Project Overview

[1944389-1] IRB# 2207119: A retrospective comparison of the effectiveness of small-bore pigtail catheters versus …

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Research Institution Children's Hospital of Orange County (CHOC), Orange, CA

Title IRB# 2207119: A retrospective comparison of the effectiveness of small-bore pigtail catheters versus traditional chest tubes for hemothorax in pediatric trauma

Principal Investigator Goodman, Laura

Keywords hemothorax

Sponsor CHOC, Eastern Association for the Surgery of Trauma

The documents for this project can be accessed from the **Designer**.

Project Status as of: 10/13/2022

Reviewing Board	Board Ref #	Initial Approval Date	Project Status	Expiration Date
[IN-HOUSE] Children's Hospital of Orange County In-House (CHOC IH) IRB, Orange, CA • Report due: 09/05/2025	2207119	09/06/2022	Exempt	09/05/2025

Package 1944389-1 is: Locked - Revisions Complete

Package 1 of 1 | Jump |

Submitted To	Submission Date	Submission Type	Board Ref #	Board Action	Effective Date	
[IN-HOUSE] Children's Hospital of Orange County In-House (CHOC IH) IRB, Orange, CA	08/24/2022	New Project	2207119	Exempt	09/06/2022	| Review Details |

Shared with the following users:

User	Organization	Access Type
Dinh, Peter	Children's Hospital of Orange County (CHOC), Orange, CA	Full
Gibbs, David	Children's Hospital of Orange County (CHOC), Orange, CA	Read
Goodman, Laura	Children's Hospital of Orange County (CHOC), Orange, CA	Read
Hoang, Van	Children's Hospital of Orange County (CHOC), Orange, CA	Full
Plouffe, Nicole	Children's Hospital of Orange County (CHOC), Orange, CA	Read
Waunch, Amy	Children's Hospital of Orange County (CHOC), Orange, CA	Read

Hemothorax Data Collection

Please complete the survey below.

Thank you!

Study Site Identifier

_____

Demographics

Date and Time of ED Admission

_____

Date of Birth

_____

Sex

◯ Male
◯ Female
◯ Other
◯ Not Available

Race

◯ White
◯ African American
◯ American Indian or Alaska Native
◯ Asian
◯ Native Hawaiian or Other Pacific Islander
◯ Other

Ethnicity

◯ Hispanic
◯ Non-Hispanic

Height (cm)

_____

Weight (kg)

_____

Body Mass Index (BMI)

_____

Diagnoses

Mechanism of Injury

◯ Blunt
◯ Penetrating

External Cause of Injury (ICD10 code to which injury is attributed)

_____
(ICD10 Code)

Primary Diagnosis

_____
(ICD10 Code)

Secondary Diagnosis

_____

Secondary Diagnosis _____

Secondary Diagnosis _____

Secondary Diagnosis _____

Secondary Diagnosis _____

Secondary Diagnosis _____

Secondary Diagnosis _____

Secondary Diagnosis _____

Secondary Diagnosis _____

Secondary Diagnosis _____

Injury Severity Scoring

Injury Severity Score (ISS) _____

Abbreviated Injury Scale (AIS)

	0	1	2	3	4	5	6
Head	◯	◯	◯	◯	◯	◯	◯
Neck	◯	◯	◯	◯	◯	◯	◯
Chest	◯	◯	◯	◯	◯	◯	◯
Abdomen	◯	◯	◯	◯	◯	◯	◯
Extremities	◯	◯	◯	◯	◯	◯	◯

Chest Tube or Percutaneous Pigtail Catheter Placement

Date and Time of Placement _____

Who Placed the CT/PC?

