Journal of Trauma and Acute Care Surgery, Publish Ahead of Print
DOI: 10.1097/TA.0000000000003612

A Team Approach to Peripartum Hemorrhage Control Incorporating Resuscitative Endovascular Balloon Occlusion of the Aorta

Rachel M. Russo, MD, MS[1,2], Alissa Carver, MD[3], Caitlin Clifford, MD[3], Aimee Rolston, MD[3], Shitanshu Uppal, MD[3], Lena M. Napolitano, MD[4]

[1]United States Air Force, 60th Medical Group, Travis AFB, CA

[2]Department of Surgery, University of California Davis, Sacramento, CA

[3]Department of Obstetrics and Gynecology, University of Michigan, Ann Arbor, MI

[4]Department of Surgery, University of Michigan, Ann Arbor, MI

Corresponding author:

Rachel M. Russo, MD, MS

University of California Davis Medical Center

Department of Surgery

Division of Trauma, Acute Care Surgery, and Surgical Critical Care

2335 Stockton Blvd, North Addition 5th Floor

Sacramento, CA 95817,

Phone: (850) 341-2724, Fax: (916) 734-5633

RachelMRusso@gmail.com

The authors have no conflicts of interest to declare.

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This information has not been presented elsewhere.

Disclosure of Funding: This work was not funded.

Disclaimer: The views expressed in this material are those of the authors, and do not reflect the official policy or position of the U.S. Government, the Department of Defense, or the Department of the Air Force.

Author contribution statement: All authors participated in the development and implementation of the protocol described in this manuscript and had an opportunity to provide key edits of the final draft. RMR, AC, and LN authored the manuscript and developed the figures/tables.

Media Summary: Development of a protocolized, multidisciplinary approach to the control of obstetric hemorrhage can facilitate expedient hemostasis in emergencies. We detail our protocol and the technique of using REBOA in high-risk obstetric surgeries.

Hashtags: #TraumaSurgery, #REBOA, #UMPAS, #UMOBGYN

Author email addresses:

Russo: RachelMRusso@gmail.com

Carver: arcarver@med.umich.edu

Clifford: cmcliff@med.umich.edu

Rolston: aimeerol@med.umich.edu

Uppal: uppal@med.umich.edu

Napolitano: lenan@med.umich.edu

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Introduction

Hemorrhage is a leading cause of preventable maternal death. Multidisciplinary approaches to bleeding parturients' care, particularly those with abnormal placentation, has improved patient outcomes.[1] Trauma Surgeons can support obstetric providers with expertise in management of hemorrhagic shock, resuscitation, and definitive hemostasis. This aligns with increasing reports citing the benefits of resuscitative balloon occlusion of the aorta (REBOA™) for obstetric patients with non-compressible hemorrhage.[2-6] Our hospital is a regionalized center for the care of women at high-risk of peripartum hemorrhage including those with placenta accreta spectrum. As such, a multidisciplinary team was convened to develop a strategy for high-risk obstetric surgeries in accordance with the American College of Obstetricians and Gynecologists-Society for Maternal Fetal Medicine Obstetric Care Consensus for Placenta Accreta Spectrum (PAS).[7] In this manuscript we will outline the development of our maternal hemorrhage control program including risk stratification, operative planning, and implementation of a REBOA protocol.

Stratifying the risk of major hemorrhage

Major obstetric hemorrhage can present emergently from several potential causes (ectopic pregnancy, uterine rupture, uterine atony, complicated dilation and curettage/evacuation, and placenta accreta spectrum (PAS)). The highest risk of hemorrhage for women with PAS occurs at the time of delivery, when as many as 90% of these patients require blood transfusion.[8] A stepwise, protocolized approach to the care of these patients can facilitate expedited hemorrhage control and appropriate resuscitation.

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Treatment of PAS in the United States primarily involves a Cesarean hysterectomy (C-hyst) in the late preterm period. Though we follow national guidelines[7] in planning scheduled C-hyst at 34-36 weeks, some of these patients develop preterm labor or spontaneous hemorrhage prior to their scheduled operation.

