# Proposal

Background:

Thoracic trauma is extremely common, accounting for up to 25% of traumatic death [1]. Intervention is usually limited to patients presenting with either a pneumothorax (PTX) or a HTX (HTX) [2, 3]. HTX is defined as collection of blood in the pleural cavity or a pleural fluid hematocrit concentration greater than 50%. An estimated 300,000 HTX cases occur annually in the United States of America [1, 4]. It is classified as traumatic, spontaneous, or iatrogenic; with blunt traumatic injury (73.3%) being the most common etiology [4].

A chest radiograph (CXR) and/or ultrasound/FAST may be used to evaluate patients with suspected HTXs; however, both imaging modalities face major limitations[5]. Computed tomography (CT) with intravenous contrast of chest is used to visualize a HTX not apparent or quantifiable on CXR [4, 6]. Patients with traumatic HTX are at an increased risk for multiple serious complications including respiratory failure; hence the current consensus recommendations from the Eastern Association for the Surgery of Trauma (EAST) is to evacuate all cases of HTX with tube thoracostomy (TT) [7]. HTX is effectively managed with TT placement, this intervention carries up to a 21% complication rate. This includes empyema, bleeding, retained HTX, and/or iatrogenic injury [8, 9]. Selective placement of TT can help minimize these risks. On the contrary, a subset of patients may fail initial conservative management and require delayed TT placement. There is a paucity of data comparing outcomes in patients who failed initial observation to those who received TT without initial conservative management [1].

The size of a HTX is crucial in guiding intervention or conservative management [10]. Quantifying the volume of a HTX remains a subject of debate. Several approaches were utilized to deduce a volume for the HTX. Risken et al, quantified pleural measurements as small (<1.5 cm), moderate (1.5-4.5cm), and large (>4.5cm) based on the deepest lamellar fluid stripe at the most dependent portions [5]. These measurements were matched to an approximated total HTX volume. In 1999, Mergo et al designed the proposed method of quantification (VTE), using CT scan, to approximate HTX volume and guide management ($V=d^2xl$; V: volume; d:depth; L: length) . This method was found to be superior to the estimation by visual inspection. Multiple retrospective institutional-based cohort studies were conducted to assess the safety of observational management in patients with a small HTX (<300mL) [11]. Currently, no consensus has been reached regarding the optimal cutoff point for TT placement in trauma patients presenting with HTX.

A guideline was implemented at our institution recommending observation of a traumatic HTX (<300cc) in hemodynamically stable patients. We conducted a retrospective study comparing observation failure and pulmonary complications rates between the pre- (2015-2016) and the post-implementation (2018-2019) cohorts. Based on the results of our recent study, the implementation of the 300cc guideline led to a decrease in TT placement correlated with a decreased LOS with no increase in failure or complication rates. Accordingly, we seek to prospectively observe the current practice across multiple Level I trauma centers in treating

traumatic HTX. We aim to determine the frequency of failed observation. We aim to determine the difference in outcomes between patients receiving early chest tubes to patients who failed initial observation. The results of our proposed multi-center prospective observation study (optimal HTX volume cutoff point) will facilitate future randomized clinical trials comparing observation to TT placement with a better informed size cut-off of traumatic HTX.

Rationale/Purpose of study:

1. Observe the current practice in treating traumatic HTX
2. Determine the frequency and reason for failed initial observation
3. Compare outcomes in patients who failed initial observation to those who received early TT
4. Derive predictors of observation failure
5. Derive a cutoff point volume at which initial observation was determined to be safe

Hypothesis

Moderate HTX (400cc) is a safe cut-off point for observation in traumatic HTX

Primary Outcome measure: Failure of observation

Methods:

*Study design*

This study is a WTA prospective multi-center observational study. IRB approval is required followed by a data use agreement (DUA) between all involved institutions/academic hospitals. Approved study staff at MCW will be responsible for analyzing the data collected from different institutions. Patients will be stratified into observation versus early TT cohorts.

*Study setting*

Adult trauma patients (≥18 years of age) at trauma centers

*Inclusion criteria*

Patients must be 18 years or older and presenting with a traumatic HTX with a CT scan prior to TT placement

*Exclusion criteria*

Patients younger than 18 years old, mortality within 48 hours of admission, no CT scan, or TT prior to CT scan

*Data Collection will be via red-cap*

Pre-TT placement HTX volume will be calculated using Mergo's formula. Early TT is defined as TT placement ≤24 hours of admission. Patient's electronic medical records will be accessed by approved study staff only to collect data. Baseline characteristics (Age, Sex, Race, Gender,

BMI), mechanism of injury, type of injury, time of injury, time of admission, labs on admission, vitals on admission (SBP, HR, $SpO_2$, GCS, AIS, ISS) CXR findings on admission, FAST, CT scan findings on admission (number of rib fractures, presence of pulmonary contusions, concurrent ipsilateral PTX, size of concurrent PTX, volume of HTX, length of HTX, diameter of HTX, presence of bilateral HTX), need for TT, type of TT, reason for TT, irrigation, ED disposition (ICU, regular floor, OR), chest operation, length of ICU stay, length of hospital stay, CXR/CT/Ultrasound findings on day N, inpatient complications (pneumonia, empyema, ARDS, bleeding, progression of HTX, progression of concurrent PTX, retained HTX, physiologic deterioration, mortality), day TT removal, daily TT output, observation failure (TT, VATS or thoracotomy >24 hours after admission), discharge destination (home, rehab, long-term acute care, morgue, hospice), and discharge status (alive or dead)

*Outcomes:*

Observation failure (defined as TT placement > 6 hours after diagnosis of hemothorax), hospital length of stay (LOS), ICU (LOS), pulmonary complications (empyema, pneumonia, iatrogenic PTX, pulmonary embolism, lung abscess, need for VATS, need for TPA) will be reviewed and documented.

*Analysis:*

We will compare baseline characteristics, injury characteristics, and admission findings between both groups. Etiologies of observation failure and volume of HTX will be assessed. This is followed by comparison of outcomes between early TT and observation failure (pulmonary complications, length of stay, TT duration). Multivariate logistic regression model will be constructed to derive predictors of observation failure. Finally, a curve estimation regression will be performed to derive an optimal cutoff point for safe observation in traumatic HTX.

Risks and Safety:

The study possesses minimal risk of breach of confidentiality and privacy. This is an observational study; no interventions will be applied to the patient. Patient will receive the institution's standard of care.

Cost to subjects:

There are no costs incurred to subjects associated with the study except those that have to do with their standard of care.

References:


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