◯ Attending Surgeon
◯ Resident
◯ Fellow
◯ Radiologist
◯ Midlevel Provider
◯ ED Physician
◯ Other

Specify Other Role	_____
Location within the Hospital in which the Placement Occurred	◯ Emergency Department ◯ Radiology Department ◯ Hospital Ward ◯ ICU ◯ Other
Specify Other Location	_____
Type of Catheter Placed	◯ Chest Tube ◯ Percutaneous Catheter
Size of the Chest Tube (Fr)	◯ 8 ◯ 10 ◯ 12 ◯ 14 ◯ 16 ◯ 20 ◯ 24 ◯ 28 ◯ 32 ◯ 36 ◯ 38 ◯ 40
Size of the Percutaneous Catheter (Fr)	◯ 5 ◯ 6 ◯ 8 ◯ 8.5 ◯ 10 ◯ 12 ◯ 14 ◯ 16 ◯ Other
Specify Size	_____
CT Guidance for CT/PC Placement?	◯ Yes ◯ No
Ultrasound Guidance for CT/PC Placement?	◯ Yes ◯ No
Hemodynamically Unstable at the Time of Placement?	◯ Yes ◯ No
HR Prior to Insertion of CT/PC	_____
Systolic Blood Pressure (mm Hg) Before Insertion	_____
Diastolic Blood Pressure (mm Hg) Before Insertion	_____

Diagnostics

CT Imaging Used for Dx?
- ◯ Yes
- ◯ No

Estimated Size Based on CT (mLs)

_____

Chest X-ray Used for Dx?
- ◯ Yes
- ◯ No

Estimated Size Based on CXR or Unmeasured CT
- ◯ Trace
- ◯ Small
- ◯ Moderate
- ◯ Large

Drainage Volume

Immediate Drainage Volume (mLs)

_____

First 24-hour Period After Placement

_____
(Include immediate drainage volume)

Second 24-hour Period After Placement

_____

Third 24-hour Period After Placement

_____

Total Drainage Volume

_____

PRBC Transfusion

PRBC Transfusion >/= 10 mL/kg
- ◯ Yes
- ◯ No

Massive PRBC Transfusion >/= 40 mL/kg
- ◯ Yes
- ◯ No

Total Volume Transfused (in mLs)

_____

mL/kg of PRBCs Transfused

_____

Removal of Drainage Device

Date and Time CT/PC was Removed

_____

Was Drainage Device Removed Due to Failure/Complication?

◯ Yes
◯ No

Reason for Drainage Device Removal

◯ Treatment completed/hemothorax resolved
◯ Non-functioning tube replaced with a new tube
◯ Infection
◯ Other

Specify Other Reason for Drainage Device Removal

_____

Was a Second CT/PC Inserted?

◯ Yes
◯ No

Retained HTX on Chest Xray?

◯ Yes
◯ No

Second Drainage Device

Date and Time of Second Device Placement

_____

Who Placed the CT/PC?

◯ Attending Surgeon
◯ Resident
◯ Fellow
◯ Radiologist
◯ Midlevel Provider
◯ ED Physician
◯ Other

Specify Other Role

_____

Location within the Hospital in which the Placement Occurred

◯ Emergency Department
◯ Radiology Department
◯ Hospital Ward
◯ ICU
◯ Other

Specify Other Location

_____

Type of Catheter Placed

◯ Chest Tube
◯ Percutaneous Catheter

Size of the Chest Tube (Fr)	◯ 8 ◯ 10 ◯ 12 ◯ 14 ◯ 16 ◯ 20 ◯ 24 ◯ 28 ◯ 32 ◯ 36 ◯ 38 ◯ 40
Size of the Percutaneous Catheter (Fr)	◯ 5 ◯ 6 ◯ 8 ◯ 8.5 ◯ 10 ◯ 12 ◯ 14 ◯ 16 ◯ Other
Specify Size	_____
CT Guidance for CT/PC Placement?	◯ Yes ◯ No
Ultrasound Guidance for CT/PC Placement?	◯ Yes ◯ No
Hemodynamically Unstable at the Time of Placement?	◯ Yes ◯ No
HR Prior to Insertion of CT/PC	_____
Systolic Blood Pressure (mm Hg) Before Insertion of Second Device	_____
Diastolic Blood Pressure (mm Hg) Before Insertion of Second Device	_____
Immediate Drainage Volume (mLs)	_____
First 24-hour period after placement (second device)	_____ (Include immediate drainage volume)
Second 24-hour Period After Placement (second device)	_____
Third 24-hour Period After Placement (second device)	_____