Upon diagnosis of PAS, we stratify cases based on complexity predicted at the time of surgery (Table 1). Maternal-fetal medicine specialists review patient history and imaging to classify patients pre-operatively, and the management plan for each patient is then discussed with the multidisciplinary team to coordinate the surgical approach and schedule delivery. An additional "time-out" is performed after each delivery amongst operating room team members to assess patient stability and other strategies for hemostasis.

Early prophylactic REBOA in patients with PAS has been shown to be a safe and effective strategy to control major bleeding and results in improved outcomes when compared to traditional C-hyst.[3] Though it has not been our practice to pre-operatively obtain internal iliac artery occlusion at our institution, temporary abdominal aortic occlusion has been associated with less blood loss and improved clinical outcomes in direct head-to-head comparison.[9] Our experience echoes these studies.

Setting up the room

These cases involve a large number of operating room personnel and equipment. A spacious operating room and thoughtful layout plan can aid workflow and reduce chaos when emergencies occur. (Fig. 1)

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Patient positioning.

The patient should be positioned in low lithotomy, minimizing the angle between the femurs and the floor (Fig. 2). This will facilitate access to the common femoral arteries, vagina, and bladder. Draping may require alterations in the surgical drapes. We have found that Cesarean drapes can be modified to allow access to both groins, the vagina, and the abdomen. After preparing the skin, placing the under-buttock drape, and draping the legs, we drape the abdomen and groins with sterile towels and a Cesarean drape. Through an opening cut into this drape and taking care to avoid incising the blood collection pocket, common femoral access is then obtained under ultrasound guidance using the Seldinger technique. The sheath is secured in place and covered with a sterile towel or gauze and then secured with an iodine-impregnated drape, allowing the Cesarean drape to settle over the groin dressing. A retractor system can then be set up.

When applying a ring retractor system, be mindful of the position of the ring over the groin sheath and any instrument sleeves secured near the patient's hips or thighs. Ample vertical clearance should be maintained to allow rapid exchange of the arterial sheath and insertion of the REBOA if necessary. The ergonomic challenges of exchanging a sheath in this position beneath a gravid abdomen may increase the risk of dislodging the wire and losing arterial access in an emergency. For this reason, when we expect the potential for large volume hemorrhage to be high, we favor starting the case with the 7F sheath.

Arterial Monitoring

The side port of the sheath is connected to sterile arterial line tubing that is passed toward the head of the bed within the sterile field. This tubing is secured against the patient's side in a

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pocket made from a stapled fold in the drape. The anesthesiologist can attach non-sterile extension tubing outside the sterile field. This technique allows invasive blood pressure monitoring when the REBOA is not inflated, permits arterial monitoring distal to the balloon when partial REBOA is performed, and facilitates continuous flushing of the sheath to prevent thrombosis. A second radial arterial line is set up for continuous blood pressure monitoring proximal to the REBOA during occlusion.

REBOA Positioning

We typically aim for infrarenal aortic occlusion (Zone 3) to halt blood flow through the hypogastric, ovarian, and uterine arteries (Fig. 3). Occlusion in proximal Zone 3 is desirable to ensure occlusion of the ovarian arteries, which provide significant collateral blood flow to the gravid uterus and placenta. Anatomical landmarks are variably exaggerated by pregnancy, such that measuring surface landmarks can overestimate the insertion length needed to achieve Zone 3 occlusion. When approximating the level of occlusion using distance markers, catheter insertion to 28cm is sufficient to achieve Zone 3 occlusion. The data supporting this measurement is derived from a population of both men and women, such that 28cm may be more proximal than Zone 3 in smaller women but safely avoids inflating the balloon within the iliac arteries. The average length of the infrarenal aorta in women is 8.45cm ± 1.20 cm which affords some error in measurements with little consequence (unpublished data). In any case, temporary occlusion of Zone 2 is preferable to inflation within the iliac artery, both because of insufficient hemostasis and because of the higher risk of iliac rupture from balloon over inflation. In the event that the ovarian arteries are known to have a high origin, more proximal occlusion is possible.

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While balloon occlusion of Zone 2 is typically avoided in blunt trauma when occlusion in this zone may augment collateral flow leading to increased bleeding, or in vascular surgery when atherosclerotic plaques may rupture and embolize to abdominal organs, obstetric patients do not typically have either of these risk factors. Nonetheless, the risks of acute kidney injury and increased abdominal ischemia must be considered when more proximal occlusion is employed. Desired balloon position is confirmed by palpation through the open abdomen.

