The Evaluation of an Abdominal Aortic Tourniquet for the Control of Pelvic and Lower Limb Hemorrhage

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ABSTRACT Despite improved body armor, hemorrhage remains the leading cause of preventable death on the battlefield. Trauma to the junctional areas such as pelvis, groin, and axilla can be life threatening and difficult to manage. The Abdominal Aortic Tourniquet (AAT) is a prehospital device capable of preventing pelvic and proximal lower limb hemorrhage by means of external aortic compression. The aim of the study was to evaluate the efficacy of the AAT. Serving soldiers under 25 years old were recruited. Basic demographic data, height, weight, blood pressure, and abdominal girth were recorded. Doppler ultrasound was used to identify blood flow in the common femoral artery (CFA). The AAT was applied while the CFA flow was continuously monitored. The balloon was inflated until flow in the CFA ceased or the maximum pressure of the device was reached. A total of 16 soldiers were recruited. All participants tolerated the device. No complications were reported. Blood flow in the CFA was eliminated in 15 out of 16 participants. The one unsuccessful subject was above average height, weight, body mass index, and abdominal girth. This study shows the AAT to be effective in the control of blood flow in the pelvis and proximal lower limb and potentially lifesaving.

INTRODUCTION

Advances in combat body armor, helmet design, and medical care have significantly contributed to the survivability of modern battlefield trauma. However, as we make advancesso does the enemy. Powerful improvised explosive devices (IED) have produced casualties in both Iraq and Afghanistan over the last decade, causing almost 60% of all U.K. fatalities in Helmand.¹ Weapon yields have increased and nonmetalcontaining IEDs have been constructed to avoid the traditional metal detectors carried on foot patrols. Increasingly proximal lower limb amputations now result. A review of the work from the Role 3 Hospital in Camp Bastion showed 483 traumatic amputations were treated or performed over a 2-year period from 2008 to 2010, a rate of 5 a week. 48% of these amputations were above the knee.² These injuries can clearly result in life-threatening hemorrhage. However, a recent study³ has questioned the efficacy of traditional windlass tourniquets in cases that necessitate a high thigh application. A significant rise in the number of concomitant severe perineal, pelvic, and scrotal injuries requiring surgery has also been noted.²

Junctional trauma, that is injury to the relatively unprotected pelvis, groin, and perineum, as well as the axilla and neck, is increasingly being identified as a preventable cause

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of death in wounded combatants. The rate of vascular injury in battlefield casualties is now as high as five times that of previous wars. $^{4-6}$

Noncompressible hemorrhage in junctional zones therefore remains a focus of much concern and current research in military medicine. Many believe that the liberal use of novel hemostatics and extremity tourniquets in battlefield trauma management has saved thousands of lives over the past decade.⁷

However, these proximal injuries have now reached the point where a traditional tourniquet often cannot practically be applied and hemostatic dressings are often not appropriate. Holcomb reviewed preventable causes of death in U.S. Special Forces Soldiers in 2007 and found that truncal or nontourniquetable junctional trauma was implicated in 47% of deaths.⁸ Walker et al⁹ were able to identify 21 British casualties in Iraq and Afghanistan, between 2008 and 2011, who died from potentially survivable pelvic and groin hemorrhage. They concluded that further research was required into devices or methods for proximal and junctional vascular control.

Other methods or devices have been devised in an attempt to control this junctional hemorrhage where tourniquets and hemostatic dressings are not appropriate. These include invasive techniques, such as "Resuscitative endovascular balloon occlusion of the aorta" (REBOA), or truncal external compression devices. REBOA is unlikely to be practical in the battlefield or disaster environment and requires significant expertise and training. A recently introduced device was the Combat Ready Clamp (Fig. 1). However, critics of the Combat Ready Clamp suggest that its shape and design lead to significant potential for it to dislodge in combat conditions or in transit.

