Abdominal Aortic Junctional Tourniquet - Stabilized (AAJTS) can be applied both successfully and rapidly by Combat Medical Technicians (CMTs)

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ABSTRACT

Background 'Non-compressible' haemorrhage is the leading cause of preventable battlefield death, often requiring surgical or radiological intervention, which is precluded in the pre-hospital environment. One-fifth of such bleeds are junctional and therefore potentially survivable. We examine the use of the Abdominal Aortic Junctional Tourniquet - Stabilized (AAJTS) among UK Combat Medical Technicians (CMTs) as a device to control junctional haemorrhage with external compression of the abdominal aorta—compression of junctional haemorrhage previously considered 'non-compressible.' This follows animal studies showing that the AAJTS achieves control of haemorrhage and improves physiological parameters.

Methods CMTs were selected and applied the AAJTS to each other following a 1-hour training package. A consultant radiologist-operated hand-held ultrasound monitored flow changes in the subjects' common femoral artery. CMTs were then surveyed for their opinions as to utility and function.

Results 21 CMTs were screened and 17 CMTs participated with 34 total applications (16 day and 18 low-light). 27/34 (79%) achieved a successful application. The median application time was 75 s in daylight and 57 s in low-light conditions. There was no significant difference in Body Mass Index (p=0.23), median systolic blood pressure (p=0.19), nor class of CMT (p=0.10) between successful and unsuccessful applications. Higher systolic blood pressure was associated with longer application times (p=0.03). Users deemed the device easy to use (median score 4.4 on a 5-point Likert scale).

Conclusion CMTs can use AAJTS successfully after a 1-hour training session in the majority of applications. Application was successful in both daylight and low-light conditions. Self-reported usability ratings were high.

Key messages

- Presently, no Combat Medical Technician (CMT)–delivered intervention exists to achieve control of 'non-compressible' haemorrhage in the groin and pelvis.
- We demonstrate that CMTs can successfully deploy Abdominal Aortic Junctional Tourniquet - Stabilized (AAJTS) on healthy military volunteers following a training period of 1 hour, with an initial success rate of 79%.
- We demonstrate no significant difference in AAJTS success for Body Mass Index, systolic BP nor grade of CMT.
- Application time is just over a minute and can be even shorter with further training and practice.
- Application is successful in both daylight and low-light conditions. Self-reported usability ratings were high.

INTRODUCTION

Military medical services should be continuously striving to improve patient outcomes. It is known that 'non-compressible' haemorrhage is a leading cause of preventable battlefield death[1–4] and often requires surgical or radiological intervention.[5] The treatment of such injuries in the pre-hospital environment remains a challenge, particularly in junctional areas that are not amenable to conventional tourniquet application. One in five cases of potentially survivable 'non-compressible' haemorrhage are junctional[1–4]—39% neck and the remaining 61% not differentiated between pelvic or axillary. There is no device readily available for Combat Medical Technicians (CMTs) to use for junctional or pelvic injury.[6] Treatment options for these injuries by CMTs are currently limited to just direct pressure—which often proves unsustainable or unachievable[7]—and novel haemostatic agents. AAJTS provides a method to successfully compress junctional haemorrhage—this was previously considered 'non-compressible.'

An analysis of UK Joint Theatre Trauma Registry data from Afghanistan between 2008 and 2011 showed that significant upper thigh, groin or pelvic injuries were recorded in 124 casualties, of which 93 died. Pelvic injury was the cause of death in 37 cases, and 32 further casualties were identified with cause of death being vascular injury between the aortic bifurcation and inguinal ligament. Eight survived to a medical facility but later died of wounds. For these patients, vascular control proximal to the inguinal ligament could potentially have altered the outcome.[2 3]

The Abdominal Aortic Junctional Tourniquet - Stabilized (AAJTS) (Compression Works Ltd, Birmingham, AL 35216, USA) is an externally applied device that compresses the aorta via the inflation of a pneumatic bulb (Figure 1). It has been shown in animal and human cases[8 9] to be effective at stopping haemorrhage previously considered 'non-compressible'[10–12] below the aortic bifurcation (and to improve physiological parameters.)[9 13 14] There is currently no published evidence that non-physicians

Figure 1 AAJTS is a CE-marked and FDA-approved product available on the open market from Compression Works.

or CMTs can effectively use such a device. The AAJTS is a more stable improvement on the AAJT. The tightening mechanism of the former device is a ratchet buckle in place of the windlass rod employed by the latter device—thus one can maintain pressure without threat of losing grip on a windlass rod.