Duration of occlusion

The balloon is managed throughout the case by the Trauma Surgery team in accordance with the procedure outlined by Manzano-Nunez et. al.[3] We begin inflation at a time that is mutually agreed upon by the surgeon who is performing the C-hyst and the Trauma attending managing REBOA. Inflation may begin just after delivery of the infant when the risk of hemorrhage is high, upon vascular pedicle ligation, or may be delayed until hemorrhage is encountered depending on the clinical features of the case. Although there has been as many as 150 published cases of REBOA inflation prior to delivery with reportedly good fetal outcomes in Asia,[10] our practice emphasizes avoiding pre-delivery aortic occlusion when the fetus is viable.

The maximum duration of Zone 3 occlusion for obstetric hemorrhage is not known. While we anticipate that the absence of pre-inflation hemorrhagic shock and a level of occlusion distal to vital intraabdominal organs may afford a longer safe duration of occlusion than is the standard limit for Zone 1 occlusion in trauma, we nonetheless strive for a total occlusion time of less than 30 minutes. If a longer duration of occlusion is required, we employ intermittent or partial REBOA when able.

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Troubleshooting

Sheath Resistance

When inserting the catheter, the peel-away sheath facilitates the initial introduction of the balloon into the 7F vascular introducer sheath (Fig. 4). Advancing the orange peel-away sheath over the balloon can be facilitated by applying negative pressure to the balloon with a 10mL syringe while twisting the sheath forward. Dipping the balloon in water may also help reduce friction. The updated manufacturer's recommendation is to avoid testing the balloon prior to insertion to maintain its original compact conformation. The updated version of the ER-REBOA catheter, the ER-REBOA Plus is packaged with the orange peel-away sheath already in place. This version is replacing the original ER-REBOA catheters.

The peel-away sheath can be peeled back partially to expose the catheter, maintaining the distal portion of the peel-away sheath intact over the balloon. This maneuver will allow the inserter to grasp the catheter closer to the introducer, reducing the risk of kinking the catheter and decreasing resistance to balloon entry. Once the balloon is completely inside the introducer, the peel-away sheath can be retracted. Retracting the peel-away sheath will stop the back flow of blood out of the vascular introducer and will maintain the distal portion of the sheath intact, in case removal and reintroduction of the REBOA is required.

Catheter occlusion

Commonly, the arterial line port of the REBOA catheter is connected to a pressurized bag of saline throughout the procedure. Attention must be paid to the pressure indicator to ensure that the pressure in the bag is maintained at a higher level than the systolic blood pressure during

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complete occlusion. If at any point systolic blood pressure exceeds the pressure of the saline, blood will back up into the arterial line port of the catheter. The backflow of blood is not visible but could nonetheless lead to a loss of arterial waveform and monitoring capabilities. Flushing the line does not always restore flow once clot has formed. The same is true of distal pressure monitoring from the side port of the vascular introducer sheath. To reduce this risk, some users advocate using a dilute solution of heparinized saline when flushing the catheter. We have found that frequent flushing and careful attention to the pressure bag indicator is sufficient to maintain patency. We typically designate a dedicated member of the Trauma Surgery team to facilitate diligent sheath management throughout the case and thereafter until the sheath has been removed (Table 2).

Sheath removal

We follow a standard sheath removal protocol outlined in Table 2. Typically, sheath removal can be accomplished in the operating room prior to emergence from anesthesia. We have found digital pressure sufficient to provide arterial hemostasis after 7F sheath removal in patients with a normal coagulation profile. Vascular surgery assistance is available if needed should there be a change in distal pulse exam, complication from vascular access, or persistent bleeding after sheath removal. Duplex ultrasonography and/or arteriography is used liberally if there is any uncertainty about a vascular complication.

Conclusion

A multidisciplinary approach to obstetric patients at a high-risk of bleeding can improve the coordination of care in planned and emergency cases.

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Figure 1: Example operating room layout, notes, and supply list for planning an obstetric surgery with a high risk of massive hemorrhage. Designating a large operating room, developing a protocolized approach, and involving all necessary personnel in preoperative planning for high-risk elective surgeries can assist with expedient hemorrhage control in emergent cases.

