



TITLE: Junctional Tourniquets for Controlling Hemorrhage from Wounds in Adults: A Review of Clinical Effectiveness, Cost-Effectiveness, Safety, and Guidelines

DATE: 10 April 2014

CONTEXT AND POLICY ISSUES

The majority of combat casualties in modern warfare die from their injuries prior to obtaining medical care in a treatment facility.¹ The nature of the weapons used, now dominated by improvised explosive devices, and of the protective gear, which only cover the torso and skull, have rendered the pelvis and lower limb junctions susceptible to penetrating wounds.² The disruption of major arteries in that area can lead to life-threatening hemorrhage and exsanguination. It is estimated that 90.9% of deaths from these potentially survivable combat wounds are due to fatal blood loss and that 19.2% of these hemorrhages are located at anatomical junctions.²

Bleeding in an emergency tactical setting can be controlled with gauze impregnated with hemostatic agents, such as Combat Gauze (Z-Medica Corp).³ Pressure must also be applied at or near the trauma site in order to occlude blood flow. This operation can be facilitated with the use of an appropriate tourniquet, which also provides the benefit of freeing the hands of the healthcare provider. The expanded use of pre-hospital extremity tourniquets is believed to have saved the lives of 1,000 to 2,000 U.S. military personnel during the recent conflicts.¹ Tourniquets of various designs can also be applied to the truncal area as well as at anatomical junctions (groin, neck, armpits). The Canadian experience in Afghanistan also highlighted the importance of proper management of axillary and inguinal bleeding.³

Until recently, three junctional tourniquet models were available on the market: the Junctional Emergency Treatment Tool (JETT), the SAM Junctional TQ, and the Combat Ready Clamp (CRoC). The Abdominal Aortic & Junctional Tourniquet (AAJT), previously only indicated for truncal use to prevent inguinal bleeding, can be now added to this list since it has recently received FDA clearance for junctional use.⁴ According to the American Committee on Tactical Combat Casualty Care (TCCC), the desirable traits of junctional tourniquets include: effective control of hemorrhage from junctional areas, safety, amenable to battlefield and tactical situations, low weight, low cost, ease of use, speed of application and stability.¹

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The introduction and appropriate use of junctional tourniquets has the potential to save many lives. A review of the clinical effectiveness and safety of the various junctional tourniquets on the market, along with the associated guidelines, will inform decisions on the best model to select for pre-hospital control of hemorrhages.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of junctional tourniquets for controlling hemorrhagic wounds in adults?
2. What is the safety associated with using junctional tourniquets for controlling hemorrhagic wounds in adults?
3. What is the cost-effectiveness associated with the use of the following types of junctional tourniquets for controlling hemorrhagic wounds in adults: Abdominal Aortic Junctional Tourniquet, Junctional Emergency Treatment Tool, SAM Junctional TQ, and Combat Ready Clamp?
4. What are the guidelines associated with the use of junctional tourniquets for controlling hemorrhagic wounds in adults?

KEY FINDINGS

No comparative clinical trials were identified on the effectiveness and safety of junctional tourniquets, and no cost-effectiveness information was found. The body of clinical evidence consists of case reports and prospective trials involving non-wounded volunteers. No clinical evidence was found on the JETT and SAM junctional tourniquets. A single case report illustrated the effectiveness of the CRoC in a field situation. Case reports of low quality and small size observational trials suggest that the AAJT can successfully prevent blood flow to the limbs, potentially saving lives. No safety concern was reported for any device. Guidelines primarily based on expert consensus recommend all devices except the AAJT, but the rationale for excluding the latter no longer applies.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 3), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and March 13, 2014.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final article selection was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults ages 18 and over
Intervention	Emergency application of a junctional tourniquet to interrupt blood flow to the limbs, when an extremity tourniquet is not indicated
Comparator	Abdominal Aortic Junctional Tourniquet, Junctional Emergency Treatment Tool, SAM Junctional TQ, and Combat Ready Clamp
Outcomes	Q1: Hemorrhage or surrogate measurements of blood flow such as Doppler ultrasound. Q2: Safety, risks and adverse events. Q3: Cost-effectiveness Q4: Guideline recommendations
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials (RCTs), non-randomized studies, case studies and guidelines

Exclusion Criteria

Studies were excluded if they did not fulfil the selection criteria in Table 1, if they were duplicate publications, or were published prior to January 1, 2009. Studies using models such as mannequins, cadavers or animals were excluded.

