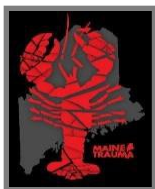


Maine Medical Center Trauma Clinical Practice Guideline (MMCT-CPG)



Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock (MMC-CPG ID: 2019-02)

Provides guidelines and recommendations for the use of REBOA as a component of Damage Control Resuscitation (DCR) in the management of trauma patients

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Guidelines translate best evidence into best practice. A well-crafted guideline promotes quality by reducing healthcare variations, improving diagnostic accuracy, promoting effective therapy, and discouraging ineffective – or potentially harmful – interventions.

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PURPOSE

These guidelines are not intended to supplant physician/provider judgement. This guideline is intended to provide a basic framework for the range of accepted management approaches to profound shock and post-traumatic cardiac arrest and establish a pathway for Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as a hemorrhage control adjunct in that paradigm. The specific management approach will depend on the patient's physical location, mechanism and pattern of injury, and the experience level of the clinician. The optimal management strategy is best determined by the clinician at the bedside.

BACKGROUND

Hemostatic resuscitation combined with a heightened focus on early control of bleeding and contamination is known as damage control surgery (DCS) (1). Damage control resuscitation (DCR) is an extension of damage control surgery (DCS) and focuses on limiting interventions to those which address life-threatening injuries and delaying all other care until metabolic and physiologic derangements have been corrected (2). DCS along with DCR is a treatment strategy that attempts to maintain oxygen delivery to essential organ systems while mitigating, and if possible avoiding, conditions that exacerbate hemorrhage in trauma patients while source control is achieved. Contemporary understanding of DCR and DCS advocates early control of hemorrhage and contamination, permissive hypotension, asanguineous fluid minimization, and the use of plasma and balanced blood products (e.g. fixed ratio blood product transfusion such as 1:1:1) (1,3-4).

Over the past 15 years, DCR has proven successful in combat casualty care and has been extended to civilian trauma care (it is beyond the scope of this chapter to delve into the surgical principals and techniques utilized in DCR and DCS) (5-7). An initial definition of DCR states "DCR addresses the entire lethal triad immediately upon admission to a combat hospital" (1). However, interest in the concept of DCR has extended into the pre-hospital realm where it is known as remote damage control resuscitation (RDCR). Since early identification and treatment of hemorrhagic shock may improve outcomes, some authors contend that the distinction between RDCR and DCR is an important one since there are differences in capabilities, and in some cases optimal management strategies between pre-hospital and in-hospital care (8). However, others see it as a continuum as illustrated by the expansion of plasma first resuscitation and blood products into pre-hospital trauma care in the United States (9, 10).

Effective DCR places high value on a rapid and well-coordinated resuscitation effort focused on arresting hemorrhage, reversing shock, and preventing coagulopathy (11). DCR has been adapted to truncating initial surgical procedures on severely injured patients to provide only interventions necessary to control hemorrhage and contamination and to focus on reestablishing a survivable physiologic status (12).

DCR principles include: 1) Hemorrhage control; 2) Low volume, permissively hypotensive resuscitation; 3) Rapid control of bleeding and contamination; 4) Avoiding overuse of crystalloids and colloids; 5) Prevention or correction of acidosis, hypothermia, and

hypocalcemia; and 6) Hemostatic resuscitation (early use of a balanced amount of red blood cells (RBCs), plasma, and platelets (1). Research and technology continue to focus on more efficient ways of delivering and assessing the progress of DCR, and one rapidly evolving adjunct, REBOA, is the main topic of this CPG (13, 14).

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) may be an effective technique for truncal hemorrhage control. REBOA is the evolution of a concept for control of hemorrhage via balloon occlusion of the aorta that was first used in the Korean War (15). Resuscitative Aortic Occlusion (RAO) via REBOA offers the opportunity to control bleeding in the abdomen and pelvis by endovascular occlusion of the aorta; avoiding surgical skills/maneuvers to occlude the aorta by direct clamp application. The current ER-REBOA is able to be placed via a 7-French introducer sheath that is able to be placed percutaneously without a vascular cut down, especially when used with ultrasound visualization of the common femoral artery. A review from two US Level I trauma centers comparing REBOA with resuscitative thoracotomy (RT) in critically injured peri-moribund patients demonstrated a higher probability of survival with REBOA compared to RT; however, in the concept of DCR a maneuver such as an RT is potentially not an option, therefore comparison of REBOA to emergency RT may not be overtly valuable (16). Additionally, recently the concept of “Step Up in Care” to include simply placing the REBOA introducer early has been reported to improve survival outcome in critical injured patients (17).

