

Intraluminal Pressure in a Uterine Tamponade Balloon Is Curvilinearly Related to the Volume of Fluid Infused

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ABSTRACT

We studied the effect of incremental infusion of fluid volume in a tamponade balloon on intraluminal pressure and uterine blood flow. Following placental delivery, a tamponade balloon was inserted into the uterus and incrementally inflated. Intraluminal pressure was measured at incremental volumes. Ultrasound was used to determine positioning of the catheter, uterine wall thickness, and uterine artery velocity waveforms in eight patients. Pressure-volume relationship was estimated by regression analysis. Significance was $p < 0.05$. There was a significant exponential curvilinear relationship between balloon pressure and infused volume at the maximum volume for each subject ($R = 0.64$, $p = 0.01$). Doppler ultrasound showed that at or above 1000 mL inflation volume, 5/6 patients (83%) showed reversal of uterine artery diastolic flow. At maximal inflation volume, all of the patients with reversed diastolic flow had intraluminal pressure less than systolic blood pressure. Intraluminal pressure increases curvilinearly as volume of an intrauterine tamponade balloon is increased. The mechanism of action of tamponade balloons is likely related to a reduction in uterine artery perfusion pressure. Whether this is the result of direct compression of the artery in the lower segment or due to wall conformational changes is not clear.

KEYWORDS: Tamponade balloon, reversed diastolic flow, pressure-volume relationship

Balloon tamponade has become an important part of our armamentarium for the management of postpartum hemorrhage (PPH). There are now several different devices being used for this purpose, some specifically designed for PPH (Bakri balloon [Cook Medical, Bloomington, IN], BTCath [Utah Medical, Midvale, UT]) and some used off-label (Foley urinary catheter, Rusch urinary catheter [Rusch Inc., Research

Triangle Park, NC], Sengstaken-Blakemore tube).¹ These balloon devices have been used following vaginal delivery and cesarean section, in women with postpartum uterine atony and in patients with contracted uteri but bleeding from other causes such as placenta accreta or postabortal hemorrhage.

The mechanism of action of these devices is still unclear. It may be related to any or all of the following:

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(1) distension of the uterine wall causing increased wall pressure and global decreased perfusion pressure, (2) local surface contact of the balloon material with open venous sinuses leading to reduced oozing, (3) stretching of the uterine wall and reflex contraction of the uterine musculature, and (4) direct pressure on the uterine arteries at the level of the lower segment and cervix decreasing distal perfusion pressure.

Cho et al demonstrated cessation of bleeding in a PPH patient after 320 mL of saline was placed in an intrauterine Senstaken-Blakemore tube.² Postplacement ultrasound in their case demonstrated that the inflated balloon was not in the fundus but in the lower uterine segment and that it was not tamponading an area of myometrium sufficient to be effective at controlling PPH. They suggested that the mechanism of action was by uterine artery compression rather than direct myometrial tamponade.

A recent publication by Georgiou suggested that the pressure-volume relationship in the Bakri balloon is curvilinear and that both in vivo (in uterine atony) and in vitro, the maximal pressure is attained at around 100 mL of volume and thereafter does not change significantly as volume is increased.³ This same article showed that in two cases, the maximum pressure in the balloon never exceeded the systolic pressure at the time of control of the hemorrhage.

Because the only available balloon tamponade in vivo pressure-volume data reflect use in the atonic uterus, and because tamponade balloons are frequently used in the contracted uterus, we sought to establish the intraluminal pressure-volume relationship in the well-contracted postpartum uterus. In addition, given the

suggestion that the mechanism of action of tamponade balloons is, at least in part, due to uterine artery compression, we wished to determine the relationship between balloon distension and uterine artery blood flow patterns as evidenced by Doppler waveform shape.

METHODS

Data for this study were collected using a new Obstetric Tamponade System (OTS-Ebb, Glenveigh Medical, Chattanooga, TN; Fig. 1) developed, in part, by the authors of this article. The device was cleared by the Food and Drug Administration in April of 2010 for use in providing temporary control or reduction of postpartum uterine bleeding. This OTS consists of two balloons, a uterine balloon and a vaginal balloon. The vaginal balloon is movable and can provide countertraction and help seat the uterine balloon in the lower segment. Vaginal bleeding can also be controlled by the vaginal tamponade balloon. In this study, we did not inflate the vaginal balloon and addressed only the uterine balloon characteristics.

