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Effectiveness of condom catheter balloon tamponade in the management of atonic post-partum haemorrhage

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Abstract
Introduction: Post-Partum haemorrhage accounts for a quarter of maternal mortality all over the world. In 2017 atonic haemorrhage was the cause for more than 38000 maternal death among which >90% happened in (LMIC's) low and middle income countries. In low resource countries PPH is the foremost, 30%, cause of maternal mortality. Thus we are in a need to develop cheap and economically feasible method for PPH management.
Materials and Methods: We conducted a prospective intervention study to evaluate the effectiveness of condom catheter balloon tamponade in atonic PPH management and its efficacy to reduce the need for surgical intervention. Condom balloon tamponade kit assembled with reference to C-G Balloon and inserted into the uterine cavity when atonic PPH becomes refractory to medical management.
Observation & Results: In this study, out of 41 mothers with atonic PPH, success rate of condom balloon tamponade was 76.9% without any need for surgical intervention. In the remaining 23.1%, 7.7% needed hysterectomy. In all the failed patients, hysterectomy was required in 75% to control the haemorrhage and this was found to be statistically significant (Pearson's chi- square test was used p <0.05).
Discussion: The effectiveness of condom tamponade in reducing the need for invasive procedures like compression sutures, uterine artery ligation and hysterectomy was proved in 89.7% of patients with PPH. All the 4 Patients in whom tamponade failed to achieve haemostasis underwent caesarean section and developed intra operative atonic haemorrhage. We observed that uterine atonicity developing intra-operatively during caesarean section highly required invasive surgical intervention like compression sutures and hysterectomy as heamostasis was not achieved with condom balloon tamponade.
Conclusion: The results of our study was comparable to that conducted by Condous GS *et al*. Who evaluated the efficacy of tamponade test in the management of massive PPH in 16 patients. The timely usage of condom catheter balloon tamponade decreased the mortality rate and also the morbidity following surgical intervention and anaesthetic complications in atonic PPH patients.

Keywords: Condom catheter, Balloon tamponade, atonic post-partum haemorrhage, UBT (Uterine balloon tamponade), surgical intervention, hysterectomy

Introduction

Primary Postpartum haemorrhage is classically defined as blood loss from the genital tract, >500ml within 24 hours of vaginal delivery and 1000ml during a caesarean section. PPH can be minor (500-1000ml) or major (>1000ml). Major PPH further divided into moderate (1000-2000ml) and massive (loss of 30%-40% of total blood volume or resulting in haemodynamic instability. The American College of Obstetricians and Gynaecologists (ACOG) revitalise programmes define PPH as cumulative blood loss accompanied by signs or symptoms of hypovolaemia within 24 hours of birth process that includes intrapartum blood loss regardless of route of delivery [11].

Post-Partum haemorrhage accounts for a quarter of maternal mortality all over the world.[1] According to the recent Confidential Enquiries into Maternal and Child Health report (CEMACH), PPH occurs in around 3.7 per 1000 births every year with uterine atony being the most common and most preventable cause of maternal death [2]. It significantly contributes to severe maternal morbidity and long term disability including shock and multi organ dysfunction [3, 4]. Regarding PPH a famous quote says 'Too little being done Too late' as the reason for its high morbidity and mortality. In 2014, WHO reported 8% of all maternal death due to PPH in developing countries of eastern Asia and 32% in northern Africa [5]. In 2017 atonic haemorrhage was the cause for more than 38000 maternal death among which >90% happened in (LMIC's) low and middle income countries [5, 6].

In low resource countries PPH is the foremost, 30%, cause of maternal mortality [3].

Thus we are in a dire need to implement methods which are cheap, easily accessible and applicable with minimal training and with maximum efficiency when atonic PPH become resistant to conservative treatment like oxytocics and bimanual uterine compression. The recently incorporated uterine balloon tamponade for atonic uterus is improvised with the condom catheter and made economically feasible. Tindal *et al*. conducted a systemic analysis to evaluate the effectiveness of various types of uterine balloon tamponade in the PPH management in poor resource countries [7]. The study utilised different types of UBT, including condom catheter, Foleys' catheter and Sengstaken Blakemore oesophageal catheter. In these studies condom balloon tamponade successfully treated intractable PPH in 234 out of 241 women.

Among uterine balloon tamponade, condom catheter proved to be a cheap easily available and applicable with high success rates than S-B catheter, Rusch balloon and Bakri catheter and most importantly condom catheter proved to play a main role as tamponade in low resource countries as proved by Jennifer *et al*. in her study in India and Tanzania.

