

Balloon Internal Uterine Tamponade: Experience with 39 Patients from a Single Institution

S. Ferrazzani, A. Perrelli, C. Piscicelli and S. De Carolis

INTRODUCTION

During the past several years, a number of new and simple techniques have been developed in the attempt to avoid major surgical procedures for treatment of postpartum hemorrhage (PPH). In addition, a variety of surgical and radiological options have been proposed to avoid hysterectomy. Unfortunately, a suitable conservative technique is still lacking for all situations¹, and it is well recognized that all proposed options have risks as well as advantages. A practice bulletin from the American College of Obstetricians and Gynecologists (ACOG)² suggests that tamponade of the uterus can be effective in decreasing hemorrhage secondary to uterine atony, and that procedures such as uterine artery ligation or B-Lynch suture may be used to obviate the need for hysterectomy.

In general, four types of procedures can summarize all the conservative interventions in PPH: balloon tamponade, compression sutures, arterial embolization and pelvic devascularization. Among these, the uterine balloon tamponade has the advantage of simplicity and safety so that it can be easily carried out by doctors with minimal training and/or experience. Of interest, balloon tamponade has been used to control hemorrhage in other obstetric conditions in which bleeding is of a serious nature, for example, following first- and second-trimester termination of pregnancy^{3,4}, cervical pregnancy⁵⁻⁷ as well as to control PPH from vaginal lacerations⁸.

THEORETICAL PRINCIPLE OF ACTION

The effect of the balloon tamponade is such that temporary and steady mechanical compression of the bleeding surface of the placental site can be accomplished while waiting for the natural hemostatic mechanisms of the blood to take effect. The balloon, inflated inside the uterine cavity in order to stretch the myometrial wall, provides an intrauterine pressure that overcomes the systemic arterial pressure, thus resulting in cessation of the intrauterine blood flow⁹. More recently, an alternative mechanism of action has been

proposed, which involves the hydrostatic pressure effect of the balloon on the uterine arteries¹⁰.

In all probability, a quite different mechanism can be proposed for the efficacy of a balloon in the case of uterine atony. With separation of the placenta, the numerous uterine arteries and veins that carry blood to and from the placenta are severed abruptly. Elsewhere in the body, hemostasis in the absence of surgical ligation depends upon intrinsic vasospasm and formation of blood clots locally. At the placental implantation site, however, the most important factors for achieving hemostasis are contraction and retraction of the myometrium in order to compress the vessels and obliterate their lumens. Uterine atony from any origin can prevent this physiological mechanism, leading to massive hemorrhage.

The most common approach to atony is based on the use of uterotonic agents and mechanical stimulation by massage of the uterus. In such situations, the efficacy of the tamponade balloon may derive from the mechanical stimulation of myometrial contraction caused by the balloon's elasticity pressing against the myometrial wall. The simultaneous and continuous stimulation of myometrial contraction and the tamponade effect on the open vessels, reached with the contraction, explain its efficacy. However, the uterus must be empty for the tamponade to be successful.

THE BALLOON TAMPONADE TEST

To date, there is no diagnostic test to identify which patients with intractable hemorrhage will require surgery. Condous and colleagues⁹ proposed the use of an inflated Sengstaken–Blakemore balloon catheter as a test to create tamponade and identify those patients who will or will not need surgery ('tamponade test'). With positive results, the tamponade test not only halts the blood loss and preserves the uterus, but also gives an opportunity to reverse and correct any consumptive coagulopathy. More than 87% of their patients (14/16) with intractable PPH responded to the tamponade test. Seror and colleagues¹¹ reported that,

in a series of 17 cases, tamponade treatment prevented surgery in 88% of patients; furthermore, Doumouchtsis *et al.*¹² showed that hemostasis was achieved in 22/27 (81%) women who had placement of the balloon catheter. From these clinical experiences, it is possible to state that early use of the balloon catheter may reduce total blood loss, and, in all probability, any type of inflatable balloon with high fluid-filling capacity could be used for the same purpose¹³.

