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# RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA (REBOA)

## *Evidence Based Medicine Guideline*

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Approved: 7/24/2018 Revision(s): 5/20/2023

**SUMMARY**
Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a minimally invasive technique utilizing a balloon catheter to temporarily occlude the aorta to prevent hemorrhagic death. Placement of an endovascular balloon for both traumatic and nontraumatic causes of hypovolemic shock secondary to blood loss can temporize hemorrhage until definitive surgical control can be achieved. Proper placement can be performed in minutes and minimize and/or avoid the need for resuscitative thoracotomy, as well as decrease patient mortality. This guideline details the indications for use of REBOA as well as techniques for successful placement of a REBOA device./

**RECOMMENDATIONS**

- **Level 1**
  - **None**
- **Level 2**
  - **Patients most likely to benefit from REBOA are those with blunt and penetrating trauma who are hypotensive (SBP < 80-90 mmHg) and unresponsive to resuscitation.**
    - **Early placement of a femoral artery catheter in the hypotensive trauma patient (SBP < 90 mmHg) should be performed to facilitate rapid upsizing to a 7-French sheath to accommodate a REBOA catheter if necessary.**
    - **REBOA should only be utilized as part of a larger system of damage control which can expeditiously proceed to definitive hemorrhage control within 15 to 30 minutes for Zone I activation and 30 to 60 minutes for Zone III.**
  - **REBOA can be safely used for the prevention and management of massive maternal hemorrhage due to abnormally adherent placenta.**
  - **Interfacility transportation with REBOA is not recommended due to required timing for definitive management.**
- **Level 3**
  - **REBOA may also be considered for the management of severe gastrointestinal bleeding.**
  - **Partial occlusion can be considered in experienced centers in an attempt to minimize total occlusion time.**

## INTRODUCTION

Endovascular balloon occlusion of the aorta was first described in 1954. Today, there are over 600 articles and publications reporting the use, indications, outcomes, and complications of REBOA including national consensus statements from the American College of Surgeons Committee on Trauma and American College of Emergency Physicians. This guideline is intended to provide an overview of the indications, technique, and use of REBOA. This is not a substitute for appropriate training. The Basic Endovascular Skill for Trauma (BEST) and Endovascular Skills for Trauma and Resuscitative Surgery Course are both CME-approved and should be considered for proper education into this life-saving technique (1). REBOA is a tool that facilitates damage control resuscitation but is not

**LEVEL OF RECOMMENDATION DEFINITIONS**

- **Level 1:** Usually based on Class I data or strong Class II evidence if randomized testing is inappropriate. Conversely, low quality or contradictory Class I data may be insufficient to support a Level I recommendation.
- **Level 2:** Reasonably justifiable based on available scientific evidence and strongly supported by expert opinion. Usually supported by Class II data or a preponderance of Class III evidence.
- **Level 3:** Supported by available data, but scientific evidence is lacking. Generally supported by Class III data. Useful for educational purposes and in guiding future clinical research.

a definitive hemorrhage control technique. Its main benefit is to temporize patients at high risk of mortality related to non-compressive torso hemorrhage and pelvic bleeding. Rapid placement of a REBOA catheter increases central aortic pressure, perfusion to the brain and heart, and systemic afterload while halting hemorrhage below the level of inflation.

**INDICATIONS**

Hemorrhage from non-compressible torso injury is a leading cause of death in both civilian and military trauma (2). Early placement of a REBOA catheter has been shown to temporize bleeding in such high-mortality injuries and provide a window of opportunity to provide definitive treatment, potentially preventing progression to cardiac arrest or need for resuscitative thoracotomy and aortic cross clamping. The REBOA catheter can be inflated in either Zone 1 to occlude the descending thoracic aorta or Zone 3 to occlude the infrarenal aorta and blood supply to the pelvis and lower extremities.

