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# Intrauterine Balloon Tamponade Condom Foley's Catheter Vs Cg Balloon Catheter in Management of PPH in A Tertiary Care Hospital of Bihar

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***Abstract***
***OBJECTIVE:*** *Postpartum haemorrhage (PPH) is a deadly condition. Intrauterine balloon tamponade has been suggested as an easily administered, effective, minimally invasive treatment option to control uterine bleeding. In our study , we aimed to evaluate and compare the clinical efficacy of two types of condom uterine balloon tamponade systems, namely Chhattisgarh condom balloon device "CG balloon (CGB)" and conventional condom uterine balloon device (C-UBT) as a second-line intervention in post-partum haemorrhage (PPH).*
***METHODS:*** *This was a prospective randomized controlled trial conducted on 40 women having PPH which was refractory to first-line management and who were treated with either of the two condom balloon tamponade devices prepared on spot and outcome studied in terms of time to assemble, leakage, expulsion, lumen occlusion, volume of fluid used, time to arrest bleeding, inflation deflation interval.*
***RESULTS:*** *Most of the women were belonging to age group 20-30, unbooked , with mean parity 4. There was leakage in three, lumen occlusion and expulsion in four in the conventional balloon catheter whereas no leakage, lumen occlusion or expulsion in second group. The inflation deflation interval and mean volume of fluid are almost same in both the group.*
***CONCLUSION:****CGB and conventional condom balloon tamponade both are easy to use, feasible and efficacious for control of PPH, but CGB condom balloon device has a central drainage lumen for real-time assessment of blood loss and therefore early corrective action.*

***Keywords: atony, CG balloon catheter, condom balloon catheter, post partum haemorrhage.***

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## I. Introduction

According to world Bank data, MMR for India 145 per 100,000 live births in 2017, which is a significant decline from the 215 figure that was reported in 2010. MMR in the Bihar state has taken a dip from 165 deaths per 100,000 live births in 2014-16 to 149 deaths per 100,000 live births in 2016-18.[1] World wide, major cause of maternal morbidity and mortality is Obstetrical haemorrhage. World health organization, states that obstetrics hemorrhage contributes of 127,000 deaths annually worldwide .It is mainly due to retained placental tissues, uterine rupture, coagulopathy, lower genital tract trauma etc. Postpartum haemorrhage is defined as >500 ml approximate blood loss after vaginal delivery or >1000 ml after caesarean section (CS). Diagnosis is to be considered as atonic PPH after excluding uterine and cervical trauma, deficient coagulation or retained placental tissue.

Majority of PPH is due to uterine atony; up to 80% of the cases result from suboptimal contraction of the myometrium following placental separation. In acute postpartum haemorrhage refractory to medical and other conservative interventions, invasive therapies may include arterial embolization, uterine compression sutures, uterine artery ligation and ultimately hysterectomy may be required. However, these measures are highly invasive, require extensive expedient, expertise and are associated with significant morbidities. Intrauterine balloon tamponade has been suggested as an easily administered, effective, minimally invasive treatment option to control uterine bleeding while preserving the mother's ability to bear additional children. Multiple types of balloons are available like Bakri balloon, BT-Cath balloon tamponade catheter, Foley catheters, Rusch balloon, condom catheters and the Sengstaken-Blakemore tube etc. Intrauterine balloon act by exerting inward to outward pressure against the uterine wall, resulting in a reduction in persistent capillary and venous bleeding from the endometrium and the myometrium. Presently RCOG guidelines advocates Uterine Balloon Tamponade for the management PPH after the exclusion of retained products and genital tract trauma, failure of use of first line uterotonics (such as oxytocin, ergometrine, misoprostol and prostaglandin F2 alpha). Overall success of balloon tamponade reported in 80–100% cases[5]. So, in our study, we aimed to evaluate the

clinical efficacy of two types of condom uterine balloon tamponade systems, namely Chhattisgarh condom balloon device "CG balloon and conventional condom uterine balloon device as a second-line intervention in management of post-partum haemorrhage.

## II. Methods

This was a prospective study conducted during period of December 2019 to 2020 in the department of obstetrics and gynecology at patna medical college and hospital, patna. The study recruited 40 patients having postpartum haemorrhage

after excluding uterine and cervical trauma, deficient coagulation or retained placental tissue. After obtaining informed consent and satisfying inclusion and exclusion criteria, any of the two devices was prepared on the spot and dipped in antiseptic solution for 3 min before insertion. Twenty women were inserted conventional condom balloon catheter and rest 20 were inserted CG balloon and statistical analysis done.

