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Clinical use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in civilian trauma systems in the USA, 2019: a joint statement from the American College of Surgeons Committee on Trauma, the American College of Emergency Physicians, the National Association of Emergency Medical Services Physicians and the National Association of Emergency Medical Technicians

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ABSTRACT

This is a joint statement from the American College of Surgeons Committee on Trauma, the American College of Emergency Physicians, the National Association of Emergency Medical Services Physicians and the National Association of Emergency Medical Technicians regarding the clinical use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in civilian trauma systems in the USA. This statement addresses the system of care needed to manage trauma patients requiring the use of REBOA, in light of the current evidence available in this patient population. This statement was developed by an expert panel following a comprehensive review of the literature with representation from all sponsoring organizations and the US Military. This is an update to the previous statement published in 2018. It has been formally endorsed by the four sponsoring organizations.

INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) was developed to address the challenge of managing non-compressible torso hemorrhage, a major cause of potentially preventable death after traumatic injury.[1] Although balloon occlusion of the aorta has been used extensively in vascular surgery, its use in trauma was first described by a military surgeon as an attempt for hemorrhage control in three injured patients during the Korean War.[2] Resurgence of the concept of REBOA along with recent evolution of the technology, which enhances the feasibility of REBOA, has led to increased interest in this approach as a bridge to hemorrhage control for critically injured patients. REBOA is also being explored for other indications, such as management of postpartum hemorrhage and use in medical cardiac arrest.

REBOA is not without significant risk. Occlusion of the aorta results in tissue ischemia followed by reperfusion injury, predisposing to organ dysfunction and cardiovascular collapse. In addition, several technical complications have been reported which impact lower limb perfusion. As a result, appropriate patient selection is critical to balancing the potential risks and benefits of REBOA use. Given the time-sensitive nature of this intervention, the system of care that surrounds this procedure is vital to minimizing delays to definitive hemorrhage control as well as the ischemic insult of aortic occlusion.

In 2018, the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP) issued a joint statement on the clinical use of REBOA to address patient safety with the swift adoption of this technology.[3] Due to the rapid evolution of this field and emerging clinical data, we committed to periodic re-evaluation and update of this statement. Consistent with this goal, a multidisciplinary, expert panel was convened to review the current literature and make recommendations in this regard. In addition to the original organizations, representatives from the National Association of EMS Physicians (NAEMSP) and the National Association of Emergency Medical Technicians (NAEMT) were invited to help address issues related to the proposed use of REBOA in the prehospital and interfacility transport environments.

This document focuses on the use of REBOA in civilian trauma patients and integration within civilian trauma systems in the USA. Our emphasis is on patient safety as the most important principle while recognizing the variability in trauma systems, trauma centers, and provider training across the

USA. This document does not make recommendations regarding the US military's use of REBOA, which is governed by the Joint Trauma System (JTS), the Department of Defense reference body for trauma care. This document also does not address potential indications for REBOA other than the management of patients with traumatic hemorrhage.

APPROACH

A multidisciplinary expert panel was convened in June 2019 to review the current evidence on the use of REBOA for injured patients and make recommendations for revision of the joint statement published in January 2018. The panel included emergency medicine physicians, acute care surgeons, vascular surgeons, emergency medical service (EMS) medical directors, a nationally registered paramedic, and members of the active and reserve components of the US military. Experts were nominated by the sponsoring organizations and also included investigators who study the clinical applications of REBOA as well as those who have developed training programs for REBOA use.

