Abstract and Introduction

Abstract

Objectives: To evaluate the efficacy of a condom as a tamponade for intrauterine pressure to stop massive postpartum hemorrhage (PPH).

Design and Setting: This prospective study was done in the Obstetrics and Gynecology Department of Dhaka Medical College and Hospital, Bangladesh, between July 2001 and December 2002.

Patients: During the study period, 152 cases of PPH were identified; 109 were managed medically; 20 were managed using the B-Lynch procedure, and 23 were managed using the condom catheter. Patients were selected for intervention with the condom catheter when PPH that occurred as a result of atonicity or morbid adhesion (accreta) could not be controlled by uterotonics or a surgical procedure. In patients who were in shock due to massive hemorrhage, a condom catheter was introduced immediately without prior medical management.

Intervention: With aseptic precautions, a sterile rubber catheter fitted with a condom was introduced into the uterus. The condom was inflated with 250-500 mL normal saline, according to need. The condom catheter was kept for 24-48 hours, depending upon the initial intensity of blood loss, and gradually deflated when bleeding ceased.

Main outcome measures: (1) Ability of condom catheter to stop bleeding; (2) time required to stop bleeding after the tamponade was applied; (3) subsequent morbidity in terms of severe infection, despite use of prophylactic antibiotics.

Results: In all 23 cases in which the condom catheter was used, bleeding stopped within 15 minutes. No patient needed further intervention. No patient went into irreversible shock. There was no intrauterine infection as documented by clinical signs and symptoms and culture and sensitivity of high vaginal swab.

Conclusion: The hydrostatic condom catheter can control PPH quickly and effectively. It is simple to use, inexpensive, and safe. In developing countries where PPH remains a primary cause of maternal mortality, any healthcare provider involved in delivery may use this procedure for controlling massive PPH to save the lives of patients.

Introduction

Postpartum hemorrhage (PPH) is a leading cause of maternal death all over the world.[1] In developing countries, it is responsible for an annual mortality of approximately 150,000 women per year. It remains a serious complication of childbirth in both developed and developing countries. From 2% to 5% of deliveries may lead to PPH with a blood loss of > 1000 mL within the first 24 hours.[2] The most common cause of PPH is uterine atony. A delay in correction of hypovolumia and delay in the control of bleeding are the main avoidable factors in most maternal deaths caused by hemorrhage. A population-based study has shown that PPH accounts for 28% of all maternal deaths in 8 developing countries.[3] In Bangladesh, PPH remains the number 1 killer of mothers, and PPH contributes to 26% of all maternal deaths.[4]

Whatever the cause of PPH, death should be preventable, and outcome is largely dependent upon timely interference and efficiency and vigor of medical practitioners. Active management of the third stage of labor reduces uterine atony and is the mainstay of prevention of hemorrhage.[5] The rapid correction of hypovolumia with crystalloid and red cells is the first priority of management of PPH. Uterotonic drugs, such as oxytocin or ergometrine, are used as prophylaxis and for controlling PPH. Modern management of atonic PPH entails the use of prostaglandins administered parenterally, orally, rectally, or vaginally.[6-8] Each has advantages and disadvantages in terms of efficiency, availability, cost, stability, and ease of administration. Bimanual compression, uterine packing, and such surgical interventions as B-Lynch suture,[2,9] ligation of uterine artery, ovarian artery, and internal iliac artery, and embolization are effective methods for controlling intractable hemorrhage. Hysterectomy is the procedure of last resort, and a few patients really need it to save their lives (Rouf S et al, unpublished data).[10-12]

After failed medical treatment, and before proceeding to surgical intervention and possible hysterectomy, attempting to compress the uterine sinuses and to stop bleeding via uterine packing is a reasonable option for management of

PPH. Successful results have been shown by many researchers by using a Sengstaken-Blakemore tube and a Rusch urologic hydrostatic balloon catheter.[13,14] In light of these results, we tried an inflated condom as a tamponade for control of massive PPH after failure of medical treatment. Condoms are inexpensive and widely available throughout the world. Our aim in this trial was to establish the efficacy of this inexpensive device to control massive PPH and to evaluate postpartum morbidity related to this intervention.