The two main disadvantages of condom catheter balloon tamponade was the non-availability of drainage port and minimal chances of slipping from the site thereby resulting in leakage of normal saline. These two pitfalls were overcome by Nalini Mishra *et al.* who conducted a study with an innovative condom balloon tamponade namely C-G balloon tamponade for PPH management [8]. A drainage port is created by cutting the distal tip after ligating the condom with two rubber band like rings made from cutting the free connecting end of the catheter. C-G balloon was successful in 92.3% cases as second line management in atonic PPH management protocols [8]. Using this CG balloon as reference a prospective study was conducted to evaluate the efficiency of condom balloon tamponade in PPH management and reducing the need for highly invasive, highly morbid surgical intervention like Subtotal or Total hysterectomy.

Aim

The aim of the study is to evaluate the effectiveness of condom catheter balloon tamponade in the management of atonic postpartum hemorrhage.

Objectives

The objective of this study is to evaluate the use of condom catheter balloon in terms of

1. Efficiency of condom catheter balloon uterine tamponade to arrest bleeding during atonic PPH within 24 hours.
2. Time interval between condom catheter balloon intervention and haemostasis.
3. Condom catheter balloon tamponade inflation and deflation interval.
4. Any infections following condom catheter balloon tamponade usage despite the use of broad spectrum prophylactic antibiotics.

Materials and methods

We conducted a prospective interventional study at Raja Muthiah Medical College and Hospital, Chidambaram, India. From October 2018 to October 2020. Patients delivered vaginally or by caesarean section and also patient who terminated the pregnancy in second trimester, who developed atonic post-partum haemorrhage refractory to primary medical management were selected. Sample size for the study 41 with relative precision 10% and level of significance 5% after getting oral and verbal consent from patient and attenders the procedure performed. No anaesthesia and analgesics given. Initially PPH diagnosed with general condition of the patient assessed with vital signs and clinical examinations, per abdominal examination done and uterus palpated for tone. Blood loss estimated by visual method including blood spillage over the floor and blood collected in the kidney tray. As per FIGO guidelines active management of third stage of labour done. Primary medical management with Inj.Oxytocin 40U IV infusion, Inj.Methyl Ergometrine, Inj.Carboprost. Tab.Misoprostol 800mg per rectal was given after individualising the patient's condition and associated co-morbidities. Concurrently bimanual uterine compression done. Those patients with refractory massive haemorrhage were selected for this study. First, patient in lithotomy position, examined for retained placental tissue. Meanwhile a condom balloon tamponade kit was organised under aseptic precautions. A latex condom, Foley's catheter, 10ml syringe, urobag was taken. The free end of the catheter was cut and two rubber band like rings made. The condom was tied at the distal end of the catheter at two points, one at the tip of the catheter and another near the open end of the condom. A drainage port was created by cutting the distal tip of the overlying condom. Urobag was connected. Patient was in lithotomy position after draining the bladder. Anterior lip of the cervix held with sponge holding forceps and posterior vaginal wall retracted. Condom balloon tamponade assembly inserted into the uterine cavity and inflated with appropriate volume of normal saline using a 10ml syringe till bleedimg stops and uterus become palpable. Maximum volume of normal saline was 500ml, but in most cases haemostasis achieved with 350ml. Intrauterine bleeding if present gets collected in the urobag. Bleeding observed for 15 minutes. If bleeding continued again normal saline inflated and observed for bleeding. If bleeding was stopped condom tamponade was left in situ until 12 to 24 hrs. Prophylactic broad spectrum antibiotics mostly intravenous given. Concurrent oxytocin infusion was started and continued for around 4 hours. After 12 to 24 hours if the uterus was well contracted with stable vitals and no bleeding was further collected in the urobag. The balloon was deflated slowly at the rate of 5ml per minute. Bleeding observed for30 minutes. If there was no bleeding condom-catheter tamponade removed and the patient was kept under observation for 2hrs.

Intervention

All patients had atonic PPH except one who also had associated genital tract injury which was repaired. Bladder catheterised. Condom catheter balloon tamponade inserted and tamponade test done. Tamponade test means inflating appropriate volume of normal saline until uterus becomes palpable per abdomen and no or only minimal bleeding observed for 15 minutes, then test result considered positive, indicating that surgical intervention with hysterectomy was unnecessary. Out of 41 patients 4 patients have negative tamponade test and resulted in surgical intervention.

