

## Intrauterine balloon tamponade for the control of postpartum haemorrhage

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### Abstract

**Objective:** To evaluate the effectiveness of balloon tamponade in the management of postpartum haemorrhage.

**Methods:** The study was conducted at the Dow University of Health Sciences and Civil Hospital Karachi from January to July 18, 2012, and comprised women aged 18-35 years, parity 1-6 and gestational age 31-41 weeks, who developed or were admitted with primary postpartum haemorrhage due to uterine atony in whom medical treatment had failed. SPSS 10 was used to analyse the data.

**Results:** The mean age, parity, gestational age of 139 women was 26.4±4.2 years, 3.4±1.3, 37.81±1.67 respectively. Mean estimated blood loss was 1155.8±350.6 ml, mean systolic blood pressure 90.96±18.1 mmHg, diastolic blood pressure 55±7.5 mmHg and mean pulse was 108.3±10.89 bpm. Balloon tamponade was effective in 126(90.4%) cases.

**Conclusion:** Condom catheter balloon tamponade was an effective means of controlling postpartum haemorrhage. There should be a low threshold for use of balloon tamponade as it is effective, easy to use, easily available, has low complication rate, and an inexpensive modality to manage non-traumatic postpartum haemorrhage, especially in resource-limited settings, and still maintain reproductive ability.

**Keywords:** Postpartum haemorrhage, PPH, Balloon tamponade. (JPMA 66: 22; 2016)

### Introduction

Postpartum haemorrhage (PPH) is one of the major causes of maternal mortality and morbidity worldwide.<sup>1</sup> It is estimated that 600,000-800,000 women die in childbirth each year and 99% of these occur in developing countries.<sup>2</sup> Overall, 25% of deaths in developing world are due to PPH, while the prevalence in Pakistan is 34%.<sup>3</sup>

Primary PPH is defined as bleeding in excess of 500ml following vaginal delivery or 1000ml following caesarean section (CS) from the birth canal within 24 hours.<sup>4</sup> It has many potential causes, but the commonest is uterine atony, responsible for 80% of cases. Other causes of primary PPH include retained placental tissues, uterine rupture, lower genital tract trauma, uterine inversion and consumptive coagulopathy.<sup>3</sup>

Guidelines for the management of PPH involve a stepwise approach, including the exclusion of retained products and genital tract trauma. Uterine atony is dealt with uterine rubbing and various uterotonic agents such as oxytocin, ergometrine, misoprostol and prostaglandin F2 alpha (PGF2 $\alpha$ ).

If these attempts fail, surgical intervention would be

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required such as internal iliac artery ligation, uterine compression sutures and peripartum hysterectomy. Recently uterine balloon tamponade has been added to this armamentarium in the management of PPH.<sup>5</sup> This procedure is used before any surgical intervention is done. Previously tamponade was used to control PPH by uterine packing. Given the difficulty and potential traumatic procedure of insertion of roller gauze packs, the use of uterine balloon tamponade has been favoured more recently.<sup>6</sup>

Successful use of variety of balloon devices has been reported, including Sagstaken-Blakemore tube, Bakri balloon, Rusch balloon, Foley catheters and Condom catheters.<sup>5</sup> Success rates of 84% (95% confidence interval [CI], 77.5%-88.8%)[6] has been reported with the use of various balloons. Although reports of success and failure in the use of balloons for obstetric haemorrhage exist, but they do not necessarily include specific indications, methods used, balloon type or reasons for failure.<sup>5</sup> Success rates have been reported with use of condoms in low-resource settings.<sup>7</sup> As this is the least invasive and most rapid approach, it would be logical to use this as the first step in the management after medical treatment fails and before proceeding to surgical intervention and possible hysterectomy.<sup>6</sup> Advantages of this method include avoidance of laparotomy, easy and rapid insertion with minimal anaesthesia, the fact that it can be performed by

relatively inexperienced personnel, painless removal, and rapid identification of failed cases.<sup>8</sup>

As this is a simple procedure to perform, primary health workers can implement it before referring the patient to a tertiary care centre which will minimise blood loss and prevent irreversible shock and mortality.