The current literature identifies four main potential uses for REBOA (3):

1) Zone 1 for ongoing hemorrhage and impending traumatic cardiac arrest (4)
2) Zone 1 for severe hemorrhagic shock due to abdominal +/- pelvic injuries
3) Zone 3 for severe pelvic fractures or junctional groin bleeding
4) Zone 3 for obstetrical emergencies such as morbidly adherent placenta

A systematic review in 2022 evaluated the literature pertaining to patient selection and algorithms for REBOA utilization (5). This included 10 studies and seven institutional guidelines demonstrating that patients most likely to benefit from REBOA are blunt and penetrating trauma patients who are hypotensive and unresponsive to resuscitation.

Given the potential complications and risk associated with use of REBOA, proper patient selection is imperative. There is significant risk of life and limb threatening complications including (4):

- Spinal cord injury secondary to prolonged ischemia
- Reperfusion injury leading to kidney failure
- Femoral artery aneurysm, dissection, pseudoaneurysm, and hematoma
- Lower extremity ischemia leading to limb loss
- Balloon rupture leading to aortic injury

Contraindications to REBOA include major thoracic hemorrhage or pericardial tamponade. In great vessel injury there is limited data, mostly in case reports, for the use of REBOA and is typically used in conjunction with resuscitative thoracotomy (6). Some studies suggest major bleeding proximal to the subclavian artery is a contraindication, as well as suspicion of thoracic aortic injury, severe blunt chest injury, major thoracic vascular injury or thoracic hemorrhage (5). There is limited data regarding use in pediatric or geriatric patients; further studies required to determine appropriate use in these populations.

**REBOA EQUIPMENT AND PLACEMENT**

REBOA should only be utilized by a physician capable of definitive hemorrhagic control or by someone trained in its use in conjunction with a physician who will provide the definitive intervention. Several different types of endovascular catheters may be used to achieve balloon occlusion of the aorta. Older 9 to 12 French balloon catheters require a larger arterial sheath as well as an open primary arterial repair after sheath removal. Newer versions utilize a 7-French nitinol-reinforced balloon catheter that may be inserted through a 7-French arterial sheath and do not require arterial repair. The nitinol reinforcement resists retrograde pulsation and negates the need for placement over an endovascular wire. The catheter includes an integrated arterial pressure port to allow arterial blood pressure monitoring proximal to the balloon. There are also radiopaque markers on the catheter to facilitate proper placement. Ultrasound guided percutaneous access is the preferred method for cannulating the common femoral artery.

The aorta is divided into three zones (Figure 1). Proper placement of the REBOA catheter is in either Zone I or Zone III. Zone I is located just distal to the take-off of the left subclavian artery and ends at the celiac trunk. Inflation in this zone allows for control of intra-abdominal or retroperitoneal hemorrhage. Patients should have definitive hemorrhage control available within 15 minutes. Occlusion times >30 minutes are associated with increased

complications and mortality (7). Zone III is located just distal to the lowest renal artery and ends at the aortic bifurcation. Inflation in this zone is used for severe pelvic, junctional, or proximal lower extremity hemorrhage not amenable to a tourniquet. Longer durations of inflation are acceptable in Zone III, but should still target less than 30 minutes and no great than 60 minutes. Zone II is between the celiac artery and lowest renal artery; balloon catheters should not be placed in this zone.

