Intraluminal Pressure Readings whilst Achieving a Positive 'Tamponade Test' in the Management of Postpartum Hemorrhage

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INTRODUCTION

Whereas pharmacological agents such as oxytocin, ergometrine, prostaglandin F2 α and misoprostol used in the treatment of postpartum hemorrhage (PPH) normally result in a generalized contraction of uterine size^{1,2}, the use of uterine tamponade results in a temporary enlargement of the uterine cavity. Uterine packing as a method of tamponade was described as early as 1856, and is still used throughout the world today³. Sterilized cotton gauze is commonly used to pack the uterus, and although considered effective by those who have used the method regularly over the years, one of the arguments against this methodology was the 'unphysiological' nature of expanding the uterus⁴, as the uterus normally is expected to 'contract down'⁵. This paradoxical concept of expanding the uterine cavity, together with the possibilities of causing trauma and/or infection, ineffective packing and the coincidental development of effective pharmacological uterotonic agents, resulted in a gradual decline in its use 6,7 .

More recently, a marked resurgence of interest in the use of uterine tamponade for the management of PPH has occurred using balloon technology⁸. A variety of balloons are available, including the purpose designed uterine balloons (Figure 1) such as the Bakri balloon, EbbTM balloon and BT-Cath[®] as well as the Foley and condom catheters^{9–14}. In addition, other non-uterine specific types of balloons, previously used in other body cavities where bleeding can be problematic, have also been used in the therapy of PPH. Two examples are the Sengstaken–Blakemore tube (esophagus) and the Rusch balloon (bladder)^{15,16}.

Despite publication of recent guidelines recommending the use of balloon tamponade in the management of PPH, the mechanism by which these balloons provide their effect remains controversial^{17,18}. In practice, the term 'tamponade' is often used to explain the effect of the balloon. One proposed mechanism by which balloons provide tamponade effect is by 'exerting an inward-to-outward pressure' within the uterine cavity 'that is greater than the systemic arterial pressure'¹⁷.

Variations exist with respect to how balloons are insufflated; some authors place a fixed or predetermined volume in the balloon, whereas others suggest titrating the volume to clinical effect⁸. However, none of the published methods describe measuring intrauterine pressures. Furthermore, although the term 'tamponade test' has been used to characterize the process with respect to using balloon tamponade in the management of PPH, studies do not specifically relate to this terminology during balloon insufflation^{8,19}.



Figure 1 Uterine specific balloons. The Bakri balloon and the BT-Cath are single balloon devices. The Ebb balloon is designed for one balloon in the uterine cavity (Ut) and the other within the vagina (Va). *Drainage channel for each balloon system. Bar = 5 cm

This chapter describes a prospective study that was designed to investigate the hypothesis that it was necessary for the intraluminal pressure (ILP) to exceed the patient's systolic blood pressure in order to achieve a positive tamponade test. The study describes the measurement of intrauterine ILPs whilst achieving a positive tamponade test in a series of seven cases.

Ethics approval was granted for the study from the University of Wollongong/South Eastern Sydney Illawarra Area Health Service and Medical Human Research Ethics Committee (HE09/240 and HE09/241). Cases 1 and 2 have been previously published²⁰.

IN VITRO INTRALUMINAL PRESSURES OF THE BAKRI, BT-CATH AND EBB BALLOONS

ILP recordings were determined for the various uterine-specific balloons and the condom catheter in the laboratory setting. These readings were obtained using a DigiMano (Netech Corporation, New York, USA) pressure recorder (Figure 2) as previously described²⁰.

Briefly, the ILP was recorded after 50-ml aliquots of normal saline were used to insufflate the various



Figure 2 Intraluminal pressure recording apparatus. (A) The Bakri balloon is connected via a three-way tap to a pressure meter (DigiMano, Netech Corporation, Farmingdale, NY, USA). This enables the intraluminal pressures to be measured independent of insufflation of the balloon with normal saline. (B) and (C) By clasping the balloon the intraluminal pressure increases and is recorded by the pressure meter device. Bar = 4 cm. Reproduced from Figure 1 in reference 20, with permission

balloons. This was continued until a final volume of 500 ml was reached for all balloons. Each 50-ml aliquot series was repeated three times using a single balloon (Figure 3).