The experience at the Catholic University of Rome, Italy

A longitudinal study is currently continuing at the Obstetrics and Gynaecology Department of the Catholic University of Holy Heart in Rome, Italy; it started in January 2002 and was approved by the Institutional review board. The study's aim is to evaluate the efficacy of the balloon tamponade, its advantages in terms of subsequent hysterectomy (not only in terms of fertility loss, but also of blood loss and maternal morbidity), and the medium- and long-term reproductive follow-up of the patients.

Patients and methods

Between January 1 2002 and June 30 2010, a total of 25,918 patients delivered in the maternity department. During this time, 39 women who experienced PPH underwent treatment by intrauterine tamponade. PPH was defined as a blood loss of more than 500 ml after vaginal delivery quantified with a collection pouch placed after delivery or more than 1000 ml of blood loss during a cesarean section. Additionally, the blood loss was defined as persisting and not responding to conventional uterotonic therapy.

The initial medical treatment included the use of oxytocic agents, prostaglandin analogues and ergometrine. According with our hospital's protocol, every woman had an intramuscular prophylactic dose of oxytocin (5 IU) (Syntocinon®) and ergometrine (0.2 mg) (Methergin®, only in normotensive women) after spontaneous delivery and an intramyometrial dose of oxytocin in case of cesarean section. If bleeding persisted, oxytocin was administered at a dose of 10–20 IU in 500 ml of glucose 5% solution; sometimes, intravenous sulprostone (Nalador®, 0.5 mg in 250 ml of saline solution) was infused; seldom, five intrarectal tablets (1 mg total) of misoprostol (Cytotec®, tablets 200 µg) were used. Other obstetric measures included uterine massage to stimulate uterine contraction and evaluation for the presence of retained placental tissue or vaginal/cervical lacerations under regional or general anesthesia. When present, retained placental tissue was removed and lacerations were sutured. Coagulation studies were carried out simultaneously to exclude coagulopathy as the first or the complementary cause of the hemorrhage.

In those patients delivering by the vaginal route who showed no response to these measures, a sterile

hydrostatic (bladder distension) balloon catheter size 5.3 mm, Rüschi balloon (Rüschi (UK), High Wycombe, UK), was inserted into the uterine cavity via the cervix. This was achieved using minimal analgesia or regional anesthetics. Insertion was facilitated by grasping the anterior and lateral margins of the cervix with sponge forceps and placing the empty balloon into the uterine cavity with another sponge forceps. The balloon catheter was then filled with warm saline solution until a contracted uterus was palpable through the abdomen. Applying gentle traction at this stage confirmed that the filled balloon was firmly fixed in the uterine cavity. If no or minimal bleeding was observed through the cervix, laparotomy was avoided and gauze packing was placed in the vagina to avoid expulsion of the balloon from the dilated cervical os. If significant bleeding continued through the cervix, the 'tamponade test' had failed and laparotomy was performed.

In patients delivering by cesarean section, the problem of abnormal placental insertion or suspicion of morbid adhesions was confirmed by ultrasound scan before surgery. The placenta was delivered by firmly controlled cord traction, or by manual removal if it was abnormally attached to the uterine wall. According to Benirschke and Kaufmann¹⁴, the histological diagnosis of accreta can be made only when the uterus is removed with the attached placenta remaining *in situ*; in case of removal of the placenta from the uterus, the diagnosis of placenta accreta was necessarily based on clinical criteria consisting of the inability to remove the placenta by controlled cord traction because of an adherence to the underlying myometrium and the failure to develop a cleavage plane between the placenta and uterus.

If severe bleeding persisted despite a contracted uterus after local intramyometrial and intravenous infusion of oxytocin and prostaglandin analogues, the hydrostatic balloon catheter filled with warm saline solution, was inserted intra-abdominally (Figure 1) through the uterine incision and the lower end brought through the cervical canal by a sponge forceps, thus leaving the balloon in the uterine cavity.