Prior to the meeting, two of the participants (ZQ and BB) conducted a systematic literature review of all clinical data published on the use of REBOA since the previous statement (January 2017–March 2019). A literature search was conducted in Medline via Ovid and in Google Scholar for clinical studies of the use of REBOA in humans. Isolated case reports were excluded, except for those with direct relevance to the issues encompassed in the joint statement when higher quality data was unavailable. Thirty-eight articles were identified and relevant data were abstracted by the two reviewers and presented to the panel during the meeting. A recent systematic review and scoping review of the literature were also reviewed by the panel members.[4 5] The panel reviewed unpublished data from the most recent analyses of the Aortic Occlusion for Resuscitation in Trauma and Acute care surgery (AORTA) registry (JD) along with an updated analysis of the 2017 data from the ACS Trauma Quality Improvement Program (TQIP) (BJ). Participants also reviewed the current JTS Clinical Practice Guideline for the use of REBOA by the US military in the deployed environment as well as curriculums from civilian training programs. After the meeting, evidence related to aortic occlusion in the cardiothoracic and vascular literature was also reviewed.

Although animal studies were not reviewed in detail by the panel, the recent review by Kauvar *et al* was included, which highlights the limitations and the variability of the large animal models that have been used to study REBOA.[6] In particular it is noted that pigs have a well-developed subclavian-to-iliac mammary collateral system which may provide a 'bypass' during acute occlusion of the thoracic aorta, maintaining pressure in the distal aorta and some perfusion to the viscera and hindlimbs. Although collateral flow may occur in humans with chronic aortic stenosis, it is not as likely in trauma patients and may limit translation of the animal data to humans.

The panel evaluated each section of the prior joint statement and updated it with evidence-based recommendations, whenever possible. When evidence was lacking, expert consensus of the panel members was used. A new section was added to the statement to discuss the use of REBOA in the prehospital environment. All panel members and the sponsoring organizations support this statement.

QUALITY OF EVIDENCE

The quality of clinical evidence to support REBOA use in trauma patients is poor with no Class I or II data and thus the existing data must be interpreted with caution. Interpreting retrospective studies of patients receiving REBOA is challenging due to difficulty in identification of an appropriately matched cohort. Comparing REBOA to resuscitative thoracotomy (RT) introduces both survival bias and bias by indication, as the patients undergoing RT are almost uniformly in cardiac arrest, thereby favoring REBOA. When comparing patients with hemorrhagic shock requiring emergent hemorrhage control procedures, with and without REBOA, selection bias for REBOA use in patients who fail to respond to resuscitation confounds this comparison, thereby favoring other hemorrhage control measures. Many studies also do not report patient outcomes beyond the initial resuscitation period neglecting delayed complications and mortality. Case reports and case series are subject to publication bias.

In addition, much of the data in the USA comes from a small number of trauma centers with extensive experience with REBOA and these results may not be generalizable to all US trauma centers. Review of the TQIP data from 2017 identified 51 TQIP centers reporting REBOA cases with a median of six cases/center/year (IQR 4–7). Of these 51 centers, 87% were Level 1, 11% Level 2, and 2% Level 3 trauma centers. There are currently more than 800 trauma centers contributing data in TQIP which suggests that in 2017 the majority of US trauma centers were not using REBOA. The practice of REBOA management is also evolving, with some of the experienced centers experimenting with newer techniques including intermittent and partial balloon occlusion, which can further confound analysis of aortic occlusion times and outcomes.

GENERAL OBSERVATIONS

- There is no high-grade evidence demonstrating that REBOA improves outcomes or survival compared with standard treatment of severe traumatic hemorrhage.[5 7]
- In the civilian setting, hypotension and the need for emergent surgical hemorrhage control are associated with significant mortality; however, the majority of hypotensive trauma patients will respond to resuscitation and conventional hemorrhage control without the need for aortic occlusion.[8]
- At a small number of high volume trauma centers experienced with this procedure, REBOA has emerged as a protocolized option in select patients with non-compressible torso trauma.[9–11] The majority of trauma centers in the USA are using this procedure infrequently or not at all.
- REBOA is a tool that should only be employed as part of a larger system of damage control resuscitation, definitive hemorrhage control, and postoperative critical care. It is used to temporize patients at high risk of mortality from non-compressible torso hemorrhage.[12] It is not a definitive hemorrhage control device.
- Aortic occlusion is a time-critical intervention which requires rapid access to resuscitation and hemorrhage control. Aortic occlusion should never be undertaken without expedient access to definitive hemorrhage control.[13–15]
- REBOA carries significant risk of life-threatening and limb-threatening complications.[7 16–18]
- REBOA has been employed in a variety of settings each of which have specific considerations. The system of care must be considered and not all are comparable.
- The specific resources and capabilities available within a trauma system or center must be considered when developing a protocol for REBOA utilization. Not appreciating the time-critical and necessary system elements to successful

