Missing expectations: Windlass tourniquet use without formal training yields poor results

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The authors have nothing to disclose.

Reviewer Disclosures

The reviewers have nothing to disclose.

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BACKGROUND: Despite significant attempts to educate civilians in hemorrhage control, the majority remain untrained. We sought to determine if laypersons

can successfully apply one of three commercially available tourniquets; including those endorsed by the United States Military and the

American College of Surgeons.

METHODS: Preclinical graduate health science students were randomly assigned a commercially available windless tourniquet: SAM XT, Combat Ap-

plication Tourniquet (CAT), or Special Operation Forces Tactical Tourniquet (SOFT-T). Each was given up to 1 minute to read package instructions and asked to apply it to the HapMed Leg Tourniquet Trainer. Estimated blood loss was measured until successful hemostatic pressure was achieved or simulated death occurred from exsanguination. Simulation survival, time to read instructions and stop bleeding,

tourniquet pressure, and blood loss were analyzed.

RESULTS: Of the 150 students recruited, 55, 46, and 49 were randomized to the SAM XT, CAT, SOFT-T, respectively. Mean overall simulation survival

was less than 66% (65%, 72%, 61%; p = 0.55). Of survivors, all three tourniquets performed similarly in median pressure applied (319, 315, and 329 mm Hg; p = 0.54) and median time to stop bleeding (91, 70, 77 seconds; p = 0.28). There was a statistical difference in median blood loss volume favoring SOFT-T (SAM XT, 686 mL; CAT, 624 mL; SOFT-T, 433 mL; p = 0.03). All 16 participants with previous ex-

perience were able to successfully place the tourniquet compared with 81 (62%) of 131 first-time users (p = 0.008).

CONCLUSION: No one should die of extremity hemorrhage, and civilians are our first line of defense. We demonstrate that when an untrained layperson is

handed a commonly accepted tourniquet, failure is unacceptably high. Current devices are not intuitive and require training beyond the enclosed instructions. Plans to further evaluate this cohort after formal "Stop the Bleed" training are underway. (J Trauma Acute Care Surg.

2019;87: 1096–1103. Copyright © 2019 Wolters Kluwer Health, Inc. All rights reserved.)

KEY WORDS: Tourniquet; hemorrhage control; medical training; extremity trauma; exsanguination.

As recently as the Vietnam conflict, the deaths from isolated extremity hemorrhage have been unacceptably high. As body armor has improved and the use of improvised explosive devices has increased, the military has seen a shift from torso injuries to extremity trauma. The military has taken significant steps to address this issue and has achieved great success by broadening the uses of pressure dressings, tourniquets. Civilian trauma care has traditionally been guided by our military experiences. The Hartford Consensus called to focus on lifesaving extremity hemorrhage control to make death from such injuries a never event. Despite these efforts, acceptance and training of the civilian sector has faced many challenges and is far from ubiquitous.

Tourniquet use by civilian emergency medical services (EMS) has long had to combat the myth of resultant limb loss.⁵ The EMS providers were frequently taught that where you place the tourniquet is where the patient will lose his/her limb, despite significant literature to the contrary.^{6–8} This thinking has created a negative stigma surrounding the use of tourniquets and is hypothesized to have been a contributor to lives lost with authors citing up to an overall 29% mortality rate due to extremity hemorrhage in the civilian world.⁹

Tactical Combat Casualty Care (TCCC) has prioritized the control of ongoing hemorrhage, especially extremity hemorrhage by sanctioning the early use of both pressure dressings and tourniquets. ^{10–12} The ever increasing threat of explosive terrorism worldwide has made the risk a reality

and preparedness a must. This has brought the success of the TCCC concept center stage, forcing civilian providers to take notice and to begin to translate the TCCC methodology to the civilian system. ^{13–16} In addition to this, many entities both public and private, including the American College of Surgeons, have begun training and preparing civilians to intervene with early hemorrhage control via direct pressure, pressure dressing, wound packing, and tourniquet application. ^{3,17–20} They have selected to train using only those windlass tourniquets recommended by the TCCC as they have been successfully field tested by the military.

