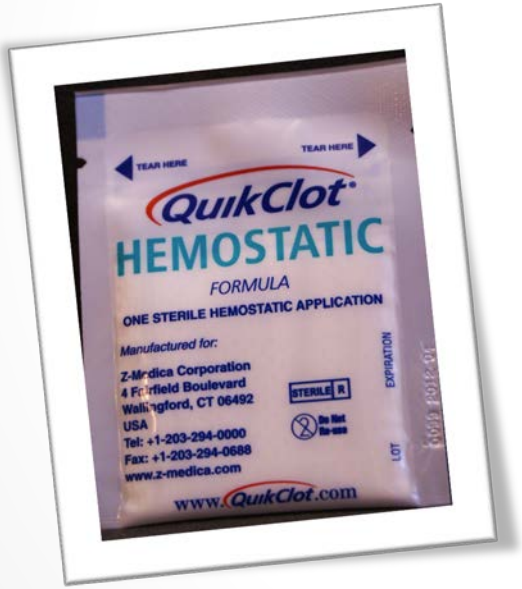
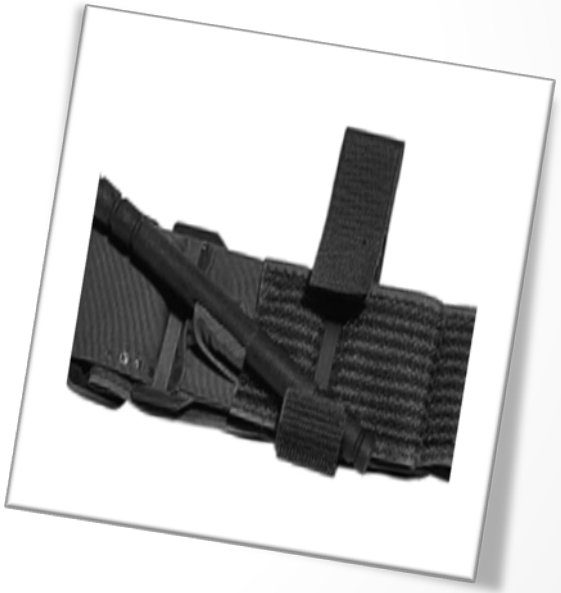
Costal Emergency Medicine Conference

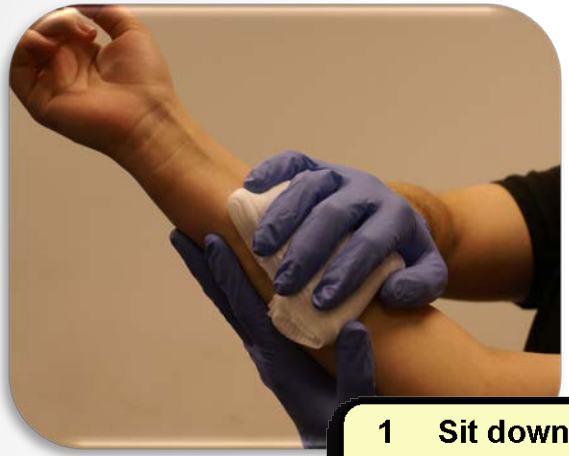
Advanced Hemorrhage Control Solutions and Devices





Eric Ossmann, MD, FACEP
Associate Professor
Duke University Medical Center

Bleeding Wound



Direct Pressure

1. Use 4x4 cotton gauze if available
2. Use gloves if available
3. Hold pressure for at least 5 minutes

Categorize Bleeding

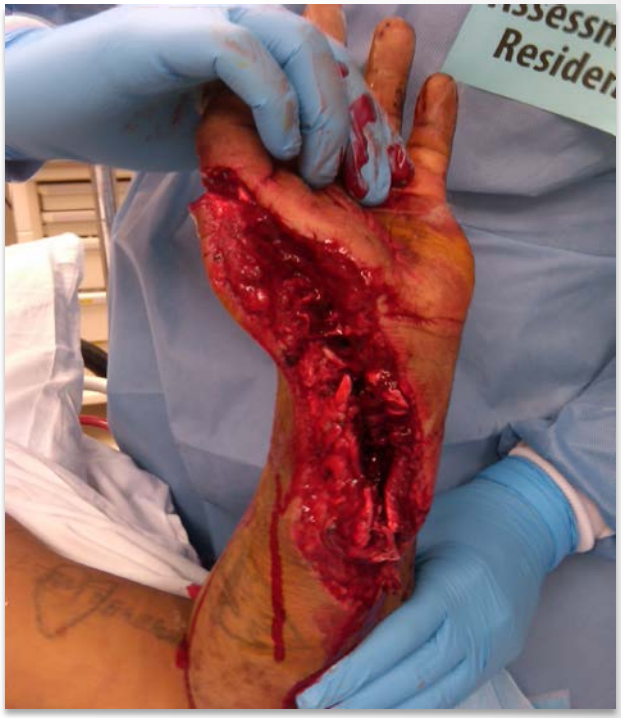
MILD

1. Sit down out of direct sunlight
2. Apply sterile 4x4 cotton gauze to cover wound
3. Wrap with rolled cotton gauze

SERIOUS

Serious Bleeding

- Requires advanced maneuvers
- Arterial Bleeding
- Major Venous Bleeding
- Uncontrolled bleeding
- Bleeding associated with
  - Cool/sweaty skin
  - Lightheadedness/dizziness
  - Change in alertness



Improved (Individual) First Aid Kit

- Utility Pouch
- Combat Application Tourniquet
- Emergency Elastic Bandage (Israeli Pressure Dressing)
- Compressed Gauze Bandage
- 2” Adhesive Tape
- Combat Gauze Dressing
- Nasopharyngeal Airway
- Patient Exam Gloves

Tourniquets

Prehospital Utilization

Tourniquet Use

Survival With Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma

COL John F. Kragh, Jr., MC, USA, Thomas J. Walters, PhD,* David G. Baer, PhD,* LTC Charles J. Fox, MC, USA,† Charles E. Wade, PhD,* Jose Salinas, PhD,* and COL John B. Holcomb, MC, USA**

Objective: The purpose of this study was to determine if emergency tourniquet use saved lives.