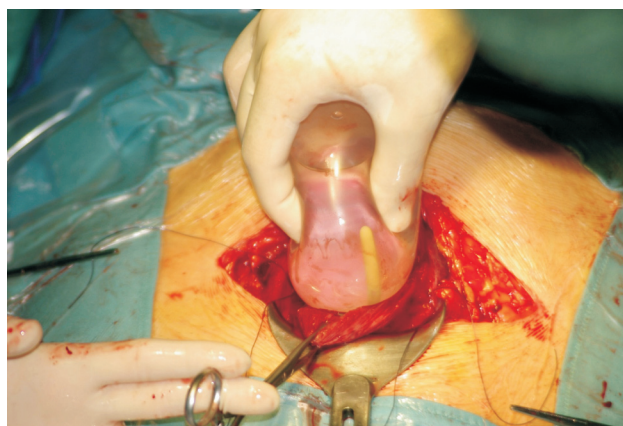


Figure 1 Intra-abdominal insertion of the hydrostatic balloon catheter into the uterine cavity (surgery drill)

Tamponade was achieved by pulling the distal end of the catheter shaft out of the vagina. Uterine contraction over the balloon was maintained after the uterine closure by a slow oxytocin infusion (20–40 IU) that was administered over the next 24 h. A single-layer closure of the uterine incision was performed, taking care not to include the balloon in the suture line. Only when the bleeding was adequately controlled was the abdominal wall closed.

Patients who responded to the balloon catheter therapy, irrespective of route of delivery, were stabilized in the labor and delivery unit for ongoing management. In all cases, intravenous broad-spectrum antibiotics were administered for at least the first 24 h. The balloon catheter was left *in situ* until the next day. During this time interval, blood transfusion and coagulopathy correction were possible. Once the above parameters were within acceptable limits, the balloon catheter was slowly deflated and withdrawn, and the patient observed for any active bleeding.

A second sample of 30 patients was randomly extracted from 79 historical cases of postpartum hysterectomy performed as first-line treatment for PPH from 1985 to 2001 before the introduction of the use of the balloon in January 2002. This second group (hysterectomy sample) was compared to the balloon sample in order to observe differences in co-morbidity (in addition to fertility loss) between the historical aggressive method and the conservative approach of recent years.

Normally distributed continuous variables were compared using a two-sample Student *t* test. Cross-tabulation and χ^2 (with Yates' continuity correction) were used to examine the relationship between nominal variables. All *p* values less than 0.05 were considered statistically significant. Patients, treated successfully with the balloon were subsequently contacted by phone in order to evaluate the subsequent fertility, pregnancy rates and possible medium- and long-term complications.

Results

The mean patient age was 34.6 years (26–46 years), and the mean gestational age at delivery was 35.9 weeks (21–42 weeks). Seventeen patients were multiparous (44%). The mean parity was 1.29 ± 0.6 . Ten patients had a vaginal delivery and 29 underwent cesarean section (of which 15 were planned). In 17 instances, an atonic uterus caused PPH, whereas placenta previa/accreta was diagnosed in 22, of which four were associated with uterine atony.

Table 1 displays the results of the study. The 'tamponade test' was successful in 31 out of 39 cases; the hydrostatic catheter immediately arrested hemorrhage in 9/10 (90%) cases of vaginal delivery and in 22/29 (75%) cases of cesarean section.

The mean volume of saline solution used to inflate the balloon was 318 ± 163 ml; if bleeding ceased, the balloon was maintained in place for a median of 21.3 ± 10 h. Twenty-five patients required blood

transfusions during the acute episode of hemorrhage; six patients received fresh frozen plasma (FFP). No platelet transfusions were required.

Additional surgery was deemed necessary in eight cases (20%) where the tamponade procedure failed. One patient with placenta previa and accreta, one patient with placenta accreta and uterine atony, one patient with placenta previa, accreta and uterine atony, and one patient with placenta previa, uterine atony and abruptio placentae required immediate hysterectomy. In a case of uterine atony following cesarean section, a B-Lynch compression suture was performed after the balloon application. However, the B-Lynch suture was unsuccessful and hysterectomy was necessary. In another case of atony, Hayman compression suture was able to stop bleeding where the balloon had been unsuccessful. Bilateral O'Leary ligation was performed successfully in one case of emergency cesarean section for hemorrhage in placenta previa and in one case of elective cesarean section for placenta previa and accreta.

The comparison between the balloon and the hysterectomy samples is shown in Table 2. A statistically significant difference was found between the two samples in terms of blood loss, transfused units of red blood cells and days of postpartum admission.

