Management of Junctional Hemorrhage in Tactical Combat Casualty Care: TCCC Guidelines–Proposed Change 13-03

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ABSTRACT

The vast majority of combat casualties who die from their injuries do so prior to reaching a medical treatment facility. Although most of these deaths result from non-survivable injuries, efforts to mitigate combat deaths can still be directed toward primary prevention through modification of techniques, tactics, and procedures and secondary prevention through improvement and use of personal protective equipment. For deaths that result from potentially survivable injuries, mitigation efforts should be directed toward primary and secondary prevention as well as tertiary prevention through medical care with an emphasis toward prehospital care as dictated by the fact that the preponderance of casualties die in the prehospital environment. Since the majority of casualties with potentially survivable injuries died from hemorrhage, priority must be placed on interventions, procedures, and training that mitigate death from truncal, junctional, and extremity exsanguination. In response to this need, multiple novel and effective junctional tourniquets have recently been developed.

KEYWORDS: junctional hemorrhage, Tactical Combat Casualty Care Guidelines

Proximate Cause for the Proposed Change

1. Now that extremity tourniquets are in widespread use by the U.S. military, junctional hemorrhage is the most common cause of death from compressible hemorrhage.1

2. The current Tactical Combat Casualty Care (TCCC) Guidelines mention only the Combat Ready Clamp as a junctional tourniquet.2 Since this recommendation was approved, three other devices have been cleared by the U.S. Food and Drug Administration (FDA) for junctional hemorrhage control.

3. In his letter of 5 August 2013 approving the Defense Health Board recommendation that the Combat Ready Clamp be used to control junctional hemorrhage on the battlefield, the Assistant Secretary of Defense for Health Affairs directed that the Committee on TCCC (CoTCCC) also considers the other junctional tourniquets that have been recently cleared by the FDA.3

Background

More aggressive and definitive control of external hemorrhage had a profound impact on the survival of U.S. casualties from Afghanistan and Iraq. The combined efforts by the U.S. Special Operations Command ( USSOCOM), U.S. Central Command (USCENTCOM), and U.S. Army Institute of Surgical Research (USAISR) led to a much expanded use of prehospital tourniquets early in the current wars. TCCC guidelines advocated for a change in the tourniquet use paradigm from the intervention of last resort to the intervention of first resort for life-threatening extremity hemorrhage. This change was one of the most significant medical breakthroughs of the war. Estimates of lives saved by tourniquet use suggest that 1,000 to 2,000 U.S. military Servicemembers’ lives were saved by the application of prehospital extremity tourniquets during the current conflicts.4 Combat units that train all of their members in external hemorrhage control techniques have seen remarkable success in reducing preventable deaths on the battlefield.5

With preventable deaths from extremity hemorrhage greatly reduced by tourniquet use, junctional hemorrhage has surpassed extremity hemorrhage as the leading cause of death from external hemorrhage.1

Another factor contributing to the increasing incidence of death from junctional hemorrhage is the expanded use of anti-personnel, pressure-activated improvised explosive devices (IEDs) in the Combined Joint Operating Area–Afghanistan (CJOA-A), which was first noted in the summer of 2010. Junctional hemorrhage is one

component of the injury complex produced by these dismounted IED attacks that has become known as Dismounted Complex Blast Injury (DCBI).6

A comprehensive study of U.S. combat fatalities from 2001 to 2011 noted that 17.5% (171/976) of potentially preventable prehospital deaths resulted from junctional hemorrhage.1 In January 2013, a USCENTCOM and Joint Trauma System (JTS) report on prehospital trauma care in Afghanistan noted the above findings and advocated for more research and expanded fielding of junctional tourniquets.7

Junctional hemorrhage is defined for the purposes of this discussion as hemorrhage that occurs at the junction of an extremity with the torso of the body at an anatomic location that precludes the effective use of an extremity tourniquet to control the bleeding. The definition also includes the base of the neck.8

Junctional hemorrhage includes bleeding from: the groin proximal to the inguinal ligament, the buttocks, the gluteal and pelvic areas, the perineum, the axilla and shoulder girdle, and the base of the neck. The lethality of limb injuries is less than junctional areas as hemorrhage is slower due to the smaller lumen size of the injured vessels.8 Junctional hemorrhage also includes extremity bleeding from sites too proximal for effective use of extremity tourniquets.