Summary Background Data: Tourniquets have been proposed as lifesaving devices in the current war and are now issued to all soldiers. Few studies, however, describe their actual use in combat casualties.

Methods: A prospective survey of injured who required tourniquets was performed over 7 months in 2006 (NCT00517166 at ClinicalTrials.gov). Follow-up averaged 28 days. The study was at a combat support hospital in Baghdad. Among 2838 injured and admitted civilian and military casualties with major limb trauma, 232 (8%) had 428 tourniquets applied on 309 injured limbs. We looked at emergency tourniquet use, and casualties were evaluated for shock (weak or absent radial pulse) and prehospital versus emergency department (ED) tourniquet use. We also looked at those casualties indicated for tourniquets but had none used. We assessed survival rates and limb outcome.

Results: There were 31 deaths (13%). Tourniquet use when shock was absent was strongly associated with survival (90% vs. 10%; $P < 0.001$). Prehospital tourniquets were applied in 194 patients of which 22 died (11% mortality), whereas 38 patients had ED application of which 9 died (24% mortality; $P = 0.05$). The 5 casualties indicated for tourniquets but had none used had a survival rate of 0% versus 87% for those casualties with tourniquets used ($P < 0.001$). Four patients (1.7%) sustained transient nerve palsy at the level of the tourniquet. No amputations resulted solely from tourniquet use.

Conclusions: Tourniquet use when shock was absent was strongly associated with saved lives, and prehospital use was also strongly associated with lifesaving. No limbs were lost due to tourniquet use. Education and fielding of prehospital tourniquets in the military environment should continue.

(*Ann Surg* 2009;249: 1–7)

From the *US Army Institute of Surgical Research, Fort Sam Houston, TX; and †Walter Reed Army Medical Centre, Georgia Avenue North West, Washington DC.

Study performed at 10th Combat Support Hospital, US Army Task Force North, APO AE 09348 (Ibn Sina Hospital, International Zone, Baghdad, Iraq).

COL Kragh conceived and designed the work, collected the data, analyzed data, and produced the article. Drs Walters and Baer participated in conception, design, and writing. MAJ Fox, Dr Wade, and COL Holcomb participated in data collection, analysis, and writing. Dr Salinas participated in design, analysis, and writing. Drs Wade, Baer, and COL Kragh participated in the regulatory oversight.

The funding of this work was only for the general salary of the investigators in the course of their federal employment. There was no sponsor and the authors declare no conflicts of interest.

No reprints are available from the authors. There was no grant; the work was supported by US Army internal funds. We consult at no cost with tourniquet companies that engage us on design improvements. We have cooperative research and development agreements and material transfer agreements with such companies that protect intellectual property rights and the like.

ISSN: 0003-4932/09/24901-0001

DOI: 10.1097/SLA.0b013e31818842ba

Hemorrhage from injured extremities continues to be one of the leading sources of preventable death on the battlefield.[1–4] Data from recent conflicts involving US military personnel confirmed the continued importance of improving prehospital hemorrhage control.[3,5–7] In response, the US Army implemented a design, testing, training, and fielding program for battlefield tourniquets,[8–11] resulting in policy that all military personnel in theater carry tourniquets. As a result of this effort, tourniquets are now common on the battlefields of Iraq and Afghanistan, both in the hands of medical and nonmedical personnel.

With the Tactical Combat Casualty Care initiative, the US military is not alone in establishing procedures and equipment for use of tourniquets in the prehospital environment by both medical and nonmedical personnel.[12,13] However, this renewed emphasis on tourniquets for prehospital hemorrhage control of extremity injuries is not agreed upon by all authors[14–16] with some authors discouraging prehospital use of tourniquets altogether.[17–20] Dorlac et al[21] showed that tourniquet use is indicated in civilian trauma, albeit in a very small percentage of patients. However, the lifesaving capability of tourniquets has been unproven. Most of the controversy regarding the capacity of tourniquets to save lives versus tissue damage has been based more on speculation rather than actual data, as research in the human use of emergency tourniquets is limited. Clearly, the discussion would be better informed with actual data regarding these critical concerns. In 2003, we initiated data collection regarding emergency tourniquet use, and this study is a continuation and amplification of that effort.[22]

We performed a prospective observational study at the US combat support hospital in Baghdad, Iraq of patients who had tourniquets applied to determine if emergency tourniquet use saved lives.

METHODS

Study Design

The protocol was approved by the institutional review board, and the study was registered (NCT00517166 at ClinicalTrials.gov). The study period was from March 19 to October 4, 2006, the first author's arrival and departure dates at the study site, Ibn Sina Hospital, Baghdad, Iraq. This was a prospective observational survey with cohort and subgroup analyses. All patients at the combat support hospital who had a tourniquet of any type used in their emergent health care [prehospital, emergency department (ED), or intensive care unit (ICU)] were included in the study. Detainees and prisoners of war are restricted from research by military policies and were excluded. No experimental interventions were made, and the procedures were conducted in accord with the ethical standards of the Helsinki Declaration of 1975. The informed consent waiver was approved.

Data Collection

Data collected included patient age in years, gender, application time (time between injury and use) in minutes, setting of tourniquet application (prehospital or ED), mechanism of injury, injury type (such

Practical Use of Emergency Tourniquets to Stop Bleeding in Major Limb Trauma

John F. Kragh, Jr., MD, Thomas J. Walters, PhD, David G. Baer, PhD, Charles J. Fox, MD, Charles E. Wade, PhD, Jose Salinas, PhD, and COL John B. Holcomb, MC

Background: **Previously we showed that tourniquets were lifesaving devices in the current war. Few studies, however, describe their actual morbidity in combat casualties. The purpose of this study was to measure tourniquet use and complications.**

Methods: **A prospective survey of casualties who required tourniquets was performed at a combat support hospital in Baghdad during 7 months in 2006. Patients were evaluated for tourniquet use, limb outcome, and morbidity. We identified potential morbidities from the literature and looked for them prospectively. The protocol was approved by the institutional review board.**

