 15 min	41 (13.8%)

Table 7 Duration of Catheterization (N=296)

	Mean
12 hours	36 (12.1%)
12 – 24 hrs	14 (47.6%)
24 – 48 hrs	99(33.4%)
>48 hrs	20 (6.7%)

There was no major complications except in 10 patients who had complain of abdominal pain in follow up of 6 weeks.

DISCUSSION

PPH a disastrous complication of labour, is a leading problem faced by obstetricians all over the world. It gives a very small window of time to save the life of the patient who if develops intractable bleeding can quickly become hemodynamically unstable and develop a cascade of complications which can lead to death of the patient.

We therefore follow the protocol of achieving hemostasis within one (golden) hour of beginning of PPH. In keeping up with the policy, we go in a step wise 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 any surgical intervention if

needed. The intrauterine balloon is believed to act by exerting inward to outward pressure that is greater than the systemic arterial pressure to prevent bleeding.

In this prospective study we found that condom balloon tamponade was highly effective in the management of postpartum hemorrhage unresponsive to standard therapy, approaching to success rate of 95.6%which is comparable to other studies done by [Ahmad SN et al \(2016\)](#), [Rathore AM et al \(2012\)](#), [Rather et al \(2010\)](#) and [Shivkar et al \(2003\)](#), in which success rate of condom balloon tomponade was 93.9%, 94%, 96.2% and 93.2% respectively. In some other studies by [Akhter S et al \(2003\)](#), [Thapa K et al \(2010\)](#) and [Lydia R et al \(2008\)](#), successful condom balloon tamponade was reported in 100% cases although sample size of studies was small. In systemic review by [georgiou C et al \(2009\)](#), success rate of uterine balloon tamponade was 80-100%. [Tindell K et al \(2012\)](#) also conducted a systemic analysis to evaluate the effectiveness of various types of uterine balloon tamponade in the management of PPH in low resource poor settings. Condom catheter UBT method was used to treat 193 cases of PPH and was successful in 186 cases (96.4%). Condom was most often filled with 250-500 ml saline and time required for PPH to controlled after placement of the condom catheter ranged 4-15 minutes. In our study, mean age was 25.2 years, parity 3.2±1.1 and mean gestational age was 37.12±3.31weeks which was comparable to study done by [Lohano R et al \(2016\)](#), in which mean age, parity and gestational age was 26.4 years, 3.4±1.3 and 37.81±1.67 weeks respectively³⁰. Majority of patients were unbooked and referred. Most of them had severe anemia and multiple complications.

Atonicity was major cause of PPH similar to studies done by [Ahmad SN et al](#), [Akhtar S et al](#) and [Rathore AM et al](#)^{21,22,25}. Average blood loss in our study was 1450 ml which was comparable to studies done by [Ahmad SN](#) (1.48 litre), [Rathore AM et al](#) (1330 ml), [Lohano R et al](#) (1155.8 ml) and [Sheikh et al in 2006](#) (≥1500 ml).

Mean volume of fluid required to inflate condom catheter was 379.93 ml with range of 180-480 ml which was comparable to studies done by [Ahmad SN et al](#) (381.06 ml), [Akhtar S et al](#) (336.4 ml) and [Rather et al](#) (342.8 ml) while mean amount of fluid required by [Rathore et al](#) was 409 ml. Till date maximum volume of fluid a condom catheter can hold has not been described, so the end point for fluid inflation was till the bleeding stopped and not the upper capacity limit as in case of other devices like Sengstaken black more, foley’s catheter, bakri balloon and Rusch urological catheter, all of which have a defined upper limit.

In our study the mean time taken to arrest bleeding after the application of balloon tamponade was 7.2 minutes while in studies by [Ahmad SN et al](#), [Rathore AM et al](#) average time was 6.66 and 6.06 minutes respectively. While waiting for arrest of hemorrhage, simultaneous arrangement can be done to proceed to surgical measures. So waiting for 10-15 minutes for the hemorrhage to stop while patient and operation theatre are prepared for laparotomy can be justified. Our study offers practical data on catheter placement including the range of volumes used to inflate the balloons and duration of therapy.

In our study we routinely use sterile roller gauze for vaginal packing to prevent condom catheter from falling out of uterus.

In systemic analysis conducted by Tindell K *et al*, seven of eight studies (n=191/193 women) used vaginal pack to prevent slippage of condom catheter. One study did not report any procedure to maintain placement of uterine balloon tamponade (UBT). No study reported the UBT falling out before it was deliberately removed.

We used oxytocin infusion for 6-24 hours post catheter placement depending upon severity of anemia and associated complications; while in systemic review by Tindell K *et al* six out of eight studies, described running an oxytocin infusion for up to 6 hours from the time of insertion until the time of removal²⁹. Shivkar *et al* did not report use of any uterotonics concurrent with condom catheter (n=73). In one successful case reported by Manaktala *et al* (2011), oxytocin was administered only during the removal of condom catheter³².

In this study, condom catheter was kept ranging from 12 to 48 hours depending upon clinical condition. The length of time reported between insertion of condom catheter and removal ranged widely from >24 hours to as long as 72 hours. Other studies (n=87) reported duration of placement <24 hours.

In this study, we routinely used prophylactic antibiotics for 24-48 hours as per the case. In systemic review by Tindell K *et al* also, 7 out of 8 studies reported prophylactic use of broad spectrum antibiotics. Shivkar *et al* did not report using any antibiotic with condom catheter and no case of infection and fever reported in their case series (n=73).

In this study apart from failed catheter placement and mild abdominal pain (10 cases), no other complication like fever and infection was noted. Similarly no reports of increased infection rates, fever or endometritis with longer use of condom UBT was noticed in systemic review of all 8 studies by Tindell K *et al*.

Although in our study we used balloon tamponade for atonic PPH only, in other studies it was also used in traumatic PPH. In resource poor countries like ours, where a lot of deliveries take place at peripheral centres, such low cost and minimal skill requiring device can manage PPH and ultimately able to prevent maternal morbidity and mortality.

Limitation of this study is that condom catheter is not compared with other uterine balloon tamponade devices and long term outcomes like asherman's syndrome, menstrual disturbances and future fertility were not studied.

CONCLUSION

Post partum haemorrhage is a potentially life threatening event. In order to meet the Millenium Development Goals, we must achieve a reduction in deaths due to postpartum haemorrhage which is the major contributor in developing countries. Balloon tamponade with condom catheter is a simple, low cost, easily available alternative to manage PPH especially in resource poor underdeveloped and developing countries. It does not require any special training or technique, so even trained midwife can apply it. Uterine balloon tamponade has the potential of being a life saving procedure and should be an integral part of all obstetric emergency protocol for massive PPH as it may prevent the need for hystrectomy and therefore preserve reproductive capacity as well as prevent the operative morbidity in well selected cases. There should

also be a low threshold for prophylactic use of balloon tamponade in women at high risk of PPH, considering its rapid placement, immediate results and easy removal, low complication rate and ability to maintain reproductive ability. In this prospective study condom catheter successfully controlled PPH in 95.6% and it was certainly 100% successful in reducing blood loss while shifting the patients who required laparotomy.

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