

29

THE BALLOON INTERNAL UTERINE TAMPONADE AS A DIAGNOSTIC TEST

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INTRODUCTION

During the last several years, a number of new and simpler techniques have been developed in the attempt to avoid major surgical procedures for treatment of postpartum hemorrhage¹⁻⁸. Although a variety of surgical options have been proposed to avoid hysterectomy including uterine artery ligation, ovarian artery ligation, internal iliac artery ligation, and B-Lynch Brace suture⁹, a suitable conservative technique is still lacking¹ and all proposed options have risks as well as advantages¹⁰.

In most cases, procedures are effective in avoiding hysterectomy, but a delay carries a poorer prognosis. Moreover, each of these techniques entails a laparotomy and skilled personnel must perform the procedure. Rarely, major complications follow radical surgery for postpartum hemorrhage; these include loss of fertility, other morbidity and even maternal death¹¹.

B-Lynch and colleagues^{12,13} used brace sutures to compress the uterus without compromising major vessels. The advantage of the B-Lynch procedure is that identification of specific blood vessels is not necessary, a process which is often difficult. Although helpful during Cesarean section, the B-Lynch procedure requires a laparotomy and therefore may not be ideal as the first approach in cases of postpartum hemorrhage following vaginal delivery¹⁴.

This chapter will focus on one of the recently reported conservative measures to control hemorrhage – internal uterine tamponade. Although uterine atony is the main indication for internal uterine tamponade, this methodology is also useful for postpartum hemorrhage arising from placenta previa/accreta. The technique can be

easily carried out by doctors in training while awaiting help from a senior colleague.

UTERINE PACKING

Control of postpartum hemorrhage by uterine packing is not new¹⁵. For many years, uterine packing with sterile gauze has been used in the clinical management of severe postpartum hemorrhage and as the last resort before hysterectomy¹⁶. Because of the availability of better uterotonic medications, this practice lost its appeal, but reports on its successful use continued to appear¹⁷⁻¹⁹. Recently, some authors raised concerns about concealed bleeding and infection²⁰; a newer technique, however, has allayed some of these concerns²¹.

Uterovaginal packing may sometimes obviate the need for surgery altogether. In cases of deliveries complicated by postpartum hemorrhage, after excluding uterine rupture, genital tract lacerations, and retained placental tissue, efforts are directed toward contracting the uterus by bimanual compression and uterotonic agents. If these are not successful, one must resort to surgical techniques. At this stage, an alternative option to remember is uterovaginal packing. Easy and quick to perform, it may be used to control bleeding by tamponade effect and stabilize the patient until a surgical procedure is arranged.

Chapter 28 describes the technique of uterine packing in more detail.

BALLOON TAMPONADE

Tamponade with different types of balloon catheters used prior to surgery is a conservative

procedure that is available before invasive surgical techniques are needed^{1,3}. Chapter 28 describes the various types of balloon catheters that are available.

Balloon tamponade of the uterus is a recognized procedure in those with massive and intractable hemorrhage^{17,22–29}.

The use of the Sengstaken–Blakemore esophageal or gastric catheter is described in the literature for the control of massive postpartum hemorrhage due to an atonic uterus not responding to oxytocics including prostaglandins^{3,17,23,30,31} or due to placenta accreta³². Multiple Foley catheters in the case of a vaginal delivery^{22,25} have also been used and even rubber catheters fitted with a condom have been used successfully to control postpartum hemorrhage in undeveloped countries³³. Urological fluid-filled catheters (300–500 ml)^{26,28,29} or of silicone balloons designed for tamponade function²⁷ also seem to be very effective, with further possibilities in cases of hemorrhage after Cesarean section for placenta previa/accreta.

Theoretical principle of action

The theoretical principle of the balloon tamponade is that temporary and steady mechanical compression of the bleeding surface of the placental site can be performed 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, can exert an intrauterine pressure that overcomes the systemic arterial pressure, resulting in cessation of the intrauterine blood flow. Probably, a quite different mechanism can be advocated for its efficacy in the case of uterine atony. With separation of the placenta, the many 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, 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 first therapeutic approach to this situation is mechanical stimulation by massage of the uterus and then the use of uterotonic drugs. In this case, 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.