Results: **The 232 patients had 428 tourniquets applied on 309 injured limbs. The most effective tourniquets were the Emergency Medical Tourniquet (92%) and the Combat Application Tourniquet (79%). Four patients (1.7%) sustained transient nerve palsy at the level of the tourniquet, whereas six had palsies at the wound level. No association was seen between tourniquet time and morbidity. There was no apparent association of total tourniquet time and morbidity (clots, myonecrosis, rigor, pain, palsies, renal failure, amputation, and fasciotomy). No amputations resulted solely from tourniquet use. However, six (2.6%) casualties with eight preexisting traumatic amputation injuries then had completion surgical amputations and also had tourniquets on for >2 hours. The rate of limbs with fasciotomies with tourniquet time ≤2 hours was 28% (75 of 272) and >2 hours was 36% (9 of 25, $p = 0.4$).**

Conclusions: **Morbidity risk was low, and there was a positive risk benefit ratio in light of the survival benefit. No limbs were lost because of tourniquet use, and tourniquet duration was not associated with increased morbidity. Education for early military tourniquet use should continue.**

Key Word: **Tourniquet, Hemorrhage, Resuscitation, Mangled extremities, Mass casualties.**

J Trauma. 2008;64:S38–S50.

Hemorrhage from injured limbs continues to be a leading source of battlefield death,[1,2] and we recently showed in the current war that emergency tourniquet use improves survival rates in patients with major limb trauma.[3] In response to the US Army design, testing, training, and fielding of battlefield tourniquets,[4,5] all military personnel in theater carry tourniquets, and they are now common on the battlefields of Iraq and Afghanistan, both in the hands of medical and nonmedical personnel.

Although the US military is not alone in establishing procedures and equipment for the use of tourniquets in the prehospital environment by both medical and nonmedical personnel,[6,7] tourniquet use remains controversial and not agreed upon by all authors,[8–10] with some authors banning prehospital use of tourniquets altogether.[11] Because we showed that tourniquets were lifesaving devices, the next important controversy regards tourniquet capacity to damage tissue and cause amputation. Because research in the human use of emergency tourniquets is limited, the morbidity controversy has been based more on speculation rather than actual data. Since 2003, we collected data regarding emergency tourniquet results, and this study is a continuation and amplification of those efforts (see Beekley in this supplement to *Journal of Trauma*).

We performed a prospective observational study at the United States combat support hospital in Baghdad, Iraq, of patients who had tourniquets applied in the field or in the emergency department (ED). Our objective was to measure tourniquet use and complications attributable to their use.

Submitted for publication October 29, 2007.

Accepted for publication October 30, 2007.

From the US Army Institute of Surgical Research (J.F.K., T.J.W., D.G.B., C.E.W., J.S., J.B.H.), Fort Sam Houston, Texas; and Walter Reed AMC (C.J.F.), Washington, DC.

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DOI: 10.1097/TA.0b013e31816086b1

METHODS

Study Design

The protocol for this study was approved by the Brooke Army Medical Center institutional review board. The study period was from March 19 to October 4, 2006. This was a prospective observational survey with cohort and subgroup analyses. All patients at the combat support hospital who had a tourniquet of any type used in their emergent health care (prehospital, ED, or intensive care unit) were included in the study. Patients with tourniquets ready at the bedside, purposefully left loose, or whose first applied tourniquet was in the

What Do We Know

- Tourniquets Appear to be Effective
- Tourniquets Appear to Have a Low Complication Rate
  - Retrospective studies
  - Complex extremity injuries
  - Unique population
  - Limited number of subjects

Survival With Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma

COL John F. Kragh, Jr., MC, USA, Thomas J. Walters, PhD,* David G. Baer, PhD,* LTC Charles J. Fox, MC, USA,† Charles E. Wade, PhD,* Jose Salinas, PhD,* and COL John B. Holcomb, MC, USA**

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Data Collection

Data collected included patient age in years, gender, application time (time between injury and use) in minutes, setting of tourniquet application (prehospital or ED), mechanism of injury, injury type (such

Study Question

Does the use of emergency tourniquets save lives?

- Under what circumstances
- What are the complications

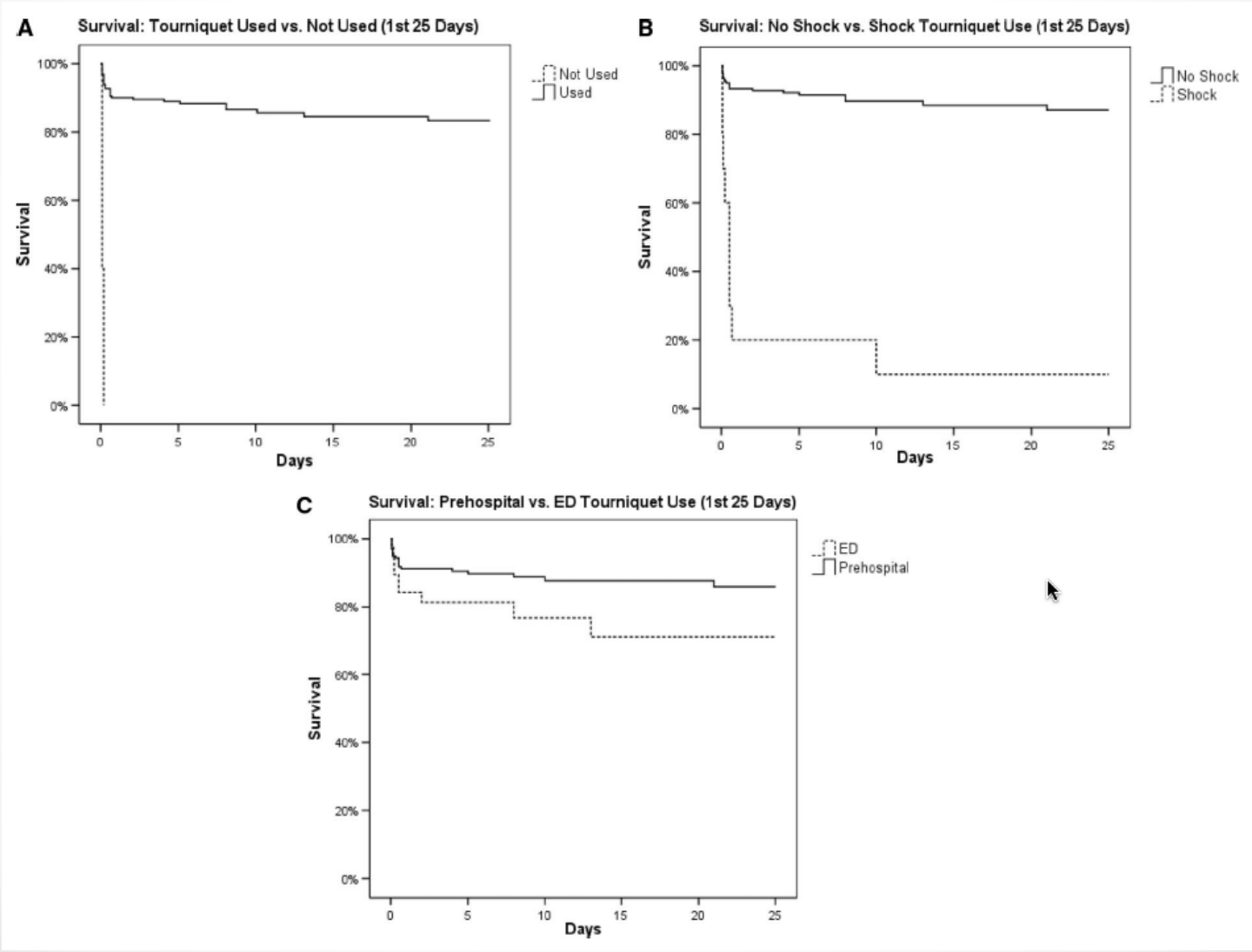
Survival With Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma

