

## **Role of intrauterine condom tamponade in control of postpartum haemorrhage in patients with placenta praevia**

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### **Abstract**

Postpartum haemorrhage is the most common type of obstetric haemorrhage and accounts for the majority of the 14 million cases annually. Approximately 7% of the maternal deaths caused by obstetric hemorrhage are related to placenta praevia. This condition complicates approximately 4 in 1,000 pregnancies that are over 20 weeks of gestation. Over the last two decades, use of balloon tamponade has been reported for the management of postpartum hemorrhage. This study was done to evaluate the effect of intrauterine condom tamponade in control of PPH in patients with placenta praevia. This prospective study was done in the Department of Obstetrics and Gynaecology at Pt. B.D. Sharma Postgraduate Institute of Medical Sciences, Rohtak on thirty patients with placenta praevia undergoing caesarean section. Patients who developed intractable postpartum haemorrhage (PPH) and did not respond to the conventional medical management were included in the study. Analysis was carried out using SPSS (Statistical Package for Social Studies) for Windows version 20.0. It was found that with condom balloon tamponade 26(86.66%) women had no complications postoperatively. Out of 30 patients 19 patients required single or multiple blood transfusion while 11 (36.66%) patients did not require any blood transfusion. It may be concluded that early attention and intensive management of PPH are mandatory for good maternal outcome. Condom balloon tamponade a minimally invasive procedure, is very effective for control of uterine/placental bed bleeding following delivery of placenta. It provides a very effective tamponade effect and reduces the need of further surgical intervention to great extent. It is cost effective, readily available, easy to assemble and has minimal side effects with high success rate.

**Key words:** intrauterine condom tamponade, Postpartum haemorrhage, placenta praevia

### **Introduction**

Obstetric haemorrhage is one of the leading direct causes of maternal mortality worldwide and it accounts for nearly 25% of all maternal deaths.<sup>1</sup> Approximately 30% (in some countries, over 50%) of direct maternal deaths worldwide are due to haemorrhage, mostly in the postpartum period.<sup>1</sup> The Millennium Development Goal of reducing the maternal mortality ratio by 75% by 2015 will not be achieved unless the prevention and treatment of postpartum haemorrhage (PPH) in low-resource areas is prioritised.<sup>2</sup>

Postpartum haemorrhage is the most common type of obstetric haemorrhage and accounts for the majority of the 14 million cases annually.<sup>3</sup> Conventionally PPH has been defined as blood loss of more than 500 ml following vaginal delivery and 1000 ml following a caesarean section.<sup>4</sup> Another definition labels PPH as any blood loss which causes a 10% drop in hematocrit or which threatens the hemodynamic stability of the patient and

necessitates blood transfusion.<sup>5,6</sup> Blood loss during first 24 hours after delivery is known as primary PPH (placental / extra-placental, depending upon the site of bleed), whereas blood loss from after 24 hours up to six weeks is termed as late or secondary PPH. Approximately 7% of the maternal deaths caused by obstetric hemorrhage are related to placenta previa.<sup>7</sup> This condition complicates approximately 4 in 1,000 pregnancies that are over 20 weeks of gestation.<sup>8</sup> Its prevalence in Asian women has been shown to be significantly higher than other races and ethnicities.<sup>9</sup> The established risk factors of placenta previa include advanced maternal age, multiparity, multiple gestation, previous caesarean section and smoking during pregnancy.<sup>10</sup>

Interventions to treat PPH generally proceed from less to more invasive and include compression techniques, medications, procedures, and surgeries. PPH management may also involve adjunctive therapies, such as blood and fluid replacement and/or an anti-shock garment to treat the blood loss and other sequelae that result from PPH. Over the last two decades, use of balloon tamponade has been reported for the management of postpartum hemorrhage.<sup>11</sup> Success rates for control of postpartum bleeding have ranged from 76 to 87%.<sup>12</sup> The principle of balloon tamponade therapy is to fill the uterine cavity to control bleeding with pressure. Further, some balloons have a drainage port to allow blood to escape as a way to monitor continued bleeding.

