

Form "EAST Multicenter Study Proposal"

Details #62 (submitted 09/20/2018)

Study Title Multi-center Trial Examining Prehospital Procedures in Penetrating Trauma Patients.

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My Multicenter Study proposal is... Prospective

Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined

The establishment of Advanced Life Support by emergency medical services has led to an increasing number of procedures carried out in the field. These procedures, such as IV fluid administration and intubation, can be beneficial in traumatic brain injury, and in rural settings where transportation to definitive care is prolonged, however, retrospective studies have shown that prehospital procedures in penetrating trauma patients in urban locations are not beneficial. Despite this, prehospital procedures continue to be carried out in the field on a regular basis.

Primary aim

Determine if penetrating trauma patients brought to the hospital without prehospital procedures (specifically endotracheal intubation, IV fluid administration, and spine immobilization) have a survival advantage over those that did not.

Secondary aims

Determine if patients that do not receive prehospital procedures have decreased morbidity as measured by hemodynamics, laboratory values, development of complications, development of organ failure, length of stay, ICU length of stay. Determine if patients brought in by private transport have better survival than those brought in by medical transport crews (BLS, ALS).

Inclusion Criteria

1) Penetrating trauma patients, age 18 or older, with gunshot or stab wound to the torso, presenting at urban trauma centers. (Torsodefined as area between clavicles, proximal to elbows and above inguinal ligaments, pubic symphysis, and gluteal folds) AND

2) Patients with combined torso and extremity penetrating injury OR

3) Patients with combined penetrating torso injury and blunt injury

1)Those with injury above the clavicle only, including head injury.

2)Patients with combined torso and injury above the clavicle

3)Patients with extremity injury only

Exclusion Criteria

4)Patients with isolated blunt mechanism of injury

5)Patients that are transferred from outside institutions

6)Patients under the age of 18

Therapeutic Interventions

Prospective observational study only. Patients will be managed according to prehospital responder protocols.

Survival or Mortality Location: ED, OR, ICU, floor, 30-day mortality, 3-month mortality

Primary Outcome

Secondary Outcomes

Development of organ failure, development of complications such as ARDS, DVT/PE, AKI, UTI, stroke, brain death, length of stay, ICU length of stay, ventilator days

1)Demographics such as age, gender, race, penetrating injury type (knife, GSW), blunt injury type (if present), injury anatomical location: Torso with non-compressible hemorrhage (yes, no), Extremity with compressible hemorrhage (yes, no), Junctional with compressible hemorrhage (yes, no)

2)For patients transported by EMS: Initial GCS, Initial Heart Rate, Initial Systolic Pressure, Shock Index (SI), Trauma CPR code (yes, no), length of time from initial 911 call to on scene dispatch, length of time on scene, length of time from on scene to trauma center.

3)For patients transported by private own vehicle: trauma CPR code (yes, no) length of time from initial injury to arrival to trauma center.

4)Type of transport (private vehicle, police vehicle, fire department, BLS crew, ALS crew)

5)Prehospital EMS interventions (IV access, IO placement, IVF initiated, IVF volume in ml, endotracheal intubation, C-Spine immobilization, Full-Spinal immobilization, needle decompression, cricothyroidotomy, tourniquets, pressure dressing, pelvic immobilizers, extremity immobilizers)

List specific variables to be collected & analyzed

6)Prehospital private own vehicle interventions: pressure dressing, tourniquets.

7)Emergency Department: Initial GCS , Initial Heart Rate, Initial Systolic Pressure, Shock Index (SI), Injury site (s), Injury Severity Score (ISS), Abbreviated Injury Score (AIS),

8)Emergency Department resuscitation: IV access, IO Access, crystalloids (type, volume in ml), MTP activated (yes, no), Ratio of PRBC, FFP, TXA, Trauma Code CPR (yes, no), Thoracotomy (yes, no), Clamshell (yes, no), REBOA (yes, no)

9)Emergency Department laboratory values: Initial TEG, PT, PTT, INR, lactate, ABG, basic metabolic panel, and CBC

10)Patient underwent Damage Control Intervention (yes, no), Extremity (yes, no), Abdomen (yes, no), number of surgical interventions

The study will be carried out through a secure, deidentified web-based data entry system, REDCap. Each center will be able to enter their data in a secure data collection instrument; allowing study staff to monitor subjects. Communication via secure email, telephone and monitoring the data collection instrument will provide exchange of information and questions.

Comparisons will be made based on types of prehospital procedures performed and modes of transport used. The endpoints listed above will then be compared between the different groups. The statistics performed will be t-tests and/or Mann-Whitney U and chi-square. Multiple variable analysis will be carried out using logistic regressions with any end-data points with p-value <0.2.

Outline the data collection plan and statistical analysis plan succinctly

Our power analysis is based on data from prior retrospective studies. To detect a 7.5% difference in absolute risk of overall mortality of penetrating trauma patients transported by private vehicle vs EMS, a total sample size of 840 (140 in PV, 700 in EMS) (with a 2-sided alpha of 0.05 and assuming an allocation ratio of 5 to 1) will have 80% power to detect to detect a difference. This will also yield 80% power to detect a 10% difference in absolute risk of mortality in patients transported by EMS who receive pre-hospital ALS vs BLS procedures.

Outline consent procedures here, if applicable

This is a prospective observational study only so consent will not be necessary as patients will be managed according to surgeon discretion.

Succinctly outline a risk/benefit analysis

Retrospective studies have shown that prehospital procedures, such as IV fluid administration and intubation, are not beneficial in penetrating trauma patients in urban locations. Despite this, prehospital interventions continue to be performed on a regular basis in this patient population. A factor that may contribute to worse outcomes include increased time to definitive control of hemorrhage. In addition, these procedures cause physiological changes in penetrating trauma patients that exacerbate severe hemorrhagic shock. A multi-institutional trial will help determine if prehospital procedures in this specific patient population are truly harmful and allow for changes in care that improve outcomes.

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Taghavi S, Jayarajan SN, Khoche S, Duran JM, Cruz-Schiavone GE, Milner RE, et al. Examining prehospital intubation for penetrating trauma in a swine hemorrhagic shock model. *J Trauma Acute Care Surg.* 2013;74(5):1246Y1251.

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**Include a brief listing of
key references**

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