JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Emergent Resuscitative Thoracotomy (ERT) (CPG ID: 20)

Summarizes recommendations and technique for ERT in a Military Treatment Facility (MTF) in a combat or operational environment. The primary goal is to rapidly identify and correct any life threatening pathology and to provide care that results in a survivor with a meaningful level of function and cognition.

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SUMMARY OF RECOMMENDATIONS & GUIDELINES *

Emergency Resuscitative Thoracotomy (ERT) is a potentially lifesaving intervention for patients who develop or have impending post-injury cardiovascular collapse or full arrest from a potentially reversible cause. While Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) can be considered as an alternative in the absence of thoracic bleeding, there are still several indications for which ERT is a preferred or equivalent option.

The purposes of this procedure are:

- Control of intrathoracic hemorrhage

- Release of cardiac tamponade

- Internal cardiac massage

- Aortic occlusion to control infra-diaphragmatic hemorrhage and maximize cerebral and coronary perfusion.

Consider the following before performing ERT:

1. ERT should only be performed only at a forward military treatment facility with surgical and resuscitation capability (typically Role 2 or higher) and by individuals familiar with and trained in this procedure.

2. Absolute indications for ERT in the combat/operational environment include:

   - Penetrating truncal/extremity trauma with recent loss of vitals (less than 15 minutes) or impending cardiac arrest.

   - Blunt truncal/extremity trauma with pre-hospital vital signs and either witnessed arrest after arrival or refractory shock with impending cardiac arrest.

3. Additional relative indications for ERT in the combat/operational environment include:

   - Penetrating or blunt truncal/extremity trauma with pre-hospital arrest but with signs of life on arrival (narrow complex EKG rhythm and/or organized cardiac contractile activity on ultrasound)

   - Potentially salvageable blunt or penetrating cranial injury with vital signs and then arrest after arrival or impending arrest (uncommon)

4. ERT should NOT be performed for blunt trauma with arrest before arrival and with no signs of life (absent organized narrow complex EKG rhythm and/or organized contractile activity on cardiac ultrasound.)

5. ERT should NOT be performed during multiple or mass casualty (MASCAL) events or when performance will expend critical resources (such as blood products/surgeons/ORs) needed more salvageable patients.

6. The critical steps of an ERT include identification and release of tamponade, control of major thoracic hemorrhage, initiation of open cardiac massage, and cross-clamping the descending aorta.

7. The performance of a simultaneous right anterolateral thoracotomy or extension to a "clamshell" thoracotomy is indicated for evidence of right thoracic or mediastinal injury not reached from the left side.

8. Critical adjuncts to a successful ERT include adequate IV or IO access, endotracheal intubation, initiation of damage control resuscitation, and placement of an oro/naso-gastric tube.

9. For the patient with impending arrest, if immediate or direct transfer to the OR is available then this should be strongly considered versus performing an ERT in the resuscitation area.

10. All necessary equipment/supplies for ERT should be packaged together and stored in an easily accessible location in the resuscitation area, and should be regularly inspected and replaced/replenished as needed.

11. Trauma team training and simulation exercises should be performed at regular intervals and should include review of the necessary equipment, individual tasks, and sequence of events for an ERT

12. All personnel must wear full personal protective equipment and strict attention must be paid to control of needles/sharps to avoid iatrogenic injuries or infectious exposures (needle sticks, cuts, eye splash, etc.).

*These are general guidelines are not intended to replace expert clinical judgment and decisions based on evaluation of an individual patient, local capabilities, and operational considerations.

BACKGROUND

ERT, also called "emergency department thoracotomy," is an extreme procedure, performed in the small subset of patients who arrive either in full post-injury arrest, who rapidly progress to arrest after arrival, or who have impending arrest that precludes immediate transport to an operating room. Exsanguinated patients with profound hypotension or in hemorrhagic shock do not improve with external chest compressions.[1]

The physiologic rationale of ERT is based on both

1. treating several potential sources of bleeding (control cardiac or other intrathoracic bleeding and prevent infra-diaphragmatic exsanguination) and

2. restoring an adequate cardiac output (releasing pericardial tamponade, improving cerebral and coronary perfusion, performing open cardiac massage).

