D A Ranasinghe Oration 2013

Post partum haemorrhage, severe acute maternal morbidity and the condom catheter uterine tamponade

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Introduction

Motherhood is a cherished dream of every woman and most pregnant mothers go through childbirth to have a satisfying and happy ending. Unfortunately, some mothers do encounter serious complications, leading to severe morbidity and sometimes mortality. Sri Lanka has successfully reduced maternal mortality from approximately 2000 per 100,000 live births in 1930 to 33.3 per 100,000 live births by 2010[2]. Although the rate of decline was steep from 1930 to 1970s, it has become less marked thereafter.

Primary post partum haemorrhage (PPH), defined as a loss of 500ml or more of blood within the first 24 hours of childbirth, is still one of the leading causes of maternal morbidity and mortality worldwide. It occurs in approximately 2% of women who give birth vaginally or by caesarean section. Obstetric haemorrhage is estimated to occur in approximately 30.8% (95% CI 5.9 - 48.5%) of maternal deaths and is the leading cause of maternal mortality in Asia[1]. PPH is also a significant contributor to severe maternal morbidity and long-term disability as well as other severe maternal conditions such as shock and organ dysfunction. It remains the leading cause of maternal mortality in Sri Lanka and accounted for 5.8 maternal deaths per 100,000 live births in 2010[2]. This is in spite of approximately 99% of women having hospital deliveries with a skilled birth attendant present[3], and a recommendation of universal practice of active management of the third stage of labour[4].

Study of mortality due to PPH does not give us an insight in to the real picture as it constitute only the tip of the iceberg of a much broader problem leading to significant morbidity. The small numbers in mortalities makes it difficult to audit service provision, especially in a single unit. Therefore other indicators such as severe acute maternal morbidity (SAMM), also referred to as 'Near Misses', have been proposed as a supplementary indicator for the assessment of the quality of maternity care. Criteria based clinical audits using this concept, have been suggested as being effective tools in improving the management and the quality of care and thus leading to reductions of maternal morbidity and mortality in general as well as in PPH[5-9]. SAMM refers to a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy.

Table1. Study group according to WHO near miss criteria[6,8] (n = 91)

Group	*Near miss criterion*	*Total Cases*	*Percentage*
1	**Severe post partum haemorrhage**	**33**	**36.3**
2	Severe pre-eclampsia	12	13.2
3	Eclampsia	06	6.6
4	Sepsis/severe systemic infection	03	3.3
5	Ruptured uterus	02	2.2
6	Severe complication of abortion	02	2.2
	Critical interventions		
7	Admission to intensive care unit fulfilling study inclusion criteria	91	100
8	Interventional radiology	-	-
9	Laparotomy	22	24.8
10	Use of blood products	40	43.9
	Life-threatening conditions		
11	Cardiovascular dysfunction	09	9.9
12	Respiratory dysfunction	01	1.1
13	Renal dysfunction	02	2.2
14	Coagulation/haematological dysfunction	18	19.8
15	Hepatic dysfunction	05	5.5
16	Neurological dysfunction	01	1.1
17	Uterine dysfunction (hysterectomy)	18	19.8

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Use of severe acute maternal morbidity (SAMM) in a Sri Lankan tertiary care institution[10]

Objective

To study SAMM in order to identify strategies which could be adopted to improve quality of care.

Design, setting and methods

Using the WHO near-miss criteria, a clinical audit was carried out at the Castle Street Hospital for Women (CSHW), Colombo, including all five consultant units, from 1st February 2011 to 31st January 2012[10]. Of the admissions to the intensive care, only those who conformed to the WHO near-miss inclusion criteria were studied.

Results and discussion

There were a total of 91 cases of SAMM and five maternal deaths out of 16511 live births during the period studied. The maternal mortality ratio was 30.3 /100,000 live births, and the SAMM ratio was 5.5/1000 live births. The SAMM: mortality ratio was 18.2. There were no maternal deaths due to PPH during the period studied. Of the 91 cases of SAMM, PPH was the leading cause (n=35, 38.5%) and included two cases of uterine rupture. The second commonest morbidity group was thrombocytopenia and coagulo-pathy due to Dengue fever (n=18, 19.8%). However this was a seasonal cause during the study period, and in general not seen as a major contributor in the previous years.

Among the women who had PPH, the rate of emergency and elective caesarean section was 43% and 26% respectively (Figure 1) and this was approximately double the rate of emergency and elective caesarean section (23% and 12% respectively) in the CSHW (Figure 2)[10]. It should be noted that this in contrast to a study carried out in Mahamodara, Galle, where it was shown that PPH following instrumental vaginal delivery was approximately 3.5 times higher and PPH following CS was only 1.3 times higher compared to PPH after normal vaginal deliveries[11].

Uterine atony was the commonest cause of PPH and was associated with 57% of cases in our study at CSHW[10]. However genital tract trauma was associated with 49% of cases of PPH in the Mahamodara study[11].