Critical Appraisal of Individual Studies

A formal quality assessment of non-comparative studies and case reports was not conducted since they provide limited information. The quality of these studies will be discussed in the limitations section.

The quality of the included guidelines was assessed using AGREE checklist.⁵ Numeric scores were not calculated. Instead, the strengths and limitations of the guidelines are summarized and presented.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search yielded 147 citations. Upon screening titles and abstracts, 133 citations were excluded and 14 potentially relevant articles were retrieved for full-text review. No additional potentially relevant report was identified in grey literature. Of the 14 potentially relevant reports, 8 were excluded. Three case report studies, two observational studies and one guideline met the inclusion criteria. No economic evaluation was found. The process of study selection is outlined in the PRISMA flowchart (Appendix 1).

Additional references that did not meet the inclusion criteria but may be of potential interest are provided in Appendix 2.

Summary of Study Characteristics

The two non-comparative studies and three case reports are described below.

Lyon and colleagues⁶ conducted a prospective observational trial on the Abdominal Aortic tourniquet (AAT, now AAJT) effectiveness and safety involving nine human volunteers. The primary outcome was interruption of blood flow in the common femoral artery as measured by Doppler ultrasound. Safety was assessed by a qualitative statement of discomfort.

The report by Taylor and colleagues⁷ describes an independent prospective observational trial on AAJT effectiveness and safety involving 16 human volunteers. The primary outcome was interruption of blood flow in the common femoral artery as measured by Doppler ultrasound. Safety was assessed by a visual analog scale of pain.

A 2013 case report by an anonymous author⁸ describes the use of the AAJT in Afghanistan to treat a casualty suffering from bilateral amputation of the lower limbs. The report is narrative; it describes the procedure in detail and includes clinical readings.

Tovmassian and colleagues⁹ report on the battlefield use of the CRoC in 2011. The report begins with a detailed description of the technique with illustrations, followed by a qualitative description of the case. No quantitative medical data are provided.

Croushorn and collaborators¹⁰ report on a non-military case of axillary bleeding that was treated by the off-label (as of the time) use of the AAJT applied to an upper anatomical body junction. The narrative report provides a chronological description of the treatment with clinical data and pictures.

The included proposed guideline changes¹ by the U.S. Department of Defense Joint Trauma System on Tactical Combat Casualty Care (TCCC) examined the performance of all four junctional tourniquets reviewed here. The publication was intended to update the 2012 TCCC guidelines.¹¹ This guideline targets non-civilian tactical medical technicians who are required to perform emergency procedures on combat casualties. Collection of the evidence was not systematic; evidence was graded based on the American College of Cardiology/American Heart Association clinical practice guidelines.¹²

Summary of Critical Appraisal

The document on proposed guideline changes¹ features a review based mostly on expert consensus, reportedly because of the scarcity of empirical evidence. However, the literature search methodology and selection criteria were not provided. Evidence was derived from case studies, observational studies, nonhuman or cadaver models and unpublished observations. The strengths and limitations of the guidelines are summarized in Appendix 3. Briefly, the guideline clearly defines the scope, purposes and target users, and the level of evidence is reported. However, its value suffers from a lack of clarity surrounding the literature search and review methods. No consideration appears to be given to patient preference (arguably a secondary issue in situations where a junctional tourniquet would be employed), and to risks and safety issues. The document does not describe the process used for formulating the

recommendations and does not propose mechanisms to pilot or update the guidelines. This information is also absent from the parent guideline.¹¹

Summary of Findings

Main findings of included studies and guidelines are summarized in detail in Appendix 4.

