Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock

Original Release/Approval		16 Jun 2014	Note: This CPG requires an annual review.	
Reviewed:	05 May 2014	Approved:	16 Jun 2014	
Supersedes:	**This is a new CPG and must be reviewed in its entirety.**			
☐ Minor Changes (***or)***	☒ **Changes are substantial and require a thorough reading of this CPG (or)**			
☐ Significant Changes				

1. **Goal**. Review background, explain rationale, establish indications, itemize resources, and describe technique for Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an interventional capability for control of hemorrhagic shock in the setting of uncontrolled truncal and extremity bleeding in surgically capable theater facilities. This Clinical Practice Guideline has been substantially adapted from the Stannard, Eliason, and Rasmussen 2011 publication in the Journal of Trauma.[1]

2. **Background**. Truncal hemorrhage is the leading cause of preventable death on the battlefield. Balloon occlusion as a resuscitative adjunct is not a new or novel intervention. This technique was described as a resuscitative intervention by Hughes in 1954 in the review of three cases in which it was utilized in three moribund casualties undergoing what was then the convention of pre-operative resuscitation prior to laparotomy for trauma in the setting of combat injury with the goal of improving coronary perfusion and stabilizing the shock state. Since this publication, REBOA has been described as an adjunct in the setting of hemorrhagic shock as a selective alternative to thoracotomy with aortic compression in a number of animal and human applications. Despite its potential advantage over resuscitative thoracotomy for the control of hemorrhage it has not, heretofore, been widely adopted. With increasing practice experience and improved technology for endovascular therapy, it has been applied in the setting of emergent control of hemorrhage associated with abdominal aortic aneurysm. Given that: (1) the skill and technology for application of this technique are available in theater; and (2) it provides a less invasive and expedient means to control life threatening hemorrhage in appropriately selected casualties, this intervention is recommended as an adjunct to control life-threatening hemorrhage in the setting of truncal and extremity injury.

3. **Rationale and Indications**. Hemorrhage leads to cardiovascular collapse and death unless myocardial and cerebral perfusion can be maintained. Non-Compressible Torso Hemorrhage (NCTH) is defined as hemorrhage arising from trauma to the torso vessels, pulmonary parenchyma, solid abdominal organs and disruption of the bony pelvis. In the setting of NCTH resulting in hypotension or shock, external cardiac compression has not proven beneficial. Rather, resuscitative aortic occlusion for NCTH mitigates hemorrhage and increases afterload and central aortic pressure until hemostasis can be achieved.

   Resuscitative aortic occlusion (RAO) has traditionally required a thoracotomy or a laparotomy for aortic exposure. For trauma patients in extremis, this procedure occurs in the resuscitation bay where a left thoracotomy and direct aortic compression are performed to

evaluate and treat reversible causes of cardiovascular collapse. The resuscitative thoracotomy has a high mortality rate, significant potential for casualty and trauma team morbidity, and high resource utilization, due largely to the nature of the injuries leading to arrest. Nonetheless, data from theater indicate that there is a reasonable probability of long-term survival and recovery following RAO in appropriately selected casualties as described in the US CENTCOM Emergent Resuscitative Thoracotomy Clinical Practice Guideline.

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an alternative to resuscitative thoracotomy. REBOA is performed using transfemoral arterial access to facilitate aortic occlusion and allow both monitoring and support of the central circulation in patients at risk of imminent cardiovascular collapse. Animal studies have demonstrated the benefit of REBOA in shock with occlusion times of up to 90 minutes.

This clinical practice guideline reviews the range of accepted management approaches to profound shock and post-traumatic cardiac arrest and establishes indications to consider REBOA as a hemorrhage control adjunct. The specific management approach—within the parameters of mission, resources, and tactical situation—will depend on the casualty's physical location, mechanism and pattern of injury, and the experience level of the surgeon. The optimal management strategy is best determined by the surgeon at the bedside.

Traumatic Arrest & Profound Shock

Initial Management

Cardiac arrest in combat injury is most often caused by exsanguination. Initial management priorities include early control of hemorrhage and hemostatic resuscitation as described in the US CENTCOM Damage Control Resuscitation Clinical Practice Guideline. Closed chest cardiac massage has little benefit if the intravascular space is empty. Thus, the initial focus in patients who present without a pulse must be to determine the following:

1. Mechanism and pattern of injury
2. Duration of CPR
3. Presence of a pulse
4. Presence of an organized, narrow complex cardiac rhythm and/or organized cardiac activity by FAST exam

Based on this data, a decision either for or against RAO can be made using the algorithm presented in APPENDIX A. If RAO is to be performed, closed chest cardiac massage can continue while the surgeons are preparing for this procedure. If RAO is not to be performed, resuscitative efforts should cease unless there is a compelling reason to consider a non-traumatic arrest.

Early identification of patients who are at risk for profound shock or traumatic arrest is also essential as early application of REBOA prior to impending arrest will lead to improved outcomes (APPENDIX B). Casualties who lost vitals in the field and underwent CPR for some period of time followed by return of spontaneous circulation (ROSC) should be considered high risk for traumatic arrest. In addition, the following indicators of a need for massive transfusion (MT) can indicate others at high risk for profound shock or traumatic arrest:

SBP <90	T<35.5
HR >120	INR >1.5
Positive FAST	Base Deficit >6
Penetrating mechanism	Hgb <11

Resuscitative Thoracotomy

Aortic occlusion is best performed through a left anterolateral thoracotomy. See US CENTCOM Emergent Resuscitative Thoracotomy Clinical Practice Guideline.