Dr. Nicholas Senn stated "The fate of the wounded rests in the hands of the one who applies the first dressing." During mass casualty incidents, as illustrated by the experiences in Boston, Orlando, Las Vegas, Dallas, and others, EMS response is often delayed leaving the immediate response to those in proximity. It is the civilian layperson who will be called to act during these moments of need. Tourniquets have been proven an effective cornerstone in temporarily controlling extremity bleeding and thus reducing mortality. Unfortunately, training the general public is a daunting task and a majority of civilians remain without formal training. Hemorrhage control and tourniquet application can be challenging, especially for those without any training. We hypothesized that untrained laypeople would not be able to effectively place commercially available tourniquets using only the included printed directions.

METHODS

In this prospective randomized study, preclinical graduate health science students were recruited during orientation week to participate via the Midwestern University intranet portal. During August 2018, 150 students were assigned a commercially available windlass tourniquet: SAM XT, Combat Application Tourniquet (CAT), or Special Operation Forces Tactical Tourniquet (SOFT-T). An open source randomizer program was used to create a list sequentially randomizing participants to the three groups. As the participants were check-in, they were given the tourniquet designated by the next random selection on the list.

DOI: 10.1097/TA.0000000000002431

Submitted: February 13, 2019, Revised: April 14, 2019, Accepted: June 18, 2019, Published online: July 2, 2019.

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Meetings at which paper presented: 49th Annual Meeting of the Western Trauma Association, March 3–8, 2019 in Snowmass, Colorado.

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Volunteers completed a questionnaire to determine their basic knowledge of hemorrhage control, prior experience, and comfort using tourniquets. Each volunteer was asked to read an explanation of the study and agreed not to discuss the project with other students. Once assigned a tourniquet, each student was given a scenario of life-threatening hemorrhage from a leg injury set to exsanguinate in 2 minutes without intervention. They were given up to 1 minute to read the manufacturer instructions (Fig. 1) and told where on the HapMed Leg Tourniquet Trainer to place the tourniquet (2 inches above the injury), in order to isolate the application process itself. The trainer leg is designed such that as the tourniquet pressure increases, the wound is illuminated less, and the distal pulse decreases. The tourniquet placement indicator on the model evaluated appropriate placement (Good, Inappropriate, or None) and the pressure was measured as the tourniquet was tightened. When the tourniquet was positioned correctly and sufficient pressure was applied, the patient status changed from "Bleeding" to "Stable" and the timer stopped. The leg was set such that exsanguination occurred at 2 minutes without intervention. A partially occlusive tourniquet would still lead to exsanguination at a time greater than 2 minutes. Those attempts that did not lead to "Stable" status were deemed nonsurvivors. The amount of simulated blood lost was collected from the model. The following parameters were recorded by the HapMed system: time to read the instructions, time to stop the bleeding, patient status (stable/survivor, dead/nonsurvivor), tourniquet placement (good, incorrect or none), tourniquet pressure, and blood loss. Only one attempt was allowed per participant.

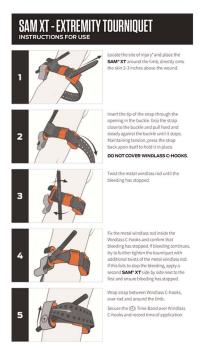
Subset analysis was performed on the stable/survivor group and first-time users only to evaluate for any differences between the tourniquets. Further analysis was performed comparing outcomes of those with previous experience and first-time users and male versus female sex. Institutional Review Board approval was obtained at the participants' home institution.

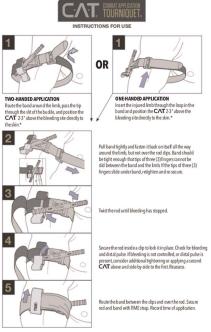
Statistical Analysis

Collected data were entered into Microsoft Excel (V16.13.1). All statistical analyses were done using R, version 3.5.1 of R Core Team (R Foundation for Statistical Computing, Vienna, Austria, 2018). Descriptive statistics were summarized as frequencies with percentages for categorical variables, and as medians with interquartile ranges, for continuous variables. p Values less than 0.05 were considered statistically significant. Comparisons of participants across tourniquet assignments were performed by χ^2 analysis. Given nonnormal distribution, the nonparametric Kruskal-Wallis test was utilized to evaluate the time to stop bleeding, and blood loss volume. The parametric ANOVA test was used for the normally distributed time to read instructions, tourniquet pressure applied. When a difference was found, this was confirmed with Tukey's post hoc analysis. Analysis of continuous variables between survivor and nonsurvivor groups was performed with the Mann-Whitney U test.