- Methods
  - Study Design
    - Prospective observational study
    - Cohort and subgroup analysis
    - All patients presenting to the hospital with a tourniquet were included
  - Definitions
    - Tourniquet = any limb constrictive device used to stop extremity bleeding
    - Use categorized:
      - Geographically
      - Physiologically
  - Statistical Analysis
    - Descriptive
    - Chi-squared and student-t
    - Kaplan-Meier survivorship analysis

Survival With Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma

- Results
  - Demographics
    - 232 patients
    - 428 tourniquets placed on 308 limbs
    - Mean ISS = 14
    - Explosions were the most common mechanism

Survival With Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma



Survival With Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma

- Conclusions
  - Survival Rate Was Higher in Patients With Tourniquets Used Versus Tourniquets Not Used - Effective
  - Survival Rate Was Higher if Shock Was Absent Before Tourniquet Use Than if it Was Present – Early is Better
  - Survival Rate Was Higher With Earlier Application (Prehospital) of Tourniquet - Early is Better
  - Palsies Were Infrequent and Transient With Tourniquet Use

The Journal of Emergency Medicine, Vol. 41, No. 6, pp. 590–597, 2011
Published by Elsevier Inc.
Printed in the USA
0736-4679/$–see front matter

doi:10.1016/j.jemermed.2009.07.022

ELSEVIER

Original Contributions

BATTLE CASUALTY SURVIVAL WITH EMERGENCY TOURNIQUET USE TO STOP LIMB BLEEDING

John F. Kragh, Jr, COL, MC, USA,* Michelle L. Littrel, CPT, AN, USA,† John A. Jones,*
Thomas J. Walters, PHD,* David G. Baer, PHD,* Charles E. Wade, PHD,* and John B. Holcomb, MD*†

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☐ **Abstract—Background: In a previous study conducted at a combat support hospital in Iraq, we reported the major lifesaving benefits of emergency tourniquets to stop bleeding in major limb trauma. Morbidity associated with tourniquet use was minor. Study Objectives: The objective of this study is to further analyze emergency tourniquet use in combat casualty care. Design and Setting: This report is a continuation of our previous study of tourniquet use in casualties admitted to a combat support hospital (NCT00517166 at www.ClinicalTrials.gov). Methods: After verifying comparable methodologies for the first study and the current study, we compared patient results for these two time periods and then pooled data to analyze outcomes with a larger sample size. Results: The total study population was 499 (232 in the previous study and 267 in the current study). In all, 862 tourniquets were applied on 651 limbs. Survival was 87% for both study periods. Morbidity rates for palsies at the level of the tourniquet were 1.7% for study 1 and 1.5% for study 2; major limb shortening was 0.4% for both. Survival was associated with prehospital application (89% vs. 78% hospital, $p < 0.01$) and application before the onset of shock (96% vs. 4% after). Conclusions: This study shows consistent lifesaving benefits and low risk of emergency tourniquets to stop bleeding in major limb trauma. Published by Elsevier Inc.**

☐ **Keywords—tourniquet; trauma; major; military; limb injury; hemorrhage control**

INTRODUCTION

Despite recent positive reports of the use of emergency tourniquets from studies conducted at United States (US) combat support hospitals in Iraq, these devices are still considered controversial by some providers (1,2). We recently reported major lifesaving benefits and minor morbidity risks with emergency tourniquet use to stop bleeding in major limb trauma (3,4). Our goal was to see if our preliminary findings would hold true as the war progressed and tourniquets continued to be used. The fielding of tourniquets during the current war and the number of casualties permitted us to study and continue to evaluate performance (5,6). Improving prehospital hemorrhage control is vital to military and civilian trauma care, and we continue our efforts to fill knowl-

This study was performed at the 10th & 28th Combat Support Hospitals, US Army, (Ibn Sina Hospital, International Zone, Baghdad, Iraq). The trial number is NCT00517166 at www.ClinicalTrials.gov.

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the Department of Defense or United States Government. The authors are employees of the US government. This work was prepared as part of their official duties and, as such, there is no copyright to be transferred.