Trans-abdominal Aortic Occlusion

The aorta can also be occluded trans-abdominally at any point along its length. It can be occluded with either application of a clamp or compression with a retractor or manually. In obese patients with a large volume of hemoperitoneum or other intra-abdominal pathology, a trans-thoracic approach to the aorta is sometimes preferable. As with all other forms of aortic occlusion, restoration of aortic perfusion should be carefully coordinated with the rest of the team to minimize the effects of re-perfusion and blood volume shifts.

REBOA

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an alternative approach to resuscitative thoracotomy in some cases of traumatic arrest. Furthermore, an endo-aortic balloon can be placed preemptively in patients with high-risk injury patterns and unstable physiologic parameters as described above. In this way, REBOA can be proactive rather than reactive in the appropriately selected patient. The indications for REBOA are summarized in APPENDIX A for traumatic arrest and APPENDIX B in cases of profound shock.

4. **Resources and Technique**. This section is transferred directly from the Stannard, Eliason, and Rasmussen 2011 publication that appears in the Journal of Trauma (see references).

   To simplify, this maneuver can be considered in the following five steps each with specific technical considerations:

   1. Arterial access and positioning of sheath
   2. Selection and positioning of the balloon
   3. Inflation of the balloon
   4. Deflation of the balloon
   5. Sheath removal

STEP 1: ARTERIAL ACCESS AND POSITIONING OF INITIAL SHEATH

Establishing Arterial Access

Access to the arterial circulation for REBOA for trauma should be obtained through the femoral artery using one of three techniques: percutaneous, open exposure (i.e., cut down), or exchange over a guide wire from an existing femoral arterial line. Percutaneous access is

now commonly accomplished under ultrasound guidance using the same probe applied for the focused abdominal sonography for trauma examination. A linear array transducer is superior to a curvilinear transducer. Ultrasound or direct surgical identification of the femoral artery lateral to the vein is especially important in the hypotensive patient without a palpable pulse. Once identified, the artery should be entered at a 45-degree angle with a hollow 18-gauge needle through which a 0.035-inch wire can be passed. After the wire has been passed into the artery, the needle is removed and a small incision made at the interface of the wire and the skin. A 10- to 15-cm long vascular introducer sheath will then be positioned in the femoral and external iliac artery. The sheath is placed over the wire into the artery. It is important that any time a sheath is passed over a wire into the arterial system, the sheath's internal dilator is firmly in place to allow a smooth reverse taper from the wire to the diameter of the sheath. Once the dilator and sheath have been advanced over the wire through the skin into the artery, the dilator is removed leaving the sheath as a working port through which other maneuvers can be accomplished. To avoid bleeding from the side port of the sheath after the dilator is removed, it is important that the operator assure that the stopcock is in the "off" position to the patient.

Selection and Positioning of Initial Sheath

Common initial sheaths are 5 Fr to 8 Fr and come in lengths from 8 cm to 15 cm. As long as the operator is confident that the femoral artery has been accessed and the 0.035-inch starter wire passes without resistance, placement of this short sheath can be accomplished. As noted, the initial sheath can also be placed after removing an existing arterial line over a wire (i.e., "rewiring"). This maneuver is accomplished by placing a wire greater than 2X the length of the existing arterial catheter through its inner lumen allowing the catheter to be removed over the wire while maintaining arterial access. After a larger opening is created at the wire/skin interface, the short working sheath with its internal dilator in position can be inserted over this wire as previously described.

STEP 2: SELECTION AND POSITIONING OF THE BALLOON

Selection of a Balloon

A balloon inflated inside the aorta to occlude flow must be soft or compliant and of large diameter. It is critical that stiff or noncompliant balloons be avoided in this scenario as their inflation inside of the aorta poses a higher risk of damage including dissection or rupture. Examples of compliant balloons with their range of diameter and required sheath sizes are as follows (1) Coda balloon (Cook Medical): 32 mm to 40 mm, 14 Fr; (2) Reliant balloon (Medtronic): 10 mm to 46 mm, 12 Fr; and (3) Berenstein balloon (Boston Scientific): 11.5 mm, 6 Fr. The balloon which has greatest application to the theater of operations is the Coda as it would be very unlikely for combat casualties to have ectactic aortas.

Positioning of the Balloon (Zones of the Aorta)

To select the most appropriate compliant balloon, the user needs to decide which aortic zone is to be occluded. Aortic zones can be considered I, II, and III spanning from cranial or proximal to caudal or distal (APPENDIX C). Zone I is the descending thoracic aorta between the origin of the left subclavian and celiac arteries. Zone II represents the paravisceral aorta

between the celiac and the lowest renal artery and zone III the infrarenal abdominal aorta between the lowest renal artery and the aortic bifurcation. In most instances of shock and pending cardiovascular collapse, the aim will be to position the compliant balloon to occlude zone I. In this case, a longer sheath will be advanced into the thoracic aorta. REBOA in zone I requires a longer sheath (45–60 cm) to be positioned in the descending thoracic aorta to support or hold the balloon against aortic pulsation once it is inflated. Inflation of a compliant balloon in aortic zone III may provide specific utility in cases of pelvic or junctional femoral hemorrhage. Because the aortic bifurcation will support or hold the inflated balloon against pulsation, this maneuver can be accomplished using a large diameter but shorter (10–15 cm) sheath.