Resuscitative thoracotomy has been extensively described in the civilian trauma literature and has a high mortality rate, largely due to the nature of the injuries leading ERT.[2-5] The survival rates are highest (10 to 30%) for penetrating truncal injuries and patients who arrive with vital signs. They are significantly lower (less than 5%) for blunt trauma victims, particularly those who arrest in the field or during transport (1% or less). In addition, the likelihood of survival with intact neurologic function is significantly lower than the overall survival rates, particularly for blunt trauma victims and for pre-hospital arrest.

In a combat or operational environment, several specific factors must be considered as studies of wartime ERT are available and indicate that there is a reasonable probability of long-term survival and recovery following ERT in appropriately selected casualties.[6-10]

INDICATIONS FOR ERT IN CIVILIAN TRAUMA

In the setting of civilian trauma, ERT is generally indicated only for penetrating trauma with either witnessed cardiac arrest or recent loss of vital signs. These indications were formalized by a working group of the American College of Surgeons Committee on Trauma after collectively reviewing the results of over 4,500 ERT procedures.[3] There was an overall survival rate of only 5% for ERT, although survival was over 30% in patients with low velocity penetrating cardiac injury. When ERT was limited to penetrating trauma and appropriate indications, it is associated with an 8.8% survival rate. Although this remains a very low rate of success, ERT is a true salvage procedure, without which survival is essentially zero even in indicated scenarios. The working group formulated the following recommendations (Class II):

1. ERT is best applied to patients sustaining penetrating cardiac injuries that arrive at trauma centers after a short scene and transport time with witnessed or objectively measured signs of life (pupillary response, spontaneous ventilation, presence of carotid pulse, measurable or palpable blood pressure, extremity movement, or organized cardiac activity).

2. ERT should be performed in patients sustaining penetrating non-cardiac thoracic injuries, but these patients generally experience a low survival rate. Because it is difficult to ascertain whether the injuries are non-cardiac thoracic versus cardiac, ERT can be used to establish the diagnosis.

3. ERT can be performed in patients sustaining exsanguinating abdominal vascular injuries, but these patients generally experience a low survival rate. Judicious selection of patients should be exercised. REBOA may be an equally appropriate salvage procedure. This procedure should be used as an adjunct to definitive repair of the abdominal-vascular injury.

4. ERT should rarely be performed in patients sustaining cardiopulmonary arrest secondary to blunt trauma because of its very low survival rate and poor neurologic outcomes. It should be limited to those that arrive with vital signs at the trauma center and experience a witnessed cardiopulmonary arrest.

The Western Trauma Association (WTA) algorithm recommends ERT for patients with prehospital arrest and CPR duration of less than 10 minutes for blunt trauma and less than 15 minutes for penetrating injury.[5-11] ERT is also recommended for patients undergoing CPR with signs of life (respiratory or motor effort, organized cardiac activity, or pupillary reflexes) or with profound shock (systolic pressure < 60 mmHg). WTA's recommendation for ERT in blunt trauma patients with prehospital arrest and CPR<10 minutes is more liberal than others who recommend against ERT in this cohort; it is noteworthy, however, that this is based on only 5 patients (4 who arrived with organized electrical activity and 1 with tamponade from an atrial laceration).

Most recently, the Eastern Association for the Surgery of Trauma (EAST) Practical Management Guidelines for ERT analyzed 72 relevant studies utilizing the GRADE methodology for assessing the strength of the evidence, but also taking likely patient preferences into account.[12] They defined "signs of life (SOL)" as presence of any of the following: pupillary reactivity, spontaneous breathing, palpable carotid pulse, measurable blood pressure, motor movement, or organized electrical activity. They identified 6 pre-defined patient categories depending of 3 conditions (penetrating or blunt mechanism, thoracic or extra-thoracic location and presence of SOL), and made either strong or conditional recommendations for ERT in pulseless patients, as following:

1. Penetrating thoracic trauma with signs of life but pulseless on arrival (Strong).

2. Penetrating thoracic trauma without signs of life and pulseless on arrival (Conditional).

3. Penetrating extra-thoracic (non-cranial) trauma with signs of life but pulseless on arrival (Conditional).

4. Penetrating extra-thoracic (non-cranial) trauma without signs of life, pulseless on arrival (Conditional).

5. Blunt injury with signs of life but pulseless on arrival (Conditional).

6. For the sixth category of blunt trauma patients without signs of life and pulseless on arrival they gave a conditional recommendation against proceeding with ERT.

Results from prehospital thoracotomy has been reported by a few authors.[13,14] These studies concerned only the subgroup of stab wounds to the chest and described a 10 to 18% survival rate. This experience remains strictly limited to very few experienced teams acting within a trauma system with well-established training and quality assurance.