In the presence of placenta accreta, the balloon must be used with great caution, as a failure or delay to control hemorrhage in such patients could be catastrophic.

In the small series reported in the literature, in which the different types of balloon catheter were filled with various volumes, ranging from 30 to 500 ml, Seror and colleagues chose an inflation volume of 250 ml, since this value corresponds to the approximate volume of the uterine cavity after delivery³¹.

BALLOON TAMPONADE AS A TEST

To date, there is no diagnostic test to identify those patients with intractable hemorrhage who will need surgery. Condous and colleagues³ proposed the use of an inflated Sengstaken–Blakemore balloon catheter as a test to create tamponade and identify patients who will or will not need surgery ('tamponade test'). When its results are positive, 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 postpartum hemorrhage responded to the tamponade test³. More recently, Seror and colleagues reported that, in a series of 17 cases, tamponade treatment prevented surgery in 88% of patients³¹.

According to these clinical experiences, an early use of the balloon catheter may reduce the total blood loss, and it is probable that any type of inflatable balloon with high fluid-filling capacity could be used for the same purpose.

POSTPARTUM HEMORRHAGE

The experience at the Catholic University of Rome, Italy

A longitudinal study is currently running in the Obstetrics and Gynecology Department of the Catholic University of Rome, Italy; it started in January 2002 and the Institute review board approved the study.

Patients and methods

In the period January 2002–August 2005, 10 773 patients delivered in our maternity ward. During this period, there were 124 (1.15%) instances of postpartum hemorrhage. Of these, 13 were considered critical and the women underwent treatment by intrauterine tamponade.

An atonic uterus caused postpartum hemorrhage in one case and placenta previa/accreta was noted in 12 cases, of which two were associated with uterine atony.

The mean age of the patients was 35 years (26–39 years). The mean gestational age at delivery was 36 weeks from the first day of the last menstrual period (26 weeks and 5 days to 40 weeks and 1 day). Nine patients were multiparous (69.2%). The mean parity was 2.1.

Labor was spontaneous in three cases, and stimulated with dinoprostone intravaginal gel or oxytocin infusion in two cases. The mean duration of labor was 6 h and 42 min (5–9 h). Three patients had a vaginal delivery, and ten had a Cesarean section (of which seven were planned).

Routinely, the patients who delivered by the vaginal route had prophylactic intramuscular oxytocin/ergometrine in the third stage of labor and all the patients who underwent Cesarean section had intramyometrial and intravenous oxytocin during/after the placenta was delivered.

In the 13 cases of postpartum hemorrhage considered in this study, patients were treated with appropriate oxytocic agents and prostaglandin analogues (intravenous infusions of oxytocin (40–100 U), intramyometrial oxytocin (20 U), intramuscular ergometrine (0.25–0.5 mg), and/or intravenous infusion of sulprostone (500 mg)).

In the three patients delivering by the vaginal route, an examination was performed under regional or general anesthesia for retained tissue and lacerations and, when necessary, retained tissue or placenta was removed and lacerations were sutured.

Coagulation studies were carried out simultaneously to exclude coagulopathy as the first or the complimentary cause of the hemorrhage.

In those patients considered for the study who showed no response to these measures, a sterile hydrostatic (bladder distention) balloon catheter size Ch. 16, 5.3 mm (Rüsch UK High Wycombe, England) (Figure 1) was inserted into the uterine cavity via the cervix. This was achieved using minimal analgesia or regional anesthetic. The insertion was facilitated by grasping the anterior and lateral margins of the cervix with sponge forceps and placing the balloon into the uterine cavity with another sponge forceps. The balloon catheter was then filled with 120–300 ml of 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