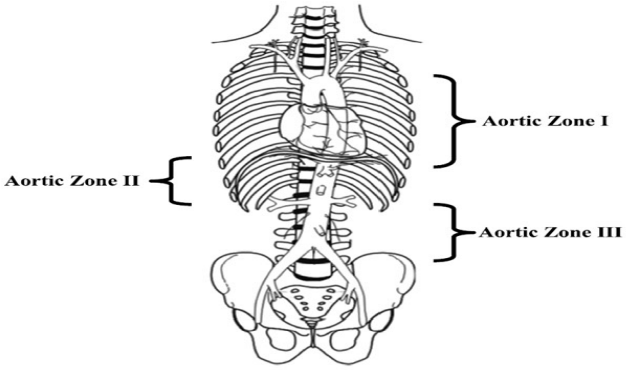



Figure 1: Three Zones of the Aorta

Commercially available REBOA kits include the REBOA catheter as well as a 7-French arterial sheath and the necessary supplies to perform sterile insertion of the device. Institutions may also create their own kit using readily available supplies. Prophylactic insertion of a common femoral arterial line should be considered in any trauma patient with hypotension as this enables rapid upsizing of the catheter to a 7-French introducer sheath should REBOA be deemed necessary. Utilization of beside ultrasound aids in successful placement as arterial cannulation can often prove to be difficult in the severely hypotensive patient. The arterial line must be placed within the common femoral artery and not in the superficial femoral artery to avoid complications such as avulsion, dissection, thromboembolic events, and occlusion of distal arterial blood flow. If unable to place percutaneously, surgical cutdown can be performed.

Anatomic landmarks for placement of the catheter involve measuring from the groin insertion site to the sternal notch with the “p” tip of the catheter for Zone I and from the groin insertion site to the xiphoid process with the “p” tip for Zone III. One cm markings on located on the catheter and are used to guide appropriate position. Zone I should be reached at approximately 46 cm, and Zone III should be reached at approximately 28 cm. Once the catheter is in place, the balloon should be slowly inflated while watching the arterial blood pressure. When inflating the balloon, the catheter must be held in place to prevent migration. The balloon should be filled with either sterile water or normal saline. Contrast is not necessary as there are radiopaque markers on the catheter to verify location. Maximum recommended balloon inflation is 8 ml for Zone I, and 2 ml for Zone III.

Once arterial blood pressure has improved, the catheter should be secured in place with suture, a central catheter clip, or held by hand. It is crucial to note that if the catheter is not held in position, it may migrate distally due to the pulsation of aortic blood flow. The time of inflation should be noted. Deflating the balloon in Zone I intermittently may help maintain perfusion to the kidneys and lower extremities. Removal of the catheter should be completed as soon as adequate hemorrhage control has been achieved.