The sample size was determined empirically based on the availability of suitable, consenting patients during the study period (with a minimum acceptable sample size of 15 patients). Nineteen subjects were enrolled between the months of April 2009 and October 2009. The investigators obtained written informed consent from each subject before the start of the procedure. The study consisted of a screening phase (informed consent and collection of demographic data prior to delivery), a procedures phase (the insertion and evaluation of the OTS catheter), and a follow-up phase (final evaluation

Glenveigh OTS Device with color coding and banding human factor solutions applied

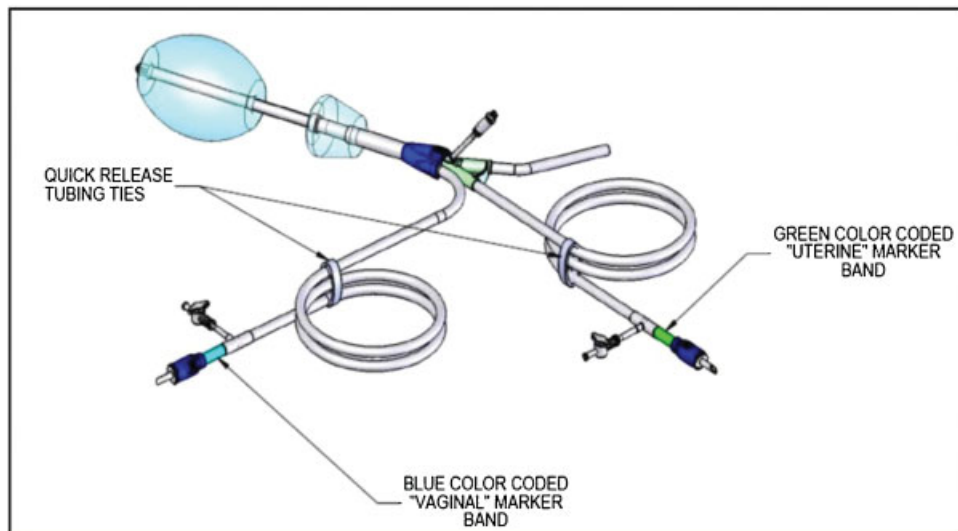


Figure 1 The Obstetric Tamponade System (OTS) used in this study. Note the uterine and vaginal balloons. Only the uterine balloon was inflated in this study. The combined effect of inflation of both the uterine and vaginal balloons on uterine artery blood flow is the subject of further study.

and discharge at 48 hours postpartum). Patients included were ≥ 18 years of age, had a normal uterus and vagina, had known normal placental location, and had a vaginal or cesarean delivery ≥ 36 weeks without maternal or neonatal complications. All participants had a functional epidural in place at the time of delivery. No subject included had any clinical or hematologic evidence (complete blood count) of infection at the time of delivery. All patients agreed to remain in the hospital for a minimum of 48 hours postremoval of the balloon catheter.

Following the delivery of the placenta and placement of a urinary catheter, and after administration of 500 mg amoxicillin/clavulanate and 500 mg azithromycin orally, the OTS catheter was inserted. No oxytocin was administered prior to balloon insertion or while the balloon was in situ. Blood pressure prior to balloon inflation was recorded. A handheld manometer (Model PM-9100HA, Omega Engineering, Taiwan) was connected to an auxiliary inflation port on the device to measure intraluminal balloon pressure during inflation. The uterine balloon was carefully and incrementally inflated under ultrasound guidance until it filled and mildly distended the uterine cavity. The time to maximum inflation, volume of saline infused, and pressure within the balloon were recorded during the inflation process or at the final inflation as dictated by clinical conditions, with multiple pressure measurements taken on seven subjects. Two-dimensional ultrasound evaluation of the uterus before and during the balloon inflation was also performed in eight of the patients studied, and color and pulsed wave Doppler examinations of the uterine artery flow velocity pattern were recorded as clinical circumstances allowed (Mindray Medical DC-6, Nanshan, P.R. China). The amount of blood draining from the drainage channel of the catheter was recorded. Following completion of these assessments, the balloon was deflated and the catheter was removed. The entire procedure was mandated, per protocol, to take less than 20 minutes. In some cases, to logistically comply with the time constraint, it was not possible to make all of the ultrasound or pressure measurements.