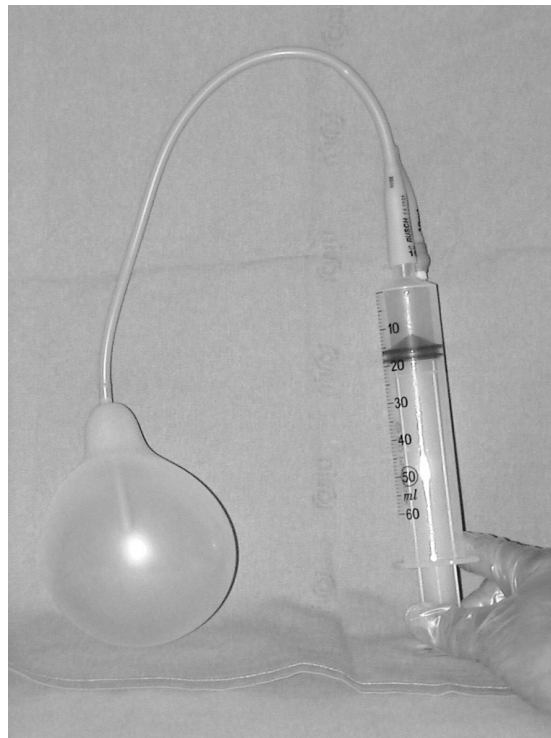


Figure 1 The Rüsch hydrostatic balloon catheter

The balloon internal uterine tamponade as a diagnostic test

fixed in the uterine cavity. If no or minimal bleeding was observed through the cervix, laparotomy was avoided and a gauze packing of the vagina was performed to avoid self-expulsion of the balloon from the completely dilated cervical os. If significant bleeding continued through the cervix, the 'tamponade test' had failed and laparotomy was performed.

In all the patients delivering by urgent or planned Cesarean section, the problem of abnormal insertion or suspicion of morbid adhesion of the placenta was detected by ultrasound scan before surgery. The placenta was delivered by firmly controlled cord traction, or by manual removal if it was abnormally adherent to the uterine wall. If severe bleeding persisted despite a contracted uterus after local intramyometrial and endovenous infusion of oxytocin and prostaglandin analogues, the hydrostatic balloon catheter previously described was inserted intrabdominally, through the uterine incision, into the cervical opening and through the cervical canal by a sponge forceps, leaving the balloon in the uterine cavity (Figure 2). The balloon was then filled with 180–300 ml of

warm saline solution, using a 60 ml bladder syringe. Tamponade was achieved by pulling the distal extremity of the catheter shaft out of the vagina. The uterine contraction over the balloon was maintained, after the uterine closure, by a slow oxytocin infusion (20–40 U) that was given 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. The Cesarean section was concluded following the classical technique. Only when the bleeding was adequately controlled was the abdominal wall closed.

Those who responded to the balloon catheter therapy 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.

