

DOI: <http://dx.doi.org/10.18203/2320-1770.ijrcog20184513>

## Original Research Article

# Evaluation of uterine condom catheter tamponade in management of atonic postpartum haemorrhage in poor responders to medical management

Aditi Aggarwal, Ashoo Gupta\*, Puneeta Mahajan, Ketan Zala

Department of Obstetrics and Gynecology, Sanjay Gandhi Memorial Hospital, New Delhi, Delhi, India

**Received:** 25 August 2018

**Accepted:** 27 September 2018

### \*Correspondence:

Dr. Ashoo Gupta,

E-mail: [ashoogupta99@yahoo.com](mailto:ashoogupta99@yahoo.com)

**Copyright:** © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

## ABSTRACT

**Background:** Postpartum haemorrhage is major cause of obstetric morbidity and mortality. It is estimated that worldwide, 1 woman dies every 4 minutes due to postpartum haemorrhage. The incidence is said to be approximately 4% in vaginal deliveries and 7% in caesarean deliveries. The most common cause of postpartum haemorrhage is uterine atony which accounts for 80% cases of PPH. In patients poorly responding to medical management and before major surgical intervention and hysterectomy is envisaged, uterine tamponade is reasonable option for management of PPH. The condom catheter has been shown to be effective in managing severe PPH, and is a simple, cheap and quick intervention which may prove valuable in resource-poor countries. However, limited data is available regarding efficacy of uterine condom catheter tamponade. In this study, authors hypothesized that uterine condom catheter tamponade will reduce the need for surgical intervention by 70±10% for management of atonic PPH in patients who respond poorly to medical management.

**Methods:** Prospective data of 26 women who went into atonic Primary PPH was collected over period of one year.

**Results:** Out of 26 women who had atonic PPH, 12 were inserted with condom balloon catheter after medical management. Success rate was 11/12 (91.7%).

**Conclusions:** Authors conclude that uterine condom catheter tamponade is 91.7% effective in controlling atonic postpartum haemorrhage poorly controlled with medical management, and hence is effective in averting laparotomy on 91.7% such patients.

**Keywords:** Condom catheter, Maternal morbidity, Maternal mortality, Postpartum haemorrhage, Tamponade

## INTRODUCTION

Postpartum haemorrhage or excessive blood loss after child birth is major cause of obstetric morbidity and mortality in both developed and developing countries. Haemorrhage probably has killed more women than any other complication of pregnancy in the history of mankind. It is estimated that worldwide, 1 woman dies every 4 min due to post-partum haemorrhage with an average yearly incidence of about 1,40,000 women deaths, the majority of which is contributed by women in

underdeveloped and developing countries.<sup>1</sup> The incidence is higher in operative deliveries especially when conducted under general anaesthesia. The incidence is said to be 3.9% in vaginal deliveries and 6.4% in caesarean deliveries.<sup>2</sup> A significant proportion of deaths from PPH are potentially preventable. Thus, those caring for pregnant women must be aware of the risk factors for PPH and be prepared to deal aggressively with this complication when it does occur. The most common cause of PPH is uterine atony which is responsible for at least 80% of cases of PPH.

The principle of a fluid structure exerting a tamponade effect to stop bleeding has been described in literature. In patients poorly responding to medical management and before major surgical intervention and hysterectomy is envisaged uterine tamponade is reasonable option for management of PPH. The successful use of inflated stomach balloon (300ml) of a Sengstaken Blakemore tube has been reported<sup>3</sup>. This method is however complex to use and expensive. The idea of using a condom as a balloon tamponade was first generated and evaluated in Bangladesh in 2001 by Dr. Sayeba Akhter to fill a need and in response to the high cost of commercially available uterine balloon tamponade devices.<sup>3</sup> The cost of condom catheter is low, estimated in the range of 150 rupees (US\$3) to 300 rupees (US\$6). The use of condom catheter represents a cheap, simple and quick intervention which may prove invaluable in resource-poor countries.<sup>3,4</sup> Success in controlling haemorrhage is known immediately. No special expertise or extraordinary equipment is needed. It should be considered in women with massive postpartum haemorrhage who respond poorly to medical management, especially when other options are not available. Besides being used as a therapeutic intervention it helps obstetrician to identify which women will require laparotomy.