After OTS catheter removal, the subject was evaluated for any adverse events. She was given 500 mg amoxicillin/clavulanate orally at 12 and 24 hours and 250 mg azithromycin orally at 24 hours postpartum. A final follow-up examination and interview occurred at 48 hours after balloon catheter removal. At this time, the subject was again evaluated for adverse events including infection and then received a small compensation (coupon for baby clothes/diapers) for participation as approved by the Institutional Review Board.

Data were collected in an Excel spreadsheet and analyzed using Sigmasat (Aspire Software International, Ashburn, VA), Origin (OriginLab Corporation, Northampton, MA), and SPSS (IBM, New York, NY). Linear and nonlinear regression analyses were

performed. $p < 0.05$ was used to denote statistical significance.

RESULTS

Twenty-two women were screened and three were not enrolled due to inadequate anesthesia. Nineteen subjects completed the study. Demographic and delivery data are shown in Table 1. There were no complications or adverse events. Data on inflation volume were available on all 19 patients (Table 1). Fourteen patients had at least one manometric pressure determination at maximum inflation (range 150 to 1500 mL) and seven patients had multiple measurements performed. Most patients showed an incremental increase in pressure with increasing volume except for two cases (Fig. 2). These were the first two cases studied, and we believe that the pressure measurements were affected by bimanual pressure applied by the investigator during the catheter insertion. Once this issue was recognized, the measurements were made without the investigator touching the maternal abdomen or stabilizing the uterus. There was a statistically significant exponential curvilinear relationship ($R = 0.64$, $p = 0.01$) between the volume of saline infused and the intraluminal balloon pressure recorded at maximum infusion volume for each subject (Fig. 3). This relationship was defined by the following equation:

$$\text{Pressure} = 28 \cdot e^{(0.00063 \cdot \text{Volume})}$$

Second, for each subject on whom at least three sequential pressure measurements were taken ($n = 5$), linear and nonlinear regressions were performed. Individual best-fit lines for these five cases had a mean positive slope of $0.57(\pm 0.32)$ mm Hg/10 mL infused ($p = 0.02$). The volume-pressure relationship in these cases was best modeled by exponential regression (median $R = 0.84$, range 0.75 to 0.99).

Figure 4 shows data from eight patients on whom ultrasound and Doppler evaluations were performed and

Table 1 Demographic, Delivery, and Volume-Pressure Data for the 19 Participants

Height (inches)	64 (± 3)
Weight (pounds)	150 (± 18)
Gravidity/parity	2 [1-7]/1 [0-6]
Type of delivery	17 vaginal, 2 cesarean
Estimated blood loss (mL)	442 (± 440)
Gestational age (wk)	38.9 (± 1.3)
Systolic BP (mm Hg)	105 (± 10)
Maximum volume infused (mL)	966 (± 334); 1000 [150-1500]
Pressure at maximum volume (mm Hg)	56 (± 18)
Maximum Pressure at any time (mm Hg)	59 (± 25)

Results are presented as mean (SD) and median [range]. BP, blood pressure; SD, standard deviation.