Total Drainage Volume from Second Device	_____
Surgical Intervention Required (Thoracoscopy/Thoracotomy)	◯ Yes ◯ No
Date/Time of Surgery	_____
Indication(s) for Surgery	☐ High Initial Output from Chest Tube ☐ Failure of Drainage ☐ Empyema
Surgery Post-operative Diagnosis	☐ Retained Hemothorax (J94.2) ☐ Empyema (J86) ☐ Fibrothorax (J94.1) ☐ Persistent air leak (J93) ☐ Other
Specify Other Post-Operative Diagnosis	_____
Date and Time Second CT/PC was Removed	_____
Reason for Second Drainage Device Removal	◯ Treatment completed/hemothorax resolved ◯ Non-functioning tube replaced with a new tube ◯ Infection ◯ Other
Specify Other Reason for Second Drainage Device Removal	_____

Additional Interventions

Infection?	◯ Yes ◯ No
Organism	☐ Staph Aureus ☐ Staph Aureus with Methicillin Resistance (MRSA) ☐ Staph Epidermidis ☐ Streptococcus ☐ Pneumococcus ☐ Other
Specify Other Organism(s)	_____
Use of Thrombolytic Therapy?	◯ Yes ◯ No
Date/time of First Thrombolytic	_____

Date/Time of Secondary Procedures Including Second CT/PC	_____
Surgical Intervention Required (Thoracoscopy/Thoracotomy)	◯ Yes ◯ No
Date/Time of Surgery	_____
Indication(s) for Surgery	☐ High Initial Output from Chest Tube ☐ Failure of Drainage ☐ Empyema
Surgery Post-operative Diagnosis	☐ Retained Hemothorax (J94.2) ☐ Empyema (J86) ☐ Fibrothorax (J94.1) ☐ Persistent air leak (J93) ☐ Other
Specify Other Post-Operative Diagnosis	_____

Patient Discharge & Disposition

Date and Time of Discharge from ICU Order	_____
Date and Time of Hospital Discharge Order	_____
Patient Disposition	◯ Left against medical advice or discontinued care ◯ Deceased/Expired ◯ Discharged to home or self-care (routine discharge) ◯ Discharged/Transferred to home under the care of organized home health service ◯ Discharged/Transferred to somewhere other than home
Discharged/Transferred to:	◯ Short-term general hospital for inpatient care ◯ Intermediate Care Facility (ICF) ◯ Skilled Nursing Facility (SNF) ◯ Hospice care ◯ Court/law enforcement ◯ Inpatient rehab or designated unit ◯ Long Term Care Hospital (LTCH) ◯ Psychiatric hospital or psychiatric distinct part unit of a hospital ◯ Another type of institution not defined elsewhere

DATA USE AGREEMENT
For the Transfer of a Limited Data Set

This Data Use Agreement, together with its Attachments, (the "**Agreement**") is made and entered into as of the date last signed below, by and between [Name], located at [Address] ("**Covered Entity**") and **Children's Hospital of Orange County**, a California nonprofit public benefit corporation located at 1201 W. La Veta Avenue, Orange, California 92868 and [Name], located at [Address], (hereinafter referred to as "**Recipient**").

RECITALS

WHEREAS, the Covered Entity is subject to the requirements of the Health Insurance Portability and Accountability Act of 1996, as amended from time to time, including the amendments and related laws of the Health Information Technology for Economic and Clinical Health Act, and regulations promulgated thereunder, including the Standards for Privacy of Individually Identifiable Health Information at 45 Code of Federal Regulations Parts 160 and 164 ("**Privacy Regulations**");

WHEREAS, the Privacy Regulations require the Covered Entity to enter into an agreement with Recipient in order to mandate certain protections for the privacy and security of Protected Health Information (as such term is defined in the Privacy Regulations), and such Privacy Regulations prohibit the disclosure to or use of a Limited Data Set by Recipient if such an agreement is not in place;

WHEREAS, Recipient has requested that Covered Entity provide Recipient the Limited Data Set (defined below), and Covered Entity desires to provide Recipient such Limited Data Set; and

WHEREAS, Recipient intends to use the Limited Data Set for the purposes of **A retrospective comparison of the effectiveness of small-bore pigtail catheters versus traditional chest tubes for hemothorax in pediatric trauma** ("**Research Project**") as further outlined in Exhibit A.

NOW, THEREFORE, the parties hereby agree as follows:

ARTICLE I
DEFINITIONS

1.1 "**Disclose**" and "**Disclosure**" mean, with respect to the Limited Data Set, the release, transfer, provision of, access to, or divulging in any other manner of the Limited Data Set outside Recipient's internal operations or to anyone other than its employees.

1.2 "**Limited Data Set**" means Protected Health Information that excludes the following direct identifiers of the individual, or of relatives, employers, or household members of the individual: names, postal address information (other than town or city, State and zip code); telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers (including prescription numbers); health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators ("URLs"); Internet Protocol ("IP") address numbers; biometric identifiers, including finger and voice prints; full face photographic images; and any comparable images as defined in 45 CFR 164.514(e)in the Privacy Regulations.

1.3 "**Required by Law**" means a mandate contained in law that compels an entity to make a Use or Disclosure of Protected Health Information and that is enforceable in a court of law. Required by Law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by

a court, grand jury, a governmental or tribal inspector general, or any administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing benefits as defined in 45 CFR Sect. 164.501 of the Privacy Regulations.

1.4 "**Use**" or "**Uses**" mean, with respect to the Limited Data Set, the sharing, employment, application, utilization, examination or analysis of such information within Recipient's internal operations.

1.5 Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms have in the Privacy Regulations.

ARTICLE II
OBLIGATIONS OF DATA SET RECIPIENT

2.1 Permitted Uses and Disclosures of the Limited Data Set. Covered Entity hereby grants Recipient, and Recipient accepts, a non-exclusive, non-transferable, non-sublicensable, perpetual, worldwide license to Use or Disclose the Limited Data Set for the sole purpose of conducting the Research Project in accordance with this Agreement. Such license shall be irrevocable unless terminated in accordance with Section 3.2 below. Recipient agrees that the Limited Data Set as Used or Disclosed pursuant to this Agreement: (a) is to be used for the research, public health and/or health care operations purposes described in the Research Project, as outlined in Exhibit A, and may also be shared with regulatory authorities, or published in peer-reviewed publications; and (b) will not be used or further disclosed other than as permitted in this Agreement, or as Required by Law.

This Agreement is not intended to authorize the Recipient to Use or further Disclose the Limited Data Set in a manner that would violate the Privacy Regulations, if done by the Covered Entity.

2.2 Adequate Safeguards. Recipient warrants that it shall implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the Limited Data Set. Such safeguards shall be in conformance with the Privacy Regulations, as well as any applicable statutes, laws and regulations, including Public Health Service and National Institutes of Health regulations and guidelines. Any electronic transmission of the Limited Data Set shall be appropriately encrypted in accordance with standards specified by Covered Entity.

2.3 Reporting Non-Permitted Use or Disclosure. Within forty-eight (48) hours of becoming aware, Recipient will report to Covered Entity any use or disclosure of the Limited Data Set made by Recipient, its employees, representatives, agents or subcontractors which is not specifically permitted by this Agreement of which the Recipient becomes aware. Such report will be made initially by encrypted email to ComplianceHotline@choc.org, followed by a detailed written report no later than one (1) business day following Recipient's initial email report, addressed as follows:

CHOC Children's
Attn: Chief Compliance Officer
1201 W. La Veta Avenue
Orange, CA 92868

Recipient shall thereafter keep the Covered Entity's Privacy Officer informed in a timely manner of all additional information obtained or developed by Recipient with regard to any matter reportable to the Covered Entity's pursuant to this Section.

2.4 Use of Employee, Subcontractors and Agents. Recipient shall require each of its employees, agents and contractors and subcontractors that receive the Limited Data Set to execute or be obligated by an agreement to comply with the terms of this Agreement.

2.5 Prohibition on Identification and Contact. Recipient shall not utilize the Limited Data Set to identify, or attempt to identify, or contact the individuals who are the subject of the Limited Data Set.