Figure 1. **Mode of delivery and occurrence of post partum haemorrhage (n = 35).**

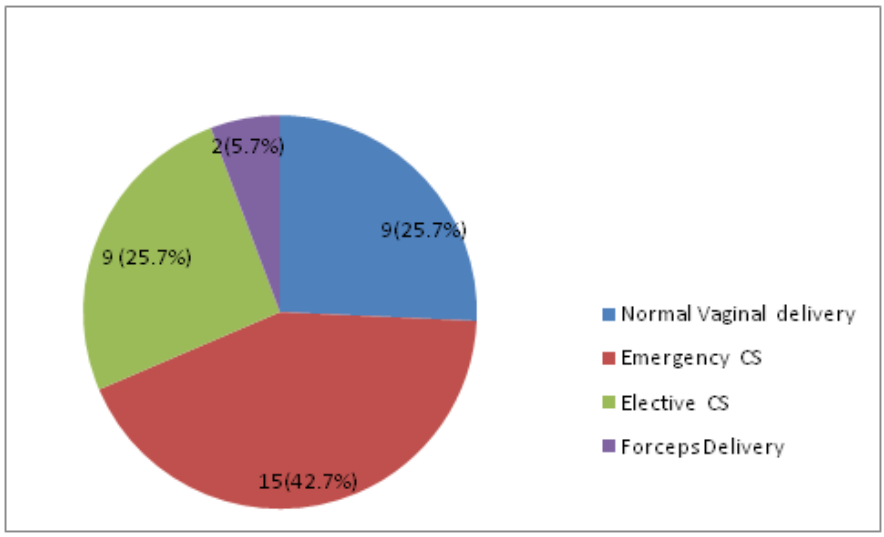


Figure 2. **Mode of delivery in the Castle Street Hospital for Women during the study period (n = 16511).**

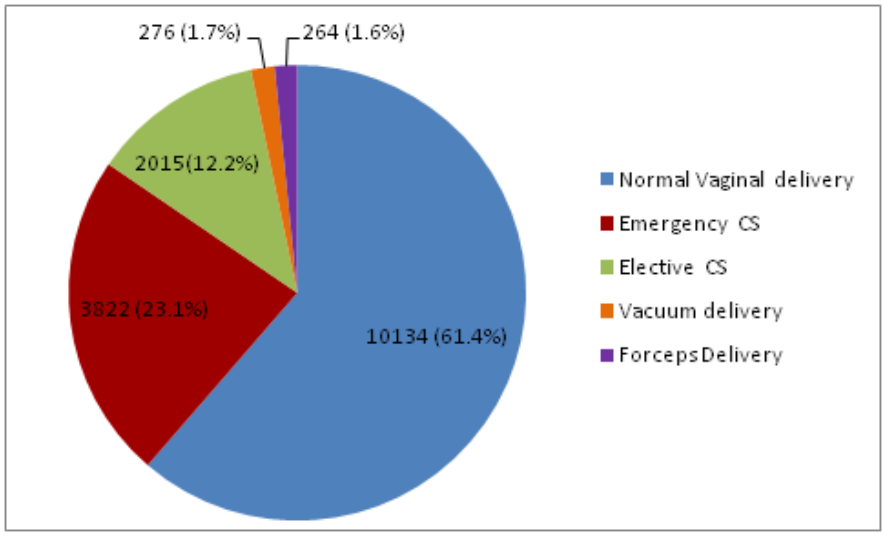


Table 2. Causes of post partum haemorrhage (n = 35)

Cause	*Number*	*Percentage*
Uterine atony	20	57.1
Placenta praevia	03	8.6
Placental abruption	02	5.7
Uterine inversion	02	5.7
Broad ligament haematoma	02	5.7
Coagulation defect (Thrombocytopenia)	02	5.7
Morbidly adherent placenta	01	2.9
Placenta praevia with morbidly adherent placenta	01	2.9
Uterine rupture	01	2.9
Vaginal and cervical laceration	01	2.9
Uterine rupture and cervical laceration	01	2.9

Conclusions

In an attempt to improve care in these SAMM patients, certain areas were identified as needing further improvement. These included documentation, estimation and documentation of blood loss, use of uterine tamponade before proceeding to hysterectomy, and knowledge and experience of uterine tamponade insertion.

The use of a condom catheter as a method of uterine tamponade

The commonest cause of PPH worldwide is uterine atony and as much as 80% of the cases result from suboptimal contraction of the myometrium following placental separation. Other causes of PPH such as genital tract trauma, uterine rupture, retained placental tissue or maternal coagulopathy are less commonly seen[12,13]. Management of PPH involves a stepwise series. Persistent bleeding is assumed to be due to atony, once retained products and genital tract trauma have been excluded, and physical methods, pharmacological methods and surgical procedures to control uterine bleeding would be employed in a stepwise manner[14].

The first line of management is pharmacological and the agents used include oxytocin, ergometrine and prostaglandin. When they fail to arrest the bleeding mechanical and surgical methods are employed. A variety of surgical options are available such as uterine artery ligation, ovarian artery ligation and internal iliac artery ligation to control the blood supply to the uterus. B-Lynch brace sutures are placed to compress the uterus and to maintain the contracted status without interfering with blood supply to control PPH[15]. These procedures are effective in avoiding hysterectomy but a laparotomy performed by skilled personnel is required. Therefore these techniques may not be ideal, especially following a vaginal delivery.

A simpler technique, which can be performed by medical personnel of reasonable skill, is the use of uterine balloon tamponade and this has gained popularity over the years. It appears to be very effective in prevention of hysterectomy and should be tried before resorting to more disabling surgical procedures. It can also be used as a method of controlling blood loss while waiting for surgery or if the patient is transferred from the periphery to a unit with better facilities[13-20].