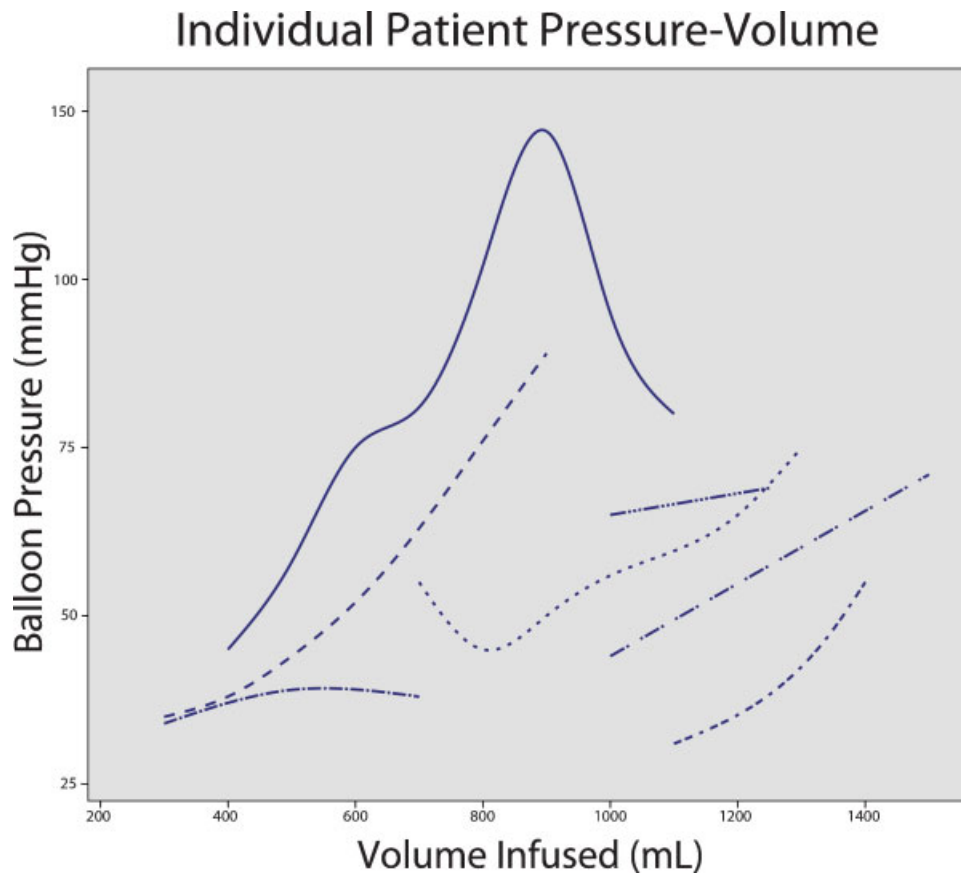


Figure 2 Volume-pressure plot for seven patients on whom at least two sequential pressure measurements were taken. One patient showed a peak in pressure between 700 and 1100 mL and this is believed to be artifactual due to the investigator performing bimanual examination for balloon placement during the manometric pressure recordings. In subsequent patients, the investigator did not examine the patient while pressure was being recorded.

demonstrates an estimated threshold volume (1000 mL) above which diastolic flow was reversed. Figure 5 shows images from one such patient demonstrating normal pre- and post-balloon inflation uterine artery Doppler waveforms and reversed diastolic flow during maximal balloon inflation >1000 mL. Manometric pressure within the balloon at the maximal volume infused did not exceed maternal systolic blood pressure in any case. In Fig. 6 the sequence of filling is shown using two-dimensional ultrasound. The catheter is placed in the contracted uterus (left upper image), partially filled such that the balloon conforms to the irregular intrauterine cavity (right upper image); with further filling to 1000 mL, the uterus is distended and seen in cross section (right lower image) and in longitudinal view (left lower image).

DISCUSSION

There are few data available addressing the pressure-volume relationship in intrauterine tamponade balloons placed in the postpartum uterus, especially the nonatonic uterus. The mechanism of action in arresting PPH in either the nonatonic or the hypotonic uterus is not

clearly understood, and there are several possibilities, as alluded to in the introduction. No Doppler waveform data have previously been published regarding the effect of tamponade balloon inflation in postpartum uteri, although Cho et al did show, using power Doppler ultrasound, that there was still appreciable blood flow in the uterine artery despite placement in the lower uterine segment of a tamponade balloon with a volume of 320 mL.² No data on the Doppler waveform were provided. Our data show that it is likely that a reduction in uterine artery perfusion pressure occurs as balloon volume increases, and that at volumes that exceed a threshold near 1000 mL, reversal of uterine artery diastolic blood flow occurs in the normotensive patient. It may be hypothesized that this effect will occur at lower volumes in the hypotensive patient. Thus, at least in part, the mechanism of action of a tamponade balloon will include a decrease in uterine muscle perfusion, either as a result of pressure on the luminal surface of the myometrium by a balloon that contacts a large proportion of the surface area and/or as a result of direct pressure on the uterine artery and its branches in the lower uterine segment (in those cases where the balloon volume is less than that of the uterine lumen).

