



ISSN: 0976-3031

Available Online at <http://www.recentscientific.com>

CODEN: IJRSFP (USA)

International Journal of Recent Scientific Research
Vol. 8, Issue, 3, pp. 16234-16239, March, 2017

**International Journal of
Recent Scientific
Research**

DOI: 10.24327/IJRSR

Research Article

INTRA UTERINE CONDOM BALLOON TAMPONADE-A LIFE SAVING MEASURE IN ATONIC PPH

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DOI: <http://dx.doi.org/10.24327/ijrsr.2017.0803.0107>

ARTICLE INFO

Article History:

Received 17th December, 2016
Received in revised form 21st
January, 2017
Accepted 05th February, 2017
Published online 28th March, 2017

ABSTRACT

Objective-To assess the effectiveness of intrauterine condom balloon tamponade in achieving haemostasis, in cases of atonic post partum haemorrhage.

Design-Prospective observational study

Setting-Emergency labour room of Obstetrics and Gynaecology Department of a tertiary care hospital & teaching institution

Study period- January 2013-December 2015

Material & methods-Thirty women having atonic PPH in whom active management of third stage of labour and uterotonics were not effective, were selected for this study.

With full aseptic and antiseptic precautions a condom was tied on a nasogastric tube and was inserted into the uterine cavity, the distal end of the tube was connected to an IV set through which 250-500cc normal saline was instilled to inflate the condom so as to achieve haemostasis.

Observation-46.6% women were between 25-30 yrs of age, 53.3% were multigravida. The gestational age was between 37-40 weeks in 80% cases. In 53.3% cases, there was some associated risk factor for PPH. In 72.72% cases placenta took longer time to separate.

In 66.6% women 250-500ml saline was instilled to inflate the condom balloon. It took 10-15 minutes time from insertion of the condom balloon catheter to achieve haemostasis in 73.3% women. The condom balloon catheter was kept in situ for 12-24 hrs in 73% women. Success rate of balloon tamponade was 90%. There was no infection in any case.

Conclusion-Intrauterine condom balloon tamponade is effective, cheap and requires little skill. It can be used as a second line intervention in the management of atonic PPH. Skilled birth attendants in remote areas can use this technique and then transfer the woman to tertiary care unit. This will help in saving many maternal lives.

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INTRODUCTION

Post partum haemorrhage accounts for a quarter of maternal deaths¹. Death from PPH can largely be avoided through proper prevention, diagnosis and management^{2,3}. 80% of maternal deaths can be prevented through actions that are effective and affordable in developing country settings [WHO, UNICEF & UNFPA -2001]. Active management of third stage of labour can prevent up to 60% cases of PPH⁴. But it still accounts for 31% of maternal deaths in Asia⁵.

Uterine atony is the commonest cause of PPH accounting for 70-80% of cases^{6,7}. If bleeding is controlled immediately severe PPH can be prevented and we can save the patient from severe morbidity and mortality. Unfortunately many women in resource scarce settings do not have access to good quality care for the delivery. They are therefore at high risk of morbidity or

death consequent to PPH^{8,9}. Uterotonic agents are the first line of management. If they fail, intrauterine balloon tamponade has been used as a second line procedure in women with PPH¹⁰.

WHO has recommended the use of balloon tamponade for the treatment of PPH due to uterine atony in its updated guidelines [2012]. FIGO included uterine balloon tamponade as a recommended second line intervention for the treatment of PPH in their updated guidelines 2012¹¹. In 1983 Goldrath published evidence that inserting foley's catheter in uterine cavity and inflating it with water could achieve tamponade¹². Among the type of balloons used to produce tamponade are Sengstaken-Blackmore tube^{13,14}- the Rush catheter¹⁵, the Bakri tamponade balloon catheter^{16,17} and the male condom balloon catheter^{18,19,20}.

Dr. Sayeba Akhtar introduced a novel device the male condom tied to the rubber catheter and used it for intrauterine balloon

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tamponade in 2001. This is very cost effective and easy to use method which requires minimum skill.

This study was carried out to find out the efficacy of intrauterine condom balloon tamponade in controlling atonic PPH.

MATERIAL AND METHODS

30 cases of post partum haemorrhage due to uterine atony were selected for the study from emergency & labour ward, Department of Obstetrics & Gynaecology of a tertiary care hospital & teaching institution. This prospective study was done between the period of January 2013 to December 2015. Selection criteria-Cases of atonic PPH following vaginal delivery in which 1st line of management by uterotonic drugs had failed.

