

Use of a novel abdominal aortic tourniquet to reduce or eliminate flow in the common femoral artery in human subjects

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BACKGROUND: Penetrating injuries of proximal femoral and iliac vessels are a common cause of death on the battlefield. Previous studies have shown that by applying 80 lb to 140 lb of pressure externally over the distal abdominal aorta, flow can be ceased in the common femoral artery (CFA). It has also been demonstrated that in a porcine model, an externally applied pneumatic abdominal aortic tourniquet (AAT) can occlude the aorta and inferior vena cava for 60 minutes without bowel injury or significant potassium elevations.

The objectives of this study were (1) determine if AAT use in humans results in flow cessation in the CFA, (2) measure the pressure required to cease flow in the CFA, and (3) measure discomfort associated with application of the AAT.

METHODS: Pulse wave Doppler measurements were taken in supine volunteers at the right CFA. The AAT was placed just above the iliac crests over the anterior abdomen. The AAT was inflated using a hand pump with an integrated manometer. Measurements were taken every 30 mm Hg. Discomfort was measured using a 10-point pain scale.

RESULTS: In all subjects, flow was reduced in the CFA. Flow ceased in seven of nine subjects at a median pressure of 180 mm Hg (150–230 mm Hg). Median discomfort at ceasing of flow was 7 (3–10), returning to 0 after device removal.

CONCLUSION: The AAT device was effective at reducing flow in the CFA and ceased flow in most of the subjects. Application of the device was associated with discomfort varying from moderate to severe and resolving with device removal. (*J Trauma Acute Care Surg.* 2012;73: S103–S105. Copyright © 2012 by Lippincott Williams & Wilkins)

KEY WORDS: Hemorrhage; abdominal tourniquet; junctional hemorrhage; combat casualty care.

Uncontrolled hemorrhage remains the leading cause of preventable death on the battlefield.^{1–3} Although body armor protects vital organs in the torso, injuries to unprotected inguinal and other junctional regions can lead to rapid exsanguination.⁴ Penetrating injuries involving the proximal femoral and iliac vasculature are particularly difficult to control because they are often not amenable to tourniquet or hemostatic agent application.^{5,6} Hemorrhage control can be difficult in ideal circumstances and nearly impossible in the austere battlefield environment. Previous studies have shown that flow in the common femoral artery (CFA) can be stopped through the application of 80 lb to 140 lb of external pressure over the distal abdominal aorta.⁷ In the setting of inguinal injury, external abdominal pressure has multiple potential advantages. Blood flow to the injury site is limited, and peripheral vascular resistance is increased, thus maximizing perfusion to vital organs such as the heart and the brain. Although applying external pressure to the abdomen is an effective technique to limit or eliminate blood flow to the

inguinal region, it is highly provider dependent and potentially dangerous. Too little pressure results in inadequate hemorrhage control, whereas excessive or misplaced pressure may result in injury to the bowel or other structures. Furthermore, the provider must maintain adequate pressure until the time of definitive treatment. In many scenarios, definitive treatment is significantly delayed, and providers inevitably become fatigued. 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 porcine 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 (Fig. 1).

We seek to determine if AAT use in humans results in the cessation of blood flow in the CFA, measure the pressure required to eliminate flow, and gauge the discomfort associated with application of the AAT.

PATIENTS AND METHODS

This was a prospective observational trial using human volunteers. After the institutional review board approval and informed consent were obtained, a total of nine subjects were enrolled. The AAT was placed just above the iliac crests with the wedge-shaped bladder over the anterior abdomen. The AAT was applied in less than 1 minute by a single provider in all

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This study was presented at the Advanced Technology Application for Combat Casualty Conference 2011. It was also submitted and accepted as poster presentation at the American College of Emergency Physicians Scientific Assembly on October 2011.