In addition, limited data is available regarding efficacy of uterine condom catheter tamponade. The Indian data on use of condom catheter balloon in management of postpartum haemorrhage is scanty. Hence, this study was carried out to evaluate the efficacy of this method which is cost effective and will avoid surgical intervention, and thus will decrease morbidity in these poor surgical risk patients.

## METHODS

Authors conducted an open label randomized controlled trial in the labour room setting of Department of Obstetrics and Gynaecology at Sanjay Gandhi Memorial, Mangolpuri, Delhi during the period of 1<sup>st</sup> April 2014 to 30<sup>th</sup> April 2015. In the intervention group, uterine tamponade using condom catheter balloon was inserted; and in the control group, laparotomy followed by surgical intervention for PPH was done (haemostatic compression sutures (B-lynch, Hayman, Cho-square); stepwise devascularization (bilateral uterine artery and ovarian arteries ligation, internal iliac ligation); hysterectomy in that order). Primary outcome variables assessed were number of cases who responded to uterine condom catheter tamponade therapy; time required to stop bleeding in both the groups and blood loss in each group. Secondary outcome variables included failure rate (percentage of patients who do not responded to uterine condom catheter tamponade but responded to surgical intervention); subsequent morbidity in both groups over next one week which involved percentage of patients developing puerperal sepsis (episodes of fever >100.40F, TLC >14,000) secondary haemorrhage, signs of endometritis; blood and blood products transfusion

needed in both groups; maternal mortality; complications; and hospital stay in each group.

In present study, authors included patients who responded poorly to medical management i.e. patients who had been managed medically according to WHO protocol for PPH, but after receiving only up to 3 doses of injection Methargine 0.2mg i.v. and up to 4 doses of inj Carboprost 200 µg i.m. and Misoprost 800µg per rectally.

### *Inclusion criteria*

All women who had non-traumatic atonic postpartum haemorrhage, were hemodynamically stable and responded poorly to the usual departmental medical management protocol of PPH were eligible for the study.

Ethical clearance was obtained from Institutional review board (ethical committee). Consent was sought from those eligible.

### *Exclusion criteria*

Refusal of consent, bleeding due to genital tract trauma or retained placental tissue, known allergy to latex, hemodynamically unstable patients, contraindications to specific drugs, PPH patients referred from outside were excluded.

24 women satisfied the inclusion criteria hemodynamically stable patients (stage 1 and 2 of Benedetti's classification), non-traumatic atonic PPH who poorly responded to medical management, delivered at labour room of Sanjay Gandhi Memorial Hospital during the study period.

### *Implementation of protocol*

Computer generated random number sequence was generated. Using these, enrolled women were randomly assigned to receive either condom catheter uterine tamponade (study group) or surgical intervention for PPH (control group).

In the condom catheter tamponade group, condom tied over proximal end of Foley's catheter with silk thread was inserted inside the uterine cavity through vagina digitally or with sponge holding forceps in vaginal deliveries; and through the uterine incision with distal end of condom catheter brought out through cervical opening in caesarean deliveries. Condom catheter balloon was filled with (200-500 ml) saline till bleeding was arrested. Vagina was packed with gauze. Oxytocin infusion (40 units in 1 litre saline) was continued for 30 minutes after removal of condom catheter. Removal of condom catheter was attempted after 8-48 hours in the OT setting if patient was hemodynamically stable and bleeding stopped. Patients in the condom catheter group were taken up for surgical intervention (hysterectomy); and labelled as failure when bleeding from vagina

continued even after inflation of balloon with 500 ml and/or 15 minutes had elapsed since the start of procedure, patient became hemodynamically unstable, bleeding recurs, increase in fundal height >1cm, expelled condom catheter or bleeding occurred after condom catheter removal after 48 hours. However, if balloon was deflated before 48 hour and patient started bleeding again, balloon was re-inflated.