With this background this study was done to evaluate the effect of intrauterine condom tamponade to control bleeding in patients with placenta praevia

### **Aims and Objectives**

This study was done to evaluate the effect of intrauterine condom tamponade in control of PPH in patients with placenta praevia

### **Materials and Methods**

This prospective study was done in the Department of Obstetrics & Gynaecology at Pt. B.D. Sharma Postgraduate Institute of Medical Sciences, Rohtak on thirty patients with placenta previa undergoing caesarean section. Patients who developed intractable postpartum haemorrhage (PPH) and did not respond to the conventional medical management were included in the study.

Patients with traumatic PPH, disseminated intravascular coagulation (DIC), retained placental tissue, infection of cervix/vagina or history suggestive of allergy to latex/rubber were excluded. A written informed consent was taken from patients after explaining all medical and surgical methods for control of postpartum haemorrhage, if required. Postpartum haemorrhage management tray containing uterotonics, intravenous cannula (18G), intravenous infusion set, blood transfusion set, condom, foley's catheter, 50cc syringes (four in number), normal saline, vaginal pack was kept ready in operation theatre. Weighed sheets and mops were used in caesarean section to compare weight of sheets and mops after section.

Initial management of PPH included resuscitative measures, hypovolemia correction, uterotonics, uterine massage and/or bimanual compression. The decision for condom catheter insertion was made on the basis of active continuous haemorrhage despite conservative measures. A sterile foley's catheter (14Fr) fitted with a condom at its tip was prepared and then introduced into the uterus. The prepared condom catheter was inserted through the uterine incision (pushing the tip to the fundus and the distal end of the foley's catheter through the cervix with an assistant pulling vaginally). After closure of uterus condom balloon was inflated with 250 to 500ml of normal saline depending upon the situation to arrest the bleeding. The distal end of catheter with gentle traction was fixed to patient's thigh. A tight vaginal pack was then applied. Pre-weighed pads and sponges were used after putting tamponade. Pads were changed 4 hourly or earlier if required and weighed. The blood loss in first 24 hour was calculated from used preweighed pads. One gram of weight was taken as one ml of blood loss.

Oxytocin infusion (10-20 U) was continued for 24 hours to keep the uterus well contracted over the condom catheter. The condom catheter was kept in situ for 24-48 hours depending on the severity of initial blood loss. Prophylactic antibiotics were administered intravenously as long as the condom catheter was in situ. Balloon was deflated gradually and vaginal bleeding was watched. Following condom catheter insertion, all the patients were closely monitored for pulse, blood pressure, temperature every 2 hourly upto 24 hours and then every 4 hourly for next 48 hours. Patients were monitored in high depending area for 72 hours.

**Failure of condom tamponade (Negative tamponade test)** – It was defined as persistence of uterine bleeding after 15-20 minutes of proper insertion of condom catheter with the need for additional procedures to stop bleeding.

**Successful tamponade (Positive tamponade test)** – The procedure was considered successful if bleeding stops within 15-20 minutes of condom inflation.

These patients were reviewed in details for any antenatal risk factor, estimated blood loss, intrapartum complications, cause of PPH, sequence of treatment, any instrumentation, post delivery haemoglobin, blood transfusion, fever and clinical outcome.

*Data analysis:* Collected data were entered in the MS Excel spreadsheet, coded appropriately and later cleaned for any possible errors. Analysis was carried out using SPSS (Statistical Package for Social Studies) for Windows version 20.0. Categorical data were presented as percentages (%). Normally distributed data were presented as means and standard deviation Student's t test for independent samples was used for comparison between quantitative variables. All tests were performed at a 5% level of significance, thus an association was significant if the p value was less than 0.05.