Design and Setting

A prospective study was done in the Obstetrics and Gynecology Department of Dhaka Medical College and Hospital, Bangladesh, between July 2001 and December 2002. Data were collected continuously from patients in 2 obstetric units. The study was approved by an institutional review board, which was constituted by the head of the department and other professors of the department. Written consent was obtained from the patient or from her attendant if the patient's condition was poor.

Patient Characteristics

During the study period, 152 cases of PPH were identified; 109 were managed medically, 20 were managed using the B-Lynch suture (named after its innovator[2,9]) during cesarean section, and 23 were managed using the condom catheter. Patients in whom PPH due to atonicity or morbid adhesion (accreta) could not be controlled by medical treatment or the surgical approach were selected for intervention with the condom catheter. Bimanual compression was given, but aortic compression was not attempted.

Primary and secondary PPH were diagnosed according to standard textbook definitions (bleeding within 24 hours of delivery and between 24 hours and 6 weeks of delivery, respectively). Of the 23 patients managed with the condom catheter, 19 (82%) had primary PPH and 4 (17%) had secondary PPH; 12 (52%) patients were in shock due to massive hemorrhage. In these latter cases, a condom catheter was introduced immediately without prior medical management. In the other cases, uterine massage and uterotonics (oxytocin or ergometrine; misoprostol is not used for PPH at our institution) had been administered without success in 10 patients, and in 1 patient a B-Lynch suture applied during cesarean section did not stop the bleeding.

The characteristics of patients selected for the condom catheter intervention are summarized in Table 1 . The patients were between the ages of 19 and 40 years, and the mean age was 26.8 years. Parity ranged from 1-6, with a median of 2. (In our experience, multiparous women are more prone to develop PPH.) The majority of the 23 cases had spontaneous vaginal delivery (61%) and developed PPH immediately after delivery (48%). In 17% (4/23) of the cases, bleeding occurred outside the hospital, and these patients were admitted to the hospital. None of the 23 cases had antenatal care, and all had some form of predisposing factors for developing PPH; 48% had active management of the third stage, 26% had hepatitis, and 17% had had a history of previous lower segment cesarean section (Table 2).

Table 1. Characteristics of Patients Selected for Condom Catheter Intervention

Characteristics	Mean	± SD
Age (yrs)	26.82	6.36
Parity	Range 1-6	Median 2
Mode of Delivery Spontaneous vaginal delivery Destructive and instrumental Lower segment cesarean section	Number 14 3 6	% 61 13 26
Type of PPH		
Primary	19	82.60

Secondary	4	17.40
Place of occurrence		
At hospital	19	82.60
Outside of hospital	4	17.40
Interval of delivery & PPH		
Immediate	11	47.83
1-24 hrs	8	34.79
72 hrs	1	4.34
2 weeks	2	8.70
1 month	1	4.34

Table 2. Predisposing Factors for PPH

Factors	Number	%
Hypertension	3	13.04
Abruptio placenta	1	4.35
IUD with fibroid	1	4.35
Previous cesarean section	4	17.39
Placenta previa	2	8.70
Hepatitis	6	26.08
Multiple pregnancy	2	8.70
Morbid adhesion	1	4.35
Prolonged labor	2	8.70
None	1	4.35
Total	23	100

Intervention

With aseptic precautions, a sterile rubber catheter fitted with a condom was introduced into the uterus. The condom was inflated with 250-500 mL normal saline according to need. Vaginal bleeding was observed and further inflation was stopped when bleeding ceased. To keep the balloon in situ, the vaginal cavity was filled with roller gauze and finally a sanitary pad. If bleeding continues, this vaginal pack will usually become soaked with blood, and if profuse it will trickle through the introitus to soak the outside pad and undergarments. This did not happen in any of our cases. Removal of a pack did reveal that it was soaked with blood, but no profuse bleeding occurred, so no blood came through introitus. Uterine contractility was maintained by oxytocin drip for at least 6 hours after the procedure. As mentioned, the condom catheter was used in those cases in which oxytocin and other drugs were not effective for management of PPH. However, as it maintains the tone of uterus, oxytocin was administered along with introduction of the condom catheter.

Figure 1. Inflated condom in a kidney tray.

Figure 2. Tying the condom to the catheter.

Figure 3. Introducing the catheter in the uterus.

Figure 4. After introduction of the catheter, a tight vaginal pack is applied and then saline is administered into the catheter.