RECEIVED: 28 October 2008; FINAL SUBMISSION RECEIVED: 11 May 2009;
ACCEPTED: 10 July 2009

Kragh 2009

Update to Original Study

- Total study population increased to 499
- Consistent findings of lifesaving benefits and low complications

Hemostatic Bandages

Prehospital Utilization

Hemostatic Bandage Use

ORIGINAL ARTICLE

Determination of Efficacy of New Hemostatic Dressings in a Model of Extremity Arterial Hemorrhage in Swine

Bijan S. Kheirabadi, PhD, Michael R. Scherer, MA, J. Scot Estep, DVM, Michael A. Dubick, PhD, and John B. Holcomb, MD

Background: The HemCon (HC) bandage and QuickClot have been used over the past 6 years for treating external compressible hemorrhage in combat casualties. Previously, we tested three new hemostatic agents in granular/powder forms that were superior to these products. In this study, four new dressings (preselected) that are more suitable for battlefield application were evaluated. The efficacy and acute safety of the dressings were tested in our standard arterial hemorrhage model.

Methods: Anesthetized pigs (n = 38, 37 kg) were instrumented, and arterial blood was collected for hematological and coagulation assays. After splenectomy, the right femoral artery was isolated, injured (6 mm arteriotomy), and unrestricted bleeding allowed for 45 seconds. A hemostatic dressing (HC RTS [n = 6], Celox-D [CXb, n = 6], TraumaStat [TS, n = 10], Combat Gauze [CG, n = 10], or placebo gauze [PG, n = 6]) was then applied over the wound randomly and compressed for 2 minutes. Fluid resuscitation was administered and titrated to maintain a mean arterial pressure of 65 mm Hg. Animals were observed for 180 minutes or until death. Computed tomography angiography was performed on survivors and tissues were collected for histology.

Results: No differences were found in baseline blood measures, pretreatment blood loss or fluid infusion among groups. HCs and CXb testing discontinued after six unsuccessful tests, and the data were excluded. Stable hemostasis was achieved in two PG, two TS, and eight CG pigs in remaining groups resulting in stabilized mean arterial pressure and significantly different survival rates (20–80%, $p = 0.03$). CG secured hemostasis for 134.6 minutes ± 22.2 minutes, which was significantly longer than TS (35.7 ± 22.0 minutes, $p < 0.05$) but not different from PG (57.9 ± 36.2 minutes). The average survival time of CG-treated animals (167.3 ± 5.9 minutes) was also significantly longer ($p < 0.05$) than that of TS- (90.0 ± 15.3 minutes) or PG-treated (121 ± 19.3 minutes) pigs. Posttreatment blood loss was less in CG (37.4 ± 17.3 mL/kg) than that of the two other groups (TS = 79.8 ± 13.8 mL/kg and PG = 75.5 ± 23.8 mL/kg), but this difference was not significant. No significant rise in wound temperature (>1°C) was recorded after treatment with dressings and computed tomography images showed no flow through the vessels. Histologic observations showed mild to moderate changes in treated vessels with no difference between CG and PG. In vitro analysis of blood treated with CG or PG (lesser extent) showed increased clotting rate and clot strength. TS treatment had no effect on blood clotting activity.

Conclusion: CG was the most effective dressing tested in this arterial hemorrhage model. The hemostatic property of CG is attributed to its raw material (nonwoven Rayon and polyester blend), kaolin coating, and the large surface area (3 inch × 4 yd) of this absorbent sponge. CG is now recommended as the first line of treatment for life-threatening hemorrhage on the battlefield, replacing HC.

Key Words: Combat gauze, TraumaStat, Celox D, HemCon, Hemorrhage control, Side effect, Swine.

(*J Trauma.* 2009;67: 450–460)

Uncontrolled hemorrhage is the leading cause of death (50%) among combat casualties and is the second major cause of death in civilian trauma patients.[1–4] Massive bleeding and trauma are major risk factors leading to the lethal triad of life-threatening coagulopathy, which include persistent hypothermia, metabolic acidosis, and inability to form clot and establish hemostasis.[5,6] Hemorrhage also plays a significant role in late morbidity and mortality because of multiple organ failure that may be caused by prolonged hypotension, sepsis, and massive red cell and plasma product transfusion.[7,8]

A review of autopsies of 982 combat deaths in the current conflict by an expert panel showed that nearly 24% of the deaths could have potentially been prevented with prompt and effective threatment.[9] Of these 24% victims, majority (85%) died of potentially preventable hemorrhage with one of three being compressible and two of three being noncompressible wounds. Although there is no hemostatic modality to treat noncompressible (internal) hemorrhage in the prehospital phase, since 2003 two new hemostatic products, QuikClot and HemCon (HC) bandage, have become available for treating compressible (external) hemorrhage in the battlefield in addition to tourniquets. Despite these advancements, some of the compressible hemorrhages could not be controlled promptly and eventually led to the death of soldiers. Thus, hemorrhage control and the search for more effective hemostatic modalities continue to have a high priority in the US Army Combat Casualty Care Research program.

As part of these efforts, we have recently identified three new hemostatic agents in granular/powder forms that were significantly more effective than the current hemostatic products used on the battlefield.[10] These included WoundStat

Submitted for publication February 9, 2009.
Accepted for publication April 15, 2009.

From the Damage Control Resuscitation Division, US Army Institute of Surgical Research, Fort Sam Houston, Texas.
Presented at the 22nd Annual Meeting of the Eastern Association for the Surgery of Trauma, January 13–17, 2008, Lake Buena Vista, Florida.
The opinions or assertions expressed herein are the private views of the authors and are not to be construed as official or as reflecting the views of the US Department of the Army or the US Department of Defense.
None of the authors has any affiliation with the manufacturer of these products, and the authors have no potential conflicts of interest to declare.
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DOI: 10.1097/TA.0b013e3181ac0c99

ORIGINAL ARTICLE

Advanced Hemostatic Dressings Are Not Superior to Gauze for Care Under Fire Scenarios

Jennifer M. Watters, MD, Philbert Y. Van, MD, Gregory J. Hamilton, BS, Chitra Sambasivan, MD, Jerome A. Differding, MPH, and Martin A. Schreiber, MD

Background: Advanced hemostatic dressings perform superior to standard gauze (SG) in animal hemorrhage models but require 2 minutes to 5 minutes application time, which is not feasible on the battlefield.

