

Joint statement from the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP) regarding the clinical use of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

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INTRODUCTION

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) provides a new tool in selected patients for the management of non-compressible torso hemorrhage.^{1–3} Recent improvements in technology have facilitated more rapid placement through smaller femoral access sheaths, which may reduce access-related complications.⁴ However, high grade evidence to guide REBOA use is limited, and there is a substantial complication risk should this approach be used inappropriately.⁵ To address the current state of implementation of this new therapeutic strategy, the American College of Surgeons Committee on Trauma (ACS COT) has worked in collaboration with the American College of Emergency Physicians to issue this joint policy statement which addresses the current practice relevant to patient indications, potential complications, implementation, patient management, and training of providers. We urge trauma centers to consider these factors in the adoption of this approach.

GENERAL OBSERVATIONS

- ▶ No current, high-grade evidence clearly demonstrates REBOA improves outcomes or survival compared to standard treatment of severe hemorrhage.^{5–10}
- ▶ REBOA is less invasive than resuscitative thoracotomy and in skilled hands may be more rapidly applied as compared with resuscitative thoracotomy.
- ▶ Acute care surgeons can learn and safely perform REBOA after a formal training course.⁹
- ▶ REBOA is currently standard practice for select patients at a small number of trauma centers where surgeons are immediately available for the management of REBOA.^{2,6}
- ▶ The major rate-limiting step to REBOA is the ability to safely and efficiently cannulate the common femoral artery (CFA) in a hypovolemic patient.^{5,10–12} If percutaneous cannulation is not possible, surgical cut down is required.

INDICATIONS FOR REBOA

- ▶ REBOA is indicated for traumatic life-threatening hemorrhage below the diaphragm in patients in hemorrhagic shock who are unresponsive or transiently responsive to resuscitation.
- ▶ REBOA is indicated for patients arriving in arrest from injury due to presumed life-threatening hemorrhage below the diaphragm. No evidence exists for the recommended duration of arrest and use of REBOA but should be used within the same time period as would resuscitative thoracotomy.
- ▶ The balloon catheter may be inflated at the distal thoracic aorta (Zone 1) for control of severe intra-abdominal or retroperitoneal hemorrhage, or those with traumatic arrest.
- ▶ The balloon catheter may be inflated at the distal abdominal aorta (Zone 3) for patients with severe pelvic, junctional, or proximal lower extremity hemorrhage.

COMPLICATIONS OF REBOA

- ▶ Reported femoral access complications include arterial disruption, dissection, pseudoaneurysms, hematoma, thromboemboli, and extremity ischemia.^{5,10}
- ▶ These complications have resulted in patch repairs, complex arterial reconstructions, bypasses, limb ischemia, and amputations.
- ▶ Reported aortoiliac injuries include intimal tear, dissection, thrombosis, and rupture which may be fatal or cause limb loss.
- ▶ Balloon rupture may occur with over inflation of the balloon relative to the aortic diameter.
- ▶ Unintended inflation of the balloon in the iliac vessels may lead to rupture or thrombosis.
- ▶ Prolonged aortic occlusion alone may lead to fatal complications or spinal cord injury due to prolonged organ ischemia.

GUIDELINES FOR REBOA USE AND IMPLEMENTATION

- ▶ REBOA protocols should be developed in conjunction with vascular surgery.



- ▶ REBOA should be performed by an acute care surgeon or an interventionalist (vascular surgeon or interventional radiologist) trained in REBOA.
- ▶ An acute care surgeon must be immediately available to definitively address the specific cause of hemorrhage to avert the dire complications of truncal and/or spinal cord ischemia from prolonged aortic occlusion.^{10–12}
- ▶ Emergency medicine (EM) physicians with added certification in critical care (EMCC) trained in REBOA, may train and perform REBOA in conjunction with an acute care surgeon or vascular surgeon trained in REBOA, as long as the surgeon(s) is/are immediately available to definitively control the focused source of bleeding.
- ▶ EM physicians with documented significant experience and training with REBOA during military deployment may train and perform REBOA in conjunction with an acute care surgeon or vascular surgeon trained in REBOA, as long as the surgeon(s) is/are immediately available to definitively control the source of bleeding.
- ▶ EMCC-certified physicians trained in REBOA must not perform REBOA unless a surgeon is immediately available.
- ▶ EM physicians without critical care training should not perform REBOA.