The current study was planned to evaluate the efficacy of condom balloon tamponade to arrest massive haemorrhage.

### Patients and Methods

The study was conducted at the Dow University of Health Sciences and Civil Hospital Karachi from January to July 18, 2012, and comprised women aged 18-35 years, parity 1-6 and gestational age 31-41 weeks, who developed or were admitted with PPH due to uterine atony following a vaginal delivery, instrumental delivery or CS in whom medical treatment (oxytocin, misoprostol and PGF<sub>2</sub>α) had failed. Patients were included via non-probability consecutive sampling with CI= 95%, p= 90%,<sup>9</sup> and d= 05%. Patients with PPH due to retained products and genital tract trauma were excluded.

The study was conducted after seeking approval from the College of Physicians & Surgeons Pakistan (CPSP). All patients admitted through emergency with PPH or those who developed PPH after delivery in the labour room were evaluated. Verbal consent was obtained in emergency according to Royal College of Obstetricians and Gynaecologists (RCOG) guidelines.<sup>10</sup>

Balloon catheters were arranged personally by self donation.

Examination was done, vital signs were noted, signs of active haemorrhage and severity of bleeding were assessed from the general condition of the patient. Blood loss was compensated by plasma expanders, blood transfusions and crystalloids. The response was monitored by the general condition of the patient, vital signs pallor and urinary output. Baseline investigation included blood group and cross-match, complete blood count (CBC), urea, creatinine, electrolytes and coagulation profile.

Medical treatment of primary PPH due to uterine atony included oxytocin, syntometrine, prostaglandins and combination of these drugs along with bimanual massage and compression. Once the initial medical management failed and before proceeding to surgical intervention, balloon tamponade for control of PPH was attempted by postgraduate trainees (R4). After taking

verbal consent, with aseptic precaution, a sterile rubber catheter fitted with condom was introduced into the uterus. The condom was inflated with 250-500ml normal saline accordingly. Vaginal packing was done once the condom was in the uterine cavity to keep it in place. Meanwhile, syntocinon infusion was started. The condom catheter was kept for up to 24 hours. However, after 6 to 8hrs if the uterine fundus felt contracted and no active bleeding was identified through the cervix, the balloon was gradually deflated 20ml/hr to half the volume in the balloon at 12 hours, and when no further bleeding for another 30 minutes occurred, it was removed in the presence of a senior staff member having more than 5 years of experience. The main outcome evaluated was the ability of balloon tamponade to arrest bleeding after 24 hours.

All data i.e., age, gestational age, parity, booking status, mode of delivery and efficacy of balloon tamponade to control PPH, was entered on a predesigned proforma. Primary PPH was defined as the loss of greater than 500ml of blood from the genital tract in the first 24 hours following vaginal delivery and 1000ml of blood loss for CS.<sup>4</sup> Blood loss was measured by collecting blood in a tray placed at the foot end of the delivery table. Contents of the tray were emptied in a plastic cylinder basin which had marking drawn at 100ml to 1000ml. Balloon tamponade was labelled effective if there was no bleeding or less than 100ml blood loss occurred post-balloon tamponade for 48 hours.

Data was analysed using SPSS 10. Quantitative variables like age, gestational age, parity, blood loss, systolic blood pressure (SBP), diastolic blood pressure (DBP) and pulse rate were presented as mean ± standard deviation. Frequencies and percentages were calculated for qualitative outcome variable like mode of delivery, booked/unbooked cases and effectiveness. Effect modifiers like maternal age, gestational age, parity and mode of delivery were controlled through stratification. Post-stratification chi-square test was applied to see the difference by taking p<0.05 as significant.

### Results

The mean age, parity and gestational age of the 139

**Table-1:** Efficacy of balloon tamponade in the management of Postpartum Haemorrhage.

Efficacy	Frequency	Percentage
Yes	126	90.4%
No	13	9.6%

**Table-2:** Frequency of effectiveness of balloon tamponade with respect to maternal age, gestational age, parity and mode of delivery.