1. What is the clinical effectiveness of junctional tourniquets for controlling hemorrhagic wounds in adults?

All three case reports⁸⁻¹⁰ describe the successful use of either the CRoC or the AAJT junctional tourniquets. It was argued that the reported use of the AAJT in combat was instrumental in the survival of the casualty.⁸ The case report on the CRoC raised practical concerns about the device.⁹

Both observational studies report on the successful use of the AAJT in a non-combat, non-hemorrhagic situation. The studies consisted of applying the tourniquet to healthy volunteers and immediately measuring blood flow in the common femoral artery (CFA) as a surrogate outcome for hemorrhage. In the study by Lyon et al.,⁶ blood pressure in the CFA fell as the AAJT bladder pressure increased, and blood flow eventually ceased in seven of the nine subjects. The two subjects with incomplete occlusion were found to actively resist the pressure, a situation unlikely to arise in an unconscious or hypotensive individuals. The study by Taylor et al.⁷ had similar findings and demonstrated the effectiveness of the AAJT in a controlled, non-hemorrhagic environment, with a single case of failure.

2. What is the safety associated with using junctional tourniquets for controlling hemorrhagic wounds in adults?

No studies were identified which were purposely designed to assess the safety of junctional tourniquets. All case reports mention that the devices did not cause any complication, although Tovmassian⁹ warned against the lack of stability of the CRoC, which might put the patient at risk of further bleeding, if not properly addressed. Both observational studies on the AAJT recorded self-reported pain and discomfort as a measure of safety, but only the trial by Taylor et al.⁷ used a numerical scale for scoring the pain. No study documented the long term effects of junctional tourniquets.

3. What is the cost-effectiveness associated with the use of the following types of junctional tourniquets for controlling hemorrhagic wounds in adults: Abdominal Aortic Junctional Tourniquet, Junctional Emergency Treatment Tool, SAM Junctional TQ, and Combat Ready Clamp?

No article was found on the cost-effectiveness of the types of junctional tourniquets reviewed here.

4. What are the guidelines associated with the use of junctional tourniquets for controlling hemorrhagic wounds in adults?

Recommendations from the TCCC guidelines⁷ stated that junctional tourniquets can effectively suppress hemorrhages from wounds and have a high potential for saving lives. Faced with a

lack of comparative clinical evidence, the Committee could not recommend a specific model, but advised against the use of the AAJT. The latter notice was based on an FDA contraindication for the AAJT in cases of penetrating abdominal injuries, which frequently occur in conjunction with junctional bleeding. However, such a contraindication has been removed from the latest FDA clearance documents,¹³ removing the main rationale for this recommendation. The guideline specified that junctional hemorrhage control should be started with Combat Gauze and direct pressure while the junctional tourniquet is being prepared and applied.

Limitations

The case reports included in this review must be solely viewed as supporting evidence to signal the potential usefulness of a technology and to promote further research. Case reports are not hypothesis-based and may not fully reflect the clinical context for which the device is indicated; hence, generalizability is hampered. The report on AAJT use in Afghanistan⁸ was written by an anonymous author, limiting the ability to assess potential conflicts of interest. It is not clear if the report by Croushorn et al.¹⁰ describes a case of military casualty. Moreover, this report has an increased risk of bias due to conflict of interest, with the primary author being both the inventor of the device and the founder of the manufacturing company.

The cited observational studies are limited by small sample sizes, a lack of long term safety outcomes, a single application/measurement per participant, a surrogate outcome that does not measure hemorrhage per se and thus may not reflect the targeted clinical state, and a controlled environment far removed from the fast-paced, unpredictable tactical context of use. All subjects were healthy volunteers, not injured patients. The study by Lyon and colleagues⁶ is also limited by conflict of interest issues and by the absence of statements on subject inclusion and exclusion criteria.

No study included a control group that would allow the comparison of the effectiveness of junctional tourniquets to that of standard care (e.g. manual compression with hemostatic gauze). Hence, based on the current state of the evidence, it cannot be formally stated that junctional tourniquets provide benefits over other procedures meant to control bleeding.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY-MAKING

Despite successful field use, the effectiveness, benefits and safety of junctional tourniquets, potentially lifesaving devices, are supported by clinical evidence of low quality, if any. The AAJT is the only device for which planned clinical studies were conducted, and the only tourniquet indicated for both truncal and junctional use. A phase 4 randomized controlled trial using the AAJT has recently been initiated and is scheduled to be completed in August 2016.¹⁴ Current clinical guidelines fail to inform decisions regarding which device to favour and recommend that military medical personnel increase data collection and conduct more thorough research. The need for richer, comparative data is also mentioned and warrants further well designed trials.