In the control group, surgical intervention for atonic PPH (compression sutures (B-lynch, Hayman, Cho-square), stepwise devascularisation and hysterectomy in that order) was done. Intraoperatively, amount of blood loss (from the start of surgery till the control of bleeding during surgery), duration of surgery and any surgical complication was noted. Post Operatively, patient's vitals, uterine fundal height, signs of any vaginal bleeding, urine input output via an indwelling Foley catheter and serum sodium was estimated if oxytocin was used >12hours. Prophylactic broad-spectrum antibiotic cover was given.

Blood loss estimation was done by collecting all the blood after delivery of baby in a pre-weighed yellow bag. 4x4 gauze sponges which have an average capacity of 10±2 were also used. Maternal blood in placenta (150ml) was also accounted for. A quick, more accurate bedside estimation of acute blood loss was made using the formula: (No. of soaked 4x4's) x (10ml) + (150ml maternal blood in placenta) + (amount of blood in yellow bag).

The defined primary and secondary outcomes were measured and documented.

Statistical testing was conducted with the SPSS 17.0 version.

## RESULTS

A total of 24 patients with massive postpartum hemorrhage poorly controlled by medical management were recruited for the study. The study group included 12 women who received uterine condom catheter tamponade whereas the control group comprised 12 women who received surgical intervention for control of PPH. In the condom catheter group, laparotomy for PPH was needed in only 1 out of 12 patients (success rate-91.7%). Mean blood loss was 0.93 litres in condom catheter group, which was significantly lower as compared to 1.83 litres in surgical intervention group (p value 0.004). Average time taken to control bleeding in condom catheter group was 10 minutes, which was significantly lower as compared to 45 minutes in surgical intervention group (p value <0.001). Need for blood transfusion was significantly lower in condom catheter group (p value <0.001) (No. of blood transfusions: 10.18±1.54 in condom catheter group versus 59.33±28.57 in surgical intervention group). Subsequent morbidity in terms of infection was significantly lower in condom catheter group as compared to surgical intervention group (25%

vs 83.3%) (p value 0.026). Mean duration of hospital stay was 5.17±3.56 days in condom catheter group which was significantly lower as compared to 9.33±1.61 days in surgical intervention group (p value <0.001). Maternal mortality occurred in 1 out of 12 patients in both the groups, which was statistically insignificant.

**Table 1: Mean blood loss.**

	Group A	Group B	P value
	Mean±SD	Mean±SD	
Blood loss (L)	0.93±0.73	1.83±0.65	0.004

Mean blood loss was 0.93 litres (SD 0.73) in study group and 1.83 litres (SD 0.65) in control group; which was statistically significant (p value 0.004), which denotes that blood loss was remarkably lower in condom catheter group when compared with surgical intervention for control of postpartum hemorrhage. Maximum blood loss in study group was 1 litre and minimum blood loss was 500 ml. Maximum blood loss in control group was 3.6 litres and minimum blood loss was 1.2 litres. Blood loss in present study was calculated from the time of start of procedure (condom catheter tamponade in study group and surgical intervention in control group) till control of bleeding.

**Table 2: Distribution of patients according to time taken to control bleeding.**

Group A (n=11)	Group B (n=12)	P value
Median-10 min	Median-45 min	
IQR 9-12	IQR 40-80	<0.001

In the study group, the average time taken to stop bleeding from start of condom catheter placement was 10 minutes, with minimum and maximum time being 8 minutes and 12 minutes respectively. In the control group, the average time taken to stop bleeding from start of surgical intervention was 45 minutes, with minimum and maximum time being 35 minutes and 120 minutes respectively. Time taken to stop bleeding is significantly lower in condom catheter study group as compared to surgical intervention control group, with p value of <0.001.