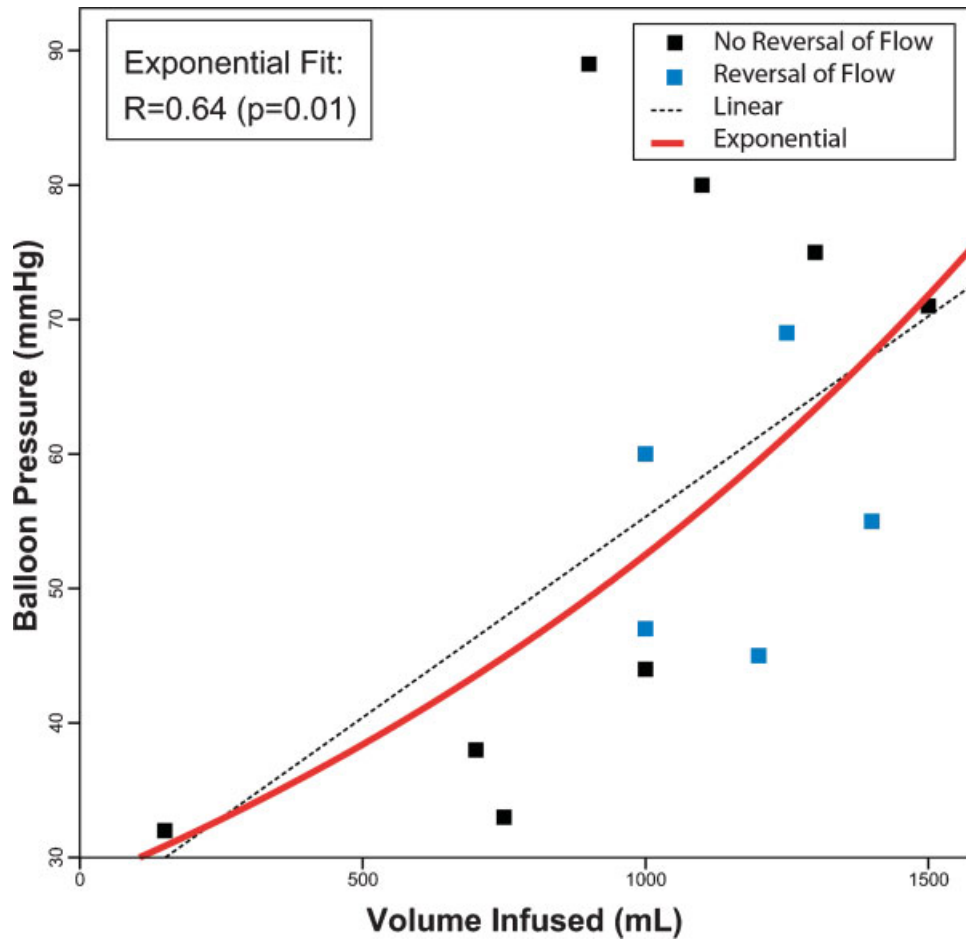


Figure 3 Exponential curvilinear relationship among data points ($n=14$) representing intraluminal pressure at maximum volume infused for each subject (note that two equivalent measurements are graphed at 1000 mL/44 mm Hg). Blue points represent five patients in whom the balloon volume was 1000 mL or more and in whom there was reversed diastolic flow as measured by Doppler ultrasound. The three patients with volume >1000 mL (above the blue points) were not studied with Doppler ultrasound.