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Figure 1. The abdominal aortic tourniquet AAT.

participants. With inflation of the bladder, pressure was applied across the abdomen but focused at the umbilicus. An integrated manometer was used to measure the pressure within the bladder. Measurements of the blood flow in the CFA were taken using a Phillips HDI 4000 ultrasound system (Phillips, Andover, MA) and a linear array transducer (5–10 MHz). Doppler measurements were made at baseline (before any inflation of the bladder, but with the AAT in place) and repeated with every 30 mm Hg increase in the bladder pressure. Measurements of the CFA flow were made in longitudinal axis using pulse wave Doppler. One investigator performed all measurements, maintaining the same Doppler angle and arterial location throughout the procedure. Collected data included flow phasicity, peak systolic blood flow, time, and bladder pressure. A verbal 10-point pain scale was used to assess subject discomfort. All data were recorded on a standardized data collection sheet.

RESULTS

Nine male subjects participated in the project. Body measurements and demographics are shown in Table 1. In all subjects (nine of nine subjects), flow was reduced in the CFA through increasing bladder pressure in the AAT (Fig. 2). The arterial wave as measured by pulse wave Doppler transitioned from triphasic to biphasic at a median bladder pressure of 120 mm Hg (60–180 mm Hg) and from biphasic to monophasic at a median bladder pressure of 150 mm Hg (150–200 mm Hg). Flow ceased in seven of nine subjects at a median pressure of 180 mm Hg (150–230 mm Hg). Figure 3 shows spectral Doppler images of the CFA during AAT bladder inflation and phasicity changes with increasing pressure. Median discomfort at cessation of flow was 7,^{3–10} which returned to 0 after device removal (Fig. 4).

DISCUSSION

There are few effective options for the provider caring for a patient with an injury to the iliac or proximal femoral

TABLE 1. Subject Measurements and Demographics

	Age, y	Height, in.	Weight, lb	Waste Circumference, in.
Mean (SD)	33.7 (7.1)	71.3 (3.2)	182.2 (13.0)	33.5 (1.7)

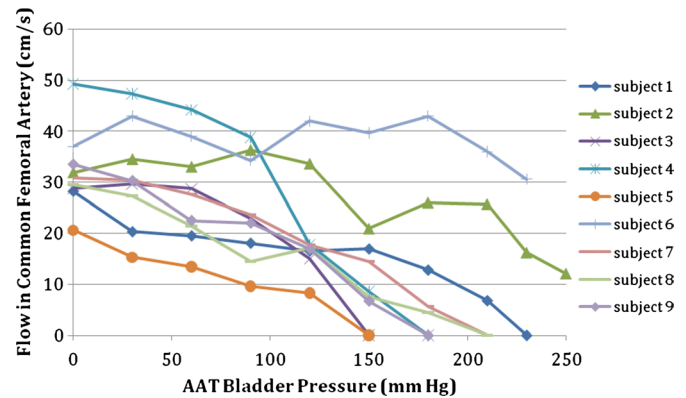


Figure 2. Blood flow in CFA.

vasculature.⁸ Direct pressure is often inadequate as the inguinal ligament limits effective transfer of external pressure. Topically applied hemostatic agents have shown efficacy in controlling external hemorrhage.^{9–13} However, hemostatic agents are often ineffective for the high femoral or iliac vessel injury due to difficulty in placing the hemostatic agent in contact with the bleeding vessel due to wound geometry, obscuration due to bleeding, as well as the anatomic near impossibility of applying hemostatic agents to the iliac vessels. To address this lack of hemostatic agent efficacy in this anatomic area, external compression devices have been developed. The first fielded, the Combat Ready Clamp (CRoC Clamp, Fyshwick, ACT, Australia), is listed with the Food and Drug Administration but has limited data to support its use. The CRoC is a large “C clamp” that is placed around the casualty, over the site of injury. This device was designed to control hemorrhage of the proximal femoral vessels but may not provide control of more proximal iliac injuries. The AAT allows a single provider in the field to control hemorrhage of proximal bilateral iliac and femoral injuries. Once the AAT is applied, the provider is free to address other injuries or even other patients of trauma.