For the Bakri balloon, the readings demonstrate that, in the absence of any external restrictions, the ILP reaches a peak of approximately 85 mmHg at 50 ml insufflation. This pressure does not vary by more than 10–25 mmHg despite the balloon being incrementally filled to a volume of 500 ml. The pattern is similar for the BT-Cath and the condom catheter, with initial peak pressures of approximately 25–30 and 10 mmHg, respectively, at volumes of 100 ml normal saline. Pressures varied by 1–5 mmHg as these latter balloons were subsequently insufflated. In contrast, the ILPs were not recordable on the Digimano manometer device from the Ebb balloon even when insufflated to 500 ml.

In contrast to these experiments, external compressive forces, such as squeezing the balloons by hand, increase the ILP for all balloons (Figure 2)²⁰.

METHODOLOGY

Case selection

Seven cases of women who experienced a PPH and were unresponsive to first-line uterotonic agents were included in this study (Table 1). Prior to insertion of the balloon, retained products of conception and genital tract trauma were excluded as a primary cause of the PPH.

Tamponade test

In this case series, a tamponade test was performed once first-line uterotonics (Syntocinon[®], syntometriene, ergometrine, misoprostol and PGF2 α) had been used and bleeding continued. A positive tamponade test was demonstrated in all cases.



Figure 3 Intraluminal pressure readings (*in vitro*). Aliquots of 50 ml of normal saline were used to insufflate each of the uterine specific balloons and the condom catheter to a final volume of 500 ml. The corresponding intraluminal pressure was then recorded after each 50 ml aliquot. Only the uterine balloon component (Ut in Figure 1) of the Ebb balloon was insufflated with normal saline. *Pressure at initial 50 ml normal saline in the Bakri balloon. ** Pressure reading at 100 ml in the BT-Cath. ***Pressure reading at 100 ml in the Ebb balloon (uterine component). Note the differences in recorded intraluminal pressures despite similar volumes in each balloon from 50 to 500 ml saline

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5	39	Augmented labor	I	41 + 5	Em LSCS		Atonic	S10, S40,	From	Νo	450	Vaccum	GA	LW-PNW	19	50% (11 h)	2.5	Not sent
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9	16	Pre-eclampsia IOL	I	35 + 6	SVD		Atonic	S10, S40,	From	No	500	Vaccum	GA	LW-PNW	27	30% (11 h)	0	Not sent
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7	23	Twins	Ι	38 + 1	El LSCS		Atonic	S10, S40,	From	Νo	300	None	RA	LW-PNW	20	33% (8 h)	2.5	Not sent
						At LSCS	uterus	Ergo	vagina			required	(spinal)			67% (20 h)		

ELSCS, elective lower segment cesarean section; Em LSCS, emergency lower segment cesarean section; Ergo, ergometrine 250–500 µg; FTP, failure to progress; GA, general anesthetic; HDU, high dependency unit; IOL, induction of labor; LW-PNW, labor ward-postnatal ward; Misc, miscarriage; Miso, misoprostol (800 µg per rectum); PGF, prostaglandin PGF200; PP, placenta previa; Prev. PPH, previous PPH; SVD, spontaneous vaginal delivery; S10, 10 IU syntocinon (oxytocin); S40, 40 IU syntocinon (oxytocin infusion, over 4 h); TOP, termination of pregnancy; RA, regional anesthetic; *ultrasound scan (USS) used for teaching technique of balloon placement

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Balloon selection

At the time that these patients were cared for, the Bakri balloon was the only uterine-specific balloon available in Australia. As such, it was used in all cases.

Using the Bakri balloon

The method of insertion, maintenance and removal of the Bakri balloon is described in Chapter 48. Briefly, the balloon is inserted digitally or using a Rampley's forceps together with a speculum, and the balloon is initially insufflated with 200 ml normal saline. The drainage channel and the cervix are then assessed for ongoing blood loss. If bleeding continues, a further 50 ml of normal saline is added, and blood loss is reassessed. This is repeated until bleeding has ceased. This tamponade method determined the final volume of normal saline insufflated in to the balloon.

Discharge and follow-up

All women were discharged within 3–7 days of their PPH. A follow-up appointment with a pelvic ultrasound scan was arranged 6–8 weeks following discharge. All endometrial cavities of these scans were reported as normal.