RESULTS

We enrolled 150 preclinical graduate health science students. These were equally split with 75 (50%) each men and women; 81 (54%) were starting their first graduate year, 65 (43%) their second, and 4 (3%) their third. Only 16 (11%) stated they had any prior training with tourniquets, and 9 of these (6% overall) had ever placed one before. Table 1 shows the randomization of the students to each tourniquet type: 55 (37%), 46 (30%), and 49 (33%) for the SAM XT, CAT, SOFT-T, respectively. There was no difference in sex (p = 0.30) or prior experience (p = 0.43) between the groups. Bleeding was successfully





SOF® TOURNIQUET



Figure 1. Manufacturer instructions for tourniquet application.

TABI F	1.	Data by	Tourniquet Type
IAPLL			TOUTHINGUEL TYPE

	SAM XT	CAT	SOFT-T	p value
Number, n (%)	55 (37%)	46 (30%)	49 (33%)	0.66*
Male sex, n (%)	32 (56%)	20 (43%)	23 (47%)	0.30*
Prior experience, n (%)	8 (15%)	3 (7%)	5 (10%)	0.43*
Patient status, n (%)				
Stable	36 (65%)	33 (72%)	30 (61%)	0.55*
Bleeding	0 (0%)	0 (0%)	2 (4%)	0.12*
Dead	19 (35%)	13 (28%)	17 (35%)	0.76*
Tourniquet placement, n (%)				
Good	33 (60%)	34 (74%)	32 (65%)	0.34*
Incorrect	5 (9%)	1 (2%)	2 (4%)	0.27*
None	17 (31%)	11 (24%)	15 (31%)	0.69*
Time to complete: median (range), s				
Read instructions	53 (17–60)	57 (25–60)	30 (11–60)	<0.0001**
Stop bleeding	113 (42–232)	97 (21–163)	126 (26–432)	0.28†
Pressure applied: median (range), mm Hg	281 (0-450)	301 (0-516)	281 (0-436)	0.48**
Blood lost: median (range), mL	807 (285–1273)	794 (193–1273)	760 (193–1273)	0.48†

Statistical analysis performed with $*\chi^2$ analysis, **ANOVA test, and $\dagger Kruskal$ -Wallis test.

stopped in only a minimal majority of attempts: 65% for SAM XT, 72% for CAT, and 61% for SOFT-T, p = 0.55. Bleeding was still ongoing at the time cut off for two participants with the SOFT-T; as hemorrhage was not controlled, these were considered nonsurvivors.

Good tourniquet placement was registered by the trainer leg in 60% to 74% of attempts by type (p=0.34). The detectors failed to register placement of a tourniquet at all for 31% to 55% of attempts (p=0.69). The time needed to stop bleeding was not different between systems (p=0.28, Fig. 2). The SOFT-T system did show a significant decrease in time needed to read the manufacturer's instructions (p<0.0001, Fig. 3). Strongest pressure applied by the tourniquet and total volume of blood lost were not different between tourniquet types (both p=0.48, Figs. 4 and 5).

Subset analysis was carried out on the attempts deemed successful in creating a "stable" patient status though to represent survival of the simulated patient (Table 2). There was no difference in survivor rates between sex or prior experience (p=0.68 and p=0.36, respectively). Again, the decreased time needed to read the instructions for the SOFT-T system was seen

(p < 0.0001). This significance was confirmed utilizing the Tukey's post hoc test (p < 0.0001). In the survivor population, this did correlate with a decrease in total blood lost using that device as measured by the trainer leg (p = 0.03). However, ultimately, no difference was seen in the time of the attempt between the survivors with each device (p = 0.28). Successful attempts demonstrated equivalence between highest pressure generated by each device (p = 0.55).

