RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA (REBOA)

SUMMARY

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a minimally invasive technique using a balloon catheter to temporarily occlude the aorta in support of hemorrhage control. Placement of the 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 and use of REBOA as well as techniques for successful placement of a REBOA device.

RECOMMENDATIONS

- **Level 1**
  - **None**
- **Level 2**
  - **None**
- **Level 3**
  - **Consider early placement of a common femoral artery catheter in the hypotensive trauma patient (SBP < 90 mmHg) to facilitate rapid upsizing to a 7-French sheath to accommodate a REBOA catheter if necessary**
  - **REBOA should be considered in patients with hemorrhagic shock and the following:**
    - **Penetrating or blunt abdominopelvic trauma patients who are hypotensive (SBP < 90 mmHg), transient responders to fluid resuscitation, or receiving a Massive Transfusion Protocol (MTP)**
    - **Positive FAST examination**
    - **Suspected pelvic or lower extremity trauma with hemorrhage**
  - **The REBOA device may also be considered for the following alternative Indications:**
    - **Prophylactic use in women undergoing surgery for abnormal placentation**
    - **Severe gastrointestinal bleeding**

INTRODUCTION

Endovascular balloon occlusion of the aorta was first described in 1954. Today, there are over 200 articles and publications reporting the use, indications, outcomes, and complications of REBOA. This guideline is intended to provide an overview of the indications, technique, and use of the REBOA catheter. This is not a substitute for appropriate training. The Basic Endovascular Skill for Trauma (BEST) and Endovascular

EVIDENCE DEFINITIONS

- **Class I:** Prospective randomized controlled trial.
- **Class II:** Prospective clinical study or retrospective analysis of reliable data. Includes observational, cohort, prevalence, or case control studies.
- **Class III:** Retrospective study. Includes database or registry reviews, large series of case reports, expert opinion.
- **Technology assessment:** A technology study which does not lend itself to classification in the above-mentioned format. Devices are evaluated in terms of their accuracy, reliability, therapeutic potential, or cost effectiveness.

LEVEL OF RECOMMENDATION DEFINITIONS

- **Level 1:** Convincingly justifiable based on available scientific information alone. 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.

Skills for Trauma and Resuscitative Surgery Course are both CME-approved and should be considered for proper education into this life-saving technique. (1)

INDICATIONS

Traumatic injury remains the leading cause of death among North Americans from 1-44 years of age with hemorrhage due to trauma as the leading preventable cause of death (90% of potentially preventable deaths). (2) A significant number of patients die of exsanguination prior to receiving definitive trauma care. Early placement of a REBOA catheter has been shown to temporize bleeding and provide a window of opportunity to get the patient to definitive treatment. The current literature identifies five main uses for REBOA:

1) Hemorrhage due to trauma
2) Ruptured abdominal aortic aneurysm
3) Non-compressible torso injuries
4) Gastrointestinal bleeding
5) Obstetrical emergencies such as morbidly adherent placenta

Contraindications to REBOA include penetrating neck/chest trauma and blunt cardiac/aortic injury where the use of resuscitative thoracotomy is more favorable. 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.

REBOA EQUIPMENT AND PLACEMENT (3)

Several different types of endovascular catheters may be used in balloon occlusion of the aorta. 9-12 French balloon catheters require a larger arterial sheath as well as an open primary arterial repair after sheath removal. Recently, a 7-French nitinol-reinforced balloon catheter has become available that may be inserted through a 7-French arterial sheath and does 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.

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. Zone III is located just distal to the lowest renal artery and ends at the aortic bifurcation. Zone II is between the celiac artery and lowest renal artery; balloon catheters should not be placed in this zone.

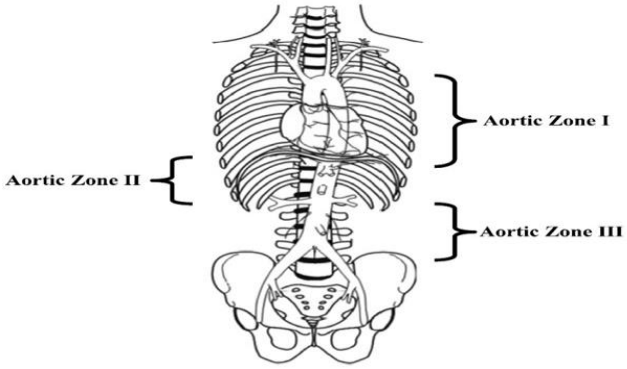


Figure 1: Three Zones of the Aorta

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 supplies that are already available. 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 with placement such as avulsion, dissection, thromboembolic events, and occlusion of distal arterial blood flow.