For PPH WHO criteria has been used

- 500ml of bleeding
- 1000 ml of bleeding in cases of severe PPH

Exclusion Criteria

- Traumatic PPH
- Known cases of bleeding disorders
- Secondary PPH
- PPH in cases of Caesarean section
- Infection

Clinical evaluation of the all the cases was done in following manner

- History
- General examination
- Systemic examination
- Per abdomen examination
- Pelvic examination

Laboratory investigation

- Complete blood count
- BTCT
- Rh typing & ABO grouping
- Routine examination of urine
- HIV, Australia Antigen and HCV
- Coagulation profile if needed

Resuscitation of the patient was done by

- Establishment of I V line by two large bore intracath no 14
- Crystalloid infusion (normal saline/ringers lactate)
- Colloids if needed
- Oxygen by mask (6-8 lit/min).
- Syntocinon drip- 20 units in 500 ml of normal saline
- Antibiotics - Broad spectrum antibiotics- Ceftriaxone 1gm IV-BD, Amikacin 500mg BD and Metronidazole IV.
- Blood sample for cross matching
- Blood & blood products according to the severity of PPH & need.
- Transfer of the patient to Operation Theater

METHODS

Male latex condom which is available in hospital was used in the study.

The patient was put in lithotomy position and with full aseptic and antiseptic precautions this procedure was done. Indwelling catheterization was done. Condom was tied on the nasogastric tube with a thread 4-5cm from the tip. With the help of two Sims speculum the cervix was visualized. Anterior lip of the cervix was held by the sponge holder. The condom which was tied on the nasogastric tube was inserted inside the uterine cavity with the help of sponge holder or digitally for up to 14-15cm. IV transfusion set was attached to the distal end of the tube and the condom was slowly filled with normal saline. After filling the condom with 250ml of fluid we watched for the bleeding [tamponade test]. If there was no bleeding or the bleeding reduced we waited and observed. If the bleeding continued the condom was inflated with more fluid. The minimum amount of fluid which we used for this study was 250ml and maximum 500ml. We waited for 5-15 minutes to see the response, if the bleeding was controlled we clipped the nasogastric tube at 6-7cm from the cervix and cut the remaining portion of the distal end. Stopper was applied on the distal end of the vaginal portion.

A tight vaginal pack was done to keep the condom catheter in position. Oxytocin drip was given for 6 hours and prophylactic antibiotics were given. When the woman became stable and vital parameters improved we kept this condom balloon in situ for a minimum of 12-24 hrs. Then we slowly deflated the condom over 10-15 minutes and if there was no bleeding we removed it from the uterus and vagina. Close monitoring of the woman's vital was done for 24 hrs. In three patients, in which bleeding was not controlled by this method, surgical intervention had to be done.

Observations

Table I Distribution of cases according to age

Age (yrs)	No. of cases	Percentage
20-24 Yrs	6	19.99
25-30	14	46.66
>30	10	33.35
Total	30	100

Majority of cases belonged to age group of 25-30 Yrs
Mean Age = 13.62±1.231 Yrs
P-value = 0.505 (Not Significant)

Table II Distribution of cases according to Parity

Parity	No. of cases	Percentage
Primi para	9	30
2 - 4	16	53.33
Grand multipara	5	16.66
Total	30	100

Most of the cases were multipara.
P. Value 0.001

Table III Distribution of cases according to the period of gestation

Gestational	No. of cases	Percentage
Term 37-40 wks	24	80
>40 wks	06	20
Total	30	100

Maximum no. of cases had 37 to 40 wks gestation.
P. Value = 0.472 (Not Significant)

Table IV Distribution of cases according to Risk factors

Risk Factors	No. of cases	Percentage
Present	16	53.33
Absent	14	46.66
Total	30	100

53.33% cases had associated risk factors.
P. Value – 0.001

Table V Type of associated risk factor present in present in 16 cases

Risk factors	No. of cases	Percentage
PET	4	25
Eclampsia	2	12.5
Prolonged Labour	3	18.75
Previous H/O PPH	3	18.75
Severe anaemia	2	12.5
Severe anaemia with PET	1	6.25
Twin pregnancy	1	6.25
Total	16	100

Highest probability of PPH is seen in cases of preeclampsia. P. Value - <0.05

Table VI Distribution cases according to active management of 3rd stage of labour (AMTSL)

AMTSL	No. of cases	Percentage
AMTSL done	22	73.33
(Referred from outside)Either not done or no record but received uterotonic drugs after PPH	8	26.66
Total	30	100

In 73.33% cases AMTSL is done.
P. Value-0.001

Table VII Duration of 3rd stage of labor in 22 cases in which AMTSL was done

Duration	No. of cases	Percentage
>5-15 minutes	6	27.27
>15-20 minutes	12	54.54
>20 minutes	4	18.18
Total	22	100