The exact mechanism or the theoretical principle of uterine balloon tamponade is not clear. Several possible mechanisms have been hypothesised. One is that it maintains a temporary and steady mechanical pressure against the bleeding sinus openings of the placental site till the natural haemostatic mechanisms form a stable clot. Another is that the balloon inflated inside creates intraluminal pressure that exceeds the patient's systolic blood pressure to stop inward blood flow[19-21]. While this maybe an effective mechanism with onset of hypotension, the same may not be that effective with normal blood pressures. Overstretching of the myometrium by the tamponade changing the anatomical alignment and angulation of the arteries to create vasospasm and formation of blood clots to control bleeding is another possible mechanism[21,22].

Different balloons used in medical practice have been tried to bring about this tamponade effect in presence of PPH. The Bakri Balloon (Cook Medical, IN, USA) and BT-Cath (Utah Medical products, UT, USA) are purpose designed uterine balloons which are in clinical use[14 -15]. Other balloons used include the Sengstken-Blakemore tube, which is designed to be used in oesophageal varices and Rusch balloon designed to be used within the urinary bladder, and they have shown to be effective alternatives. Condom catheter and saline filled surgical gloves are improvised balloon mechanisms used to achieve the tamponade effect within the uterine cavity.

The condom catheter is the most cost effective balloon for the management of PPH[18-20]. SayebaAkter and colleagues presented their experience with the use of condom catheter at the second South Asian Federation of Obstetrics and Gynaecology meeting in Dhaka, Bangladesh which was published later[18]. Having listened to their experience, we conducted a study to evaluate its use in a local setting.

Objective

Our objective was to observe the clinical effectiveness of the use of

condom catheter uterine tamponade in avoiding hysterectomy in PPH and to describe the immediate and late complications of this intervention.

Design, setting and methods

This was a prospective observational study. It was decided to use condom catheter uterine tamponade for mothers who did not respond to medical management according to the unit protocol[23] and continue to bleed after delivery. As far back as 2002 we used this method with certain modifications from the Bangladesh Model[18]. We used size 22 Foley catheter instead of a rubber catheter. We also checked the condom catheter for leaking before insertion, washed the condom with Povidone Iodine solution and marked the fundus level abdominally to assess intrauterine bleeding. Our method of filling was rapid filling with pressure followed by gravity filling to achieve the optimal volume[24]. All mothers who had condom catheter uterine tamponade for the management of PPH in ward one, Castle Street Hospital for Women, Colombo from 01.01.2006 till 31.12.2010 were included in the study.

Ethical approval for the study was obtained from the Ethics Review Committee of the Castle Street Hospital for Women, Colombo, Sri Lanka.

Insertion of a 'condom catheter' for uterine tamponade

This may be performed as an independent procedure or following inspection of the cervix and upper vagina for genital tract trauma. Therefore, whenever it is planned to inspect the cervix, the materials needed for insertion of a condom catheter for uterine tamponade should be kept ready. The procedure that was followed in insertion of the condom catheter was as follows:

1. Explained to the mother the need to insert a condom catheter and explained the procedure briefly in a reassuring manner
2. The procedure was done suing an aseptic method
3. The required items were prepared and they included:
   - A size 20 - 22 (or largest available) Foley catheter
   - A condom
   - Sterile No. 0 or 1 suture
   - Two bottles of warmed saline
   - Intravenous infusion set released from the pack
   - These were arranged on a sterile towel laid side trolley
4. Took the Foley catheter and unfolded the condom over the end of the Foley catheter to about two thirds of its length. Hand tied it to the catheter firmly, using several rounds of sterile sutures at a point about 2 cm distal to the open end of the condom
5. Had an assistant connect the infusion set to the bottle of warmed normal saline suspended at least 4-6 feet above the bed
6. Connected the other end to the catheter and ran saline into the condom to make sure the system is water tight by holding the catheter tip upwards
7. Afterwards, emptied the balloon of the saline and left it on the sterile trolley, ready for insertion
8. Washed the condom with warm saline or Betadine lotion
9. Placed the woman either in the dorsal or lithotomy position and exposed the cervix by using one or two Sim's speculae
10. Grasped the anterior lip of the cervix with a sponge holder
11. Then inserted the entire condom catheter system into the uterus. The condom catheter was held between the index and middle fingers and introduced it like exploring (or doing a pelvic examination) the uterus
12. Reconnected the catheter to a giving set and started filling the condom with warmed saline
13. Kept watching the cervix for the balloon to bulge out of it and stop filling it any further for then. Then rapid filling with pressure, up to 300ml. Cessation of bleeding from the uterine cavity may be noticed.
14. At this point the vagina was packed with a moist vaginal pack (Two inch ribbon gauze pack or a gauze towel) around the catheter in a circumferential manner
15. Then continued filling was undertaken till the gravity aided filling stopped. Usually 400 - 500 ml was needed
16. Proximal end of the catheter was folded and a tight tie placed to it to prevent backflow
17. Inserted a size 12 Foley catheter to the bladder
18. Marked the level of the fundus with a marker pen. Started a pulse rate and blood pressure chart
19. Kept the vaginal pack and the condom catheter for 12 - 18 hours
20. Administered IV antibiotics (Cefuroxime and Metronidazole)
21. If there was no vaginal bleeding and vital signs were stable, removal of the catheter was planned at a convenient time, after 12 hours
22. Released half the instilled volume of saline. Did not remove the vaginal pack at this stage
23. Observed for bleeding through the vaginal pack
24. Thirty minutes later the vaginal pack was removed, without removing the condom catheter
25. If there was no further bleeding for another 30 minutes, the total volume of instilled saline was released and the condom catheter was removed gently.