Given that one of the benefits of the AAJTS is its supposed straightforwardness, there needs to be an assessment of ease-of-use and trainability.[15 16] The aim of this study is to evaluate whether after a short period of training a CMT can *effectively* apply the AAJTS in a controlled setting on healthy military CMTs.

METHODS

Study design

There is no commercially available model or manikin on which to suitably train the AAJTS and confirm correct use. As such, this low-risk, non-invasive study was conducted on healthy military volunteer CMTs after full Ministry of Defence ethical approval.[17] In addition, a healthy human trial design avoids non-translatability from animal trials.[16]

CMTs worked in pairs with one as the 'CMT user' of the device and the other the 'CMT subject' on which the device was deployed. Once consented and screened, all CMTs underwent standardised instruction on how to use the AAJTS with a period of practice that lasted 1 hour (Figure 2). The instruction phase consisted of 20 min of anatomical training, 10 min of demonstration and 30 min of practical AAJTS use under the authors' supervision.

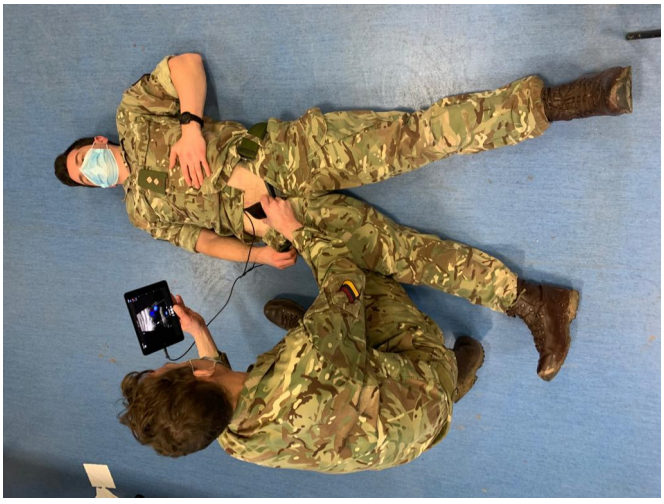

Figure 2 Consultant radiologist determines common femoral artery flow with hand-held ultrasound device.

The test phase followed immediately after the instruction phase. The 'CMT users' had to correctly place and inflate the AAJTS until absence of flow in the 'CMT subject's' common femoral artery was confirmed by ultrasound—we took this as a surrogate measure of AAJTS efficacy. One of the authors kept time with a stopwatch. Timing was started on the CMT touching the device which was positioned on the floor next to the CMT subject. Timing was stopped after the radiologist confirmed common femoral artery occlusion by stating 'full occlusion.' AAJTS was then quick-released.

The study was performed twice: once in daylight conditions and once in low-light conditions. The CMT user/CMT subject pairs were not changed, and the low-light level phase occurred directly after the daylight phase. A pilot phase of three applications was employed to confirm ultrasound technique.

The ultrasound device was a portable Butterfly Network (530 Old Whitfield St, Guilford CT 06437, USA) operated by a single experienced consultant radiologist (Figure 2). The waveform was visible and audible to the 'CMT user', and its appearance (including sound) during the application was explained. The ultrasound was used to monitor common femoral artery flow at three time-points: (1) to confirm flow pre-AAJTS application, (2) to confirm cessation of flow with successful AAJTS application and (3) to confirm return of flow following device release. Occlusion was deemed to be 'successful' or 'unsuccessful' based on the cessation of flow as determined by the radiologist. Partial occlusions were seen but characterised as 'unsuccessful' for the purposes of this study as flow dynamics were not formally measured and therefore any degree of partial occlusion was felt to be unquantifiable.

Following AAJTS application, CMTs were surveyed to assess the perceived strengths and weaknesses of the device. This involved greater breadth of questioning than previous usability surveys[16] and an open comment section.

User survey

Reproduced as an online supplemental file 1.