Figure 2: Tips for positioning a parturient to provide optimal access to the common femoral arteries, abdomen, and vagina for a Cesarean hysterectomy with possible need for resuscitative endovascular balloon occlusion of the aorta. A) view from caudad to cephalad, B) view from patient right to left, C) view from patient left to right.

Figure 3: Uterine vascular anatomy depicting endovascular balloon occlusion in the infrarenal (zone 3) aorta proximal to the ovarian arteries. The catheter has been truncated at the aortic bifurcation to indicate possible placement via either the left or right common femoral artery. Black bars denote locations of surgical ligation for a total abdominal hysterectomy. The uterus is depicted in a non-gravid state to facilitate visualization of the vascular anatomy. In the parturient the gravid uterus may obscure visualization and access to the vascular supply, which also experiences a dramatic increase in blood flow during pregnancy with an associated increase in vessel diameter. Modified from: Macdonald JA, Corrado PA, Nguyen SM, Johnson KM, Francois CJ, Magness RR, Shah DM, Golos TG, Wieben O. Uteroplacental and fetal 4D flow MRI in the pregnant rhesus macaque. Journal of Magnetic Resonance Imaging. 2019 Feb;49(2):534-45.

Figure 4: Tips for inserting the ER-REBOA catheter into the introducer sheath. A) an ER-REBOA catheter as packaged, with the orange peel-away sheath positioned over the catheter. B) Advance the peel-away sheath over the lubricated balloon by rotating the sheath and drawing negative pressure on the balloon with a syringe. C) Peel the sheath away slightly to allow a more proximal grip on the catheter. D) Sliding back the sheath over the catheter when the balloon has entered the introducer will allow reinsertion if required.

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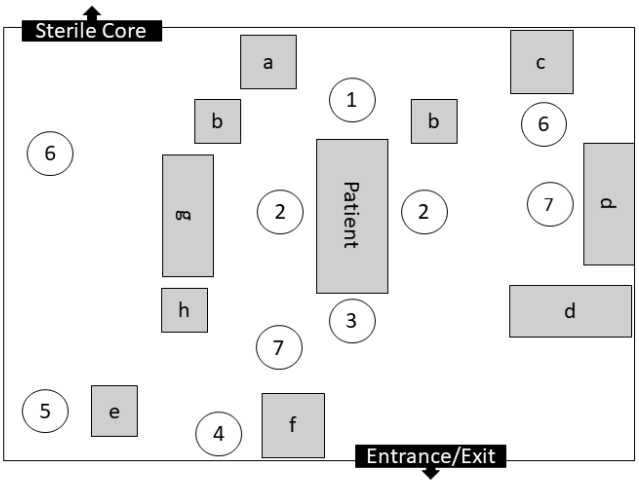
Figure 1



PERSONNEL
1: Anesthesiologist; 2: OBGYN/GYO surgeons; 3: Trauma Surgeon
4: Neonatologist; 5: Circulating Nurse(s); 6: Perfusionist; 7: Scrub Nurse(s)
EQUIPMENT
a: Anesthesia machine; b: Vitals sign monitors; c: Cell Saver; d: Instrument tables; e: Computer; f: Incubator; g: Suction/electrosurgical outlets; h: Ultrasound

(1) Anesthesia Notes:
- Two arterial line set-ups (proximal and distal BP)
- Two vital sign monitors (one toward anesthesia team, one towards surgical team)

(5) Circulator Notes:
- Always have a second REBOA available
- Obtain US with vascular probe

(7) Scrub Notes:
- Two scrub tables
- Two scrub techs, one with vascular skills
- Extra sheath and wires
- Heparinized saline, contrast available
- Place US gel inside probe cover
- Pass needle driver, suture scissors onto field
- *Don't test balloon*

Supplies:
Central Venous Catheter Tray
Sterile Basin
US Probe Cover Kit w/ Sterile Gel
12in Monitoring Extension Set
72in Arterial Pressure Tubing
10ml Syringe x 2
2-0 Nylon suture
2x2 gauze
4x4 sterile translucent adhesive
Bag Decanter
Disposable #11 Blade
Table Cover
ER-REBOA catheter
REBOA convenience kit