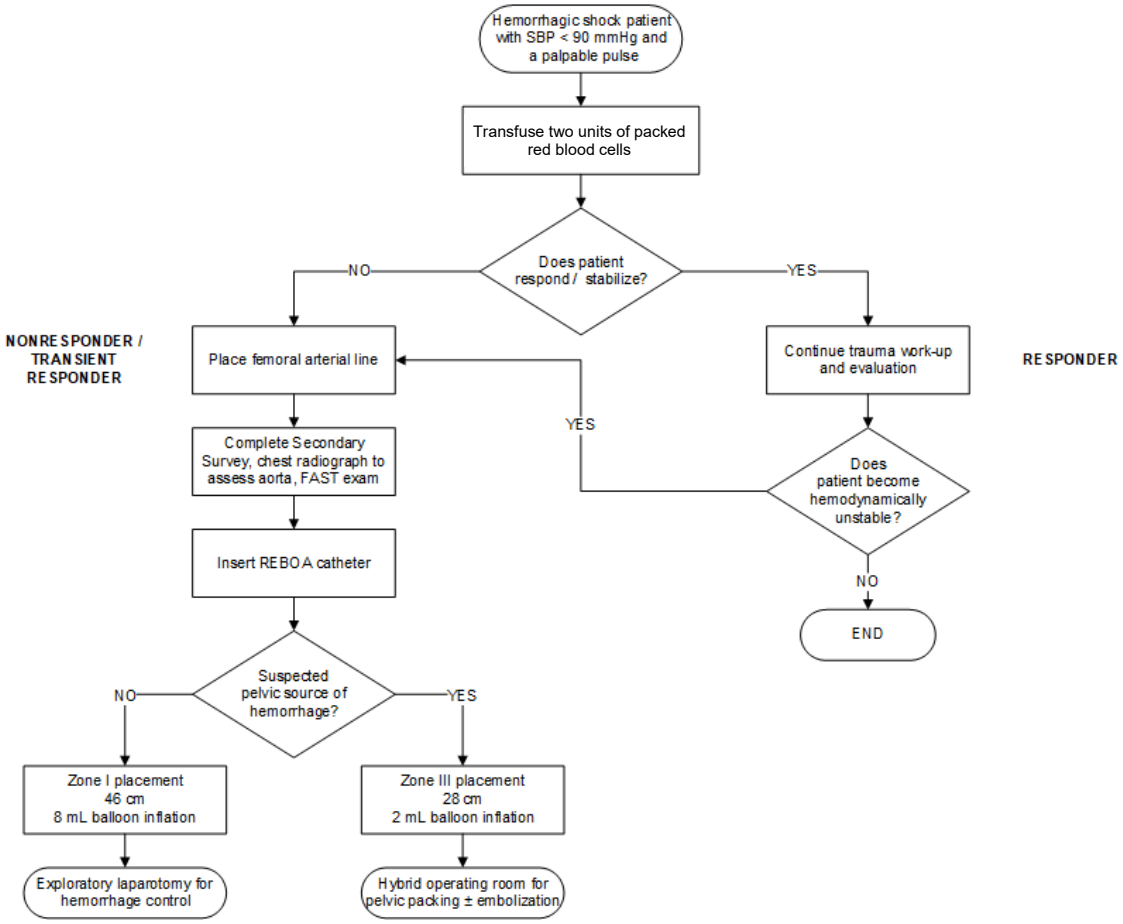
**PARTIAL REBOA PLACEMENT**

Prolonged aortic occlusion has potential complications, as discussed above, and should temporize bleeding until a surgeon can achieve definitive management within approximately 30 minutes. A novel approach known as partial REBOA has been introduced when it may not be feasible to achieve definitive control within that time frame. It allows for low volume flow past a partially inflated balloon and is thought to potentially mitigate some of the reperfusion injury after deflation and prolonged distal ischemia time. So far, animal studies have suggested that partial REBOA (p-REBOA) can maintain central perfusion with less hemodynamic burden and changes (8,9). A 2021 study performed by Madurska et al. at a single, high-volume trauma center compared complete occlusion REBOA with p-REBOA (10). Although a small study (14 p-REBOA patients and 46 complete REBOA patients) they found a non-significant trend towards lower ventilator days in the partial group as well as less dialysis. The p-REBOA group had significantly less vasopressor requirements.

## STEPS OF REBOA PLACEMENT

1. Assemble equipment for arterial access.
2. Obtain access to the common femoral artery using standard techniques (ultrasound guided if available).
3. Measure REBOA catheter and determine depth using external landmarks;
    a. Sternal notch for Zone I (46 cm), or xiphoid process for Zone III (28 cm).
4. Test balloon, then ensure balloon is fully deflated holding negative pressure and close the stopcock.
5. Flush the catheter with saline or sterile water. This injection forms the fluid column necessary for arterial pressure wave monitoring.
6. Advance peel-away sheath to cover p-tip using a clockwise twisting of sheath while advancing over the balloon and p-tip.
7. Flush and attach the arterial line (tubing should be pre-flushed to remove any air bubbles).
8. Insert peel-away sheath approximately 5 mm into the valve of the arterial sheath.
9. While holding the sheath in place, advance the catheter to the desired depth. Pull the peel-away sheath back after the balloon passes the valve.
    a. If available, use conventional x-ray or fluoroscopy to confirm position using radiopaque markers
10. Inflate the balloon slowly, watching the arterial waveform
    a. Zone I, start with 8 mL; for Zone III, start with 2 mL
    b. Do NOT over inflate. There should be a rise in systolic pressure.
11. Mark time of inflation and secure the catheter close to the introducer sheath.
12. Move to definitive hemorrhage control.

## ORLANDO HEALTH REBOA INSERTION ALGORITHM



## LITERATURE REVIEW

Endovascular balloon occlusion of the aorta was first described in 1954 by Lieutenant Colonel Carl W. Hughes, US Army. He published a three-patient case series of injured soldiers where he attempted endovascular balloon occlusion. Even though all three soldiers died, he realized the importance of early use of balloon occlusion and recommended early use of this technology (11). In 1964, Heimbecker published the use of an endovascular aortic balloon device placed via cut down of the brachial artery for hemorrhage control from a ruptured abdominal aortic aneurysm until definitive surgery could be performed (12).