Two patients experienced postpartum sepsis, both commencing after balloon removal. The first patient had a cesarean section for vaginal bleeding after a failed labor induction. Because of severe anemia (Hb 6.1 g/dl) 48 hours after delivery, a transfusion of 1 unit of red blood cells (RBC) was started but soon after stopped because of fever (38°C). Five days later, the patient presented with dyspnea, chest pain, cough, apprehension, tachycardia and leg pain. Doppler ultrasonography revealed a superficial thrombophlebitis of the left leg; computed tomographic pulmonary angiography showed lung embolism and bilateral pleural effusion. Anticoagulant therapy was initiated with subcutaneous enoxaparin (Clexane®) 6000 IU two times daily. As blood cultures were positive for *Staphylococcus* spp, intravenous therapy consisting of tazobactam plus piperacillin (Tazocin®) 4.5 g three times daily and teicoplanin (Targosid®) 400 mg daily was administered. The clinical condition gradually improved and the patient was discharged 15 days after cesarean section with oral antibiotic therapy and subcutaneous enoxaparin.

The second postpartum sepsis was observed in a woman who underwent an emergency cesarean section for placenta previa. In this case, however, fever began the first day after surgery, and blood cultures were positive for *Klebsiella pneumoniae*. She was treated with antibiotic therapy and discharged well 10 days later.

Twenty-five of the 31 women who underwent successful balloon tamponade were available for a follow-up; 18 did not wish to have any further children, three had pregnancies at term without incident, two had early spontaneous abortion, one had a tubal pregnancy and one suffered sterility.

Table 1 Causes of PPH, success rate of the intervention and results

Causes of PPH	Estimated blood loss (ml) (mean ± SD)	Hemoglobin (g/dl) (mean ± SD)		Replaced blood (units)		Successful treatment			
		Antepartum	> 24 h	RBC median (range)	FFP median (range)	Total (n)	Rate		
							n	(%)	Surgery
Uterine atony	1618 ± 588	11.4 ± 1.7	7.4 ± 0.9	2 (0–7)	0 (0–13)	17	15/17	88.2	1 case B-Lynch suture + hysterectomy; 1 case Hayman suture
Uterine atony + placenta previa and/or accreta	2925 ± 1680	11.1 ± 1.2	7.6 ± 2.6	6 (0–11)	2 (0–13)	4	1/4	25	3 cases hysterectomy
Placenta previa	1520 ± 590	10.7 ± 1.2	8.3 ± 1.6	2.5 (0–2)	0	10	9/10	90	1 case O’Leary ligation
Placenta accreta	2000 ± 1080	10.7 ± 0.7	7.5 ± 1.7	3 (0–5)	0 (0–3)	4	4/4	100	None
Placenta previa and accreta	1875 ± 942	11.2 ± 0.8	7.8 ± 1.6	1 (0–11)	0 (0–5)	4	2/4	50	1 case O’Leary ligation; 1 case hysterectomy
Total	1792 ± 886	11.1 ± 1.4	7.7 ± 1.4	1 (0–11)	0 (0–13)	39	31/39	80	8 cases

FFP, fresh frozen plasma; RBC, red blood cells

Table 2 Comparison between the historical hysterectomy and the balloon samples

	Cases of hysterectomy (n = 30)	Cases of balloon (n = 39)	P value
Age (years; mean ± SD)	37 ± 3.9	34 ± 3.6	0.003
Gestational age (weeks; mean ± SD)	36 ± 3.7	36 ± 5	NS
Number of placenta previa (%)	8 (27)	10 (25)	NS
Number of placenta accreta (%)	2 (6)	4 (10)	NS
Number of placenta previa and accreta (%)	9 (30)	4 (10)	NS
Number of uterine atony (%)	11 (37)	21 (53)	NS
Units of RBC median (range)	4 (0–11)	1 (0–11)	0.013
Hemoglobin prepartum (mean ± DS)	10.9 ± 1.4	11.1 ± 1.4	NS
Hemoglobin postpartum (mean ± DS)	7.8 ± 1.6	7.7 ± 1.4	NS
Blood loss (ml; mean ± DS)	2443 ± 1452	1792 ± 886	0.03
Day of postpartum admission (mean ± DS)	9.9 ± 8.3	6.1 ± 2.8	0.02
Maternal death	0	0	NS

NS, not significant

Discussion

PPH is the major cause of maternal death in Italy¹⁵. In the majority of cases, relatively simple methods that could be used to avert a disaster are not always employed¹⁶. Among these techniques, one of the most simple and effective is tamponade using intrauterine balloons. Successful use of tamponade has been reported in case reports and retrospective case series using the Bakri balloon³, a condom²⁰, a Foley catheter²¹, the Sengstaken-Blakemore tube^{9,11} and the Rüsçh urological hydrostatic balloon^{22–24}.

