Advanced Resuscitative Care in Tactical Combat Casualty Care: TCCC Guidelines Change 18-01

14 October 2018

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Joint Trauma System Directors’ Note

Advanced Resuscitative Care, as described below, reflects the work of the Committee on Tactical Combat Casualty Care. It is a bold change in the advancement of battlefield medicine. The interventions recommended in this paper address the largest remaining cause of potentially preventable death on the battlefield, and represent an initiative to bring the capability for massive resuscitation with whole blood and control of abdominopelvic torso hemorrhage closer to the point of injury.

In reviewing this change, we recognized that the proposed interventions cross multiple roles of care in a dynamic and fluid environment that includes various combinations of damage control resuscitation, damage control surgery, tactical field care, and enroute care. As such, Advanced Resuscitative Care is not truly specific to TCCC and is presented as the first step in what is envisioned as an area of increased focus and further development by the Joint Trauma System. The goal going forward will be to synchronize recommendations from the Defense Committees on Combat Casualty Care for Tactical, Surgical, and Enroute Care and to integrate efforts for earlier whole blood resuscitation and control of abdominopelvic torso hemorrhage throughout the continuum of care.

In order to responsibly implement the recommendations in this change, there must be accurate and thorough documentation of the care provided by damage control resuscitation and damage control surgery teams. It is essential that this information be entered into the DoD Trauma Registry in order to optimize care for each casualty and to enable continued improvements in care for all combat casualties.

—Col Jeff Bailey / Col Stacy Shackelford

The Joint Trauma System: bold, responsible battlefield medicine.

ABSTRACT

TCCC has previously recommended interventions that can effectively prevent 4 of the top 5 causes of prehospital preventable death in combat casualties—extremity hemorrhage, junctional hemorrhage, airway obstruction, and tension pneumothorax—and deaths from these causes have been markedly reduced in US combat casualties. Noncompressible torso hemorrhage (NCTH) is the last remaining major cause of preventable death on the battlefield and often causes death within 30 minutes of wounding. Increased use of whole blood, including the capability for massive transfusion, if indicated, has the potential to increase survival in casualties with either thoracic and/or abdominopelvic hemorrhage. Additionally, Zone 1 Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) can provide temporary control of bleeding in the abdomen and pelvis and improve hemodynamics in casualties who may be approaching traumatic cardiac arrest as a result of hemorrhagic shock. Together, these two interventions are designated Advanced Resuscitative Care (ARC) and may enable casualties with severe NCTH to survive long enough to reach the care of a surgeon. Although Special Operations units are now using whole blood far-forward, this capability is not routinely present in other US combat units at this point in time. REBOA is not envisioned as care that could be accomplished by a unit medic working out of his or her aid bag. This intervention should be undertaken only by designated teams of advanced combat medical personnel with special training and equipment.

KEYWORDS: Advanced Resuscitative Care; Committee on Tactical Combat Casualty Care; guidelines

Proximate Reason for This Proposed Change

TCCC has previously recommended interventions that can effectively prevent 4 of the top 5 causes of prehospital preventable deaths from these causes have been markedly reduced in US combat casualties. Noncompressible torso hemorrhage (NCTH) is the last remaining major cause of preventable death on the battlefield and often causes death within 30 minutes of wounding. Increased use of whole blood, including the capability for massive transfusion, if indicated, has the potential to increase survival in casualties with either thoracic and/or abdominopelvic hemorrhage.
Deaths on the battlefield. Deaths from extremity hemorrhage are now uncommon in combat casualties and deaths from junctional hemorrhages can be prevented with hemostatic dressings, junctional tourniquets, and XStat. Deaths from airway obstruction are now infrequent with most US combat medical personnel being trained in TCCC airway measures. Deaths from tension pneumothorax have been reduced by the use of 3.25 inch, 14 gauge needles after the study by Harcke and colleagues. Recommendations for the management of this disorder in TCCC have just been further updated to reflect emerging research findings and clinical experience. However, noncompressible torso hemorrhage (NCTH) remains the leading cause of preventable prehospital death for which TCCC currently has no definitive solution. NCTH may be either abdominopelvic or thoracic.

Patients with NCTH and shock who require a trauma laparotomy have been noted to have a mortality of 46% in civilian settings and this mortality rate has not changed over the last two decades. In the UK military, mortality for the subset of casualties with abdominopelvic hemorrhage and shock is 25%.

Improved prehospital control of abdominopelvic NCTH has the potential to reduce Died of Wounds (DOW) deaths as well. Mortality is low if the casualty survives the prehospital phase of care and reaches the care of a surgeon. Holcomb and colleagues found DOW rates to be 6.7% in Afghanistan and 4.7% in Iraq in the earlier years of those conflicts. Nessen and colleagues reported this year that while US military prehospital combat deaths (Killed in Action or KIA) decreased during the conflicts in Iraq and Afghanistan as compared to Vietnam, the incidence of DOW deaths in those who arrived alive at a Medical Treatment Facility (MTF) increased (5.3% for Iraq and Afghanistan vs 3.3% for Vietnam). Through treating hemorrhagic shock with whole blood and controlling abdominopelvic NCTH with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA), Advanced Resuscitative Care (ARC) in TCCC holds the potential to significantly decrease the incidence of DOW deaths as well as KIA deaths. Buehner and colleagues noted that 23% of 1704 casualties who arrived at a Role 3 Medical Treatment Facility (MTF) with a systolic blood pressure (SBP) less than or equal to 90mmHg did not survive. In 2009, Martin found that the two leading causes of DOW deaths were head injury (45%) and hemorrhage (32%). Martin further found that deaths from hemorrhage usually occurred in the resuscitation (31%) or operative (38%) phases of in-hospital care. It is clear that many of the casualties in the DOW category have potentially preventable hemorrhagic deaths. Having a stabilized casualty with a Zone 1 REBOA catheter in place at the time of arrival at the MTF therefore has the potential to save many casualties who would otherwise die from hemorrhage even after reaching a surgical capability.

The second major cause of death after reaching an MTF is head injury. Earlier control of hemorrhage, to include noncompressible abdominal and pelvic hemorrhage, and improved resuscitation from shock has the potential to reduce deaths from head injury as well. Avoiding prehospital hypotension was noted by Spalte to decrease the incidence of death in patients who had sustained moderate/severe Traumatic Brain Injury (TBI), indicating that improved prehospital hemorrhage control and better fluid resuscitation may offer the potential to reduce deaths in casualties who have both hemorrhagic shock and TBI as well as those who are in hemorrhagic shock without TBI.

For the critically injured, indicated lifesaving interventions must be undertaken shortly after wounding to maximize the number of lives saved. The “Golden Hour” concept applies to evacuation time. Evacuation to a treatment facility with a surgical capability within 60 minutes of approval of the Casualty Evacuation mission has been shown to reduce mortality when achieved, but death can occur well before 60 minutes in casualties with NCTH and shock. Additionally, there may be further delays to achieving definitive control of noncompressible hemorrhage even after the casualty arrives at a surgical capability. Holcomb notes that: “The peak time to death after severe truncal injury is within 30 minutes of injury. However, when adding prehospital transport time, time spent in the emergency department, followed by the time in the operating room, it currently takes 2.1 hours to achieve definitive truncal hemorrhage control.” It is clear that pre-OR hemorrhage control is required to decrease deaths from truncal hemorrhage.

Background
The Golden Hour

In 2009, Secretary of Defense Robert Gates mandated that operations in Afghanistan be planned such that all urgent casualties could be evacuated to a surgical capability within 60 minutes of TACEVAC mission approval. This action was subsequently found to be associated with a reduction in prehospital deaths among US combat casualties from 16.0% to 9.9%.

This Secretary of Defense mandate was specific to the relatively mature combat theater in Afghanistan at the time. Even in that setting, implementation of the mandate restricted operational planning and caused “surgical capability” to be redefined. The Golden Hour concept may be impossible to sustain in other combat settings, such as early entry operations, war with a near-peer nation, two simultaneous conflicts in different geographic regions, or a very large theater of conflict (Africa or the Pacific.) The present operational demands for general and trauma surgeons in the Army makes maintaining a sufficient number of fully trained and capable surgeons to meet deployed surgical requirements increasingly difficult. There is a need for a bridging capability to better sustain a severely injured casualty with NCTH from point-of-injury (POI) to a combat surgeon.

A substantial portion of the observed decrease in mortality in the years between 2001 and 2009—as compared to the time period from 2009 to 2014 after the Golden Hour mandate was in place—was due to other advances in battlefield trauma care that took place during the Afghanistan and Iraq conflicts, including the widespread adoption of TCCC interventions and the increased use of prehospital blood products.
Although faster evacuation of critically injured casualties to a surgical capability is inherently a desirable achievement, there is a substantial burden of mortality that occurs within the Golden Hour: “The peak time to death after severe truncal injury is within 30 minutes of injury.”22 A large study from the Pennsylvania trauma registry found that 5% of patients with severe injury had died by 23 minutes from time of injury, and 30% of patients with severe injury had died by 59 minutes. This further shortened to 19 and 39 minutes, respectively, for patients with penetrating injury and hypotension, the cohort with most similarity to severe combat injuries.32 Another published study notes that: “Time is the enemy: Mortality in trauma patients with hemorrhage from torso injury occurs long before the “golden hour.””25 Reaching the goal of zero preventable deaths requires that critical lifesaving interventions be performed as quickly as possible when they are indicated, not after a pre-established time period, such as 60 minutes.

As noted above, at the time that this proposed change to TCCC is being considered, the two interventions that hold the most promise for saving the lives of casualties with NCTH and shock during the prehospital phase of care are resuscitation with whole blood and—if the truncal hemorrhage is in the abdomen or pelvis—Zone 1 REBOA. NCTH from both thoracic and abdominal-pelvic bleeding sites. Zone 1 REBOA will provide additional benefit for those casualties whose NCTH is from abdominal or pelvic bleeding sites. These interventions must be integrated into a team resuscitation approach that also includes mastery of the entire spectrum of lifesaving TCCC interventions.

Current TCCC Recommendations for Preventing and Treating NCTH

Although the increased use of POI whole blood and REBOA are the two interventions for NCTH that are being addressed in this change, there are already a number of recommendations in place in the TCCC Guidelines that help to reduce NCTH and treat the hemorrhagic shock that NCTH may produce.33

Avoidance of platelet-impairing NSAIDs was recommended in the original TCCC paper10 and reinforced in 2014.34 Unfortunately, NSAID use is well-established in military culture for the treatment of the very common musculoskeletal injuries that combat troops experience. A 2012 study from Afghanistan noted that NSAID use—with the attendant impairment of platelet function—was observed in approximately 75% of deployed combat troops.35

TCCC recommends circumferential pelvic compression devices for casualties suspected of having pelvic fractures.36 These devices have been associated with reduced bleeding from this type of injury.