2.6 Indemnification. Recipient will indemnify, defend and hold harmless Covered Entity and any of Covered Entity's affiliates, and their respective trustees, officers, directors, IRB members, employees and agents ("Indemnitees") from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Limited Data Set or any other breach of this Agreement by Data Recipient or any employee, contractor, subcontractor, agent or person under Data Recipient's control.

ARTICLE III
TERM AND TERMINATION

3.1 This Agreement is effective as of the date signed by both parties ("Effective Date") and shall continue in effect until the completion of the Research Project. Without limiting any rights which either party may have at law, it is agreed that the terms of this Agreement that contain obligations or rights that extend beyond the completion the Research Project shall survive termination or completion of this Agreement, even if not expressly stated herein.

3.2 Upon Covered Entity's knowledge of a material breach or violation by Recipient of this Agreement, or a violation of the Privacy Regulations by Recipient, the Covered Entity may, in its sole discretion, either:

(a) Provide an opportunity for Recipient to cure the breach or end the violation, and terminate this Agreement if Recipient fails to cure the breach or end the violation within the time specified by the Covered Entity; or

(b) Immediately terminate the Agreement and discontinue the Disclosure of the Limited Data Set to the Recipient.

ARTICLE IV
MISCELLANEOUS

4.1 Covered Entity shall retain ownership of the Limited Data Set. Recipient shall have no right, title or interest in the Limited Data Set except for the license described herein.

4.2 Recipient and Covered Entity agree that any breach, or threatened breach, of this Agreement may cause irreparable harm to Covered Entity, that Covered Entity may not have an adequate remedy at law, and that Covered Entity may therefore be entitled to seek injunctive or other equitable relief to enforce the obligations of this Agreement.

4.3 This Agreement shall not prevent or delay publication of research findings resulting from the Research Project, provided that such publication does not breach the terms and conditions of this Agreement. Recipient agrees to provide appropriate acknowledgement of the source of the Limited Data Set in all such publications. In the event that the parties agree to jointly prepare a publication of the results of any Research Project in a mutually acceptable scientific journal the parties shall (i) jointly draft such publication through the research representatives; (ii) prepare such publication within a mutually agreed upon time; and (iii) have such joint publication reviewed and approved by the duly authorized representatives of both parties prior to submission of the publication to the agreed upon scientific journal. If the parties agree to jointly prepare a publication, except by mutual consent, neither party shall publish prior to the date on which such joint publication will be released. Nothing in this section shall preclude the Covered Entity from publishing its own analysis (not derived from the Research Project) on this Limited Data Set.

4.4 Whenever notices are required or permitted hereunder, they shall be given by registered or certified mail, return receipt requested, and postage pre-paid, or overnight delivery service, and addressed as follows:

If to Covered Entity: [Institution]
Attn: [Name]
[Address]
[Address]

If to Recipient: CHOC Children's
Attn: Office of Research Compliance
1201 W. La Veta Avenue
Orange, CA 92868

4.5 Nothing in this Agreement is intended to confer or grant, or shall be construed to confer or grant, to Recipient any license, right or other proprietary interest in the Limited Data Set or its Use, whether by implication, estoppel or otherwise.

4.6 Except as required by law or permitted by this Agreement, both parties agree that it will not refer to this Agreement or to the other party's participation or use the other party's name or the names of the other party's employees or agents in any advertising or promotional materials or statement to the public without prior written approval. However, both parties shall have the right to refer to this Agreement as appropriate in the conduct of internal business and in any filings required with any governmental agency or as otherwise required by law.

4.7 This Agreement shall be construed according to the laws of California without regard to its choice of law principles.

4.8 This Agreement, including its Exhibit(s) which are incorporated by reference, contains the entire agreement between the parties with respect to the subject matter contained herein and supersedes any previous understandings, commitments or agreements, oral or written with respect thereto, including any previous nondisclosure agreements. This Agreement may only be amended in writing by authorized representatives of the parties hereto. This Agreement may not be transferred or assigned by a party without the prior written consent of the other party, which shall not be unreasonably withheld, and any such purported assignment shall be void. Any waiver of a default or breach of any provision of this Agreement shall not be deemed a waiver as to any subsequent and/or similar breach or default. This Agreement may be executed in counterparts, each of which shall be an original, and all of which shall constitute together but one and the same document. The parties agree that execution of this Agreement by

industry standard electronic signature software or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date signed below.