implementation of this seemingly straightforward procedure will likely lead to worse outcomes.

REBOA UTILIZATION

- There is no high-grade evidence defining the specific indications for the use of REBOA.
- REBOA may be used for traumatic life-threatening hemorrhage below the diaphragm in patients in hemorrhagic shock who are refractory to resuscitation.
- REBOA does not confer any long-term survival advantage when used in traumatic cardiac arrest compared with standard of care.[19–21]
- REBOA is contraindicated in the setting of major thoracic hemorrhage or pericardial tamponade. Use of REBOA in the setting of thoracic great vessel injury is limited to case reports where open thoracotomy and/or sternotomy is performed in conjunction with REBOA. In these situations, open thoracic exposure is performed to obtain immediate proximal control of hemorrhage although aortic balloon occlusion is utilized for resuscitation.[22]
- There is insufficient data to make specific recommendations about REBOA use in the pediatric or geriatric populations; REBOA may have increased risks in these populations. Further study is needed in these patient populations.

COMPLICATIONS

- Prolonged aortic occlusion alone may lead to fatal complications or spinal cord injury due to prolonged ischemia.[23]
- Significant ischemia reperfusion injury can lead to acute kidney injury and multisystem organ failure.[7]
- Reported femoral access complications include arterial disruption, dissection, pseudoaneurysms, hematoma, thromboembolic problems, and extremity ischemia. These complications have resulted in limb loss and/or the need for patch angioplasty, complex arterial reconstructions or bypass.[16 17]
- Reported aortoiliac injuries include intimal tears, dissection, thrombosis, and rupture which may be fatal or cause limb loss.[16]
- Balloon rupture and iatrogenic aortic injury can occur with overinflation of the balloon relative to the aortic diameter.[24]
- Unintended inflation of the balloon in the iliac vessels may lead to rupture or thrombosis.
- Prolonged attempts to complete the procedure, in particular in obtaining vascular access, can delay definitive hemorrhage control.
- Prolonged sheath dwell times increase the risk of limb complications.