Previous work using eight Yorkshire swine demonstrated that the AAT successfully occluded the aorta and inferior vena cava for 60 minutes without bowel injury or significant elevations of potassium. The greatest potassium elevation of the eight swine was 1.7 mEq/L for a maximum level of 5.6 mEq/L. Mean arterial pressure changes ranged from an increase of 21 mm Hg to a decrease of 26 mm Hg. Gross and histologic examination revealed no signs of significant ischemia or necrosis. All eight animals survived the compression procedure.

Although AAT did not result in cessation of blood flow in two of nine human study subjects, it was uniformly successful in reducing blood flow in the distal CFA. In the two instances of incomplete occlusion, the subjects were noted to resist the abdominal pressure induced by the AAT. Although this situation would be expected occasionally in noninjured study subjects, an injured, hypotensive, and possibly unconscious soldier would not likely provide such resistance. Thus, we expect this device to be more effective in the critically injured population. Further experiments are needed to determine the effectiveness of this device in injured subjects.

The AAT was uniformly effective in reducing blood flow in the CFA and resulted in flow cessation in most of the subjects

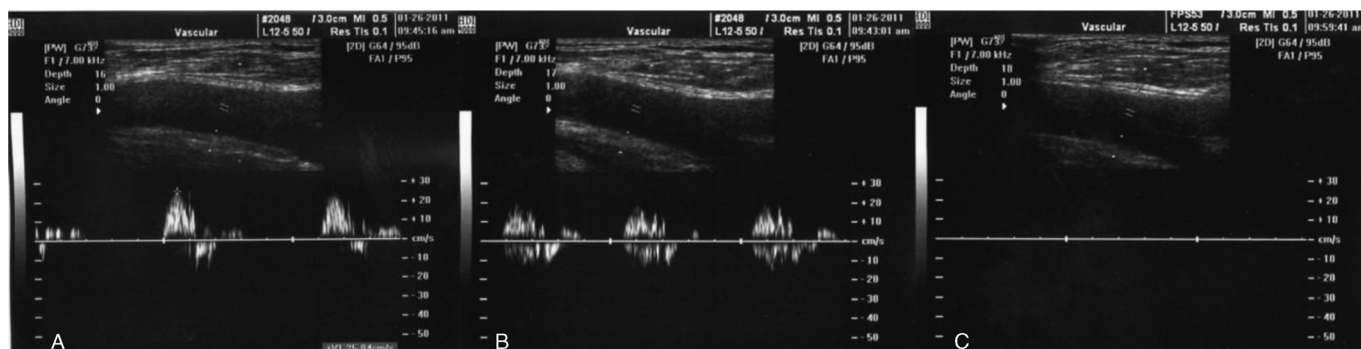


Figure 3. Spectral Doppler of the CFA during AAT bladder inflation (A and B). Pressure is increased until no blood flow is detectable using Doppler ultrasound (C).

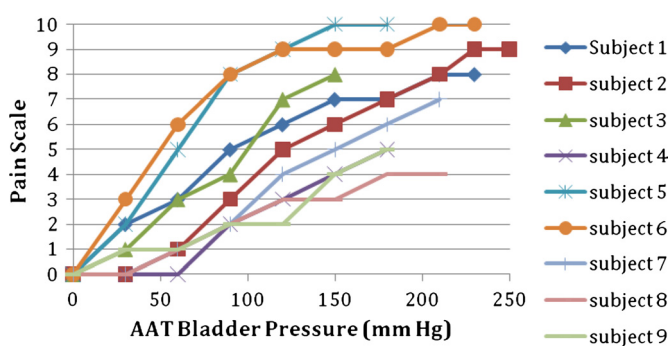


Figure 4. Subject pain scale.

(seven of nine subjects). Application of the device was associated with discomfort that varied from moderate to severe and resolved with device removal.

DISCLOSURE

Richard B Schwartz, MD, has 15% ownership of Compression Works LLC and is a patent holder of the portable pneumatic abdominal aortic tourniquet. No other author has commercial association or financial involvement that might pose a conflict of interest with regard to the submitted article.

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