Even after achieving haemostasis blood transfusion done for 15 patients, in view of severe anemia, and DIC, mostly whole blood. FFP transfusion for 3 patients in whom DIC was suspected, Platelets transfused in three patients of which 1 had gestational thrombocytopenia and 2 was suspected with DIC. Prophylactic broad spectrum IV antibiotics either a combination of Inj.Ampicillin, Inj.Metronidazole and Inj.Gentamicin, or Inj.Cefotaxime and Inj.Metronidazole was given to all patients

vitals continuously monitored for 24 hrs.

In patients who developed intraoperative atonic haemorrhage during emergency or elective LSCS condom balloon tamponade set was introduced vaginally after closing the uterine incision and observed for bleeding, before abdominal closure. Out of 5 patients 1 patient achieved haemostatsis with tamponade and abdominal closure done in that patient. In other 4 patients emergency peripartum hysterectomy proceeded as haemostasis not achieved with the balloon tamponade, Bilateral uterine artery ligation and surgical compression sutures like B-Lynch. Of 4 patients with failed tamponade 2 developed DIC with severe anemia, had intraoperative non revertable ventricular fibrillation and expired after mean duration of 6-8 hours following surgery. The remaining two patients who underwent hysterectomy was managed in surgical ICU unit with A team of intensivist and medical internists and they were discharged well after advising proper follow up. Remaining 37 patients with positive tamponade test in whom haemostatsis achieved successfully with the balloon tamponade had stable vitals during the puerperal period and discharged well after few days.

A few patients developed mild fever, who were treated with antipyretics and very few developed nausea with vomiting who were given antiemetics. No one developed signs of severe puerperal sepsis during the study.

Observation and results

The mean age of our study participants was 27.7±5.7 years and it ranged from 19 – 42 years. The primi gravid mothers constituted 30.8% and the multi gravida mothers shared the majority 69.2%.Vaginal deliveries included 65.2%, among which 15.4% were instrumental deliveries. 30.8% patients delivered by caesarean section of which 23.1% constituted emergency LSCS and 7.1% elective LSCS. Intrauterine fetal demise and expulsion constituted 5.1%. The mean gestational age was 37.6±3.1 weeks and the mean birth weight of baby 3.23±0.63 kg. The mean duration taken to diagnose PPH in majority of cases (64.2%) was 15-30 minutes.

Table 1: Diagnosis of atonic PPH and intervention parameters

	Minimum	Maximum	Mean (SD)	Median (IQR)
Volume of haemorrhage (in ml)	447	3100	1088.3 (555.5)	900 (800, 1200)
PPH to tamponade (in minutes)	10	90	28.2 (15.9)	20 (20, 30)
Volume of NS (in ml)	150	500	257.2 (90.4)	250 (200,300)
Tamponade to deflation interval (in minutes)*	18	24	21.9 (2.1)	22 (20, 24)
Tamponade to haemostasis (in minutes) *	0	18	6.9 (5.9)	5 (0, 10)
Post tamponade bleeding (in ml)*	0	150	68.6 (43.6)	80 (40, 100)
*n=37 as haemostatis was not achieved for 4 patients				

The above table narrates the most important parameters like average volume of haemorrhage, average time interval between diagnosis of PPH and tamponade application, mean volume of NS requirement, average time interval between tamponade to deflation, average time interval between tamponade and haemostasis and post-tamponade bleeding.

The mean volume of haemorrhage was 1088.3ml with maximum blood loss being 3100ml and minimum being 447ml. The mean volume of normal saline inflated was 257.2ml and the haemostasis was achieved in the mean duration of 6.9 -7.5 minutes. Post tamponade bleeding, the mean volume was 68.8ml.