## Results

**Table 1: Distribution according to period of gestation by last menstrual period at time of first episode of bleeding**

Period of gestation (weeks)	Number of patients (n)	Percentage (%)
Upto 30 weeks	1	3.33
31-35 weeks	20	66.66
>35 weeks	9	30
Mean±SD	32.03±2.52 (weeks)	

Table 1 depicts that 20 i.e. 66.66% women were with 31-35 weeks of gestation at time of first episode of bleeding and 9 women (30%) were found with >35weeks of gestation at time of first bleeding episode. Mean period of gestation age at time of first episode of bleeding was 32.03±2.52 weeks.

**Table 2: Peroperative complications**

	Number of patients (n)	Percentage (%)
Atonic PPH	14	46.66
Placental bed bleeding	15	50
Placental adherence	1	3.33

Table 2 shows that peroperatively 14 women had atonic postpartum haemorrhage (46.66%) which were managed medically along with condom balloon insertion while 15 women (50%) had placental bed bleeding for that placental bed suture were taken along with medical management and condom balloon insertion. In 1 woman placental adherence was found.

**Table 3: Amount of blood loss before putting balloon tamponade**

Blood loss(ml)	Number of cases(n)
Upto 1500 ml	22(73.33%)
> 1500 ml	8(26.66%)
Mean±SD	1343.5±223.75 (ml)

Table 3 shows that in our study, there were 22 women(73.33%) who had blood loss upto 1.5 litres before putting balloon tamponade and 26.66% women had more than 1.5 litres blood loss before putting balloon tamponade. Mean blood loss before putting balloon tamponade was 1343.5±223.75 ml.

**Table 4: Mean blood loss after condom balloon insertion**

Blood loss(ml)	Number of cases(n)
Upto 100 ml	3(10%)
100-400 ml	23(76.66%)
>400ml	4(13.33%)
Mean±SD	308.82±83.42ml

Table 4 shows that out of 30 women, 23 women (76.66%) had blood loss 100-400 ml after condom balloon insertion whereas in 4 women (13.33%) it was >400 ml and in 3 women it was upto 100 ml. Mean blood loss of the study population after balloon insertion was 308.82±83.42ml.

**Table 5: Mean comparison of blood loss before and after condom balloon insertion**

Blood loss	Before	After insertion
Mean±SD	1343.5±223.75ml	308.82±83.42ml
Statistical significance	<0.001 Significant	

Table 5 shows that mean blood loss before putting condom tamponade was 1343±223ml while mean blood loss after condom balloon insertion was 308±83.42 ml. Mean comparison of blood loss before and after condom balloon insertion was done and found to be statistically significant (p <0.001).

**Table 6: Postoperative complications**

	Number of patients (n)	Percentage (%)
Fever	3	10
Secondary PPH	1	3.33
No complications	26	86.66

Table 6 shows that majority of women (86.66%) had no complications postoperatively. 13.33% of treated patients had fever and secondary postpartum hemorrhage, who were managed conservatively.

**Table 7: Requirement of blood transfusion**

	Number of patients (n)	Percentage (%)
1 unit PCV	9	30
2 units PCV	8	26.66
3 units PCV	0	0
4 units PCV	2	6.66
No PCV	11	36.66

Blood transfusion was required in 19 patients out of which 9 patients required 1 unit PCV, 8 patients required 2 units PCV and 2 patients required 4 units PCV. In 11 (36.66%) cases PCV was not required.

## Discussion

### Period of gestation by last menstrual period

Bhutla et al in 2011 conducted a retrospective study to determine the prevalence of placenta previa in their hospital and concluded that at time of first episode of bleeding the mean gestation age of women with placenta previa was 34±1.23weeks while the study of balloon tamponade during cesarean section in postpartum hemorrhage conducted by Takako et al in 2011 concluded that mean gestation age was 33.5± 2.34 weeks during

first bleeding episode.<sup>13,14</sup> In our study mean period of gestation was  $32.03 \pm 2.52$  weeks at time of first episode of bleeding which is comparable to above studies.