Pelvic fractures may be seen in association with junctional bleeding in dismounted IED attacks.12 Medics from the United Kingdom (UK) carry pelvic binders to use on individuals with suspected pelvic fractures.7 The junctional tourniquets that are applied circumferentially around the pelvis may also provide some stabilization of pelvic fractures.12 U.S. Army 68W combat medics are also taught to apply pelvic binders for casualties who have suspected pelvic fractures (MAJ Charlie Day and Mr. Jeff Mott, personal communication, 25 July 2013).

A Performance Improvement (PI) project at the JTS reviewed a series of 504 U.S. Servicemembers who suffered traumatic amputations as a result of IED blast. This PI project identified the frequent association of proximal traumatic amputation, pelvic fracture, and massive transfusion. In this series, 16% (9/55) of Servicemembers with a unilateral above knee amputation (AKA) had a pelvic fracture and 78% (43/55) required a massive transfusion (MT, required a minimum of 10 units of blood during the first 24 hours post injury). Of Servicemembers with bilateral traumatic AKA, 30% (27/90) had a pelvic fracture and 100% (90/90) required MT. Of Servicemembers with one AKA and one below knee amputation (BKA), 32% (25/78) had a pelvic fracture and 92% (72/78) required MT. The presence of a traumatic AKA is strongly associated with a casualty who is at high risk for pelvic fracture and MT. A device that affords stability to a pelvic fracture and mitigates hemorrhage from an amputation site would be of great value to combat casualties with this pattern of injury. Hemorrhage from a traumatic AKA can be managed with a tourniquet in many cases. However, for those with a very proximal AKA, a junctional device would be of great potential benefit (COL Kirby Gross, personal communication, 9 July 2013).

Discussed

Desirable Traits of Junctional Tourniquets

The desirable traits of candidate devices for junctional hemorrhage control have been defined9–11:

- Stops bleeding effectively from junctional areas such as the groin, pelvis, buttock, shoulder, or neck
- Compresses bleeding from sites where regular tourniquets cannot be applied
- Safe to use
- Can be used effectively for prehospital care on the battlefield and in tactical situations
- Small with low profile
- Lightweight
- Low-cost
- Easy to use; requires minimal training or familiarization
- Quickly applied
- Does not slip on tightening or in use
- Provides easy release of compression
- Easy to reapply
- Long shelf life

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This data suggests dismounted casualties with a traumatic amputation higher than a BKA level warrant empiric application of a pelvic binder. Should the amputation be so high that a tourniquet is ineffective, the junctional component of the Junctional Emergency Treatment Tool (JETT) or SAM Junctional Tourniquet warrants application. Should the pelvic binder be applied at the appropriate level, the ventral aspect of the binder immediately overlies the common femoral artery” (COL Kirby Gross, personal communication, 9 July 2013).
FDA-Cleared Tourniquets for Control of Junctional Hemorrhage

As of May 2013, four devices have been cleared by the FDA for junctional hemorrhage control. Of note is that the Abdominal Aortic Tourniquet (AAT™) is a truncal tourniquet, while the other three devices listed here are junctional tourniquets.

**Abdominal Aortic Tourniquet (AAT™)**

Website: [http://www.speeroptech.com/page6/](http://www.speeroptech.com/page6/)

“The abdominal aortic tourniquet (AAT) is a pneumatic belt that allows for the constant delivery of pressure over a specific area for a prolonged period. The device has shown efficacy and safety in a swine model for aortic occlusion for up to 60 minutes. The device is designed to be applied in less than a minute by a single responder. The belt is placed around the abdomen with the inflatable section over the umbilicus. The buckle is manually cinched down, and then, the device is further tightened by the use of a windlass located on the front of the device. The pneumatic bladder is then inflated.”

