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

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

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

COL John F. Kraigh, Jr., MC, USA.*, Thomas J. Walters, PhD, David G. Baer, PhD, LTC Charles J. Fox, MC, USA, Charles R. Wade, PhD, Jose Salaman, PhD, and COL John B. Holcomb, MC, USA.*

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

Study Design: A retrospective survey of patients who required tourniquets was performed over seven months in 2006. The study was approved by the institutional review board. Follow-up data were obtained by telephone and electronic medical records.

Results: Over the study period, 359 patients received tourniquets. Among all the patients, 31 (8.6%) died. Among those patients who survived, 93 (16.1%) died. No patients who received emergency tourniquets died. Emergency tourniquet use clearly saved lives.

Conclusion: Emergency tourniquet use should be considered a first-line treatment for major limb trauma.

Methods: A prospective survey of patients who required tourniquets was performed to determine the efficacy of emergency tourniquets. The study was approved by the institutional review board.

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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
Study Question

Does the use of emergency tourniquets save lives?

- Under what circumstances
- What are the complications

Objective: The purpose of this study was to determine if emergency tourniquets save lives.

Summary Background Data: Tourniquets have been proposed as life-saving 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 (NCT00147188 at ClinicalTrials.gov). Follow-up averaged 28 days. The study was at a combat support hospital in Baghdad. Among 2454 injured and admitted civilian and military casualties with major limb trauma, 232 (9%) 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 outcomes.

Results: There were 51 deaths (39%). Tourniquet use when shock was absent was strongly associated with survival (60% vs. 83%; P = 0.001). Prehospital tourniquets were applied in 184 patients of which 22 died (11% mortality), whereas 18 patients had ED application of which 9 died (50% 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).

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


From the 478 Army Institute of Surgical Research, Fort Sam Houston, TX, and Walter Reed Army Medical Center, Georgia Avenue North West, Washington, DC.

Study performed at 10th Combat Support Hospital, US Army Task Force North, APO AE 09146, Ibn Sina Hospital, Intensive Care Unit, Baghdad, Iraq.

COL Krugh conceived and designed the study, collected the data, analyzed data, and wrote the manuscript. Dr. Walter and Drs. Flor accepted in conception, design, and writing. MAH Fox, Dr. Wade, and COL Holcomb participated in data collection, analysis, and writing. Dr. Fazio participated in design, analysis, and writing. Drs. Wade, Bearer, and COL Krugh participated in the regulatory environment.

The funding of this work was in the United States Army Institute of Surgical Research, and the study was approved by the institutional review board. The study was conducted at Ibn Sina Hospital, Intensive Care Unit, Baghdad, Iraq. This was a prospective observational study with cohort and subgroup analyses. All patients at the combat support hospital with 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. Patients and prisoners of war are not authorized to participate in 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.

METHODS

Study Design

The protocol was approved by the institutional review board, and the study was registered (NCT00651716 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 study 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. Patients and prisoners of war are not authorized to participate in 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, ED, or ICU), mechanism of injury (stab, bullet, blast, etc.), and outcomes (survival, amputation, etc.).
Survival With Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma

• Methods
  o Study Design
    • Prospective observational study
    • Cohort and subgroup analysis
    • All patients presenting to the hospital with a tourniquet were included
  o Definitions
    • Tourniquet = any limb constrictive device used to stop extremity bleeding
    • Use categorized:
      o Geographically
      o Physiologically
  o 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
  o 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
  o Survival Rate Was Higher in Patients With Tourniquets Used Versus Tourniquets Not Used - **Effective**
  
  o Survival Rate Was Higher if Shock Was Absent Before Tourniquet Use Than if it Was Present – **Early is Better**
  
  o Survival Rate Was Higher With Earlier Application (Prehospital) of Tourniquet - **Early is Better**
  
  o Palsies Were Infrequent and Transient With Tourniquet Use
Kragh 2009

Update to Original Study

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

Prehospital Utilization
Determining of Efficacy of New Hemostatic Dressings in a Model of Extremity Arterial Hemorrhage in Swine

Brijan S. Kherajradi, PhD, Michael R. Scherer, MA, J. Scot Estes, DVM, Michael A. Dubick, PhD, and John B. Holcomb, MD

Hemostatic Bandage Use

Background: The HemCon® HC® bandage and QuickClot® have been used over the past 5 years for treating external unrecoverable hemorrhage in combat casualties. Previously, we tested these new hemostatic agents in guinea pig wound models that were exposed to these products. In this study, we now demonstrated that these agents are more suitable for battlefield applications by testing the efficacy and acute safety of the dressings were used in a standard arterial hemorrhage model.