RESULTS

Demographics and pregnancy details

Table 1 outlines the demographic and pregnancy details in this series of seven cases. Case 1 and 2 have been previously published and cases 1 and 3–5 have been previously included as part of a poster on Bakri balloon methodology^{20,21}.

The average age of the women in this study was 29 years (range 16–40), with an average gestation of 38 weeks + 3 days (range 35 weeks + 6 days to 41 weeks + 5 days). Four of the seven women were in their first pregnancy (cases 2 and 5–7). Risk factors as noted in the recent Royal College of Obstetricians and Gynaecologists guidelines were present in all cases²². These included previous PPH (case 3), labor augmentation (cases 1 and 5) and twins (case 7). Both elective (cases 1 and 5) and emergency (cases 2–4 and 6) were represented.

The cause of PPH in all instances was uterine atony in accordance with the inclusion criteria of this study. However, the atony may have been secondary to manual removal of retained products (case 4), or subsequent to delivering the placenta at cesarean section during an elective (case 7), or emergency (cases 1 and 5) procedure. The remaining cases occurred after vaginal delivery following the delivery of the placenta (cases 2, 3 and 6)

First-line uterotonics

First-line oxytocics comprising oxytocin 10 IU IM and an oxytocin infusion (40 IU over 4 hours) were administered to all women (Table 1). In addition, some cases received in addition: 800 μ g misoprostol per rectum (cases 2–4 and 6), 250 μ g ergometrine iv/im (cases 3–5 and 7) or prostaglandin PGF2 α intramyometrial (cases 1, 2 and 5).

Bakri insertion

All Bakri balloons were inserted transvaginally manner (see Chapter 48). At cesarean section, balloons were inserted following a two-layer closure of the lower uterine segment and only after observing ongoing vaginally bleeding from the cervix. An ultrasound scan was used during the insertion of the balloon in case 3 to aid in teaching of the technique of balloon insertion/insufflation.

Tamponade test final volume

The tamponade test was positive at volumes of 300–500 ml normal saline (average 387 ml). The tamponade 'method' was used to clinically assess the effectiveness of balloon filling (see Chapter 48). There were no assumptions made as to the capacity of the uterine cavity and, therefore, no prior estimation of volume required to reach a positive tamponade test.

Intraluminal pressure

The ILPs are shown in Table 2. ILPs that resulted in a positive tamponade test varied from 43 to 154 mmHg. When the ILPs were plotted against the volume of normal saline used to achieve a positive tamponade test, there was no direct correlation (Figures 4 and 5). However, in cases 2, 4 and 5, the final ILP resulting in a positive tamponade test was lower than the initial ILP produced by 50 ml normal saline. The remaining cases (cases 1, 3, 6 and 7) had a positive tamponade test at ILPs greater than the initial ILP produced at 50 ml normal saline.

Correlation to patient's systolic pressure

Whether an average systolic blood pressure or a range of such readings was used, in the majority of cases (cases 1–3 and 6–7) the final ILP was lower than the systolic blood pressure. The two exceptions were cases 4 and 5 (Table 2).

Following the immediate resuscitation and subsequent stabilization of the patient, the normal saline within the balloon was removed over the next 11–27 h (average 21.4 h). Antibiotics (metronidazole and cephazolin) and an ongoing oxytocin infusion were used for the duration of balloon placement.

Case	Final volume (ml) in balloon-positive tamponade test	Corresponding intraluminal pressure (mmHg)	Range of patient's blood pressure* (systolic/diastolic – mmHg)	Average blood pressure* (mmHg)	Average mean arterial pressure* (mmHg)
1	360	83	80-110/40-65	92/46	61
2	350	43	90-140/50-60	110/55	73
3	350	76	75-110/45-60	87/49	62
4	450	118	90-120/45-60	103/52	69
5	350	154	80-140/40-85	117/63	81
6	500	90	90-130/45-90	98/59	72
7	300	81	95-130/55-100	121/62	82

 Table 2
 Intraluminal pressures and corresponding blood pressure readings when a positive tamponade test was achieved in cases 1–7. *Data from intraoperative anesthetic charts



Volume in balloon (ml)