At this time it, clear guidelines for the use of REBOA and early 7-French introducer sheath placement as well as outcomes of these maneuvers remain to be fully elucidated. Additionally, as this newer technology is incorporated into the care of trauma patients there is the distinct opportunity for misapplication and over utilization, not to mention the need to address specialty consensus statements regarding who should and should not be placing REBOA (18). Therefore, this practice guideline presents REBOA use and potential REBOA use as part of a “Step Up” strategy.

However, it should be noted that early control of truncal hemorrhage improves outcomes (13, 14). Therefore, early appreciation of hemorrhage and early, in the Emergency Department(ED), use of REBOA for truncal hemorrhage control instead of waiting for the perceived “more controlled” environment of the OR should work to improve outcomes.

Resuscitative Aortic Occlusion (RAO) in Profound Shock and Traumatic Arrest

Given the lack of large-scale human studies demonstrating the effectiveness of REBOA over other RAO techniques, the precise indications for REBOA placement are open to debate. However, suggested indications are summarized below. These indications mirror the indications for resuscitative thoracotomy with the exception that shock or arrest secondary to penetrating chest trauma is a relative contraindication to REBOA (19). Additionally, the role of invasive blood pressure monitoring and potentially utility of 7 French sheath placement without necessarily advancing to REBOA placement and RAO are unclear, however recent reports support improved outcomes with early REBOA introducer placement (independent of RAO) (17). Therefore, we recommend a “Step Up” approach to REBOA strategy.

“Step Up” Approach to REBOA Utilization

The “Step Up” approach to REBOA entails securing femoral arterial access in the form of an arterial line that is an 18 gauge or larger (smaller, arterial lines such as a 20 gauge will not accept the 0.035 wire required for the REBOA 7 French sheath), optimally prior the loss of pulse in patients who are in severe hemorrhagic shock or deemed at significant risk for decompensation as a result of blood loss as seen in **Figure 1**. This can also be extended to include patients given any blood products pre hospital or in the ED. The arterial line allows easier trending of SBP in patients with increased mortality. **Figure 2**

Subsequently, upsizing to a 7 French REBOA sheath is based upon either transient or no response to initial resuscitation as depicted in **Figures 2 or 3** to permit either potential or actual REBOA placement.

This “Step Up” approach permits incorporation of the ED in this overall process early on.

1. Femoral Arterial Line Placement

To improve hemodynamic monitoring as well as provide access for rapid blood draws early consideration and placement of a femoral arterial line should be considered in patients currently in or at risk for hemorrhagic shock. Placement of an 18 gauge femoral arterial line, 0.035 guidewire, (optimally under ultrasound guidance when available) while the patient still has a palpable pulse is optimal in these patients. This intuitively means that the arterial line is placed early while the patient is in the ED as part of the primary and secondary trauma surveys and prior to movement to the CT scanner.

This provides the additional benefit of arterial access that can subsequently be upsized, over a wire, to a 7 French REBOA introducer sheath should the patient’s condition not improve or decline with potential loss of pulse. The key is to obtain/secure 18 gauge, 0.035 guidewire, femoral arterial access before loss of pulse to facilitate monitoring and upsizing to 7 French sheath.

The arterial line should be placed for $SBP \leq 90$ mmHg, Shock Index ≥ 0.9 , increase in Shock Index of ≥ 0.3 , any call for transfusion or significant clinical concern for the risk of decompensation based on clinician judgement. These physiologic parameters are an adaptation of literature supported identifiers of severe blood loss in trauma: systolic blood pressure (SBP) ≤ 70 mmHg or SBP 71-90 with $HR \geq 108$ bpm (20,21) and Shock Index [(SI), HR/SBP] >0.9 at any point or increase in SI of ≥ 0.3 during pre-hospital through ED care; these have been correlated with severe trauma, acute hypovolemia and higher mortality (reported as up to 40%) due to hemorrhage may not be reflected by blood pressure alone (22-26). **Figure 2**

2. REBOA Femoral Sheath Placement

The current ER-REBOA is introduced via a 7-French introducer sheath that is optimally placed percutaneously without a vascular cut down Upsizing to the 7-French introducer from a previously placed 18 gauge femoral arterial line, 0.035 guidewire, via an over a guidewire exchange or initial placement of the 7 French REBOA introducer sheath should be done as

depicted in **Figure 2 & 3** for profound

shock with transient or no response to initial ATLS resuscitation or in the event of trauma arrest. A key element is early placement, optimally prior to loss of pulse.