Antibiotics were also administered prophylactically because of the presence of a foreign body inside the uterus. The triple antibiotic regimen used was amoxicillin (500 mg every 6 hrs) plus metronidazole (500 mg every 8 hrs) plus gentamicin (80 mg every 8 hrs) administered intravenously for 7 days. High vaginal culture swab was done to determine whether there was any invading organism even after giving antibiotics, as some organisms may be resistant to this triple antibiotic regimen.

The condom catheter was kept for 24-48 hours, depending upon the initial intensity of blood loss (Table 3). For those who had severe bleeding, the catheter was kept for the longer duration. Bleeding did not resume in any patient, and the condom was deflated slowly over 10 to 15 minutes during the same sitting.

Table 3. Management of the Patients

Management	Number	%
Introduction of condom		
0-4 hrs	13	56.52
5-24 hrs	8	34.78
25-48 hrs	1	4.35
Condom kept for		
24 hrs	7	30.44
36 hrs	8	34.78
48 hrs	8	34.78
Time required to control PPH		
0-15 minutes	23	
	Mean	SD
Saline needed to inflate the balloon (mL)	336.36	89.42
Blood transfusion needed (units)	3.23	2.08

The steps are summarized as follows:

1. Under aseptic precautions a sterile rubber catheter was inserted within the condom and tied near the mouth of the condom by a silk thread.
2. Urinary bladder was kept empty by indwelling Foley's catheter.
3. After putting the patient in the lithotomy position, the condom was inserted within the uterine cavity.
4. Inner end of the catheter remained within the condom.
5. Outer end of the catheter was connected with a saline set and the condom was inflated with 25-500 mL of running normal saline.
6. Bleeding was observed, and when it was reduced considerably, further inflation was stopped and the outer end of the catheter was folded and tied with thread.
7. Uterine contraction was maintained by oxytocin drip for at least 6 hours after the procedure.
8. The uterine condom was kept tight in position by ribbon gauze pack or another inflated condom placed in the vagina.
9. The condom catheter was kept for 24-48 hours and then was deflated gradually over (10-15 minutes) and removed.
10. Patient was kept under triple antibiotic coverage (amoxicillin [500 mg every 6 hrs] + metronidazole [500 mg every 8 hrs] + gentamicin [80 mg every 8 hrs]) administered intravenously for 7 days.

Main Outcome Measures

The main outcomes evaluated in this study were the ability of the condom catheter to stop bleeding, the time required to stop bleeding after the tamponade was applied, and any subsequent morbidity in terms of severe infection, despite the use of prophylactic antibiotics.

Results

After failure to control bleeding by medical measures or surgical intervention, the condom catheter was introduced. In most of the cases (56.5%), the condom catheter was introduced within 0-4 hours, and in 32.7% of cases, between 5 and 24 hours after delivery. In all 23 patients, bleeding was stopped within 15 minutes. The patients were followed up

for 48-72 hours. No patient needed further intervention. From 200-500 mL (average 336.4 mL) saline was required to inflate the balloon. The volume was increased until there was resistance to addition of more fluid and the bleeding ceased. On average, 3.23 units of blood (range 2-10 units) were needed to produce hemodynamic stability. No patient went into irreversible shock. There was no intrauterine infection documented by clinical signs and symptoms and culture and sensitivity of high vaginal swab.

Discussion

PPH remains one of the most challenging problems facing obstetricians today. About 1 in 200 women suffer from massive hemorrhage, which can be severe enough to cause hypotension and shock. Although most can be treated successfully with conservative measures, such as medication, about 10% of the women with PPH require major surgical procedures and even hysterectomy to save their lives (Rouf S et al, unpublished data). Parenteral use of prostaglandins in the management of atonic PPH is effective but not widely available. Moreover, the treatment is expensive and heat sensitive. Rectal or vaginal misoprostol, although attractive for its cost, effectiveness, stability, and ease of administration, is not always available in our country. In addition, it is associated with such side effects as diarrhea, vomiting, fever, flushing, headache, hypertension, and bronchospasm.