**Table 3: Distribution of patients according to need for blood transfusion.**

	Group A	Group B	P value
	Mean±SD	Mean±SD	
No. of whole blood (WB)/ packed cells	10.18±1.54	59.33±28.57	<0.001
No. of fresh frozen plasma (FFP)	4.44±3.43	4.83±3.10	0.789
No. of platelets (PRP)	3.50±0.71	6.00±2.83	0.349

All patients needed blood/ blood product transfusion. A total of 40 units of whole blood/ packed cells, 40 units of fresh frozen plasma and 7 units of platelets (PRP) were transfused in study group; and 66 units of whole blood/ packed cells, 58 units of fresh frozen plasma and 12 units of platelets were transfused in control group. The mean of whole blood/ packed cells transfused in study group was 10.18 and that in the control group was 59.33, which was statistically significant (p value <0.001), which denotes

that need for blood transfusion was significantly lower in study group as compared to control group.

1 out of 12 patients (8.3%) needed hysterectomy in study group, and 2 out of 12 patients (16.7%) needed hysterectomy in control group. Results in terms of need for hysterectomy in both groups were not statistically significant (p value 1.00).

**Table 4: Distribution of patients according to need for hysterectomy.**

Need for hysterectomy	Group A		Group B		P value
	Frequency	%	Frequency	%	
No	11	91.7	10	83.3	1.000
Yes	1	8.3	2	16.7	
Total	12	100	12	100	

**Table 5: Distribution of patients according to the episodes of fever in both groups.**

Episode of fever	Group A		Group B		P value
	Frequency	%	Frequency	%	
No	9	75.0	2	16.7	0.026
1	2	16.7	3	25.0	
2	0	0.0	6	50.0	
>2	1	8.3	1	8.3	
Total	12	100.0	12	100.0	

Only 3 out of 12 patients (25%) had episodes of fever >100.40 F after application of condom catheter tamponade in study group, and only 1 out of 3 such patients (8.3%) had more than 2 episodes of fever >100.40 F. The cause of fever in 1 patient was identified as urinary tract infection and in rest 2 patients, cause could not be identified, and fever subsided in next 48

hours. The blood and high vaginal swab cultures did not show any growth in any of the 3 cases. The total leukocyte count was between 18,000- 21,000/cu mm in all the 3 cases. In the control group, 10 out of 12 patients (83.3%) had episodes of fever >100.40 F postoperatively. Out of these 10 patients, 6 patients (50%) had 2 episodes of fever >100.40 F and 1 patient had >2 episodes of fever >100.40 F postoperatively.

**Table 6: Distribution of patients according to hospital stay.**

Duration of hospital stay (days)	Group A		Group B		P value
	Frequency	%	Frequency	%	
<7 days	11	8.3	0	0.0	<0.001
7-14 days	0	0.0	12	33.3	
>14 days	1	8.3	0	0.0	
Total	12	17	12	33	
Mean±SD	5.17±3.56		9.33±1.61		<0.001

**Table 7: Distribution of patients according to maternal mortality.**

Maternal mortality	Group A		Group B		P value
	Frequency	%	Frequency	%	
No	12	91.7	11	91.7	1.000
Yes	0	8.3	1	8.3	
Total	12	100	12	100	



Duration of hospital stay was <7 days in 11 patients (91.4%) and >14 days in only 1 patient (8.3%) in study group. Duration of hospital stay was between 7-14 days in all 12 patients with surgical intervention in control group. Results of study in terms of duration of hospital stay in both the groups was statistically significant (p value <0.001) with decreased duration of hospital stay in condom catheter study group.

No maternal mortality occurred in study group. 1 (8.3%) maternal mortality occurred in control group. No statistically significant differences (p value 1.00) in terms of maternal mortality in both the groups was seen.