Figure 4 Intraluminal pressure readings (cases 1–7). In each case the pressure initially increases when 50 ml saline is insufflated into the Bakri balloon. These pressures vary as further saline is insufflated until a positive tamponade test is achieved. Note that similar volumes in each case result in variable corresponding intraluminal pressure readings



Figure 5 Correlation between final volume of saline required to achieve a positive tamponade test (using the tamponade 'method') and the corresponding intraluminal pressures (correlation coefficient = 0.18)

Final PPH volumes and placental pathology

The final volume of blood loss was estimated to be between 1 and 2.8 l. *The decision to use a balloon was not based on the estimated blood loss per se, but after recognition that the first-line uterotonics were ineffective.* Placental pathology was reported as normal for the retained placenta.

DISCUSSION

The management of PPH involves a stepwise series of physical, pharmacological and possibly surgical procedures to stop uterine bleeding²³. Once retained products and genital tract trauma have been excluded, ongoing bleeding is assumed to be from an atonic uterus. Previous literature commonly describes the uterus as 'hypotonic', implying some residual ability to contract²⁴. However, the commonly used term 'atonic' implies that the uterus is unable to initiate or maintain contractions in order to achieve hemostasis. This is paradoxical because, in the majority of cases of PPH secondary to uterine 'atony', uterotonic agents are clinically successful^{1,2}.

The primary goal of the interventions used in the management of PPH is to cause uterine contraction and a corresponding reduction in the volume of the uterine cavity. In contrast, uterine tamponade using balloon technology involves a fundamentally different approach, that is, temporarily expanding the uterine cavity⁸. A balloon made of rubber or silicone is introduced into the uterine cavity and incrementally inflated with normal saline, thereby increasing the uterine cavity volume. This tamponade test is considered 'positive' if the bleeding ceases¹⁹.

Currently, one proposed mechanism of action by which these intrauterine balloons act is by exerting an inward-to-outward pressure 'that is greater than the systemic arterial pressure'^{17,25}. An analogy to the 'first aid technique to stop a vessel from bleeding' has also been made. The technique works because the pressure on the blood vessel is greater than the pressure within the vessel²⁶. This case series investigates the hypothesis that the mechanism by which an intrauterine balloon exerts a tamponade effect on the uterus is via exceeding the patient's systolic blood pressure.

In non-uterine systems where bleeding is successfully counteracted by balloon tamponade, relatively low ILPs are required. For example, based on pressures required to collapse the coronary–esphageal circuit, 25–30 mmHg is required when using the Sengstaken–Blakemore tube in the esophagus²⁷. In the bladder, 75–80 mmHg, is required 'equal to the diastolic arterial pressure' to 'induce a reduction of blood circulation'^{28,29}.

Although the original description of the Bakri balloon stated it could 'withstand 300 mmHg', there do not appear to be any experimental recordings of intraluminal postpartum pressures required to stop uterine bleeding from an atonic uterus in the literature³⁰.

Pressure-volume relationships

The case series reported in this chapter demonstrates that, as the balloon is insufflated with normal saline in order to achieve a clinically effective positive tamponade test, the numerical relationship between this volume and the resulting ILP is curvilinear (Figure 4). Furthermore, uterine bleeding is controlled with ILPs that range from 43 mmHg (case 2) to 154 mmHg (case 5). The broad range of ILPs observed arise from similar volumes of normal saline in the Bakri balloon (Tables 1 and 2, Figures 4 and 5).

The intraluminal volumes used to obtain a positive tamponade test ranged from 300 to 500 ml (Tables 1 and 2). However, a larger volume did not necessarily produce a higher ILP (Figures 4 and 5). For example, a relatively small volume of 350 ml resulted in the highest pressures recorded (cases 2 and 5), whereas the greatest volume used (500 ml) resulted in a moderate ILP of 90 mmHg (case 6), similar to the lowest volume used (300 ml) in case 7 (81 mmHg). Furthermore, a twin pregnancy in which the resulting uterine cavity might be considered larger than a singleton cavity resulted in an ILP of 81 mmHg (case 7). This compares to the other singleton pregnancies that ranged from 43 to 154 mmHg.