Because these studies primarily have been retrospective in nature, they may have been influenced by selection, reporting and publication bias^{11,23,25}. As such, the conclusions that can be drawn from such data are limited by the study design. The strength of the current study is the prospective identification of cases and method of data collection. Our results are similar to other prospective figures, suggesting that the true effectiveness of balloon tamponade approximates 80%^{9,20}. Doumouctsis *et al.* performed a systematic review of observational studies¹ that showed comparable success rates among the different conservative measures in the management of PPH unresponsive to medical treatment.

CONCLUSIONS

An ideal study design to investigate these various management options would be prospective, randomized and controlled. Unfortunately, such a study design may be difficult for a number of reasons: the urgency of the condition including the degree of on-going bleeding and the hemodynamic status of the woman, the low frequency of severe PPH needing surgical intervention, the staff skills required for each intervention, and the debate on how to perform randomized studies in a field such as PPH. When all these issues are considered, the ethics of undertaking such an investigation would not be considered in a favorable light.

Despite the absence of evidence from randomized studies, the internal balloon tamponade has several obvious advantages over arterial embolization and surgical procedures: simplicity, rapidity of application and removal (no or minimal anesthesia), availability (surgical approach needs laparotomy and technical expertise), safety (the shorter list of complications compared to surgical procedures and arterial embolization) and, finally, low cost. Given that the technology is simple to deploy and has minimal adverse effects, a balloon tamponade method should become a familiar component of existing guidelines for the management of