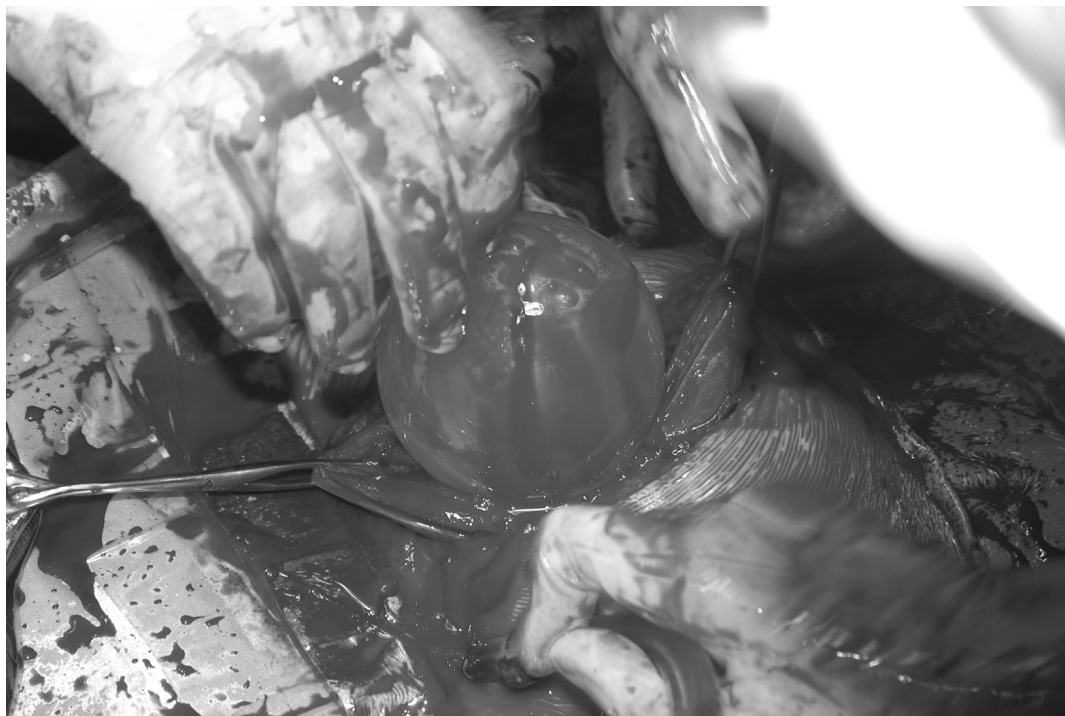


Figure 2 Intra-abdominal insertion of the hydrostatic balloon catheter into the uterine cavity

POSTPARTUM HEMORRHAGE

Table 1 Clinical details of patients with postpartum hemorrhage who underwent a balloon tamponade

Case	Age (years)	Gravidity	Parity	Gestation (weeks)	Duration of labor (h)	Mode of delivery
1	36	2	1	35	–	planned CS
2	29	5	1	35	–	planned CS
3	38	4	2	37	–	planned CS
4	30	1	0	37	–	planned CS
5	36	1	0	40	6	spontaneous labor
6	34	3	0	34	–	urgent CS
7	34	2	1	37	–	planned CS
8	36	2	1	36	–	planned CS
9	39	5	1	30	–	urgent CS
10*	35	2	0	26	–	urgent CS
11	39	3	2	40	9	induced/oxytocin
12	33	6	1	38	5	induced/oxytocin
13	26	4	1	35	–	planned CS

CS, Cesarean section; *failed 'tamponade test'

Results

The 'tamponade test' was positive in 12 out of 13 cases and the hydrostatic catheter immediately arrested hemorrhage. In one case, tamponade failed after 3 h and bleeding re-occurred. In our series of 13 cases, the primary cause for postpartum hemorrhage was bleeding at the placental site alone (ten cases), uterine atony associated with bleeding at the placental site (two cases), and uterine atony with cervical laceration and pre-eclampsia-associated disseminated intravascular coagulation (one case). Tables 1 and 2 provide details of the 13 cases.

Because, according to Benirschke and Kaufmann³⁴, the diagnosis of accreta cannot be made when the placenta is not removed with the uterus, in such a condition the diagnosis of placenta accreta was based on clinical criteria and consisted of the inability to remove it by controlled cord traction because of a severe adherence to the underlying myometrium and failure to develop a cleavage plane between the placenta and uterus.

Among the three patients delivering by the vaginal route, two deserve a more detailed description. One patient (case 5) had a pre-delivery ultrasound diagnosis of marginal placenta previa. The woman had a normal labor, but soon after delivery of the placenta a profuse hemorrhage began. The uterine cavity was

explored and the placenta accurately removed. A 3-cm fragment of the placenta was lacking but even a very vigorous examination of the uterine cavity was unsuccessful in removing that fragment. A catheter balloon inserted through the vagina soon arrested the severe bleeding. The patient was administered 2 units of blood and the balloon was removed after 24 h. The patient was discharged from the hospital 7 days later and her progress was uneventful until 11 days, when she was re-admitted to hospital for further hemorrhage due to the expulsion of the placental fragment. An examination of the uterine cavity resolved the case with no other intervention or further blood transfusion.