Upsizing should be done over a wire and provided there was good arterial waveform on the preexisting arterial line, ultrasound guidance may not be required for upsizing, though it can be used at the clinician's discretion to rapidly confirm intra-arterial wire positioning. Initial placement of the 7-French REBOA introducer, not over a wire as part of an upsizing per the "Step Up" approach, should be done under ultrasound guidance. In the situation of loss of pulses prior to the placement of the sheath, if arterial access cannot be obtained under ultrasound guidance then groin cut down should be considered and performed immediately for sheath placement.

3. REBOA Catheter Placement

REBOA catheter is inserted as described in Figure 2 for transient/non-responders to initial resuscitation or profound hypotension and as described in Figure 3 for traumatic arrest. Placement of REBOA in Zone 1 or Zone 3 as depicted in Figure 4 and as determined by algorithms in Figure 2 and 3.

NOTE: REBOA should be placed as soon as indicated as would be done for the placement of an extremity tourniquet or securing of a jeopardized airway. REBOA placement should not be delayed if it is warranted, REBOA may be placed in the ED, in the CT scanner room, in the OR, etc.

For Zone 1: REBOA should only be performed if the anticipated time to start of operation is less than 15 minutes (18).

For Zone 3: REBOA may be tolerated for longer periods of time and may be used as an immediate adjunctive bleeding control device prior to angio-embolization, pre-peritoneal packing, or exploration. The balloon should be deflated as soon as possible (18).

REBOA Zones

REBOA is only to be deployed in Zone 1 or Zone 3 for the indications in Figure 2 and 3. Zones 1 and 3 are depicted in Figure 4. Notably, Zone 1 = insertion of REBOA to 46 cm and Zone 3 = insertion of REBOA to 28 cm.

In an emergency situation, the above insertion depths should be used and REBOA inflated. Ultimately, confirmation of placement should be done with x-ray expeditiously or if going to CT scanner then may be done in CT scanner.

Anatomically zone 1 is from the takeoff of the left subclavian artery to just proximal to the takeoff of the celiac trunk and zone 3 is from just below the renal arteries to just proximal to the aortic bifurcation.

PERFORMANCE IMPROVEMENT MONITORING

Intent / Expected Outcomes

1. All patients meeting criteria as described will have femoral arterial lines placed early in their care as the initial step in a “Step Up” REBOA strategy regardless of subsequent REBOA use or not (**Figures 1 & 2**).
2. All patients meeting criteria will have 7 French REBOA sheaths and, as outlined, REBOA catheters inserted/deployed as per the CPG for non or transient hemodynamic responders of initial resuscitation (**Figure 2**).
3. All patients meeting criteria for REBOA use in traumatic arrest will have REBOA inserted/deployed (**Figure 3**).
4. Deployed and inflated REBOA catheters will be in the correct zone as planned/intended by the clinical team (**Figure 4**).

Performance / Adherence Measures

1. MMCT-CPG ID: 25 will be followed as outlined for eligible patients.
2. Incidence of patient’s meeting criteria and/or having femoral arterial lines, sheaths or REBOA placed will be actively tracked in the trauma registry via daily capture by the trauma registers as part of 24 hour reports.

Data Source

1. Patient record
2. ER Care Record and flow sheets

SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of the MMCT-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 MMC Trauma Service under the direction and responsibility of the MMC Trauma Medical Directory and MMC Trauma Medical Program Manager.

RESPONSIBILITIES

It is the Trauma Medical Director’s responsibility to ensure familiarity, appropriate compliance, and PI monitoring with this MMCT-CPG.