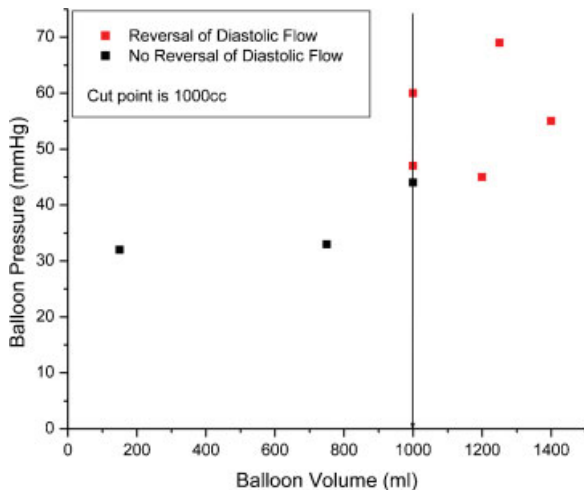


Figure 4 Data of eight patients in whom uterine artery Doppler ultrasound data were available. There was a clear cutoff at 1000 mL, above which reversal of diastolic flow occurred.

Recently, Georgiou reported two cases where a Bakri balloon was placed in atonic uteri and intraluminal pressure was recorded.³ It was proposed, based on the patterns recorded in these two cases, that the pressure-volume relationship is curvilinear and not directly proportional, at least up to a volume of ~ 350 mL. An in vitro experiment was also performed in the same study using three Bakri balloons inflated with 50 mL aliquots up to a maximum inflation volume of 500 mL, and this showed an initial linear increase in intraluminal pressure to a peak 60 to 80 mm Hg at ~ 50 mL, with no further change in pressure as the volume was increased to 500 mL. Our data show that in a well-contracted postpartum uterus, such as could be seen in a case of PPH due to placenta accreta, there is an exponential pressure-volume relationship that does not reach a peak pressure at <100 mL inflation as suggested by Georgiou, but rather persists curvilinearly up to the maximum volume we infused (1500 mL). We

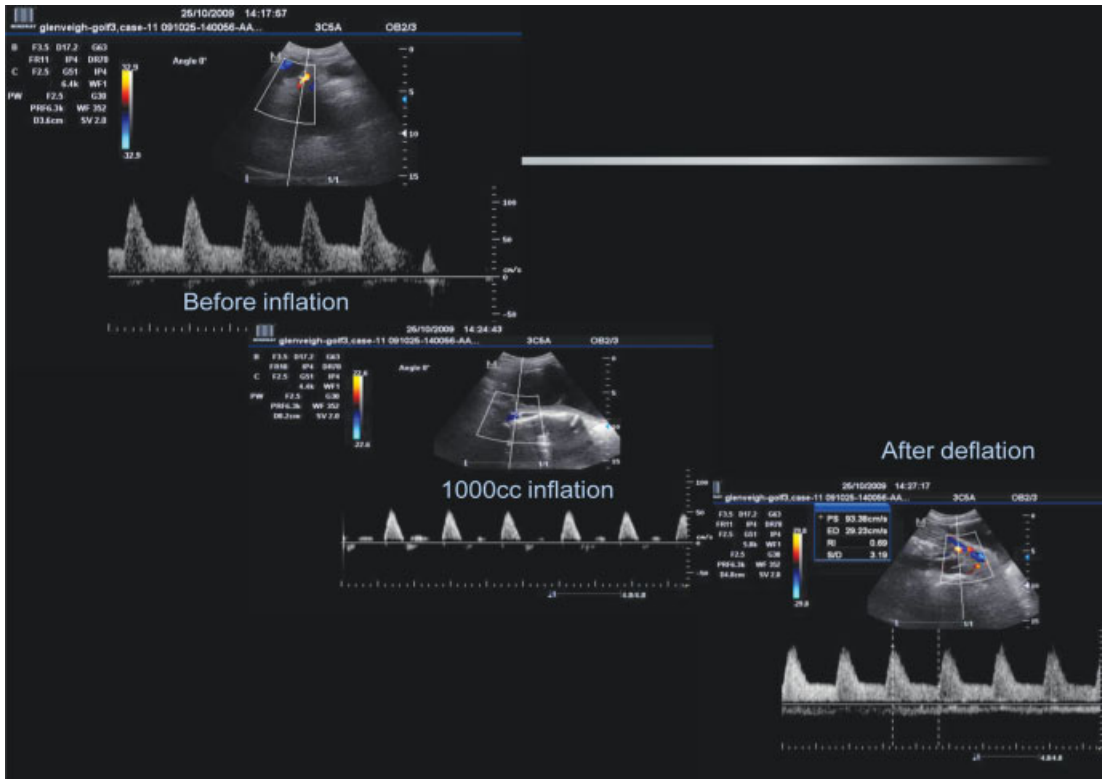


Figure 5 Typical progression from normal uterine artery flow velocity before balloon inflation, reversed diastolic flow at maximal balloon inflation, and resumption of normal flow after balloon deflation.