Immediate complications such as pain, fever, continued excessive lochia/bleeding mucopurulent discharge per vagina was observed and recorded before discharge from the hospital and during the first six weeks by reviewing them at the post natal clinic visit. We requested them to come for a checkup at one year and specific questions on commencement of menstruation, any abnormal uterine bleeding, pelvic infection and venous thrombosis were recorded. Menstrual history and the use of contraception were also inquired. In those women who did not come for review, the same information was obtained by a telephone interview. Interviews were carried out over the telephone at 24 months, 36 months and 48 months after the procedure. We inquired about the previous complications and specifically about subsequent pregnancy and its outcome, if they had a subsequent pregnancy.

Table 3. Patient characteristics and the birth weights of the babies (n = 42)

Mean age in years	(95% CI)	29.6	(27.9 - 31.3)
Range in years		18 - 40	
Parity			
Primipara		15	35.7%
Parity 2 - 4		26	61.9%
Parity 5 and above		01	02.4%
Gestational age in weeks	(95% CI)	39.3	(38.9 - 39.7)
Range in weeks		36 - 42	
Pregnancies	(36 - 40 weeks)	3685.7%	
Pregnancies	(40 - 42 weeks)	06	14.3%
Singleton pregnancy		39	92.9%
Twin pregnancy		03	07.1%
Mean birth weight	(95% CI)	3216.8 G.	(3061.9 - 3371.7 G).
Range in grammes		1780 G - 4400 G	

Results and discussion

There were 42 (0.25% of a total of 16923 deliveries) cases of intractable PPH which did not respond to standard medical management in ward one of CSHW during the period of study and these cases required intrauterine condom catheter tamponade. The characteristics of these women are shown in Table 3. The age and parity distribution of the patients requiring intra uterine condom catheter tamponade for PPH reflected the age and parity distribution of women delivering in the unit.

Intrauterine condom catheter tamponade was successful in 40 mothers (95.2%) and only two cases needed hysterectomy to control haemorrhage. This is comparable with other studies done using condom tamponade in Bangaladesh and Nepal where success rates of 100% have been reported[16,17,18]. However the reported success rates for balloon tamponade using Sengtaken Blackmore tube and Rush balloon are 87.5 and 85.5% respectively[25,26]. A systematic review of all conservative modes of management of PPH showed a cumulative success rate of 90.7% (95%CI 85.7 - 94). This review also showed success rates of 84.0% (95% CI 77.5% - 88.8) for balloon tamponade and 91.7% (95%CI 84.9 - 95.5) for compression sutures[27].

Onset and the duration of labour

Out of the 28 mothers who went through labour only 12 started labour spontaneously while 16 had induced labour. The duration of labour was less than 10 hours in 26 mothers, while in two mothers the labour was longer but within 16 hours (Figure 3).

Figure 3. **Duration of Labour (n =28).**

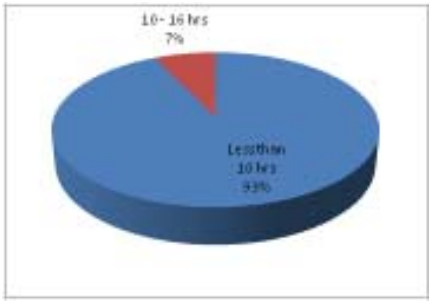


Figure 4. **Mode of delivery in the Castle Street Hospital for Women 2006 - 2010 (n = 16923).**

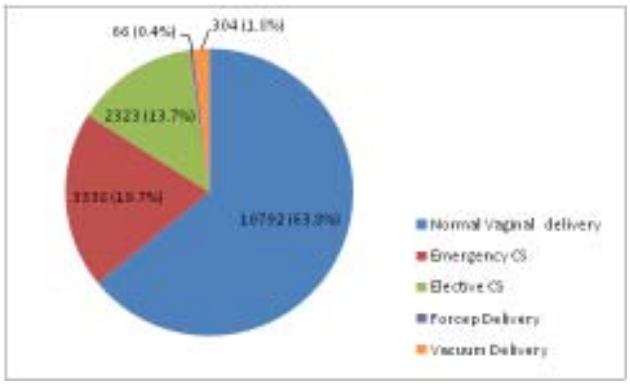
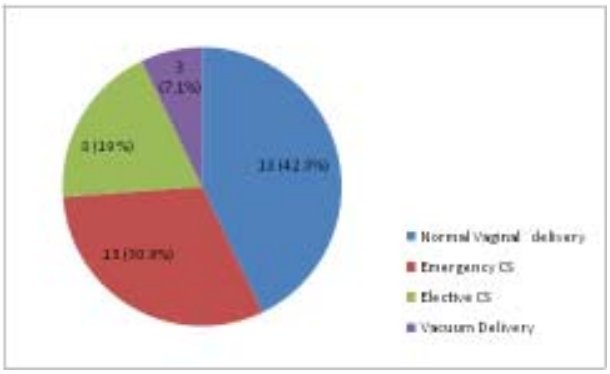


Figure 6. **Mode of delivery among the women where intra uterine condom catheter tamponade was used (n = 42).**



Out of 42 cases who required intra uterine condom catheter tamponade, 28 women underwent labour and of these cases, 18 had vaginal delivery while three needed vacuum extraction and the remaining seven had emergency CS. There were six more antepartum emergency CS and eight elective CS. Three mothers had manual removal of placenta for retained placentae. In our unit during the period 2006 - 2010 the elective CS, the emergency CS, and the vacuum delivery rates were 13% , 19% and 2% respectively. However, when we analysed the 42 cases of severe PPH who required intra uterine condom catheter tamponade the proportions of women following elective CS, emergency CS, and vacuum delivery were higher (19%, 3% and 7% respectively). This was similar to the findings of the previous SAMM data analysis study.