Medications:
Heparinized Saline 1000 units in 250cc bag of saline (on sterile field)
Oxytocin
Methylergonovine
Carboprost
Tranexamic Acid
Misoprostol
Phenylephrine
Short-acting antihypertensive of choice
(optional) 50:50 saline: iodinated contrast solution

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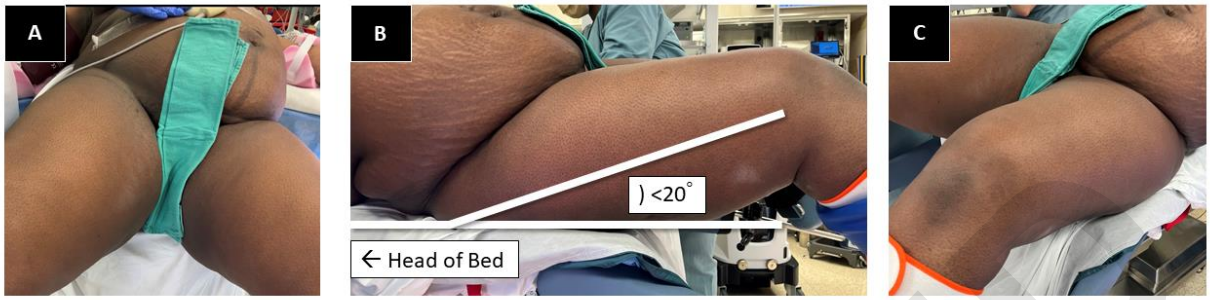
Figure 2



Left lateral decubitus, groin exposure | Minimize Angle of Hip Flexion for Groin Exposure* | Avoid hip over-rotation

Adjusted Low-Lithotomy Positioning

A: Maintain left lateral decubitus position to relieve caval compression until delivered

B: Minimize angle of hip flexion with low lithotomy

- -Ensure buttocks/sacrum positioned just above lower table break with table padding to avoid slipping
- -Angle of femur and OR bed no more than 20 degrees, taking care to avoid hip extension
- -Gentle knee flexion and minimal external rotation at hips
- -Ensure padding from knee down to avoid nerve compression, pressure points

C: Leave groin exposed, surgical prep should include bilateral groin and legs to mid-thigh

* When indicated due to maternal habitus, additional hands may be helpful for gentle retraction of the pannus to expose the common femoral artery