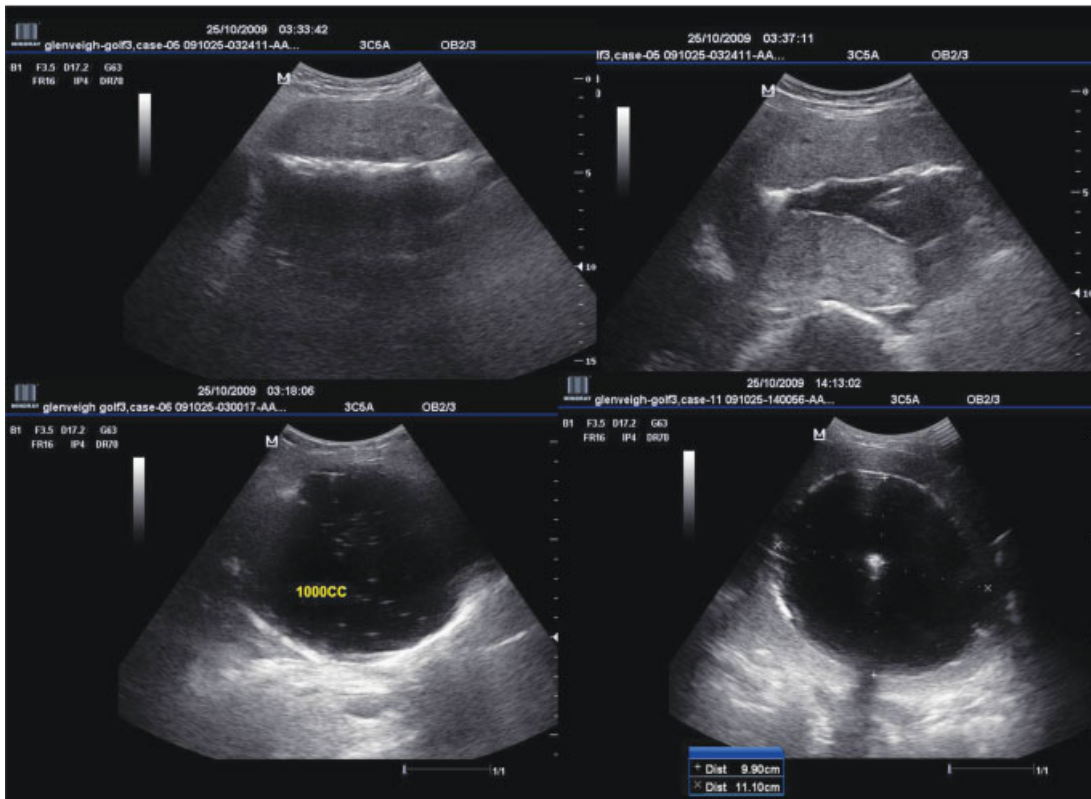


Figure 6 Balloon inserted into the uterus prior to inflation (upper left panel), partially inflated longitudinal view (upper right panel), inflated to 1000 mL longitudinal view (lower left panel), and inflated to 1000 mL cross-sectional view (lower right panel). Note the reduction in uterine wall thickness as the balloon is filled.

speculate that the volume-pressure relationship estimated by Georgiou is attributable to (1) an initially high level of resistance to inflation as the balloon material (silicone) undergoes elastic distortion up to a threshold point at which it distorts plastically and pressure no longer increases appreciably, and (2) relatively low inflation volumes (<500 mL) at which resistance of the uterine wall likely does not contribute substantially to intraluminal pressure. In our study, the OTS material (polyurethane) may have imparted an initially lower resistance to inflation (lower pressure required to undergo plastic deformation), and at higher inflation volumes (>500 mL), the resistance of the uterine wall contributed to a consistent exponential rise in intraluminal pressure. We believe further study of the volume-pressure relationship in these balloons is needed.