Methods: HemCon® HC® dressings (n = 47), QuickClot® (n = 34), and arterial control group (n = 18) were tested. Hemorrhage from wounds with hemorrhage rates of 60 ml/min was assessed. Hemorrhage control was defined as the ability to stop bleeding or significantly reduce blood flow

Results: Hemorrhage control was significantly better for the HemCon® HC® dressings (n = 6) and QuickClot® (n = 7) groups compared to the control group (n = 1). Hemorrhage control was defined as the ability to stop bleeding or significantly reduce blood flow. QuickClot® and HemCon® HC® dressings were significantly better than arterial controls (p < 0.05).

Conclusion: HemCon® HC® and QuickClot® dressings were significantly better than arterial controls in controlling hemorrhage from a standard arterial hemorrhage model.

Key Words: Combat dressing, Trauma, Critical Care, Hemostatic dressings, Hemorrhage control. Submitted for publication February 9, 2000. Accepted for publication April 1, 1999.

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Original Article

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

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

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

Methods: Twenty-four Swiss mice were anesthetized. Hemorrhage was induced by clamping the femoral artery of the mouse. Efficacy of different dressings was determined by measuring blood loss and mortality. Results: Advanced hemostatic dressings were not superior to standard gauze in terms of blood loss and mortality. However, they were better than gauze in terms of time to stop bleeding.

Conclusion: Advanced hemostatic dressings are not superior to gauze for care under fire scenarios.

Key Words: Combat dressing, Trauma, Critical Care, Hemostatic dressings, Hemorrhage control. Submitted for publication February 9, 2000. Accepted for publication April 1, 1999.

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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
  o Decrease bleeding time
  o Increase MAP
  o 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
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

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

Background: The HemCon (HC) bandage and QuikClot have been used over the past 4 years for treating extremity compressible hemorrhage in combat casualties. Previously, we tested three new hemostatic agents in granular/powder form that were applied to these products. In this study, four new dressings (preclinical formulations 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 = 18, 37 kg) were instrumented, and arterial blood was collected for hematological and coagulation assays. After exsanguination, the large femoral artery was isolated, injured (6 mm arteriotomy), and uncontrolled bleeding allowed for 45 seconds. A hemostatic dressing (HC RT3 [n = 5], Cuscin-D [n = 6], TraumaStop [n = 10], Combat Gauze [n = 10], or placebo gauze [n = 10]) was then applied over the wound and compressed for 5 minutes. Fluid resuscitation was administered and titrated to maintain a mean arterial pressure of 75 mm Hg. Animals were observed for 10 minutes or until death. Computed tomography angiography was performed on survivors and transfusions were collected for analysis.

Results: No differences were found in baseline blood pressure, pulse rate, heart rate, or mean blood pressure among groups. HC and Cuscin-D dressing demonstrated a significantly lower mean blood loss and shorter survival time (p < 0.05) compared to other treatments, but differences were not statistically significant. The mean survival time of HC-treated animals (34.6 minutes ± 22.2 minutes) was significantly longer than both HC RT3 (28.9 minutes ± 22.2 minutes, p < 0.05) and placebo dressing (28.5 minutes ± 22.2 minutes, p > 0.05). The mean survival time of Cuscin-D-treated animals (53.9 minutes ± 22.2 minutes) was also significantly longer (p < 0.05) than that of HC RT3 (28.9 minutes ± 22.2 minutes) and placebo dressing (28.5 minutes ± 22.2 minutes). Postmortem examination of the pigs showed that the group treated with HC RT3 had the least blood loss (17.2 ± 13.3 mL/kg) compared to the other groups (28.9 ± 13.8 mL/kg and 27.5 ± 22.8 mL/kg), but this difference was not statistically significant. The mean survival time of animals treated with HC RT3 was significantly longer (p < 0.05) than that of HC (28.9 minutes ± 22.2 minutes) and placebo dressing (28.5 minutes ± 22.2 minutes). Postmortem examination of the pigs showed that the group treated with HC RT3 had the least blood loss (17.2 ± 13.3 mL/kg) compared to the other groups (28.9 ± 13.8 mL/kg and 27.5 ± 22.8 mL/kg), but this difference was not statistically significant.