As previously noted and as demonstrated in these cases, when the volume of fluid increases within the balloon, the ILP also gradually increases (Figure 4)²⁰. However, subsequent ILP readings rise and fall during the establishment of a positive tamponade test (Figure 3). In some cases the final ILP, when the tamponade test is positive, is lower than previously recorded readings when bleeding was ongoing (cases 1–5). In other cases, the final ILP when the tamponade test is positive, is eventually higher than the initial ILPs (cases 6 and 7).

Relationship to systolic blood pressure

Based on the proposed mechanism of exerting an inward-to-outward pressure that is greater than the 'systolic arterial pressure', one might have expected that the final ILPs would have exceeded those of the patient's systolic pressure¹⁷. However, in some cases the ILPs were actually lower (cases 2 and 7), similar (cases 1, 3 and 6) or higher (cases 4 and 5) than the range of systolic blood pressures. With respect to the diastolic blood pressure, the final ILP was greater than (cases 1 and 3–5), similar (cases 6 and 7), or less than (case 2) the range of these documented values, respectively (Table 2).

As the relationship in this case series between ILP, intraluminal volume, systolic/diastolic blood pressures and bleeding cessation is inconsistent and variable, alternative explanations are proposed. On the assumption that the resulting ILP represents a cumulative effect in achieving a positive tamponade test, the following contributing factors are considered: uterine wall structure/compliance, balloon–uterine interface, stretching of the uterine cavity and distal effects on the uterine arteries.

Uterine wall structure/compliance

In order to achieve a tamponade effect during the management of bleeding, a relatively non-compliant surface serves as a semi-rigid barrier preventing further expansion of an enlarging collection of blood. This phenomenon should be reflected in the ILPs as the balloon is being insufflated with normal saline and the bleeding ceases.

During a PPH, if the uterus is considered completely 'atonic', it may be considered unable to counteract an increase in the uterine cavity volume (UCV) as hemorrhage ensues within the cavity. Provided that the inherent structure of the uterine wall does not limit this expansion, thereby acting as the semi-rigid surface described above, the in vivo ILP would be expected to be similar to the in vitro experiments where there were no external restrictions to balloon expansion (Figure 3). In other words, the uterine structure would be relatively inert to the expanding uterine cavity volume. Conversely, if during a given PPH the uterus is again considered 'atonic', but now able to withstand a *defined* increase in uterine cavity volume, the ILP would be expected to initially plateau as the balloon volume approximated that of the uterine cavity (Figure 3). However, as the expanding balloon becomes subsequently restricted from the non-compliant uterus, the pressure would be expected to rise again in a linear fashion.

Both of these hypothetical models, however, involve an assumption of the compliance characteristics of the uterine wall, the point at which the tamponade test becomes positive must be taken into account. The volume–ILP profiles in Figure 4 suggest that the uterine cavity expands to a point at which bleeding ceases but that this is not associated with a secondary rise in ILPs.

In the 'physiological contracting-down' postpartum uterus, a currently accepted mechanism that stops bleeding involves the structural arrangement of the uterine muscle fibers in relation to the intervening blood vessels¹⁸. Helie described a figure of eight arrangement of muscle fibers around the vasculature. When the uterus contracts, the effect is referred to as 'living sutures'³¹. Images of the uterine wall thickness following balloon placement and insufflation with normal saline demonstrate a thinning of the uterine wall (Figure 6a and c). It could be hypothesized that one of the mechanisms by which the balloon functions is by compressing the intervening vascular supply within the uterine wall (Figure 6b and d).

Balloon-uterine interface

Studies using condom catheters also result in a positive tamponade test at similar volumes to other balloons^{13,14}. From the *in vitro* pressures described in this chapter, it can be seen that compared with those of the other uterine specific balloons, these pressures are relatively low: 12–15 mmHg (Figure 3). If, *in vivo*, such low pressures are sufficient to generate a positive tamponade test, it may be that it is not the magnitude



Figure 6 Ultrasound images of Bakri balloon within uterine cavity (A) and (B), and proposed mechanism of action involving myometrial compression (C) and (D). At commencement of insufflation with saline of Bakri balloon (BB), note the myometrial thickness (arrows in (A)). Compare the myometrial thickness (arrows in (B)) after a positive tamponade test. A schematic diagram of the hypothesized compressive effect of intrauterine balloons on the blood vessels (BV) within the myometrium (Myo). (C) represents 'before compression' corresponding to the ultrasound images (A) above. (D) represents 'after compression' corresponding to the ultrasound images in (B) above. Arrowheads in (B) represent a 50% reduction in wall thickness compared with arrowheads in (A). Adapted from Figure 5 in reference 20, with permission

of the pressure exerted which is important, but the effect of balloon contact at the uterine surface that elicits a clinical response.