Volunteers

CMTs were recruited from a high-readiness medical regiment. Inclusion criteria were 18–25 years old, currently serving member of military, CMT class 1 or 2, and medically fully deployable.

Our exclusion criteria were pregnancy, smoker, history of deep vein thrombosis or vascular disease, diabetes, recent abdominal surgery, hypertension, hernias, obesity (Body Mass Index (BMI)>30), gastrointestinal symptoms, hyperlipidaemia, active lower limb infection or surgery within 6 weeks. The age ceiling of 25 years old was to reasonably rule out the possibility of abdominal aortic plaques being present which could theoretically rupture in AAJTS application. The exclusion of BMI >30 was to eliminate the potential confounding factor of excessive body fat in application success.

CMTs were dressed in standard working dress; Personal Clothing System shirt, t-shirt and trousers which were lowered to allow monitoring via ultrasound. An example of a correctly applied device can be found in Figure 3.

Data collection and analysis

Variables measured were BMI, BP at the brachial artery by manual sphygmomanometer and stethoscope, CMT class, gender and light level recorded from CMT subjects immediately prior to AAJTS application to them. Time taken to successfully

Figure 3 Correctly applied and secured AAJTS device.

apply device was recorded immediately on the radiologist calling full occlusion.

'Daylight conditions' were simulated by classroom lights being on; 'low-light conditions' were simulated by classroom lights being off with all window blinds drawn.

After the study had been performed, the applicants were asked to complete a survey to inform subjective assessments of usability. As well as quantitative questioning using a 5-point Likert scale, a qualitative free-text box was also employed.

Data were analysed with non-parametric tests using median and IQR. The Wilcoxon signed-rank test was used to compare continuous data in two dependant samples against categorical success or failure (BMI and systolic BP (SPB) in the same pairs). Spearman's correlation was used to compare time of application against two continuous variables (BMI and SBP). Chi-squared test was used to compare success against categorical data in contingency tables (CMT class and light conditions). Significance was set at $p<0.05$.

RESULTS

A total of 21 CMTs were screened; after the pilot applications and volunteers with BMI >30 were excluded, there were 17 CMT participants. Demographic data are available in Table 1. There were 34 study applications (16 daylight and 18 low-light).

There was no statistically significant association between BMI ($p=0.23$) nor SBP ($p=0.19$) and success or failure. BMI was not correlated with application times ($p=0.83$). Higher SBP was associated with longer application times ($p=0.03$). CMT class was not associated with success ($p=0.10$), and neither was light condition ($p=0.80$). Times to successful occlusion and rates of success in different light levels are found in Table 2. Survey results are presented in Table 3.

The latter three questions did not receive a Likert score of 3 or less from any CMT, with just two CMTs rating the first question as a Likert score of 3.

Table 1 Demographic data of included CMTs

Demographic data N=17		
CMT class		
Class 1	10	
Class 2	7	
Sex		
Male	10	
Female	7	
BMI		
Median (IQR)	23.8	(22.3–25.4)
Blood pressure (mmHg)		
Systolic median (IQR)	120	(118–124)
Diastolic median (IQR)	75	(68–88)

BMI, Body Mass Index; CMT, Combat Medical Technician.

Qualitative data

Perhaps more informative than Likert scales, qualitative data were captured in a free-text box. Statements included the perceived poor durability of the materials (six comments), training requirement (four comments), ease of use (three comments), the size of the device that rendered it more suitable for static treatment facilities than point of wounding use (three comments) and worry over indications for use (one comment).

DISCUSSION

The aim of this study was to evaluate whether after a short period of training a CMT could effectively use the AAJTS in a controlled setting on healthy military CMTs. The main finding was that 79% of applications were considered successful and demonstrated occlusion of the common femoral artery. Time to successful application was in the region of 60 s and higher SBP was associated with a significantly longer application time.

In our study, none of the CMTs had applied the AAJTS at any time in the past and thus could be labelled as unfamiliar with the AAJTS prior to the study. The training period was only for 1 hour and yet the majority of applications were successful. This suggests that the AAJTS is indeed easy to operate and can be moderately effective in the hands of both CMT Class 1 and Class 2 soldiers. Interestingly, no CMT failed to successfully apply AAJTS on both day and low-light applications.