GUIDELINES FOR REBOA USE AND IMPLEMENTATION

- A multidisciplinary team-based approach is required for the development of REBOA protocols specific to the environment of care. All members of the care team need to be familiar with REBOA across the continuum of care from the emergency department through to the intensive care unit.[12]
- REBOA should only be placed by a surgeon or interventionalist responsible for definitive hemorrhage control or by a physician trained and qualified in REBOA in direct consultation with the physician who will provide definitive hemorrhage control. In all circumstances, these trained clinicians should be integrated within an appropriate system of care.
- Early common femoral arterial access and continuous blood pressure monitoring should be considered in high-risk patients assuming it does not delay definitive hemorrhage control.[25]
- The major rate-limiting step to REBOA is the ability to safely and efficiently cannulate the common femoral artery (CFA) in a hypovolemic patient.[26] If feasible, ultrasound-guided percutaneous access is the preferred method. If percutaneous cannulation is not possible, surgical cutdown is required.
- If the clinical situation permits, rapid confirmation of balloon position by imaging or direct palpation is recommended.[24]
- Smaller diameter sheath devices (<8 French) have been associated with fewer limb complications.[27 28]
- Inflation in the distal thoracic aorta (Zone 1) is used for control of severe intra-abdominal or retroperitoneal hemorrhage.
- Inflation in the distal abdominal aorta (Zone 3) is used for patients with severe isolated pelvic, junctional, or proximal lower extremity hemorrhage not amenable to a tourniquet.
- Every effort should be made to limit aortic occlusion time when proceeding to definitive hemorrhage control. Occlusion time should be carefully monitored.
- Zone 1 REBOA should not be used if patients cannot proceed expeditiously to a definitive hemorrhage control procedure within 15 min. Total aortic occlusion times greater than 30 min are associated with increased ischemic complications and risk of mortality.[15 23 29 30]
- Zone 3 REBOA may be tolerated for longer periods of time and may be used as an adjunct to management of pelvic fracture bleeding including angioembolization and/or pelvic packing, and/or stabilization. Once Zone 3 occlusion has been performed, patients should proceed expeditiously to definitive hemorrhage control. Although the maximum acceptable occlusion time for Zone 3 is unknown, the system should target less than 30 min, but no greater than 60 min of total occlusion time.
- Partial occlusion or intermittent deflation/inflation of the balloon is used at some experienced REBOA centers to minimize complete occlusion time. This is difficult to achieve without continuous monitoring of the blood pressure, both above and below the balloon, along with clinical assessment of the rate of bleeding.[31] There is presently insufficient data to guide this practice.
- Once aortic occlusion has been performed, urgent operative or catheter-based hemostasis should occur and the balloon deflated as soon as possible.
- The team caring for the patient must anticipate and be prepared to manage the complications of ischemia reperfusion injury at the time of balloon deflation, which can be profound and lead to cardiovascular collapse.[32]
- Vigilant assessment of lower extremity perfusion must occur before, during, and after aortic occlusion and sheath removal. This monitoring must continue for at least 24 hours after sheath removal. As the clinical situation permits, a lower extremity angiogram should be performed prior to leaving the operating room or endovascular suite. Formal vascular evaluation should be performed for any angiographic or clinical perfusion abnormality and mitigating intervention or repair performed as necessary.
- The sheath should be removed as soon as feasible.

SYSTEMS OF CARE

- Safe and responsible REBOA implementation requires constant communication among the entire team especially during active resuscitation and transition of the care team.

All members of the healthcare team need education on REBOA principles and management.

- Prior to introduction of a REBOA program, thoughtful and careful consideration of trauma center and system capabilities should be evaluated. Systems should be optimized for rapid access to definitive hemorrhage control. Protocols should be developed to define REBOA use and review of compliance with those protocols conducted at regular intervals.[12] Systems which cannot initiate definitive hemorrhage control within the above recommended times should not use REBOA.

INTERFACILITY TRANSPORT

- Due to the lack of evidence to support safe duration of aortic occlusion, interfacility transfer of patients with REBOA is not recommended. In general, REBOA should not be placed in institutions where the patient cannot receive definitive surgical care and hemostasis at the same institution.
- In *extremely rare* circumstances in which patients with REBOA have immediate access to transportation and where the system can meet the time targets for aortic occlusion to initiation of definitive hemorrhage control (<15 min for Zone 1,<30 min for Zone 3) interfacility transfer may be considered. In this situation, protocols must be developed to ensure training of transport personnel, seamless communication among centers, and direct access to hemorrhage control at the receiving facility. This should include a direct-to-OR/IR policy, bypassing the emergency department.

PREHOSPITAL USE OF REBOA

- Due to the limited evidence to support the safe duration of aortic occlusion, the difficulty in identifying in the prehospital environment the appropriate patient for REBOA, and the uncertainty of the safety of prehospital REBOA placement for both the patient and the care team, the general adoption of prehospital placement of REBOA in the USA is not recommended. Delays in transport and definitive hemorrhage control are life-threatening and emphasis should remain on en-route resuscitation and rapid transport to definitive care.
- The limited existing experience with prehospital REBOA (case reports only) involves systems with physician-led teams outside of the USA. This does not directly translate to the majority of current US EMS systems.
- Prehospital REBOA should only be considered in the *extremely rare* circumstance in which a physician experienced in REBOA placement is on scene and the EMS system in partnership with the trauma system can meet the recommended time windows from aortic occlusion to the initiation of an in-hospital definitive hemorrhage control procedure (<15 min Zone 1,<30 min Zone 3). Ideally, this should only occur as part of a clinical trial where such patients would be entered into a database to capture time to definitive treatment and outcomes.