INCLUSION CRITERIA

- Atonic PPH
- Failed medical measures of PPH
- Active management of third stage of labour done
- Bleeding following caesarean section in case of placenta previa & accreta

EXCLUSION CRITERIA

- Traumatic PPH
- Hemodynamically unstable or in shock
- Retained placenta
- Known uterine anomaly
- DIC
- Risk of uterine rupture
- Infections
- Arterial bleeding

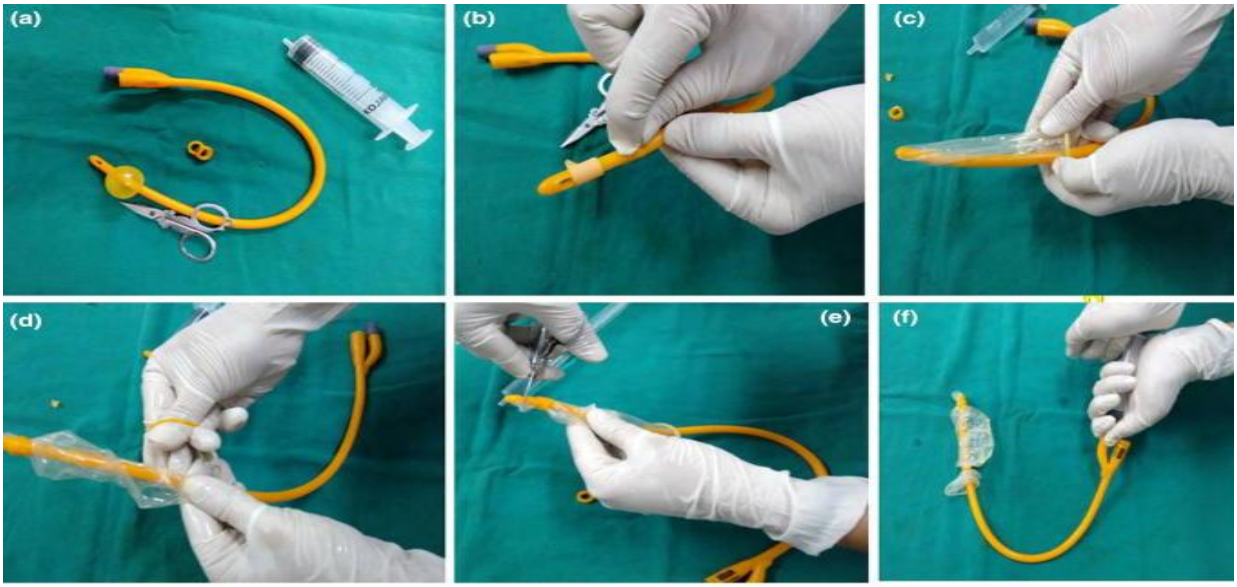
CONVENTIONAL BALLON CATHETER

With aseptic precautions, a condom was rolled over proximal part of Foley catheter (No. 20) and tied with a cotton thread or vicryl/silk on two sites 1cm apart from distal end. The cervix was identified, and the condom tamponade was introduced into the uterus manually or by help of sponge holding forceps. The condom was inflated with 100-500ml warm saline with the help of a 50ml syringe or iv set till bleeding stopped. The catheter was tightened by an umbilical clamp or cotton string and taped to either of thigh. Vagina was loosely packed with gauze.

CG BALLOON CATHETER

It was named 'CG Balloon'' as it was invented in Chhattisgarh India. It is prepared manually with all aseptic precautions as follows:-

- Take 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 in width (Fig. a).
- Excise (not only incise) the bulb of the catheter after inflating it with air (Fig. b).
- Unfold the condom over distal one-third of length of the catheter (Fig. c).
- By help of 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. d).
- Excise the tip of the Foley's catheter and condom together to facilitate drainage of blood by scissor (Fig. e). Wash the device with antiseptic solution.




Making of CG Balloon

Data was analyzed in context of Mode of delivery, Cause of PPH, Volume Of blood loss, PPH to balloon inflation interval time, Balloon tamponade volume ,inflation to haemostasis interval ,Inflation deflation interval ,Surgical intervention if required . In cases of atonic PPH, to keep the uterus well contracted over the balloon, oxytocin infusion was continued for atleast 4 hours. In all cases, as a rule the catheter was left in situ for the duration minimum 24 hrs and longest 72 hrs of balloon tamponade and in all patients vitals were closely monitored. Clinical success was defined as control of bleeding following balloon insertion without further intervention.

STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 20 software and presented in figures and tables. Chi-square test was used for comparisons with statistical significance as p value of less than or equal to 0.05.

## III. Result

**Table 1 :** sociodemographic and tamponade statistcs

| | **Conventional balloon (mean)** | **CG balloon (mean)** | P value |
|---|---|---|---|
| **Age (years)** | 26.95+-4.92 | 23.76+-5.12 | >0.05 |
| **Gravida** | 3.76+-1.52 | 4.12+-1.66 | >0.05 |
| **Gestation (weeks)** | 37.2+-3.45 | 36.71+-2.41 | >0.05 |
| **Pre-tamponade blood loss (ml)** | 1524.738+-296.64 | 1379+-503.276 | >0.05 |
| **Volume of fluid in tamponade(ml)** | 301.742+-67.45 | 278+-56.731 | >0.05 |
| **Time interval from PPH to tamponade insertion (min)** | 26.71+-19.72 | 25.13+-14.83 | >0.05 |
| **Time interval from tamponade to hemostasis (min)** | 7.33+-9.76 | 6.83+-4.85 | >0.05 |
| **Inflation deflation interval(hour)** | 26.54+-6.72 | 24.16+-5.62 | >0.05 |
| **Total blood transfusion (units)** | 2+-0.6 | 2+-0.4 | >0.05 |
| **Hospital stay (days)** | 5.32+-2.72 | 4.17+-1.64 | >0.05 |
| **Time to assemble(min)** | 2.19+-0.2 | 1.97+-0.3 | >0.05 |
| **Leakage** | 3 | 0 | 0.012 |
| **Lumen blockage** | 4 | 0 | 0.027 |
| **Expulsion** | 4 | 0 | 0.026 |

**Table 2:** Indications of tamponade insertion

| INDICATIONS | Conventionalballoon catheter (n=20) | | CG balloon (n=20) | | P- Value |
|---|---|---|---|---|---|
| | **No. of cases** | **percentage** | **No. of cases** | **Percentage** | |
| Uterine atony | 16 | 80 | 17 | 85 | 0.237 |
| Jaundice | 1 | 5 | 0 | 0 | |
| Secondary pph | 1 | 5 | 1 | 5 | 0.254 |
| Placenta previa | 0 | 0 | 1 | 5 | |
| Multiple pregnancy | 0 | 0 | 1 | 5 | |
| Abruption placenta | 1 | 5 | 0 | 0 | |
| polyhydraminos | 1 | 5 | 0 | 0 | |
| **Total** | 20 | 100 | 20 | 100 | |

Total 40 patients having postpartum haemorrhage after excluding uterine and cervical trauma, deficient coagulation or retained placental tissue selected. After obtaining informed consent and satisfying inclusion and exclusion criteria, any of the two devices was prepared on the spot and dipped in antiseptic solution for 3 min before insertion. Twenty women were inserted conventional condom balloon catheter and rest 20 were inserted CG balloon.

The descriptive statistics of sociodemographic and tamponade statistics are described in **Table 1.** Both groups are comparable and showing no significant differences(P>0.05) in terms of age groups among conventional balloon catheter were 26.95+-4.92 and CG balloon were 23.76+-5.12 (p>0.05). Mean gravida among convetional balloon catheter was 3.76+-1.52 whereas 4.12+-1.66 among cg balloon group and belonging to mean gestation of 36-38 weeks which was statistically insignificant (P>0.05). Mean volume of fluid in tamponade was 301.742+-67.45ml in conventional balloon catheter group while 278+-56.73 ml in CG balloon group. Mean pre-tamponade blood loss was 1524.7+-296.64 ml in conventional balloon catheter group while 1379+-503.2 ml in CG balloon group.

Mean time interval from PPH to tamponade insertion was 26.7min in conventional balloon catheter group while 25.13min in CG balloon group which was almost equal in both groups. Mean time interval from tamponade insertion to achieving hemostasis was 7.3min in conventional balloon catheter group while 6.8min in CG balloon group which was almost equal in both groups. Mean interval between inflation and deflation was 26.5 hr in conventional balloon catheter group while 24.1 hr in CG balloon group which was statistically significant (P>0.05). Mean blood transfused was 2 and mean hospital stay was 4-5 days in both groups. Mean time to assemble conventional balloon catheter was 2.19 min and 1.97 min in CG balloon catheter which was statistically insignificant (P>0.05). Leakage was found in 3 out of 20 cases in conventional balloon catheter while none in CG balloon group which was statistically significant (P-0.012). Lumen blockage was found in 4 out of 20 cases in conventional balloon catheter while none in CG balloon group which was statistically significant (P-0.027). Expulsion was found in 4 out of 20 cases in conventional balloon catheter while none in CG balloon group which was statistically significant (P-0.026).