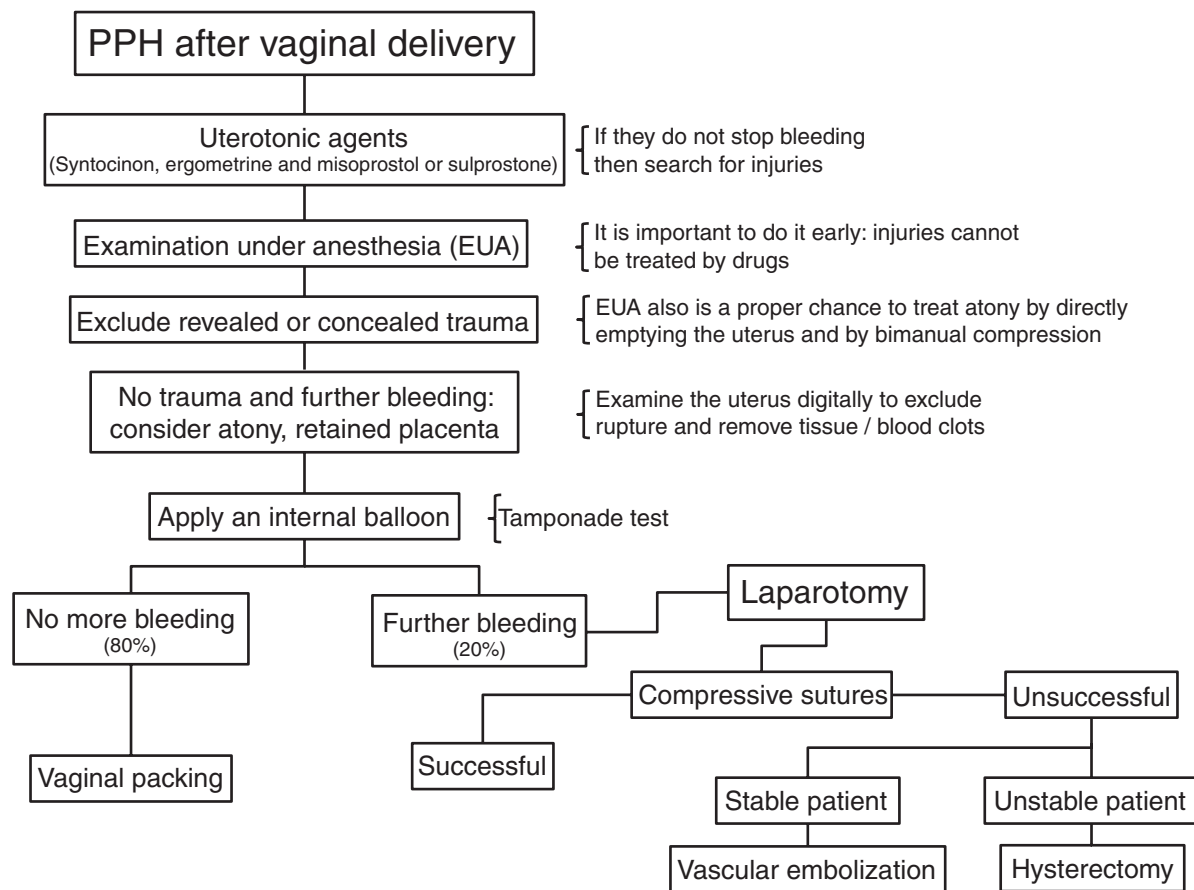


Figure 2 Proposed flowchart about the use of the uterine internal balloon as first-line conservative technique in case of postpartum hemorrhage (PPH) after vaginal delivery.

PPH, although not as an isolated form of therapy. In Figure 2 a flow chart is proposed on balloon application in case of PPH after vaginal delivery.

The RCOG guidelines of 2009²⁶ on PPH suggested that the intrauterine balloon tamponade is an appropriate first-line 'surgical' intervention for most women where uterine atony is the only or main cause of hemorrhage. As proposed in Figure 2 and from the results of the present study, we also found this technique very helpful in case of abnormal insertion of the placenta. The RCOG guidelines of 2011 on placenta previa and accreta begin to consider the balloon tamponade for these indications²⁷.

In most studies published to date, the fertility data are either not mentioned or very limited. A single pregnancy is reported following the use of the Rüsch balloon²² along with two pregnancies following the use of a Bakri balloon in combination with a B-Lynch suture²⁸. In our series, pregnancy following balloon insertion occurred in three instances, but among 25 women only seven wanted another child. This may be due to the small duration of follow-up or the patients' reluctance to experience a subsequent pregnancy after having undergone the trauma of a PPH.

In conclusion, the internal tamponade balloon was evaluated prospectively and found effective as a management option for intractable PPH due to both uterine atony and placenta previa/accreta. We believe it should be a first-line treatment in women in whom

uterotonic agents fail to arrest bleeding. The procedure can be easily carried out and may stop hemorrhage in around 80% of women. When it fails, the bleeding may be treated with further conservative measures before performing a hysterectomy. The use of the uterine internal balloon could be expected to result in reduced total blood loss and a lower rate of maternal morbidity in addition to preservation of fertility.

References

1. Doumouchtsis SK, Papageorgiou AT, Arulkumaran S. Systematic review of conservative management of postpartum hemorrhage: what to do when medical treatment fails. *Obstet Gynecol Surv* 2007;62:540–7
2. American College of Obstetricians and Gynecologists. Postpartum, haemorrhage. ACOG Practice Bulletin No 76. *Obstet Gynecol* 2006;108:1039–47
3. Bakri YN, Amri A, Jabbar FA. Tamponade-balloon for obstetrical bleeding. *Int J Gynaecol Obstet* 2001;74:139–42
4. Olamijulo JA, Doufekas K. Intrauterine balloon tamponade for uncontrollable bleeding during first trimester surgical termination of pregnancy. *J Obstet Gynaecol* 2007;27:441–2
5. Thomas RL, Gingold BR, Gallagher M. Cervical pregnancy. *J Reprod Med* 1991;36:459–62
6. De La Vega GA, Avery C, Nemiroff R, Marchiano D. Treatment of early cervical Pregnancy with cerclage, carboprost, curettage and balloon tamponade. *Obstet Gynecol* 2007;109:505–7
7. Ferrazzani S, Guariglia L, Caruso A. Therapy and prevention of obstetric hemorrhage by tamponade using a balloon catheter. *Minerva Ginecol* 2004;56:481–4