Tranexamic acid (TXA) has been found in multiple studies to reduce mortality in trauma patients who are bleeding.37-40 One large study based on combat casualty data from the DoD Trauma Registry found that TXA use “was not significantly associated with mortality due to lack of statistical power.” However, the authors also noted that “…our (hazard ratio) estimates for mortality among patients who received TXA are consistent with previous findings from the CRASH 2 trial.”41

For casualties who are in shock or who are at high risk of developing hemorrhagic shock, the TCCC Guidelines recommend that TXA be administered as soon as feasible after wounding.33,42 There is Level A evidence that TXA helps to reduce bleeding from various elective surgery procedures,43-45 and preventing hemorrhagic shock is better than treating it. Optimal use of TXA requires that it be given as soon as possible when indicated,33,46 rather than suggesting that TXA administration anytime within 3 hours after injury is acceptable, as some guidelines do.47 At present, however, there is no evidence that TXA is currently being given immediately after wounding in US casualties.41 A recent study found that only 19% of casualties in whom TXA was indicated received it in the prehospital setting.48 In contrast, the MATTERS paper noted that the 293 casualties who received TXA in that study were administered intravenous administration TXA (mean dose 2.3 gm) within 1 hour of injury.49 A recent prospective randomized trial of prehospital TXA administration in patients with traumatic brain injury (who were not hypotensive) identified a survival benefit with TXA, and found that a 2 gram dose provided the optimal benefit.49

TCCC has advocated for whole blood as the resuscitation fluid of choice for casualties in hemorrhagic shock since 2014 and for other blood products when whole blood is not available.50 There is now good evidence that prehospital blood products improve survival and that early administration of these products to casualties who require them is essential to optimal outcomes.24 Sperry et al have recently published their definitive study showing improved survival with prehospital plasma.51 Prehospital and hospital whole blood is being used by multiple civilian trauma systems.22 However, at the time of this proposed change to TCCC, whole blood or 1:1 RBCs and plasma are not being administered to most US casualties at the POI, unless the casualties occur in Special Operations units. Further, most US ground medics do not carry dried plasma, since an FDA-approved dried plasma product is not yet generally available.52,53

The addition of ketamine to the TCCC Guidelines55 and the subsequent development of the TCCC Triple-Option Analgesia plan56 have reduced the requirement for opioids to be used to achieve effective battlefield analgesia. This is especially important for casualties in hemorrhagic shock, since opioids depress cardiopulmonary function.

Hypothermia in combat casualties potentiates the coagulopathy of trauma and increases mortality.57-58 The strong TCCC emphasis on hypothermia prevention59,60 helps to reduce the incidence of coagulopathy and likely improves outcomes in all bleeding casualties, including those with NCTH, although the magnitude of this benefit has not been well-defined.

Rediscovering Whole Blood as the Preferred Resuscitation Fluid

Robertson in 1917 noted that “So far as my experience goes, there is no comparison between the results of blood transfusion and saline infusion. The effects of blood transfusion are instantaneous and usually lasting; the effects of saline too often transitory—a flash in the pan—followed by greater collapse than before.”61 Whole blood was used in the resuscitation of casualties in hemorrhagic shock in World War II, but when fractionation of whole blood into blood components became technologically feasible in the 1960s, the use of crystalloid solutions (predominantly normal saline and Lactated Ringers
The 1993 Battle of Mogadishu in Somalia documented the use and efficacy of whole blood in the modern era. The conflicts in Iraq and Afghanistan saw a resurgence of the use of whole blood for treating casualties in hemorrhagic shock. The use of whole blood was initially spurred by logistical constraints in delivering stored blood components, particularly platelets, to forward-deployed surgical teams, necessitating the use of “walking blood banks.” The beneficial effects of whole blood have been documented in research done by a number of individuals and organizations throughout the recent war years. The 2014 CoTCCC review of the fluid options for resuscitating casualties in hemorrhagic shock found that the optimal fluid to use was whole blood. A recent paper examined the impact of a number of factors on prehospital death in combat fatalities and found that the odds of KIA mortality were 83% lower in casualties who needed prehospital blood transfusion and received that intervention. Pivalizza and colleagues note that “During the course of combat trauma care in recent Iraq and Afghanistan campaigns, fresh WB has become a cornerstone of resuscitation.”

The American Association of Blood Banks recently endorsed the concept of using Low Titer Type O Whole Blood (LTOWB) as universal donor whole blood. Their recommendation for resuscitation of patients in hemorrhagic shock states: “Recipients shall receive ABO group-compatible Red Blood Cell components, ABO group-specific Whole Blood, or low titer group O Whole Blood (for nongroup O or for recipients whose ABO group is unknown).” The 31st edition of the standards goes on to indicate that the definition of “low titer” shall be made locally by each transfusion service, and that the transfusion service must have a policy specifying which patients are eligible to receive WB, the maximum quantity of WB per patient, and how to monitor for potential adverse events post-transfusion (standard 5.27.1). Figure 1 depicts a unit of LTOWB—the resuscitation fluid of choice in ARC.

The Southwest Texas Regional Advisory Council for Trauma, serving 22 counties over 26,000 square miles in Texas, has now made O+ cold-stored LTOWB its prehospital resuscitation fluid of choice for trauma patients meeting transfusion criteria. The group considered the impact of using Rh+ blood on female patients of childbearing age. In 30 months, there was only one female patient of childbearing age who met the criteria for the massive transfusion protocol, leading to the decision that O+ Type O Low Titer whole blood was safe and would best serve the needs of the community. The decision to use prehospital LTOWB was also made by the Harris County (Texas) EMS District #48 and Cypress Creek EMS in August of 2017.

A recent Joint Trauma System (JTS) review of trauma care in the US Central Command noted the increased availability of LTOWB for use in combat casualties and recommended making medics and austere surgical teams a priority for receiving LTOWB. However, LTOWB remains in limited supply across the battlefield and is not reliably available in the prehospital phase of care for all casualties who need emergent resuscitation for hemorrhagic shock.

Stopping the Bleed in Abdominopelvic NCTH

There are presently several interventions designed to control abdominopelvic NCTH that are either available or currently being developed. The first is the Abdominal Aortic Junctional Tourniquet (AAJT), a pneumatic device that applies external pressure to the abdomen through the use of a pneumatic bladder. This device has been shown to effectively occlude the aorta at the level of the bifurcation. The two primary concerns with the AAJT device are: 1) if the NCTH bleeding site is above the level of the aortic bifurcation, this device may actually increase bleeding; and 2) ischemia of the tissues distal to the occlusion site.

Even though teams with an ARC capability will have the ability to do Focused Assessment with Sonography in Trauma (FAST) exams to assess for intra-abdominal bleeding, a negative FAST exam does not completely exclude the possibility of intra-abdominal bleeding. A study of 413 combat casualties suspected of having suffered intra-abdominal injury found that while the specificity of FAST for intra-abdominal injury was 98%, sensitivity was only 56%. The patients in this study were not necessarily hypotensive, which would likely lower the sensitivity of the FAST exam in comparison to exams performed on patients with abdominopelvic hemorrhage severe enough to produce hypotension.

Aortic occlusion by both REBOA and the AAJT also entails the risk of cardiopulmonary arrest when safe aortic occlusion times are exceeded and the blood flow to—and from—distal tissues is restored. Kheirabadi reported that 3 of 6 spontaneously breathing pigs suffered a cardiopulmonary arrest when the AAJT was removed after a 2-hour application during which the aorta was occluded just above the bifurcation (which would mirror the occlusion in Zone 3 REBOA). The authors attributed these events to ischemia-induced hyperkalemia and hyperlactic acidemia.

FIGURE 1 Whole blood—the best option for resuscitation fluid on the battlefield.
metabolic acidosis. A subsequent study by Kuckelman and colleagues reported 100% mortality shortly after balloon deflation following 60 minutes of Zone 1 REBOA in an animal model that did not include post-deflation critical care support.

A second option currently being developed is ResQFoam, a novel device that uses two polymer precursors that mix as they are injected into the peritoneal cavity and expand, applying pressure to intra-abdominal bleeding sites. ResQFoam has been shown to control bleeding from both hepatopental injuries model and external iliac artery injuries in animal models. There have been preclinical safety studies of ResQFoam with 90-day survival periods to determine the optimal dosing of the foam precursors. These studies found that there were bowel lesions in all of the surviving animals. There is an FDA-cleared clinical study (not yet underway) to determine if the hemostatic benefit provided by ResQFoam outweighs the risk of enteric complications that may ensue from its use. ResQFoam is not yet FDA-approved, however, so this device may not be fielded with combat forces at the time of this writing.

The third option for controlling abdominopelvic NCTH is REBOA, which will be discussed further below. A recent publication examined the location of the primary bleeding site in 402 trauma patients who required an emergent laparotomy at a single trauma center. The study determined that Zone 1 REBOA could have been useful to stop the bleeding in 96% of patients; ResQFoam could have been effective in 87%; and AAJT could have been effective in 9%. The study also noted that the external location of the injury did not correlate well with the internal bleeding site.

The bottom line is that in 2018, neither the AAJT nor ResQFoam are viable options for controlling NCTH, so they will not be discussed further in this paper.

REBOA

REBOA is a relatively new tool that may enable casualties with abdominopelvic NCTH to survive until their bleeding can be definitively controlled at surgery.

The development of the REBOA technique evolved from the realization that NCTH is a leading cause for preventable trauma mortality for which survival has not been significantly improved in decades. The potential of the REBOA approach for saving the lives of trauma patients with abdominopelvic NCTH has caused it to be used over 4000 times in 264 hospitals (including 150 trauma centers) in the US and abroad within 30 months of the sale of the first ER-REBOA catheter (Prytime Medical, Boerne, Texas). Figure 2 shows the ER-REBOA device.

Although the presence of distal ischemia limits the time that full occlusion of the aorta can be tolerated, partial and intermittent REBOA techniques have the potential to allow for longer periods of effective control of abdominopelvic NCTH.

A 2016 report by Moore and colleagues reviewed all 31 patients for whom REBOA was performed between October 2011 and September 2013 at a Level 1 civilian trauma center. The authors note that “REBOA allows for the same physiologic result as open aortic cross-clamping through a less invasive, endovascular approach. Because of its minimally invasive nature, REBOA can be performed as a proactive (rather than reactive) measure in patients with refractory hemorrhagic shock from intra-abdominal/pelvic bleeding.”

The patients in that study were severely injured, with a median Injury Severity Score (ISS) of 34. Eighty-seven percent of them had suffered blunt trauma. Trauma patients with hemodynamic instability that was attributed to an obvious catastrophic head injury (defined as visible brain matter or transcranial gunshot wound) were not considered candidates for REBOA. Of the 10 patients who had suffered a traumatic cardiac arrest before REBOA was performed, 60% had a return of spontaneous circulation. Overall survival was 32%, but the incidence of early death from hemorrhage was 28% with only 2 of those deaths occurring prior to arrival in the operating room.

REBOA Zones

Aortic Zone 1 refers to the descending thoracic aorta between the left subclavian artery and the origin of the celiac trunk. Inflating the balloon in this zone will control hemorrhage in the abdomen and pelvis. Zone 2 is the aortic segment between the celiac trunk and the lower of the two renal arteries. This area is not used for REBOA. Zone 3 extends from the lower of the two renal arteries to the bifurcation of the aorta. Occlusion in Zone 3 can be used if there is assurance that there is no intra-thoracic bleeding and no intra-abdominal bleeding originating from vessels or solid organs above the level of the aortic bifurcation. Figure 3 illustrates the three aortic zones described above.

A significant limitation of REBOA in the prehospital environment is the relatively short time that aortic occlusion in Zone 1 is tolerated. The current JTS CPG recommends that Zone 1 balloon inflation time not exceed 30-60 minutes. There is potential for extending the time that Zone 1 REBOA can be used by employing partial or intermittent balloon inflation techniques. These will be discussed later in this paper.

