

“Testing of Junctional Tourniquets by Military Medics to Control Simulated Groin Hemorrhage”

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We read the article in the Fall 2014 issue titled “Testing of Junctional Tourniquets by Military Medics to Control Simulated Groin Hemorrhage”¹ with great interest. The study attempted to compare the success rates of four junctional tourniquets in treating a potential vascular injury at the level of the inguinal ligament. We believe that the study has a number of methodological problems that likely altered the conclusions of the article.

One major problem is that the protocol described in the Methods section appears to have not been followed. The protocol indicates that the inguinal area was studied. It states that “the right groin was assessed first; the left groin was assessed second. Unilateral groin hemorrhage was simulated. Each tester used each of the four models of tourniquet two times (once on the left and once on the right side of the groin).” This is true for three of the devices; however, the Abdominal Aortic and Junctional Tourniquet™ (AAJT) was not studied in the inguinal area but rather in the abdominal or umbilical area. It is unclear why the authors did not test all four devices in the groin area according to their written protocol. The AAJT has always had US Food and Drug Administration (FDA) approval for inguinal (groin) application. Despite this, the investigators chose to apply the AAJT in its abdominal aortic placement rather than in the groin placement. This is simply not a reasonable comparison. It is well established that placement of the AAJT in the abdominal configuration causes more discomfort than does groin placement.² The authors state that the AAJT was not FDA approved for groin placement at the time of the study; however, a review of FDA filings shows the AAJT’s initial approval was for both abdominal and inguinal application.

The validity of this study also comes into question because its findings are dramatically different than those of two published studies looking at the abdominal placement of the Abdominal Aortic Tourniquet™ (AAT). We previously published data based on use in nine healthy emergency medicine physicians. Pulse wave Doppler

measurements were made in the common femoral artery (CFA). The device was placed in the abdominal region over the umbilicus; 100% of the volunteers were able to tolerate application of the device, 100% showed reduction of flow, and 77% showed complete elimination of flow.²

In a second study, published in *Military Medicine*, we used 16 British active duty Soldiers and also applied pulse wave Doppler in the CFA.³ The device was also placed in the abdominal region over the umbilicus. Again, in this study, the device was tolerated by 100% of the study participants. The device eliminated flow in the CFA in 93.75% of the subjects.³ In the current article, only two subjects (11%) tolerated application of the device. Prior evidence from two separate investigators demonstrated that the device was tolerated in 100% of 25 subjects. The authors of the current article did not cite either of these previously published articles. The cause of this discrepancy is unclear. It is unlikely that the pain tolerance of this group of Soldiers differs from that of emergency medicine physicians or British soldiers.

One potential confounder is that in both previous studies the subjects had a single application of the device. In the current article, the subjects had the various devices placed eight times (three times on the right, three times on the left, and twice over the umbilicus) over a 3-hour time frame. The repetitive application of the device may cause anxiety or a bias with subsequent applications. However, the discomfort of the device is far less than what would be expected from a wound such as traumatic bilateral amputations from a blast injury that would require the use of an abdominal tourniquet.

Despite the discomfort associated with the abdominal placement, the AAJT is the only device that appears to be capable of safely stopping all hemorrhage distal to the aortic bifurcation.^{4,5} This becomes very important when one looks at the injury patterns of potential survivors on the battlefield. Prospectively collected data on UK military personnel in Afghanistan identified 32

casualties with the cause of death from vascular injury between the aortic bifurcation and the inguinal ligament. These injuries were considered to be potentially survivable with more proximal control. The researchers conclude that the use of groin junctional tourniquets would not provide adequate control and that there is a need for devices that provide more proximal control. The abdominal or umbilical application of the AAJT provides proximal control not provided by the groin application of any of the other devices.⁶

In the Discussion section, the authors state “the strength of the present testing is that it offers a direct comparison by military medics of the four currently FDA-approved junctional tourniquets. This strength fills a specific knowledge gap of junctional tourniquets on their differential performance in the hands of medics. Such new knowledge may aid decision-makers in choosing which one to provide medics in the future.” Given the methodological design flaws of this study, this statement should not be made. Additionally, this study should not be used to differentiate these devices.

In conclusion, the methodological problems and inherent bias in this study invalidate the results. For this study’s findings to be valid, the AAJT data should be removed from the analysis or the study should be repeated using the inguinal placement of the AAJT.

Disclosures

Dr Schwartz is a developer of the AAJT and has a financial interest. No other authors have a conflict of interest.

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