

Novel use of the Bakri® postpartum balloon in gestational trophoblastic neoplasia with bleeding vaginal metastatic lesions refractory to conventional treatment modalities

BG Goldman,  BS Makhathini,  C Ludwaba 

Department of Obstetrics and Gynaecology, Greys Hospital, South Africa
Corresponding author, email: goldmanbart@gmail.com

Introduction: Although gestational trophoblastic neoplasia (GTN) tumours are exquisitely chemosensitive with survival rates from 90% to 100%, bleeding vaginal metastatic lesions pose a clinical conundrum. Whilst these patients should be treated in specialised centres, they may present to non-specialised centres requiring emergency lifesaving treatment. We review the current management of haemorrhage from vaginal metastatic lesions and describe a novel, lifesaving technique that is readily available and easy to use in emergencies in most settings.

Methods: We discuss a 21-year-old patient referred with GTN stage III and score 14 with extensive vaginal metastasis. Sequentially she received antibiotics and tranexamic acid, percutaneous embolisation of the anterior branches of the internal iliac arteries and feeder vessels, and required haemostatic radiotherapy. Two attempts at removing her vaginal pack resulted in catastrophic bleeds and haemodynamic instability.

Results: On the third attempt, we inserted a Bakri® postpartum balloon into the vaginal canal, inflated it with 230 ml of sterile water, and strapped the balloon's catheter tubing to the patient's thigh to secure the balloon. Over the next 24 hours, after draining 150 ml, the haemorrhage seized. The controlled and slow reduction of the balloon in theatre resulted in the atraumatic removal of the balloon and no further significant haemorrhage. We suggest that using the Bakri® balloon as described is an effective and easy measure to tamponade vaginal GTN lesions. We propose that the manner in which the balloon applies the tamponade effect, by pressing against the tissue and not integrating with the tissue as a porous gauze would, ensures less tissue trauma upon removal. In addition to allowing accurate monitoring of any continuous haemorrhage, the balloon can be deflated incrementally and reinflated quickly should a haemorrhage ensue, whereas a gauze pack is removed in its entirety and replaced if bleeding is noted.

Conclusion: The use of the Bakri® postpartum balloon in bleeding vaginal GTN lesions should be considered as an emergency tamponade method in both specialised and non-specialised centres as a primary tamponading method.

Keywords: gestational trophoblastic neoplasia, vaginal metastatic lesions, Bakri® postpartum balloon, refractory haemorrhage

Introduction

Gestational trophoblastic disease is an umbrella term used to describe an abnormal pregnancy state ranging from premalignant lesions, partial hydatidiform mole (PHM) and complete hydatidiform mole (CHM), to malignant lesions such as invasive mole, choriocarcinoma, placental site trophoblastic tumours (PSTT), and epithelioid trophoblastic tumours (ETT).¹ Malignant lesions are grouped under the term gestational trophoblastic neoplasia (GTN). Disease severity is staged according to the International Federation of Gynecology and Obstetrics (FIGO) staging system that utilises the site of metastases and scored according to the World Health Organization's scoring system that incorporates eight prognostic variables.²

Excluding PSTT and ETT, these malignant tumours are exquisitely sensitive to chemotherapy with overall survival rates ranging from 90% in high-risk GTN to 100% in low-risk GTN.²

Given the excellent survival rates in adequately treated patients, even in advanced disease, it is of vital importance to prevent mortality from secondary consequences of the malignancy. Although it is advocated that these patients be treated in

specialised centres, they often present to non-specialised centres requiring emergency lifesaving measures.¹ A local review of patients referred to a tertiary hospital found that the mean age of presentation was 25.6 years old, and 61.9% of these patients were from rural areas with 60.3% of them presenting to district hospitals as a first point of contact.³

Case report

We present a 21-year-old woman, gravida 1 and parity 0, who had no medical comorbidities and was referred to us with a history of a blood-stained productive cough, fatigue, loss of weight, and a persistently positive beta-human chorionic gonadotropin (β -hCG). She had a suction curettage 18 months prior for a partial mole and defaulted the follow-up plan after two consecutive negative serum β -hCG measurements.