REBOA Complications

REBOA is increasing in use in the hospital setting at this point in time. This procedure does entail the risk of a number of potential complications, including:

1. Distal ischemia
2. Loss of a lower extremity
3. Access site bleeding
4. Arterial access site thrombosis
A recent review found that the incidence of complications related to groin access in REBOA was 4–5%. Vascular complications resulting from the common femoral artery access required to insert the REBOA catheter have been reduced by transitioning from the previously used 14 Fr sheath to the newer 7 Fr sheath. Although the 7 Fr sheath has reduced the number of access site thrombotic complications from REBOA, vigilant monitoring of the distal pulses in the lower extremities is mandatory after the procedure. If there is loss of the distal pulses, prompt surgical attention to restoring arterial patency is required to prevent ischemic damage to the extremity. Perforation of the aorta is also a potential complication of REBOA, but this complication has not been reported with the use of the Prytime Medical ER-REBOA catheter and balloon in over 4000 uses (personal communication, Dr John Holcomb, Chief Medical Officer for Prytime Medical, 16 July 2018).

**REBOA in the Prehospital Setting**

Is REBOA a reasonable procedure to undertake in the prehospital setting? A recent study from Japan found that earlier REBOA was associated with reduced mortality when REBOA was undertaken in the hospital setting. Further, the mortality for patients who are in shock upon arrival at the Emergency Department and who subsequently receive a laparotomy is high (25-46%). In light of these two observations and with the caveat that REBOA only be undertaken in casualties who are nonresponders to the first unit of whole blood, the use of Zone 1 REBOA in a carefully defined subset of critically injured casualties with abdominopelvic NCTH and shock may offer a favorable risk/benefit ratio when performed by highly trained and well-equipped resuscitation teams.

REBOA is an advanced procedure, but there are precedents for undertaking lifesaving but invasive interventions in the prehospital setting. UK Medical Emergency Response Team (MERT) providers performed prehospital resuscitative thoracotomies on their evacuation aircraft in Afghanistan for casualties who lost vital signs during their transport to medical treatment facilities (MTFs) with some reported survivors. 

Another study described 71 patients with traumatic cardiac arrest who underwent prehospital resuscitative thoracotomy. There were 13 survivors (18%), to hospital discharge, 11 of whom had good neurologic outcome.

Fisher and colleagues have advocated strongly for prehospital REBOA, stating that: “The implementation of REBOA at Role I or POI for the provider is a daunting task and while it may not come to complete fruition, it should not stop the process to put state-of-the-art medicine at the POI in the hands of the Role I provider.” Other authors have also proposed prehospital REBOA as a “survival bridge” to definitive surgical care.

The explicit requirement for the exclusion of hemopericardium by ultrasound and for the insertion of bilateral chest tubes without finding significant hemothorax greatly reduces the likelihood of bleeding proximal to the occlusion when Zone 1 REBOA is used. Using the selection criteria proposed below, the only casualties for whom REBOA is recommended are those who—in addition to the absence of hemopericardium or hemodynamically significant hemothorax—also have:

1. an injury pattern that suggests abdominopelvic NCTH, and
2. an SBP < 90mmHg, and
3. an unsatisfactory response to the first unit of whole blood.

Given the high mortality for casualties with hemorrhagic shock resulting from abdominopelvic NCTH, as well as the ARC indication criteria in this report that have been carefully crafted to restrict the use of prehospital Zone 1 REBOA to the subset of casualties for whom this procedure is likely to provide the greatest benefit, the authors believe that prehospital REBOA is warranted when performed in accordance with the recommendations in this paper.

Far-forward REBOA is being undertaken at present by austere surgical teams in deployed US forces. Manley et al reported 4 cases of REBOA performed by a US Air Force Special Operations Team (SOST) in an austere, deployed military setting. All 4 patients had suspected abdominal or pelvic hemorrhage and systolic blood pressures in these 4 patients were 90mmHg, 70mmHg, 50mmHg, and unmeasurable. There were no complications with arterial access; there was immediate normalization of blood pressure in all 4 patients; and all 4 patients survived the approximately 2-hour transfer to the next echelon of care. There was no available information to document their clinical course after being transferred to local host nation facilities.

In the largest case series of REBOA use for severely injured combat casualties to date, Northern and colleagues described the outcomes of 20 REBOA procedures performed by their SOST team. Mean initial SBP was 71mmHg and mean heart rate was 129 BPM. Zone 1 REBOA was used in 17 patients and Zone 3 REBOA in the remaining 3. SBP increased by an average of 56mmHg and all casualties survived to reach the next level of care. All patients received whole blood as their
primary resuscitation fluid. There were no access complications. This report contains the notable finding that 18 of their 20 casualties had an initial SBP below 90mmHg and that all survived their initial laparotomy, however, since this care was provided to foreign nationals who were subsequently transferred to host nation medical treatment facilities, there was no follow-up after transfer. Figure 4 lists the tasks involved in preparing for and performing far-forward REBOA in this SOST.

**FIGURE 4** Tasks in the resuscitation of a hypotensive casualty with NCTH by an austere surgical team.

Although these initial reports of successful far-forward REBOA are encouraging, it is important to note that the procedures described in both the Manley and the Northern case series involved REBOA being accomplished by well-trained surgeons or emergency medicine physicians who were functioning as part of an austere surgical team that had basic operative capabilities and could obtain direct control of torso hemorrhage at laparotomy following REBOA. It is likely that the use of REBOA in true presurgical settings will be even more challenging. This highlights the critical importance of using a “focused empiricism” approach to implementing advances in battlefield trauma care. This approach should include careful attention to defining, training for, fielding, and refining this new capability, as well as to thorough documentation and analysis of casualty outcomes.

Direct comparisons between the outcomes reported in the two far-forward REBOA papers discussed above and the higher mortality noted by Harvin and Marsden in hypotensive patients who undergo trauma laparotomies as well as the 25% mortality in combat casualties noted by Marsden are not possible because the 24-hour and 30-day outcomes for the casualties in the Manley and Northern studies are not known. The majority of deaths from hemorrhage, however, occur within 3 hours of admission to an MTF. The Manley and Northern reports cited above, however, serve to demonstrate that Zone 1 REBOA and whole blood resuscitation are feasible in an austere environment when performed by a highly trained resuscitation team, and may improve survival in combat casualties with NCTH, especially those with abdominopelvic bleeding.

The 2018 paper by Greene notes the current controversies surrounding the use of the novel REBOA procedure but, as noted by Col Todd Rasmussen, effecting advances in trauma care necessarily involves challenging existing dogma and implementing changes to the previous standards.

**Preventing Hemodynamic Decompensation in NCTH**

Avoidance of platelet-impairing NSAIDs in combat forces and early administration of TXA in casualties at risk for hemorrhagic shock may help to promote hemostasis and reduce blood loss from noncompressible bleeding sites. The use of pelvic binding devices may also help to reduce the bleeding associated with pelvic fractures.

Blood loss of sufficient magnitude to cause hemorrhagic shock produces inadequate tissue oxygenation, followed by hemodynamic collapse as manifest by hypotension. In casualties with suspected NCTH, the goal should be to prevent hemodynamic decompensation and cardiovascular collapse if possible, rather than to treat those conditions after they occur. As noted previously, in civilian trauma patients who present to the ED in shock (SBP <90) and who require an emergent trauma laparotomy, the mortality has been found to be 46%, and that incidence of mortality has not improved over the past two decades.

When significant reductions in intravascular volume occur in casualties with NCTH, compensatory mechanisms such as activation of the sympathetic nervous system and selective vasoconstriction may preserve the SBP at a normal level until well after anaerobic metabolism has begun. Occult shock (prior to a decrease in SBP) may be detected by an increased lactate level. Initiation of whole blood transfusion when elevated lactate levels are noted in the prehospital phase of care may help to prevent or delay the development of subsequent hemodynamic compensation, with its attendant increase in mortality. Other indicators such as a decrease in the intravascular Compensatory Reserve Measurement may also be useful in the near future for the early detection of decreased intravascular volume prior to the development of hypotension.

**Discussion**

**Advanced Resuscitative Care**

The central focus of this proposed change is to recommend that: 1) the use of LTOWB be expanded and moved closer to the point of injury than has been the case in the past for most US forces; and that 2) Zone 1 REBOA be used to control life-threatening abdominopelvic NCTH when the initial whole blood resuscitation has failed to raise the casualty’s SBP to at least 90mmHg. These two interventions together comprise a new capability in battlefield trauma care referred to in this document as “Advanced Resuscitative Care” or ARC. It is not envisioned that these two interventions are ones that could be accomplished by a unit medic working out of his or her aid bag, but rather would be accomplished by a purposed team of advanced combat medical providers with special training and equipment.

Advanced Resuscitative Care (ARC) as outlined in this paper could be employed in selected tactical settings to improve casualty survival. ARC entails more than Tactical Field Care (TFC) or Tactical Evacuation (TACEVAC) Care as defined previously for TCCC. It is less than a true surgical capability, but the ARC recommendations below may be of significant use to surgical
teams in certain settings, such as in very austere environments where laparotomy is not feasible or during mass casualty incidents where surgical control of NCTH may be delayed.

Although whole blood resuscitation can be provided by a single prehospital provider in some settings, to accomplish robust whole blood resuscitation, perform ultrasound, insert chest tubes, establish an advanced airway, and possibly perform subsequent REBOA, requires a team of four or more specially trained and equipped advanced providers. When a casualty meets the indications for whole blood resuscitation, transfusion should be initiated as quickly as possible, followed rapidly by Zone 1 REBOA if that procedure is indicated as outlined below. ARC could be provided to supplement Tactical Field Care by a team located near the point of injury, or it could be used to supplement TACEVAC Care on an evacuation platform. Whenever tactically feasible and operationally indicated, a team with an ARC capability should be positioned as close to the point where casualties are likely to be sustained as possible, since many casualties with NCTH will die within 15–30 minutes without ARC.21 For these casualties, Advanced Resuscitative Care may be the only thing that will effectively prevent their death from exsanguination.

Note that ARC is NOT Prolonged Field Care (PFC). The US military has recently increased its focus on strategies to improve outcomes in casualties who require field medical care for periods that exceed doctrinal planning timelines—up to 72 hours. Recommendations for care provided in such circumstances have been named Prolonged Field Care and PFC is a rapidly evolving new dimension to combat casualty care.111

ARC is a different concept and is focused on the initial resuscitation and stabilization of critically injured casualties in order to enable them to reach the next phase of care alive and with the best chance of survival. ARC needs to be performed as soon as possible after wounding and there is no representation in this proposed change that ARC will allow a critically injured casualty to be sustained in the field for a prolonged period of time. Any casualty who needs the interventions in ARC needs a surgeon and definitive hemorrhage control as soon as possible.

However, there is an expanding array of resuscitation teams in the US military that are designed to provide a bridging capability between TCCC and the casualty’s arrival at the first surgical capability. ARC will have a distinct role in enhancing the capability of these austere care teams to provide lifesaving trauma care with fewer required resources and more mobility than forward surgical teams. These teams may in time have a more important role in medical planning as they become better able to extend survival time for casualties with NCTH prior to damage control surgery.112

The intermittent REBOA technique outlined below resulted in 100% survival out to 120 minutes in the presence of an otherwise lethal vascular injury in an animal model of truncal hemorrhage.26 If these findings translate well to combat casualties with abdominopelvic NCTH, they have the potential to transform battlefield trauma care and significantly reduce a remaining cause of potentially preventable death in US combat wounded. This would have significant implications for both improving casualty survival and enabling more flexibility in operational planning.