Conclusion: HC was the most effective dressing tested in our arterial hemorrhage model. The hemostatic property of HC is attributed to its raw material (granulocyte monocytes, and fibrinogen), as well as the large surface area of the dressings. HC is now recommended as the first line of treatment for life-threatening hemorrhage on the battlefield, replacing HC.

Key Words: Combat gauze, TraumaStop, Cuscin-D, HemCon, Hemorrhage control, Side effect, Swine

U ncontrolled hemorrhage is the leading cause of death (50%) among combat casualties and the second major cause of death in civilian trauma patients. Massive bleeding and trauma are major risk factors leading to the lethal trial of life-threatening coagulopathy, which includes persistent hypothermia, metabolic acidosis, and inability to form clot and establish hemostasis. Hemorrhage also plays a significant role in late morbidity and mortality because of multiple organ failure, and it may also be caused by prolonged hypotension, sepsis, and massive red cell and plasma product transfusion.
Determination of Efficacy of New Hemostatic Dressings in a Model of Extremity Arterial Hemorrhage in Swine

• **Methods**
  o **Study Design**
    • Controlled experimental trial
    • Swine model of severe hemorrhage
    • Comparison of 4 hemostatic bandages and one standard gauze bandage (PB)
      o Trauma Stat (TS) – Silica and Chitosan
      o Combat Gauze (CG) – Kaolin
      o Celox-D (CXb) – Chitosan
      o HemCon-RTS (HC) - Chitosan
  o **Statistical Analysis**
    • Descriptive
    • Chi-squared and student-t
    • Kaplan-Meier survivorship analysis
Determination of Efficacy of New Hemostatic Dressings in a Model of Extremity Arterial Hemorrhage in Swine

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

• Results & Conclusions:
  o CG treated animals demonstrated less blood loss (not significant) and significantly higher MAPs
  o Survival:
    • Combat Gauze = 80%
    • Trauma Stat = 20%
    • Placebo Gauze = 33%.
  o 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
Study Question

Are hemostatic bandages effective in the absence of compression?

- Hemorrhage control
- Blood loss
- MAP
- Survival

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-five mice received a femoral artery injury, 30 seconds uncontrolled hemorrhage and randomization to packing with SG, Combat Gauze (CG), or Celox Gauze (CG) without external pressure. Animals were randomized to baseline mean arterial pressure 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 8/10, CG 8/8, XG 8/8) or blood loss between groups (SG 246 ml, CG: 244 ml, XG: 224 ml, p > 0.05). At 45 minutes, all groups had a significantly better time to clot formation compared with baseline (p < 0.05). At 30 minutes, the CG animals had a shorter time to clot compared with SG and CG animals (p < 0.05). All histology sections had well formed and well formed figures. No inflammation, necrosis, or deposition of dressing particles in vessels wall 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 simular to a care under fire scenario.

Key Words: Hemostatic dressing, Care under fire, Combat Gauze, Celox Gauze, Hemostatic x-kick. 

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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. Studies show noncomparable truncal hemorrhage to be the principle cause of death but compressible extremity hemorrhage also contributes to significant numbers of potentially preventable deaths. 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 torso/ticket application as the method of extremity hemorrhage control in care under fire scenarios (Fig. 1). Hemorrhage from wounds in areas not amenable to torso/ticket 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 non-capable to be applied. Unfortunately, some of the most effective granular agents designed to treat this type of injury result in local tissue destruction and distal thromboembolic events. 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. 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 seeks to minimize the necessary compression times compared the effectiveness of TraumaStat (OneMed, Lebanon, OR), Clotboost (HemCon, Portland, OR), and SG in a groin vessel transaction model, using a 30-second hold time and found TraumaStat to be superior.* 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.* 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 nonswollen chitosan-derived
Bleeding Wound

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

MILD

Categorize Bleeding

SERIOUS

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

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

Bleeding Controlled

YES

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

NO
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