Recently, the prospective observational multicenter Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery study reported the outcomes of 310 patients undergoing ERT from 2013 to 2017 after either blunt or

penetrating trauma.[15] Survival rate was 12.3% beyond 24h and 5.2% to discharge. The authors discuss the fact that neither practice nor outcomes following ERT have changed in the last 40 years.

REBOA

Recently, the technique of REBOA has emerged in the setting of trauma for control of abdominal and pelvic hemorrhage. Although not strictly comparable, REBOA is a potential alternative to ERT to achieve aortic occlusion and, therefore, control of abdominal and pelvic hemorrhage. Several recent studies tried to compare REBOA and ERT in non-compressible torso hemorrhage[16-18,] and a meta-analysis is available.[19] Even if REBOA seemed to be associated with a lower mortality, there was no significant difference in survival after risk-adjustment, mostly because ERT patients were more critically ill on presentation. This suggests that REBOA is not a comparable intervention to ERT but rather may be utilized to prevent hemodynamic collapse in non-agonal unstable patients. Ongoing study is required to better illuminate the evolving role of REBOA as a potential replacement or as a preemptive adjunct to obviate ERT. Please refer to the JTS REBOA CPG for indications and details of this procedure.[20]

ERT FOR COMBAT CASUALTIES

SPECIFIC CONSIDERATIONS

In the battlefield or operational environment, several important additional factors must be considered. First and foremost is the major difference in the epidemiology of the injured patients presenting to military facility with surgical capabilities. Unlike civilian trauma victims, these patients will generally be younger and healthier and will largely have suffered penetrating or combined blast/penetrating type mechanisms.

Additionally, in combat or austere conditions, the local tactical environment and the impact thereof on critical resources may supersede clinical factors. ERT is a resource-intensive procedure that requires multiple personnel, specialized equipment, supplies, and potentially consumable resources (e.g., blood products- see below). Considering the low overall yield of ERT, the decision to proceed must be based not only on the individual patient factors, but also with consideration of the impact of the procedure on the MTF's overall capabilities. This issue is particularly critical at Role 2 facilities with significantly less personnel, equipment, and surge capacity compared to the more robust Role 3 and higher facilities. ERT should NOT be performed during MASCAL events or multiple casualty events where it would adversely impact the care of others with more survivable injuries.

Notably, careful attention must be paid to the impact of ERT on the local supply of blood products, with immediate early termination of aggressive blood product resuscitation if there is not a prompt response and return of circulation. Termination of efforts should also be considered in the patient with return of vital signs but ongoing major hemorrhage that will exhaust the local blood product supply and an overall low estimated probability of survival.

Pre-hospital thoracotomy on military patients is likely to require complex intervention in very challenging environments. Moreover, the evidence does not support the notion that earlier thoracotomy could improve survival.[21] ERT should only be performed in a setting and facility that has the capability and resources to provide the required level of care in the event of achieving return of circulation or stabilization of impending arrest. This generally limits this procedure to forward MTFs with surgical capabilities, proper equipment, and an adequate supply of blood products.

AVAILABLE LITERATURE

A study based on four-year data from a Role 3 facility in Iraq examined outcomes after ERT in the context of combat trauma.[8] ERT was successful in restoring a perfusing rhythm in half of patients, with 46% survival to the operating room. Although only 12% of patients survived through evacuation from the facility, all survivors were reported to have good functional outcomes. All survivors were reported to be neurologically intact, and there was no difference in survival based on injury mechanism, location or injury pattern. Explosive injury and gunshot wounds were the primary mechanisms of injury for patients in this series. This case series suggests similar or better survival after combat trauma ERT compared with civilian results of ERT. In a previous study limited to wartime penetrating thoracic trauma with cardiac injuries, among 17 patients undergoing ERT, a 24% survival rate was reported.[22]

These results were confirmed in a more recent study examining outcomes among 65 patients who underwent ERT at a single Role 3 facility in Afghanistan.[9] The mechanisms were again all blast and gunshot wounds, and the overall survival rate was 22%. Although there were no survivors among patients with traumatic arrest in the field, there was a 10% 30-day survival among patients who had vital signs in the field and subsequently arrested during transport and 42% for those who arrested after arrival at the MTF. This study also demonstrates the critical aspect of time from arrest to ERT, with survivors having an average time of 6 minutes versus 18 minutes for non-survivors.