A similar observation is made in the use of an 'OAT patch' when used to stop the bleeding from a vascular bed or a large vessel such as the aorta or inferior vena cava^{32,33}. Here the approximation of a piece of autologous tissue, such as a piece of rectus sheath prevents ongoing bleeding. Again, minimal external pressures are required to stop bleeding. The authors of this method propose mechanisms which include: (1) lamina flow within the damaged vessel creates suction on the overlying patch (Venturi effect); (2) resistance to flow between the large patch and the vessel wall beyond the defect may be sufficient impedance to stop flow completely; and (3) that the Patch provides a framework for the deposition of fibrin and plate-lets^{32,33}.

Finally, low intracavity pressures obtained in the Sengstaken–Blakemore tube and the Rusch balloons are also sufficient to control bleeding²⁷.

Stretching of uterine cavity

An undulating pattern of ILPs during the establishment of a positive tamponade test may be interpreted as the uterus exhibiting an inherent contractile ability (Figure 4). Thus, the rising and falling pressures may represent phases of uterine contractile activity and relaxation, respectively. Clearly the initial phases of uterine activity are insufficient to result in hemostasis, as the tamponade test is still negative at this initial time (Figure 4). However, as the uterus distends to accommodate the increasing intraluminal volume, hemostasis is achieved. In fact this undulating pattern is also seen after a positive tamponade test is achieved²⁰.

Therefore, regardless of the pressure exerted in the uterine cavity, a hemostatic effect may be facilitated by stimulating a contractile response of the uterine musculature secondary to stretching of the uterine musculature by insufflating the balloon with normal saline. It is noteworthy that, in addition to the known association of polyhydramnios and uterine activity, stretching of human myometrial cells *in vitro* results in an increase in the oxytocin receptor synthesis/mRNA³⁴. Therefore, the uterus itself should not be considered an inert component as the term 'atonic' implies.

Distal effects on the uterine arteries

One study has suggested that the tamponade effect acts distally by compressing the uterine arteries, 'a mechanism akin to mechanical uterine artery embolization or ligation'¹⁸. This is based on a single case of PPH managed with a Sengstaken–Blakemore tube that was insufflated with normal saline within the lower uterine segment following a vaginal delivery¹⁸. In addition studies demonstrate that an extensive collateral circulation may redirect blood from the uterine arteries resulting in a lowering of the internal iliac/uterine arterial pressures, thereby facilitating clotting and therefore hemostasis. Of note, however, are the descriptions of using balloon tamponade technology in patients who have impaired coagulopathies³⁵.

SUMMARY

These seven cases suggest that although insufflating an intrauterine balloon with normal saline within a postpartum uterus is correlated with a rise in ILP, this pressure does not need to exceed the patient's systolic blood pressure to result in a tamponade effect.

Furthermore, the uterus does not appear to be entirely 'atonic', and the tamponade effect of the resulting ILPs may represent a combination of factors elicited by the distended balloon. These may involve endometrial–balloon interface interactions, alterations of vascular flow patterns within the uterine arteries, uterine activity secondary to myometrial stretching, and an occlusive effect on compressed vascular structures secondary to uterine wall attenuation.

PRACTICE POINTS

- Intraluminal pressures vary with different volumes in different uteri
- Specific intraluminal pressures do not necessarily reflect the volume used and vice versa

- Other factors may contribute to the resulting 'tamponade' effect of the balloons including:
 - Balloon-endometrial interface
 - Alterations of the uterine muscular wall
 - Local effects on the uterine artery blood flow
 - Uterine activity following stretching of the uterine cavity.

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ETHICS APPROVAL

The intraluminal pressure measurements were obtained as the balloons were inflated and did not result in any delay in establishing the tamponade test. Ethics committee approval was granted from the University of Wollongong/South Eastern Sydney Ilawarra Area Health Service and Medical Human Research Ethics Committee (HE09/240 and HE09/241).

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