Effectiveness		Yes	No	P-value
Maternal age	18-26	80	07	0.494
	26.1-35	46	06	
Gestational age	31-37	09	02	0.274
	37.1-41	117	11	
Parity	1-3	77	04	0.106
	4-6	49	09	
Mode of delivery	NVD	113	13	0.443
	Instrumental delivery	13	0	

NVD: Normal vaginal delivery.

women in the study was  $26.4 \pm 4.2$  years,  $3.4 \pm 1.3$ ,  $37.81 \pm 1.67$  respectively Only 40(28.8%) cases had been booked compared to 80(57.7%) who were un-booked, and only 19(13.5%) women had been referred from other hospitals.

Overall, 110(78.8%) women delivered at the hospital and only 27(19.2%) had home deliveries and 02(1.9%) women had delivered at some private clinic.

Of the total, 126(90.4%) women had spontaneous vaginal deliveries compared to only 13(9.6%) women who had instrumental delivery.

Mean estimated blood loss was  $1155.8 \pm 350.6$  ml, SBP  $90.96 \pm 18.1$  mmHg, DBP  $55 \pm 7.5$  mmHg and mean pulse was  $108.3 \pm 10.89$  bpm.

Balloon tamponade was effective in 126(90.4%) cases was not effective in 13(9.6%) (Table-1).

When data was analyzed with respect to maternal age, gestational age, parity and mode of delivery, it showed no significant differences ( $p=0.494$ ;  $p=0.274$ ;  $p=0.106$ ; and  $p=0.443$ ) (Table-2).

Out of 126 women in whom balloon tamponade was effective, 40(31.9%) were booked, 75(59.6%) were un-booked and 11(8.5%) were referred. Among the 13 women in whom balloon tamponade was not effective, 5(40%) were un-booked and 8(60%) were referred cases.

Out of 126 women in whom balloon tamponade was effective, 113(89.4%) had normal vaginal delivery (NVD) and 13(10.6%) had instrumental delivery, while all of 13(100%) women in whom balloon tamponade was not effective had NVD.

Failure in 13 cases was due to difficulty in correct placement due to large size of uterus in 7(54%) cases,

2(15.3%) had fibroid uterus, 2(15.3%) developed disseminated intravascular coagulation (DIC), and 2(15.3%) had expulsion of balloon.

## Discussion

PPH is one of the leading causes of maternal death and one of the major causes of mortality in women in developing countries. According to the Central Statistical Office, in 2006, in Poland 540 maternal peripartum deaths were noted, 34.7% of which due to PPH.<sup>11</sup> Therefore, active postpartum management should be the main goal in contemporary obstetrics. Some PPH management algorithms have been proposed by the World Health Organisation (WHO), the American College of Obstetricians and Gynecologists (ACOG) and Polish Gynecological Society (PGS). In the event of unsuccessful conventional management of PPH (uterotonics etc.), the method of uterine tamponade using balloons has recently been added to the armamentarium for managing PPH. There are various balloons available, including the Bakri, Foley, Sengstaken-Blakemore, Rusch and condom catheter.<sup>12</sup>

Intrauterine tamponade with balloon catheter is another option that can be employed for the management of massive PPH. A study of patients with severe PPH who were managed with this technique has been reported in literature. Though the tamponade was effective in most cases, 10% cases required hysterectomy despite successful placement of the catheter.<sup>13</sup>

One study[14] reported that during 2008, massive PPH occurred in 0.64% cases. No deaths were reported. The mean blood loss was  $2431 \pm 1817$  ml (range: 1500-9000ml). Emergency CS was the most common mode of delivery (50%) while uterine atony was the most common cause of massive PPH (54%). B-lynch suture (24%) and balloon tamponade (60%) were used more commonly compared to our previously reported experience. Caesarean hysterectomy was performed in 3(12%) cases to control massive PPH. More than 80% compliance was observed in 8 out of 10 steps of the management protocol. Initiation of blood transfusion at 1500ml blood loss (89%) and overall documentation of management (92%) were favourably observed in most cases.