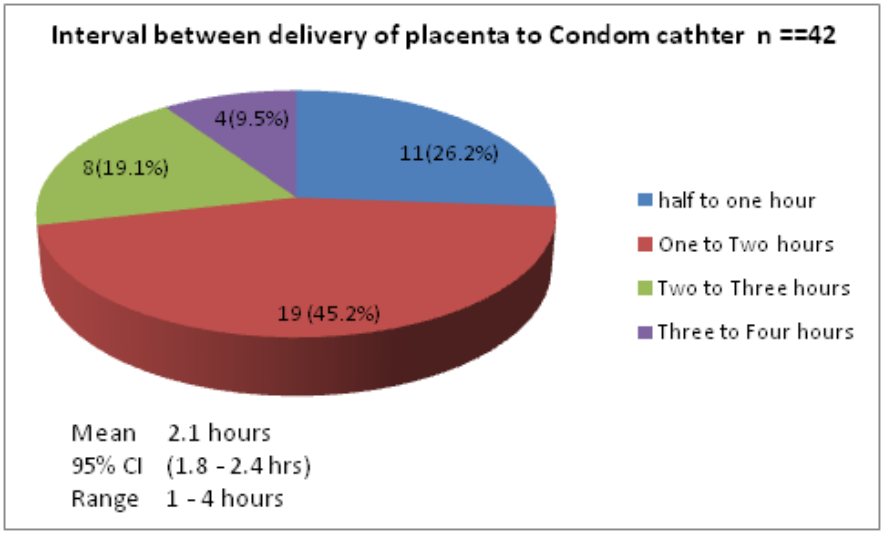
Management before condom catheter uterine tamponade

The management prior to insertion of a condom catheter uterine tamponade is shown in Table 4. There were three cases of manual removals of placentae carried out for retained placenta following vaginal delivery. Two cases of major degree placenta praevia diagnosed sonographically had elective CS. Of the 42 women, 26 (62%) received 0.5 mg of ergometrine intravenously (IV) for active management of the third stage and the others were given 5 units of oxytoccin IV.

Table 4. Management before insertion of intra uterine condom catheter tamponade (n = 42)

Crystalloids given	(95% CI)	1.9 L	(1.7 - 2 L)
Range		0.5 - 4 L	
Estimated blood loss	(95% CI)	1318 ml	(1165 - 1470 ml)
Range		900 - 3000 ml	
Repeat ergometrine 0.5 mg intramuscularly (IM)		39	(92.9%)
Oxytocin 20 units in 500 ml of N. Saline IV		42	(100%)
Tranexaemic acid 500 mg. IV		40	(95.2%)
Misoprostol 800 µg per rectally		01	(02.4%)
Examination under anaesthesia performed		10	(23.8%)
Evacuation of retained tissue		04	(09.5%)

Figure 7. **Interval between delivery of the placenta to insertion of intra uterine condom catheter tamponade (n = 42).**



There were three instances where the condom leaked and reinsertion of the intra uterine condom uterine tamponade had to be carried out. One of them continued to bleed and resulted in performing a subtotal hysterectomy.

Table 5. Blood and blood products transfused (n = 42)

Received no blood	20	(47.6%)
Blood 1 unit transfused	06	(01.4%)
Blood 2 - 3 units	14	(33.3%)
More than 4 units	02	(04.8%)
Fresh frozen plasma	15	(35.7%)
Cryo precipitate	02	(04.8%)
Platelets	02	(04.8%)

Table 6. Tamponade volume and the duration of intra uterine condom catheter tamponade (n = 42)

Tamponade volume	(95% CI)	494.8 ml	(476 - 514 ml)
Range		300 - 700 ml	
Duration of condom tamponade kept in	(95% CI)	18.9 hours	17.6 - 20.2 hours
Range		11 - 30 hours	

Timing of the insertion of the intra uterine condom uterine tamponade appears to correlate well with the successful control of PPH with minimum additional complications. Early insertion was associated with a reduction of the necessity for blood transfusion. The mean interval from delivery to insertion of the device was 2.1 hours (95% CI 1.8 - 2.4 hours). Early intervention can reduce fluid overload and associated pulmonary oedema and dilutional coagulopathy. Furthermore, the risks and complications of receiving blood and blood products could be avoided or minimized. This was more important as some of these patients had other co-morbidities like eclampsia, severe preeclampsia, diabetes mellitus, renal disease and thrombocytopenia. Performing a major surgical procedure like laparotomy and hysterectomy following PPH with unstable physiological status on a patient who has other serious medical conditions will definitely increase the morbidity and even mortality.