3rd stage was prolonged in 72.72 % cases.
P. Value - <0.05

Table VIII Amount of Blood loss observed in the study group

Amount of blood loss	No. of cases	Percentage
500 - 750	21	70
> 750 - 1000	9	30
Total	30	100

Table IX Amount of fluid used to inflate the balloon (Condom)

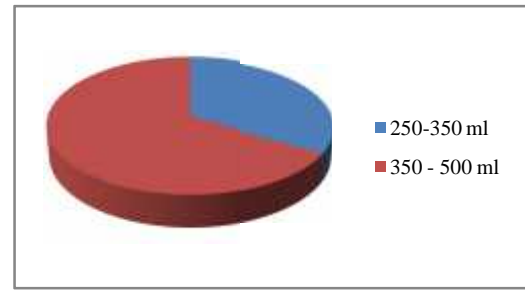
Amount of fluid	No. of cases	Percentage
250-350 ml	10	33.33
350- 500 ml	20	66.66
Total	30	100

P. Value – 0.452

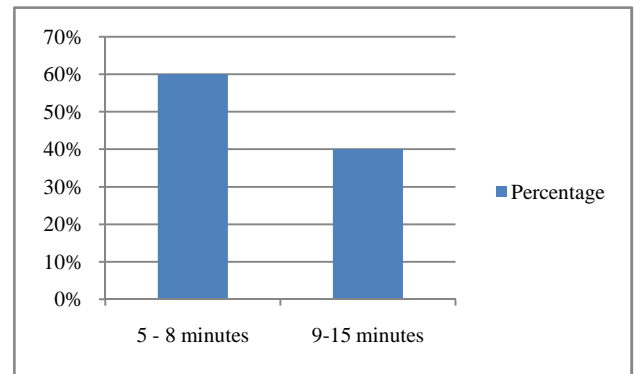
Table X Duration of time in achieving hemostasis

Duration of time	No. of cases	Percentage
5-8 minutes	18	60
9- 15 minutes	12	40
Total	30	100

The duration of time in achieving hemostasis was from 5 to 8 minutes in 60% cases & 9 to 15 minutes in 40%



Graph Amount of fluid used to inflate the balloon (condom)



Graph Duration of time in achieving hemostasis

Table XI Duration of condom catheter kept inside the uterus

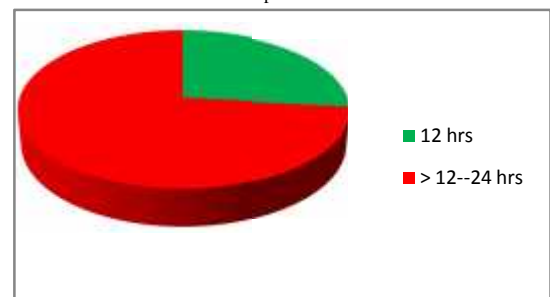
Duration	No. of cases	Percentage
12 hrs	8	26.66
12-24 hrs	22	73.33
Total	30	100

Condom balloon was kept in situ for more than 12 hours in 73.33% cases.
P. Value = 0.002

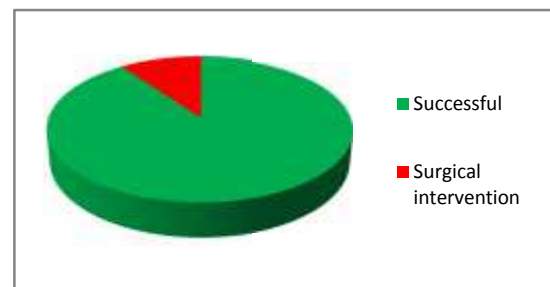
Table XII Success rate of balloon tamponade

Outcome	Cases	Percentage
Successful	27	90
Surgical intervention needed	3	10
Total	30	100

In 90% cases balloon tamponade was successful P. value – 0.001



Graph Duration of condom catheter kept inside the uterus



Graph Success rate of balloon tamponade

Table XIII Types of surgical intervention

Types of surgical intervention	No. of cases
Peripartum hysterectomy	1
B-Lynch suture	1
Haultains operation	1

10% cases required surgical intervention
P. Value = < 0.05

In 1 case balloon tamponade was done for PPH with inversion of uterus. On removing condom catheter PPH remained controlled but inversion recurred (of lesser degree) which required surgical correction.

haemorrhage in resource poor settings (2012). The studies used various types of UBT (Uterine Balloon Tamponade) including condom catheters, (n= 193), Foleys catheter, (n=5) and Sengastaken-Blakemore, Oesophageal tube, (n=1). UBT successfully treated PPH in 234 out of 241 women. We have used condom balloon catheter.

The presumed mechanism of action of the tamponade in stopping the bleeding is by creating an intrauterine pressure which exerts hydrostatic pressure on the capillaries and veins in the uterus. The pressure does not necessarily have to be higher than the systemic arterial pressure.