**Table 2:** shows various indications for intrauterine balloon tamponade insertions. In group A(conventional balloon catheter) out of 20 cases, 16 had atonic uterus, 1 had jaundice, 1 had secondary PPH, 1 had abruption placenta, 1 had polyhydraminos. In group B( CG balloon catheter) out of 20 cases, 17 had atonic uterus, 1 had secondary PPH, 1 had placenta previa, 1 had multiple pregnancy which was statistically insignificant (P>0.05).

## IV. Discussion

Postpartum haemorrhage (PPH) accounts for a quarter of maternal deaths worldwide. The commonest cause of PPH is uterine atony due to failure of the myometrium to contract and retract after the delivery of fetus to stop bleeding from the raw placental site[6]. Many risk factors associated with uterine atony have been reported in previous studies including uterine overdistension (e.g, multiple pregnancy, polyhydraminos), rapid or prolonged labour, oxytocin stimulation, obesity, maternal race, preeclampsia and chorioamnionitis. PPH can be minor (500-1000ml) or major (>1000ml). Major PPH is further divided into moderate (1000-2000 ml) or massive ( loss of 30-40% of a woman's blood volume or more han 2000ml). In our study, we have compared conventional balloon catheter with that of CG balloon in 20 subjects each. It was observed that the mean time to assemble Condom balloon tamponade was 2.1 min and that in CG balloon was 1.9 minute. This was almost similar to the study done by Dalia Y et al.[7] There was leakage in three and lumen occlusion and expulsion in four in the conventional balloon catheter. In the CG balloon catheter group there was no leakage, lumen occlusion or expulsion. Similar results were obtained in the study done by Dalia Y et al, in which the leakage, expulsion and lumen occlusion were higher with conventional balloon tamponade than with CG balloon. These differences could be due to use of thread for tying the ends which could remain loose to create a leakage or expulsion or tight which could be the reason for lumen occlusion. Also the knot tying needs expertise which is

not seen with CG balloon in which bands of catheter are used for the ends. The mean volume of fluid used to create tamponade was 301 ml in Conventional balloon tamponade and in CG balloon it was 278ml. In the study done by Mishra N et al.[8] the mean volume of fluid used was 245.7 ml. One of the best things about CG balloon is the presence of drainage port through which authors can measure bleeding in real time which makes it better than conventional balloon tamponade. In our study the mean time to arrest bleeding was 7.3 minute in conventional balloon tamponade and 6.8 minute in CG balloon and hence not so much difference is noted which was comparable to the study by Rathore AM et al.[9] (6.06 minutes). Mishra N et al.[8] noted mean time to arrest bleeding as 12.69 minutes which is almost double as that of our study which could be due to associated conditions apart from atonicity. The inflation deflation interval was almost similar in both the groups with mean of 26.5 hours and 24.1 hours respectively in CBT and CG balloon which was double to the study done by Mishra N et al. with mean inflaton deflation interval of 14.4 and 12 hr respectively. Y. Dalia et al noted mean duration of 22.56±3.84 hours which was similar to our study. Throughout the process, oxytocin infusion was given and patient were under antibiotic coverage with vitals monitoring. The conventional balloon tamponade requires Foley's catheter, condom, vicryl or silk for tying which was costly than CG balloon that requires Foley's catheter and condom only. In our study, CGB and conventional condom balloon tamponade both are seen to be efficacious for controlling PPH, but CGB condom balloon device has a central drainage lumen for real-time assessment of blood loss and therefore early corrective action and is proven to be superior in context leakage, expulsion and luminal blockage.

## V. Conclusion

Uterine balloon tamponade devices are easy to use, feasible and efficacious for control of PPH, but the Chattisgarh condom balloon device has the advantage of a central drainage lumen for real-time assessment of blood loss and therefore early corrective action along with less time to assemble,cheap, ease of insertion and tamponade with lesser inflation volume and less chances of leakage, expulsion and luminal blockage. So, it can be used as second line management for postpartum haemorrhage refractory to medical treatment.

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