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Figure 3

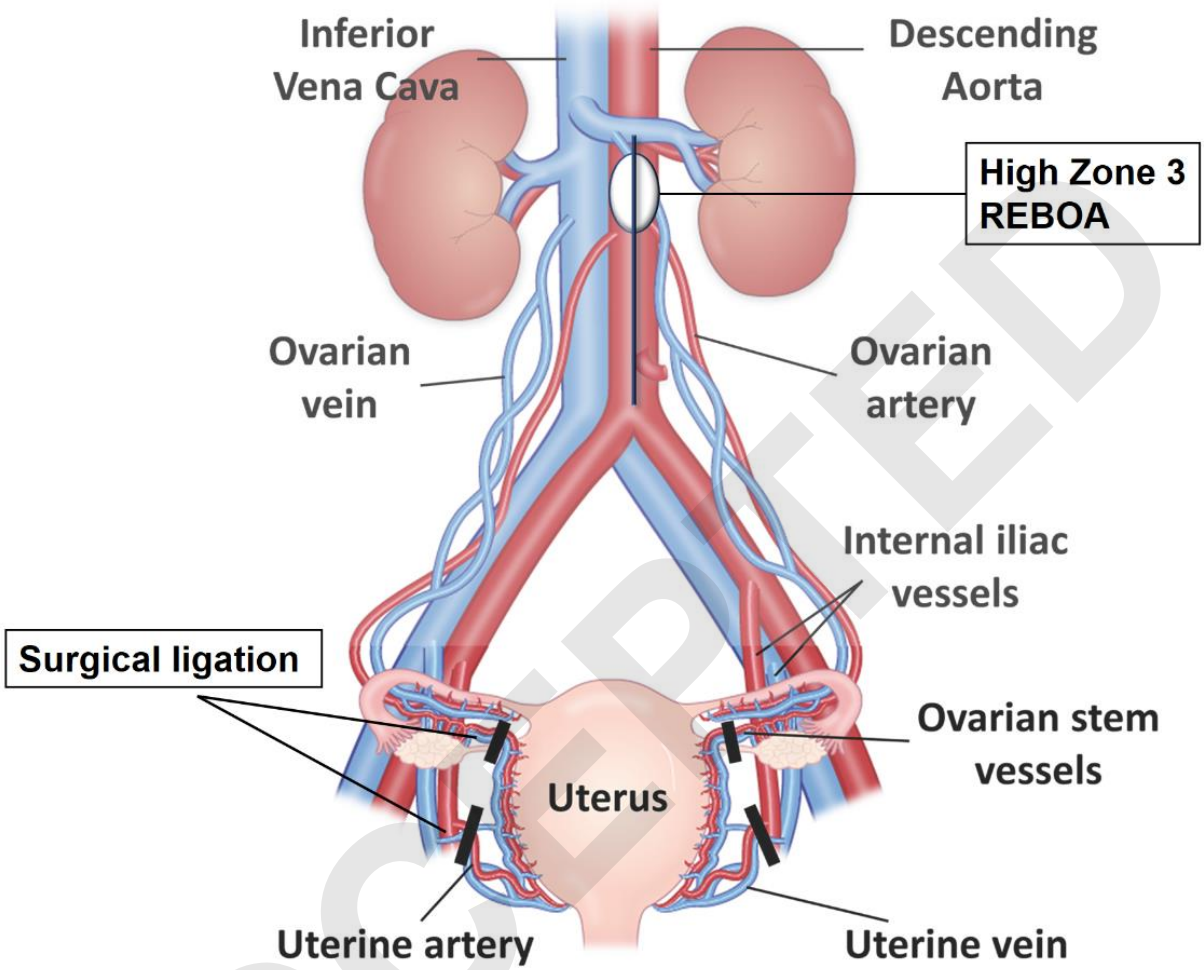

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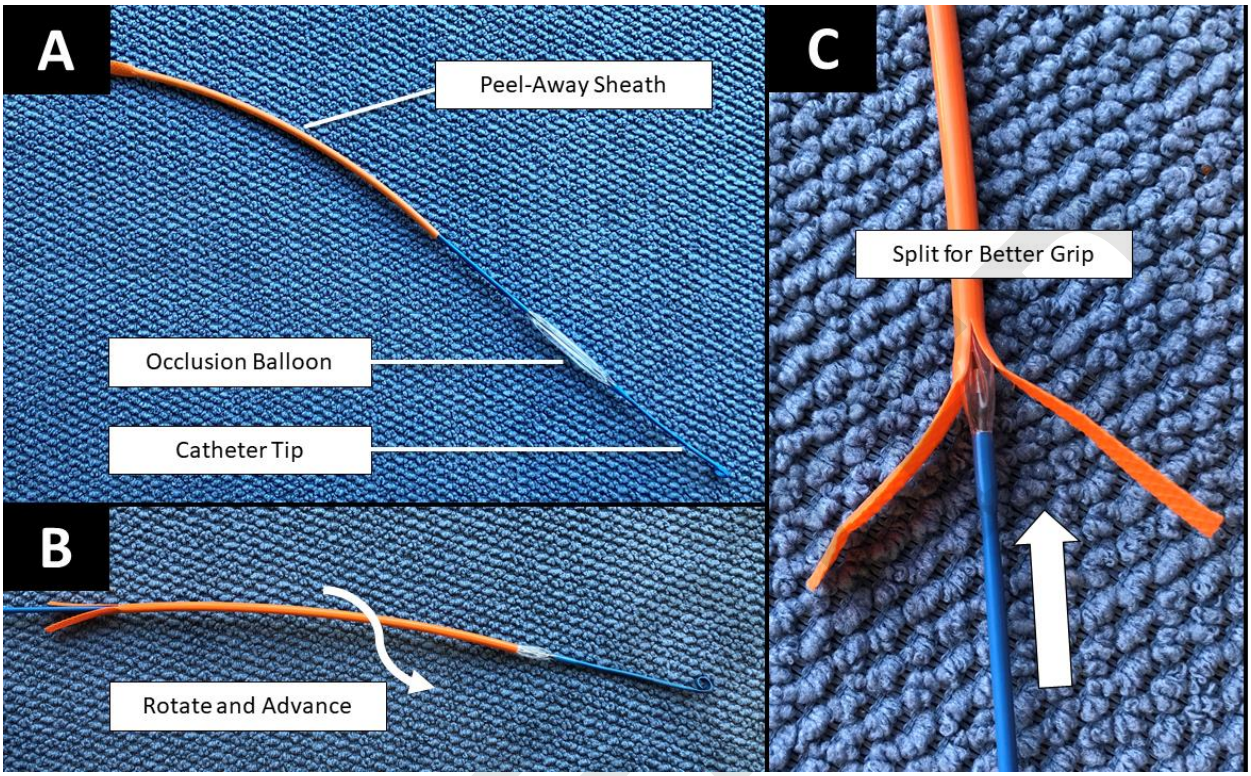
Figure 4