### **Peroperative complication**

Atonic uterus, placental bed bleeding, adherent placenta, extension of uterine incision are the common peroperative complications in cases of placenta previa reported in the literature.<sup>15</sup> In study conducted by Tirumuru et al (2013), 31 women out of 58 (53%) had atonic uterus, 12 (20.68%) women had placental bed bleeding and in one (1.7%) woman there was cervical tear.<sup>16</sup> Yaqub et al (2010) reported that in their study 36% women had atonicity of uterus while Gurung (2014) reported that atonicity of uterus was in 42.85% patients and placental bed bleeding was in 42.7% women.<sup>17, 18</sup> Comparable to above studies in our study we also found that in women with placenta previa undergoing cesarean section 50% of patients had placental bed bleeding, 46.66% women had atonic uterus and in one woman placental adherence was found.

### **Amount of blood loss before putting balloon tamponade**

Atonicity and placental bed bleeding are major factor for blood loss in cases of placenta previa. Before any effective measures there may be excessive blood loss that may threaten the life of the patients. Gurung et al studied use of condom tamponade in management of massive obstetric hemorrhage in 2014 and they found that in majority of women mean blood loss before condom tamponade insertion was  $1534 \pm 213$  ml.<sup>18</sup> Johanson et al (2001) evaluated use of hydrostatic balloon in massive postpartum haemorrhage and in their study they found  $1254 \pm 247$  ml of mean blood loss before putting balloon tamponade.<sup>19</sup> In our study, mean blood loss before putting balloon tamponade was  $1343 \pm 223.75$  ml.

### **Amount of blood loss after putting balloon tamponade**

Use of balloon tamponade has emerged to control postpartum bleeding especially in patients of placenta previa. It significantly decrease the amount of blood loss and need for more intensive surgical measures. Gao et al (2014) reported mean blood loss after balloon insertion was  $364 \pm 75$  ml.<sup>20</sup> Akhter et al (2003) found  $234 \pm 32$  ml of mean blood loss after balloon tamponade insertion.<sup>21</sup> Mean blood loss after putting balloon tamponade in our study was  $308 \pm 83.42$  ml.

### **Success rate**

Comparison of different studies in relation to success rate of balloon tamponade to control postpartum hemorrhage.

Study	Success rate
Dildy G et al (2002) <sup>22</sup>	88.84%
Seror et al (2005) <sup>23</sup>	71%
Dabelea et al (2007) <sup>24</sup>	90%
Yaqub et al (2010) <sup>17</sup>	72.5%
Tindell et al (2012) <sup>25</sup>	97%
Gurung et al (2014) <sup>18</sup>	100%
Present study (2015)	86.66%

Success rate of balloon tamponade varies from 71% to 100% according to above mentioned studies. In our study success rate was 86.66%.

### **Post operative complication**

Stavroulis et al (2009) reported that in women with balloon tamponade there was no postoperative complications.<sup>26</sup> Study conducted by Tirumuru et al (2013) showed that 13% patients presented with puerperal pyrexia.<sup>16</sup> In our study, in 86.66% women no complications were found postoperatively, three cases (10%) reported with fever and 1 case with secondary PPH.

### **Blood transfusion**

In study conducted by Tirumuru in 2013, 39.6% women required blood transfusion with mean of 4 units per patient.<sup>16</sup> Gurung et al (2014) reported 50% cases required <5 units packed cell volume and 50% cases required >5 units packed cell volume.<sup>18</sup> In our study, blood transfusion was required in 63.33% women.

### **Conclusion**

Postpartum haemorrhage still remains a major problem in developing countries. It is one of the important causes of maternal morbidity and mortality. Early attention and intensive management are mandatory for good maternal outcome. Condom balloon tamponade a minimally invasive procedure, is very effective for control of uterine/placental bed bleeding following delivery of placenta. It provides a very effective tamponade effect and reduces the need of further surgical intervention to great extent. It is cost effective, readily available, easy to assemble and has minimal side effects with high success rate. Thus, condom balloon tamponade is suitable alternative in management of postpartum hemorrhage due to placental bed bleeding especially in low resource setting.

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