1. Specific Aims

Specific aim 1: Demonstrate difference in rate of treatment failure of percutaneous catheters (PC) compared to chest tubes (CT) in a retrospective cross-sectional analysis of pediatric (< 18 years old) trauma patients with hemothorax (HTX) or hemopneumothorax (HPTX) across multiple institutions.

HTX can occur from blunt or penetrating thoracic trauma. It is rare in children, as thoracic trauma accounts for only 7-13% of all pediatric traumatic injuries.[1] Evacuation of HTX or HPTX with tube thoracostomy is diagnostic and therapeutic, allowing for evaluation of the volume of blood loss and whether hemorrhage is ongoing, as well as for re-expansion of the lung. Ongoing hemorrhage requiring operative intervention is suspected if the immediate blood volume return through the chest tube is >15 ml/kg or ongoing losses >2-3 ml/kg/hr for ≥3 hrs.[2]

Current recommendations for HTX or HPTX that is symptomatic or visible on chest x-ray includes the use of chest tubes (CT) of increasing size based on patient weight, with 20-french size recommended for children as small as 12 kg.[3] In adults, a meta-analysis demonstrated no difference between the retained hemothorax rates using 14-French percutaneously inserted pigtail catheters (PC) compared to conventional chest tubes, and the rate of re-intervention after PC was lower compared to CT (≥20-French).[4] Therefore, the Eastern Association for the Surgery of Trauma conditionally now recommends PC for HTX in hemodynamically stable adult trauma patients.[4] However, there is a paucity of data for pediatrics and no such existing recommendation.

We aim to describe differences among pediatric trauma patients with HTX or HPTX between PC and CT in terms of failure, defined by requirement for second PC or CT, thoracoscopy/thoracotomy or fibrinolytic agents for retained hemothorax.

Specific aim 2: Compare length of stay, intensive care unit (ICU) length of stay (LOS), CT or PC days, complications between PC and CT in a retrospective cohort of pediatric trauma patients with HTX or HPTX across multiple institutions.

Based upon adult data, we hypothesize that PC in this population will not be associated with longer LOS, ICU LOS, PC or CT days, or complications compared to CT.

Specific aim 3: Describe utilization of PC and CT for pediatric traumatic HTX and HPTX in a large sample across multiple institutions. Identify predictors of utilization of PC versus CT, including size of HTX/HPTX, injury severity, age, patient weight, timing of placement, and other factors.

Statement on impact

We estimate based on National Trauma Data Bank data that 16 children annually have HTX or HPTX in the United States. Adult studies have shown that PC are less painful and insertion is better tolerated compared to CT. Describing the difference between PC and CT in pediatric trauma patients with HTX or HPTX will allow us to provide evidence supporting a prospective, randomized controlled trial to measure the comparative effectiveness, and possibly to change the treatment recommendations in the future.

2. Research Strategy

1. Significance

Unintentional injury is the leading cause of death in children in the United States and leads to over 4.5 million emergency department visits for non-fatal injuries annually.[5] Thoracic trauma comprises a small subset of these injured patients, but if a significant hemothorax (HTX) or hemopneumothorax (HPTX) (symptomatic or visible on chest x-ray) is present, thoracic drainage is required. This invasive treatment can be painful and anxiety-provoking,[6] from the time of insertion through and including removal.[7]

Current recommendations for HTX and HPTX in children follow the old recommendations for adults, when it was assumed that a large-bore chest tube (CT) was required to evacuate blood due to clotting.[3] In children, PC has been shown to be effective for empyema and effusion.[8] PC as small as 7 French led to resolution of 13 of 16 non-traumatic HTX in one small study, a lower rate than for effusion, but complications of placement included HTX.[9]

The available data on effective percutaneous pigtail catheter (PC) versus CT for HTX and HPTX in hemodynamically stable trauma patients are derived from adults,[10-13] leading to the conditional recommendation for PC to treat HTX and HPTX by the Eastern Association for the Surgery of Trauma.[4]

If this study shows that PC is not significantly different from CT for HTX and HPTX in hemodynamically stable pediatric trauma patients, these data will provide the basis for a prospective, randomized, multicenter trial. In addition, clinical care of these injured children may be changed in the future following prospective corroboration and may lead to the widespread use of smaller size and less painful tube thoracostomy.