Bakri balloon has a capacity volume of 500 ml, where the Rush catheter could accommodate up to 1000 ml. Sengstaken- Blakemore tube could hold around 300 ml. However the condom balloon could accommodate up to 1500 ml. Tamponade volume in this study varied between 300 to 700 ml. Mean value was 494.8 ml (95% CI 476 - 514 ml). Gravity filling allows introducing the correct volume. As the warm saline filled condom occupy the entire uterine cavity including the fundal region where most placentae are attached, it will block the open placental bed sinuses with outward pressure and mechanical obstruction allows formation of a stable coagulum to stop bleeding. On three occasions we have used a volume of 1000 ml partially into the uterine cavity but mostly in the upper vagina in vaginal tears with successful outcome. (Hour glass fashion).

Mean duration of the tamponade in this study was 18.9 hour. (95% CI 17.6 - 20.2 hours), and it is slightly less than the time periods descrbed in studies from Bangladesh, India and

Nepal, where it has been kept over 24 hours[18,19,20]. We selected a convenient hour to remove the condom than exact timing. As too early removal may resume bleeding and also our bad experience with reinsertions, 16 to 18 hours may be a reasonable duration to keep the tamponade in place. This is further strengthened by the minimum complications seen.

Intensive care management

Out of 42 cases only 10 (23.8%) were admitted to the intensive care and the rest were managed in the postnatal ward high dependency area.

With intrauterine condom catheter tamponade, the bleeding was controlled in 40 (95.2%) cases (Figure 8). Rapid forceful filling up to 300ml followed by gravity filling of the condom tamponade and insertion of the vaginal pack and then marking the fundal level on the abdomen will allow you to observe vaginal bleeding as well as rising fundal level which will indicate failure. If bleeding continues the fundal level rises and the vital signs will show the changes. Therefore the absence of the drainage channel for the collection of a pool of blood at the fundus may not be a disadvantage. It appears that our results have not been affected by not performing a specific tamponade test with a drainage channel. In 13 (31%) patients control of PPH was achieved only after approximately one hour of the intervention.

Figure 8. **Control of Bleeding (n = 42).**

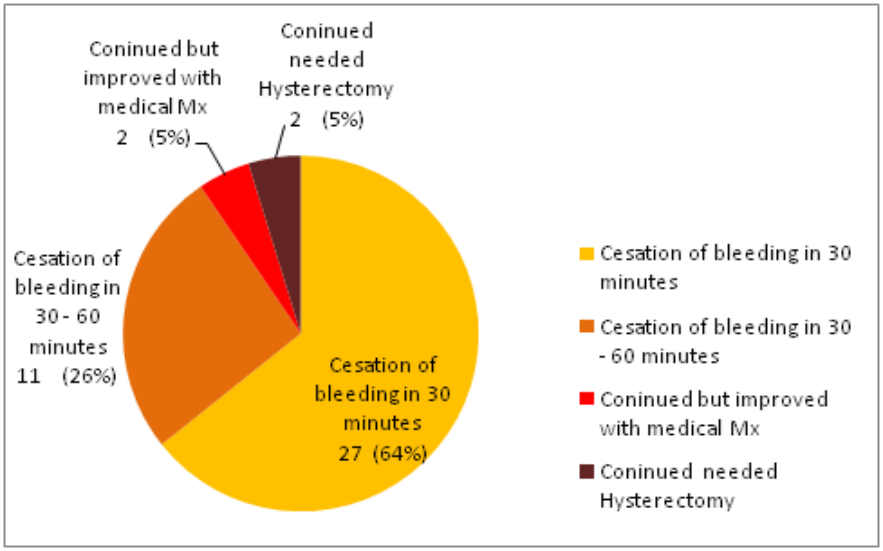


Table 7. Complications during hospital stay (n = 42)

Complication	*Number of mothers*
Fever with no other accountable pathology	08 (19.1%)
Bleeding	08 (19.1%) (two needed blood transfusion)
Abdominal pain	18 (42.9%)
Mucopurulent discharge	00

Reinsertion of the device was needed in three cases due to leakage from the condom (due to rupture or damage) and two (4.8%) of them needed hysterectomy following continued bleeding. In the first case the decision was taken early and the subtotal hysterectomy was performed at three hours from the insertion of the device. In the second case the hysterectomy was performed 16 hours after an elective CS. Spontaneous leakage of excessive watery blood stained fluid after eight hours was found to be due to rupture of the condom. Reinsertion of the device was carried out and during the initial four hours after the reinsertion her condition was stable. Mild bleeding however continued and subsequently the condition deteriorated in spite of nine units of blood, 10 units of FFP, 2 units of cryoprecipitate and 2 units of platelets. The patient required a hysterectomy seven hours after the reinsertion.

Abdominal pain was the commonest complaint and was seen in 18 (42.9%) patients. Pain in the groin was seen following the intervention after elective CS. The pain was reduced with reduction of 50 - 75 ml of saline from the condom without interfering with PPH control.