When medical treatments are not readily available, or failure of medical treatment has occurred, or contraindication to medication exists, it is important to have alternative methods of management ready. A variety of surgical techniques are used, including uterine artery ligation, ovarian artery ligation, internal iliac artery ligation, and B-Lynch Brace suture.[9,15,16] Each method has benefits and risks. In most cases, the above-mentioned surgical procedures are effective in avoiding hysterectomy, but delay in carrying out the procedure in some cases carries a poorer prognosis.[16] On the other hand, each of the above techniques entails a laparotomy, and there is a potential risk of ligature of external iliac vessels, ureteric injury, and further hemorrhage. Moreover, the procedure must be performed by skilled personnel.

B-Lynch and colleagues[2,9] used Brace suture to compress the uterus without compromising major vessels. The advantage of the B-Lynch procedure is that the identification of specific blood vessels is not required, which is invariably a difficult part in ligation of arteries. Although it is helpful during cesarean section, the B-Lynch procedure requires a laparotomy and therefore is not the first approach in cases of PPH followed by vaginal delivery.

Uterine packing has been used for long as an alternative to other surgical procedures, and it has been described for over a century,[17] but fear of the concealment of continued bleeding and infection together with increasingly effective medical and surgical measures to treat uterine atony have led to its fall from favor. (See footnote.[†]) The attractiveness of uterine packing, however, is that it does not require further invasive surgery. Although there is a chance of intrauterine infection, good packing techniques with prophylactic antibiotic therapy can minimize this complication.[18]

A good packing technique entails careful layering of the ribbon gauze pack to occlude the whole space of the uterine cavity, which is much easier in theory than in practice. Keeping the mode of action of the packing in mind, the Sengstaken-Blakemore tube and the Rusch urologic hydrostatic balloon catheter have been used by some researchers[13,14] to control intractable hemorrhage. The Sengstaken-Blakemore tube is complex to use and expensive (approximately £140, or $225 USD). The Rusch urologic hydrostatic balloon catheter, although simple and effective, is also expensive (£20, or $32 USD) and not available in our country. On the contrary, the price of a condom and catheter is only 11 taka, which is equivalent to a few pence only (about 19 cents US).

The condom was used to create a ballooning function by inflation with a reasonable amount of fluid. This balloon exerts a similar pressure to that of other balloons to the open sinuses of the uterus and stops bleeding. It conforms naturally to the contour of the uterus, does not require any complex packing, and is easy to remove. In addition, it may be associated with lower infection risk as there is no direct intrauterine manipulation. This intervention can be done cheaply, easily, and quickly, and it does not require highly skilled personnel.

Although the sample size in this study is small, we have shown that in every case, massive bleeding was controlled

very quickly by inserting and inflating the condom. No patient required further intervention, and there was no serious morbidity. We have also used this intervention in 3 cases of missed abortion when there was intractable hemorrhage after evacuation and curettage. Bleeding was controlled effectively in all of the cases. We did not include these 3 cases in our study, as we address only PPH. This intervention is named "Sayeba's method of PPH control" after Professor Sayeba Akhter, who innovated this method at our institution.

In a country such as Bangladesh where the maternal death rate from PPH is very high, this safe, inexpensive, and easy procedure can be applied in any situation to save a life and to save the uterus in young patients to conserve reproductive capacity. A study done in a tertiary level hospital of Bangladesh has shown that 17.7% of peripartum hysterectomies were performed because of PPH (Rouf S et al, unpublished data). (See footnote.[‡]) In spite of this intervention, lives could not be saved in 7/11 (63.6%) cases (Rouf S et al, unpublished data). As the condom catheter procedure is safe and very easy to perform, primary health workers and other healthcare providers can apply this procedure before referring the patients to a higher center. It is essential to exclude genital tract trauma before undertaking this procedure. But in remote areas where primary healthcare providers are unable to detect or repair the injury in those cases, this intrauterine tamponade method followed by vaginal packing will minimize the blood loss until the patient's arrival to the hospital, which will protect the patient from irreversible shock and even death. So we recommend use of this easy and economic condom catheter as a tamponade in all cases at all levels of healthcare when medical management is not effective to control the bleeding in PPH.

[†] Concealment is less of an issue with the condom balloon because the pressure is evenly distributed and there is less chance of leftover venous sinuses.

[‡] The majority of peripartum hysterectomies (66.1%) were done because of ruptured uterus, 17.7% were done for PPH, and 6.5% for cesarean section scar rupture.