Another patient (case 12) had a normal vaginal delivery with no pre-delivery suspicion of abnormal adherence of the placenta. After delivery of the placenta, the lack of a 3-cm placental fragment was observed. The examination of the uterine cavity was unsuccessful but, in the absence of further bleeding, the patient was kept under observation with no other intervention. During the subsequent 24 h, sub-acute vaginal bleeding was associated with a progressive fall of the hematocrit level. A further examination of the uterine cavity was planned, and the removal of the retained placental fragment caused a severe hemorrhage that was quickly stopped by introducing a balloon catheter through the vagina into the uterine cavity.

Table 2 Cause of bleeding and medical treatment before tamponade procedure

Case	Cause of bleeding	Estimated blood loss (ml)	Intrapartum RBC and FFP	Postpartum RBC	Medical treatment	Postpartum hospital admission (days)
1	total placenta previa	1000	0	0	intramyometrial oxytocin, oxytocin infusion	5
2	total placenta previa	3000	RBC 2 U	0	intramyometrial oxytocin, oxytocin infusion	11
3	total placenta previa	1000	0	0	intramyometrial oxytocin, oxytocin infusion	4
4	total placenta previa	1200	RBC 1 U	RBC 2 U	intramyometrial oxytocin, oxytocin infusion	6
5	marginal placenta previa, focally accreta	1200	0	RBC 2 U	oxytocin infusion, i.m. ergometrine	8
6	total placenta previa	1500	0	0	intramyometrial oxytocin, oxytocin infusion	5
7	total placenta previa	1500	0	0	intramyometrial oxytocin, oxytocin infusion	5
8	focal placenta accreta	1000	0	0	intramyometrial oxytocin, oxytocin infusion	4
9	focal placenta accreta, atony	3300	RBC 6 U, FFP 6 U	0	intramyometrial oxytocin, oxytocin infusion, sulprostone infusion	5
10*	marginal placenta previa, focally accreta, atony	5000	RBC 9 U	0	intramyometrial oxytocin, oxytocin, sulprostone infusion	6
11	atony, cervico-isthmic tear and DIC in pre-eclampsia	1100	0	RBC 2 U	i.m. oxytocin, oxytocin infusion	7
12	focal placenta accreta	1500	RBC 2 U	RBC 2 U	oxytocin and sulprostone infusion, i.m. ergometrine	5
13	total placenta previa/accreta	1100	0	0	intramyometrial oxytocin, oxytocin infusion	5

RBC, red blood cell; FFP, fresh frozen plasma; DIC, disseminated intravascular coagulation; i.m., intramuscular; *failed 'tamponade test'

Among the ten cases resulting in Cesarean section, one patient (case 13) showed at ultrasound scan high suspicion of morbid adhesion of the placenta (accreta/increta) before the planned Cesarean section for total placenta previa. During Cesarean section, in order to prevent severe bleeding at delivery of the placenta by reducing the blood flow to the uterus, a prophylactic

O'Leary suture³⁵ was positioned around the uterine arteries immediately after delivery of the infant, with the placenta still *in situ*, using a 2-monofilament absorbable suture on a high-curve needle. Subsequently, a bilateral utero-ovarian vessel ligation was performed with a 1-monofilament absorbable suture, including the broad ligament close under the tubal insertion to

POSTPARTUM HEMORRHAGE

the uterus and the utero-ovarian ligament. The placenta was found to extend across the internal cervical os. The inability to remove it by firmly controlled cord traction because of a severe adherence to the underlying myometrium and to develop a cleavage plane between the placenta and uterus became the clinical confirmation of placenta accreta³⁴. Therefore, the placental tissue was manually removed in fragments and the placental site inspected. No myometrial defects were found, as the adhesion was limited to the myometrial layer. In order to control a persistent, although moderate, bleeding from the placental site which did not respond to pharmacological uterotonic therapy, a hydrostatic balloon catheter was inserted through the uterine incision, leaving the balloon in the uterine cavity as previously described. The patient did not need blood transfusion and a 6-month follow-up by Doppler ultrasound demonstrated regular reperfusion of the uterus.

