EAST MULTICENTER STUDY PROPOSAL
(Proposal forms must be completed in its entirety, incomplete forms will not be considered)

GENERAL INFORMATION

Study Title:
Hemothorax Management and Outcomes in Blunt and Penetrating Trauma

Primary investigator / Senior researcher:
Jeremy Cannon, MD, SM, FACS

Co-primary investigator:
Mark Seamon, MD, FACS

BACKGROUND AND SIGNIFICANCE

Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined:
The true incidence and outcomes of traumatic hemothorax remains unknown. The landmark study by the AAST Retained Hemothorax Study Group described the management course in these patients once a retained hemothorax has been identified. However, management during the index presentation with a hemothorax remains poorly quantified. In addition, interventions which might mitigate the progression of a hemothorax to either a retained hemothorax or empyema have not been fully characterized.

Presently, the management options for primary traumatic hemothorax include observation, open tube thoracostomy, percutaneous/small-bore tube thoracostomy, or surgical drainage. To fully characterize the ideal management strategy for hemothorax following blunt or penetrating trauma, the natural history of this disease needs to be captured from initial presentation through to post-discharge follow-up.

The specific aims of this multicenter study are:
Primary aim:
Primary aim should be succinctly stated here – single sentence ideal:
We aim to fully characterize the incidence and outcomes of hemothorax management in blunt and penetrating trauma.

Secondary aims:
Any secondary aims should be stated here:
EXPERIMENTAL DESIGN/METHODS

Inclusion Criteria:
Any age, blunt or penetrating trauma resulting in a hemothorax of any size on initial Chest CT on the day of admission for trauma.

Exclusion Criteria:
None

Therapeutic Interventions:
Prospective observational study managed at the surgeon’s discretion with observation through the 1st follow-up visit post-discharge.

Outcomes Measures:
Primary Outcome:
(List here)
Retained hemothorax ≥ 300 mL on Chest CT obtained at any time after initial Chest CT

Secondary Outcomes:
(List here)
Death
Hospital Length of Stay
Ventilator-free days in 1st 30 days of admission
Glasgow Outcomes Scale-Extended
SF-36
Fibrothorax
Empyema
Number of interventions including tube thoracostomy, VATS, thoracotomy or other procedures

Variables:
List the specific variables to be collected and analyzed here. For organization, it is useful to divide these into categories for consideration. Examples of categories might include: Demographics, Admission physiology, Management variables, Surgical variables, Outcomes
DEMOGRAPHICS
Age
Gender
COPD/Home O2
Antiplatelets/Anticoagulants
Obesity (BMI)

ADMISSION PHYSIOLOGY
HR
Blood Pressure
HCT
Cr
INR
Base Excess
Lactate

INJURY CHARACTERISTICS
Mechanism of injury (blunt, penetrating, both, other)
Hemothorax Side
Hemothorax Size (mL--measured on CT)
Diaphragmatic injury
Rib fractures (number, location)
Flail chest
ISS
AIS head
AIS chest
AIS abdomen
Pulmonary contusion

MANAGEMENT
Initial Management-Injury Day 1
   Observation
   Open tube thoracostomy
   Percutaneous tube thoracostomy ("pigtail")
   VATS
   Open Evacuation
Estimated Hemothorax Evacuated (mL)
Antibiotics used
YATS used

Follow-up CT Imaging
   Indication (abnormality on CXR, respiratory symptoms, other)
   Day of follow-up imaging
   Size of retained hemothorax or effusion, if present (mL)
   Other findings (PE, consolidation, pneumatocele)

Management—Injury Day 2 to Discharge
   Successful initial management
   Subsequent tube (injury day)
   Subsequent thrombolytics (injury day)
   Subsequent VATS (injury day)
   Subsequent Thoracotomy (injury day)

OUTCOMES
   Retained hemothorax (describe management)
   Death
Discharge (LTAC, SNF, Rehab, or Home)
Hospital LOS
Ventilator-free days in the first 30
Post-discharge visit x1
Post-injury day at follow-up
CXR findings on post-discharge visit (if obtained)
CT findings on post-discharge visit (if obtained)
Empyema (describe management and cultures)
Fibrothorax
Glasgow Outcomes Scale-Extended (at discharge, at 1st follow-up and at 6 months)
SF-36 (at 1st follow-up and at 6 months)
Need for additional interventions after initial discharge

Data Collection and Statistical Analysis:
Outline the data collection plan and statistical analysis plan succinctly here

The above data will be collected on each patient starting within 24 hours of admission and continuing through their hospital course. Follow-up data will be collected within 24 hours of their post-discharge visit. Data will be entered into a de-identified online data repository. Target enrollment is 500 patients over 2 years. Risk factors for retained hemothorax or empyema development will be assessed using univariate and multivariate analysis. Continuous variables will be compared using Student’s t-test and the Mann Whitney U test. The Chi-squared tests or Fisher’s exact test will be used to compare categorical variables. All variables with a p value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis to identify independent risk factors for retained hemothorax or empyema development. Data will be reported as adjusted odds ratios with 95% confidence intervals. Statistical significance will be set at a p<0.05.

Consent Procedures:
Outline consent procedures here, if applicable. As an example for a prospective study where waiver of consent will be sought, verbiage might include:

“This is a prospective observational study, designed to prospectively record data on patients who are managed according to institutional patient management protocols. Thus, waiver of informed consent is requested. Data will be recorded on a data sheet and transferred to a secured database that is devoid of patient identifiers.”

This is a prospective observational study intended to record data on patients who are managed according to institutional patient management protocols. Waiver of informed consent will be requested; however, we appreciate that some institutional IRBs may request formal consent from the patient or a legally authorized representative. Data will be recorded on a data sheet and transferred to a secured database that is devoid of patient identifiers.
Risk/ Benefit Analysis:
Succinctly outline a risk / benefit analysis. An example of this might include:

“The incidence and natural history **DISEASE PROCESS TO BE STUDIED** is unknown. If the optimal timing for and type of intervention can be identified to optimize outcomes in these patients, then significant benefit will result.”

The incidence and natural history of traumatic hemothorax is unknown. If the optimal timing for and type of intervention can be identified to optimize outcomes in these patients, then significant benefit will be realized by future patients.

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**Instructions for submitting data collection tools:**
All data submissions should be entered through the EAST Multicenter Trial Taskforce website portal. Instructions can be found on the EAST website. The data collection sheet located under the Multicenter Trial Taskforce heading for this study can be utilized to record the data, and then the information transferred to the portal entry system. For any questions regarding this study, please contact the PI.
References:

Include a brief listing of key references here:


