REVIEW

The Combat Application Tourniquet Versus the Tactical Mechanical Tourniquet

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Background:
Exsanguination from limb injury is an important battlefield consideration that is mitigated with the use of emergency tourniquets. The Combat Application Tourniquet (C-A-T®) is the current British military standard tourniquet.

Methods:
We tested the self-application of a newer tourniquet system, the Tactical Mechanical Tourniquet (TMT), against self-application of the C-A-T. A total of 24 healthy British military volunteers self-applied the C-A-T and the TMT to their mid thigh in a randomized, sequential manner. Popliteal artery flow was monitored with a portable ultrasound machine, and time until arterial occlusion was measured. Pain scores were also recorded. Results The volunteers allowed testing on their lower limbs (n = 48 legs). The C--A-T was applied successfully to 22 volunteers (92%), and the TMT was successfully applied to 17 (71%). Median time to reach complete arterial occlusion was 37.5 (interquartile range [IQR], 27–52) seconds with the C-A-T, and 35 (IQR, 29–42) seconds with the TMT. The 2.5-second difference in median times was not significant (p = .589). The 1-in-10 difference in median pain score was also not significant (p = .656). The success or failure of self-application between the two tourniquet models as assessed by contingency table was not significant (p= .137).

Conclusion:
The TMT is effective when self-applied at the mid thigh. It does not offer an efficacy advantage over the C-A-T.

Introduction
Limb exsanguination and junctional hemorrhage remain important causes of preventable battlefield mortality. Limb tourniquets, therefore, are essential equipment during the Care Under Fire and Tactical Field Care phases of care. The British Army currently uses generation 6 of the Combat Application Tourniquet ® (C-A-T; C-A-T Resources, www.combattourniquet.com) for casualty care at point of wounding. Preclinical evidence is clearly required when new styles of tourniquets become available in the marketplace, particularly if an established tourniquet model is under consideration for potential revision or redesign.

Combat Application Tourniquet
The C-A-T has saved many lives, particularly in the American and British military campaigns. Studies have found that a single self-applied C-A--T may not always be sufficient to arrest bleeding when applied to the mid thigh.1,2 American and British military doctrine advocates the use of two C-A-Ts side by side if bleeding is uncontrolled with one tourniquet.3,4 In fact, a real-world study reported the percentage failure of a singly applied C-A-T to be 18%, with the thigh being the least successful body region.5 The C-A-T has benefitted from spiral development: a continual improvement cycle refining model design in response to battlefield feedback. The seventh generation C-A-T has been manufactured and is being distributed for use. Improvements to the generation 6 model are intended to accommodate c mmon user mistakes and include a single routing buckle, windlass rod of increased diameter, beveled windlass clip, reinforced strap, and beveled stabilization plate. Manufacturer C-A-T Resources postulates that these improvements increase application speed, simplify training, increase strength, and improve comfort. Initial manikin testing showed that the generation 7 outperformed the generation 6 in hemorrhage control, ease of use, and user preference. Figure 1 shows the C-A-T applied to the mid thigh.

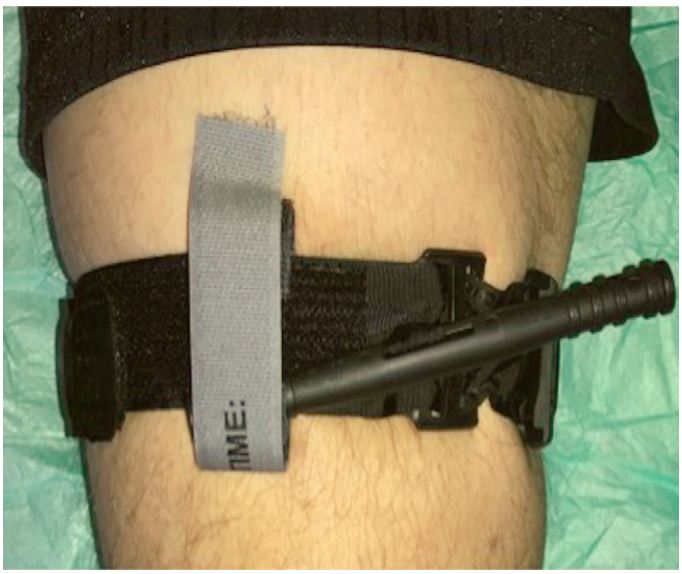

Figure 1: *Combat Applied Tourniquet positioned at the mid thigh but not fully tightened.*