The ideal device for lower extremity junctional trauma would prevent all infraumbilical blood flow, not damage or

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FIGURE 1. Combat ready clamp.

penetrate tissues, be reapplicable after release, be rapidly applied by feel, and be secure in transit. One such potential device is the Abdominal Aortic Tourniquet (AAT) (Compression Works, Birmingham, Alabama). This novel, proprietary device uses a circumferential abdominal strap with a windlass mechanism and an inflatable wedge-shaped bladder to compress the aorta at the level of the umbilicus (Fig. 2). A small pilot study by the inventor and developer of the device, carried out on the on the article's coauthors and their team, showed that it reduced femoral flow in all 9 subjects studied and reduced it completely in 7 of the 9 rate at the right common femoral artery (CFA), a success rate of 78%. Before this they had carried out an in vivo porcine study to assess both the efficacy of more prolonged application and potentially detrimental physiological effects. They were able to demonstrate both its efficacy and safety in those more prolonged



FIGURE 2. Abdominal aortic tourniquet.

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applications, with no bowel injury or physiological effects to suggest significant ischemic tissue injury.¹⁰

AIM

Our aim was to add to the weight of evidence by carrying out a larger and fully independent trial in young, serving soldiers to evaluate the efficacy of the AAT in reducing or preventing lower extremity blood flow as an aid to treating our current injury patterns in Afghanistan, in future conflicts as well as a wide variety of civilian prehospital scenarios.

METHOD

A power calculation, performed by an independent statistician, based on a "yes-no" result of femoral artery blood flow occlusion, recommended a requirement for 16 participants to demonstrate statistical significance. It was felt that this number would allow exposure of the device to a wide variety of body shapes and variables. Formal approval for the study was obtained from the Ministry of Defence's Research Ethics Committee. This required a review of the current literature on the subject of external aortic compression and specifically evidence of the safety of such a procedure on test volunteers in particular the minimal or negligible risk of atherosclerotic plaque detachment within the aorta.

Tight exclusion criteria were imposed. This was based on the evidence from a large autopsy study looking at atherosclerosis in the aorta.¹¹ There is believed to be negligible risk of atherosclerosis in those less than 26 years of age who are nonsmokers, nondiabetic, nonhypertensive, nonobese, and nonhyperlipidemic. In addition, as a result of the nature of the abdominal compression and the brief cessation of lower limb blood flow, those with abdominal or vascular complaints were also excluded. Females were excluded because of the potential risk to an unidentified pregnancy (Table I).

Serving soldiers were recruited from a U.K. Medical Regiment. Soldiers were invited to attend an initial briefing. The study was explained and the AAT demonstrated. Those who wished to participate were then seen individually for a further explanation of the process and clarification of exclusion criteria. A focused medical history was taken and formal signed consent was gained. Age, height, weight, blood pressure, and abdominal girth at the level of the umbilicus were recorded. Body mass index (BMI) was calculated. Recent micturition was ensured to minimize bladder volume. Participants

TABLE I. Exclusion Criteria

Age Over 25 Years	Female
Smoker	History of Deep Vein Thrombosis or
	Vascular Disease
Diabetes	Recent Abdominal Surgery
Hypertension	Presence of Hernias
Obesity	Gastrointestinal Symptoms
Known Hyperlipidemia	Active Lower Limb Infection or Surgery Within 6 Weeks



FIGURE 3. AAT in-built pressure gauge with pressure release valve at 300 mm Hg.

were then laid supine. The right femoral pulse was located using pulse wave Doppler ultrasound (SonoSite Edge with Linear array 13-6 MHz probe, SonoSite Inc, Washington, DC) by a senior ultrasound-trained radiographer (MC).

The AAT was then applied around the abdomen at the level of the umbilicus. The pull strap was tightened and the windlass mechanism used to further tighten and secure the device. The common femoral pulse was constantly monitored with Doppler as the balloon was inflated. The time taken to inflate the balloon was recorded. The balloon was inflated until either blood flow ceased in the CFA or the maximum recommended pressure in the balloon was reached. The pressure at which femoral flow became biphasic and at which all flow ceased was recorded. The basic pressure gauge integral with the device was used as the measure of pressure, which allowed only broad pressure categories to be recorded. The gauge also has an inbuilt pressure release valve to prevent balloon pressures greater than 300 mm Hg (Figs. 3 and 4).



FIGURE 4. AAT in situ with Doppler ultrasound measurement and screen capture with (A) normal flow and (B) complete cessation of flow.