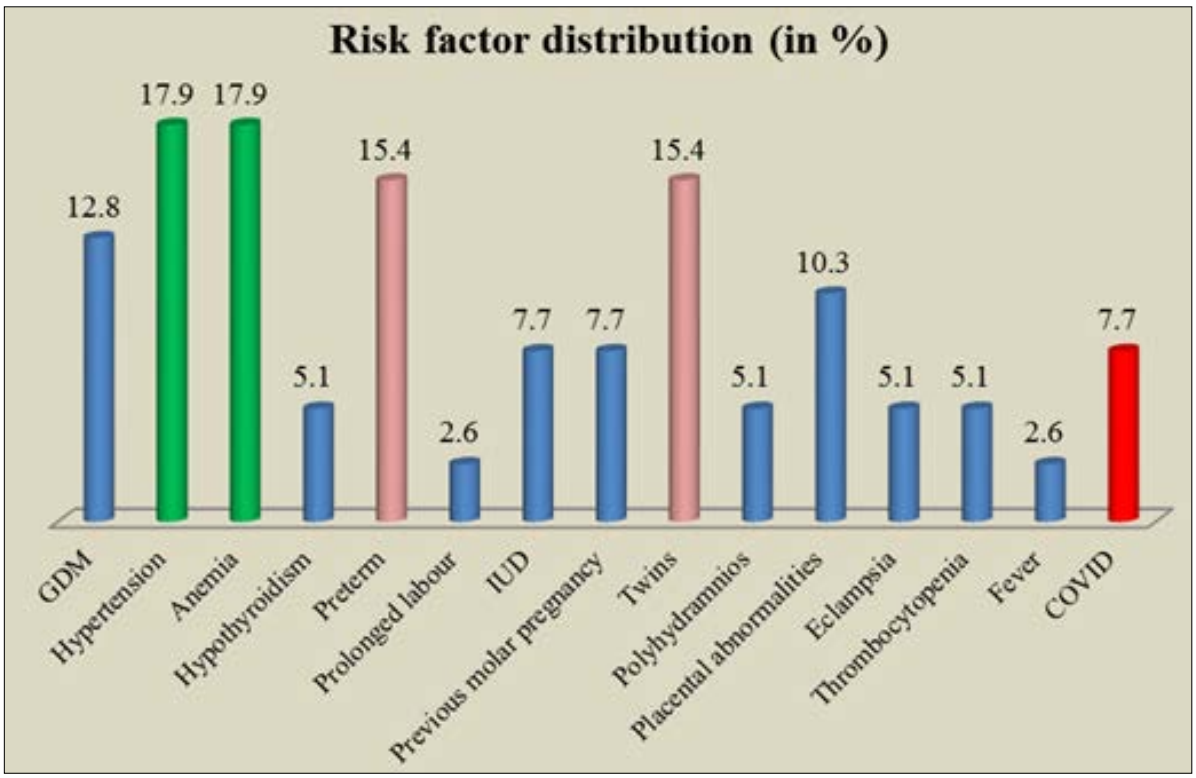

Fig 1: Distribution of co-morbidities and other risks (n=39)

The figure shows that, hypertension and anemia were the major risk factors (17.9%) followed by preterm and twin deliveries (15.4%). It was evidenced that COVID has been contributing to 7.7% risk in the study population.

In this study, out of 41 mothers with atonic PPH, success rate of condom balloon tamponade was 76.9% without any need for surgical intervention. In the remaining 23.1%, 7.7% needed hysterectomy.

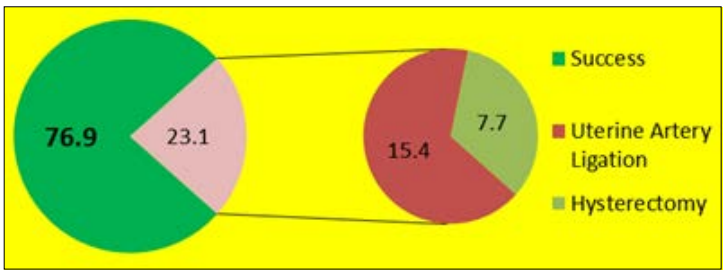

Fig 2: Success rate of condom balloon catheter and procedures required in %

Of the 37 mothers who achieved haemostasis with balloon tamponade, concurrent uterine artery ligation was performed in 8.6% while among the failed candidates (n =4) 75% required uterine artery ligation and this difference was found to be statistically significant. (Pearson's chi-square test was used p <0.05) In all the failed patients, hysterectomy was required in 75% to control the haemorrhage and this was found to be statistically significant (Pearson's chi- square test was used p <0.05).

In the distribution of outcome (n=41) in this study, it was noticed that nearly 90% of the outcome was uneventful i.e. haemostasis achieved with condom balloon tamponade while 5.1% became morbidly sick being admitted in obstetric ICU and remaining 4.9% died of complications.

Table 2: Distribution of post-partal complications (n=39)

Co-morbidities/ Risk	Frequency	Percentage
DIC	2	5.1
Shock	2	5.1
Ventricular Fibrillation	2	5.1
Hypotension	3	7.7
Anemia	22	56.4
Thrombocytopenia	1	2.6
Cervical/Perineal tears	2	5.1

The mean volume of haemorrhage in ICU patients or in expired patients was 2500ml whereas in those who achieved haemostasis with balloon tamponade it was 900ml.