Tactical Mechanical Tourniquet
The TMT (Alphapointe™, www.alphapointe.org) has been developed in a similar manner to the C-A-T. Important differences include a wider strap, a larger back plate, a “snap in” self-application buckle, and a greater travel in the inner linear band between buckles. The manufacturer hypothesizes these features potentially improve both ease of use and ability to occlude the popliteal artery when compared with the C-A-T. A single tourniquet that could be used at the mid thigh without the need for a second (in side-by-

side mode) would represent a logistical and tactical improvement. The TMT has been shown to be effective when applied to a manikin thigh.7 Another study determined the TMT to be 100% effective at occluding the popliteal artery within an acceptable pain threshold in healthy volunteers when applied by a researcher.8 Figure 2 shows the tactical mechanical tourniquet applied to the mid thigh. Table 1 illustrates the specifications of the TMT and the C-A-T.

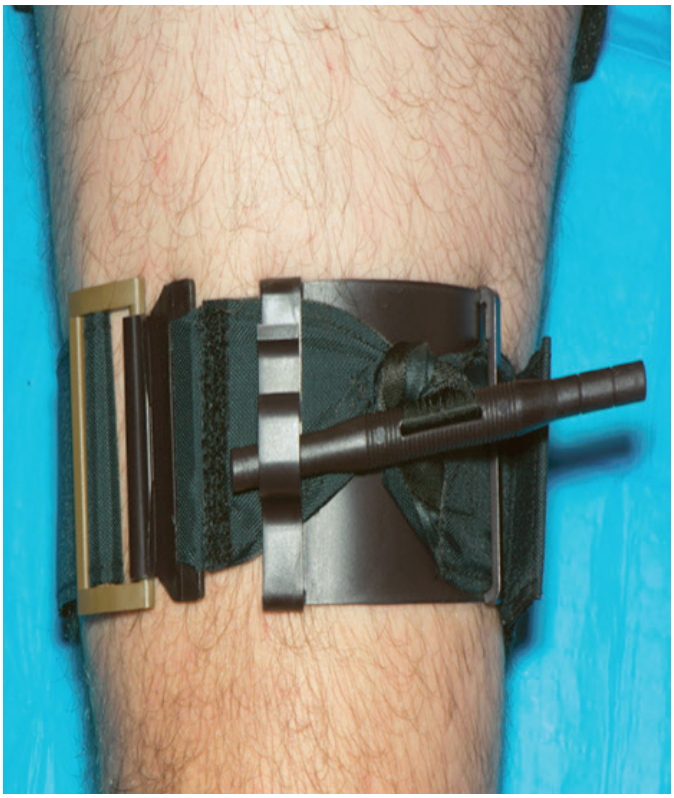

Figure 2: *Tactical Mechanical Tourniquet applied at the mid thigh but not fully tightened.*

Aim

The C-A-T has been designed to be self-applied as well as applied by a third person. The aim of this study was to compare self-application performance of the C-A-T with that of the TMT in a simulated model of lower limb hemorrhage among healthy British military volunteers.

Methods

Design

A pilot study was performed before recruiting 24 healthy volunteers. Ministry of Defence Research ethical application was formally applied for and granted (712/MODREC/15). Trials took place between May and July 2016.

Pilot

In a pilot phase trial, feasibility, equipment, simulated hemorrhage model, tolerance, and methodology were to be tested and validated. Three healthy British military volunteers were enrolled. The data from this pilot trial are included in the totals presented in Results.

Volunteers

The population of interest were currently serving British military personnel in a deployable role. Twenty-four healthy, actively serving British military personnel were recruited to participate (inclusive of three pilot volunteers). Inclusion criteria were actively serving British soldiers (any rank), two intact lower limbs, and volunteering to participate. Exclusion criteria were participation in a previous tourniquet study, medically unfit to deploy in role, and vascular disease or previous surgery that would preclude tourniquet application. Volunteers were recruited from 202 Field Hospital. No volunteers had previously self-applied a C-A-T except during training.