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Figure 1: “Step Up” Approach to REBOA Utilization

“Step Up” Approach to REBOA Utilization

Figure 1

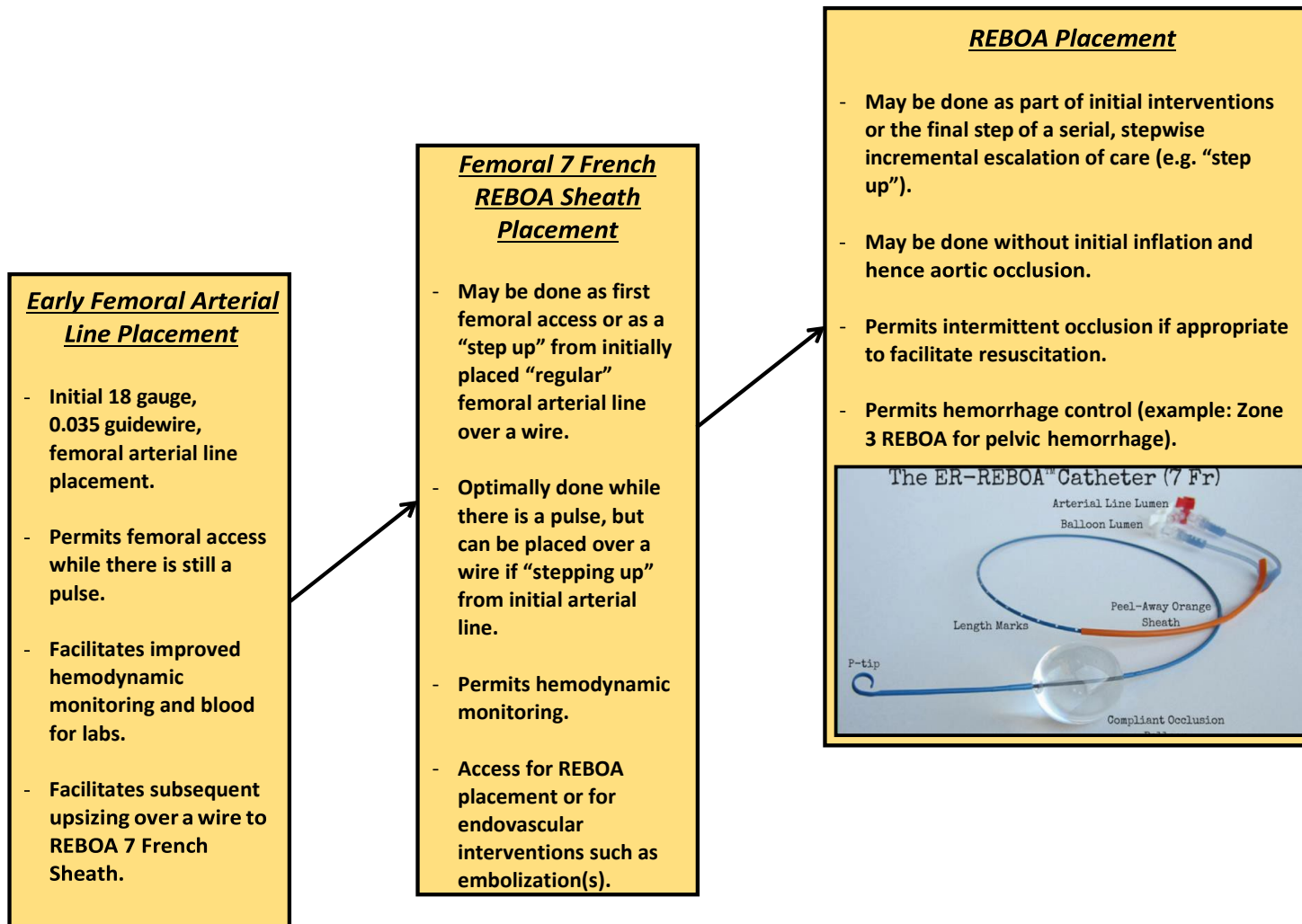


Figure 2:

A-Line - SBP ≤ 90 mmHg or Shock Index ≥ 0.9 or Clinical Worry Regarding Hemodynamics

Place Femoral 18 Gauge, 0.035 guidewire, Arterial line for monitoring and for access for potential "step up" to REBOA 7 French Introducer Sheath.