A recent retrospective 8-year study of Operations Enduring and Iraqi Freedom resuscitative thoracotomies showed a 9.9% survival rate among 81 patients.[10] Survivors had significantly higher extremity Abbreviated Injury Scale, (suggesting the usefulness of aortic occlusion in penetrating pelvic or junctional exsanguination), higher initial oxygen saturation, and higher post-procedural blood product and volume resuscitation (possible survival bias). Although not statistically significant, all survivors also had an explosive/blast mechanism. This work suggests that ERT may improve the outcomes in primary extremity blast injuries who were in extremis at arrival.

RECOMMENDATIONS

A recommended algorithm for ERT in traumatic arrest in the combat or operational environment is presented in [Appendix A](#).

PENETRATING INJURIES

- Resuscitative thoracotomy at an MTF in the combat or operational environment is most strongly indicated and warranted in patients with penetrating injuries who present to an MTF in extremis or with a recent witnessed loss of vital signs, especially those with penetrating thoracic injuries. Although there is controversy on the exact definition of "recent" loss of vital signs, the majority of data supports up to 10-15 minutes as a cutoff for pre-hospital arrest with penetrating truncal or extremity trauma.

- Though most of these casualties will not survive, up to 25% of penetrating trauma patients who undergo ERT at a forward military facility can be salvaged with acceptable neurological outcomes.

BLUNT TRAUMA

- In the deployed setting, victims of blunt trauma are less common but most commonly present after vehicle crashes or falls from height. The previously noted study from a combat trauma setting found no ERT survivors after blunt injury, although the blunt cohort was small.

- In the operational setting, ERT for blunt trauma should be based upon clinical judgment, recognizing that the data from civilian studies has demonstrated a very low survival rate. It should be limited to those who have either witnessed in-hospital arrest, pending arrest, or those with definite vital signs in

the field and who arrive with clear and present signs of life (organized narrow complex EKG and/or organized cardiac contractile activity on bedside cardiac ultrasound).

- Blunt trauma patients with no vital signs at the scene of injury and during transport, or with reported vital signs during transport but who arrive in arrest should NOT have ERT performed.

SPECIAL CIRCUMSTANCES

- Patients with injuries that have a low likelihood of salvage, such as traumatic brain injury or high total body surface area burns, should be either declared expectant on arrival or at most managed with non-operative resuscitation and interventions (intubation, chest tubes, fluid/blood resuscitation) and then reassessed.

- In patients with arrest or impending arrest with severe blunt or penetrating traumatic brain injury, ERT is generally contraindicated unless there is evidence of preserved neurologic function and a potentially salvageable and survivable brain injury.

REBOA to control life-threatening sub-diaphragmatic hemorrhage in surgically capable theater facilities may be a selective alternative to ERT, as detailed in the JTS REBOA CPG.[20]

TECHNIQUE

The objectives of the ERT are always the same, no matter the injuries: to stop the bleeding and restore adequate central perfusion. Immediate attention should be paid to the most lethal potential findings, such as cardiac tamponade, penetrating cardiac injury, great vessel injury, and massive pulmonary injury. In the event that the injury is on the right side of the heart or chest, the standard ERT incision may be extended to the bilateral thoracotomy or "clamshell" incision with extension across the sternum. ERT is a well-codified procedure that can be considered in several steps:

1. Left anterior-lateral thoracotomy incision

2. Opening the pericardium

3. Control of a cardiac injury

4. Temporary control of active lung bleeding

5. Cross-clamping of the descending aorta

6. Internal cardiac massage and defibrillation

7. Repair of other thoracic, abdominal or peripheral injuries

Concurrent massive transfusion protocol, as well as potential pharmacological adjuncts, is essential. Rapid successful restoration of cardiac function is the key to deciding on the relevance of continuing the procedure.

The detailed technical steps are presented in detail in Appendix B.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

Patients with AIS chest, abdomen, pelvis, and/or lower limb ≥3 with SBP >0 and <90 or CPR in progress on arrival to first MTF AND not isolated head injury (AIS head/face/neck = 5 or 6).

INTENT (EXPECTED OUTCOMES)

ERT is not performed in patients with no signs of life or CPR >15 minutes or isolated severe TBI.