One prospective observational study<sup>15</sup> evaluated the use of a 'uterine sandwich' technique (uterine compression sutures in association with intrauterine tamponade) in women who had had unsuccessful medical treatment for PPH. Ten of the 11 patients had CS (complicated by placenta previa and uterine atony) and 1 had a normal delivery. The median estimated blood loss and units of

blood transfused were 1500ml (range: 750-4000ml) and two units (range 0-9), respectively. B-Lynch sutures were placed in two patients and Hayman's modification was used in 9. Bakri balloon tamponade was in place for a median of 22 hours (range: 17-27 hours), while the median volume infused in the balloon was 300ml (range: 150-350ml). The combined technique was successful in avoiding hysterectomy in all cases, and there was no documented postpartum morbidity. This is a simple and quick surgical technique that can be used to treat atonic PPH, particularly in conjunction with placenta previa.

One study<sup>9</sup> reported that there were 27 women who had placement of the catheter. In 22(81%) case haemostasis was achieved, while in 5(19%) cases the Sengstaken-Blakemore oesophageal catheter (SBOC) failed in arresting haemorrhage. Of the 5 failures, hysterectomy was required in 4 cases and in the remaining case the failure was associated with expulsion of the balloon, but haemostasis was achieved with further conservative measures. Among the failed cases, there was one maternal death due to amniotic fluid embolism with cardiac arrest and PPH secondary to coagulopathy. In cases where the balloon was successful, it was removed around 24 hours later. In these cases, no further bleeding was observed, and no complications occurred from the procedure.

Uterine tamponade can be lifesaving in PPH associated with deranged coagulation; as such women are at high risk for surgical intervention or angiographic embolisation. Successful tamponade with Rusch balloon catheter, Sengstaken-Blakemore tube, rolled gauze and recently with condom catheter are reported.<sup>16</sup>

Condom catheter is an inexpensive and readily available method. It is simple to use and in developing countries with a low institutional delivery rate, can be practised by trained birth attendants (TBAs) while they make arrangements for transportation to a hospital. The inflated condom conforms naturally to the uterine contour and exerts uniform pressure on the sinuses, which stops the bleeding. It is inflated until the bleeding is controlled and usually 250-300ml suffices. The saline flows freely initially and later slows down. This coincides with reduction in bleeding. An anaesthetic is not required, but analgesia (pethidine) may be used.

A case series<sup>17</sup> reported that 23 PPH patients unresponsive to medical therapy were managed with intrauterine balloon tamponade. When properly placed, catheters controlled PPH in 18 of 20 cases (90%). In two cases, hysterectomy was required

despite successful placement of the catheter. For haemorrhage due to uterine atony, the success rate was 100% (11/11 cases). In three cases, technical difficulties led to placement failure. For bleeding due to retained placenta, the success rate was 80% (4/5; failure with placenta percreta). Vaginal bleeding was stopped with the catheter in 2 of 3 cases of amniotic fluid embolus and in 1 case after dilation and curettage for postpartum septic shock. Thus balloon tamponade is an effective adjunct in the treatment of severe PPH, especially when due to uterine atony when medical therapy fails.

One study<sup>[18]</sup> reported that the success rate of condom catheter balloon in controlling haemorrhage was 94%. The mean amount of fluid filled in the condom catheter balloon was 409 mL. The average time taken to control bleeding was 6.2 min. The mean duration for which condom catheter balloon was left in situ was 27.5 h. The average amount of blood loss was 1330 mL. Five patients (28%) had infective morbidity.

In comparison, in our study majority of women [113(89.4%)] delivered by NVD while 13(10.6%) delivered by instrumental delivery. Mean estimated blood loss was 1155.8±350.6 ml. Balloon tamponade was effective in majority of cases [126(90.4%)].

## Conclusion

Condom balloon tamponade was effective in controlling PPH. Further study of such interventions is required to better understand the barriers for successful implementation and its use in resource-limited settings. There should also be a low threshold for prophylactic use of balloon tamponade in women at high risk of PPH, considering its ease of use, low complication rate and ability to maintain reproductive ability.

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