Outcomes based on prior tourniquet experience are shown in Table 3. Of the 16 (11%) participants with prior exposure to tourniquets, 100% were able to successfully stop the bleeding in a timely manner after reviewing the instructions as compared with 62% of those using it for the first time (p = 0.006). This was further shown in decreased time to stop bleeding (54 seconds vs. 120 seconds, p = 0.0002), and decreased blood volume lost (400 mL vs. 877 mL, p < 0.0001). When sex was evaluated, 41 (55%) of the 75 women were able to apply the tourniquet to stop the bleeding compared with 58 (77%) of the 75 men (p = 0.006). This correlated with the maximal pressure applied: 271 mmHg (0–516 mmHg) vs. 302 mm Hg (0–450 mmHg), respectively (p = 0.005).

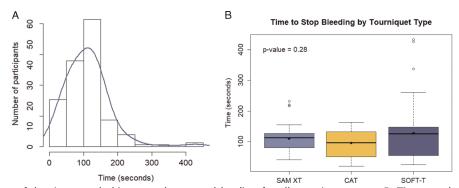


Figure 2. A, Histogram of the time needed in seconds to stop bleeding for all tourniquet types. B, Time needed in seconds to stop bleeding by tourniquet type.

Time to Read by Tourniquet Type

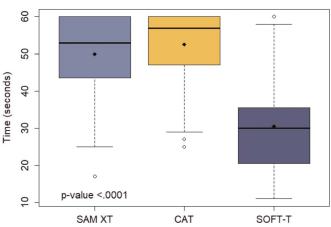


Figure 3. Time needed in seconds to read instructions by tourniquet type.

Comparing the survivor and nonsurvivor groups, the expected differences in time needed to stop bleeding and maximum pressure applied were seen for all tourniquet types (all p < 0.0001). However, there was no difference between the time needed to read the tourniquet instructions between the survivor and nonsurvivor groups (SAM XT p = 0.09, CAT p = 0.29, SOFT-T 0.09).

DISCUSSION

In the United States, it is unclear as to the exact number of preventable extremity trauma deaths. According to Davis et al., 29% of civilian prehospital trauma deaths are preventable and 64% of these are because of hemorrhage. To stop life-threatening extremity hemorrhage by producing arterial occlusion, a tourniquet should be promptly applied with a pressure approximately 100 mmHg over the systolic blood pressure. We have demonstrated that the untrained layperson cannot reliably read the enclosed directions and successfully apply commercially available windlass tourniquets with sufficient efficacy. The cohort included young professional health science students,

Pressure Applied by Tourniquet Type

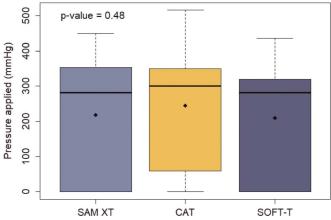


Figure 4. Pressure applied in mm Hg by tourniquet type.

Blood Loss by Tourniquet Type

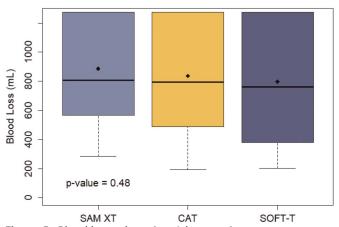


Figure 5. Blood loss volume in mL by tourniquet type.

at orientation, randomly selected prior to clinical experience. Most had no previous tourniquet knowledge. Only 66% of those studied successfully placed the tourniquet to positively impact survival. The median blood loss of those survivors, despite the tourniquet type, was over 1500 mL thus qualifying as Class III hemorrhagic shock. In a life and death situation, 66% success is hardly reassuring. Even with combined web-based and Just-In-Time teaching, only 75% of laypersons were shown to be able to properly place a windlass tourniquet.²⁵ While junctional arterial occlusion devices have come a long way, this brings to light the concern that the currently available windlass tourniquets are not universally intuitive.²⁶ Additionally, since all those studied were given time to read the directions prior to application, it also calls into question the quality of the enclosed instructions, especially as time spent reading them did not correlate with hemorrhage control (p = 0.09-0.29). We demonstrated clear difference in the maximal pressure applied by women vs. men (p = 0.005) and thus worse outcomes (p = 0.006), further suggesting that the windlass design is not optimized for all users.