Methods: Twenty-four swine received a femoral artery injury, 30 seconds uncontrolled hemorrhage and randomization to packing with SG, Combat Gauze (CG), or Celox Gauze (XG) without external pressure. Animals were resuscitated to baseline mean arterial pressures with lactated Ringers and monitored for 120 minutes. Physiologic and coagulation parameters were collected throughout. Dressing failure was defined as overt bleeding outside the wound cavity. Tissues were collected for histologic and ultrastructural studies.

Results: All animals survived to study end. There were no differences in baseline physiologic or coagulation parameters or in dressing success rate (SG: 8/8, CG: 4/8, XG: 6/8) or blood loss between groups (SG: 260 mL, CG: 374 mL, XG: 204 mL; $p > 0.3$). SG (40 seconds ± 0.9 seconds) packed significantly faster than either the CG (52 ± 2.0) or XG (59 ± 1.9). At 120 minutes, all groups had a significantly shorter time to clot formation compared with baseline ($p < 0.01$). At 30 minutes, the XG animals had shorter time to clot compared with SG and CG animals ($p < 0.05$). All histology sections had mild intimal and medial edema. No inflammation, necrosis, or deposition of dressing particles in vessel walls was observed. No histologic or ultrastructural differences were found between the study dressings.

Conclusions: Advanced hemostatic dressings do not perform better than conventional gauze in an injury and application model similar to a care under fire scenario.

Key Words: Hemostatic dressing, Care under fire, Combat Gauze, Celox Gauze, Hemorrhagic shock.

(*J Trauma.* 2011;70: 1413–1419)

Despite all the advances in trauma care and personal protective equipment such as body armor, hemorrhage continues to be the leading cause of preventable death for both civilian and war fighter trauma victims.[1,2] Studies show noncompressible truncal hemorrhage to be the principle cause of death but compressible extremity hemorrhage also contributes to significant numbers of potentially preventable deaths.[1,3] Delivering care on the battlefield during combat places the medic and casualty at continued risk for injury and death. In addition, the medic's primary responsibility may be fire suppression before, during, and after care. For these reasons, the Committee on Tactical Combat Casualty Care recommends tourniquet application as the method of extremity hemorrhage control in care under fire scenarios (Fig. 1).

Hemorrhage from wounds in areas not amenable to tourniquet application but still accessible for compression such as the groin, neck, or axilla may be treatable by application of advanced hemostatic dressings. In fact, many published studies have compared the effectiveness of various advanced hemostatic dressings to one another and to standard gauze (SG) for compressible vascular injuries to which tourniquets cannot be applied.[4–6] Unfortunately, some of the most effective granular agents designed to treat this type of injury result in local tissue destruction and distal thromboembolic events.[7] Gauze-based hemostatic dressings do not lead to the same negative local and embolic phenomena and have been shown to be more effective than SG dressings when applied to a severe groin injury.[5] However, all require prolonged hold times (manufacturers recommend 2–5 minutes of compression), which is simply impractical in the care under fire scenario.

Previous work in our laboratory seeking to minimize the necessary compression times compared the effectiveness of TraumaStat (OreMedix, Lebanon, OR), Chitoflex (HemCon, Portland, OR), and SG in a groin vessel transection model, using a 30-second hold time and found TraumaStat to be superior.[8] More recent work, conducted in a groin sidewall vessel injury model, demonstrated slight superiority of Combat Gauze (CG, Z-Medica, Wallingford, CT) compared with TraumaStat.[9] CG is rolled, flexible gauze dressing impregnated with kaolin, clay that activates clotting. It is the current dressing recommended for use by the Tactical Combat Casualty Care when injured combatants reach secure locations (Tactical Care). CG is in every soldier's first aid kit. (Fig. 2) Celox Gauze (XG, SAM Medical Products, Wilsonville, OR) is a rolled fabric made with nonwoven chitosan-derived

Submitted for publication October 5, 2010.
Accepted for publication February 21, 2011.

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Supported, in part, by The American Association for the Surgery of Trauma/Ethicon Research Scholarship Award and in part by an institutional grant from SAM Medical Products.
No member of the study team has any financial or vested interest in SAM Medical Products and there are no conflicts of interest.
Presented at the 69th Annual Meeting of the American Association for the Surgery of Trauma, September 22–25, 2010, Boston, Massachusetts.
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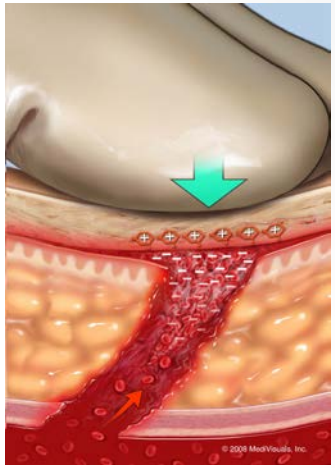
DOI: 10.1097/TA.0b013e318216b796

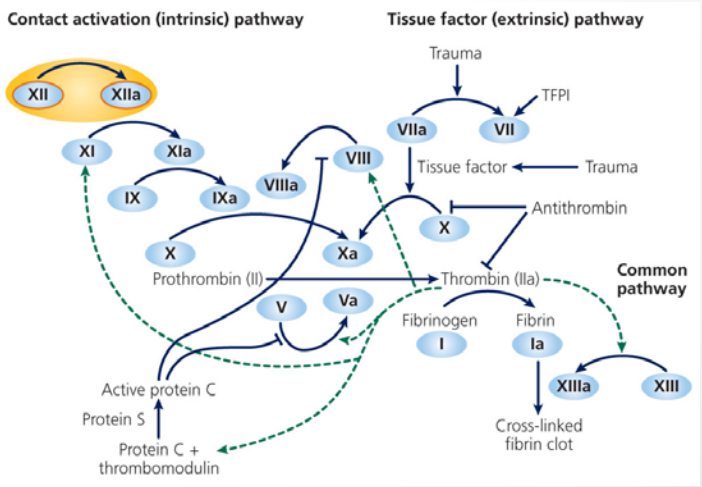
What Do We Know

- Hemostatic bandages are widely deployed and utilized by U.S. and foreign armed forces
- Hemostatic bandages are effective in animal models
  - Decrease bleeding time
  - Increase MAP
  - Improve survival