Wire Control and Positioning of the Large Sheath and Balloon

Positioning of the balloon in the aorta must take place over a 0.035-inch wire and through an appropriately sized sheath (diameter and length). The sheath through which the balloon will be introduced takes the place of the previously described initial sheath. To accomplish this maneuver, a 260-cm long, 0.035-inch wire (e.g., Amplatz Stiff Wire Guide; Cook Medical) (Table 2) should be inserted through the initial sheath in the femoral artery. The wire should be advanced carefully such that the floppy tip is in the distal aortic arch. If time permits this should be done under fluoroscopic guidance, otherwise measure the distance from the femoral head to a point halfway between the 12th rib and the medial clavicular head, and mark the wire and sheath with this length. The extent of the wire outside of the sheath at this point should be noted and marked so that the wire is not advanced or withdrawn significantly (_5 cm). Failure to maintain control of the wire's insertion depth during this and subsequent maneuvers may result in inadvertent injury to coronary or cerebral vessels if it is advanced too far or inability to advance the balloon to the occlusion zone if it is withdrawn. At this stage, the small diameter sheath in the groin should be removed and backed off of the wire with pressure held proximally over the femoral artery for hemostasis. Once the sheath clears and is removed from the end of the wire, the larger sheath led by its internal dilator is advanced over the stiff wire through the skin opening and into the femoral and iliac artery. This maneuver plugs the opening of the femoral artery and allows the operator to stop and ready him or herself for the next step. It is important to emphasize that as sheaths or balloon catheters are advanced over this wire, the wire itself does not change its position (i.e., is not advanced or withdrawn more than 3–5 cm). To accomplish this, the fingers grasping or "pinning" the wire are held fixed against the patient's leg with the wire straight and taut. In this position, the wire acts as a rail over which the large sheath or balloon catheter can be advanced or withdrawn as the operator focuses on the fluoroscopic image. To occlude zone I, the larger, longer sheath should be advanced over the stiff wire under fluoroscopic guidance if time permits, otherwise use the above measurements for placement into the thoracic aorta to the desired location of occlusion. Zone I can be estimated to extend from the medial head of the clavicle to the 12th rib. Next, the internal dilator should be removed from the sheath and the back end of the extended wire. To avoid significant bleeding after the internal dilator is removed, it is important that the stopcock on the side port of the sheath is in the "off" position to the patient. The balloon is next loaded on and advanced over the stationary wire into and through the sheath. Once the balloon advances from the end of the sheath, it is ready to be inflated. If possible, this should also be done under fluoroscopic guidance, however,

deploying it at a length 5cm longer than the sheath will allow the balloon to be deployed. After the balloon is inflated its position must be confirmed with a radiologic study ensuring its location and occlusion of the aorta. It is worth repeating that these steps (advancing the sheath and the balloon catheter) must be done with care not to advance or withdraw the wire. To occlude zone III requires a large diameter but shorter sheath (10–25 cm) to allow passage of the balloon into the terminal aorta. The concept in this scenario is that once the balloon is inflated, any aortic pulsation will push the balloon to the terminal aorta and its bifurcation. If possible this should also be done under fluoroscopic guidance, otherwise measure from the femoral head to 5-7cm above the umbilicus and deploy the balloon. Position should be confirmed radiologically after the balloon is inflated if fluoroscopy is not used for placement.

STEP 3: INFLATION OF THE BALLOON AND SECURING OF THE APPARATUS

Inflation of the Balloon

A large-volume syringe (usually 30–60 mL) is filled with a 1⁄2 and 1⁄2 solution of sterile saline and iodinated contrast. This mixture allows visualization of the balloon inflation as well as more rapid inflation and deflation times by reducing viscosity. The balloon is inflated until the outer edges of the balloon change from convex to parallel as the balloon takes on the contour of the aortic wall, this should be confirmed radiologically. One may notice that during systole, the balloon will change shape and create a “mushroom cap” as it is pulsed inferiorly. In zone I occlusion, the previously positioned long sheath can then support the balloon and maintain its position within the aorta. When inflation appears adequate to gain aortic wall apposition and augment central blood pressure, the three-way stopcock on shaft of the balloon should be turned off toward the balloon to maintain inflation and occlusion while other maneuvers are undertaken.

Securing the Inflated Balloon, Sheath, and Wire Apparatus

It will next be important to hold the balloon, sheath, and wire securely so that none change position as the central aortic pressure returns pushing the balloon caudal. Although the balloon, sheath, and wire can be secured with sutures or an occlusive dressing that pin the apparatus to patient, these need to be observed continuously to assure no downward or caudal migration. If zone I REBOA is accompanied by a return of a central aortic pressure, the most reliable way to keep the inflated balloon, sheath, and wire in the desired location is to assign an assistant the task of holding the apparatus until balloon deflation is desired. This assistant should monitor and communicate the “big three” factors imperative to maintenance of successful REBOA: mean arterial pressure, maintenance of position, and maintenance of occlusion (balloon inflation).

STEP 4: DEFLATION OF THE BALLOON

Communication with the assistant holding the apparatus and the anesthesia team is critical before consideration of balloon deflation. Once a decision to attempt deflation is made, care must be taken to turn the three-way stopcock and deflate the balloon slowly as this step can be anticipated to result in a significant decrease in afterload and hypotension. Generally speaking, the main operator should be the person to deflate the balloon while the identified assistant continues to hold the balloon, sheath, and wire in the desired location. After

prolonged balloon inflation or in situations where incomplete resuscitation has occurred, deflation of the balloon can be expected to result in reperfusion, washout of metabolic byproducts, and acidosis. As such, intermittent balloon inflation and deflation may be necessary until some hemodynamic stability is restored.