2. Innovation

The current practice of placing large bore chest tubes (CTs) for hemothorax (HTX) or hemopneumothorax (HPTX) in hemodynamically stable pediatric trauma patients is based on antiquated surgical dogma, which has been replaced in adults with data showing that percutaneous pigtail catheters (PC) of 14-french size are as effective as larger bore CT. The commonly used Broselow Pediatric Emergency Tape, a pediatric weight estimation tool for calculating medication dosage and determining equipment size, directs the user to CT 20-French in size for ≥11 kg, and up to 32-38-French for children ≥29kg. This is despite adult data demonstrating that smaller sizes were sufficient for adult HTX,[14, 15] in addition to improved patient comfort with smaller tube insertion and the adult data on PC summarized above.

However, due to the lack of data in the pediatric population, current pediatric surgical textbooks still recommend CT for children with HTX or HPTX.[3] The practice change to PC is best made with good clinical data, as complications from retained hemothorax (rHTX) can result from inadequate drainage, and the rate of rHTX between PC and CT in pediatric traumatic HTX and HPTX is not known. RHTX occurs in approximately 30% of adult HTX cases,[16] and can become infected leading to empyema[17, 18]. While the rate of complication from rHTX has been suggested to be very low in children, when this occurs it is devastating both physically as well as psychologically for the child who may require further surgery and/or prolonged tube thoracostomy.

A single-center study of 46 traumatic HTX cases found only one child required surgery for rHTX.[19] The same study also demonstrated that in patients who had blunt trauma and HTX, only 30% received chest tubes while the remainder had small HTX (seen on chest x-ray) and occult HTX (seen only on computed tomography) that were observed without intervention or complication.[19] A review of 378 pediatric blunt and penetrating thoracic trauma cases at Red Cross War Memorial hospital demonstrated 19 with HTX and 24 with HPTX, of whom 36 (84%) required CT placement.[20] Two required surgery for HTX and rHTX was not reported.

One of the few previous studies of PC in children with HTX demonstrated that 13 of 16 HTX resolved with PC as small as 7-french, but these were non-traumatic HTX in ICU patients.[9] There have been no studies on PC versus CT among pediatric trauma patients with HTX or HPTX, and this study seeks to begin to fill that gap with retrospective data from multiple trauma centers. This approach will allow us to rapidly gather data about the treatment, outcomes, complications, and failures in this population. If these identify no significant difference from PC, as the adult data would suggest, then we will proceed with an already-established collaborative group to a multicenter randomized prospective trial.

3. Approach

Study Population

Pediatric trauma patients <18 years of age treated for hemothorax (HTX) or hemopneumothorax (HPTX) with percutaneous catheter (PC) or chest tube (CT) from 2010-2022. Each participating institution will query their local trauma registry for patients less than 18 years of age with ICD-10 diagnosis codes S27.1 and S27.2 or ICD-9 codes 860.2 and 860.4 for traumatic HTX or traumatic HPTX. Excluded patients will be those who had pneumothorax only without HTX component, were hemodynamically unstable at the time of the chest tube placement, required an Emergency Department thoracotomy, had PC or CT placed as part of a larger operation (e.g. video-assisted thoracoscopy) in the operating room.

Study approach

This retrospective multi-institution cross-sectional study will describe the intervention of percutaneous catheter versus conventional chest tube placement for HTX or HPTX in pediatric trauma. Collaborators will be recruited through personal contacts and EAST. The null hypothesis that PC are not significantly different from CT in the treatment of HTX and HPTX (measured in terms of treatment failure by use of a secondary hemothorax treatment: second PC or CT, thoracoscopy/thoracotomy, or thrombolytics), and through the measurement of secondary endpoints listed below.

Data Collection

Data from the trauma registry at each institution will be securely uploaded to the REDCap database and will include patient demographics (age, gender, race/ethnicity, body mass index) and injury information including mechanism of injury, external cause of injury, diagnosis, injury profile (injury severity score and abbreviated injury scale for the head, neck, chest, abdomen and extremities), disposition, and hospital length of stay. Additional data will be abstracted from the electronic medical record including chest tube or percutaneous pigtail catheter placement, if patient was hemodynamically unstable at the time of placement, size of drainage tube, hospital location of placement, time from admission until placement, HTX/PNTX size, volume of drainage at 24, 48, and 72 hours, days of CT/PC placement, intensive care unit length of stay, infection, retained hemothorax on chest x-ray, use of thrombolytic therapy, and any secondary procedures including second CT/PC, and surgery (thoracoscopy and thoracotomy), as well as indication for surgery and post-operative diagnosis. Only de-identified data will be provided to the coordinating institution through REDCap.

Data Collection software to be used

A password-protected encrypted REDCap online electronic database will be used to collect the data. Deidentified data will be securely warehoused at the primary research institution.