PERFORMANCE/ADHERENCE METRICS

1. Number and percentage of patients who underwent ERT (or REBOA) in the population of interest.

2. Number and percentage of patients who did not undergo ERT (or REBOA) in the population of interest.

3. Number and percentage of patients who underwent ERT who survived 24 hrs, 7 days, 30 days (assume alive if discharged alive prior to each time point).

4. Number and percentage of patients who did not undergo ERT (or REBOA) in the population of interest who were declared KIA/DOA or who survived 24 hrs, 7 days, 30 days (assume alive if discharged alive prior to each time point).

DATA SOURCES

- Patient Record.
- Department of Defense Trauma Registry (DoDTR)
- Morbidity and Mortality Conference Reports

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 JTS Chief and the JTS PI Branch.

RESPONSIBILITIES

It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.
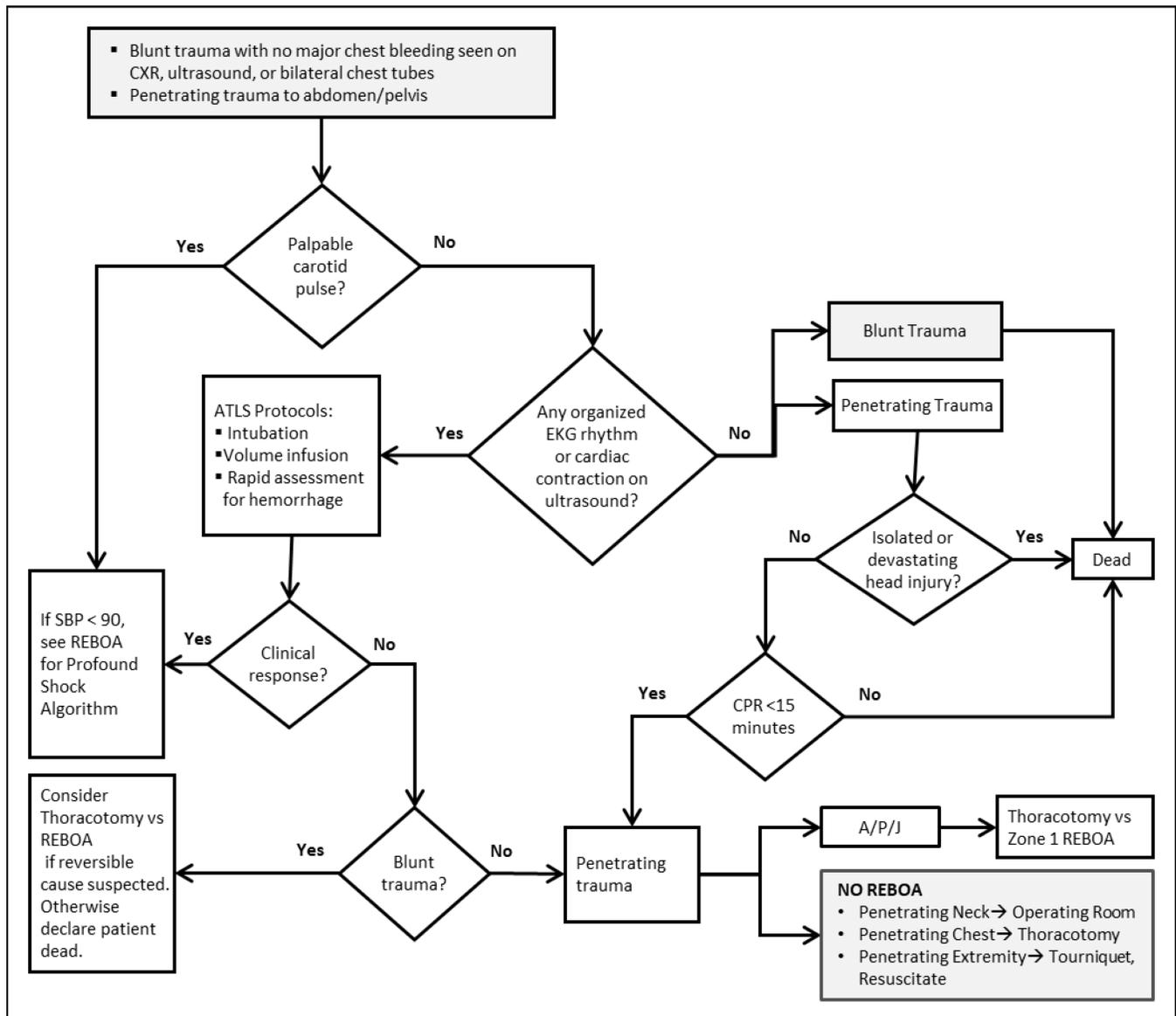
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APPENDIX A: RECOMMENDED ALGORITHM FOR ERT IN TRAUMATIC ARREST

APPENDIX B: TECHNIQUE OF EMERGENCY RESUSCITATIVE THORACOTOMY

PREPARATION

All emergency and surgical personnel at a Role 2 or higher facility should be trained in their roles and actions to facilitate performance of an ERT.