Remember the TCCC Basics

Advanced Resuscitative Care should not be undertaken until the lifesaving interventions already recommended in the existing TCCC Guidelines have been accomplished:

- External hemorrhage control should be accomplished with limb tourniquets, hemostatic dressings, XStat, and junctional tourniquets as needed.
- The airway should be opened if needed.
- Suspected tension pneumothorax should be treated with needle decompression.
- Circumferential pelvic compression devices applied as indicated.
- TXA should be given immediately if indicated and not already given.
- If the casualty is in cardiac arrest, bilateral NDC should be performed.1

Additional Capabilities (beyond Standard TFC) that Should Be Available in ARC

- Electronic blood pressure monitoring
- Advanced airway
- Whole blood—Preferably FDA-Compliant Cold Stored LTOWB or LTOWB collected from donors in a unit-based Walking Blood Bank, such as that established in the 75th Ranger Regiment.91 (1:1 RBCs and plasma are better than crystalloids or colloids, but should only be used when, for some reason, whole blood is not available.10,112)
- Point-of-care ultrasound and the capability to perform EFAST to in order to identify intrathoracic and intra-abdominal bleeding and to rule out hemopericardium before undertaking REBOA
- Tube thoracostomy—ideally with suction—to more definitively role out intrathoracic bleeding before undertaking REBOA
- Zone 1 REBOA
- Point-of-care lactate monitoring
- Blood warming devices
- Supplemental oxygen
- A timing device for balloon inflation times
- Foley catheter—both to guide resuscitation and to assist in hemostasis
- A reliable plan for complete documentation of casualty care in ARC

Indications for Whole Blood Transfusion in ARC

Which casualties require whole blood transfusion in ARC? Combat medical personnel should adhere to the JTS Damage Control and Whole Blood Transfusion Clinical Practice Guidelines (CPGs) insofar as possible:

*TCCC-specific considerations include:

- The casualty has known prior external hemorrhage (even if that hemorrhage is now controlled) and/or is suspected to have NCTH AND
- Systolic Blood Pressure (SBP) is less than 90mmHg OR
- Point-of-care lactate is 4mmol/L or greater10,7,10,11,113

The use of 90mmHg SBP as a threshold value for initiating whole blood resuscitation is consistent with both the current JTS CPG for DCR and the present TCCC Guidelines.3,112
Point of care or emergency department lactate measurement is being increasingly recognized as a way to identify trauma patients in whom anaerobic metabolism has begun to occur and in whom lifesaving interventions are more likely to be required. In a prospective 2008 study of 124 patients who required emergency transport and had SBPs of 100 or below, Jansen et al noted that individuals with a prehospital lactate (performed at the time of ambulance arrival at the scene) of 3.5mmol/L or higher, had a significantly higher mortality (41%) than those with a lactate level of 3.4 or lower (12%). Guyette and colleagues noted that a threshold POI lactate of 2.5mmol/L had the same specificity for predicting the need for resuscitative care as an SBP of 90mmHg or less. They noted further that there was a linear association of POI lactate and the need for resuscitative care in the range of 2.5 to 3.9mmol/L, and that beyond a threshold value of 4.0mmol/L, higher POI lactates were not associated with further increases in the need for resuscitative care. In their review of POI lactate measurement, Lewis and colleagues noted that all of the patients in the 2015 Guyette study who required resuscitative care had a POI lactate greater than 3.4mmol/L. The Southwest Texas Regional Advisory Council chose a prehospital lactate of 5mmol/L or greater as an indication for prehospital blood transfusion.

Additionally, many combat casualties have Traumatic Brain Injury (TBI) as well as NCTH. The presence of prehospital hypotension has been shown to increase mortality in casualties with TBI. The use of point-of-care lactate measurements may allow identification of patients with ongoing NCTH before they become hypotensive and thus increase survival in the subset of casualties with both NCTH and TBI. Many point-of-care lactate monitoring devices are FDA-approved for use in monitoring the level of anaerobic metabolism in athletic events. Two devices that have been FDA-approved for use as medical devices are the Lactate Pro 2 (Arkray) and the StatStrip (Nova Biomedical). The i-Stat device (Abbott) also includes lactate measurement in its capabilities.

Compensatory Reserve Measurement is a technology in development that may also improve early identification of occult hemorrhage in casualties with NCTH by detecting the presence of significant loss of intravascular volume through continuous analysis of arterial pulse waveform before there is an observed decrease in systolic blood pressure. At present, however, a device that has been proven to accurately and reliably measure the compensatory reserve in an austere environment is not commercially available.

Whole Blood Transfusion Procedure in ARC

Individuals performing whole blood resuscitation in ARC should follow the JTS Damage Control and Whole Blood CPGs except as follows:

*TCCC-Specific Considerations:

a. Resuscitation should be initiated with FDA-compliant Cold-Stored Low Titer Type O+ Whole Blood (LTOWB) as the preferred option and every effort should be made to have cold-stored LTOWB available.

b. LTOWB from a unit-based, pre-screened and pre-titered walking blood bank (WBB) should be used as the second option if FDA-compliant cold-stored LTOWB is not available.

c. If there is a unit based, pre-screened WBB designed to collect whole blood but that does not include quantification of Anti-A and Anti-B antibody titers as part of the prescreening process, utilize untitered Type O units of whole blood as the third option.

d. If there is a unit-based WBB designed to collect, type, and transfuse type-specific whole blood, that is a fourth option.

*NOTE: Option (d) may result in morbidity or even death due to ABO mismatch if the wrong blood type is transfused.

*NOTE: 1:1 Type O RBCs and plasma should be used in the suboptimal circumstance that FDA-compliant whole blood is not available, but FDA-compliant red blood cells and plasma are available.

*NOTE: Use of non–FDA-compliant whole blood requires additional post-transfusion monitoring per DoD directives.

e. Continue resuscitation until an SBP of 80–90mmHg is present.

f. If the casualty has an altered mental status due to suspected TBI, resuscitate as necessary to restore and maintain a target SBP of at least 90mmHg.

g. During resuscitation, blood products should be warmed using a fluid warmer and infused rapidly.

h. As whole blood transfusion is being performed, consider obtaining early common femoral artery access so that REBOA can be undertaken quickly after the first unit of whole blood has been administered should the casualty subsequently be found to meet the criteria for REBOA.

Whole blood has been previously identified as the preferred resuscitation fluid in TCCC for casualties in hemorrhagic shock. In the previously mentioned case series by Northen et al, the authors noted that in caring for their 20 critically injured casualties, they transfused 128 units of whole blood (57% of blood products transfused). Their paper stated that: “It is the opinion of the authors that all patients requiring damage control resuscitation should be treated with only whole blood (Low Titer O Whole Blood) and/or FWB) when massive transfusion is anticipated.” Resuscitation should be initiated with FDA-compliant, cold-stored LTOWB as the preferred option and every effort should be made to have cold-stored LTOWB available. FDA-compliant LTOWB is now being shipped from the US and distributed across the battlefield in the US Central Command. The logistics of cold-stored whole blood carriage are a challenge for ground medics, although small portable containers capable of maintaining cold storage conditions for up to 72 hours without power are now available. Teams with an ARC capability should have access to larger capacity passive cold-storage blood storage containers or actively cooled containers.

Although cold-stored, FDA-compliant LTOWB is the first choice for whole blood resuscitation when logistically feasible, there are other options for obtaining whole blood on the battlefield. The 75th Ranger Regiment has pioneered a unit-based WBB in which all members of the unit are typed, screened for transfusion-transmitted pathogens, and have anti-A and anti-B immunoglobulin (IgM) levels quantitated. Those with an IgM titer < 256 are considered to be universal donors. When whole blood is needed to transfuse casualties in the prehospital phase of care, blood is collected from the universal donors for this purpose. Fresh, Type O, low-titer whole blood from unit-based, pre-screened and pre-titered WBBs should be used as the second option if FDA-compliant cold-stored LTOWB is not available.
Another option for a walking blood bank capability is to use a simpler and less expensive process to identify potential FWB donors. Approximately 40% of the US population is Type O and, in the event of a mass casualty, these individuals could be called upon to serve as universal donors without the expensive additional step of quantifying their Anti-A and Anti-B titers. As noted in the 2013 paper by Nessen, despite the extensive use of untitered Type O whole blood during World War II, there were no reports of the intravascular hemolytic transfusion reactions (IHTR) typical of the transfusion reactions caused by high Anti-A and Anti-B titers until 1944, when a few incidents were noted.125,126 These episodes of IHTR did not cause any fatalities, but did result in a subsequent US policy of screening Type O donors for Anti-A and Anti-B titers. Those found to have high titers were excluded from serving as “universal donors.”126 Nessen described the use of FWB in 94 patients, 51% of whom received type-specific FWB and 49% that received un-cross-matched Type O FWB. The authors concluded that: “Mortality was similar for patients transfused un-cross-matched Type O FWB compared with ABO type-specific FWB in an austere setting. Further studies evaluating outcomes related to the use of un-cross-matched Type O FWB in these settings are warranted.”123

Type specific fresh whole blood drawn from a walking blood bank is standard massive transfusion practice for US Role 2 facilities.130 The paper by Miller et al describes the mass casualty incident that was managed by the surgical team aboard the USS Bataan.124 The ship carried 20 units of Type O PRBCs and 8 units of frozen plasma to support its embarked Role 2 capability. In addition, however, the ship’s crew and embarked Sailors and Marines are also considered potential blood donors. It is the practice of Navy casualty-receiving ships to transfuse type-specific FWB, not fresh LTOWB, and 34 units of warm, fresh, type-specific whole blood were obtained and used for 2 of the patients cared for by the team on the Bataan. In the Role 2 shipboard setting, blood-typing and transfusion-transmitted disease testing is performed by a trained laboratory technician.124 While this option is feasible, it is clearly a less-desirable choice for ARC than either cold-stored or fresh LTOWB because of the potential for a potentially fatal major ABO mismatch, especially when done in the prehospital setting rather than by a Role 2 surgical team.

Cordova published a case report of a critically-injured casualty who was treated with type-specific FWB in Afghanistan. The casualty did not survive his wounds, but the transfusions resulted in temporary improvements in his condition.131 This option may also be feasible for Special Forces medics, who are taught to use Eldon cards to enable type-specific transfusions for small Special Forces teams if needed.

In summary, the two preferred options for whole blood transfusion in ARC are cold-stored, FDA-compliant LTOWB or fresh LTOWB from a pre-screened and pre-titered walking blood bank. Untitered Type O FWB entails additional risk over a low-titer product, but the risk of reaction is not high and fatal hemolytic reactions are rare. Type specific FWB may be used as a last resort, but a type mismatch using this option carries the risk of potentially fatal hemolytic reaction.

The latter two options are less desirable, especially when blood-typing is not performed by trained and experienced technicians, but may be considered when cold-stored LTOWB or fresh LTOWB donors are not available.