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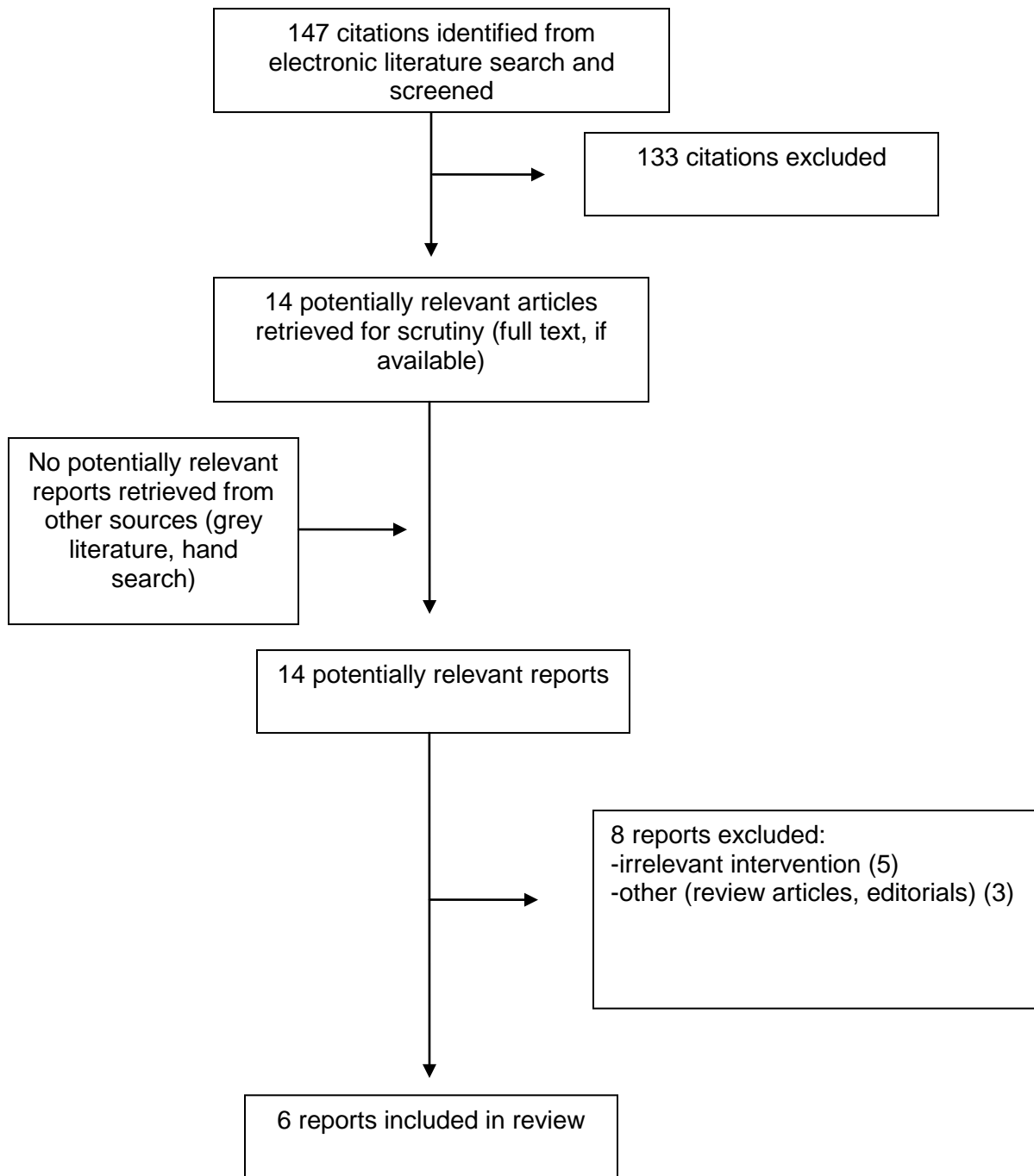
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<http://clinicaltrials.gov/ct2/show/NCT01965561>

APPENDIX 1: Selection of Included Studies



APPENDIX 2: Other references of potential interest

Cadaver models for tourniquet effectiveness

Gates KS, Baer L, Holcomb JB. Prehospital emergency care: evaluation of the junctional emergency tourniquet tool with a perfused cadaver model. *J Spec Oper Med*. 2014;14(1):40-4.