In 1986, Low et al. published a preliminary report on the use of the Percluder occluding aortic balloon demonstrating a 13% survival among 15 patients (13). In 1989, Gupta et al. evaluated the use of intra-aortic balloon occlusion in penetrating abdominal trauma demonstrating a 35% survival in 20 patients (14). Operative control of hemorrhage was accomplished in 11 patients; seven patients survived and were discharged with a functional status. In both studies, several problems were noted with the use of the aortic occlusion device and the need for earlier application. In 2011, White et al. compared intra-aortic balloon occlusion to open thoracotomy with aortic clamping in 19 pigs with hemorrhagic shock (15). Central aortic pressure, carotid blood flow and brain oxygenation were measured and compared. Results showed that aortic balloon occlusion increases central perfusion pressures with less physiologic disturbance than thoracotomy and aortic clamping.

In 2013, Brenner et al. published a clinical series of 6 trauma patients (4 blunt, 2 penetrating) undergoing REBOA (16). Three catheters were placed in Zone 1 and three in Zone 3. There were no complications secondary to REBOA placement. Four patients survived and two died of neurological complications. This series showed that REBOA was instrumental to patient survival without the morbidity of a resuscitative thoracotomy.

The American Association for the Surgery of Trauma (AAST) developed the Aortic Occlusion for the Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry in 2013 to collect data and demographics, injury patterns, and outcomes to better identify the optimal use of REBOA among patients greater than 18 years of age. In 2016, DuBose et al. prospectively identified trauma patients requiring aortic occlusion (AO) from eight ACS Level 1 centers through the registry (17). Presentation, intervention, and outcome variables were collected and analyzed to compare REBOA and open aortic occlusion. 114 patients were reported (46 REBOA; 68 open). There was no difference in time to successful aortic occlusion between REBOA and open procedures (6.6 ± 5.6 vs. 7.2 ± 15.1 minutes; p=0.84). Overall survival was 21.1% (24 of 114) with no significant difference between REBOA and open patients with regard to mortality. This study showed that REBOA was a viable alternative to open aortic occlusion.

Brenner et al. subsequently reported data from the AORTA registry in the AORTA2 study evaluating 285 patients that underwent either REBOA placement or resuscitative thoracotomy (RT) (18). This study looked specifically at patients who underwent Zone I occlusion. 202 patients underwent RT (70.9%) and 83 patients underwent REBOA (29.1%). Patients with penetrating thoracic injury were excluded. Patients were categorized into survival beyond the ED and survival to discharge. In the survival beyond ED group, survival was 44.1% vs. 62.7% (p=0.004) while in the survival to discharge group, survival was 2.5% vs. 9.6% (p=0.023). Prognostic value of prehospital CPR was analyzed and found to be an important component in the value of REBOA. If CPR was needed prior to either RT or REBOA placement, there was no difference in outcomes. The best outcomes of REBOA were found to be in patients who were hypotensive without the need of CPR prior to placement. In the survival beyond ED group who did not require CPR, survival was 48.3% vs. 92.6% (p=0.001) while in the survival to discharge group survival was 3.4% vs. 22.2% (p=0.048). These patients benefited most from placement of REBOA as a bridge to definitive repair.

In 2017, Ibrahim et al. published a case report describing the repeated use of REBOA in a patient that had ongoing bleeding after surgery (19). The REBOA catheter was left in place for 40 hours and inflated more than once without complications.

A 2022 study reported an 8.6% incidence of arterial access related limb ischemia complications in 418 patients from the AAST AORTA registry (20). Those with this complication had larger profile devices (p=0.009), cutdown access (p=0.02) and presence of either a pelvic binder or fixator (p=0.01). These complications did not affect mortality but did prolong hospital length of stay (31 vs. 24 days; p=0.02).

