

Study Title: Prospective, observational multi-center analysis of pre-hospital tourniquet use in extremity injury

1. Study aim, background, and design

Tourniquets have a longstanding though controversial role as a lifesaving measure for hemorrhage from severe extremity injuries. Despite limited evidence regarding complications associated with tourniquet use, they have traditionally not been advocated in the civilian population because of concern for iatrogenic injuries such as nerve palsy, limb ischemia, and increased amputation rates.¹ However, recent military conflicts in Iraq and Afghanistan have seen resurgence in tourniquet use with military studies showing increased survival and few long term complications when tourniquets were applied in the field.²⁻⁵ Accordingly, it has been proposed that tourniquets could be used in the management of civilian trauma patients with severe limb injuries.⁶⁻⁹ Despite this increased interest, few studies have evaluated tourniquet use in civilians.¹⁰⁻¹¹

We recently published a retrospective multi-institutional analysis of pre-hospital tourniquet use for civilians transported to 9 US Level 1 trauma centers.¹² Our study showed that tourniquets were applied effectively and with similar rates of complications as seen in military studies. However, due to the retrospective nature of our study we were unable to determine whether tourniquets had an effect on outcomes. We now propose to conduct a second phase of our study consisting of prospective data collection for all patients with extremity injuries presenting to participating centers with or without tourniquets in place to determine whether tourniquet placement has an effect on outcomes. This is an observational study consisting of prospective data collection only and will not entail changes in treatment based upon enrollment in the study.

Objective: To compare outcomes of patients with extremity injuries presenting with or without pre-hospital tourniquet placement. We hypothesize that prehospital tourniquet use will result in improved outcomes compared to non-use in similarly injured patients without a significant increase in complication rates.

Primary Outcome: Incidence of arrival in shock (SBP <90.) **Secondary Outcomes:** Tourniquet effectiveness (as determined both subjectively by trauma surgeon and objectively by presence vs absence of pulse below level of tourniquet application), total number of units of blood products transfused within first 24 hrs, 24 hr and overall mortality, and complication rates including amputation, nerve palsy, ischemia/reperfusion injury, compartment syndrome and secondary infection.

2. Subject Population

Inclusion Criteria: All adults (18 years or older) who present to participating emergency departments with extremity injuries either: a) with a tourniquet in place OR b) who the treating physician deems could have

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benefitted from tourniquet placement. All patients who present to the participating EDs who meet inclusion criteria will be identified by the treating trauma surgeons.

Power analysis: Using data from our previously conducted retrospective study, we have found 8.3% of tourniquet patients arrive in shock (SBP <90) vs 13% of similarly injured non-tourniquet patients, with an enrollment ratio of 2:1 non-tourniquet to tourniquet patients. For 80% power and p 0.5 we estimate we will need to enroll 1479 total patients in our current prospective study. We estimate each large trauma center participating in this study should be able to enroll an average of 40 patients per year. If this study runs for 3 years, we will need 13 participating trauma centers to adequately power this study.

Exclusion criteria: Children, prisoners, pregnant women, patients with non-traumatic bleeding requiring tourniquet use.

3. Procedure

Data points to be collected: (please see attached data collection tool)

Age
ethnicity/race
sex
length of followup
injury mechanism (gunshot wound, stab wound, blunt/crush, blast injury, or other)
Injury severity score (ISS)
abbreviated injury score (AIS) of the injured limb or limbs
incidence and type of non-extremity injuries
incidence of improvised tourniquet placement at the scene
materials used
effectiveness and length of time in place
incidence of commercial tourniquet placement, type, effectiveness
time between injury and tourniquet application
total time tourniquet in place (both commercial and improvised)
vital signs including systolic blood pressure (SBP), heart rate (HR) and Glasgow Coma Score (GCS) both at time of tourniquet application and at arrival to the emergency department.
volume prehospital crystalloid and blood products infused
Outcomes:
total number of blood packed red blood cells (PRBCs) and fresh frozen plasma (FFP) transfused in the first 24 hours
amputation incidence and indication (traumatic, completion, loss of function, inability to re-perfuse, other)
nerve palsy incidence and location (level of tourniquet vs injury)
incidence of other complications including ischemia/reperfusion injury, compartment syndrome, and secondary infection
incidence of mortality, hospital day of occurrence and whether or not attributable to hemorrhagic shock

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4. Risks

This study qualifies as minimal risk research. The only risk to the patients enrolled in this study is a risk of confidentiality. This is a prospective observational study only with de-identified data. We will apply for a waiver of informed consent due to negligible risk to the patients in this study. Patients will be identified for enrollment by the treating trauma surgeon in the emergency department. Data collected on individual collection sheets which will be given to the PI who will keep them in a locked cabinet until such time as the de-identified information can be entered in a database after which point they will be shredded. The database will be located on the computer in the PI's locked office and password protected.

5. Benefits

There is no benefit to the patients who are enrolled in the study; however information learned from this analysis has potential to benefit future patients in helping to understand the risks/benefits of tourniquet use in civilian patients.

6. Remuneration

There will be no payment for participation in this research study.

7. Academic or Extra Credit

N/A

8. Costs

There will be no costs to the subject for participating in this research study.

9. Alternatives

N/A. There will be no intervention or change in treatment course for subjects in this study as it is purely observational.

10. Consent process and documentation

We are applying for waiver of informed consent due to the nature of our study.

11. Qualifications of the investigators

Rebecca Schroll, MD, is Assistant Professor of Clinical Surgery and a trauma surgeon at Tulane University School of Medicine and practices at University Medical Center.

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Alison Smith, MD is a surgery resident at Tulane University School of Medicine. Both Dr. Schroll and Dr. Smith have previously conducted multi-center research regarding pre-hospital tourniquet use in trauma patients.

12. References

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