In none of our cases, at maximal balloon volume, did the intraluminal pressure exceed the maternal systolic blood pressure. However, maternal blood pressure measured at the brachial artery may not be representative of uterine artery pressure given the different vessel diameters and the reduction in perfusion pressure as distance from the heart increases and because of aortocaval compression from an enlarged atonic fluid-filled uterus.⁴ Considering our patients were normal postpartum women who were not experiencing PPH, if the mechanism of action of a tamponade balloon is restricted to uterine artery compression, we would have expected some observed bleeding from the uterus during the balloon inflation because there is a drainage channel in the tip of the device. This did not occur. It may be speculated, therefore, that a further aspect of the tamponade effect is coverage of the internal uterine surface with the balloon material. Furthermore, it should be appreciated that the distal intravascular blood pressure at the level of the arterioles and capillaries, where direct pressure of the balloon is applied, is less than half that of the proximal systemic circulatory system (e.g., aorta and large arteries).

In our study, the balloon was deliberately inflated under ultrasound guidance to the point that it filled and distended the uterine cavity (Fig. 2). Filling did not occur in a uniform spherical fashion, but rather it appeared to take the path of least resistance, conforming to the unique shape of each uterine cavity. In most cases, until the balloon was inflated to at least 200 mL, there was a tendency for it to be expelled through the cervix into the vagina, and the device required the operator to hold it within the uterine cavity as it was inflated to prevent expulsion. Only once when more than 300 to 500 mL was infused did the balloon allow traction on the stem without it being withdrawn from the uterus. At volumes of greater than 500 mL, it was possible to apply traction in all

cases such that the balloon could be definitively seated in the lower segment. No patient exhibited a vagal response (bradycardia or hypotension) to intrauterine balloon inflation.

Ultrasound was very helpful in the placement of the catheter. It allowed clear visualization of the insertion and advancement of the tip of the catheter to the fundus of the uterus. This approach may decrease any risk of uterine perforation and deserves future study. Using ultrasound, as the balloon was inflated it was possible to see the extent of the uterine cavity that was being covered by the balloon material, and it allowed us to determine when the balloon was sufficiently inflated by noting when the rostral portion of the balloon extended beyond the tip of the catheter. The wall thickness of the uterus was also visible. The pulsed Doppler waveform pattern in the uterine arteries showed an increase in the systolic velocity/diastolic velocity ratio as the balloon volume increased until, at and above 1000 mL, 5/6 patients showed clear reversal of diastolic flow.

The current restriction of balloon inflation to 500 mL⁵ may in some cases limit the usefulness of balloon tamponade, especially if used in cases of uterine atony where the uterine volume is greater than 500 mL. If the mechanism of action is related to surface coverage and wall distension, as opposed to simple lower segment uterine artery compression, a 500-mL balloon may not provide surface coverage or wall distension sufficient to arrest bleeding. Clearly there is a risk of uterine rupture with unchecked inflation of a balloon within the uterus. When intentionally exceeding 500-mL inflation, ultrasound guidance to the point where the balloon fills the cavity but does not overdistend the wall of the uterus seems advisable. Further research as to the optimum uterine wall thickness or intraluminal pressure to arrest hemorrhage in women with and without uterine atony is required. In our study of women with nonatonic uteri, volumes in excess of 500 mL were uniformly tolerated without adverse effects. In two cases, the balloon was inflated under direct vision of the lower uterine segment at the time of cesarean section to volumes in excess of 1000 mL without evidence of hysterotomy separation or bleeding. Thus, although most patients with a nonatonic uterus will require less than 500 mL to stop bleeding, it is not unreasonable to suggest that, with the correct precautions (incremental filling of the balloon in 100 to 200 mL aliquots under ultrasound guidance), volumes of up to 1000 mL may in some cases be required to realize the full benefit of a tamponade balloon and prevent more invasive and extirpative options for the management of PPH.

Our study is limited by the small number of cases and the fact that clinical circumstances did not allow complete data collection in all cases. Our

data are also limited by the fact that the device was only inflated in normal postpartum uteri, not atonic uteri. Thus, although we believe that these data are generalizable to women with normal uterine tone, they may not be applicable to women with uterine atony.

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