All needed supplies and equipment for an ERT should be pre-packaged and stored in a readily accessible location in the resuscitation area, and periodically inspected for completeness and service ability.[23]

The surgeon and designated team members should review the contents and composition of the ERT supply package.

All personnel performing, assisting, or otherwise participating in an ERT should be wearing full personal protective equipment including a gown, gloves, and eye protection.

The urgency of the procedure, coupled with the mix of multiple assistants and multiple potential sharps represent a high-risk scenario for accidental injuries and infectious disease exposure to the involved medical personnel (See [JTS Infection Prevention in Combat-Related Injuries CPG](.)[24] Great care must be taken during training and actual ERT procedures to highlight safety precautions including control of all needles, syringes, scalpels, and other sharps.

Sterile preparation is not required for ERT, as the nature of this procedure does not afford the time for prep solutions to dry and assume their antimicrobial efficacy.

If at all possible, definitive airway control should be obtained prior to or during ERT, but ERT should not be delayed solely to establish a secure airway.

Efforts to obtain adequate intravenous or intraosseous access for blood product infusion should proceed simultaneous to ERT, keeping in mind that in the case of penetrating thoracic trauma, infusions via the upper extremities may be ineffective until bleeding is controlled. Similarly, lower extremity, pelvic, or abdominal wounds with exsanguination should be resuscitated via an upper extremity or central venous catheter. In the patient with difficult intravenous access, intraosseous access should be immediately established, preferably in the sternum or humerus.

Placement of a right chest tube if there is any possibility of injury/hemorrhage on the right side should be strongly considered. Alternatively, the right chest may be open through an extended thoracotomy or clamshell incision.

Effective suction should be available for successful ERT.

INCISION AND EXPOSITION

1. ERT begins with a generous curvilinear left anterolateral thoracotomy (from the sternum to the table) at approximately the fourth intercostal space. If previously performed, a tube thoracostomy incision can serve as a starting point for the thoracotomy. Exposure can be significantly improved by placing a towel or roll under the left back to elevate and rotate the left chest.

2. The nipple line in males and the inframammary crease in females is a reasonable anatomic landmark (time should not be spent attempting to count ribs). If in doubt, it is best to err more superiorly rather than make too low an incision.

3. After the initial incision with a knife to/through the level of the chest wall muscles, heavy scissors may be used to rapidly and safely open the remaining tissues through the full extent of the incision by sliding the partially opened scissors along the superior rib border.

4. The internal mammary vascular pedicle is located 1-2cm lateral to the sternal border and will be transected during ERT. Transection of these vessels is of no physiologic consequence, but control of associated bleeding (only after return of circulation in case of successful procedure) with suture or clips will be necessary.

5. If after initial left ERT, additional right-sided thoracic, cardiac or pulmonary hilar exposure is needed, the incision should rapidly be extended across the sternum (with a Lebsche knife or simple trauma shears) and continued on the right side (bilateral thoraco-sternotomy or "clamshell" incision).

6. Once the incision is completed, a rib retractor is placed (with the handle downward), the ribs are spread and the lung is initially packed posteriorly with laparotomy pads or sterile towels, or manually retracted by an assistant; this can be facilitated by incision of the inferior pulmonary ligament. After evacuating blood and/or formed clot from the left pleural space, the pericardium is visualized to assess for cardiac activity and for hemopericardium.

   NOTE: One of the most common technical errors in ERT is poor exposure due to inadequate length of the skin incision and lack of complete division of the subcutaneous and muscle layers.

CARDIAC PROCEDURES

1. Pericardotomy: The pericardium is opened longitudinally at least one finger breadth anterior to the phrenic nerve which can be identified in its cranio-caudal course along the lateral pericardium, generally within 1-2cm of the pulmonary hilum. The pericardium should be opened by grasping with a forceps and using a tissue scissor, followed by extension down to the diaphragm and cephalad to below the thoracic inlet. In cases with a large hemopericardium, tension may make grasping the pericardium with forceps difficult. The heart can then be delivered partially out of the pericardium to inspect for injury and facilitate open cardiac massage if needed.