STEP 5: REMOVAL OF THE BALLOON AND SHEATH

After REBOA is no longer required, the deflated balloon and wire may be removed from the large sheath which should then be flushed with 100 mL of heparinized saline (1,000 units of heparin in 1 L of saline). The large diameter sheaths required to deploy currently available compliant balloons are best removed with open surgical exposure of the femoral artery. This can be accomplished using a longitudinal or transverse groin incision with dissection through the soft tissues overlying the femoral sheath. The femoral artery proximal and distal to the sheath entry site should be exposed to allow control. Proximally, this often requires dissection for 2 cm to 3 cm underneath the inguinal ligament as an assistant uses a narrow handheld retractor (e.g., short Wylie renal vein retractor) to lift the inguinal ligament off of the femoral sheath. During this maneuver, the surgeon must be mindful of the circumflex iliac veins which course over the top of the distal external iliac and proximal common femoral artery. Exposure distal to the sheath entry site often requires identification and control of both the superficial and profunda femoris arteries. Once proximal and distal exposure and control have been accomplished, the sheath may be removed. The resulting arteriotomy should be closely examined and tailored with Potts scissors if necessary to allow primary transverse closure. Closure of the arteriotomy should be performed using 5-0 or 6-0 permanent monofilament suture in either an interrupted or running fashion with care to capture all layers of the arterial wall with passage of the needle. Before closing the last of the suture, fore bleeding and back bleeding of the arterial segments should be allowed followed by flushing of the surface with heparinized saline. Restoration of flow through the arterial segment can be confirmed using manual palpation for pulses and use of continuous wave Doppler of both the artery and more distal extremity. Closure of the femoral artery exposure is accomplished in layers using absorbable suture in the soft tissues.

5. Performance Improvement (PI) Monitoring.

a. Intent (Expected Outcomes).

1) REBOA is performed only at surgically capable facilities.

2) REBOA is performed in patients in hemorrhagic shock associated with uncontrolled truncal and extremity bleeding.

b. Performance/Adherence Measures.

1) All REBOA interventions in theater are performed at surgically capable MTFs.

2) REBOA was not performed in any patient without signs of shock associated due to hemorrhage.

3) All applications of REBOA are identified to the JTTS TNCs to ensure appropriate capture of data in the JTTS CENTCOM REBOA Data Tool. (See 5.c.2. and APPENDIX D.)

c. Performance Improvement Data Capture and Reporting.

1) DoD Trauma Registry to be customized to capture REBOA as a discreet field.

2) Number of REBOA interventions, performance, and adherence measures will be reported quarterly by Joint Trauma System Performance Improvement Division Director to US CENTCOM Joint Theater Trauma System Director.

a) Performance improvement will be facilitated by use of the JTTS CENTCOM REBOA Data Tool (APPENDIX D.)

b) Pages 1 through 3 of the JTTS CENTCOM REBOA Data Tool are to be completed prior to departure from the CENTCOM AOR.

c) Page 4 is to be completed by a surgeon providing care for the patient at their Level IV or Level V facility.

d) The JTTS TNC at the corresponding Level III in theater is responsible for completing the administrative information on the JTTS CENTCOM REBOA Data Tool. The data tool will also require the input of the attending surgeon at the corresponding Level III.

e) The JTTS Program Manager will keep a password-protected database of patients in whom REBOA has been performed. Digital copies of the JTTS CENTCOM REBOA Data tool will be maintained in a password protected manner along with the database.

f) The JTTS Program Manager will contact the Level IV PI coordinator upon transfer of the patient out of theater. The Level IV PI coordinator will be requested to ensure page 4 of the JTTS CENTCOM REBOA Data tool is scanned and sent to the JTTS Program Manager at jtts_ldrs.mail@swa.army.mil.

g) The JTTS Program Manager will also contact the Level V PI coordinator to serve as a reminder of completion of the JTTS CENTCOM REBOA Data tool is requested to be sent to jtts_ldrs.mail@swa.army.mil.

h) Any correspondence of PHI material is to be transferred in an encrypted manner. Alternatively, the AMRDEC SAFE Transfer file system is to be used to transfer information. https://safe.amrdec.army.mil/safe/Welcome.aspx

d. Data Source.

1) Patient Record

2) Department of Defense Trauma Registry (DoDTR)

e. System Reporting & Frequency.

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Theater Trauma System (JTTS) Director, JTTS Program Manager, and the Joint Trauma System (JTS) Performance Improvement Branch.