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Risk Class	Characteristics	*Example*/Notes	Management Strategy
I	Placenta previa with additional PAS risk factors* but no sonographic markers of invasion	*Planned cesarean section with low likelihood of postpartum hysterectomy* Contact Acute Care Surgery if needed	• Managed by Maternal-Fetal Medicine surgeons • 4 units of blood available in the operating room • Contact info of adjunctive services on hand • REBOA cart available • Patients are positioned in low lithotomy with groins prepped to allow for femoral arterial access if needed
II	PAS risk factors and sonographic evidence for PAS	*Previous uterine scar and placenta previa, evidence of PAS on imaging*	• Maternal-Fetal Medicine, Gynecologic Oncology, and Acute Care Surgeons in the room from induction, through delivery and inspection • Massive transfusion blood packs, rapid intravenous infusers, cell salvage equipment, and perfusionist available • Femoral artery access is obtained prior to incision • REBOA kit ready in case of unplanned hemorrhage • Following delivery, the uterus and placenta are inspected and the need for REBOA is assessed
A	low suspicion for bladder, cardinal ligament, or parametrial invasion	Acute Care Surgery on standby	
B	indeterminate suspicion for bladder, cardinal ligament, or parametrial invasion	Acute Care Surgery scrubbed, 5F femoral access	
C	high suspicion for bladder, cardinal ligament, or parametrial invasion	Acute Care Surgery scrubbed, possible primary 7F femoral access	

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III	Obstetric hemorrhage or trauma resulting in potential maternal or fetal instability in a patient >22 weeks' gestation (or visibly gravid if gestational age is uncertain)		• All above mentioned personnel and supplies are in the room and ready for use • Common femoral arterial access is obtained with a 5F or 7F sheath based on hemodynamic stability • REBOA or aortic cross-clamping, whichever is most rapid given the context of the case, is performed.
A	hemodynamically stable, blood loss <1500ml	*Anticipated cesarean hysterectomy presenting prior to scheduled date of surgery with uterine activity, small volume bleeding, or ruptured membranes*	
B	hemodynamically unstable, blood loss >1500ml, or receiving transfusion	*Retained placenta or refractory postpartum atony and hemorrhage or suspected PAS with antepartum hemorrhage*	

PAS, Placenta Accreta Spectrum. REBOA, Resuscitative Endovascular Balloon Occlusion of the Aorta

*Previous cesarean section, surgical pregnancy termination, dilation and curettage, myomectomy, endometrial resection, Asherman Syndrome, in vitro fertilization, uterine artery embolization, chemo/radiation, endometritis, intrauterine device, manual placental removal, prior accreta, bicornuate uterus, adenomyosis, submucosal fibroids, or myotonic dystrophy

Source: Jauniaux e, et al Int J Gynecol Obstet 2018;140:265-273

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Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as Adjunct for Obstetric Hemorrhage

REBOA is used for temporary aortic occlusion in hemorrhagic shock due to bleeding from below the diaphragm. REBOA supports proximal aortic pressure and minimizes hemorrhage until definitive hemostasis is obtained.