8. Tattersall M, Braithwaite W. Balloon tamponade for vaginal lacerations causing severe postpartum haemorrhage. *BJOG* 2007;114:647–8
9. Condous GS, Arulkumaran S, Symonds I, Chapman R, Sinha A, Razvi K. The 'tamponade test' in the management of massive postpartum hemorrhage. *Obstet Gynecol* 2003;101:767–72
10. Cho Y, Rizvi C, Uppal T, Condous G. Ultrasonographic visualization of balloon placement for uterine tamponade in massive primary postpartum hemorrhage. *Ultrasound Obstet Gynecol* 2008;32:711–3
11. Seror J, Allouche C, Elhaik S. Use of Sengstaken-Blakemore tube in massive postpartum hemorrhage: a series of 17 cases. *Acta Obstet Gynecol Scand* 2005;84:660–4
12. Doumouchtsis SK, Papageorghiou AT, Vernier C, Arulkumaran S. Management of postpartum hemorrhage by uterine balloon tamponade: Prospective evaluation of effectiveness. *Acta Obstet Gynecol* 2008;87:849–55
13. Georgiou C. Balloon tamponade in the management of postpartum haemorrhage: a review. *BJOG* 2009;116:748–57
14. Benirschke K, Kaufmann P, eds. *Pathology of the Human Placenta*, 4th edn. New York: Springer, 2000:554
15. Biaggi A, Paradisi G, Ferrazzani S, De Carolis S, Lucchese A, Caruso A. Maternal mortality in Italy, 1980–1996. *Eur J Obstet Gynecol Reprod Biol* 2004;114:144–9
16. Knight M. On behalf of UKOSS. Peripartum hysterectomy in the UK: management and outcomes of the associated haemorrhage. *BJOG* 2007;114:1380–7
17. Dildy GA 3rd. Postpartum hemorrhage: New management options. *Clin Obstet Gynecol* 2002;45:330–44
18. Grotegut CA, Larsen FW, Jones MR, Livingston E. Erosion of a B-Lynch suture through the uterine wall: A case report. *J Reprod Med* 2004;49:849–52
19. Porcu G, Roger V, Jacquier A, et al. Uterus and bladder necrosis after uterine artery embolization for postpartum haemorrhage. *BJOG* 2005;112:122–3
20. Akhter S, Begum MR, Kabir Z, Rashid M, Laila TR, Zabeen F. Use of a condom to control massive postpartum hemorrhage. *MedGenMed* 2003;5:38
21. Goldrath MH. Uterine tamponade for the control of acute uterine bleeding. *Am J Obstet Gynecol* 1983;147:869–72
22. Johanson R, Kumar M, Obhrai M, Young P. Management of massive postpartum haemorrhage: use of a hydrostatic balloon catheter to avoid laparotomy. *BJOG* 2001;108:420–2
23. Keriakos R, Mukhopadhyay A. The use of the Rusch balloon for management of severe postpartum haemorrhage. *J Obstet Gynaecol* 2006;26:335–8
24. Majumdar A, Saleh S, Davis M, Hassan I, Thompson PJ. Use of balloon catheter tamponade for massive postpartum haemorrhage. *J Obstet Gynecol* 2010;30:586–93
25. Dabelea V, Schultze PM, McDuffie RS. Intrauterine balloon tamponade in the management of postpartum hemorrhage. *Am J Perinatol* 2007;24:359–64
26. RCOG Prevention and Management of Postpartum Haemorrhage. Green-top Guidelines 52. London, UK: Royal College of Obstetricians and Gynaecologists, 2009
27. RCOG Placenta praevia, placenta praevia accreta and vasa praevia: diagnosis and management. Green-top Guidelines 27. London, UK: Royal College of Obstetricians and Gynaecologists, 2011
28. Nelson WL, O'Brien JM. The uterine sandwich for persistent uterine atony: combining the B-Lynch compression suture and an intrauterine Bakri balloon. *Am J Obstet Gynecol* 2007;196:e9–10