Whole blood should be warmed during transfusion. A recent review of battery-powered blood warmers found that the Warrior device (QinFlow, Tel-Aviv, Israel) performed better than the Buddy Lite and the Thermal Angel.132

Bjerkvig and colleagues have recently examined the question of transfusion speed when using sternal interosseous devices as compared to peripheral intravenous access.133 450mL of autologous blood was collected from volunteers and reinfused (along with 63mL of CPDA-1) using either an 18-gauge peripheral IV, the Tactically Advanced Lifesaving IO Needle (T.A.L.O.N.) or the FAST1 IO. There were 10 subjects in each group. The reinfusion was accomplished with gravity alone, without the use of pressure infusers. The median reinfusion rate was found to be 32.4mL/min in the T.A.L.O.N. group, 46.2mL/min in the FAST1 group, and 74.1mL/min in the intravenous group. There was no evidence of hemolysis resulting from the procedure. The authors noted that the FAST1 group, had 1 (9%) failure in 11 procedures, whereas the T.A.L.O.N. group had 4 (29%) of 14 procedures fail. The authors’ conclusion was that peripheral IV access is preferable if it can be obtained, but that IV access is often problematic in bleeding casualties and that the sternal IO route is an acceptable alternative.

As whole blood transfusion is being accomplished, the provider should be aware of the need to prepare for REBOA should it appear likely that this further intervention will be needed to stabilize the casualty. It is helpful to obtain common femoral artery access before SBP drops to a level that makes the procedure more difficult. A recent paper by Matsumura noted that “Moreover, since the difficulty in obtaining arterial access increases exponentially according to hemodynamic instability, the decision to access early influences the subsequent resuscitation and hemostasis.”95

**Indications for REBOA in ARC**

The indications for REBOA listed below reflect the indication specified in Appendix B of the Joint Trauma System REBOA CPG: “SBP < 90 with Transient or No Response to Initial ATLS Resuscitation”135 with additional provisions made for the prehospital environment.

*TCCC-Specific Considerations:*

a. Relevant Tactical Field Care interventions (external hemorrhage control, pelvic binding, and TXA) have been accomplished; AND
b. Advanced monitoring (Electronic blood pressure measurement) has been established; AND
c. ARC resuscitation has been previously initiated with whole blood if feasible or other blood products as noted previously; AND
d. SBP remains < 90mmHg immediately after 1 unit of whole blood or 1 unit each of RBCs and plasma have been administered as quickly as possible; AND
e. The casualty has penetrating or severe blunt force injury to the abdomen or pelvis and a positive FAST exam or is judged to be at high risk for abdominopelvic NCTH or is noted to have difficult-to-control junctional hemorrhage. AND
f. Intrathoracic bleeding and hemopericardium have not been found on bilateral chest tube insertion and chest ultrasound exam.
The indications listed above are designed to rule out intrathoracic bleeding and hemopericardium that might be worsened by Zone 1 REBOA. In discussing REBOA in a pending paper, King notes that: "The major principle of reasonably excluding hemorrhage in any cavity proximal to proposed balloon occlusion is of paramount importance. Occlusion distal to a vascular injury may result in rapid proximal blood loss and death." 134

There was some advocacy among our author group for Zone 3 REBOA in carefully selected clinical settings when performed by experienced providers for casualties who are believed to have hemorrhage isolated to the pelvis or lower extremity junctional regions. The FAST exam has been found to be reliable in ruling out abdominal NCTH in some specific trauma settings. Christian and her co-authors found a false negative rate of only 2% for the FAST exam when used to evaluate hemodynamically unstable patients with pelvic fractures. 135 In such cases, if no immediate improvement is noted in the blood pressure or if there is recurrent hypotension, then the balloon should be immediately advanced to the Zone 1 position. In the prehospital combat setting, however, where there is often injury caused by high-velocity projectiles or fragments, the results of a negative FAST exam are less definitive. There are studies that have shown that a negative FAST exam does not always exclude the presence of intra-abdominal hemorrhage with certainty. 79, 136, 137 A second reason to favor Zone 1 REBOA in the prehospital environment is that, for casualties with abdominal pelvic NCTH and shock, immediate hemodynamic support is needed. Tibbits et al found that Zone 1 REBOA produced a significantly greater proximal mean arterial pressure than Zone 3 REBOA—(127.9mmHg vs 53.4mmHg) in an animal model—and recommended that Zone 3 REBOA not be used for hypotensive patients. 138 Lastly, the study by Cantle et al described a case series of 402 patients who required an emergent trauma laparotomy at one trauma center. Based on the location of their bleeding sites, Zone 1 REBOA would have been potentially helpful in controlling hemorrhage in 384 (96%) of patients, whereas aortic occlusion in Zone 3 would have helped control bleeding in only 35 patients (9%). 78

REBOA Procedure in ARC
REBOA in TCCC Advanced Resuscitative Care will be done in accordance with the current version of the REBOA CPG posted on the Joint Trauma System website (presently the one dated 6 July 2017) with the following additional recommendations to make it more suitable for the TCCC setting:

*TCCC-specific considerations:

a. Placement of REBOA should be done in consultation with a surgeon at the receiving medical treatment facility (MTF), if at all possible. This will both provide expert assistance on the decision to use REBOA and alert the receiving MTF so that they can prepare for the casualty.

b. Teams with an ARC capability should have a CoTCCC-recommended junctional tourniquet available to control access site bleeding should that be encountered. 7

c. If the junctional tourniquet has already been used for another casualty, 30 minutes of direct pressure with Combat Gauze or another TCCC-recommended hemostatic dressing should be used to control access site bleeding.

d. Ketamine can be used for procedural analgesia and sedation. Opioids should be avoided in hypotensive casualties. 84

e. All REBOA in TCCC is Zone 1, since intra-abdominal hemorrhage originating above the aortic bifurcation cannot be definitively ruled out by a negative FAST exam.

f. Once the casualty has been determined to meet the criteria for REBOA, the procedure should be undertaken promptly, since further decreases in systolic blood pressure will make common femoral artery access significantly more difficult to obtain.

g. Placement of the balloon in aortic Zone 1 is guided by the markings on the ER-REBOA catheter. 75

h. Fully inflate the balloon in Zone 1. Start with 8–10mL of any crystalloid IV fluid. Confirm full occlusion by noting that the contralateral femoral pulse is extinguished.

i. If the contralateral femoral pulse is still present, add more mL of IV fluid and recheck the pulse. Repeat until the pulse is extinguished or a maximum of 24mL of fluid has been used.

j. Leave the balloon inflated for 15 minutes. The SBP should increase quickly and substantially after balloon inflation when the bleeding site is distal to Zone 1.

k. After 15 minutes, slowly deflate the balloon completely over 30 seconds.

l. Re-assess the casualty. If he or she has an SBP of 80mmHg or greater, leave the balloon deflated.

m. Continue to monitor.

n. If the SBP drops below 80mmHg, re-inflate the balloon and use either Option 1 or Option 2 as guidance for further inflation while continuing whole blood resuscitation.

o. Balloon Inflation Timing—Option 1:

As long as the periods of balloon deflation without SBP dropping below 80mmHg continue to be 3 minutes or longer, use 10-minute inflation periods followed by another deflation for as long as is tolerated (SBP remains 80mmHg or higher) out to a maximum of 120 minutes. Continue resuscitation with whole blood.

p. Balloon Inflation Timing—Option 2:

If the casualty does not maintain an SBP of 80mmHg or higher for at least 3 minutes after balloon deflation, then re-inflate the balloon and use a maximum of 30 minutes total balloon inflation time. Continue resuscitation with whole blood.

q. If the casualty has stabilized (SBP remains above 80mmHg without balloon inflation) after the inflation times specified above, but is more than 4 hours from the care of a surgeon, remove the sheath and hold pressure for 30 minutes with a junctional tourniquet or with Combat Gauze or another TCCC-recommended hemostatic dressing. Evaluate for distal pulses in the extremity.

r. If the casualty has stabilized as noted above, but is within 4 hours of surgical care, leave the sheath in place, and flush the side port every 15–30 minutes with 3mL of IV fluid.

s. Document distal pulses frequently.

t. Once REBOA has been performed, every effort should again be made to communicate with the surgeon who will be receiving the casualty and obtain his or her recommendations for subsequent management.

u. Document all aspects of the REBOA procedure.

The challenge in using Zone 1 REBOA for temporary control of NCTH below the diaphragm is to effectively control or...
minimize abdominopelvic hemorrhage while also minimizing the negative consequences of the ischemia sustained in the tissues below the occlusion.

The intermittent REBOA protocol above is based largely on the recent publication by Kuckelman and his colleagues from the research laboratory at Madigan Army Medical Center. In a swine model of abdominopelvic NCTH that was 100% lethal in untreated control animals (n=7), intermittent Zone 1 REBOA techniques (both time and pressure-based) resulted in 100% survival in 16 animals for the 120-minute study period. In contrast, all 5 animals treated with full occlusion REBOA survived the 60 minute occlusion period, but died shortly after the balloon was deflated. Mean time to death was 63 minutes—or 3 minutes after balloon deflation. The Intermittent Zone 1 REBOA protocol proposed above uses the time-based intermittent REBOA technique developed at Madigan and described in the Kuckelman study in conjunction with a modification proposed by Col Todd Rasmussen of the Uniformed Services University: if the casualty remains stable after the balloon is deflated following the initial 15-minute inflation, the balloon is left in place but not re-inflated unless SBP drops below 80mmHg again. There is at present no data on the safety and efficacy of this intermittent REBOA technique beyond the 120 minutes study period used in the Kuckelman paper.

There is limited evidence to support recommendations for a specific safe maximum time for Zone 1 aortic occlusion, however most authors agree that an occlusion time of less than 30 minutes is safe. King states in a pending paper that “Abdominal visceral ischemia limits occlusion time to less than 30 minutes.” The current JTS CPG specifies that balloon inflation in Zone 1 be limited to 30-60 minutes. In a survey of participants in the International Endovascular and Hybrid Trauma and Bleeding Management Symposium, DeSoucy found that, of 86 respondents to a post-conference survey, 35% stated that the maximum time for aortic occlusion in Zone 1 should be 30 minutes or less; 9% favored an occlusion time of 45 minutes or less; 6% favored an occlusion time of 60 minutes or less; 19% believed that there should be no limit if the patient remains unstable; and 31% believed that current available data is insufficient to provide a recommendation.

As noted previously, all 5 animals treated with full occlusion Zone 1 REBOA survived the 60 minute occlusion period, but died at a mean time of 3 minutes after the balloon was deflated. Reva and colleagues studied survival in sheep that underwent thoracic occlusion of the aorta for either 30 or 60 minutes. Hemorrhagic shock was induced in 18 animals through 35% controlled hemorrhage accomplished over 30 min. The sheep were randomized into three groups: 60-minutes of REBOA begun 30 minutes after the bleeding (60-REBOA); 30 minutes of REBOA begun 60 minutes after the bleeding (30-REBOA); and no-REBOA as controls (n-REBOA). Fluid resuscitation was accomplished with crystalloids and whole blood initiated 20 and 80 minutes after shock was induced. The duration of the study period was 24 hours with autopsies performed to evaluate organ damage. Twenty-four hour survival was noted to be 0/6 in the 60-REBOA group; 5/6 in the 30-REBOA group; and 4/6 in the control group (P = 0.002). As with the Kuckelman study, there was no provision of critical care interventions to mitigate reperfusion sequelae after balloon deflation. At autopsy, acute tubular necrosis was seen in all of the REBOA animals that died.