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The balloon was deflated immediately that complete cessation of flow was confirmed or the maximum pressure was reached. The CFA was then monitored with the Doppler to ensure that normal triphasic flow was restored. Participants were instructed that the balloon could be deflated at any time if they could not tolerate the discomfort of application.

Participants were monitored for a suitable period before discharge, in which time they completed a visual analog scale to describe the level of discomfort. Follow-up contact was made with the unit after 2 weeks regarding any reported complications. All data were recorded and analyzed on an Excel (Microsoft Corps, Washington, DC) spreadsheet kept on an AES 128-bit encrypted IronKey device.

RESULTS

18 serving soldiers volunteered following the initial briefings. 2 subsequently withdrew before collection of baseline data, leaving 16 participants who completed the study. Baseline demographics are outlined in Table II.

Tourniquet application was tolerated in all 16 participants. No complications were reported at the time of the study nor at a later stage.

All flow in the CFA ceased in 15 of the 16 participants. The balloon was inflated for less than 1 minute in all cases and normal triphasic flow was restored in all participants immediately upon deflation of the balloon. No immediate complications were identified. The median and modal pressure at which flow occluded was less than 250 mm Hg. The mean phase change occurred at less than 150 mm Hg.

In the single case in which the tourniquet failed to occlude flow, the maximum balloon pressure of 300 mm Hg was achieved without any phase change in the CFA identified on Doppler. The subject in whom the device failed to occlude flow was found to have a height, weight, BMI, and abdominal girth greater than the average in the study but a normal systolic blood pressure. He also reported a pain score higher than average, and it is possible that tension in the abdominal wall

TABLE II. Base line Subject Data

	Average	Range
Age (Years)	22.8	19–25
BMI	23.7	20.3-27.5
Systolic Blood Pressure (mm Hg)	126.25	105-145
Abdominal Girth (cm)	79.1	71-89

TABLE III. Measurements of the Subject with Failed Application vs. the Mean for the Cohort

	Failure	Success
Height (cm)	189	180
Weight (kg)	91	77.1
BMI	25.5	23.7
Abdominal Girth (cm)	86	79.1
Pain Score	7	6
Systolic Pressure (mm Hg)	125	126.25

contributed to this failure. Following statistical advice, no attempt was made to perform formal statistical analysis of this single failure (Table III). A repeat application was not permitted by the terms of our ethical approval for the study.

DISCUSSION

Joseph Lister (1827–1912) is credited with inventing the first tourniquet or device designed to compress the abdominal aorta (AA) while working at the Royal Infirmary in Glasgow. He abandoned the tourniquet after a number of modifications because it caused damage to other internal organs, such as the large and small intestines, with prolonged use.¹² Subsequently, F.C. Skey (1816–1927) modified and improved the device,¹³ but such devices fell into disrepute as better methods of direct vascular control and better anesthesia became available.

However, the principle lived on both in obstetric care and battlefield casualty care. Traditional teaching in postpartum hemorrhage and exsanguinating pelvic or perineal battlefield trauma has long been to place a knee or a fist in the umbilical area or groin with all or most of the body weight to control hemorrhage.¹⁴ In addition, an external aortic compression device was designed for use in postpartum hemorrhage but appears not to have made it into common use nor transferred outside the specialty of obstetrics.¹⁵

However, as mentioned above, junctional trauma and vascular injury has become an increasing cause for concern in recent conflicts.¹⁶ As such, the concept of external aortic compression has been revisited. In 2006, Shiver et al¹⁷ placed 9 volunteers supine on the floor to simulate an injured soldier and applied dumbbells of increasing weight over the distal AA on top of a padded towel sized to simulate the surface area of a human knee. Pulsed-wave Doppler measurements were taken at the right CFA. Compression of the AA ranging from 80 to 140 pounds resulted in no flow in the CFA. A steady decrease in mean flow velocity was seen starting with 20 pounds. Flow velocity decreased more rapidly with compression of the proximal right iliac artery and stopped in all 9 volunteers by 120 pounds of pressure. For all 9 volunteers, up to 80 pounds of pressure over the distal iliac artery failed to decrease CFA flow velocity, and no subject was able to tolerate more weight at that location.