Communication and approval

The primary mode of communication between the PI and primary research institution research coordinator and the collaborators will be via email. Virtual meetings for all collaborators will be held monthly (or more frequently if needed), before data collection begins, to ensure that all approvals and agreements are completed, and that all collaborators have access to the REDCap tool. Questions about data collection will be addressed in the group meetings. Meetings will be held quarterly during data collection, and more frequently during analysis and writing. IRB and data use agreements will be housed securely on the primary research institution servers. All collaborators will be provided with the PI cell phone number for emergent questions.

Data Analysis

The difference in distribution of PC in comparison to CT for pediatric HTX and HPTX (measured in terms of treatment failure/retained HTX on x-ray and use of a secondary HTX treatment), with a null hypothesis of no difference in distribution, will be tested using the chi-squared test of proportions with an alpha value of 0.05. Additional continuous measures of 24-hour, 48-hour, and 72-hour PC/CT drainage, in addition to LOS and tube days will be compared and tested for difference in distribution setting an alpha value of 0.05. The distribution of continuous variables across treatment type will be reported using mean and standard deviation and tested using a Shapiro-Wilk test of normality, and a Wilcoxon signed rank test if the data fail to meet statistical criteria for normality. The distribution of categorical variables will be represented with frequency and percentages and tested using a chi-square test, and corresponding odds ratios, 95% confidence intervals, and p-values will also be reported.

Sample Size & Power Estimates

A preliminary analysis of National Trauma Data Bank (NTDB) data 2016-2019 querying cases with diagnosed HTX (S27.1XXA) or HPTX (S27.2XXA), placement of drainage device with open approach (0W9880ZZ, 0W9800Z) or percutaneous approach (0W9840Z, 0W9830Z, 0W983ZZ), yielded 35 CT cases, and 32 PC cases. Using the ICD9 code 34.01, 107 additional cases of pediatric traumatic HTX with "Incision to chest wall" were identified. From 2007 to 2019 combined there were 174 cases that met inclusion and exclusion criteria. Assuming the distribution of approach is consistent across all time periods, this study would have adequate power to detect a 35% difference in the proportion of cases that ended in procedure failure, assuming an alpha value of 0.05 with a distribution of a minimum of 65 CT cases and a minimum of 45 PC cases.

Using a Wilcoxon rank sum test, this study would have an 82.3% power to detect a significant difference in distribution given a true location shift of 50% in the distribution and up to a 2-fold difference in variance of the endpoint. This difference between reported registry data and sample size reported in power analysis will allow 37% of the patients reported to the NTDB to have cases lost to clerical/administrative purge or other source of data loss such as a failure to enroll all contributing centers within the trial, or loss of data due data purge or conversion to a different EMR.

Bias/Confounding

To account for bias in missingness, Little's test of missingness completely at random will be conducted to identify bias in missingness and account for it through subset analysis or n-1 bootstrapping analysis. Bias by center will be modeled using a logistic regression model with center set as the predictor and drain failure set as the response. Variance in procedure outcomes reported by each center will be presented in a descriptive table, sensitivity analysis will be carried out as necessary to address single center skew of results. All analysis will be conducted in R statistical programming language version 4.1.3.

Study Limitations

Potential Limitation 1: The retrospective nature of study necessarily limits the data that can be obtained from electronic medical records. We don't have the power to control for variability in institutional characteristics or population heterogeneity.

Potential Limitation 2: There may be historical bias in terms of practice changes over time that could account for some difference in failure rates. We will attempt to control for this by reporting failure rates across each year of device use observed in the study.

Potential Limitation 3: Sample size may be limited by the rarity of HTX in children, with an estimated 16 cases in the United States annually. We will collect data from 2010-2022 and enroll as many centers as possible.

Anticipated Results

We anticipate that PC and CT for traumatic HTX and HPTX in children have the same failure rate, measured by additional PC or CT placement, need for surgery, or thrombolytics. We do not expect to find differences in outcome measured by LOS, ICU LOS, complications. We expect to find that PC have been used with increasing frequency in pediatric patients, as the data demonstrating that PC are effective for HTX in adults have been published over the last decade. We expect CT to be used in larger HTX compared to PC. There may also be a sub-population of patients with small HTX who were not treated with PC nor CT (no intervention).

Describing the difference between PC and CT in pediatric trauma patients with HTX or HPTX will allow us to provide evidence supporting a prospective, randomized controlled trial to measure the comparative effectiveness, and possibly to change the treatment recommendations in the future.

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