It has been demonstrated that this device can also be effective in low-light conditions, even without the use of personal light systems. Self-reported scores of ease of use were high with an average score of 4.4 out 5. This demonstrates a certain simplicity

Table 2 Application times and successful occlusions

	Daylight	Low light	P value
Successful	13	14	
Unsuccessful	3	4	
Total	**16**	**18**	
Application time (s)*			
Median (IQR)	75 (60–100)	57 (51–71)	0.80

*Of successful applications.

Table 3 Results of CMT survey N=17, 100% of CMTs

Question	Mean score Likert scale[1–5]
The AAJTS is easy to use	4.4
The AAJTS has a role on the battlefield	4.7
I would like access to the AAJTS in Role 1	4.6
The AAJTS could save lives	4.7

AAJTS, Abdominal Aortic Junctional Tourniquet - Stabilized; CMT, Combat Medical Technician.

of application and lends weight to the notion that this device can be effective even after a minimal period of training.

We detected no significant difference in BMI, systolic blood pressure, nor class of CMT between successful or unsuccessful applications. The study was not designed to detect these differences, however. Our finding of a longer application time with a higher SBP is unlikely to be a practical problem as severely injured casualties will almost certainly have a lower SBP than the study population due to haemorrhage. The observed application time of 75 s is considered clinically acceptable.

There were four applications where common femoral artery occlusion was not fully achieved, but radiographically the flow appeared diminished—a 'partial occlusion.' We had no way of quantifying the flow rate within the study's methodology, hence we reported these applications as 'unsuccessful.' It may be that in a real-life application, these partial occlusions would contribute to arrest of catastrophic haemorrhage and allow some form of clot stabilisation. This is of course intuitive supposition.

Soldiers applying the AAJTS in low-light levels were an average of 18 s faster than in daylight conditions, although this finding did not reach statistical significance. The same soldiers were used in each light level, and low-light conditions were tested after daylight conditions. We cannot believe that the AAJTS is easier to apply in low-light conditions than in daylight, therefore we assert that the decreased application time seen in low-light levels is due to practice and prior experience rather than any difference in surroundings. This gives weight to the impression that further training and familiarity would decrease application times even further, and the device is simple enough to be used in conditions where visibility is not perfect. Improved success after increased practice is already a known entity for medical interventions—for example, with paediatric intubation.[18]

There are of course invasive methods of arresting 'non-compressible' haemorrhage such as resuscitative endovascular balloon occlusion of the aorta (REBOA),[19 20] but this is not a CMT-delivered intervention.[5 6 21] The American College of Surgeons Committee on Trauma and the American College of Emergency Physicians state that REBOA should *only* be deployed when an acute care surgeon is immediately available.[21] Due to its non-invasive nature, the AAJTS offers a potential solution for 'non-compressible' haemorrhage that may be delivered by non-specialist personnel such as CMTs.

We note that severe pelvic and lower limb injuries which necessitate the clinical need for AAJTS deployment may present with extreme anatomical disruption. Such derangement might make AAJTS positioning more difficult than on healthy CMTs. It must also be considered that in those soldiers who are shorter than average, the position of application may be different and therefore less effective, but there is no research considering this currently. A battlefield-deployed AAJTS must be successful in the wide variety of abdominal dimensions and pelvic anatomy in the British Army. We used BMI as a metric rather than waist circumference and did not assess overall body fat percentage. It is unclear if body composition adversely affects AAJTS application, but it remains effective in both male and female service personnel.

The AAJTS works by direct vascular compression (against the spinal column) rather than circumferential pressure (in the manner of a Combat Application Tourniquet or Tactical Mechanical Tourniquet for example). This being the case, it would stand to reason that the distance between the external umbilicus and the aorta might have more of an effect on the success of aortic compression than say BMI or body fat composition or intestinal contents. Without anatomical or imaging analyses these hypotheses are difficult to examine and may form part of a future study.

Regarding the user survey, all CMTs reported favourable opinions with regard to ease of use, battlefield utility and its potential role in saving lives. The response rate was 100% of CMTs. Responses were overwhelmingly positive with all domains reporting very high agreement with utility statements. More informative were the qualitative responses which scrutinised the durability of such a device when used in the dismounted combat medic role. The device was complimented for its ease of use, but some felt that extra training would be required to ensure correct application.