Kheirabadi noted that 50% of the spontaneously breathing animals in his study died from cardiopulmonary arrest shortly after AAJT removal following 2 hours of aortic occlusion just above the bifurcation. In contrast, the intermittent Zone 1 REBOA approach studied by Kuckelman produced 100% survival out to 120 minutes, demonstrating that intermittent Zone 1 REBOA can be performed with good results and less risk of ischemic complications than application of the AAJT for the same period of time. The modification suggested by Rasmussen builds on this work—and in theory increases the safety of the procedure—by calling for the balloon to remain deflated after the initial 15-minute inflation—unless it is clinically needed, as indicated by the casualty’s SBP dropping below 80mmHg after balloon deflation.

Advanced Resuscitative Care—A Team Effort

TCCC has in the past been focused on interventions that can be accomplished by a single combat medical provider working out of his or her aid bag. To restate the point made previously, ARC is NOT that. REBOA is not proposed as an addition to the standard skill set of combat unit physicians, physician assistants, or combat medical personnel unless they are part of a team that has been specifically designated and designed to have an ARC capability. REBOA should be performed by these designated, trained, and equipped teams. The individual who actually performs the procedure should be skilled at arterial access and ultrasound; should have been trained at an approved REBOA training course; should have demonstrated the ability to successfully accomplish this procedure; and should be trained as well in the ARC intermittent Zone 1 REBOA procedure that is specifically designed for the prehospital setting.

The optimal composition of teams performing ARC remains to be determined, but Figure 4, discussed previously, outlines the multiple tasks that must be performed rapidly in order to ensure that whole blood resuscitation and REBOA—if indicated—can be undertaken without delay. Among the tasks that will need to be performed are: ensuring an adequate airway, electronic monitoring of vital signs, establishing IV or IO access, preparing and infusing blood products, performing EFAST and bilateral chest tubes, establishing common femoral artery access, prepping the REBOA site, performing the REBOA procedure, and recording the events that occur during the resuscitation. Collectively these interventions and actions require a team of at least 3 or 4 individuals in order to be done quickly and efficiently.

Although a Joint Statement from the American College of Surgeons and the American College of Emergency Physicians stated that REBOA use should be restricted to surgeons and emergency medicine physicians who have done a critical care fellowship, this recommendation has been contested by other authors, including US military medical officers. Northern and colleagues noted that 7 of their 20 REBOA procedures were performed by Emergency Medicine (EM) physicians. Matsumura and colleagues reported in a study of 142 REBOA procedures from 18 hospitals in Japan that 94% of REBOA procedures were performed by EM physicians.
Teams with an ARC capability could be unit-based or assigned to support combat units when indicated for specific operations. Medical leaders in the military services or combat unit commanders will decide whether or not to establish teams with an ARC capability and would determine the composition, training, and employment plan for these teams. In addition to having completed an approved training course, every effort should be made for individuals who will be performing REBOA on combat casualties to maintain an ongoing experience in this procedure using simulators or as part of a trauma team in a civilian trauma center. Procedural fluency is the key to success.

Options for Fielding an ARC Capability

While an organized effort to incorporate routine use of whole blood to resuscitate casualties in hemorrhagic shock and the use of prehospital REBOA is a new concept, all of the services have organizational entities already in place that could serve as teams through which ARC concepts could be employed:

- USMC—Shock Trauma Platoons/Squads
- Special Operations Forces—Special Operations Resuscitation Teams
- Conventional Army—Battalion Aid Stations
- Maritime—Shipboard-based care on vessels
- Special Operations Forward Operating Bases
- Advanced Capability Evacuation Platforms (eg—UK Medical Emergency Response Team—Enhanced; 160th Special Operations Aviation Regiment Tactical Evacuation teams; and USAF Tactical Critical Care Evacuation Teams)

Some of these potential users of ARC already have Emergency Medicine and/or Critical Care physicians included in the teams. It is also worthy of note that, in some locations and situations, austere surgical teams might function in a resuscitation capacity enroute to a higher level of care and could make use of the ARC intermittent REBOA protocol outlined above in order to delay the need for laparotomy. For casualties with abdominopelvic NCTH and shock, early resuscitation with whole blood and REBOA may well improve the results of surgical intervention when that becomes feasible.

Training for Advanced Resuscitative Care

Preparing surgeons—and other combat medical providers—to care for the casualties of war requires that lifesaving skills needed for the combat environment be mastered in noncombat settings. Both the American College of Surgeons (ACS) and the US military have REBOA training programs. Likewise, whole blood administration training is available in a number of venues. Training for teams that will be performing ARC must include either a single course that incorporates all of the skills enumerated above or a combination of courses that do so—and provides assurance that these skills have been successfully learned by the provider. Northern noted that USAF Special Operations Surgical Team physicians were all trained using the Basic Endovascular Skills for Trauma (BEST) course offered by the American College of Surgeons. This training enabled these Air Force teams to successfully perform 19 of 20 attempted REBOA procedures in austere environments with good short term hemodynamic results and no major procedural complications, although the long-term outcomes for these patients (who were not US casualties) was not able to be determined.

A recent study of 1,399 emergency department thoracotomies (EDT) performed at 28 centers compared high-volume with low-volume centers. The overall survival of patients in this study was 6.8% with survival being over 4.5 times greater if EDT was performed at a high-volume center. There is not yet a comparable study for REBOA outcomes, but it should be expected that high-volume experience with this procedure will also result in greater procedural success. This suggests that teams who will be performing ARC should spend substantial time in high-volume trauma centers or training with high-fidelity simulators.

Once baseline training has been accomplished, organizations with teams that will be performing ARC must develop a sustainment program that will maintain competency. Ideally, this would include ongoing experience with trauma patients in addition to simulation or perfused cadaver-based training as well as a training and clinical experience that allows the individual performers to function as a team. There are multiple venues that could provide training in ARC. To list a few:

- the Air Force C-STARS programs
- the Army Trauma Training Center
- the Navy Trauma Training Center
- the Army Center for Prehospital Medicine
- the Defense Medical Readiness Training Institute
- Military trauma centers such as the San Antonio Military Medical Center
- Civilian trauma centers
- Commercial training vendors
- Individual military units who set up courses using organic assets

Documenting Care in ARC

Recording the injuries sustained, vital signs, interventions and responses to ARC interventions is an absolute requirement. This information will be vital for the providers at the next level of medical care and to JTS-led performance improvement efforts as experience is gained with this new capability. ARC should not be undertaken without the commitment to document these details of care precisely. Required documentation includes:

- Time and mechanism of injury
- Time of arrival at the ARC capability
- Vital signs on arrival
- Diagnostic measures and interventions performed and the times at which they were performed
- Transfusion products and amounts administered
- Balloon location, volume infused and total balloon inflation or “up” time
- Response to interventions
- Time and clinical condition when the casualty leaves the ARC location
- Time of arrival to a Role 2 or Role 3 facility
- Eventual outcome

As recently as June 2018, many users of LTOWB are not documenting the care provided to their casualties and are not forwarding it to the JTS for incorporation in the DoD Trauma Registry. Failure to document prehospital care detracts from the US military’s efforts to optimize care both for the individual casualty and for other casualties throughout the DoD. This documentation is especially important when using new battlefield trauma care innovations such as LTOWB and REBOA.
The Biggest Challenge—Getting an ARC Capability Close (within 15–30 minutes) to the Point of Injury

In caring for a casualty with severe truncal injury, suspected ongoing NCTH, and shock—every minute counts. Getting casualties with NCTH to a resuscitative team with an ARC capability as soon as possible is the challenge, since many casualties in this category will not survive their “Golden Hour.” The optimal treatment for these casualties would be immediate surgical repair of the noncompressible bleeding site and immediate replacement of blood loss, but the surgical resources of the US military are already severely strained trying to achieve casualty evacuation times to a surgical capability that are less than 60 minutes in combat theaters. With the time and location at which casualties will be sustained unknown until the event occurs, how can an ARC capability be made available within a very short time span (15–30 minutes)? This is the time frame within which peak mortality occurs in severe NCTH and within which prehospital blood products have been observed to improve survival.

In some operational settings, this may simply not be possible. In other scenarios, however, operational planners will be able to identify missions that entail a high risk of casualties. In those instances, planners have a number of options for placing a resuscitation team with an ARC capability close to where casualties are likely to be sustained. Possible options include a loitering CH-47 or CV-22; an ARC vehicle that follows a unit on a ground assault operation; a dedicated ARC vehicle on convoy operations; and a CH-47 or CV-22 based ARC platform with WB and REBOA capability on call for TACEVAC Missions.

Operationalizing Advanced Resuscitative Care

TCCC is now mandated as the standard for battlefield trauma care in the DoD by DOD Instruction 1322.24, but ARC is a new capability for TCCC. Now that this change has been approved by the CoTCCC, what is the best approach to transitioning it into use in the DoD?

One option would be definitive action undertaken at the OSD level, as was done with Secretary Gates’ Golden Hour Mandate. This would be the most direct path to implementation throughout the US Military and has the advantage of impacting the entire Department of Defense with one directive, but new innovations in battlefield trauma care have not historically been directed at the SecDef level.

An alternate course of action for implementation of ARC could be as follows:

1. The CoTCCC/JTS documents the need for ARC, provides an estimate of how many lives could be saved with this initiative, and defines the desired capability;
2. Senior line and/or operational medicine leaders are briefed on the ARC concept and—if desired—statements of need and operational requirements are prepared.
3. Training programs for ARC teams are identified.
4. A pilot program is undertaken to demonstrate the feasibility of ARC and the outcomes that it produces. The USSOCOM/USAISR TCCC Transition Initiative is an excellent model for how new innovations in battlefield trauma care can be expeditiously fielded.

Execution of the latter course of action is presently underway. The first operational implementation of ARC has occurred in a Special Operations unit that has far-forward medical elements that routinely conduct complex medical procedures in austere environments. Experience gained in this initial rollout will help to identify challenges that will need to be addressed in the event that ARC is subsequently implemented on a larger scale in the US military.

Potential Civilian Applications for ARC

ARC has important implications for the civilian sector as well as the military. In a mass casualty incident, local trauma centers may be overwhelmed with critically injured trauma patients. Having an ARC capability with hospital-based WBs to provide LTOWB and clinicians trained to perform REBOA would enable critically injured patients with abdominopelvic NCTH to be kept alive until they can be taken to surgery. This would also be an important new capability for the everyday management of trauma that occurs in rural settings, where long transports are often required to reach surgical care. Perhaps the most important application for the ARC concept in the civilian sector would be for the initial stabilization of the everyday hypotensive urban trauma patient who needs a laparotomy—whose current mortality is 46%,.