Methodology

The C-A-T and the TMT were tested by all subjects sequentially, one tourniquet on each lower limb at a time. Thus, the number of replicates (tests) was 48: 48 limbs, 24 users. The order of tourniquet models and the order of the limb laterality in which tourniquets were applied were randomized per a previously detailed technique.8 A prerandomized algorithm was used to determine order for the whole cohort before testing began. Participants received a scripted brief on the correct application of the models based on the instructions for use. Briefing occurred regardless of whether the volunteers had had previous training.

Simulated Hemorrhage

A model of simulated hemorrhage was used to aid subjects in determining how tightly to apply to the windlass to their lower limb. Portable ultrasound machines were used to monitor popliteal artery flow. Ultrasound machines were a portable SonoSite® (FUJIFILM SonoSite Inc, www.sonosite.com/) machine with a 10Mhz probe, and a portable GE Logiq-e (GE Healthcare, http://www3.gehealthcare.com/) machine with a 12mHz probe, each operated by a single consultant radiologist. The ultrasound Doppler waveform was visible to the study subject, and its appearance (including sound) during cessation of arterial flow explained. The aim was for the participants to understand the point at which arterial occlusion occurred. The ultrasound operator aided subjects in interpretation of results by offering verbal cues. These cues helped determine the point when Doppler waveform evidenced absence of flow, and included phrases such as "you're still bleeding"

and "bleeding has stopped."
The subject was asked to self-apply each tourniquet sequentially to separate limbs at the mid-thigh level (defined as the midpoint between the superior pole of the patella and greater trochanter) to bare skin. Subjects were able to stop tourniquet use at any time, such as if pain was intolerable. After release of the tourniquet, return of arterial flow was assessed by leaving the probe in situ and monitoring Doppler waveform.

End Point
The application was considered successful if (1) ultrasound showed total occlusion of the popliteal artery; (2) the windlass mechanism was locked into the plastic gate; (3) the study participant deemed discomfort to be tolerable; and (4) arterial flow resumed at tourniquet release.

Data Collection
Demographic data on age and sex were collected. The time taken to successfully apply each tourniquet (from first receiving the tourniquet to arterial occlusion) and maximum pain scores on a 0 to 10 verbal numeric pain rating scale (0 = no pain, 10 = worst pain ever experienced) were also collected.
An answer (either C-A-T or TMT or same) was requested to two questions: "Which tourniquet is easiest to use?" and "Which tourniquet is the most painful?" Non-normally distributed data are represented as a median and interquartile range (IQR). The Kruskal-Wallis test was used to compare medians of continuous, non-normally distributed, independent variables. $P < .05$ is considered significant.
Kurtosis calculations were performed to analyze for skewness. Fisher exact test was used analyze 2×2 contingency tables with two-tailed p values for significance testing. Data were processed in Excel (Microsoft, www.microsoft.com).

Results
The 24 volunteers allowed testing on their collective total of 48 lower limbs. Times to application were positively skewed (kurtosis = 3.52). Pain scores were negatively skewed (kurtosis = 2.59). The C-A-T was applied successfully to 22 volunteers (92%), and the TMT was successfully applied to 17 (71%). The time to reach complete arterial occlusion was median of 37.5 (IQR, 27–52) seconds with the C-A-T, and 35 (IQR, 29–42) seconds with the TMT. The 2.5-second difference in median times was not significant (p = .589). The 1-in-10 difference in median pain score also was not significant (p = .656).
When analyzed by a 2×2 contingency table considering success or failure of the tourniquet based on the tolerance or intolerance of pain, the C-A-T was better tolerated. The difference, however, again failed to reach statistical significance (two-tailed p = 0.137).
The TMT was rated most painful by 11 volunteers, 10 volunteers rated the C-A-T most painful, and 3 volunteers rated them equally painful. Thirteen volunteers rated the C-A-T easier to use, seven rated the TMT easier, and four thought they were equally easy to apply. A histogram of pain scores for each tourniquet system is shown in Figure 3. The pain scores for the C-A-T were more tightly grouped around the median score than were the TMT pain scores, which were more widely distributed around the median of 6 out of 10.