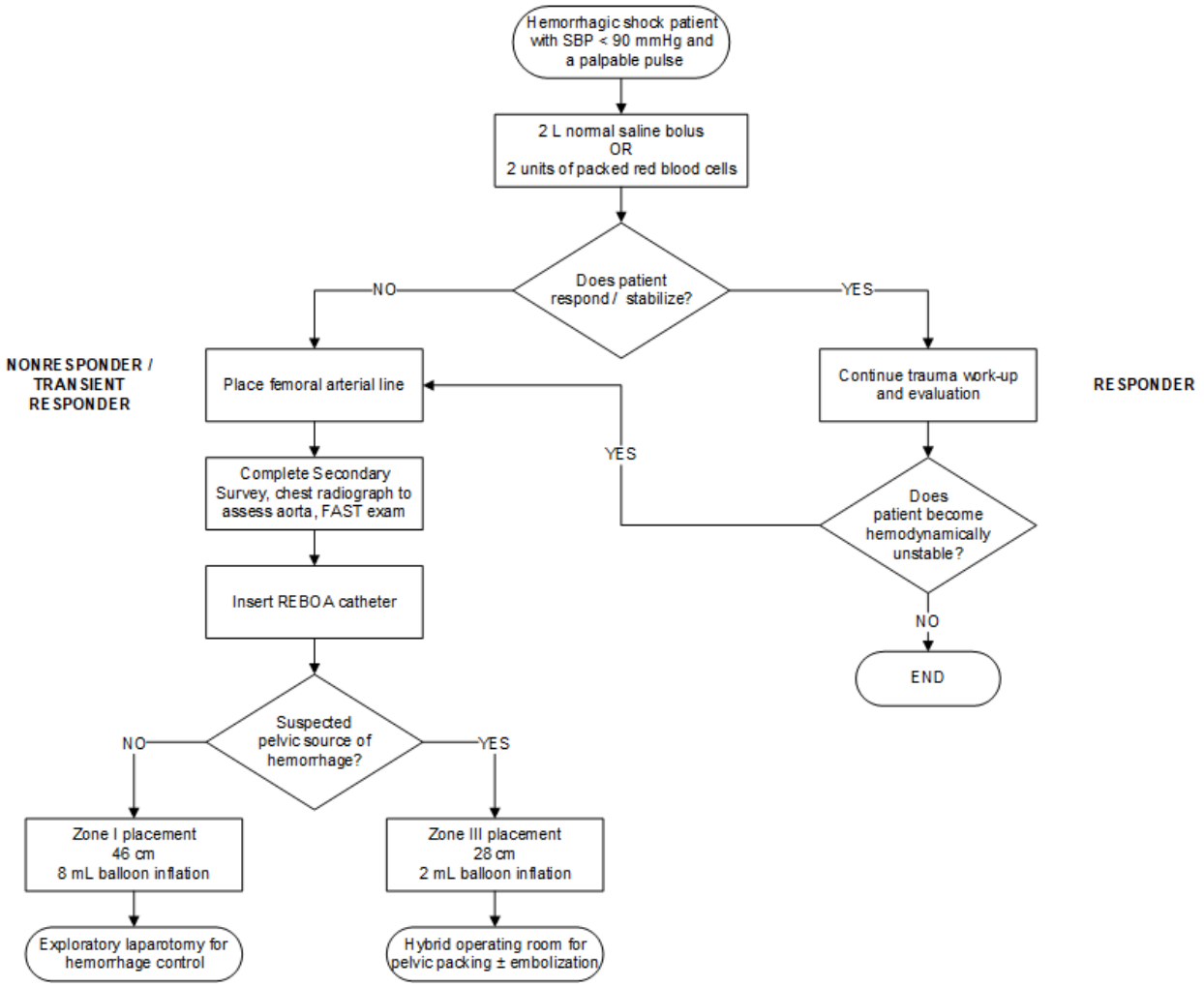
Anatomic landmarks for placement of the catheter involve measuring from the groin insertion site to the sternal notch with the “p” tip of the catheter for Zone I and from the groin insertion site to the xiphoid process with the “p” tip for Zone III. One cm markings on located on the catheter and are 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. The balloon should not be inflated continuously for more than 30 minutes. 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.

STEPS OF REBOA PLACEMENT

1. Assemble equipment for arterial access.
2. Obtain access using standard techniques (ultrasound guided if available) into the common femoral artery.
3. Measure REBOA catheter and determine depth using external landmarks; 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 0.5 cm into valve of 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.
10. Inflate the balloon slowly watching the arterial waveform (for Zone I, start with 8 mL; for Zone III start with 2 mL). 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.
13. Optimal balloon inflation time should be less than 30 minutes.

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 earlier use of this technology. (4) In 1964, Heimbecker published the use of an endovascular balloon device placed via cut down of the brachial artery into the aorta for hemorrhage control from a ruptured abdominal aortic aneurysm until definitive surgery could be performed. (5)

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. (6 In 1989, Gupta et al. evaluated the use of intra-aortic balloon occlusion in penetrating abdominal trauma demonstrating a 35% survival in 20 patients. Operative control of hemorrhage was accomplished in 11 patients; seven patients survived and were discharged with a functional status. (7) 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. (8) Central aortic pressure, carotid blood flow and brain oxygenation was 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) that had a REBOA catheter placed. Three 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 thoractomy. (9)

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 in an effort 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 from the registry. (10) 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). (11) 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 who underwent 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 more than once. The REBOA catheter was left in place for 40 hours and inflated more than once without complications. (12)

A systematic review and meta-analysis was performed by Borger van der Burg et al. with the aim to examine the use of REBOA, the morbidity and mortality associated with its use as well as evidence-based rationale for its use. 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) favoring 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. This is the largest meta-analysis of REBOA to-date and supports the use of REBOA for early hemorrhage control. (13)

Partial REBOA occlusion is a newer technique being performed by several institutions throughout the world. There is currently insufficient data published to make recommendations regarding utilization of this technique. Further studies are warranted to fully evaluate its efficacy and potential advantages.

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