SPECIAL CIRCUMSTANCES: DEPLOYED MILITARY SETTINGS

- The battlefield continuum of care has unique and distinct considerations. Capabilities along this care continuum have been moved closer to the point of injury. The US military's use of REBOA is guided by the JTS guidelines to include the REBOA Clinical Practice Guidelines and the Advanced Resuscitative Care (ARC) Guidelines.[33 34] The JTS guidelines are reflective of the unique battlefield environment and military trauma system; the ARC guidelines are very prescriptive about the use of REBOA to include physician-led teams and resuscitation with whole blood prior to considering the use of REBOA.[35]
- Although military experiences have helped to guide the development of REBOA use in the civilian setting, the military experience cannot be directly translated to the civilian environment. Further analysis of data from the US military experience, including longitudinal data from all phases of care, will support evaluation of the impact on outcome. Ongoing military–civilian collaborations will help inform an improved understanding of the optimal role of REBOA.

REBOA TRAINING

- Training for REBOA implementation is important for all members of the care team.
- Physicians who will be responsible for placing REBOA should receive comprehensive didactic and hands-on skills training in all aspects of the procedure.
- Didactic training includes the following topics: patient selection; anatomy and physiology of REBOA; complications of REBOA and management of these complications; management of the catheter; management of the patient from the point of aortic occlusion to balloon deflation and the immediate postoperative phase; limb assessment; sheath management and establishing an appropriate system of care to support REBOA use and its complications.
- Skills training can be achieved through various means, including high-fidelity simulation, perfused cadaver or live tissue training. Critical skills include: ultrasound-guided percutaneous access to the CFA along with surgical cutdown as needed, sheath and device management, appropriate positioning of the catheter, management of inflation volumes, and avoiding catheter migration.
- Anatomically correct models are critical to support training for CFA access, which is the rate-limiting step in REBOA placement. Perfused cadavers are currently the best option to meet this requirement.
- There are a number of training courses that may meet these requirements. Course directors should have significant clinical experience with the use of REBOA. Courses should include evaluation of knowledge acquisition and skill proficiency. Ideally, courses should assess skill retention over time.
- Prior to the implementation of a REBOA program, team-based training in the care environment where these complex patients will be managed is essential.

CREDENTIALING

- Each institution and department is responsible for analysing qualifications for providers to perform REBOA.
- Comprehensive training programs as outlined above are recommended for providers responsible for performing REBOA.
- Given that this procedure may be rarely performed by an individual physician, in depth initial training and a skill sustainment training is recommended.

QUALITY ASSURANCE (QA) & PERFORMANCE IMPROVEMENT (PI)

- Given that REBOA use is an uncommon, high-risk procedure, and the benefits of REBOAare as yet unproven, monitoring of patient safety and performance improvement arecritical.

- There should be a strong Trauma QA program at each institution evaluating eachplacement of REBOA for (1) appropriateness of patient selection, (2) complications ofREBOA, (3) timeliness of definitive hemorrhage control.Provider performance and skill maintenance should be monitored by the Trauma QAprogram.
- Defining the optimal use of REBOA requires rigorous and complete data acquisition,including: details of patient characteristics, physiology, timeliness of access to definitivehemorrhage control, device and access complications, aortic occlusion time, and clinicaloutcomes.
- In order to support PI, all REBOA procedures should be coded in the trauma registryusing ICD 10 procedure codes. Institutions performing REBOA are encouraged to submitdata to national registries and multicenter trials.

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