TRANSFER OF PATIENTS

- ▶ Due to the inability of prehospital providers to appropriately manage and troubleshoot the devices during transport, and the lack of evidence to support safe duration of aortic occlusion, transfer of patients with REBOA is not recommended. Thus, REBOA should not be placed in Emergency Departments in institutions where the patient cannot receive definitive surgical care and hemostasis at that same institution.

MANAGEMENT OF THE PATIENT WITH REBOA

There are no rigorous clinical data to guide absolute duration of full or partial aortic occlusion. However, the following guidelines are current best practice:

- ▶ REBOA in Zone 1 should only be performed if the anticipated time to start of operation is less than 15 min.
- ▶ REBOA in Zone 3 may be tolerated for longer periods of time and as such may be used as an immediate adjunctive bleeding control prior to angioembolization, preperitoneal packing or exploration. Once Zone 3 aortic occlusion has been performed, urgent operative or interventional hemostasis should occur, and the balloon deflated as soon as possible.
- ▶ Partial balloon inflation at either location may prolong this interval; however, this is not well studied. Furthermore, this can result in distal migration of the balloon catheter which may cause intimal injury if the balloon is not completely deflated or is reinflated in the iliac vessels.
- ▶ The balloon should be deflated as soon as possible, and the catheter and sheath removed as soon as possible. Vigilant assessment of lower extremity perfusion must occur before, during, after aortic occlusion, and after sheath removal. This monitoring must continue for at least 24 hours. If the patient leaves the OR/interventional suite with the sheath in place, demonstration of adequate extremity perfusion by angiography is recommended. Vascular surgery colleagues should participate in the assessment of distal perfusion and management and removal of the sheath.

SPECIAL CIRCUMSTANCES: DEPLOYED MILITARY SETTINGS

- ▶ Military surgeons who act as general or trauma surgeons during deployment should complete a formal training course (Basic Endovascular Skills for Trauma (BEST Course®)) and include REBOA in their skill set.
- ▶ Military EM physicians who work on a team with acute care surgeons during deployment must complete formal training (BEST Course®) and may include REBOA in their skill set. REBOA must be performed in conjunction with an acute care surgeon.⁸
- ▶ The ability to analyze which patient may benefit from a REBOA is more difficult in austere environments, and careful attention must be paid to patient selection and immediate availability of operative resources.⁸

REBOA TRAINING

- ▶ Formal, basic training consists of completion of the ACS COT BEST Course®.
- ▶ Proficiency in ultrasound-guided and open, cut-down cannulation of the CFA is a critical skill required for REBOA.

REBOA CREDENTIALING: INSTITUTION DEPENDENT

- ▶ Each institution and department is responsible for determining qualifications and permitting providers to perform REBOA.
- ▶ Leadership from vascular surgery, acute care surgery, and EM must establish institution-specific guidelines for integration of REBOA into clinical practice, including training, credentialing and guidelines for insertion and monitoring.

QUALITY ASSURANCE, MAINTENANCE OF COMPETENCE, PERFORMANCE IMPROVEMENT AND PATIENT SAFETY

- ▶ REBOA will be uncommon in most settings. As such and given that the benefits of REBOA are as yet unproven, patient safety and performance improvement are critically necessary components of a REBOA program.
- ▶ After initial training, there should be an ongoing competency program, either through simulation or cadaver labs, attendance at a BEST Course® or Workshop, or completion of the ASSET™ Course ‘Introduction to REBOA Module’.
- ▶ There should also be a strong quality management program at each institution evaluating (1) each placement for appropriateness and complications to maximize patient safety and (2) availability and timeliness of definitive surgical or angioembolic control of bleeding following REBOA.
- ▶ All REBOA procedures should be coded according to the 2017 NTDS Data Dictionary ICD-10 Hospital Procedures: REBOA, ICD-10 04L03DZ.
- ▶ Any institution performing REBOA should enroll patients in the American Association for the Surgery of Trauma, multi-institutional Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery trial: <http://www.aast.org/Research/MultiInstitutionalStudies.aspx>.

These guidelines are based on published data, best evidence, and expert opinion.^{1–12}

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