The authors cannot recommend one device over another given no difference in overall survivability with use (p = 0.55). The directions vary considerably among the devices. All had written instructions and drawings associated with numbered steps (Fig. 1). Drawings were similar across all three devices, but CAT and SAM XT included extensive paragraph form instructions associated with each step, while SOFT-T had a maximum of three words associated with each drawn step. Concordantly, less time was used to read the directions of SOFT-T. This time difference was nearly 50% shorter for SOFT-T and translated into a several hundred milliliter reduction in overall blood loss among survivors. However, this did not effect an overall survival benefit. The CAT tourniquet was shown previously to be inferior to a pneumatic design when self-applied to the mid-thigh by active soldiers.²⁷ This suggests that since they all work by similar windlass mechanism, application was universally poor and thus bears to ask whether this is the best mechanism for the untrained layperson market.²⁸

There frequently exists a translation gap between lessons learned in the military environment and civilian applicability. Both environments have unique needs that do not always align.

TABLE 2. Survivor Data by Tourniquet Type

	SAM XT	CAT	SOFT-T	p
Number survived, n (% of overall)	36 (65%)	33 (72%)	30 (61%)	0.55*
Male sex, n (% of survivors)	23 (64%)	19 (58%)	16 (53%)	0.68*
Prior experience, n (% of survivors)	8 (22%)	3 (9%)	5 (17%)	0.36*
Time to complete: median (range), s				
Read instructions	50 (17–60)	56 (25–60)	27 (11–58)	<0.0001**
Stop bleeding	92 (42–232)	77 (21–158)	71 (26–337)	0.28†
Pressure applied: median (range), mm Hg	320 (41–450)	329 (265–516)	315 (265–516)	0.56**
Blood lost, mL, median (range)	686 (285–1136)	624 (193–1256)	433 (203–1115)	0.03†

Statistical analysis performed with *\chi^2 analysis, **ANOVA test, and †Kruskal-Wallis test.

Collectively, these data suggest that the current tourniquets are designed and approved for the military with specific requirements set forth by the Committee on Tactical Combat Casualty Care to be applied by trained military users who re-train at regular intervals. 10,29 Data, such as these, force the question of whether these devices are the best choice to be cross pollinated to the civilian market as a majority of civilians will never receive appropriate training. Our study demonstrated minimal skill decay after rapid review of the instructions for those with previous experience, but still a quite high failure rate of 38% for those with no prior training. Layperson perception of skill may not correlate to ability, and these tasks are certainly subject to skill decay.^{30,31} A current large-scale study showed that only 54% of Bleeding Control Basic participants were able to place a windlass tourniquet 3 months to 9 months following initial training without any training update. 32 Others report as low as 14.4% proper tourniquet placement by laypersons without any prior training.³³

An analogy can be drawn by examining the development current layperson automatic external defibrillators (AEDs). Prior to the age of the current AED, defibrillation was only attainable via professional devices specifically for trained EMS

TABLE 3. Outcomes by Prior Experience

	First Time User	Prior Experience	p
Number, n (%)	131 (89%)	16 (11%)	
Patient status, n (%)			
Stable	81 (62%)	16 (100%)	0.006*
Bleeding	2 (1%)	0 (0%)	0.99*
Dead	48 (37%)	0 (0%)	0.008*
Tourniquet placement, n (%)			
Good	83 (63%)	14 (88%)	0.10*
Incorrect	6 (5%)	2 (12%)	0.46*
None	42 (32%)	0 (0%)	0.02*
Time to complete: median (range), s			
Read instructions	49 (11-60)	43 (12-60)	0.38**
Stop bleeding	120 (24-432)	54 (21–232)	0.0002^{\dagger}
Pressure applied: median (range), mm Hg	285 (0–516)	302 (231–412)	0.09 **
Blood lost, mL, median (range)	877 (203–1273)	400 (193–1136)	<0.0001

Statistical analysis performed with *\chi^2 analysis, **ANOVA test, and \(^t\)Kruskal-Wallis test.

professionals.³⁴ Had these devices been placed directly in the hands of untrained civilians, they would likely have caused injury and have been far less successful. Automatic external defibrillators were initially designed to simplify this stressful task and they continued to evolve to ensure safety and success, catering to both trained and untrained civilians alike.³⁵ Today, AEDs are designed to be simple enough to be used by any individual regardless of training and can even be delivered by drone to reduce time to intervention.³⁶ If we are to best impact the masses, we must create devices that are not only effective at accomplishing the task required, but they must be simple, easy to use, and universally intuitive with little to no training. Seconds matter.