These figures are certainly similar to the weight applied in the military teaching of the knee in the groin, however, with significant IED-related pelvic injury rates in Afghanistan currently running at 14% for single limb amputations and 39% for bilateral above-knee amputations—such advice can no longer be considered safe practice.¹⁸ All battlefield amputations in Afghanistan now have a pelvic binder applied as a matter of policy.¹⁹ Any device for control of junctional bleeding would have to be compatible with this current binder policy as the two might well be used together. The picture below demonstrates that the two devices can be applied alongside one another without any interference (Fig. 5).

More recent research has showed that there were no significant differences in the stability conferred by an external fixator

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FIGURE 5. AAT with pelvic binder (SAM Pelvic SlingII) in situ.

or a pelvic belt (Trauma Pelvic Orthotic Device, T-POD) for unstable pelvic injuries.²⁰ This would seem to obviate the previously perceived requirement for emergent external fixation in such cases. As death from the most severe pelvic fractures is from bleeding with those dying requiring over 10 units of blood,²¹ any device that could prevent prehospital blood loss in combination with a pelvic stabilization device would have the potential to save lives.

The work previously carried out by Lyon et al¹⁰ both in swine models and a human trial introduced the device as a safe and potentially effective one. This pilot was small and carried out, by the patent holder, on himself and others. They produced quantified flow rates in the femoral artery at 30 mm Hg. Although they had 2 cases in which some flow remained, it had been reduced significantly in one of them. No attempt was made to identify the cause of their failures, but it was noted that both were unable to tolerate the pressure. One of them had a higher than average blood pressure. Their swine model was able to demonstrate effective control of flow for up to 60 minutes and also showed that no injurious effects resulted to the abdominal organs nor were there any adverse physiological effects during compression or upon the release of the balloon after this protracted application.¹⁰

The results of our study clearly demonstrate the efficacy of the AAT in preventing blood flow distal to the infrarenal aorta as demonstrated by complete cessation of flow in the CFA on highly sensitive Doppler ultrasound. Our results confirm the findings of the manufacturer in their pilot study with a larger cohort, statistical advice, zero conflict of interest, and greater efficacy, achieving a 94% complete occlusion of flow.

Our one failure cannot be fully explained, but it has been shown that the subject was larger than average in all measurements and this may be a contributing factor. He was also shown to have above average discomfort during the application—a similar issue was noted by Lyon et al¹⁰ in those in whom the device failed in their study. However, no statistical significance can be shown from an isolated failure. Our expectation is that resistance by the abdominal muscles would be less likely in the injured casualty. Although his blood pressure was not outside the normal limits, casualties on the battlefield requiring the AAT are unlikely to be normotensive. Therefore, it is reasonable to assume that the device is more likely rather than less likely to be successful in such a situation.

This study was carried out on a young, physically fit cohort of subjects to minimize the theoretical possibility of injury to a volunteer. These were all medically fit serving soldiers and clearly representative of the majority of casualties currently suffered on military operations. To avoid confounding variables, device was applied to the bare abdomen. The effect of significant layers of clothing would have to be further evaluated if felt to be appropriate and be reflected in the policy and training given to those charged with using it in the field. The device, when applied, was also completely stable in that it could not be moved up or down the abdomen. This is a useful property in military casualty evacuation situations.

Further work is being carried out to evaluate the safety and efficacy of the device by means of bench testing with mannequins as well as the effects of atmospheric pressure changes in airmobile evacuation. These are encouraging and show no insurmountable difficulties or significant alterations in pressure. Finally, soldiers arriving at deployed field hospitals are often at the very edge of survivability and undergo exsanguination cardiac arrest in transit or just on arrival at the emergency department. Although massive transfusion with hemostatic resuscitation protocols via large-bore lines and rapid-infuser systems coupled with concomitant emergent surgical proximal vascular control can be considered the gold-standard, the use of the AAT in such peri-arrest situations may be quicker and easier-particularly when manpower, resources, and expertise are limited such as forward surgical teams and the prehospital environment.

SUMMARY

We have demonstrated that a simple deployable device that does no further harm and prevents blood flow below the bifurcation of the aorta works. This device could be of great potential benefit in present battlefield scenarios as well as

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those in future conflicts where surgical facilities may be more primitive and casualty evacuation times far greater. We also feel that such a device could be of benefit in exsanguination cardiac arrest, as well as civilian disaster relief events or terrorist incidents.

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