6. Responsibilities. It is the responsibility of the Chief, JTS PI Division to ensure system-level compliance with this CPG. It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

7. References.

1. Stannard A, Eliason JL, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. *J. Trauma*. 2011: 71(6): 1869-1872.
2. Hughes CW. Use of an intra-aortic balloon catheter tamponade for controlling intraabdominal hemorrhage in man. *Surgery*. 1954;36: 65–68.
3. Edens JW, Beekley AC, Chung KK, Cox ED, Eastridge BJ, Holcomb JB, et al. Longterm outcomes after combat casualty emergency department thoracotomy. *Journal of the American College of Surgeons. American College of Surgeons*; 2009 Aug;209(2):188–97.
4. Tien HC, Spencer F, Tremblay LN, Rizoli SB, Brenneman FD. Preventable deaths from hemorrhage at a level I Canadian trauma center. *The Journal of Trauma: Injury, Infection, and Critical Care*. 2007 Jan;62(1):142–6.
5. Stannard A, Morrison JJ, Scott DJ, Ivatury RA, Ross JD, Rasmussen TE, et al. The epidemiology of noncompressible torso hemorrhage in the wars in Iraq and Afghanistan. *J Trauma Acute Care Surg*. 2012;00(00):1–5.
6. Mattox K, Feliciano D. Role of external cardiac compression in truncal trauma. *The Journal of Trauma*. 1982;64(1):1–7.
7. White JM, Cannon JW, Stannard A, Burkhardt GE, Spencer JR, Williams K, et al. Direct vascular control results in less physiologic derangement than proximal aortic clamping in a porcine model of noncompressible extrathoracic torso hemorrhage. *The Journal of Trauma: Injury, Infection, and Critical Care*. 2011 Nov;71(5):1278–86; discussion 1286-7.
8. Seamon MJ, Fisher C a, Gaughan J, Lloyd M, Bradley KM, Santora T a, et al. Prehospital procedures before emergency department thoracotomy: "scoop and run" saves lives. *The Journal of Trauma: Injury, Infection, and Critical Care*. 2007 Jul;63(1):113–20.
9. Kidher E, Krasopoulos G, Coats T, Charitou A, Magee P, Uppal R, et al. The effect of prehospital time related variables on mortality following severe thoracic trauma. *Injury*. Elsevier Ltd; 2011 May 10;
10. Burlew CC, Moore EE, Moore F a, Coimbra R, McIntyre RC, Davis JW, et al. Western Trauma Association critical decisions in trauma: resuscitative thoracotomy. *J Trauma Acute Care Surg*. 2012 Dec;73(6):1359–63; discussion 1363–4.

11. Seamon MJ, Fisher C a, Gaughan JP, Kulp H, Dempsey DT, Goldberg AJ. Emergency department thoracotomy: survival of the least expected. *World Journal of Surgery*. 2008 Apr;32(4):604–12.

12. Seamon MJ, Pathak AS, Bradley KM, Fisher C a, Gaughan J a, Kulp H, et al. Emergency department thoracotomy: still useful after abdominal exsanguination? *The Journal of Trauma: Injury, Infection, and Critical Care*. 2008 Jan;64(1):1–7; discussion 7–8.

13. Avaro J-P, Mardelle V, Roch A, Gil C, De Biasi C, Oliver M, et al. Forty-minute endovascular aortic occlusion increases survival in an experimental model of uncontrolled hemorrhagic shock caused by abdominal trauma. *The Journal of Trauma: Injury, Infection, and Critical Care*. 2011 Sep;71(3):720–5; discussion 725–6.

14. Working Group, Ad Hoc Subcommittee on Outcomes AC of S-C on T. Practice management guidelines for emergency department thoracotomy. *J Am Coll Surg*. 2001;7515(01):303–9.

15. Ledgerwood AM, Kazmera M, Lucas CE. The role of thoracic aortic occlusion for massive hemoperitoneum. *J Trauma*. 1976;16:610–615.

16. Gupta BK, Khaneja SC, Flores L, Eastlick L, Longmore W, Shaftan GW. The role of intra-aortic balloon occlusion in penetrating abdominal trauma. *J Trauma*. 1989;29:861–865.

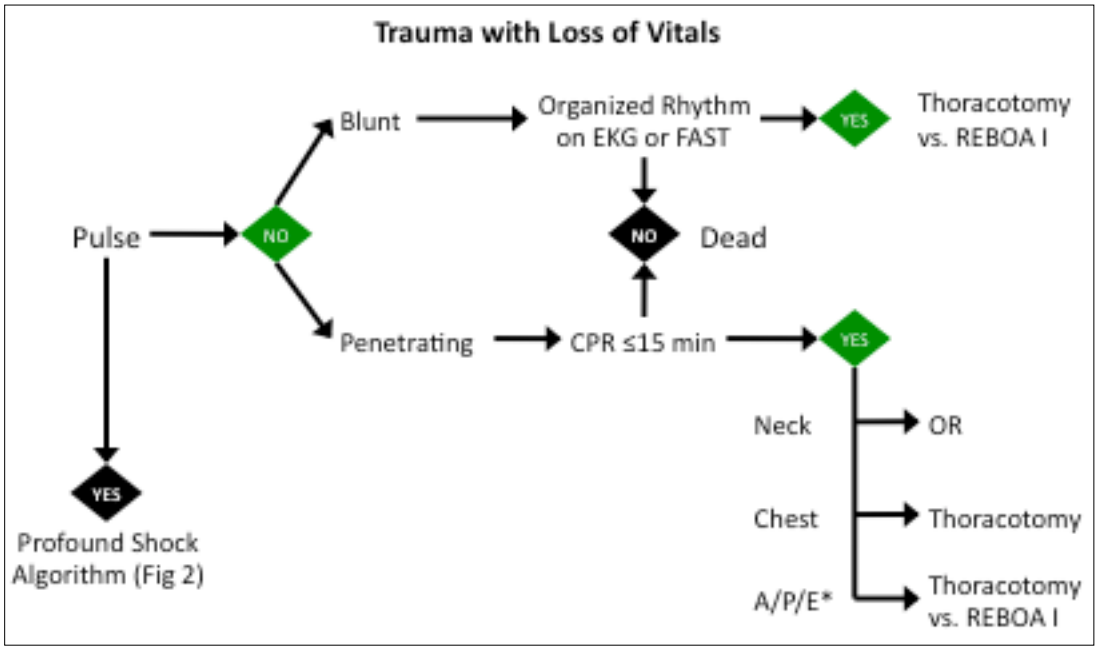
17. White JM, Cannon JW, Stannard A, Markov NP, Spencer JR, Rasmussen TE. Endovascular balloon occlusion of the aorta is superior to resuscitative thoracotomy with aortic clamping in a porcine model of hemorrhagic shock. *Surgery*. 2011;150:400–409.

