THE MILITARY EMERGENCY TOURNIQUET PROGRAM: DEVICES, DESIGNS, AND DATA

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INTRODUCTION

As no prior study, ours or others, analyzes recovered tourniquets, a knowledge gap persists. The aim of this study is to report the emergency tourniquet device lessons learned from a large emergency tourniquet program, and in particular, analyze devices recovered after clinical use.

METHODS

This report of the experience of the US Department of Defense's Emergency Tourniquet Program is based primarily on data derived from a performance improvement project at a combat support hospital in Baghdad. The program leader was an orthopedist. After emergency combat casualty care was complete, discarded tourniquets were collected by investigators. Devices were sent to the US Army Institute of Surgical Research (USAISR) for analysis.

We recorded where on the device wear occurred and where it was minimal or absent. We noted when wear occurred or what was associated with wear particularly device deformity and breakage. When possible, we associated wear and tear with clinical data from our clinical reports as some devices had care data written on them or attached to them. Since we could learn the most from devices that had the most extreme problems compared to devices with routine performance, we were most interested in outlier analysis.

RESULTS

The recovered devices numbered 159 from clinical use (97 CATs, 37 SOFTTs, 13 EMTs, 8 Improvised, 2 M2s, 1 SATS, and 1 London Bridge;). Of the 159 devices, 110 passed testing after recovery, and 49 failed. Devices failed post-recovery testing because the devices were cut off with scissors (14), had a lost cap (4), had a cut bladder (4), had a lost bulb (1), had a lost screw (1), had a lost securing strap (5), had a stabilization plate break (2), or had a rod locking clip break (1). Devices were cut off during emergency care by providers at their discretion in order to not manhandle a fractured limb and simply slip off the cut tourniquet.

Every device had some wear usually manifest by minor fraying or abrasions about the edges of the strap or bladder. Some residual deformity about the strap or bladder was present in each device. The effectiveness data when known were similar to prior reports (28 ineffective, 52 effective, 79 unknown; Kragh et al, 2008). Ineffectiveness was associated with failure to stop the distal pulse commonly, failure to control hemorrhage, and device breakage rarely. Prehospital effectiveness (76%) was less than emergency department effectiveness (86%) indicating that ED devices may be more effective than prehospital devices (Kragh et al, 2008).

The EMT was only an emergency department (ED) device in the trial, and it was the most effective tourniquet probably because of its design and width. However, even when ED personnel used prehospital devices such as the CAT and SOFTT, users could adjust the devices or put them side-by-side in use to improve effectiveness which indicated that user knowledge was associated positively with effectiveness. The effectiveness single devices was 82% but 92% when two or more tourniquets were used side-by-side which underscores the importance of width particularly when one realizes that side-by-side use is only done when hemorrhage control has failed (Kragh et al, 2008).

Several features of how many hands are needed in actual tourniquet application can be analyzed from use data. Of the 16 casualties (16/499, 3.2%) with tourniquets applied to both upper extremities, we expected the casualty himself to have difficulty in self-application of tourniquets, and the survival rate for these 16 was 75% (12/16) vs. 87% (422/483) for those 483 casualties that did not have both upper extremities with tourniquets. This infrequent and small, 12% disparity (75% vs. 87%) may indicate that those casualties with both upper extremities needing tourniquets may get hemorrhage control later or less well than those with one or less upper extremities needing a tourniquet. The small disparity is not

significant statistically ($p>0.05$). Although the bilateral data help de-emphasize the need to make a tourniquet one-handed in application, they do not discount the fact that bilateral injuries bleed more and faster and thus are more lethal. In sum, there is not a common need for one-handed tourniquet application, and even if every applier of those 16 casualties did use only one hand, the potential survival benefit is clinically small and infrequent and currently evidenced to be statistically insignificant. Obviously one-handed application is more important in those few cases in the field at the point of injury during self-application when one upper extremity is injured, but one-handed application is less important in aid stations, ambulances, or EDs. As a matter of fact, one-handed application in these latter settings has not yet been reported. One-handed tourniquet application is desirable but not essential to success in general use.

Tourniquet designs should be able to accommodate limb circumferences of 14cm (5.36inches, 1st percentile of female wrists) to 71 cm (28.13 inches, 99th percentile of male thighs). This range is an estimate of the expected need in clinical use of tourniquets in adults, although the clinical burden of injury is disproportionately weighted to the thigh since it is the largest target for penetrating trauma. The needs of children have not been delimited with data, but the experience of the program is that the devices used in the clinical trial could be used in children (Kragh et al, 2009). Effectiveness has been high while being safe in children, probably because the limb circumferences are small. Tourniquet design should account all relevant science including casualty anthropometry.

The spectrum of device designers has ranged from medics with operational military experience making simple, heavy, devices in their garage from parachute rigging materials permitting high torque that were similar to clinical engineers with surgical instrument designing experience making complex, delicate, precise, and costly devices supported by extensive evidence. In laboratory testing, the background of the device designer was associated with a successful device in that those who knew from experience how tourniquets were effective designed effective devices and those who understood how devices were effective and safe designed devices that were both safe and effective. The title, author(s), and affiliation(s) should be in a 3.8 cm (1.5") space, as shown above.