In addition, hydrostatic pressure effect of the balloon on the uterine arteries has been proposed and stimulation of uterine contractions by balloon in the cervix has also been demonstrated.

Majority of our patient 46.6% were in the age group of 25-30 years and 53.3% cases were multipara. In Tindell review²¹ women who underwent UBT for PPH ranged in parity from 1 to 10 and were aged 18-40 years.

The gestational age was 37 to 40 weeks in our series. Active management of labour was done in 73.3% of our cases. In Tindells review²¹ there were 9 studies in which active management of labour was done. There were associated risk factors in 53.3% cases in our study. Studies of Doumouchtsis SK *et al*²², Claudio G. Sosa²³, Xione Q. *et al*²⁴, A Briley *et al*²⁵ and Akhtar S. had similar observations.

The estimated blood loss in our study was from 500-1000 ml. The highest reported estimated blood loss successfully managed by UBT was 5000 ml in Thapas study reviewed by Tindell. In our series we had selected all cases of atonic PPH

DISCUSSION

Thirty cases of atonic PPH were selected for this study to know the effect of intrauterine condom balloon tamponade in controlling atonic PPH in which the 1st line management of uterine drugs had failed.

K. Tindell *et al*²¹ did a systematic review of trials of intrauterine balloon tamponade for the treatment of postpartum

where as in the review by Tindell²¹ additional causes of PPH included coagulopathy, placenta accreta and placenta previa. The third stage of labour was prolonged >15-20% in 12 cases (72.72%). In those cases in which the third stage of labour was prolonged there was atonic PPH.

We inserted the condom catheter in the uterine cavity manually and in some cases by sponge holding forceps. We used gravity inflation and an intravenous infusion set to inflate the condom. Once inside the uterus we used 250-500 ml of saline to inflate the condom and inflation was stopped when bleeding ceased or there was resistance to saline.

The time required for PPH to be controlled after placement of condom catheter ranged from 5-15 minutes in our study. This had similarity with other studies reviewed by Tindell²¹. We packed the vagina with gauze dressings to prevent catheter from falling out of the uterus once bleeding had ceased. Seven of the eight studies (n=191) reviewed by Tindell²¹ used a vaginal pack to prevent condom catheter from falling out of the uterus.

We had given oxytocin drip for six hours from the time of insertion of the condom catheter. Tindell²¹ in his review has observed that in six studies (n=118 women) an oxytocin drip was given upto 6 hours from the time of insertion of catheter. Shivkar *et al*²⁶ did not report the use of any uterotonics concurrent with condom catheter (n=73). In one successful case reported by Rathore, Manaktala *et al*²⁷ oxytocin was administered only during the removal of condom catheter.

The catheter was kept in situ for 12-24 hours in our study. In Tindell review²¹ the length of time reported between insertion of condom catheter and removal ranged from 6 hours to 72 hours. We deflated the catheter slowly from 10-30 minutes. The time taken to deflate the UBT varied from 10 minutes to 6 hours in Tindells review²¹.

We did not have infection in any case. In eight studies reviewed by Tindell²¹ (n=193) in women using the condom catheter there were no reports of increased infection rate. Seven of the studies (n=120) reported prophylactic use of broad spectrum antibiotics. Shivkar *et al*²⁶ did not report using any antibiotic and reported no case of infection or fever in their series (n=73). We used prophylactic antibiotic Ceftriaxone 1 gm IV twice, Amikacin 500mg IM twice daily and Metronidazole I.V infusion.

We had three failures for which surgical intervention was done. Rathore *et al*²⁷ reported success in 25 of 26 women with one failure for which emergency hysterectomy was done. Shivkar *et al* reported 5 failures in their study for which surgical intervention was done.

In our study UBT was successful in 90% of cases in the review by Tindell²¹ the success rate of UBT varied from 93% to 100% in various studies.

CONCLUSION

Intrauterine condom balloon tamponade has been found to be effective in managing atonic post partum haemorrhage. It is easy, safe and effective and preserves fertility. It should be an integral part of labour ward protocols for management of post partum hemorrhage. It can be used by the skilled birth

attendants for transferring the patient from remote periphery to tertiary care centres.

Hence, we conclude that intrauterine condom balloon tamponade is an effective method in saving maternal lives from PPH.

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How to cite this article:

Alka Pandey and Chitra Sinha.2017, Intra Uterine Condom Balloon Tamponade-A Life Saving Measure in Atonic Pph. *Int J Recent Sci Res*. 8(3), pp. 16234-16239. DOI: <http://dx.doi.org/10.24327/ijrsr.2017.0803.0107>