Kragh JF Jr, Murphy C, Steinbaugh J, Dubick MA, Baer DG, Johnson JE, et al. Prehospital emergency inguinal clamp controls hemorrhage in cadaver model. *Mil Med*. 2013 Jul;178(7):799-805.

Manikin model for tourniquet effectiveness

Mann-Salinas EA, Kragh JF Jr, Dubick MA, Baer DG, Blackbourne LH. Assessment of users to control simulated junctional hemorrhage with the combat ready clamp (CRoC). *Int J Burns Trauma* [Internet]. 2013 [cited 2014 Mar 14];3(1):49-54. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3560489/pdf/ijbt0003-0049.pdf>

Technology overviews

Kragh JF Jr, Murphy C, Dubick MA, Baer DG, Johnson J, Blackbourne LH. New tourniquet device concepts for battlefield hemorrhage control. *US Army Med Dep J*. 2011 Apr;38-48.

Kragh JF Jr, Dubick MA, Aden JK 3rd, McKeague AL, Rasmussen TE, Baer DG, et al. U.S. military experience with junctional wounds in war from 2001 to 2010. *J Spec Oper Med*. 2013;13(4):76-84.

General guidance on military junctional trauma

Parker P, Limb Trauma Working Group. Consensus statement on decision making in junctional trauma care. *J R Army Med Corps*. 2011 Sep;157(3 Suppl 1):S293-S295.

Tai NR, Dickson EJ. Military junctional trauma. *J R Army Med Corps*. 2009 Dec;155(4):285-92.

APPENDIX 3: Summary of Critical Appraisal of Included Studies

Table A1: Summary of Critical Appraisal of Included Guideline (AGREE ⁵)		
First Author, Publication Year	Strengths	Limitations
<i>Kotwal et al., 2013</i> ¹	<ul style="list-style-type: none"> • scope and purpose of the guidelines are clear • target users of the guideline are clearly defined • strength of evidence is reported 	<ul style="list-style-type: none"> • unclear whether the guideline was piloted among target users • health benefits, side effects and risks were not stated in the recommendations • the method for searching for and selecting the evidence are unclear • recommendations are ambiguous • unclear whether patients' views and preferences were sought • potential cost implications of applying the recommendation not included • methods used for formulating the recommendations are not clearly described • procedure for updating the guidelines not provided

APPENDIX 4: Main Study Findings and Authors' Conclusions

Table A1: Main Observational Study Findings and Authors' Conclusions		
First Author, Publication Year	Main Study Findings	Authors' Conclusions
Lyon, 2012 ⁶	The AAJT successfully ceased CFA blood flow in 7 of 9 subjects. No complications were observed and discomfort was transient.	Page S104 : <i>"The AAT was uniformly successful in reducing blood flow in the distal CFA. Further experiments are needed to determine the effectiveness of this device in injured subjects."</i>
Taylor, 2013 ⁷	The AAJT successfully interrupted CFA blood flow in 15 of 16 subjects. No harm was noted; pain was tolerable and transient.	Page 1200: <i>"This device could be of great potential benefit in present battlefield scenarios as well as those in future conflicts where surgical facilities may be more primitive and casualty evacuation times far greater."</i>

AAJT = Abdominal Aortic & Junctional Tourniquet; AAT = Abdominal Aortic Tourniquet; CFA = common femoral artery

Table A2: Main Guideline Findings	
First Author, Publication Year	Recommendation
Kotwal, 2013 ¹	<p>Page 91: Tactical Field Care <i>"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."</i></p> <p>Tactical Evacuation Care <i>"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."</i></p>

CoTCCC = Committee for Tactical Tactical Combat Casualty Care