DISCUSSION

We are not aware of a prior study that has extensively analyzed the performance and wear and tear of any used first aid devices. Compelled to fix the most preventable cause of death on the battlefield, limb exsanguination, the US Army Institute of Surgical Research formed a program to develop emergency tourniquets and solved the problem. How tourniquets work, i.e., adequate transmural arterial pressure gradient, is not how they work best, as the intraneural gradient has to be limited. Thus. a moderate pressure gradient over a safe width seems the best. The scientific key is a tissue pressure gradient below a threshold that injures nerves, e.g., 500mmHg. The pressure in or under the tourniquet is not the key to optimal use. The key is the pressure in tissues about the arteries, and the nerve is the tissue most vulnerable to pressure gradients. These facts indicate that a refinement of tourniquet training and doctrine is due, and new device designs should incorporate these new findings in order to improve on the performance of current tourniquets and techniques. We changed how we thought about emergency tourniquet use in that effectiveness is within the constraints of specific safety knowledge with which users and makers are often unfamiliar. Users often assumed that optimal use required more force, but optimal use is not synonymous with effective use as optimal use must be safe. Mechanical effectiveness is essential to optimal use, but it is only one of multiple essentials. Although tourniquets are often preconceived as a simple 18th Century technology, the problems are deep, the science is subtle, and the facts are stubborn. They are not error-proof or indestructible, and they come with instructions most of which are sound although unread.

The current work reinforces a growing body of knowledge indicating that tourniquet width and design are associated with safety and effectiveness. Specific problems were design specific such as sandy ratchets or bladder leaks. Wear and tear were also design specific such as a rusted levers or screws.

Using a comprehensive approach, the emergency tourniquet program worked with many organizations successfully to change first aid in combat. Progress was made with accrual of experience, iterative refinement of training, and intermittent updating of doctrine based on the best available evidence. Incremental performance improvement projects with concordant clinical and laboratory research helped with systematic analysis reconciling all known but disparate knowledge prioritized by quality and quantity. With compilation of cases and reports, the effectiveness of arterial tourniquet use including side-by-side use became clear. Similarly with experience, suboptimal use such as device misplacement distal to wounds, and late or loose use, and pitfalls such as venous tourniquet, or under tourniquet kit, became clear. Different devices have different components that wear or break depending on use or misuse.

Given the variability of real world results, the evidence indicates that it is not whether a device is effective or not, but how often a given device is made effective. Any device designed to be used by minimally trained users in highly stressful situations is prone to failures due to misuse. In other words, it is not a yes or no ultimatum, but what proportion of uses is effective. The latter invites a consideration of multiple issues such as when devices are used, the manner of their use, and the types of injuries for which they are used, and all of these are recently evidenced to be essential in determining outcomes. Newly evidenced in the current report are expectations or the assumptions of users which determine the wear and tear of devices. By clarifying the details that affect outcomes, the current report can help users pay attention to the key details in order to avert problems and attain optimal use and also can help interested device manufacturers refine their products to increase the likelihood of successful hemorrhage control. For example, complying with the instructions to remove slack before tightening the tourniquet improved results over not doing so.

Design and width were not wholly independent or separable. For example, the VTAC design made for a poor tourniquet yet it was the widest device. The VTAC, a compression wrap, was not designed as a tourniquet but was improvised for one. Improvised tourniquets performed worse than commercial devices but better than no tourniquet at all. The dominance of width as a device trait should not be exaggerated by designers as occasionally narrowness was useful as noted with the SOFTT in the occasional, very proximal wounds. Similarly, design traits, besides width, have been associated with effectiveness. Also, misuse can be reduced with careful design that accounts common issues.

A ‘more is better’ assumption came from lay users in the field in their spontaneous solution to a common, and lethal problem when they started using more field tourniquets side-by-side to the first after the first failed to control hemorrhage. This solution was successful for an unexpected reason, in that it was wider, not that more force was required. This fortunate finding led to higher effectiveness rates and a refinement in clinical guidelines (Kragh, 2008). Another ‘more is better’ assumption led to the problem of the twist cap falling off after the end of the threads was overridden during stressful applications. A third ‘more is better’ assumption was indicated in the initial special operations forces response to the need for better tourniquet designs in that there was first a search ‘for a stronger dowel’ while the science clearly indicated that there should have been a search for a wider strap. Some users felt it was intuitively obvious to the casual observer that the SOFTT was superior to the CAT because it was sturdier and simpler, but they could not reconcile contrary effectiveness data, account safety concerns, or recognize the complexities of the non-linear associations among pressure, limb circumference, and device width. Best care is not the simplest, easiest, or least care. Reducing devices to cheaper, unproven ones risks lethal mistakes. Given that the users know that width is the key to effectiveness, width can easily and safely attain effectiveness by using wide devices or using narrow ones side-by-side. Pressure, particularly the tissue gradient, is dangerous when the user assumes pressure amplitude is the key to effectiveness. Force, deformation, damage, and failure are sequential when finesse is absent.

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