

**Title: Chest Tube Use in Trauma: A Western Trauma Association (WTA) Multi-Center Trials Committee (MCTC) Prospective, Observational Study**

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**Sub-Investigators:** Western Trauma Association (WTA) Multi-Center Trials Committee (MCTC) Institutions

**Background:**

Insertion of a chest tube (tube thoracostomy) is a routine component of care used for patients that have sustained traumatic injury to the chest wall, thoracic structures, or lungs. Although chest tubes are used frequently, for a variety of indications, there are many technical details that vary in terms of insertion, maintenance, and removal. Chest tube are the most common procedure performed for thoracic injury and may represent the definitive intervention for upwards of 80-85% of thoracic injuries. Indications for chest tube insertion include the following traumatic injuries: pneumothorax, hemothorax, hemopneumothorax, tension pneumothorax, open pneumothorax, empiric placement for shock of unknown etiology, and potentially prophylactic placement in patients that to be at high risk for respiratory distress. Chest tubes are inserted in the ED, the OR, in the ICU, on the ward, and in some cases in the field. The training and experience of individuals that insert chest tubes also varies widely and may differ significantly between institutions, based on local experience and preferences.

Each year thousands of chest tubes are inserted in trauma patients. Although chest tube insertions are frequent and may be considered "routine", numerous studies have documented complication rates ranging from 9-38% associated with use of chest tubes (1-14). Deaths secondary to chest tube insertion are exceedingly rare, but have been reported (10, 13). Complications reported from chest tubes are listed in Table 1. Furthermore, in addition to the directly harmful complications the presence of a chest tube can complicate pulmonary toilet and ventilator management, delay hospital discharge, and create logistical challenges for patient mobilization and transport. Improper placement or chest tube malfunction may also predispose to retained hemothorax, "trapped lung", and empyema. While chest tubes are commonly used there have been no evidence-based guidelines or best clinical practices regarding their use in trauma patients, although one older guideline exists for "best practice" in non-trauma patients (14).

**Objectives:**

**Primary objective:** Provide a contemporary description of the current use of chest tubes in hospitalized adult trauma patients, including indications, type of tube, technique of insertion, criteria and technique of removal, complications, and experience/training of individuals performing insertion.

**Secondary objective:** Compare use of imaging, duration of chest tube drainage, rate and type of complications, criteria for chest tube removal, hospital LOS, impact of tube size, and a variety of technical factors between institutions.

## **Hypotheses:**

It will be possible to identify differences in techniques, experience, and management of chest tubes,

Opportunities for improvement will be identifiable by comparing chest tube management.

## **Study design:**

- Observational study
- Data points (see Data Collection sheet) will be obtained from medical record review of (all) eligible patients at the participating institutions within the timeframe of the study
- Each participating hospital will receive a hospital identification number. Each patient enrolled will be numbered sequentially starting with #1. Individual chest tube(s) will be noted sequentially with numbers, beginning with the number "1". Local participating investigators need to track individual chest tubes (e.g., upper right, lower right, left anterior superior, etc.).
- A maximum of 10 (total) chest tubes per patient per admission will be tracked
- Patient's names and hospital record numbers will be kept at the local sites, but not entered into the study database. No identifiable PHI will be entered into the study database or shared outside of the respective hospitals.
- Characteristics of participating centers (institutions) will be entered on the Center Information Form (Form CT-A)
- Information will be recorded for each individual subject who meets inclusion/exclusion criteria and about each individual chest tube inserted (#1 up to #10) on the Chest Tube Insertion Information. (Form CT-B)
- Daily information about each individual chest tube will be entered via the Chest Tube Daily Information form. (Form CT-C)
- Information will be collected about removal of each individual chest tube using the Chest Tube Removal Information Form (Form CT-D)
- De-identified information about the hospital course will be recorded on Additional Hospitalization Information page (Form CT-FINAL)

## **Setting:**

- Trauma centers, multi-institutional
- Included hospitals will be trauma centers that have been designated by State agencies or the American College of Surgeons

## **Methodology:**

- A data collection form (see attached) will be used to obtain study-related information about chest tubes placed in trauma patients during the period May 14, 2018 through August 17, 2018 as outlined in the detailed study protocol (see below).
- Information for all trauma patients that meet inclusion/exclusion criteria during the study time frame should be included.
- Institutional description and characteristics will be recorded for each facility participating in the multi-center study.

**Patients:**

- Inclusion Criteria:
  - Patients  $\geq$  18 years of age
  - Primary admission diagnosis of traumatic injury
  - Hospital length of stay  $\geq$  2 days
  - Patient had one or more chest tube placed during admission for traumatic injury.
- Exclusion Criteria: children
  - $<$  18 years of age
  - Death within 48 (?) hrs of admission
  - prisoners.

**Interventions:** *None*

**Study group:** *Not applicable*

**Control group:** *Not applicable*

**Randomization process (if applicable):** *Not applicable*

**Study End Points:**

**Primary End Points:** Duration of chest tube drainage. Chest tube-related complications (including, but not limited to, bleeding, infection/empyema, need for new chest tube)

**Secondary End Points:** Hospital length of stay, ICU length of stay, Duration of mechanical ventilation, Presence of retained hemothorax/ need for decortication procedure.

**Proposed Duration of the Study:** The study will encompass eligible trauma patients who undergo chest tube placement during the 14 week period May 14 to Aug 19, 2018.

**Statistical analysis to power the study:** Descriptive analysis with reporting of continuous variables (mean/std dev or median/25<sup>th</sup> & 75<sup>th</sup> perc) and categorical variables (percentages). For comparisons, t-test, Kruskal-Wallis, chi-square, or Fisher's exact test will be used, as appropriate.

Based on the fact that North Memorial placed chest tubes in 183 patients during 2017, we anticipate that we would identify at least 50 subjects over the 3 month Summer study period. Trauma centers with higher volume would be expected to enroll double that number (~ 100 pts over 3 months). Most multi-center trials through the Western Trauma Association have had participation from 10-20 trauma centers. Therefore, it is estimated that if we have 14 participating trauma centers with an equal number of high ( $>$  4000 trauma admissions) and lower ( $<$  2000 trauma admissions) that there should be information on a total of at least 850 trauma patients. Using the range of reported incidence of chest tube complications (9-38% complication rate), it is reasonable to anticipate that there would the study would identify between 76 and 323 complications. In attempting to estimate the power to analyze differences in the data, assuming an  $\alpha = 0.05$  and a  $\beta = 0.8$  it should be possible to detect a 20% difference (for example 16% vs 20% complication rate) between subgroups as small as 32 subjects in each subgroup.

**Budget:** None

**Feasibility:** Very feasible. Requested information should be readily available from the institution's EHR. Since the design is a contemporaneous descriptive, non-interventional study, there are no risks to study subjects. Only de-identified data will be forwarded to the study coordinator for analysis.

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**Table 1: Complications of Chest Tubes for Trauma (adapted from Mao M, ref#9)**

Bronchopleural fistula  
Vascular injury  
Cardiac Injury  
Diaphragm injury  
Hemothorax  
Retained hemothorax  
Inadequately secured chest tube  
Abdominal organ injury  
Incorrect insertion distance (insufficient or excessive)  
Malposition of the chest tube  
Subcutaneous placement  
Pneumonia  
Empyema  
Mechanical complications  
Tube dislodgement  
Tube kinking  
Tube occlusion  
Thoracic duct injury  
Surgical Site Infection