The outcome of atonic PPH was very difficult to predict, although it was clearly depicted in the study that 50% of patients who developed hypotensive shock and DIC following PPH, died and this was found to be statistically significant.

Table 3: Comparison of vital parameters between the outcome groups

	Seriously ill/Expired (n=4)		**Discharged** (n=35)		**p-value**
	Median	**IQR**	**Median**	**IQR**	
SBP (mmHg)	60	52.5, 105	100	100, 120	0.03
DBP (mmHg)	40	32.5, 70	60	60, 70	0.06
Volume of haemorrhage (in ml)	2500.0	1900, 3025	900.0	800, 1033	<0.001
Volume of NS required (in ml)	500.0	425, 500	250.0	200, 250	<0.001
PPH to tamponade (in minutes)	22.5	12.5, 73.75	20	20, 30	0.84
Mann Whitney U test used; p-value <0.05 is significant					

Table 3 demonstrates the comparison of vital parameters between the discharged and critically ill or died patients.

Discussion

The primary outcome measured in this study was the rate of surgical intervention needed if any, following condom catheter balloon tamponade insertion in atonic postpartum haemorrhage. We also observed the risk factors playing a role in developing atonicity. Also we studied the clinical indicators determining the success rate of condom tamponade like vitals of patients, volume of blood loss, volume of NS required for hemostasis and time interval between PPH and tamponade insertion.

The effectiveness of condom tamponade in reducing the need for invasive procedures like compression sutures, uterine artery ligation and hysterectomy was proved in 89.7% of patients with PPH. In Patients who delivered vaginally either normal labour or abnormal labour like preterm delivery, twin delivery, assisted breech delivery or instrumental delivery condom tamponade 100% achieved haemostasis. All the 4 Patients in whom tamponade failed to achieve haemostasis underwent caesarean section and developed intra operative atonic haemorrhage. In all these 4 patients tamponade test results were negative. Emergency peripartum hysterectomy was done as a final rescue and inspite of that 2 patients expired during the study. They both developed hypotensive shock with DIC and went in for cardiac arrest. One of them was COVID positive patient with severe anemia and the other was a case of prolonged obstructed labour referred from outside hospital with baby head entrapped and

baby also died. They both developed ventricular fibrillation intra-operatively and died after a mean duration of 6hours after surgery.

Condous GS *et al.* [9] evaluated the tamponade test in the management of massive PPH in 16 patients and success was met with in 14 of them i.e. 87.5%. Two of them i.e. 12.5% gave negative tamponade test and hence underwent hysterectomy. Thus this diagnostic test rapidly identified patients with postpartum haemorrhage who required laparatomy. The results of our study was comparable to that conducted by Condous GS *et al*., In 2009 to 2012 Rathore AM *et al.* [10]., conducted a prospective study evaluating the efficacy of condom catheter balloon tamponade in the management of non-traumatic postpartum haemorrhage resistant to medical therapy in 18 patients with a success rate of 94% but in his study all those patients delivered vaginally. The success rate in our study was nearly 90% for both LSCS and vaginal delivery and the success rate was 100% while taking only vaginal delivery into account.

We observed that uterine atonicity developing intra-operatively during caesarean section highly required invasive surgical intervention like compression sutures and hysterectomy as heamostasis was not achieved with condom balloon tamponade. Mostly patients undergoing LSCS were not in established labour and internal OS was tightly closed making it difficult and time consuming for tamponade insertion. Also when patient was under anaesthesia shifting her from supine position to lithotomy position proved time consuming and also resulted in blood pressure deterioration as patients were already in hypotension. Also we observed that anemia, polyhydramnios with gestational diabetes mellitus, placental implantation problems like placenta accreta and percreta acted as hindering factors in achieving haemostasis with condom balloon tamponade and leading to hysterectomy.

Conclusion

Further studies evaluating the efficacy of condom catheter balloon tamponade in atonic PPH following caesarean or intraoperative atonic PPH during caesarean section need to be conducted for definitive results. The timely usage of condom catheter balloon tamponade decreased the mortality rate and also the morbidity following surgical intervention and anaesthetic complications in atonic PPH patients. It proves as an easily accessible, economically feasible and a method with few side effects. It also proved to be an effective intervention while transferring an atonic PPH patient from a primary health care centre to a higher centre and also during preparing for emergency surgical intervention if needed.

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