Summary

In summary, adding an Advanced Resuscitative Care capability to TCCC has the potential to reduce mortality from NCTH—the largest remaining cause of preventable prehospital death—with currently available technology in 3 ways:

1. Early whole blood resuscitation from hemorrhagic shock will benefit all casualties with NCTH and may enable those casualties who would not otherwise have survived for 60 minutes (the Golden Hour) to reach the care of a surgeon alive;
2. For casualties in immature combat theaters who are not able to reach a surgical capability within 60 minutes, the ARC Zone 1 Intermittent REBOA technique—as described by Kuckelman and modified by Rasmussen—offers the potential to extend their survival time well beyond 60 minutes, even in the presence of life-threatening abdominopelvic NCTH;
3. Having a REBOA catheter in place in Zone 1 in casualties who arrive at a surgical capability with suspected major abdominopelvic hemorrhage is of great potential benefit, even if the balloon is deflated, in that it provides the surgeon a ready option for proximal aortic control. During trauma laparotomy, the balloon may be inflated long enough for the operating surgeon to remove collected blood from the abdomen, identify major vascular injury, obtain more selective vascular control, and manage the injury without having to contend with both the physiological instability and the operative exposure difficulty imposed by massive ongoing bleeding (personal communication, Col Jeff Bailey, June 2018).

To evaluate the potential impact of adding an ARC capability to Tactical Combat Casualty Care, an estimate is needed of the number of lives that could be saved by better prehospital interventions for torso hemorrhage. Figure 5 provides this estimate based on the data reported in COL Brian Eastridge’s landmark 2012 paper. This paper noted that NCTH caused 67% of potentially preventable prehospital hemorrhagic deaths, with abdominopelvic hemorrhage causing 64% of the deaths from...
NCTH and thoracic hemorrhage responsible for the remaining 36%. Thus, for an assumed group of 100 potentially preventable prehospital combat deaths:

- 92 of those deaths would have occurred as a result of hemorrhage.
- 67% of those deaths—62 individuals—would have been due to NCTH.
- 64% of NCTH deaths—40 individuals—would have resulted from NCTH in the abdomen or pelvis.

Effective interventions to mitigate mortality resulting from abdominopelvic hemorrhage therefore offers an opportunity to save 40 out of every 100 potentially preventable prehospital combat deaths in future combat casualties—if the interventions can be performed shortly after the time of wounding.

Proposed ARC Change Wording

*Insert a new section with the text below between the Tactical Field Care” and “Tactical Evacuation Care” sections of the TCCC Guidelines

*New text in red

Advanced Resuscitative Care (ARC)

1. Combat casualties who are in shock from noncompressible torso hemorrhage (NCTH) in the prehospital setting have a high mortality rate and need life-saving interventions to be performed as soon as possible. The two most important of these interventions can be provided by Advanced Resuscitative Care in TCCC: transfusion of whole blood to provide optimal resuscitation for the casualty’s shock and Zone 1 REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta) to temporarily control NCTH below the diaphragm.

2. ARC is an advanced capability in TCCC. Although whole blood resuscitation can be provided by a single prehospital provider in some settings, to do both robust whole blood resuscitation and possibly subsequent REBOA, requires a team of 4 or more specially trained and equipped individuals. When a casualty meets the indications for whole blood resuscitation, transfusion should be initiated as quickly as possible, followed rapidly by Zone 1 REBOA if that procedure is indicated as outlined below. ARC could be provided to supplement Tactical Field Care by a team located near the point of injury, or it could be used to supplement TACEVAC Care on an evacuation platform. Whenever tactically feasible, a team with an ARC capability should be positioned as close to the point where casualties are likely to be sustained as possible, since many casualties with NCTH will die within 15-30 minutes without ARC. For these casualties, Advanced Resuscitative Care is likely to be the only thing that will effectively prevent their death.

3. The team providing ARC should first ensure that all of the hemorrhage control interventions recommended in Tactical Field Care have been successfully accomplished:
   - Extremity hemorrhage has been controlled with tourniquets;
   - Junctional and other external hemorrhage has been controlled with hemostatic dressings, XStat, and junctional tourniquets as needed;
   - Pelvic binders have been applied for suspected pelvic fractures;
   - The first dose of TXA has been administered without delay if hemorrhagic shock is present or judged likely to occur;
   - If the casualty is in traumatic cardiac arrest, bilateral NDC should have been performed.

4. Indications for Whole Blood Transfusion:
   *Follow the JTS Damage Control and Whole Blood Transfusion Clinical Practice Guidelines (CPGs) except as follows:

   *TCCC-specific considerations:
     - Casualty has known prior external hemorrhage (even if that hemorrhage is now controlled) or suspected non-compressible torso hemorrhage (NCTH) AND
     - Systolic Blood Pressure (SBP) is less than 90mmHg OR
     - Point of Injury lactate is 4mmol/L or greater

5. Whole Blood Transfusion Procedure in ARC:
   *Follow the JTS Damage Control and Whole Blood Transfusion CPGs except as follows:

   *TCCC-specific considerations:
     a. Resuscitation should be initiated with FDA-compliant Cold-Stored Low Titer Type O Whole Blood (LTOWB) as the preferred option and every effort should be made to have it available.
     b. LTOWB from a unit-based, pre-screened and pre-titered walking blood bank (WBB) should be used as the second option if FDA-compliant cold-stored LTOWB is not available.
     c. If there is a pre-screened—but untitered—unit-based WBB designed to collect whole blood, utilize only Type O units of whole blood as the third option.
     d. If there is a unit-based WBB designed to collect, type, and transfuse type-specific whole blood, that is a fourth option.

   *NOTE: Option (d) may result in morbidity or even death due to ABO mismatch if the wrong blood type is transfused.
   *NOTE: 1:1 RBCs and plasma should be used in the suboptimal circumstance that FDA-compliant whole blood is not available, but FDA-compliant red blood cells and plasma are available.
NOTE: Use of non–FDA-compliant whole blood requires additional post-transfusion monitoring per DoD directives.

e. Continue resuscitation until an SBP of 80–90mmHg is present.
f. If the casualty has an altered mental status due to suspected TBI, resuscitate as necessary to restore and maintain a target SBP of at least 90mmHg.
g. During resuscitation, blood products should be warmed using a fluid warmer and infused rapidly.
h. As whole blood transfusion is being performed, consider obtaining early common femoral artery access so that REBOA can be undertaken quickly after the first unit of whole blood has been administered should the casualty subsequently be found to meet the criteria for REBOA.

6. Indications for REBOA in ARC:
  *See Appendix B in the Joint Trauma System REBOA CPG: “SBP < 90 with Transient or No Response to Initial ATLS Resuscitation.” (6 July 2017)

*TCCC-specific considerations:
  a. Relevant Tactical Field Care interventions (external hemorrhage control, pelvic binding, and TXA) have been accomplished;
     AND
  b. Advanced monitoring (Electronic blood pressure measurement) has been established;
     AND
  c. ARC resuscitation has been previously initiated with whole blood if feasible or other blood products as noted previously;
     AND
  d. SBP remains < 90mmHg immediately after 1 unit of whole blood or 1 unit each of RBCs and plasma have been administered as quickly as possible;
     AND
  e. The Casualty has penetrating or severe blunt force injury to the abdomen or pelvis and a positive FAST exam or is judged to be at high risk for abdominopelvic NCTH or is noted to have difficult-to-control junctional hemorrhage.
     AND
  f. Intra-thoracic bleeding and cardiac tamponade have not been found on bilateral chest tube insertion and an EFAST exam.

7. REBOA Procedure in ARC
*REBOA in TCCC Advanced Resuscitative Care will be done in accordance with the current version of the REBOA CPG posted on the Joint Trauma System website with the following exceptions to make it more suitable for the TCCC setting:

*TCCC-specific considerations:
  a. Placement of REBOA should be done in consultation with a surgeon at the receiving medical treatment facility (MTF), if at all possible. This will both provide expert assistance on the decision to use REBOA and alert the receiving MTF so that they can prepare for the casualty.
  b. Teams with an ARC capability should have a CoTCCC-recommended junctional tourniquet available to control access site bleeding should that be encountered.
  c. If the junctional tourniquet has already been used for another casualty, 30 minutes of direct pressure with Combat Gauze or another TCCC-recommended hemostatic dressing should be used to control access site bleeding.
  d. Ketamine can be used for procedural analgesia and sedation. Opioids should be avoided in hypotensive casualties.
  e. All REBOA in TCCC is Zone 1, since intra-abdominal hemorrhage originating above the aortic bifurcation cannot be definitively ruled out by a negative FAST exam.
  f. Once the casualty has been determined to meet the criteria for REBOA, the procedure should be undertaken promptly, since further decreases in systolic blood pressure will make common femoral arterial access significantly more difficult to obtain.
  g. Placement of the balloon in aortic Zone 1 is guided by the markings on the ER-REBOA catheter.
  h. Fully inflate the balloon in Zone 1. Start with 8–10mL of any crystalloid IV fluid. Confirm full occlusion by noting that the contralateral femoral pulse is extinguished.
  i. If the contralateral femoral pulse is still present, add 2 more mL of IV fluid and recheck the pulse. Repeat until the pulse is extinguished or a maximum of 24mL of fluid has been used.
  j. Leave the balloon inflated for 15 minutes. The SBP should increase quickly and substantially after balloon inflation when the bleeding site is distal to Zone 1.
  k. After 15 minutes, slowly deflate the balloon completely over 30 seconds.
  l. Re-assess the casualty. If he or she has an SBP of 80mmHg or greater, leave the balloon deflated.
  m. Continue to monitor.
  n. If the SBP drops below 80mmHg, re-inflate the balloon and use either Option 1 or Option 2 as guidance for further inflation.
  o. Balloon Inflation Timing—Option 1:
     As long as the periods of balloon deflation without SBP dropping below 80mmHg continue to be 3 minutes or longer, use 10-minute inflation periods followed by another deflation out to a maximum of 120 minutes. Continue resuscitation with whole blood.
  p. Balloon Inflation Timing—Option 2:
     If the casualty does not maintain an SBP of 80mmHg or higher for at least 3 minutes after balloon deflation, then re-inflate the balloon and use a maximum of 30 minutes total balloon inflation time. Continue resuscitation with whole blood.
  q. If the casualty has stabilized (SBP remains above 80mmHg without balloon inflation) after the inflation times specified above, but is more than 4 hours from the care of a surgeon, remove the sheath and hold pressure for 30 minutes with a junctional tourniquet or with Combat Gauze or another TCCC-recommended hemostatic dressing. Evaluate for distal pulses in the extremity.
  r. If the casualty has stabilized as noted above, but is within 4 hours of surgical care, leave the sheath and place, and flush the side port every 15–30 minutes with 3mL of IV fluid.
  s. Document distal pulses frequently.
  t. Once REBOA has been performed, every effort should again be made to communicate with the surgeon who will be receiving the casualty and obtain his or her recommendations for subsequent management.
  u. Document all aspects of the REBOA procedure.
8. Document all care provided in ARC, to include as a minimum:
   - Time and mechanism of injury
   - Time of arrival at the ARC capability
   - Vital signs on arrival
   - Diagnostic measures and interventions performed
   - Details of the REBOA procedure as noted above.
   - Response to interventions
   - The time and the casualty’s condition upon leaving ARC

Levels of Evidence for the Above Recommendations
The levels of evidence used by the American College of Cardiology and the American Heart Association were outlined by Tricoci in 2009:
- Level A: Evidence from multiple randomized trials or meta-analyses.
- Level B: Evidence from a single randomized trial or non-randomized studies.
- Level C: Expert opinion, case studies, or standards of care.\(^{1,2}\)

Using the taxonomy above, the levels of evidence for the recommendations in this change are shown below.