Conservative treatment with the balloon catheter was unsuccessful in two cases and hysterectomy was performed (cases 9 and 10). In case 9, the balloon catheter was inserted, after Cesarean section was concluded, by the vaginal route because of a persistent vaginal bleeding. The 'tamponade test' was successful and the patient was monitored for 3 h. However, the patient then had a hemorrhage due to secondary uterine atony not responding to oxytocics and sulprostone infusion. Even further filling of the balloon was unsuccessful and, soon after the removal of the balloon, a large amount of blood and clots were expelled from the cervical os, so that urgent hysterectomy was mandatory. In case 10, the 'tamponade test' failed and no other surgical approach was attempted before hysterectomy. The reason for the failure of the 'tamponade test' was uterine atony refractory to any pharmacological treatment.

The 13 patients had a total estimated blood loss of 23.4 liters. The lowest and highest estimated blood losses experienced were 1 and 5 liters. A total of 28 U of blood and 6 U of fresh frozen plasma were transfused.

Discussion

The effectiveness of the Rüschi urological hydrostatic balloon as a conservative procedure in the

therapy of postpartum hemorrhage has been shown in two cases described by Johanson³⁶ and in four cases more recently reported^{28,29}. However, its efficacy in severe postpartum hemorrhage needed to be evaluated in a larger series. In the present provisional study, the insertion of the Rüschi urological hydrostatic balloon in patients with massive postpartum hemorrhage was very successful and was associated with no significant complications. The procedure failed in only two cases. As opposed to the traditional gauze uterine packing, the technique with the balloon catheter provides immediate knowledge of its effectiveness in controlling the postpartum hemorrhage, so that subsequent surgery can be expedited in failed cases.

If bleeding continues despite the insertion of a balloon, the Rüschi urological hydrostatic balloon gives less information than a Sengstaken-Blakemore catheter, since bleeding is noted only through the cervix but not from the uterine fundal cavity. However, the Rüschi urological hydrostatic balloon is simpler and cheaper than the other. At the same time, its overturned pear-shape better fits in the uterine cavity, with probably less risk of self-expulsion. The uterus must be empty for successful tamponade. If the uterine cavity is completely empty and uterine contraction sustained by adequate pharmacological assistance, there is probably no need for monitoring bleeding from the uterine fundal cavity. A larger series of cases will be necessary to support this last opinion.

The Rüschi urological hydrostatic balloon takes a few minutes to insert, is unlikely to cause trauma and is easy to place with minimal or no anesthesia, whereas its removal is painless and simple. Whether the patient is going to bleed after removal of the balloon is a general concern, but this series demonstrates that there were no cases of rebleeding after the planned removal of the Rüschi urological hydrostatic balloon. In case of rebleeding, it is possible to replace the balloon while planning an opportune uterine arterial embolization in a patient who is now in a stable condition³⁶⁻³⁹.

There were two cases of failure; atony was the cause of failure and subsequent hysterectomy in both. In these cases, an attempt to mechanically favor uterine contraction by applying a B-Lynch Brace suture of the uterus

combined with an additional insertion in the uterine cavity of a balloon catheter could possibly have resolved the problem, with the combined conservative approach already described by Danso and Reginald⁴⁰.

One of the difficulties in the management of patients with intractable postpartum hemorrhage, not responding to uterotonic agents, is the decision to perform a laparotomy and, in case of Cesarean section, the decision to perform a hysterectomy. The delay can be catastrophic. In the present series, average blood loss was considerably less than that of other series recently reported^{3,31}. In all the cases but two, the risk of postpartum hemorrhage was known in advance. When there is confidence that the management of postpartum hemorrhage can be conservative, easy and effective, as in the case of application of a balloon catheter, there is no reason for a delay.

In conclusion, the safe, low-cost, and easy procedure of utilizing a balloon catheter can be applied in any situation of life-threatening postpartum hemorrhage and avoids radical surgery in patients so that reproductive capacity is preserved.

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POSTPARTUM HEMORRHAGE

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