Upon referral, she was anaemic, tachypnoeic, and hyperthyroidic with a serum β -hCG of 793 675 mIU/ml. On examination, she had mild pallor and tachycardia. A 16-week size uterus with bilateral adnexal masses and metastatic vaginal lesion were noted on pelvic-abdominal and per speculum assessment, respectively. Ultrasound revealed a heterogeneous mass in the uterine cavity

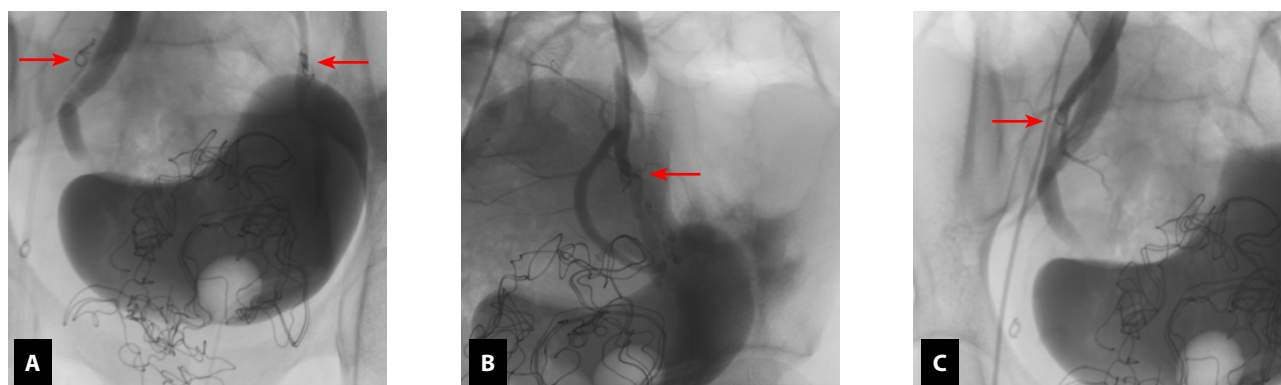


Figure 1: Image A (left), Image B (centre), and Image C (right); arrow indicates coil

Image A – Bilateral anterior branches of internal iliac arteries occluded with coils

Image B – Left anterior branch of internal iliac artery occluded with coil

Image C – Right anterior branch of internal iliac artery occluded with coil

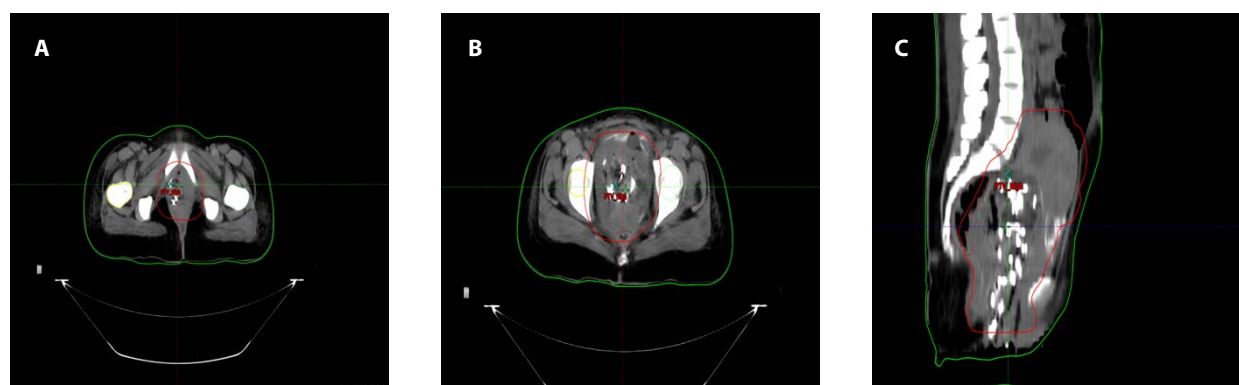


Figure 2: Image A (left), Image B (centre), and Image C (right)