2. If after pericardiotomy, a cardiac injury is identified, initial temporary control may be achievable with digital pressure, a large side-biting clamp, a Foley catheter, or even a surgical skin stapler.

3. In the absence of effective cardiac activity, open cardiac massage should be rapidly instituted at this point using a two-handed technique, which is less traumatic and produces a better cardiac output. This will be ineffective unless concurrent volume resuscitation has occurred sufficient to provide adequate preload.

4. Defibrillation must be early attempted in cardiac arrest. If internal paddles are available, an electric shock is typically delivered at 20 Joules. If not, external paddles can also be used in the usual cutaneous position at 200 J, after temporarily removing the costal retractor so as to briefly close the chest cavity.

5. If there is no cardiac injury and no cardiac activity (asystole), resuscitative efforts should be terminated after a reasonable time (5-10 minutes).

6. In case of successful restoration of cardiac activity, cardiac or other intrathoracic injuries should be more definitively repaired, and exploration completed.

AORTIC CROSS-CLAMPING

1. If there is known or suspected hemorrhage from below the diaphragm, initial attention after thoracotomy should be focused on clamping the descending thoracic aorta. The lung is retracted and packed anteriorly and superiorly to identify the aorta in its location just anterior to the vertebrae. This can be facilitated by incising the inferior pulmonary ligament.

2. The aorta should be clamped just above the diaphragm to maximize collateral flow and spinal cord perfusion.   In exsanguinated or asystolic patients (i.e. with a "flat" aorta"), the esophagus is easily mistaken for the aorta. Placing an orogastric or nasogastric tube will help identify and avoid injury to the adjacent esophagus (located just medial/anterior to the aorta).

3. Opening the mediastinal pleura, limited blunt dissection is used on either side of the aorta to facilitate the placement of a large, atraumatic DeBakey vascular clamp.

4. After the clamp is placed, aggressive resuscitation may be instituted and immediate plans made for direct surgical control of the patient's injuries. If a patient remains severely hypotensive despite fluid resuscitation after aortic clamping, it is unlikely that he has a survivable injury.

5. The duration of intra-thoracic aortic cross clamp should be carefully monitored, and the maximum tolerated duration in the patient already in hemorrhagic shock is 30-40 minutes. It should be removed at the earliest possible time, or the level of cross clamp could be moved inferiorly to the abdominal aorta or iliac vessels if proximal control of abdominal, pelvic, or extremity vascular injuries is still required. Once the injury is addressed, as the clamp is removed, the team should be prepared for rapid hemodynamic shifts and the potential development of hyperkalemia and/or metabolic acidosis (ischaemia-reperfusion injury or "reperfusion syndrome.").

INJURY WITHIN THE THORAX

If after thoracotomy, there is a direct injury to the lung or hilar vessels, direct pressure (with a finger, rolled gauze, or laparotomy sponge) is generally sufficient for temporary control of bleeding in this low pressure system. Using lap pads to collapse the lung parenchyma medially will pack the hilum and free up your hands initially to allow a more detail inspection of the chest, heart, and vessels for sites of hemorrhage, and allow the placement of the aortic clamp. Some major pulmonary injuries might need early hilar cross-clamping en masse.

Once temporary control is in place, resuscitation can be instituted and the patient may be taken to the operating theatre for definitive lung repair with stapled resection, suture repair, stapled "tractotomy," or in extreme cases pneumonectomy (which carries a very high mortality in the trauma setting, even in the absence of pre-procedural arrest).

Large pulmonary injuries also create a risk for air embolism which can result in entrained air entering the pulmonary veins and subsequently the left heart and coronary vessels. Early pulmonary hilar clamping, rapid direct control of lung lacerations or temporarily submerging the area in irrigation fluid can help prevent this risk.

If there is a thoracic great vessel injury, temporary control may be achievable with digital pressure or atraumatic vascular clamps. If these are insufficient to control a great vessel injury in the setting of an ERT, this likely represents a non-survivable injury.

Unlike pulmonary bleeding, intercostal and chest wall bleeding is under arterial pressure and will require more focal and firm pressure for initial control, followed by mass suture ligatures and/or clip

APPENDIX C: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

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.

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.

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.

ADDITIONAL PROCEDURES

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.

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.

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.