Our study is inherently limited by the fidelity of the simulation scenario. We cannot recreate the psychological stress a layperson undergoes when faced with a massively exsanguinating patient. This study addresses performance in a controlled setting and may not take into account stress-induced cognitive dysfunction.³⁷ Further, our study cohort represents preclinical graduate health science students, who likely surpass the general population as a whole in terms of medical literacy.

The future of civilian tourniquets must market end users to capture the greatest numbers of individuals independent of their level of training. By focusing on only military approved devices that are designed specifically for trained users, it is likely that we have focused on the windlass mechanism and the ensuing tunnel vision has resulted in selecting the wrong device for civilians. Such devices should not be bound by military constraints. For example, pneumatic tourniquets have been demonstrated to be able to occlude vessels at lower pressures, ³⁸ but are discouraged in the combat environment due to durability. ³⁹ That constraint should not apply to this market. There are multiple alternate tourniquet device options available, yet most are not produced and marketed because they are not appropriate for military use—currently considered the product standard. Most importantly, civilian bleeding control courses are not including alternate tourniquets, but instead, teaching to a single-style device with both unacceptably high failure rates and considerable skills decay. An independent broader civilian standard for tourniquets should be established by the Food and Drug Administration.

We recognize that civilians are the first line of defense when it comes to stopping extremity hemorrhage and saving lives. ⁴⁰ We also acknowledge that training makes a difference. ^{41–43} Unfortunately, universal training is a daunting task, and most will never acquire tourniquet experience. Our data suggest that even in the hands of graduate level educated untrained users, current

devices are not simple enough to achieve greater than 66% success. Training efforts must continue, but future devices must not only have clear and concise instructions they must also be simple enough that any untrained user can pick it up and make it work.

AUTHORSHIP

A.D., F.B., V.S., A.I., K.I., A.L., T.P. created the study design and collected data. A.D., F.B., V.S., L.C.T. performed the literature search and wrote the article. A.D., V.S., L.C.T., A.I., K.I. analyzed the data. All authors participated in data interpretation and critical revision of the article.

ACKNOWLEDGMENT

The authors wish to acknowledge Amy Stein of Midwestern University for her assistance with statistical analysis. We wish to thank SAM Medical for lending us the HapMed Leg Tourniquet Trainer for this study.

DISCLOSURE

The authors declare no conflicts of interest.

No funding was received for this work from the National Institutes of Health (NIH); Wellcome Trust; or the Howard Hughes Medical Institute (HHMI).

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COMMENTARY

The presence of automatic external defibrillators has become commonplace in any public arena such as schools and shopping malls. The key to their success is that they are indeed automatic except for pad placement, turning the device on, and pushing a button when instructed. Wouldn't it be great if once a tourniquet is placed on a bleeding extremity, one could push a button and allow the computer to do the rest of the work? Just 20 years ago, the common thought was that tourniquets do nothing but create more harm. We as a trauma community have come a long way since then, now going as far as advocating that the public should be comfortable with applying an effective tourniquet. The authors should be commended for calling out the need for further public education with tourniquets. The success rate of hemorrhage control in this study was quite poor. As the authors pointed out, one must assume that the performance of the general public would be much worse considering the participants in this study were graduate students in the health sciences. This supports the American College of Surgeons' initiative to widely disseminate the Stop the Bleed Course. Even more importantly, this study should stimulate industry to work with experts in adult education and psychology to come up with new user-friendly tourniquet designs and concise, effective instructions to ensure successful application of their devices. This would provide the best chance for a member of the public to quickly and successfully stop bleeding with a tourniquet in an extremely stressful situation.

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