## DISCUSSION

Uterine condom catheter tamponade works on the principle of exerting mechanical compression on uterine vascular sinuses, thus helping in achieving haemostasis. The 'intrauterine balloon' is believed to act by exerting an inward-to-outward pressure, that is greater than the systemic arterial pressure to prevent continual bleeding. Also, it exerts hydrostatic pressure effect on uterine arteries. Condom catheter balloon conforms naturally to the contour of uterus, does not require complex packing techniques, and is a cheap, simple and quick intervention in controlling haemorrhage. Success in controlling haemorrhage is known immediately. No special expertise or extraordinary equipment is needed. In present study, condom catheter tamponade was successful in 91.7% of cases, and only 1 out of 12 patients needed hysterectomy. In study by Rather SY et al, success rate was found to be 96.2%; whereas in some other studies, condom catheter tamponade has been found to be successful in 100% patients (Akhter et al, Bagga et al, Thapa K et al).<sup>3,5-7</sup> Nahar et al reported success rate of 98.1%, whereas Shivkar et al reported success rate of 93.2% in controlling postpartum haemorrhage in 53 patients due to placenta accrete, placenta previa and uterine atony using condom catheter balloon tamponade.<sup>8,9</sup> In present study also, uterine condom catheter tamponade was able to successfully control bleeding in 2 out of 3 patients having postpartum haemorrhage due to placenta accreta and placenta previa; and in 1 patient with coagulopathy. In studies by Akhter et al and Thapa K et al, in all the patients bleeding stopped within 15 minutes; whereas Manaktala et al reported maximum and minimum time taken to stop bleeding of 12 minutes and 4 minutes respectively; which was comparable to present study.<sup>3,7,10</sup> Mean duration for which tamponade was left in situ in present study was 18.91 hours which was comparable to that of 26.14 hours in study by Condouset al and 24-48 hours in study by Akhter et al.<sup>3,11</sup> Postpartum haemorrhage, according to Cochrane review (February 2014).<sup>12</sup>

Mean amount of fluid filled in condom catheter balloon was 413.64 ml in present study; which was comparable with the studies by Tort J et al (443.4 ml) and Thapa K et al (425ml).<sup>7,13</sup> Average blood loss of 0.93 litre as found in

present study in condom catheter group as compared to 1.83 litres in surgical intervention group which is significantly lower. In study by Thapa K et al, average blood loss was found to be 1.2 litres whereas in study by Condous et al, average blood loss was found to be 3.1 litres.<sup>7,11</sup> Quantification of blood loss by different methods can lead to underestimation or overestimation of blood loss. In present study, blood loss estimation was done by visual estimation and calibrated mops, pads and gauze pieces. When health providers are asked to quantify blood loss in stimulated vaginal or operative deliveries, the results are inaccurate especially at higher volumes. According to Cochrane review, no studies are available till date which compares blood loss in surgical procedures for postpartum haemorrhage.<sup>12</sup>

In study by Akhter et al, each patient on an average received 3.23 units of blood, which is comparable to present study.<sup>3</sup> In study by Rather et al, each patient received on an average 2.5 units of blood whereas Condous et al reported an average of 6.2 units of blood per patient.<sup>5,11</sup> The difference in number of transfusions as compared to present study can be attributed to difference in mean estimated blood loss (0.93 litres versus 3.1 litres). No case of sepsis or endometritis or ulceration from pressure effect was noted in condom catheter study group in present study. Literature also does not report any major infectious morbidity associated with uterine condom catheter tamponade.<sup>14</sup> In present study, infectious morbidity in the surgical intervention control group was quite higher as compared to condom catheter study group (83.3% versus 25%). In study by Clark SL et al, 66% patients had infectious morbidity postoperatively after peripartum hysterectomy done for postpartum haemorrhage.<sup>15</sup> The main advantage of present study is that it is first of its kind in literature i.e. it is a randomized controlled trial which compares various parameters viz. blood loss, need for blood transfusions, time taken to stop bleeding, infectious morbidity, duration of hospital stay etc. in two different modalities of treatment (uterine condom catheter tamponade vs surgical intervention) for massive atonic postpartum haemorrhage poorly managed medically. Even after extensive search, authors could not find literature comparing blood loss and other parameters in surgical management of postpartum haemorrhage. According to latest Cochrane review (Feb' 2014), no trials are available that evaluate various surgical techniques for women with primary postpartum hemorrhage.<sup>12</sup>

## CONCLUSION

Uterine condom catheter tamponade is simple, cheap, easy to use, easily available and effective modality to manage atonic postpartum haemorrhage. It can prove as a valuable tool in primary health care centers, subcentres etc; where facilities for laparotomy are not available immediately, especially while shifting the patient with atonic PPH poorly responding to medical management to higher centre; and also in tertiary level

hospitals while making arrangements for laparotomy. The procedure is simple and safe even in the hands of junior doctors and can be applied in labour room without any need for anaesthesia. There was no procedure related complications in this study.