Covered Entity	**Children's Hospital of Orange County**
By: _____	By: _____
(Signature of Authorized Representative)	(Signature of Authorized Representative)
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

Exhibit A
Limited Data Set and Research Project

Procedures: 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.

The REDCap database will house a limited set of de-identified data.

Variable Name:

date/time of admission
Study Site Identifier
age
Sex
race/ethnicity
Ethnicity
body mass index
mechanism of injury
external cause of injury
diagnosis
ISS
AIS head
AIS neck
AIS chest
AIS abdomen
AIS extremities
after-hospital disposition
chest tube or percutaneous pigtail catheter placement
hemodynamically unstable at the time of placement?
HR prior to insertion of CT/PC
BP prior to insertion of CT/PC
PRBC transfusion at least 10 ml/kg
Massive transfusion at least 40 ml/kg total
size of drainage tube
hospital location of placement

date/time of CT/PC placement
HTX/PNTX size
chest X-ray use for Dx
CT imaging use for Dx
Ultrasound guidance for CT/PC placement
CT guidance for CT/PC placement
size of hemothorax
Role of the person who placed the CT/PC
volume of drainage at 24 hours
volume of drainage at 48 hours
volume of drainage at 72 hours
date/time CT/PC removed
date/time of intensive care unit discharge
infection
Organism
retained hemothorax on chest x-ray
use of thrombolytic therapy
date/time of first thrombolytic
date/time of secondary procedures including second CT/PC
date/time of surgery (thoracoscopy and thoracotomy)
indication for surgery
surgery post-operative diagnosis
Was drainage deviced removed due to failure/complication
Reason for drainage device removal
date/time second CT/PC removed
date/time hospital discharge

CHILDREN'S HOSPITAL OF ORANGE COUNTY
RESEARCH INSTITUTE

INSTITUTIONAL REVIEW BOARD (IRB)

EXEMPT RESEARCH PROTOCOL OUTLINE

1. Core Information

☒ **In-House IRB** ☐ **Industry Track IRB** ☐ **Reliance Verification**

Protocol Title	A retrospective comparison of the effectiveness of small-bore pigtail catheters versus traditional chest tubes for hemothorax in pediatric trauma
Today's Date	**8/9/2022**
IRB Number *(*Issued by the ORC)*	2207119
Study anticipated starting date:	9/14/2022
Exempt Category	**Exempt 4** *See exempt request form for category description
Anticipated Length of Project:	2 years

2. Investigator Information

Principal Investigator's Name	Laura Goodman
Principal Investigator's Phone	714-509-3737
Principal Investigator's Email	lgoodman@choc.org
Co-Investigator(s) Name *duplicate line as needed	David Gibbs

3. Funding/Sponsor Information

Research Sponsor	**CHOC department funded-specify department** Specify if needed: **General Surgery**

4. Please provide the following information

A. Background and 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.

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.

B. Purpose: 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.

C. Hypothesis (research question) and Study Aims

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.

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) blunt 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.

D. Methods

a. Experimental Design: 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.

b. **Procedures:** Data from the trauma registry at each institution will be securely uploaded to the CHOC 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 a limited data set will be provided to the coordinating institution through REDCap.

The REDCap database will house a limited data set.

c. Duration: There is no direct participant involvement.

E. Analysis Methods:

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.

We estimate that 350 charts will be entered into the database from all participating sites, with 50 charts anticipated from CHOC. We estimate that the project will take 2 years to complete.

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.

F. Subjects

a. **Subject or Records Selection Criteria:** 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.

b. **Subject or Records Exclusion Criteria:** 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.

c. **Vulnerable Populations:** Retrospective chart review of children ages <18 years who fit the selection criteria above.

d. **Risks and Benefits to Subjects:** No participants will be enrolled in this retrospective study. The primary risk is that of breach of confidentiality of data.

e. **Managing Adverse Reactions:** N/A. No participants will be enrolled in this retrospective study.

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Please upload on the IRBNet package, the data collection tool that will be used (e.g. Excel spreadsheet).