References

1. Hayman RG, Arulkumaran S, Steer PJ. Uterine compression sutures: surgical management of postpartum haemorrhage. Obstet Gynaecol. 2002;99:502-506.
2. Vangsgaard K. "B-Lynch-suture" in uterine atony. Ugeshr-Laeger. 2000;162:3468.
3. Maine D, Rosenfield A, Wallis M, et al. Prevention of maternal death in developing countries. New York, NY: The Center for Population of Family Health; 1999.
4. BIRPERHT. Bangladesh Institute of Research for Promotion of Essential and Reproductive Health and Technologies. Report on Baseline Survey for Assessment of EOC Services in Bangladesh; 1995.
5. Prendiville WJ, Elbourne D, McDonald S. Active vs expectant management of the third stage of labour (Cochrane Review). In: The Cochrane Library. Issue 3, 2000. Oxford: Update software.
6. O'Brien P, El-Refaey H, Gordon A, Geary M, Rodeck C. Rectally administered misoprostol for the treatment of postpartum haemorrhage unresponsive to oxytocine and ergometrine: a descriptive study. Obstet Gynaecol. 1998;92:212-214.
7. Ramsey PS, Ramin KD. Rectally administered misoprostol for the treatment of postpartum haemorrhage unresponsive to oxytocine and ergometrine: a descriptive study. Obstet Gynaecol. 1999;93:157-158.
8. Abdel-Aleem H, El-Nashar I, Abdel-Aleem A. Management of severe postpartum haemorrhage with misoprostol. Int J Gynaecol Obstet. 2001;72:75-76.
9. B-Lynch C, Coker A, Lawal AH, Abu J, Cowen MJ. The B-Lynch surgical technique for the control of massive

postpartum haemorrhage: an alternative to hysterectomy? Five cases reported. Br J Obstet Gynaecol. 1997;104:372-375.

10. Stanco LM, Schrimmer DB, Paul RH, Mishell DR. Emergency peripartum hysterectomy and associated risk factors. Am J Obstet Gynaecol. 1993;168:879-883.

11. Zelop CM, Harlow BL, Frigoletto FD, Safon LE, Saltzman DH. Emergency peripartum hysterectomy. Am J Obstet Gynaecol. 1993;168:1443-1448.

12. Abu-Heija AT, Jallad FF. Emergency peripartum hysterectomy at the Princess Badees Teaching Hospital in North Jordan. J Obstet Gynaecol Res. 1999;25;193-195.

13. Katesmark M, Brown R, Raju KS. Successful use of a Sengstaken-Blakemore tube to control massive postpartum haemorrhage. Br. J Obstet Gynaecol. 1994;101:259-260.

14. Johanson RB, Kumar M, Obhrai M, Young P. Management of massive postpartum haemorrhage: use of a hydrostatic balloon catheter to avoid laparotomy. Br J Obstet Gynaecol. 2001;108:420-422.

15. O'Leary JA. Stop of haemorrhage with uterine artery ligation. Contemp Obstet Gynaecol. 1986;28:13-16.

16. Burchell RC. Physiology of internal artery ligation. J Obstet Gynaecol Br Comnwlth. 1968;75:642-651.

17. Ramsbotham PH. *Principles and Practice of Obstetrical Medicine and Surgery.* Philadelphia, Pa: Blanchard and Lea; 1856: 415-416.

18. Maier RC. Control of postpartum haemorrhage with uterine packing. Am J Obstet Gynaecol. 1993;169:317-323.

Authors and Disclosures

Sayeba Akhter, FCPS, DRH, FICMCH, Professor and Head, Department of Obstetrics and Gynecology, Dhaka Medical College and Hospital, Dhaka, Bangladesh; **Mosammat Rashida Begum, FCPS, MS**, Assistant Professor, Department of Obstetrics and Gynecology, Dhaka Medical College and Hospital, Dhaka, Bangladesh; **Zakia Kabir**, Medical Student, Bangladesh Medical College, Dhaka, Bangladesh; **Maliha Rashid, FCPS**, Associate Professor, Department of Obstetrics and Gynecology, Dhaka Medical College and Hospital, Dhaka, Bangladesh; **Tarafder Runa Laila, FCPS**, Department of Obstetrics and Gynecology, Sadar Hospital Tangail, Tangail, Bangladesh; **Fahmida Zabeen, FCPS**, Consultant, Department of Obstetrics and Gynecology, Dhaka Medical College and Hospital, Dhaka, Bangladesh