Extra hospital stay

In uncomplicated cases standard duration of stay was 24 hours following normal delivery and 96 hours following CS in our unit. Without any other reason to remain in hospital the extra hospital stay after condom catheter uterine tamponade varied from 24 hours to 120 hours with a mean 40 hours (95% CI 33.5 - 47.5 hours). Especially during the first two years we were over cautious and kept them an extra day for observations. Fever (19.1%), lower abdominal pain (42.9%) and bleeding per vaginum (19.1%) were the common immediate complications. All cases of fever settled within five days with antibiotics. There was no mucopurulent discharge suggestive of endometritis. No patient had clinical picture suggestive of pelvic sepsis or pelvic peritonitis. We subjected most of the

Table 8. Postnatal review at six weeks (n = 38)

Complaint	*Number of mothers*
Watery vaginal discharge	05 (13.1%)
Mucopurulent discharge	00
Increased lochia continued over three weeks	04 (10.5%)
Significant abdominal pain requiring analgesics/medical opinion	03 (07.9%)
Fever	00
Readmission	00

Figure 9. **Commencement of menstruation – First year review (n = 27).**

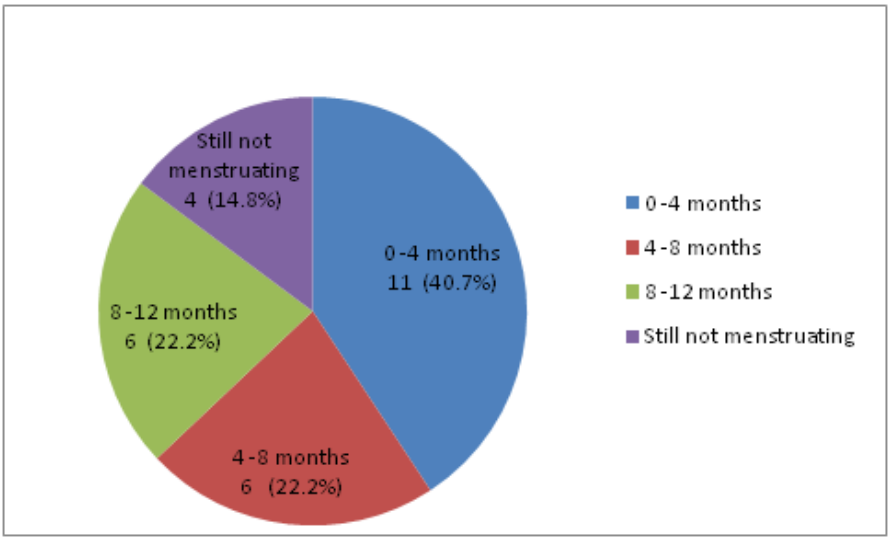
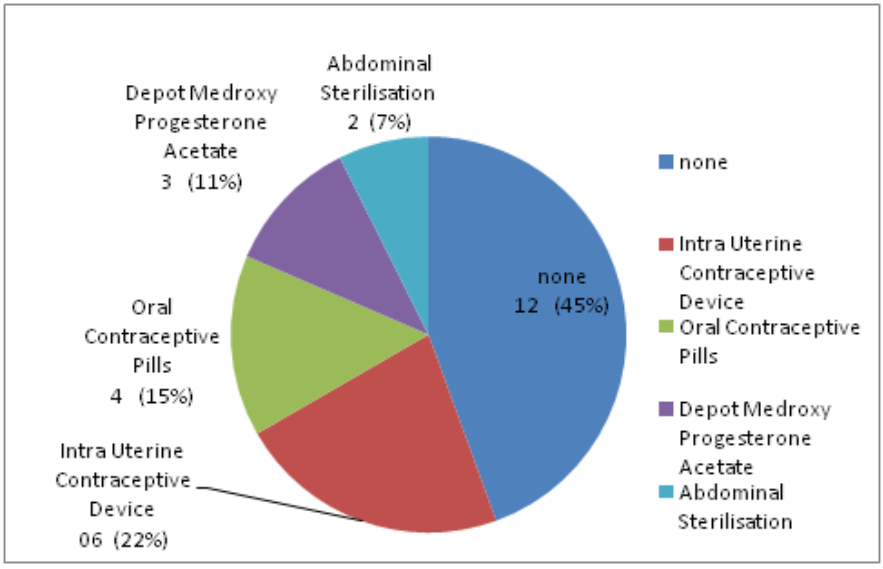


Figure 10. **Contraception usage (n = 27).**



varieties of condom for microbiological examination. The report revealed no bacterial growth, but occasional inert spores seen. The condom catheter was washed with Povidone iodine solution or with normal saline before insertion.

Follow up

Postnatal review at six weeks: Thirty eight mothers came for the six weeks review. Five patients complained of scanty watery discharge but high vaginal swab for culture revealed no bacterial growth. Increased lochia over three weeks was seen in four patients while three patients complained of significant pelvic pain. None of them had any clinical features suggestive of endometritis. Overall the complications were minimal.

Review after one year: Twenty three mothers attended the hospital clinic for review at one year. We were able to get the information through telephone interview in four more cases. There were no major complaints. Twenty-two of them (81.5%) have started menstruation. In ten patients (37%) menstruation has commenced within four months. They all had normal regular periods. There were no issues related to the methods of contraception they used. The details of the menstrual pattern and the use of contraception showed in Figure 9 and 10. All except four were still breastfeeding. Two mothers had stopped breastfeeding within six months. There was no evidence of venous thrombosis in any of the patients. None of the mothers were pregnant again. Some mothers were not in the given Colombo addresses and they have gone to their native places away from Colombo.

Review at 24 months: The number has reduced to 24 as three mothers have gone abroad. There were no additional complications. Two more have had IUD inserted for contraception. Another two had changed from COC and DMPA to IUD use, while two more had started on COC. There were two ongoing pregnancies.