Mechanisms

- Factor Concentrators
  - Inert minerals
  - Rapid absorption of water
  - Exothermic reaction
- Mucoadhesive Agents
  - Chitosan
  - Cross-link erythrocytes with wound surface
  - Independent of platelets or clotting factors
- Pro-coagulant Agents
  - Kaolin
  - Enhances activity in the “intrinsic” arm of the clotting cascade





Determination of Efficacy of New Hemostatic Dressings in a Model of Extremity Arterial Hemorrhage in Swine

Bijan S. Kheirabadi, PhD, Michael R. Scherer, MA, J. Scot Estep, DVM, Michael A. Dubick, PhD, and John B. Holcomb, MD

Background: The HemCon (HC) bandage and QuickClot have been used over the past 6 years for treating external compressible hemorrhage in combat casualties. Previously, we tested three new hemostatic agents in granular/powder forms that were superior to these products. In this study, four new dressings (preselected) that are more suitable for battlefield application were evaluated. The efficacy and acute safety of the dressings were tested in our standard arterial hemorrhage model.

Methods: Anesthetized pigs (n = 38, 37 kg) were instrumented, and arterial blood was collected for hematological and coagulation assays. After splenectomy, the right femoral artery was isolated, injured (6 mm arteriotomy), and unrestricted bleeding allowed for 45 seconds. A hemostatic dressing (HC RTS [n = 6], Celox-D [CXb, n = 6], TraumaStat [TS, n = 10], Combat Gauze [CG, n = 10], or placebo gauze [PG, n = 6]) was then applied over the wound randomly and compressed for 2 minutes. Fluid resuscitation was administered and titrated to maintain a mean arterial pressure of 65 mm Hg. Animals were observed for 180 minutes or until death. Computed tomography angiography was performed on survivors and tissues were collected for histology.

Results: No differences were found in baseline blood measures, pretreatment blood loss or fluid infusion among groups. HCs and CXb testing discontinued after six unsuccessful tests, and the data were excluded. Stable hemostasis was achieved in two PG, two TS, and eight CG pigs in remaining groups resulting in stabilized mean arterial pressure and significantly different survival rates (20–80%, $p = 0.03$). CG secured hemostasis for 134.6 minutes ± 22.2 minutes, which was significantly longer than TS (35.7 ± 22.0 minutes, $p < 0.05$) but not different from PG (57.9 ± 36.2 minutes). The average survival time of CG-treated animals (167.3 ± 5.9 minutes) was also significantly longer ($p < 0.05$) than that of TS- (90.0 ± 15.3 minutes) or PG-treated (121 ± 19.3 minutes) pigs. Posttreatment blood loss was less in CG (37.4 ± 17.3 mL/kg) than that of the two other groups (TS = 79.8 ± 13.8 mL/kg and PG = 75.5 ± 23.8 mL/kg), but this difference was not significant. No significant rise in wound temperature (>1°C) was recorded after treatment with dressings and computed tomography images showed no flow through the vessels. Histologic observations showed mild to moderate changes in treated vessels with no difference between CG and PG. In vitro analysis of blood treated with CG or PG (lesser extent) showed increased clotting rate and clot strength. TS treatment had no effect on blood clotting activity.

Conclusion: CG was the most effective dressing tested in this arterial hemorrhage model. The hemostatic property of CG is attributed to its raw material (nonwoven Rayon and polyester blend), kaolin coating, and the large surface area (3 inch × 4 yd) of this absorbent sponge. CG is now recommended as the first line of treatment for life-threatening hemorrhage on the battlefield, replacing HC.

Key Words: Combat gauze, TraumaStat, Celox D, HemCon, Hemorrhage control, Side effect, Swine.

(*J Trauma.* 2009;67: 450–460)

Uncontrolled hemorrhage is the leading cause of death (50%) among combat casualties and is the second major cause of death in civilian trauma patients.[1–4] Massive bleeding and trauma are major risk factors leading to the lethal triad of life-threatening coagulopathy, which include persistent hypothermia, metabolic acidosis, and inability to form clot and establish hemostasis.[5,6] Hemorrhage also plays a significant role in late morbidity and mortality because of multiple organ failure that may be caused by prolonged hypotension, sepsis, and massive red cell and plasma product transfusion.[7,8]

A review of autopsies of 982 combat deaths in the current conflict by an expert panel showed that nearly 24% of the deaths could have potentially been prevented with prompt and effective threatment.[9] Of these 24% victims, majority (85%) died of potentially preventable hemorrhage with one of three being compressible and two of three being noncompressible wounds. Although there is no hemostatic modality to treat noncompressible (internal) hemorrhage in the prehospital phase, since 2003 two new hemostatic products, QuikClot and HemCon (HC) bandage, have become available for treating compressible (external) hemorrhage in the battlefield in addition to tourniquets. Despite these advancements, some of the compressible hemorrhages could not be controlled promptly and eventually led to the death of soldiers. Thus, hemorrhage control and the search for more effective hemostatic modalities continue to have a high priority in the US Army Combat Casualty Care Research program.

As part of these efforts, we have recently identified three new hemostatic agents in granular/powder forms that were significantly more effective than the current hemostatic products used on the battlefield.[10] These included WoundStat

Submitted for publication February 9, 2009.
Accepted for publication April 15, 2009.

From the Damage Control Resuscitation Division, US Army Institute of Surgical Research, Fort Sam Houston, Texas.
Presented at the 22nd Annual Meeting of the Eastern Association for the Surgery of Trauma, January 13–17, 2008, Lake Buena Vista, Florida.
The opinions or assertions expressed herein are the private views of the authors and are not to be construed as official or as reflecting the views of the US Department of the Army or the US Department of Defense.
None of the authors has any affiliation with the manufacturer of these products, and the authors have no potential conflicts of interest to declare.
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DOI: 10.1097/TA.0b013e3181ac0c99

Study Question

Do hemostatic bandages work better than standard gauze?