"*AAJTS is easy to use*" scored 4.4 on average with two CMTs giving this category a score of 3 out of 5. The accompanying comment from one CMT was "*limb tourniquets can be used when not needed, this will be the same, and if done for no good reason could mean death of more of limb than needed. Need to be clear when we would apply this*." Should AAJTS be adopted by the British military, we would hope that it would be supported by an effective and comprehensive training regime.

Another CMT free-text comment was "*More kit to carry. In a mass casualty situation, I would want kit that takes up less space and can treat more casualties rather than spending all my time on one seriously wounded casualty*." The AAJTS is not a bulky piece of equipment, actually packing down smaller than a SAM splint. However, one can understand this CMT's sentiment in wanting to have the range of equipment for mass casualty situations rather than treating a single seriously wounded casualty.

A few other CMTs gave constructive criticism "*when rammed into a bergan, the plastic will snap, will this make AAJTS unusable*." One of the AAJTS we were using did actually snap during repeat application but still achieved successful occlusion of the common femoral artery. Previous testing of AAJT by military medical personnel also demonstrated devices breaking after one or two uses.[22]

"*Worried this will fall off during a stretcher move and start the bleed again*." This is a concern shared with limb tourniquets. The authors observed sliding of the device during inflation of the balloon, but not once the device was fully deployed and common femoral flow occluded. We felt that the sliding may be due to individuals tensing their abdominal wall against the AAJTS pressure. The effects of movement after application (ie, a casualty evacuation over uneven terrain) were not tested in the present study but may be included in future research.

An observing Medical Officer made an observation "*Will this not splint the diaphragm and prevent proper breathing… especially if we've given fentanyl or ketamine etcetera they will struggle*." CMTs did anecdotally report restricted breathing; this remains unquantified.

Mitigation of junctional and torso bleeding will be important in future conflicts. Military operations may be conducted without integrated surgical support or advanced pre-hospital care techniques. Balanced against this particularly is the distal warm ischaemia time.[13 23–29] Patients who have an AAJTS applied

will still require immediate medical evacuation. As a guide, the manufacturer recommends the device only be used for 1 hour before release.[28]

Study limitations

This study does not seek to comment on the battlefield utility of the AAJTS, but rather explores the ability of CMTs to successfully apply the device to healthy military CMTs in a controlled environment with 1 hour's training time.

The version of the Compression Works AAJTS device used in this study has since been updated with different materials, following customer feedback on product durability. This was not as a result of this study, but in response to manufacturer feedback. This may improve future study efficacy.

During four of the seven failed applications, the recipient could not tolerate the pain of application and therefore full occlusion was not achieved. Others tensed their abdominal muscles in response to discomfort which appeared to make the device more difficult to apply. This limitation is a recognised flaw of healthy volunteer tourniquet trials. Were the device being applied to unconscious or very seriously injured battlefield patients, then this limitation would likely be of less relevance.

We felt that the variance in successful application was in large parts due to user ability. It is previously demonstrated that up to 67% of variance in successful abdominal tourniquet application was down to user ability[10]—although this study was conducted on manikins and with a variety of abdominal tourniquets including the AAJT.

Real-life applications are different to applications in healthy controls. One may imagine a patient with considerable body armour or personal equipment in a confined space that may increase application times when compared with the experimental environment. The immediacy of a real-life application could also affect application times or success by virtue of increased operator stress or focus. The pain of injuries may also be assumed to be worse, or at least different, to the pain of the applied device.

We have only examined the application of the AAJTS over zone 3 of the aorta—the potential amenable injury pattern being abdominopelvic junctional 'non-compressible' haemorrhage. This is only a subset of junctional haemorrhage and the AAJTS could be tested in other junctional areas.

CONCLUSION

The Abdominal Aortic Junctional Tourniquet can be successfully applied by CMTs to healthy CMTs in a controlled environment after just 1 hour of training with an initial 79% success rate. Application time is just over a minute and can be even shorter. Application is successful in both daylight and low-light conditions. Self-reported usability ratings were high.

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