Image A – Planning image of vaginal disease

Image B – Planning image of pelvic disease

Image C – Planning image of all disease, sagittal view

with bilateral theca lutein cysts and she had cannonball lesions on chest X-ray. Staging computer tomography (CT) excluded brain metastasis. We diagnosed her as ultra-high risk GTN stage III with a score of 14.

Whilst being worked up and clinically optimised, she experienced an unprovoked catastrophic bleed from metastatic vaginal lesions (estimated at 2 500 ml). Resuscitation protocols were activated and the vagina was packed with adrenaline and saline-soaked 9" gauze for local tamponade and vasoconstriction. This managed to stem the bleeding; however, she was slowly trickling past the packs. Her haemoglobin (Hb) and platelets (plt) had dropped to 5.8 g/dl and $47 \times 10^9/L$, respectively.

She was taken to the radiology department for transcatheter arterial embolisation (TAE). Multiple bleeding vessels with tumour stains were identified and systematic TAE was required from distal (inferior gluteal and uterine) to proximal (anterior branch of internal iliac) on the left and right (Figure 1). The immediate response was satisfactory. She stopped bleeding past the vaginal pack and we were able to continue fluid and blood product resuscitation.

After 48 hours, her coagulopathy was corrected, her Hb and plt count were 9.8 g/dl and $154 \times 10^9/L$, respectively, and she was deemed stable enough for pack removal. The removal of the vaginal packs resulted in an immediate large haemorrhage

of 1 500 ml. In response, a new 9" vaginal packing gauze was meticulously and gently inserted. Her blood parameters had again worsened to a Hb of 6.1 g/dl, fibrinogen of 2.2, and international normalised ratio (INR) of 1.47. Because she was still trickling past the pack, we administered a haemostatic radiation dose of 8 Gy to the pelvis and vaginal area (Figure 2).

Unfortunately, she experienced another large bleed (1 200 ml) when we removed that pack 48 hours later. We hypothesised that the trauma of removing the gauze from the friable lesions resulted in bleeding.

In an attempt to replicate the tamponade effect of the gauze, but alleviate the potential trauma upon removal, we decided to insert a Bakri® postpartum balloon into the vaginal cavity and inflated it with 230 ml of sterile water. At this point, we saw a clinical reduction in blood loss and felt resistance when trying to insufflate more fluid. We strapped the drainage segment of the balloon to the patient's thigh using the modified cow-hitch technique (Figure 3).⁴

After 48 hours, we were able to remove the Bakri® balloon without any more significant bleeding. We did this by slow and controlled deflation of the balloon (60 ml at a time) in the theatre. Subsequently, the patient was able to start her chemotherapy and had no more significant bleeding episodes.

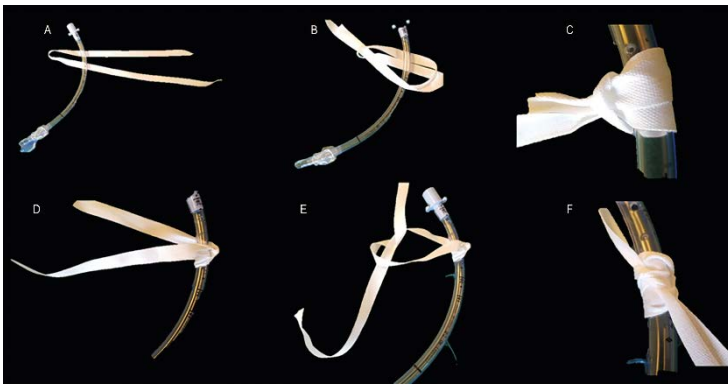


Figure 3: The modified cow-hitch technique of securing the drainage tube of the Bakri® balloon, the two loose ends after completing A–F are loosely tied around the thigh of the patient

With permission from Walters et al.⁴

She had a complete response to chemotherapy and is currently in her 12-month post-treatment surveillance phase.