- Hemorrhage control
- Blood loss
- MAP
- Survival

Determination of Efficacy of New Hemostatic Dressings in a Model of Extremity Arterial Hemorrhage in Swine

- Methods
  - Study Design
    - Controlled experimental trial
    - Swine model of severe hemorrhage
    - Comparison of 4 hemostatic bandages and one standard gauze bandage (PB)
      - Trauma Stat (TS) – Silica and Chitosan
      - Combat Gauze (CG) – Kaolin
      - Celox-D (CXb) – Chitosan
      - HemCon-RTS (HC) - Chitosan
  - Statistical Analysis
    - Descriptive
    - Chi-squared and student-t
    - Kaplan-Meier survivorship analysis

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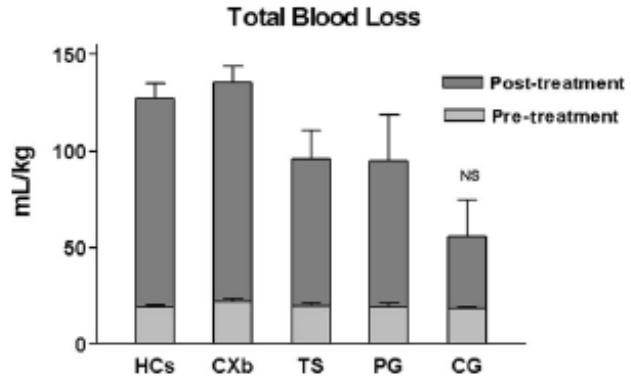

Figure 2. The pretreatment and posttreatment blood loss (mean ± SEM) of pigs treated with hemostatic dressings. No difference was found in initial hemorrhage (pretreatment blood loss) among groups. The posttreatment blood loss in CG was <50% of the volumes in the other groups (TS or PG), but this difference was not statistically significant (HCs and CXb data were not included).

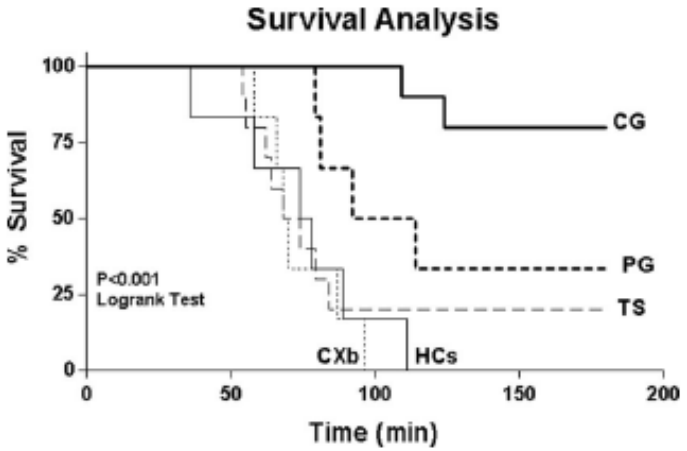

Figure 4. Kaplan-Meier analysis of survival time of pigs treated with each dressing. The CG-treated animals lived significantly longer than PG- or TS-treated ($p < 0.05$) pigs.

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- Results & Conclusions:
  - CG treated animals demonstrated less blood loss (not significant) and significantly higher MAPs
  - Survival:
    - Combat Gauze = 80%
    - Trauma Stat = 20%
    - Placebo Gauze = 33%.
  - Combat Gauze was the most efficacious dressing
    - It works by increasing blood clotting activities and the formation of a hemostatic clot
    - Thus it might not be as effective in the coagulopathic patient

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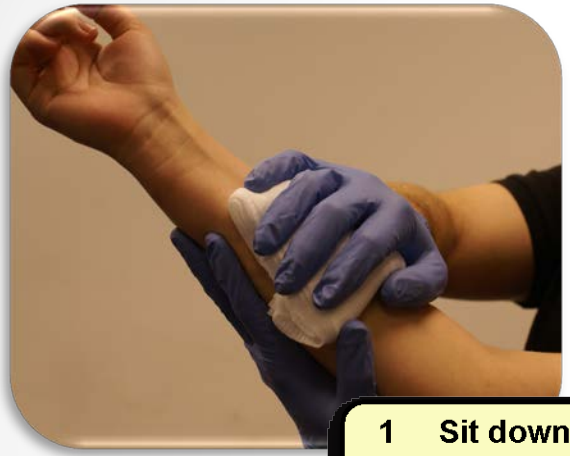
DOI: 10.1097/TA.0b013e318216b796

Study Question

Are hemostatic bandages effective in the absence of compression?

- Hemorrhage control
- Blood loss
- MAP
- Survival

Bleeding Wound



Direct Pressure

1. Use 4x4 cotton gauze if available
2. Use gloves if available
3. Hold pressure for at least 5 minutes

Categorize Bleeding

MILD

1. Sit down out of direct sunlight
2. Apply sterile 4x4 cotton gauze to cover wound
3. Wrap with rolled cotton gauze

SERIOUS

Serious Bleeding

Serious

- Decreased alertness
- Bright red blood
- Spurting blood
- Large quantity of blood

- External Emergency Response Activated
- Bleeding is Serious
- Direct Pressure is Being Applied

1. Sit down out of direct sunlight
2. Apply QuickClot® Advanced Clotting Sponge to wound
3. Apply The Emergency Dressing (Trauma Wound Dressing) over the Sponge

Bleeding Controlled

YES

1. Await Emergency Responders or Seek Immediate Medical Help
2. Reassess Bleeding Control

NO

1. Apply Combat Application Tourniquet®
2. Await Emergency Responders or Seek Immediate Medical Help

Hemorrhage Control

1. No one should die from a compressible extremity wound

2. Rapidly and appropriately applied direct pressure is a critical intervention

3. Hemostatic bandages are effective when utilized as specified

4. Tourniquets save lives when used early in the setting of major limb trauma