A systematic review and meta-analysis was performed by Borger van der Burg et al. with the aim to examine the use of REBOA and its associated morbidity and mortality (21). Articles from 1990-2017 were searched. After exclusion, 89 articles were selected with a total of 1482 patients treated with REBOA. Patients were placed in 3 categories: traumatic abdominopelvic hemorrhage (18 studies), hemorrhage arising from ruptured abdominal aortic

aneurysm (50 studies), and miscellaneous causes including gastrointestinal bleeding, pelvic procedures, and post-partum bleeding (21 studies). 79.3% of patients had hemodynamic instability and were transient responders to fluid resuscitation. Overall mortality difference was statistically significant ($p$<0.001) for patients treated with REBOA compared with other means. Risk difference of 0.27 (0.14-0.49) favored REBOA. Occlusion times were recorded according to zones of occlusion with a median time of 58.4 minutes in Zone I and a median occlusion time of 55.2 minutes in Zone III. There were 3 studies that documented Zone II occlusion with a median time of 43.6 minutes.

Partial REBOA occlusion has been developed to minimize effects of distal ischemia. In 2021, Kinslow et al. published a review including 14 randomized control trials utilizing animal models to evaluate partial vs. complete REBOA occlusion and Zone I vs. III placement (23). Eleven of these studies evaluated partial vs. complete REBOA occlusion and found there was similar attainment of proximal MAP but significantly less ischemic burden. Mortality benefit was observed in three studies. Survival time was also improved in Zone III vs. Zone I placement. However, it is difficult to translate these results to human models given differences in collateral circulation.

A 2022 study compared partial and complete REBOA occlusion in a retrospective patient analysis REBOA registry from 2016 to 2019 (10). They evaluated adult trauma patients who had a Zone I complete or partial REBOA occlusion and an occlusion time of greater than or less than 30 minutes. 46 patients were included, 14 with partial occlusion. Prolonged (greater than 30 minutes) REBOA use, in both partial and complete occlusion was associated with increased mortality (32 vs. 0%; p=0.044). The prolonged partial REBOA group demonstrated a trend towards lower ventilator days (10 vs. 6; p=0.483 and dialysis 35.4 vs. 16.7%; p=0.228) and did demonstrate significantly less vasopressor requirements (72 vs 33%; p=0.026). Although these trends are promising, there is no improved survival demonstrated with partially occluding for prolonged occasions. A recent study by Polcz et al. evaluated the pREBOA-PRO which is a partial occlusion catheter in a swine model (24). They randomized the animals into two groups that had either partial aortic occlusion with a target MAP of 35-400 mmHg and complete occlusion for 90 minutes after targeted 30% total blood volume loss. Flow rate and MAP were recorded during a 2-hour critical care phase. MAP distal to the balloon was maintained in the partial group at 35.8 vs. 27.1 mmHg in the complete group which corresponded to higher flow rates as well (202.0 vs. 25.9 ml/min; p <0.05). Creatinine returned to baseline in the partial but not complete occlusion group. The authors demonstrate technical feasibility with pREBOA-PRO in porcine models. This may allow for extension of the window of inflation and minimize complications such as ischemia. Further studies in humans need to be evaluated.

In addition to traumatic populations, REBOA has been explored as a feasible option to control maternal hemorrhage due to morbidly adherent placenta. A systematic review published in 2018 evaluated eight studies with 336 patients who had REBOA as an adjunct for prophylactic hemorrhage control prior to cesarean delivery with morbidly adherent placenta (25). These studies included patients with average blood loss of >500 mL to severe hemorrhagic shock. This review demonstrated a decrease in the amount of blood loss and need for transfusion. The REBOA catheter can be inflated either at the time of umbilical cord clamping or at the discretion of the obstetrician when dissecting the most vascularized area. Another systematic review looked at the use of REBOA specifically in elective cesarean section in women with morbidly adherent placenta (26). Their results, similarly, demonstrated reduced blood loss and decreased need for transfusion.

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