The authors of a recent study note that the AAT occludes blood flow at the level of the infrarenal aorta. In addition to controlling junctional hemorrhage, aortic compression at this level might also help with hemorrhage control in the pelvis, since flow in the internal iliac arteries and their branches would also be expected to be occluded. Application time should not exceed 1 hour. The AAT is absolutely contraindicated in pregnancy and in patients with known abdominal aortic aneurysms. It is relatively contraindicated in penetrating abdominal trauma.

**Combat Ready Clamp (CRoC™)**


“In 2009 inspired by Lister’s abdominal tourniquet, the Combat Ready Clamp (CRoC) was designed to exert mechanical pressure directly over the wound or indirectly over the groin area to occlude underlying blood vessels and stop hemorrhage. It has also been FDA-cleared for use in control of axillary hemorrhage.”

The CRoC has been shown to be efficacious in a cadaver model of axillary junctional bleeding.

“The final design has a small cube (stored dimensions: height, 3.5 in; width, 11.5 in; diameter, 1.5 in) with an aluminum structure that weighs 1.6 lb. In 2010, it received the U.S. Food and Drug Administration approval as a medical device for the control of difficult inguinal hemorrhage on the battlefield.”

The application time of the CRoC should not exceed 4 hours.

**Junctional Emergency Treatment Tool (JETT™)**


The Junctional Emergency Treatment Tool (JETT) was developed through a joint effort between the University of Texas Health Science Center for Translational Injury Research and North American Rescue Products. This device incorporates a windlass and is designed to treat junctional hemorrhage in both the military and the civilian prehospital environments. It incorporates both a pelvic binder application and bilateral pads designed to occlude unilateral or bilateral common femoral artery blood flow to the lower extremities. The device can be used instead of manual pressure, allowing the healthcare provider to attend to other casualties. The JETT consists of a belt assembly, with two trapezoidal pressure pads and threaded T-handles. Application time should not exceed 4 hours.

**SAM® Junctional Tourniquet**


The SAM Junctional Tourniquet for hemorrhage control is designed to control bleeding in areas where standard tourniquets would not be effective, such as with IED or blast injuries or high level amputations. Its components include a belt and two pneumatically inflatable bladders called Target Compression Devices (TCDs). The TCD is placed at or proximal to the injury site and inflated until the bleeding stops. Two TCDs can be used to occlude blood flow bilaterally if needed. The SAM Junctional Tourniquet also has FDA clearance for stabilizing pelvic fractures and for controlling junctional bleeding in the axillary area. Application time should not exceed 4 hours. The SAM Junctional Splint is FDA-cleared for junctional bleeding in the inguinal and axillary areas and to stabilize suspected pelvic fractures.

Review of the Available Evidence on Junctional Hemorrhage Control Devices

There are no prospective trials that support the efficacy of current FDA-cleared junctional hemorrhage control...
devices on casualties in the prehospital environment. The available evidence as discussed in this report are laboratory studies and case reports.

In a study of the four FDA-cleared junctional hemorrhage control devices and manual compression using a manikin bleeding model, hemorrhage was successfully controlled with all four devices. The average times to achieve hemorrhage control were AAT, 102 seconds; CRoC, 59 seconds; JETT, 41 seconds; and SAM, 26 seconds. The average blood loss for each junctional tourniquet was AAT, 787ml; CRoC, 581ml; JETT, 342ml; and SAM, 35ml.18