Discussion

The incidence of GTN is difficult to determine without a national registry and dedicated GTN centres; however, one referral centre in South Africa estimates this to be 0.5 : 1 000 deliveries.⁵

The incidence of metastatic GTN following CHM is estimated to be 2–4%, whilst GTN after PHM is usually non-metastatic. Vaginal metastasis accounts for 30% of cases, whilst the lungs, liver, and central nervous system account for 80%, 10%, and 10%, respectively.^{6,7} Even though cases of metastatic vaginal lesions as the presenting symptom have been described, this remains a rare presentation.⁸

Table 1: Strategies to obtain haemostasis in haemorrhage associated with gynaecological malignancy

Conservative measures	<ul style="list-style-type: none"> Medical therapies, such as tranexamic acid Correcting and preventing coagulopathy by sustaining normal calcium, Ph, and temperature and using point-of-care viscoelastic tests to guide transfusion requirements Tamponading the bleeding site (i.e. the vagina) by using surgical gauze, gynaecological tampons, or a haemostatic balloon
Fertility-preserving surgical options	<ul style="list-style-type: none"> Resection of tumour Ligation of ovarian, uterine, or internal iliac arteries Local haemostatic suturing
Non-fertility preserving surgical options	<ul style="list-style-type: none"> Removal of the reproductive organs
TAE	<ul style="list-style-type: none"> Occlusion of the ovarian, uterine, or internal iliac arteries
Haemostatic radiotherapy	<ul style="list-style-type: none"> Traditionally 8 Gy of external beam radiotherapy to the pelvis

When considering vaginal lesions of GTN, the feasible options to consider are conservative compression and medical techniques, surgical plication or tissue suturing, TAE, and haemostatic radiotherapy (Table 1).

Surgical packing to cause a tamponade effect is a well-known surgical intervention that can be immediately lifesaving. Achieving local pressure above that of the systemic vascular pressure allows for the cessation of haemorrhage and local clot formation.⁹ It can serve as a valuable temporising measure whilst factors contributing to bleeding are corrected and allows time for effective resuscitation.

The traditional use of sterile gauze as vaginal packing material may be associated with infection risk, difficulty in achieving a uniform tamponade effect, concealed bleeding, and trauma.¹⁰ Trauma to these friable lesions can occur at insertion and removal of the gauze as the uneven surface of the gauze can abrade the lesions and wipe away the haemostatic clot formed by the tissue.

The Bakri® balloon offers several advantages when compared to gauze packing. We postulate that it applies more uniform pressure to achieve an evenly distributed tamponade effect on the vaginal tissue and that local trauma, as described above, is minimised by the smooth surface of the silicon balloon as it applies pressure without sticking to the vaginal lesions and is only insufflated once inside the vagina. Continuous monitoring and quantification of any ongoing bleeding with the balloon in situ is another advantage as it has a catheter drainage channel. Furthermore, its removal is less traumatic and more controlled, with the possibility of quick re-insufflation should it be necessary.

The asymmetrical shape of the Bakri® balloon, with the larger diameter at the tip, has been said to aid in the retention of the balloon within the vagina.¹⁰ However, it is important to remember that the balloon is designed for intrauterine use, where the lower uterine segment and cervix assist in retaining the balloon in the uterine cavity. For this reason, we recommend that the balloon's catheter channel is stabilised in the vaginal introitus by securing the catheter channel to the thigh, using either a catheter securement device (cost permitting) or the modified cow-hitch technique of securing an endotracheal tube. These recommendations are based on the fear of inadvertent balloon expulsion, which could result in the resumption of catastrophic haemorrhage at a time when the patient is not yet optimised or the ideal setting and staff are not in place.