Review at 36 and 48 months: Twenty two patients were reviewed at 36 and twenty patients at 48 months. One patient has had deep vein thrombosis and had treatment with anticoagulants. She developed venous thrombosis at two and a half years after the intervention, and she has used COC in the previous year. No other significant complications were seen among the others. Three more mothers had become pregnant.

There were two ongoing pregnancies in the second year and they delivered in the third year. There were three more pregnancies in the third year and they all had uncomplicated pregnancies. There were three vaginal deliveries and two elective CS due to previous CS and low lying placenta. One more pregnancy was reported in the fourth year and following an uncomplicated antenatal period had anormal vaginal delivery. One vaginal delivery had retained placenta and manual removal of placenta was performed. None had a repeat PPH and all had uncomplicated puerperiums.

So far we have seen seven pregnancies occurring in the second and third year after the previous PPH and intra uterine condom catheter tamponade. All of them had become pregnant within five months of trying for a pregnancy. Two had elective CS. One was due to a previous CS with possible cephalo-pelvic disproportion in the current pregnancy. The second was on maternal request, which could not be changed in spite of intense counselling.

There were no cases who were trying for a pregnancy over six months but unsuccessful. In most of the mothers the reasons for delaying a pregnancy were, employment related reasons, economic and family reasons. But there were six mothers the main reason was the fear of similar complication occurring in her next pregnancy. However our experience in this study with uncomplicated pregnancy and delivery will be reassuring to these mothers

Table 9. Pregnancies following intra uterine condom catheter tamponade (n = 7, 06 delivered, one ongoing)

Interval between the intervention and the current pregnancy	Mean	25.6 months
	95% CI	(19.8 - 31.2 months)
	Range	18 -36 months
Duration tried for a pregnancy	Mean	2.8 months
	95% CI	(1.9 3.7 months)
	Range	14 months
Antenatal complications	None	
Mode of delivery	El CS	02
	NVD	03
	Successful VBAC	01
Third stage complications	None	05
	Retained Placenta (MROP)	01
PPH	None	
Post natal complications	None	

NVD = Normal Vaginal Delivery, El CS = Elective Cesarean Section, VBAC = Vaginal Birth After Cesareandelivery

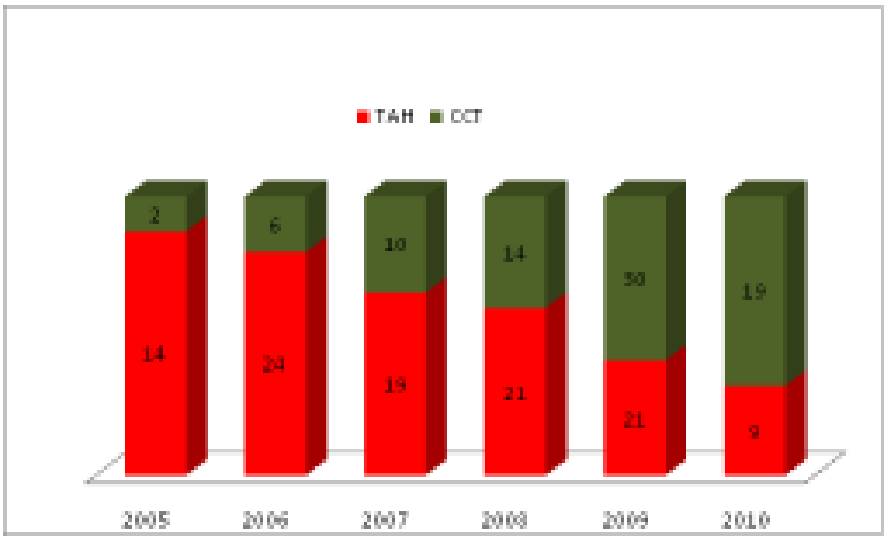
The cost of the intervention in comparison to other methods

The total cost estimated for the equipment in the insertion of a condom catheter tamponade is a around Rs. 200. This icluded the cost of the condom, suture, foley catheter and the vaginal pack used. The cost of a purpose designed uterine balloon catheter (Bakri balloon) is estimated to be around Rs. 25,000. Therefore, a condom catheter is 100 times cheaper than the purpose designed balloon catheter. But we have not seen any evidence to suggest that the condom catheter is inferior in efficacy or safety to this expensive purpose designed balloon.

The effect of intrauterine condom catheter tamponade on the rate of hysterectomies performed

We see a very favourable trend of reduction in percentage of hysterectomies associated with a steady increase in the usage of intra uterine condom catheter tamponade, during the period 2005-2010. It is satisfying to see that the use of intra uterine condom catheter tamponade is gaining acceptance as a safe method before embarking on complicated surgical procedures.

Figure 11. **The trend of hysterectomies and the use of intra uterine condom catheter tamponade in Castle Street Hospital for Women 2005 - 2010.**



Conclusion

PPH remains the leading cause of maternal mortality in Sri Lanka. However maternal deaths reflect only the tip of the iceberg and SAMM is approximately 18 times greater than the number of deaths at CSHW, and PPH is the leading cause of SAMM. Uterine atony is the commonest cause of PPH. The insertion of an intra uterine condom catheter tamponade for the management of PPH in atonic uterus, is an effective, low cost, easily administered minimally invasive treatment option which can be performed by medical personnel of average skill. This appears to have minimum early and long term complications and most importantly, it controls uterine bleeding while preserving the mother's ability to conceive again.

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