* Permits access procurement while there is a pulse

REBOA For Profound Shock: SBP < 90 mmHg with Transient or No Response to Initial

ATLS Resuscitation

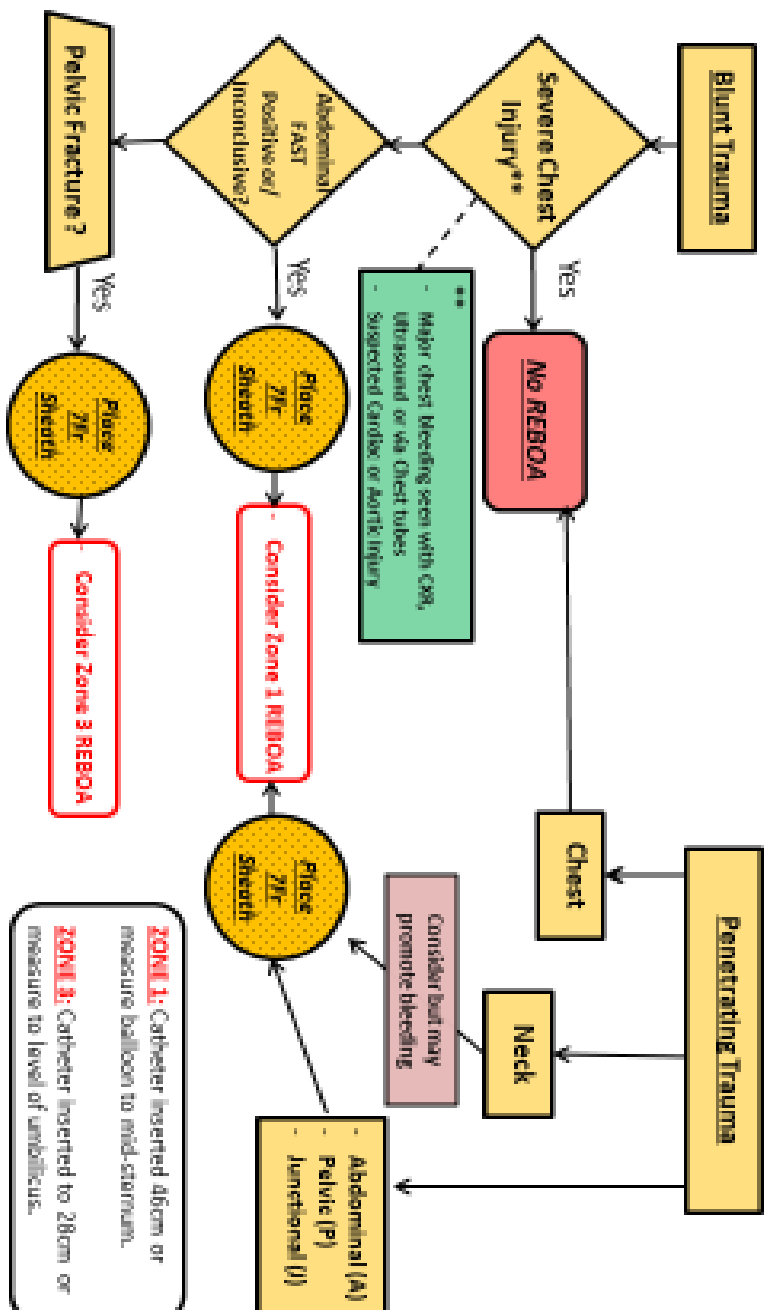


Figure 3:

