EAST MULTICENTER STUDY PROPOSAL

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 non-perative management options for primary traumatic hemothorax include observation, open tube thoracostomy, percutaneous/small-bore tube thoracostomy, or Yankauer-assisted evacuation (i.e. "YATS"). 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: We aim to fully characterize the incidence and outcomes of hemothorax management in blunt and penetrating trauma.
Hypothesis: YATS results in fewer moderate to large retained hemothorax as compared to all other non-operative techniques

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:
Hemothorax requiring initial operative evacuation.

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:
Retained hemothorax ≥ 300 mL on chest CT (moderate-large) obtained at any time after initial chest CT

Secondary Outcomes:
Death
Hospital length of stay
Ventilator-free days in 1st 30 days of admission
Glasgow Outcomes Scale-Extended
SF-36
Empyema/pleural infection
Number of interventions including tube thoracostomy, VATS, thoracotomy or other procedures

Variables:

DEMOGRAPHICS
Age
Gender
COPD/Home O2
Antiplatelets/Anticoagulants
Obesity (BMI)
Interval from trauma to hemothorax diagnosis (hours)
ADMISSION PHYSIOLOGY
HR
Blood Pressure
HCT
Cr
INR
Base Excess
Lactate
TEG/TEM

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")
"YATS"
Estimated hemothorax evacuated (mL)
Antibiotics 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 (pneumothorax, pulmonary embolism, consolidation, pneumatocele)

Management—Admission 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)
Persistent/loculated pneumothorax (describe management)
Hemo-pneumothorax (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
Data Collection and Statistical Analysis:
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 640 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 identify differences among management techniques. 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:
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:
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.

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:


EAST MULTICENTER STUDY PROPOSAL
HEMOTHORAX
MANAGEMENT & OUTCOMES IN BLUNT & PENETRATING TRAUMA

DATA DICTIONARY

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Hemothorax</td>
<td>Fluid in the pleural space identified on a CT after trauma to the ipsilateral hemithorax; Hounsfield units of acute blood should be 35-40</td>
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<tr>
<td>Hemothorax Volume</td>
<td>Mergo Definition: ( V = d^2 \times n \times s ) where ( d ) is the A-P depth in cm, ( n ) is number of C-C slices, and ( s ) is the slice thickness in cm</td>
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<tr>
<td>Retained Hemothorax (RH)</td>
<td>Blood-density fluid identified on a CT any time after the initial diagnosis of hemothorax</td>
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<tr>
<td>Large RH</td>
<td>&gt; 900 mL by CT</td>
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<tr>
<td>Moderate RH</td>
<td>301-900 mL by CT</td>
</tr>
<tr>
<td>Small RH</td>
<td>≤ 300 mL by CT</td>
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<tr>
<td>Empyema/Pleural Infection</td>
<td>Positive cultures from pleural fluid; positive Gram stain from pleural fluid; pus drained from the pleural space; pleural fluid with ( pH &lt; 7.2 )</td>
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<tr>
<td>Observation</td>
<td>No intervention on the diagnosed hemothorax</td>
</tr>
<tr>
<td>Open Tube Thoracostomy</td>
<td>Tube thoracostomy placed using a standard open tube technique</td>
</tr>
<tr>
<td>Percutaneous Tube Thoracostomy (i.e. “pigtail”)</td>
<td>Tube thoracostomy using a closed technique with a small bore catheter (10-16 Fr) which assumes a curled shape on entry or with a drawstring</td>
</tr>
<tr>
<td>Yankauer-assisted Thoracostomy (i.e. “YATS”)</td>
<td>Use of a suction device during the initial open tube thoracostomy placement to evacuate part or all of the hemothorax prior to insertion of a tube</td>
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<tr>
<td>VATS</td>
<td>Evacuation of a hemothorax using Video-assisted Thoracoscopic Surgery</td>
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<tr>
<td>Open Evacuation</td>
<td>Evacuation of a hemothorax through a full surgical thoracotomy</td>
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HEMOTHORAX

Management and Outcomes in Blunt and Penetrating Trauma

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Background

**RETAINED** Hemothorax Thoroughly Studied

- DuBose et al. J Trauma. Jan 2012. 328 patients; 20 centers. 27% (88) empyema; 20% (67) thoracotomy

Limited Scope & Multiple Management Strategies

- Only focused on **retained** hemothorax
- No follow-up
- Observation? Pigtail Drainage? “YATS”? 
Aim / Hypothesis

• Fully characterize the incidence and outcomes of hemothorax management in blunt and penetrating trauma.

• YATS results in fewer moderate to large retained hemothorax as compared to all other non-operative techniques.
Methods

• Study Design: Prospective, Observational over 2 years
  - Inclusion criteria: Hemothorax on admission CT
    Mergo definition: depth^2*slices*slice thickness
    Volume in mL: 300 mL—900 mL
  - Exclusion criteria: initial operative evacuation

• Groups: Observation, “Open Tube”, “Pigtail”, “YATS”

• Outcomes
  - Primary Outcome: Retained Hemothorax by CT
  - Secondary Outcomes: Function at 1st follow-up, Empyema/Pleural Infection, Interventions
Methods Analysis Plan

• ANOVA for any differences among groups
• MVLR for independent predictors of retained mod to large hemothorax & secondary outcomes
• Power analysis indicates a need for 160 patients per group
  - 10% absolute reduction in retained hemothorax
  - 640 patients=16 patients/ctr/year
Progress / Needs

• Progress
  - 2 of 20 centers identified (SAMMC & UPenn)
  - Protocol development

• Needs for participating centers
  - IRBs may require consent
  - 0.1-0.25 FTE Research Coordinator
  - Functional assessment in clinic

• Funding?
Goals / Timeline

Protocol Development
July 1, 2015

→ IRB Submission
September 1, 2015

→ Patient Enrollment
January 1, 2016

→ Study Closure
December 31, 2017

→ EAST submission
July 1, 2018
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