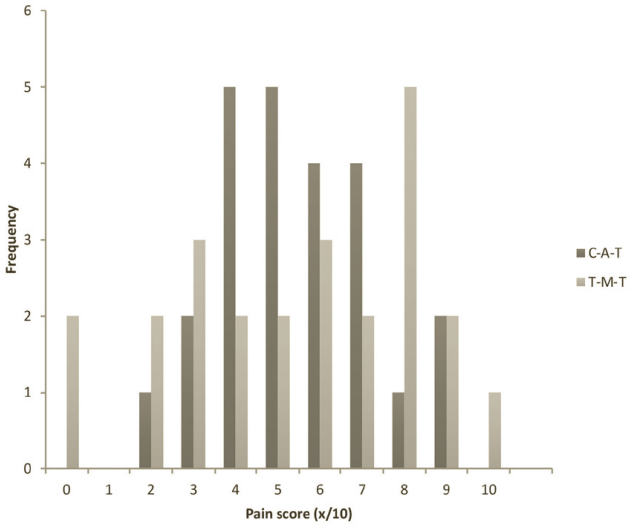

Figure 3: *Pain score histogram for each tourniquet model.*

Pain description
Volunteers described the pain from application of the TMT during the study, although it was not a metric formally explored in the methodology. Pain was experienced where the circumferential hook-and--loop strap met the plastic back plate. As tightening occurred, the strap was drawn across the backplate nonuniformly, and the skin was pinched in this area.

Discussion
Efficacy
In our study, the TMT was less effective during self--application at the mid thigh than was the C-A-T in healthy serving military volunteers. This difference was not statistically significant either in terms of application time, median pain scores, or success/failure scores. Furthermore, the contingency table also shows that the differences in tolerance between the two tourniquets did not reach statistical significance.

Although a previous study demonstrated that the TMT can be tolerated when applied by another person,8 self-application appears less well tolerated in the present study. Based on the current study, there is no evidence to suggest that the TMT is better during self-application than the C-A-T, which remains an appropriate option for the self-arrest of catastrophic lower-limb bleeding.

The TMT was not tolerated by 29% of volunteers. The sole reason cited was pain, specifically pain from the skin being pinched underneath the tourniquet. This reason was the same for both tourniquets, although it was threefold more common in the TMT than the C-A-T (six versus two volunteers). Author application suggested that the rear surface of the TMT in contact with the skin caused the painful stimulus. This was felt to be due to shear forces rather than pure compression. Future generations of the TMT may benefit from redesign of the interface between the device and the skin. All the study participants had self-applied the C-A-T before during training, and some had applied the C-A-T to other wounded Soldiers, but none had used the TMT before. Therefore, participants could be described as familiar with the C-A-T but unfamiliar with the TMT. Although of similar design, unfamiliarity may have slowed TMT use in the current study, which could be improved once familiarity is attained. Another limitation is that on the battlefield, when faced with an actively bleeding limb, the incentive to fully tighten a tourniquet to avoid exsanguination is greater. It could be likely that the pain of injury would mask the pain of a self-applied tourniquet, and therefore tests in healthy volunteers of this kind are less relevant. Equally, one can imagine a situation where a casualty is overwhelmed by injury, and self-application, therefore, is impossible. Thus, as a test of tourniquet utility, measures of self-application at the mid thigh may be of limited generalizability; however, the methodology used in this paper represents an acceptable balance between practicality and translatability.

It is known that arterial occlusion pressures are greater in thighs of larger circumference.9,10 Knowing this association may further the understanding of tourniquet users; however, a battlefield tourniquet must be effective across a wide range of body sizes. We chose not to measure thigh circumference in our volunteers, because we felt the tourniquets should work regardless of thigh shape.

The simulated hemorrhage model is not equivalent to experiencing real catastrophic hemorrhage; however, it is a methodology that has been used in previous studies of this kind. Additional research could be conducted under conditions of stress to simulate the physiological conditions of a Soldier in a fire fight.

Conclusion

The TMT is effective at occluding the popliteal artery when self-applied at mid thigh in healthy military volunteers. There was no statistically significant difference between the C-A-T and the TMT in terms of self-application time, pain, or overall tolerance. There is no evidence to suggest that the TMT should be used in preference to the C-A-T.

Disclosure

Fenton Pharmaceuticals supplied the tourniquets with a material transfer agreement for research. No funding was received.

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