18. Avaro JP, Mardelle V, Roch A, et al. Forty-minute endovascular aortic occlusion increases survival in an experimental model of uncontrolled hemorrhagic shock caused by abdominal trauma. *J Trauma*. 2011;71: 720–725.

19. Martinelli T, Thony F, Declety P, et al. Intra-aortic balloon occlusion to salvage patients with life-threatening hemorrhagic shock from pelvic fractures. *J Trauma*. 2010;68:942–948.

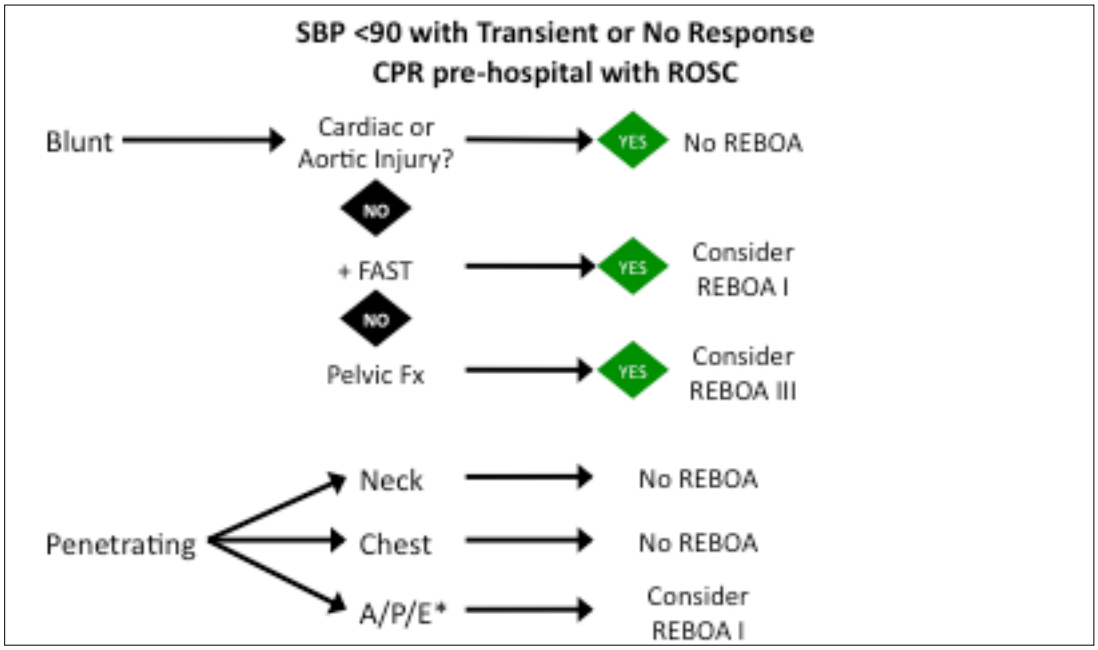
Approved by CENTCOM JTTS Director, JTS Director and CENTCOM SG