**AAT**

A 2006 study of nine human subjects showed that flow through the common femoral artery could be stopped with compression of the abdominal aorta with dumbbells weighing from 80 to 140 lb.19 The study noted that: “The amount of time the volunteers could tolerate the compression was not measured. However, in a real-life situation, responders and victims would be motivated differently. Last, maintaining ongoing compression at a pressure equal to a 120-lb dumbbell may not only exhaust medical personnel but also commit them to continue to exert the pressure indefinitely. It may be helpful if a lightweight mechanical device able to be left alone once set in place, could achieve such compression.”19

In another human study, the AAT application resulted in the interruption of blood flow in the common femoral artery in seven of nine volunteer subjects. Cessation of flow was achieved at a median pressure of 180mm Hg (range 150–230mm Hg).20

On a numeric rating scale for pain of 0–10, the median discomfort experienced by volunteer subjects at a pressure sufficient to cause cessation of flow was 7 (range 3–10). This discomfort returned to 0 after the device was removed.20

There is a recently published case report of AAT use by a deployed military physician who requested to remain anonymous for operational security reasons. The casualty had bilateral traumatic amputations of his lower extremities. He was reported to be unresponsive with no carotid pulse at the time he was loaded onto the evacuation helicopter. Combat Application Tourniquets were applied to both legs, but a pool of bright red blood was noted on the stretcher between his legs. Treatment included: intraosseous access, rapid sequence intubation, blood transfusion, tranexamic acid, and calcium chloride. Despite the above, he continued to do poorly and an AAT was applied. He also received 2 units of plasma and three of packed red blood cells prior to arrival at the hospital. By the time of his arrival in the Emergency Department, his end-tidal CO2 had gone from 0.6–5.4kPa and his carotid pulse had returned. The casualty survived and had no evidence of renal failure or ischemic bowel in the first 48 hours after his initial operation.21

There is a case report pending publication for the off-label use of the AAT on a civilian patient with a gunshot wound to the left axillary area. He had uncontrolled hemorrhage from the two wounds and was in hemorrhagic shock. The AAT was placed in the left axillary area with the strap tightened around the opposite shoulder. The hemorrhage was controlled using this technique.22

In a recent study from the UK, the authors note that “the ideal device for lower extremity junctional trauma would prevent all infra-umbilical blood flow, not damage or penetrate tissues, be re-applicable after release, be rapidly applied by feel and be secure in transit. One such potential device is the Abdominal Aortic Tourniquet or AAT. (Compression Works, Birmingham, AL, USA).” In this study of 16 human subjects, AAT application was tolerated by all 16 participants. Blood flow in the common femoral artery was completely stopped in 15 of the 16 participants. The balloon remained inflated for less than 1 minute during the study and normal tri-phasic flow resumed in all subjects immediately following deflation of the balloon. No complications were reported either during or after the study.12

By occluding the aorta above its bifurcation when applied, the AAT has the potential to be able to control pelvic bleeding from the branches of the internal iliac arteries.

Several participants in the 7 August 2013 CoTCCC “Management of Junctional Hemorrhage in Tactical Combat Casualty Care TCCC Guidelines–Proposed Change 13-03” teleconference noted reliability issues in that the AAT was easily broken in their experience and use of the device during training. As the AAT is a truncal tourniquet by design, it directs pressure in a broad manner over more than just a junctional area, and has a relative contraindication for penetrating abdominal trauma. These characteristics must also be considered if procurement of the current AAT device is done exclusively with the intent for junctional hemorrhage control.

Since many of the casualties from Afghanistan have both junctional bleeding and penetrating abdominal injuries, the AAT would be contraindicated for these individuals. Both trauma surgeons and combat medics expressed concerns about recommending this truncal tourniquet as a result of the short duration of application, the contraindication in penetrating abdominal injury, the reliability
problems noted above, the discomfort produced by the inflation of the device, and possible adverse effects on the casualty’s ventilation.