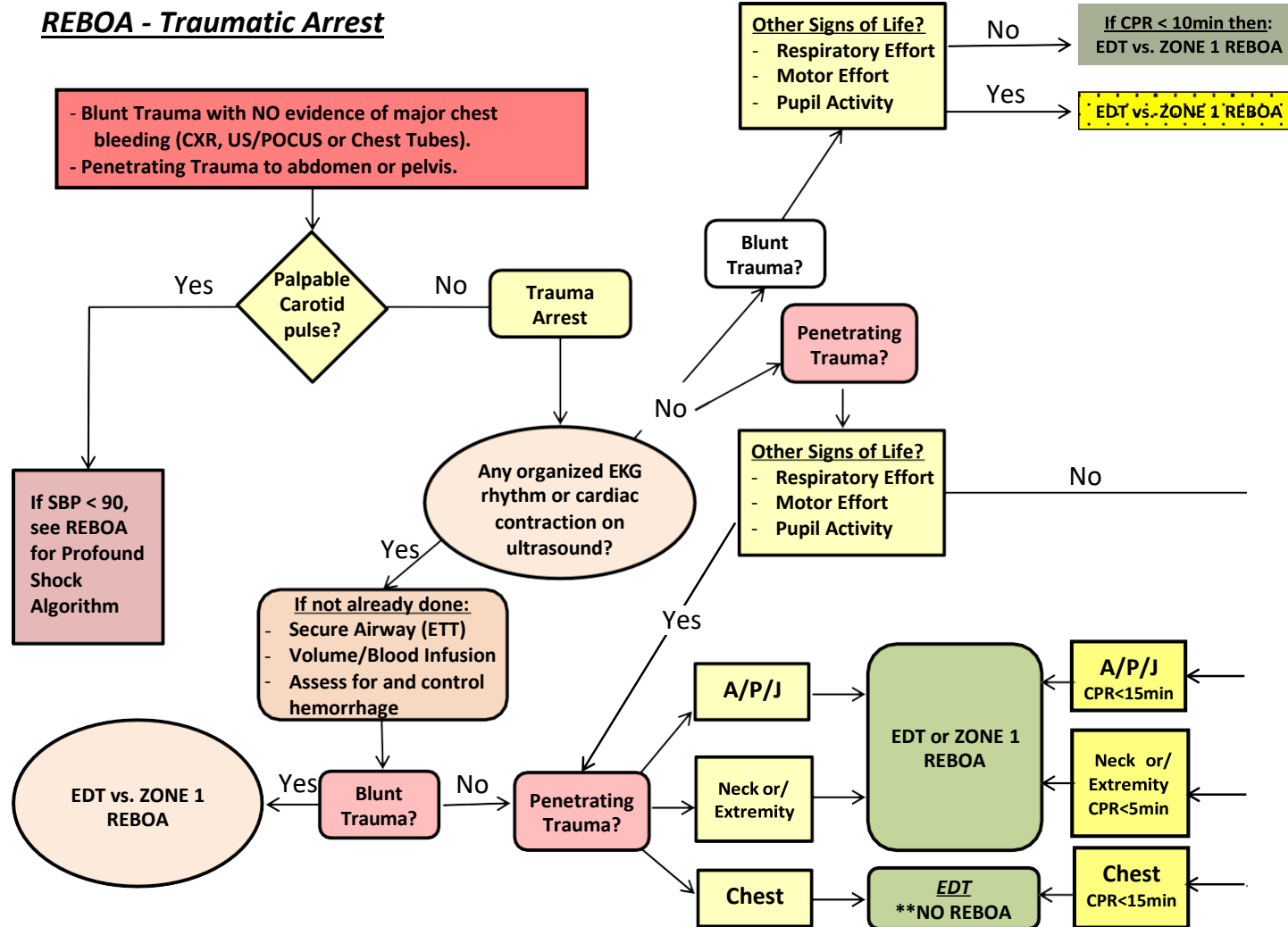
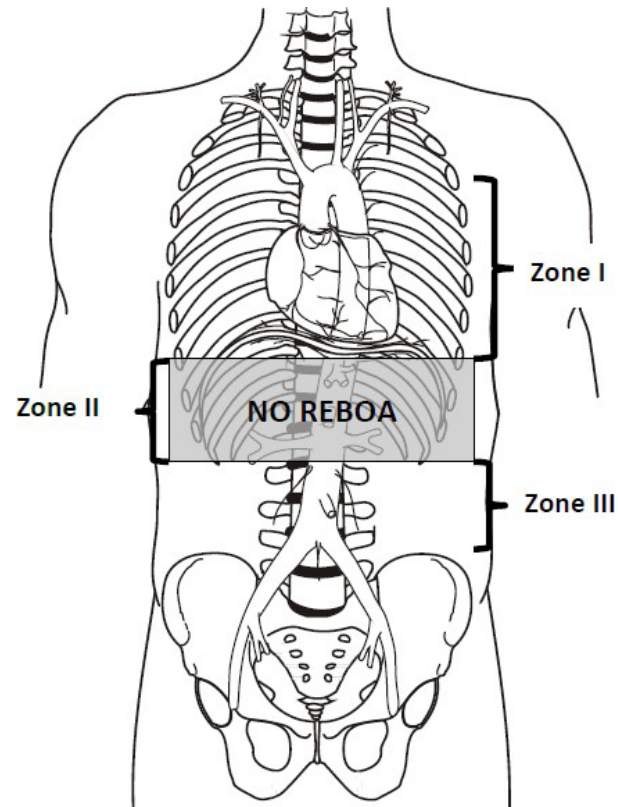


Figure 4:

REBOA Aortic Placement Zones



ZONE 1: Catheter inserted 46cm or measure balloon to mid-sternum.
- Distal to the take-off of left subclavian artery and proximal to the celiac trunk.

ZONE 3: Catheter inserted to 28cm or measure to level of umbilicus.
- Distal to the lowest renal artery and just proximal to aortic bifurcation.