REBOA Steps in Obstetrical Patients:

1. **Patient Preparation**
    a. Low lithotomy, femurs flat and parallel to floor
    b. Cesarean drapes modified to expose groins
2. **Arterial Access and Sheath Placement**
    a. Ultrasound-guided common femoral arterial access with Micropuncture kit (21-gauge needle, 4 or 5 French catheter and dilator, 0.018 inch guidewire)
    b. Upsize to 7-French Sheath
3. **Balloon Selection and Positioning**
    a. ER-REBOA catheter (32mm max balloon diameter)
    b. Flush ER-REBOA catheter with saline; connect arterial line to transduce while inserting
    c. Measure sheath to P-tip distance in cm REBOA: Zone 1 ~46 cm; **Zone 3 ~28cm**
    d. Insert ER-REBOA to pre-measured distance
4. **Balloon Inflation**
    a. 10cc syringe; NS
    b. Inflate balloon, tactile feedback/change in proximal SBP/loss of distal arterial waveform; Zone 1 8cc; **Zone 3 2cc** "2 or 8, don't overinflate"
    c. Mark Inflation time; Minimize balloon inflation time <30min if possible
    d. Suture catheter and sheath; transduce arterial line
    e. Anesthesia team should maintain maternal normotension with targeted resuscitation and short-acting vasoactive medications. Avoid excessive hypertension during occlusion.
5. **Balloon Deflation – Partial REBOA**
    a. Intermittent or partial deflation of the REBOA balloon can be used to optimize visceral perfusion during longer occlusion periods, goal SBP > 90 mm Hg
    b. Deflate 0.5-1ml/min following definitive hemorrhage control
6. **Femoral Artery Sheath Removal**
    a. Ensure hemodynamic stability and normal coagulation profile. Remove sheath.
    b. **30 min** digital pressure at sheath site, keep patient supine for 6 hrs, no hip flexion
    c. Check distal pulses Q15min x4, Q30min x2, then hourly x4hrs
    d. Femoral arterial duplex at 24-48 hours to evaluate patency of femoral artery

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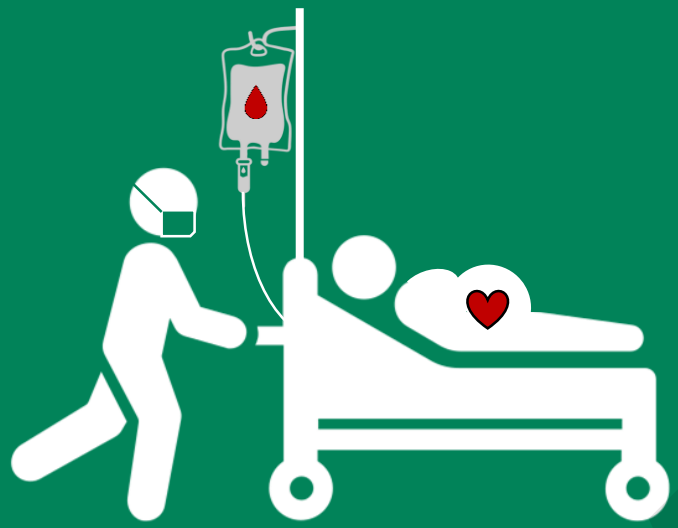
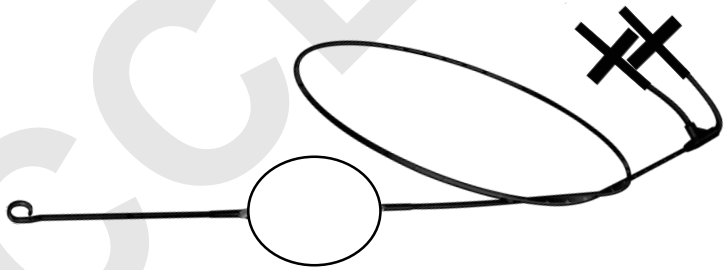
A Team Approach to Peripartum Hemorrhage Control Incorporating Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

The highest risk of bleeding for women with placenta accreta occurs at the time of delivery, when as many as 90% require blood transfusion



REBOA placed by acute care surgeons is a safe and effective strategy to control major bleeding during high-risk obstetric surgeries and peripartum emergencies



We describe a protocolized, multidisciplinary approach to obstetric hemorrhage, including patient selection, operating room procedures, and REBOA techniques

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Russo RM et al. *Journal of Trauma and Acute Care Surgery*. Mar 2022 [doi]

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