1. Whole blood is more effective at reducing mortality in casualties suffering from hemorrhagic shock than resuscitation with the current point of injury resuscitation fluids used by most of the US military (Hextend or crystalloids): Level B
2. REBOA can reduce the incidence of preventable death resulting from abdominopelvic hemorrhage in combat casualties. Level C

Results of the CoTCCC Vote:
This proposed change as presented above was approved by the required 2/3 or greater majority of the voting members of the CoTCCC.

Future Directions and Research Priorities Related to ARC Implementation

1. A TCCC ARC Rapid Fielding Initiative (RFI) will be required to optimally translate the concepts outlined in this paper into realized advances in combat casualty care. This RFI could be modelled after the successful USSOCOM/USASPR TCCC Transition Initiative\(^{1,2}\) that was responsible for the first widespread use of TCCC in the US military. This program should include expedited procurement and fielding of the equipment required to perform ARC, followed by delivery of this equipment along with the required training targeted to units that are about to deploy and want to field teams with an ARC capability. The program should also include meticulous documentation of the care provided to casualties treated with ARC as part of this initiative, along with ongoing JTS performance improvement recommendations as experience is gained.

Whole Blood

2. How can whole blood availability, efficacy, and safety be improved for ARC?
   - Further extending the storage limit for whole blood?
   - Better far-forward transport and storage capability for whole blood?
   - Can packaging, processing and storage solutions be optimized for whole blood to increase oxygen delivery and hemostatic function?
   - Can lyophilized products be combined to develop a dried whole blood equivalent?
   - Is there a benefit or risk to leukoreduction of whole blood that is to be used for trauma patients with life-threatening hemorrhage?
   - Can improved rapid screening methods be developed to identify transfusion-transmitted diseases?

3. Are pathogen-reduced blood products as efficacious as nontreated products for treating shock and hemostatic dysfunction?
4. Is there a difference in efficacy between pathogen-treated products in oxygen delivery and hemostatic function?

REBOA Technology and Technique

5. Research should be conducted to explore techniques to extend the safe aortic occlusion time for Zone 1 REBOA, studying various patterns of both intermittent and partial REBOA and the impact on these various techniques in reducing mortality in NCTH. Every effort should be made to determine the true limits of how long survival can be prolonged using these techniques in animal models of otherwise lethal NCTH, rather than stopping the study at an arbitrary cut-off time.

6. Another research effort might explore the use of slower balloon deflation techniques and adjuncts to resuscitation that might mitigate untoward reperfusion effects (hyperkalemia and acidosis) and allow for longer periods of continuous Zone 1 aortic occlusion when intermittency is not feasible because of the severity of the casualty’s bleeding.

7. In particular, the use of calcium supplementation should be studied as an adjunct to optimizing survival during Zone 1 aortic balloon deflation. In research conducted in Dr Matt Martin’s lab, almost all of the animals get hyperkalemic upon balloon deflation, but the ones who die are the ones who also have a lower calcium, whereas those with higher serum calcium levels (8 or higher) tolerate the hyperkalemia and don’t go into arrest (Dr Matt Martin, personal communication, September 2018).

8. There should be further investigation into the use of the Rasmussen modification of the Madigan REBOA protocol. That is, after an initial 15-minute period of occlusion, how often will bleeding from a lethal vascular injury have stopped as a result of the initial balloon inflation period with resulting stabilization of the casualty? Is three minutes truly the shortest balloon deflation period that will successfully allow intermittent Zone 1 REBOA to prolong survival in NCTH?\(^{7}\)

9. Once a maximal safe Zone 1 REBOA occlusion time is determined (that is—one that does not produce sudden cardiac arrest from rapidly-occurring hyperkalemia and acidosis) a survival study should be performed to look for any untoward long-term effects resulting from the occlusion period.

10. Better technology—suitable for use in austere environments—with which to monitor and control partial REBOA would be of benefit to teams performing ARC. Automated, feedback-based balloon volume controllers offer the potential to optimize the control of aortic flow based on the casualty’s bleeding rate and his or her response to whole blood resuscitation. Such technology would allow for optimization of blood pressure both proximal and distal to the aortic occlusion.\(^{1,3}\)

11. The critical procedural step in performing REBOA is obtaining common femoral artery access. Technology and
methodology that facilitates and possibly automates this step and decreases the need for cutdowns to obtain femoral access would be very useful.

12. There is not good consensus about the use of REBOA in casualties with TBI. Hypotension has been shown to increase mortality in patients with moderate/severe TBI, but the large rise in blood pressure proximal to the inflated Zone 1 REBOA balloon could potentially increase intracranial hypertension and exacerbate intracranial hemorrhage. Identification of which subsets of TBI might be helped or harmed by REBOA should be an area of investigation.

13. Optimization of REBOA balloon deflation technique offers the potential to mitigate the risk of post-deflation hyperkalemia and acidosis. Studies examining this issue, however, have reported that return of distal aortic flow as a factor of balloon volume removed was inconsistent in study animals. This topic deserves further investigation.

14. REBOA is new to the prehospital phase of care. Careful monitoring of outcomes achieved from these procedures as well as any complications ensuing from its use should be accomplished by a focused JTS performance improvement monitoring program.

15. ARC entails both whole blood resuscitation and REBOA when the bleeding site is determined to be below the diaphragm. The effect on outcomes achieved by whole blood resuscitation without REBOA is also a topic of research interest. A review of casualties for whom ARC is used may be able to help answer that question. Casualties with NCTH and shock who are found to have intrathoracic bleeding on chest tube placement will not be candidates for REBOA, but they will continue to receive whole blood resuscitation. Outcomes from this subset of patients should be reviewed to help determine the magnitude of benefit obtained from whole blood resuscitation alone.

16. Smaller arterial catheters have been found to reduce the risk of thrombotic complications associated with arterial access. The feasibility of further decreases in the size of the REBOA device from the current 7 Fr ER-REBOA catheter to a 5 Fr or smaller device should be explored.

17. Expert opinion varies with regard to how long the REBOA sheath should be left in place after the initial procedure so that the balloon could be inflated again if needed. Additional techniques and technology to enable longer periods of safe intra-arterial dwell time should be investigated.

18. Research evaluating current and future REBOA devices to validate their safety, performance, and any limitations that would be encountered in-flight during the aeromedical evacuation and transport process should be conducted.

19. The emerging literature on REBOA contains studies with variations in the bleeding models, resuscitation (timing, volumes, and types of fluids), post-deflation critical care provided to the animals, and other study methodologies. An NCTH model that is standardized insofar as feasible would be helpful in comparing studies.

Training
20. Research is needed in many aspects of REBOA training, to include:

- Is training best accomplished with simulators, perfused cadavers, or live tissue training?
- How many successful REBOA procedures are needed to assure competency?
- Flow can virtual reality technology assist in REBOA training?
- How often should REBOA training be refreshed in order to assure competency?
- How can the clinical experience with REBOA for ARC team members be optimized?

Additional ARC-Related Topics
21. Research attention should be directed towards better identification of which subsets of casualties will benefit the most from ARC, in particular, how to identify patients who are experiencing life threatening noncompressible intra-cavitary hemorrhage, but who have not yet decompensated into hemorrhagic shock. The Compensatory Reserve Measurement devices, better POI lactate monitoring techniques, and vital-sign-based prediction algorithms all have promise in this area.

22. How can teams with an ARC capability be best utilized in combat operations to minimize the time from wounding to initiating ARC and still maintain an acceptable risk level to the resuscitation team?

23. What additional medications or hemostatic adjuncts would offer the most benefit to casualty survival and should be used by ARC teams?

- Modified TXA dosing?
- Calcium administration during/after REBOA?
- Valproic acid?
- Fibrinogen?
- Factor concentrate mixtures?
- Vasopressors?
- Naloxone?
- Hormones?
- Others?

24. Improved methodology is still needed for all prehospital care documentation, but especially for documenting care in ARC. Research in this area should include hands-free recording techniques, electronic transcription, better quality of voice-to-text transcription, automatic time stamping technology, and better ability to both protect the care documentation data and transmit it to subsequent providers and the electronic health record.

25. What is the mortality in US military casualties who present with shock and subsequently require an emergent laparotomy? The US military needs to conduct a counterpart study to the recent Harvin and Marsden studies in our nation’s combat casualties.

26. Care provided during ARC should be meticulously documented and reviewed in near-real-time for performance improvement purposes, but in addition to the PI process, examination of patient care and outcome data should be conducted under research protocols to better understand the factors affecting casualty outcomes.

27. Diligent performance improvement monitoring and subsequent research into outcomes should also be conducted for casualties who met the criteria for whole blood and REBOA, but who did not receive these interventions.

28. Optimal target blood pressures using whole blood resuscitation during ARC should be a research topic. Consideration should be given to both casualties with and without TBI and to how best to incorporate the response to initial resuscitation and balloon deflation into subsequent resuscitation.
29. Additional hemostatic adjuncts, in particular the prehos-
	pital use of ResQFoam, should be studied. ResQFoam use

might be further optimized through better access tech-


iques and shorter periods of use to help mitigate bowel


injuries from this device.

30. The AAJT is a much simpler device to use than undertak-


ing a REBOA procedure. Development of technology that


would enable prehospital medical providers to reliably


exclude the possibility of NCTH from sites above the aor-


tic bifurcation would enable pelvic and lower extremity


junctional hemorrhage to be treated with the AAJT in the


prehospital phase of care.

Acknowledgments

The authors gratefully acknowledge the research assistance


provided by Mrs. Danielle Davis of the Joint Trauma System.

The authors also thank the Department of Defense Trauma


Registry for providing the casualty data discussed in this paper.


Disclaimers

The opinions or assertions contained herein are the private


views of the authors and are not to be construed as official or


as reflecting the views of the Defense Health Agency or the De-


partment of Defense. This recommendation is intended to be


a guideline only and is not a substitute for clinical judgment.

Disclosures

Dr Holcomb is the Chief Medical Officer for Prytime Medi-


cal, which markets the ER-REBOA device discussed in this

paper. He is also on the Medical Advisory Board for Arse-


nal Medical, the Founder and a Board Member of Decisio


Health, a consultant to Terumo BCT, and the co-inventor of


the Junctional Emergency Treatment Tool. Dr King is a funded


investigator on the ResQFoam project, which has been sup-


ported by the Defense Advanced Research Projects Agency,


the Army Medical Research and Materiel Command, and the


National Institute of Health. He is the Principal Investigator


for the REVIVE clinical trial, registered at clinicaltrials.gov.

Dr Rasmussen is an active duty service member who has con-


tributed to the Aortic Occlusion System (AOS) patent which


is assigned to the United States Air Force. The Air Force has


received payments from the University of Michigan as part of


a Joint Ownership Agreement pertaining to this patent. After


receipt and withholding of a percentage of any such payment,


the Air Force has distributed compensation to Dr Rasmussen.

He holds no paid consulting or advisory board positions; he


holds no stock in Prytime Medical; and receives no payment


related to commercialization of the ER-REBOA catheter.

Dr Spinella is the Co-Founder and on the Board of Directors of

Kaloxy Inc.

Release

This document was reviewed by the Director of the Joint

Trauma System and by the Public Affairs Office and the Op-

erational Security Office at the DoD’s Defense Health Agency. It

is approved for unlimited public release.

References can be found online at:

https://www.jsomonline.org/References/2018435Butler.php