Conclusion

The Bakri® postpartum balloon adds a valuable tool to the arsenal against bleeding metastatic vaginal GTN lesions. It offers several advantages over traditional surgical gauze: it is readily available in most settings, it is easy to use and familiar to doctors, and it applies a uniform tamponade effect with minimal trauma to the fragile GTN lesions upon insertion or removal. The tamponade effect that the balloon offers allows for patients to be stabilised and resuscitated whilst definitive treatment is undertaken, or the patient is transferred to a specialised centre. This is a lifesaving tool to be considered when managing patients with this very curable condition who otherwise may suffer great morbidity, or even mortality, due to haemorrhage. Methods of securing the device must be ensured to prevent accidental “slip out” and

subsequent haemorrhage. Scheduled monitoring of catheter output and balloon placement is crucial.

Conflict of interest

The authors declare no conflict of interest.

Funding source

No funding source to be declared.

Ethical approval

The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.

ORCID

BG Goldman  <https://orcid.org/0000-0002-9547-8263>

BS Makhathini  <https://orcid.org/0000-0002-8739-4481>

C Ludwaba  <https://orcid.org/0000-0001-6730-0495>

References

1. Tidy J, Seckl M, Hancock BW. Management of gestational trophoblastic disease. *BJOG*. 2020;128(3):e1-27. <https://doi.org/10.1111/1471-0528.16266>.
2. Ngan HYS, Seckl MJ, Berkowitz RS, et al. Diagnosis and management of gestational trophoblastic disease: 2021 update. *Int J Gynaecol Obstet*. 2021;155(S1):86-93. <https://doi.org/10.1002/ijgo.13877>.
3. Makhathini BS, Dreyer G, Buchmann EJ. Gestational trophoblastic disease managed at Grey's Tertiary Hospital: a five-year descriptive study. *South Afr J Gynaecol Oncol*. 2019;11(2):15-9. <https://doi.org/10.1080/20742835.2019.1667627>.
4. Walters HR, Young HE, Young PJ. A modified tie technique for securing endotracheal tubes. *Respir Care*. 2018;63(4):424-9. <https://doi.org/10.4187/respcare.05655>.
5. Moodley M, Tunkyi K, Moodley J. Gestational Trophoblastic Syndrome: An audit of 112 patients. A South African experience. *International Journal of Gynecological Cancer*. 2003;13(2):234-239.
6. Berkowitz RS, Goldstein DP. Current management of gestational trophoblastic diseases. *Gynecol Oncol*. 2009;112(3):654-62. <https://doi.org/10.1016/j.ygyno.2008.09.005>.
7. Lurain JR. Gestational trophoblastic disease I: epidemiology, pathology, clinical presentation and diagnosis of gestational trophoblastic disease, and management of hydatidiform mole. *Am J Obstet Gynecol*. 2010;203(6):531-9. <https://doi.org/10.1016/j.ajog.2010.06.073>.
8. Mamede R, Beja M, Djokovic D, Costa C. Invasive mole presenting as a heavily bleeding vaginal lesion 3 weeks after uterine evacuation. *BMJ Case Rep*. 2021;14(6):e242208. <https://doi.org/10.1136/bcr-2021-242208>.
9. Ferrazzani S, Guariglia L, Dell'Aquila C. The balloon internal uterine tamponade as a diagnostic test. In: Arulkumaran S, Karoshi M, Keith LG, Lalonde AB, B-Lynch C, editors. *A comprehensive textbook of postpartum haemorrhage*. 2nd ed. London: Sapiens Publishing; 2012.
10. Yoong W, Sivashanmugarajan V, McMonagle M, et al. Pelvic and vaginal packing for intractable venous obstetric haemorrhage: practical tips for the obstetrician. *Obstet Gynaecol*. 2014;16(4):276-80. <https://doi.org/10.1111/tog.12129>.