CRoC

The CRoC was found to be successful at controlling hemorrhage in a perfused cadaver model when used for several different inguinal wound patterns: one wound, two ipsilateral wounds with hemorrhage from one artery (common iliac artery), and bilateral inguinal wounds (compression of the origins of bilateral common iliac arteries).15

The CRoC was noted to be effective in both swine models and perfused cadaver models of bleeding.23

The CRoC controlled bleeding from a 6-mm femoral arteriotomy in a swine model of groin wounding. Hemorrhage was controlled in all six animals in the study for 1 hour. Removal of the clamp at 1 hour, however, resulted in rebleeding in five of six experiments, and all five of these animals exsanguinated during the second hour of observation despite continuous fluid resuscitation.16

CRoC preparation and application were noted to take 1–2 minutes (even with some pre-assembly), during which time a casualty could lose a significant amount of blood from a junctional wound.16

An Afghani male was injured by an explosion in Kandahar province in 2011. The casualty sustained a very proximal left lower extremity traumatic amputation, too proximal for application of an extremity tourniquet. When the evacuation helicopter arrived, the casualty was alert and oriented, but in early hemorrhagic shock. There was little active bleeding when the evacuation providers first evaluated the casualty. The bleeding from his amputation site became more severe just as the evacuation helicopter took off from the point of injury. The medic on the evacuation aircraft applied direct pressure on the wound, initially with a hand and then with his knee while preparing the CRoC for use. The CRoC was assembled and applied in approximately 90 seconds, resulting in prompt and sustained hemorrhage control. The patient’s condition stabilized. When he reached the Afghani hospital near Kandahar; however, he was triaged as expectant and the CRoC was removed. The casualty subsequently exsanguinated from his injuries.24

A manikin study used the CRoC to control simulated junctional bleeding. The study found that the CRoC was effective in this laboratory setting and that the surface the casualty rested on made some difference in CRoC application. Six subjects were successful in all nine of their iterations of CRoC use. The CRoC users were able to control the simulated bleeding in a mean time of less than one minute.25

JETT

The JETT was found to be successful at controlling bilateral lower extremity junctional hemorrhage in a perfused cadaver model.26

There are two unpublished cases of successful JETT use in civilian trauma patients with junctional hemorrhage (Dr John Holcomb, personal communication, August 2013).

There was one use of the JETT in a U.S. military casualty in whom junctional hemorrhage was reported to be controlled, but the casualty did not survive (Mr Ricardo Flores, personal communication, August 2013).

Although the JETT is not currently FDA-cleared for treatment of pelvic fractures, current investigations supporting such an indication are under way (Dr Keith Gates, personal communication, August 2013). Unpublished
data from a recent study conducted by the University of Texas Health Science Center for Translational Injury Research and the Texas Trauma Institute show that the JETT device compresses pelvic fractures and has the potential to improve hemorrhage control from both junctional hemorrhage and pelvic fractures (Dr John Holcomb, personal communication, August 2013).

**SAM Junctional Tourniquet**

No case reports or case series were published at the time of this review. The SAM Junctional Tourniquet is also FDA cleared for the treatment of suspected pelvic fractures.

The characteristics of the four junctional tourniquets discussed above are summarized in Table 1.

**Technique for Use of Junctional Tourniquet**

Combat Gauze is currently recommended by the CoTCCC for external hemorrhage at a site not amenable to tourniquet placement.27,28

Combat Gauze has been reported to be safe and effective in controlling external hemorrhage in complex combat injuries, including bleeding from sites where tourniquets could not be applied, such as junctional hemorrhage.29

The application of Combat Gauze with direct pressure on the bleeding site will help to minimize blood loss during assembly and application of junctional tourniquets and should be used for preliminary hemorrhage control. If other team members are available to help, they may be recruited to perform direct pressure while the medic readies the junctional tourniquet.