APPENDIX A TRAUMATIC ARREST ALGORITHM



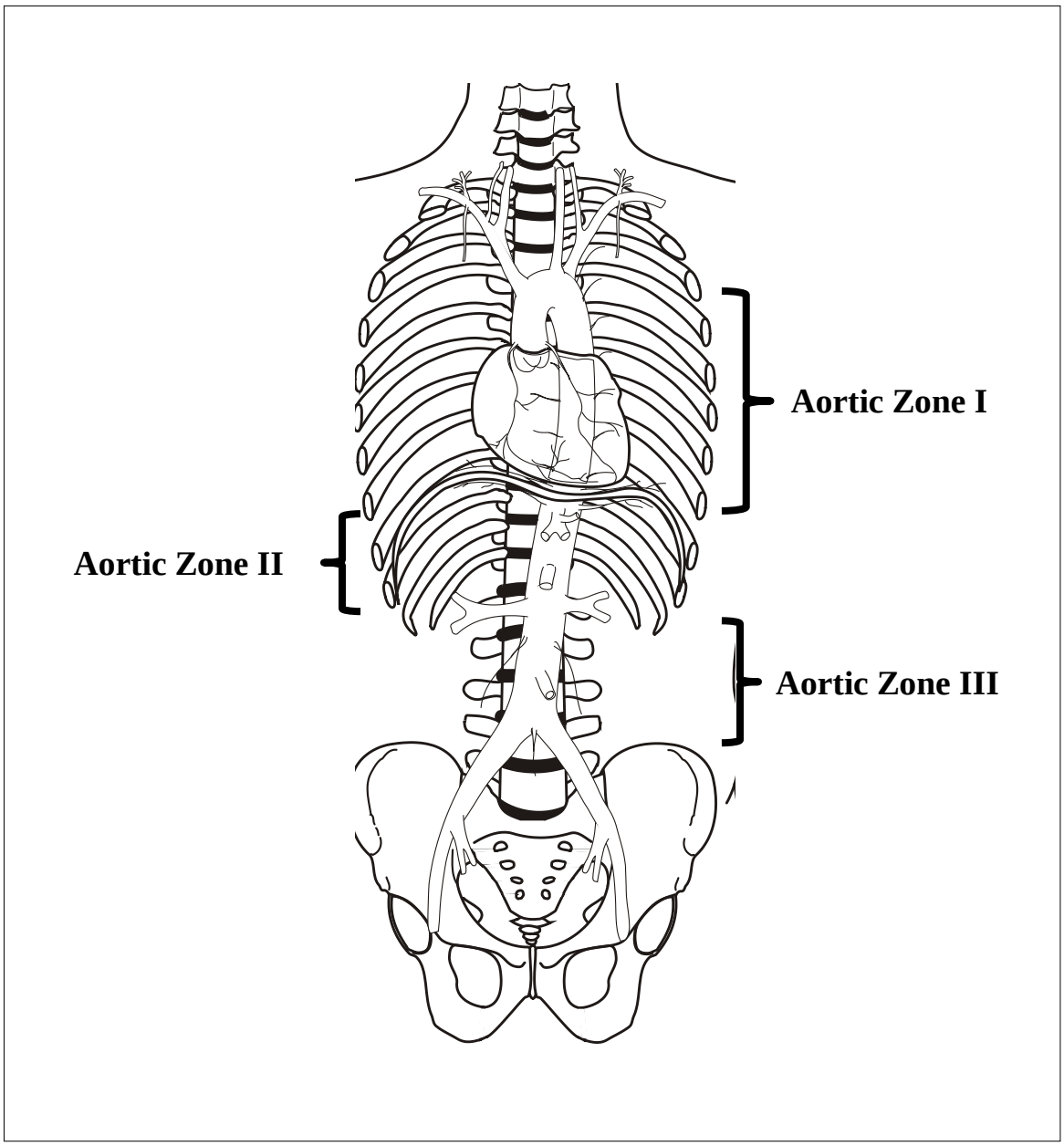
*Abdomen/Pelvis/Extremity; REBOA I=Placement of aortic balloon in the thoracic aorta (2-8 cm above the xyphoid)

APPENDIX B ALGORITHM FOR THE MANAGEMENT OF PROFOUND SHOCK



*Abdomen/Pelvis/Extremity; ROSC, Return of Spontaneous Circulation; REBOA I Placement of aortic balloon in the thoracic aorta (2-8 cm above the xyphoid); REBOA III Placement of aortic balloon directly above the aortic bifurcation (1-2 cm above the umbilicus)

APPENDIX C AORTIC ZONES



APPENDIX D JTTS CENTCOM

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Data Tool

(Imported from AORTA) Page 1 of 4

Patient: _____ Location: ___BAF ___KAF ___BAS ___Role 2, Specify Role 2_____

Date/time of Injury: _____ Time of arrival to REBOA MTF: _____

Age (years): _____ Gender: _____ Height (inches): _____ Weight (lbs.): _____

Known prior history of peripheral vascular disease? _____Yes _____No

1st MTF from POI: _____Yes _____ No If yes, sending MTF: _____

Injury Data

Mechanism Classification (Check one): _____Penetrating _____Blunt

Mechanism Type (Check **most** appropriate):

_____Mounted IED _____Dismounted IED

_____Gunshot Wound _____Stab Wound

_____Motor vehicle accident _____Motorcycle accident

_____Auto vs. pedestrian _____Fall

POI Vitals

First SBP: _____ First HR: _____ First GCS: _____

Prehospital CPR required? _____Yes _____No

Time from injury to first MTF (in minutes): _____

REBOA MTF Admission Physiology / Data

SBP: _____ HR: _____ GCS: _____ Temperature: _____

Presence of other signs of life? (Check all that apply):

_____Pupillary Response _____ Organized Rhythm on Monitor _____Spontaneous Movement

CPR in progress on arrival? _____Yes _____ No

Total duration of CPR (Prehospital and hospital, in minutes): _____

Admission Labs:

Hgb: _____mg/dL INR: _____ pH: _____ Base deficit +/-:_____ Lactate: _____mg/dL

REBOA Initiation Data

Where did initial REBOA attempt take place? (Check one): _____ED _____OR _____IR

Type of AO initially attempted? (Check one): _____ Open _____ Endovascular

Was active CPR ongoing during initial AO attempt? _____Yes _____ No

Physiology at time REBOA procedure initiated:

SBP: _____ HR: _____ GCS: _____

Who was the **PRIMARY** performer (**SENIOR** member directly involved in hands on conduct)? (Check one):

_____Trauma / Acute Care Surgeon _____Vascular Surgeon

_____Interventional Radiology _____Emergency Medicine

_____General Surgeon

Who was assisting **PRIMARY** performer?