Authors recommend that further studies should be conducted with bigger sample sizes to study the impact of uterine condom catheter tamponade on long term outcomes like future fertility, development of Asherman syndrome etc. Further research may be directed at further improvisation of this technique like an addition of a separate rubber catheter, to allow drainage of uterine cavity etc., and studying long term complications.

## ACKNOWLEDGMENTS

Authors would like to thank all the consultants, nursing staff and resident doctors for maintaining the records and data which helped in the study.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

## REFERENCES

1. Abouzahn C. Global burden of maternal death and disability. *Br Med Bull.* 2003;67:1-11.
2. Devine PC. Obstetrical haemorrhage. *Semin Perinatol.* 2009;33:76-81.
3. Goldrath MH. Uterine tamponade for the control of acute uterine bleeding. *Am J Obstet Gynecol.* 1983;147:869-72.
4. Akhtar S, Begum MR, Kabir J. Condom hydrostatic tamponade for massive postpartum haemorrhage. *Int J Gynaecol Obstet.* 2005;90:134-5.
5. Rather SY, Qadir A, Parveen S, Jabeen F. Use of condom to control intractable PPH. *JK Science.* 2010;12(3):127-9.
6. Bagga R, Jain V, Sharma S, Suri V. Postpartum haemorrhage in two women with impaired coagulation successfully managed with condom catheter tamponade. *Indian J Med Sci.* 2007;61:157-8.
7. Thapa K, Malla B, Pandey S, Amatya S. Intrauterine condom tamponade in management of postpartum haemorrhage. *J Nepal Health Res Counc.* 2010;8(16):19-22.
8. Nahar N, Yusuf N, Ashraf F. Role of intrauterine balloon catheter in controlling massive PPH: experience in Rajshahi Medical college Hospital. *Orien Med J.* 2009;32(3):682-3.
9. Shivakark S, Khadilkar SS, Gandhewar M. Pressure balloon therapy in uncontrolled obstetrical haemorrhage. *J Obstet Gynecol India.* 2003;53:338-41.
10. Manaktala U, Dubey C, Takkar A, Gupta S. Condom catheter balloon in management of massive nontraumatic postpartum haemorrhage during caesarean section. *J Gynecol Surg.* 2011;27:115-7.
11. Conous GS, Arulkumarah S, Symonds I, Chapman R, Sinha A, Razvi K. The tamponade test in the management of massive postpartum haemorrhage. *J Obstet Gynecol.* 2003;101:767-72.
12. Mousa HA, Blum J, Abon EL, Senom G, Shakir H, Alfirevic Z. Treatment for primary postpartum haemorrhage (Review). *Cochrane Database of Systematic Review.* 2014;2. Art. No: CD003249.
13. Tort J, Hounkpatin B, Popowski T, Traore M, Baodin C, Perrin R, et al. A randomized controlled trial to test the effectiveness of intrauterine balloon tamponade with condom catheter in severe postpartum haemorrhage management. A Feasibility study in Benin. *J Women's Health Care* 2013;2:4.
14. Tindell K, Garfinkel R, Abu-Hayder E, Ahn R, Burke T, Conn K, et al. Uterine balloon tamponade for treatment of postpartum haemorrhage in resource poor settings: A systematic review. *Br J Obstet Gynecol.* 2012;120:5-14.
15. Clark SL, Yeh S, Phelan JP, Bruce S, Paul RH. Emergency hysterectomy for Obstetric haemorrhage. *J Obstet Gynecol.* 1984;64:376.

**Cite this article as:** Aggarwal A, Gupta A, Mahajan P, Zala K. Evaluation of uterine condom catheter tamponade in management of atonic postpartum haemorrhage in poor responders to medical management. *Int J Reprod Contracept Obstet Gynecol* 2018;7:4592-7.