“It is recommended that these junctional tourniquet devices be removed only when the option of immediate proximal surgical hemorrhage control is available. This may include endovascular control as well as external surgical vascular occlusion. Specific surgical technique for gaining control will depend on the device that has been placed, the supplies and resources immediately available, and the skills and capability of the operating surgeon.”8

**Conclusions**

There are now three junctional tourniquets and one truncal tourniquet (the AAT) cleared by the FDA for control of junctional hemorrhage. The junctional tourniquets are important new tools for combat medical personnel

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Prehospital Tourniquets Cleared by FDA for Control of Junctional Hemorrhage</th>
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<tbody>
<tr>
<td>Name</td>
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<td>Indication(s)</td>
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</tr>
<tr>
<td>Contraindication(s)</td>
<td>Pregnancy; abdominal aortic aneurysm; penetrating abdominal trauma</td>
</tr>
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</table>
Management of Junctional Hemorrhage in Tactical Combat Casualty Care

There is presently insufficient evidence to make a recommendation for which of the four currently cleared devices is the optimal choice for junctional hemorrhage control.

Because of the relatively short maximum duration of application (one hour) recommended for the AAT and the relative contraindication to using this device in penetrating abdominal trauma (which is often present in conjunction with junctional hemorrhage), the AAT has significant limitations that make it the device of last resort among the four devices being considered for junctional hemorrhage control. The AAT is a truncal rather than a junctional tourniquet.

The three CoTCCC-recommended junctional tourniquets are:
1. The Combat Ready Clamp
2. The Junctional Emergency Treatment Tool
3. The SAM Junctional Tourniquet

The JETT and the SAM may also play an important role in stabilizing pelvic fractures, which are often seen in association with proximal lower extremity amputations and junctional hemorrhage.

Junctional hemorrhage control should be started with Combat Gauze and direct pressure while the junctional tourniquet is being prepared and applied. Note that if junctional bleeding is controlled with Combat Gauze and direct pressure alone, there may not be an immediate need for the junctional tourniquet.

**Proposed Change**

**Current Wording in the TCCC Guidelines**

**Tactical Field Care**

4b. Bleeding: “If the bleeding site is not amenable to tourniquet application and cannot be controlled by hemostatics/dressings, consider immediate application of mechanical direct pressure including CoTCCC recommended devices such as the Combat Ready Clamp (CRoC).”

**Proposed New Wording in the TCCC Guidelines**

**Tactical Field Care**

4b. Bleeding: If the bleeding site is appropriate for use of a junctional tourniquet, immediately apply a CoTCCC-recommended junctional tourniquet. Do not delay in the application of the junctional tourniquet once it is ready for use. Combat Gauze applied with direct pressure should be used if a junctional tourniquet is not available or while the junctional tourniquet is being readied for use.

**Tactical Evacuation Care**

3b. Bleeding: If the bleeding site is appropriate for use of a junctional tourniquet, immediately apply a CoTCCC-recommended junctional tourniquet. Do not delay in the application of the junctional tourniquet once it is ready for use. Combat Gauze applied with direct pressure should be used if a junctional tourniquet is not available or while the junctional tourniquet is being readied for use.

**Level of evidence: Class C**

**Vote:** The proposed change noted above passed by the required 2/3 or greater majority of the CoTCCC voting members.

**Considerations for Performance Improvement and Further Research**

1. Medical personnel who monitor performance improvement or conduct research should gather and analyze data on junctional tourniquet use in the prehospital environment in conjunction with morbidity and mortality outcomes for both military and civilian casualties.

2. Military medical personnel who conduct research, work at training centers, or work at centers for lessons learned should gather and analyze feedback from combat medics, corpsmen, and PJs about their experiences with all of the FDA-cleared junctional tourniquets as well as the AAT.

**Disclaimers**

The recommendation contained herein is the current position of the Department of Defense Joint Trauma System Committee on Tactical Combat Casualty Care. This recommendation is intended to be a guideline only and is not a substitute for clinical judgment.

This document was reviewed by the Director of the Joint Trauma System, the Public Affairs Office, and the Operational Security Office at the U.S. Army Institute of Surgical Research and approved for unlimited public release as of 26 August 2013.
Disclosures
None of the authors have a financial interest in the products or companies discussed in this manuscript.

References

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