_____Trauma / Acute Care Surgeon _____Vascular Surgeon

_____Interventional Radiology Attending _____Emergency Medicine

_____General Surgeon

JTTS CENTCOM REBOA Data Tool, Page 2 of 4

REBOA Technical Features

Access Site (Check one): _____Femoral _____ Brachial / Axillary _____Other, Specify: _____

Side (Check one): _____Right _____Left

Technique utilized to achieve arterial access (Check one):

_____Ultra-sound guided

_____Fluoroscopic guided

_____Percutaneous using external landmarks and palpation

_____Cut-down to facilitate direct visualization and access

Initial catheter diameter size (Check one):

_____4 French _____5 French _____Other, Specify: _____ French

Was initial catheter upsized? _____Yes _____No

Final catheter / sheath diameter utilized for balloon occlusion (Check one):

_____11 French _____12 French _____ Other, Specify: _____French

Type of balloon AO device utilized (check one):

_____Coda _____ Coda Stat _____Reliant _____Other, Specify: _____

What imaging was utilized to facilitate positioning of balloon for AO (Check one)?

_____None, blind insertion using external landmarks only

_____Ultrasound

_____Plain Film

_____C-Arm Fluoroscopy

_____Formal Angiography Suite

_____Hybrid Operating or Resuscitation Room (THOR/ RAPTOR)

Where was balloon deployed (Check one)?

_____Zone 1 (Origin of left subclavian artery to the celiac artery}

_____Zone 2 (Celiac artery to the lowest renal artery)

_____Zone 3 (Lowest renal artery to the aortic bifurcation)

Was successful AO achieved? _____Yes _____ No

Was balloon migration observed? _____Yes _____ No _____Not applicable (blind inflation)

Was conversion to open AO required? _____Yes _____ No

Response to REBOA

Were hemodynamics improved with AO? _____Yes _____ No

Was hemodynamic STABILITY (SBP consistently above 90 mm/Hg) with AO? _____Yes _____ No

Within **first 5 minutes** after AO, what was the physiologic response **(Best values)**?

SBP: _____mm/Hg HR: _____bpm GCS: _____

Duration of initial AO (by balloon inflation or clamp time, in minutes): _____ mins

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Timing of REBOA Phases (All Values in MINUTES from TIME of MTF Arrival)

Admission to **start** of AO procedure (arterial access for endovascular, skin incision for open): _____

Admission to **successful aortic occlusion** (by balloon inflation or clamp): _____

Admission to **hemodynamic stability** (SBP>90 consistently, if achieved; blank if not): _____

Admission to **definitive hemorrhage control** (via IR, ex-fix, or ex-lap/surgery): _____

Was an uncontrolled bleeding source ABOVE the aortic occlusion ultimately identified? _____Yes _____ No

What was the source of the predominant source of hemorrhage (Select most appropriate):

_____Arterial source _____Venous source _____Unclear

HOSPITAL COURSE / COMPLICATIONS / OUTCOMES

Additional procedures required during 1st 24 hours of hospitalization (Check all that apply):

_____Pelvic binder	_____Exploratory laparotomy	_____Hepatic packing
_____Pelvic packing	_____Hepatic resection	_____Splenectomy
_____Bowel resection	_____Craniectomy / Craniotomy	_____Pelvic external fixation
_____Embolization of the liver	_____Embolization of the spleen	_____Embolization of the pelvis
_____Thoracotomy (for intervention other than AO)		_____Lung resection (lobectomy or greater)

_____Cardiac repair. If yes, which location (Select all that apply):

_____Left Ventricle _____Right Ventricle _____Left Atrium _____Right Atrium

Resuscitation Requirements FIRST 24 HOURS

Packed red blood cells (units): _____

Fresh frozen plasma (units): _____

Platelets (Total packs: i.e., one six pack = 6): _____

Cryoprecipitate (units): _____

Total crystalloids (liters) required 1st 24 hrs: _____

Vasopressors required 1st 24 hours: _____

Factor VIIa given? _____Yes _____ No

Tranexamic acid (TXA) given? _____Yes _____ No

Lab values 1st 24 Hours

Lowest Hgb: _____mg/dL

Highest INR: _____

Lowest Base Deficit - / + _____

Lowest pH: _____

Highest Lactate: _____ mg/dL

COMPLICATIONS

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Level IV and Level V

General Complications (Check all that apply):

_____Acute kidney injury requiring dialysis
_____Acute Kidney injury NOT requiring dialysis
_____ALI or ARDS
_____Bacteremia
_____Pneumonia
_____Sepsis or Septic Shock
_____Stroke / CVA
_____Paraplegia
_____Myocardial infarction
_____Multi-organ dysfunction (MODS)
_____Neuro deficit secondary to spinal cord ischemia

Local access site complications, related to Endovascular AO Access Site Only (Check all that apply):

_____Hematoma
_____Pseudoaneurysm
_____Arteriovenous fistula
_____Extremity ischemia
_____Stenosis
_____Distal embolism
_____Infection requiring antibiotics only
_____Infection requiring surgical Intervention
_____Need for patch angioplasty
_____Need for arterial bypass
_____Need for amputation

OUTCOMES

Ventilator Days: _____ Intensive Care Unit Length of Stay (days): _____

Hospital Length of Stay (days): _____ Discharge GCS: _____

Discharge GOS: _____

Discharge Disposition (Check one): _____**Rehab/Nursing Facility** _____**Home** _____**Mortality**

In-MTF Mortality? _____Yes _____ No (Mortality Hospital Day: _____)

DoDTR Data

Injury Scores

ISS: _____

Head AIS: _____

Chest AIS: _____

Abdomen AIS: _____

APPENDIX E
ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

1. **Purpose**. The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

2. **Background**. Unapproved (i.e., "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

3. **Additional Information Regarding Off-Label Uses in CPGs**. The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

4. **Additional Procedures**.

   a. Balanced Discussion. Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

   b. Quality Assurance Monitoring. With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

   c. Information to Patients. Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.