



## P-CAT Trial - The Small 14-French (Fr) Percutaneous Catheter vs. Large (28-32Fr) Open Chest Tube for Traumatic Hemothorax

**Reference:** Kulvatunyou N, Bauman ZM, Edine SBZ, et al. The small 14-french (Fr) percutaneous catheter vs. Large (28-32Fr) open chest tube for traumatic hemothorax (P-cat): a multi-center randomized clinical trial. *J Trauma Acute Care Surg*. Published online March 16, 2021.

### **Background**

- Chest injury occurs in 30–40% of all trauma patients resulting in approximately 300,000 cases of hemothorax in the United States each year.
- Traumatic hemothorax (HTX) has been traditionally managed with a large-bore (36-40 French [Fr]) chest tube (CT), in fact, current EAST guidelines recommend that all hemothorax be drained with tube thoracostomy to prevent morbidity related to a retained hemothorax.
- The incidence of retained hemothorax is reported to be between 5 and 30%, leaving these patients at high-risk for developing empyema and other complications.
- Rationale for smaller vs larger chest tube is that patients presenting immediately after trauma should have unclotted blood in the chest cavity, that should be able to drain similarly through either a large- or small-bore catheter.
- A previous single-center RCT that showed 14Fr CTs were equally effective as large bore chest tubes at draining a traumatic hemothorax, but in order to ensure these results are generalizable, a multi-center trial needed to be conducted.

### **Objective**

- Test the hypothesis that a 14Fr percutaneous pigtail catheter would be equally effective at draining a traumatic hemothorax compared to an open thoracostomy with a 28-32 Fr chest tube

### **Study**

- Multi-center trial registered with ClinicalTrials.gov
- 4 centers across the United States
- Inclusion:
  - Adult subjects greater than or equal to 18 years of age
  - Traumatic hemothorax (HTX) or hemo-pneumothorax requiring drainage
  - CXR or CT confirming HTX or if
  - If the patient had a CT scan, with a HTX > 300mL (CT volumetric calculation)
- Exclusion:
  - Patients with a predominant pneumothorax with minimal hemothorax

- Hemodynamic instability (no time for consent)
  - Catheter placed in OR as part of a surgical procedure
  - Unable to obtain consent from patient or next-of-kin
- Study design and Intervention
    - Randomized control trial
    - PI was blinded to the intervention assignment
    - **Treatment arm:** 14 Fr percutaneous pig-tail catheter (Cook Medical LLC)
    - **Control arm:** 28-32 Fr chest tube
    - All other trauma medical care was at the discretion of the clinical team
    - Insertion Procedure:
      - Local anesthetic with 1% lidocaine given with IV analgesic chosen by clinical team (anesthesia was not standardized between sites)
      - **Pig-tail Catheters** were inserted by modified Seldinger technique at the 4<sup>th</sup> or 5<sup>th</sup> intercostal space, anterior-or mid-axillary line
      - **Chest tubes:** were inserted by traditional cut-down method in same anatomical location
    - CXR was performed post-procedure to evaluate tube position and confirm the resolution of the HTX.
    - All chest tubes were left on continuous -20 mmHg suction
    - A chest CT or Ultrasound was performed if there was a concern for retained HTX
  - Primary Outcome
    - **Drainage catheter failure rate** defined as a retained HTX (radiographically apparent hemothorax after tube thoracostomy) requiring additional intervention.
      - Additional interventions: Second drain insertion, chest tube thrombolysis, or a video-assisted thoracoscopy surgery (VATS).
  - Secondary Outcomes
    - Initial drainage output 30-minutes after insertion
    - Total chest tube output, Total chest tube days
    - Insertion-related complications
    - Ventilator days, ICU LOS, Hospital LOS
    - **Patient survey:** Insertion perception experience
      - Institutionally created, unvalidated ordinal scale (1: “it was ok, I can tolerate it, I can do it again through 5: “It was the worse experience of my life!”
      - All patients were asked 30-minutes after drain insertion

## Results

- 222 screened patients, 120 were enrolled
  - 14 Fr Pigtail: 56 patients (Note: 1 patient excluded from final analysis as effusion was found to be chronic rather traumatic hemothorax)
  - 28-32 Fr Chest tube: 63 patients
- Baseline characteristics
  - Similar characteristics including ISS score, % blunt trauma, gender, age, number of rib fractures, and duration of time from initial trauma prior to CT insertion
- Primary Outcome
  - **Drain failure rate was not different** ( $p=0.74$ )
    - 14Fr pigtail: 11%
    - 28-32Fr CT: 13%
- Secondary Outcomes
  - **Drain output was similar**
  - **Patient experience** (IPE score): Lower median IPE score for 14 Fr pigtail (Score of 1) compared to open thoracostomy (Score of 3, "It was a bad experience")
  - Two insertion-related complications
    - Pigtail: large volume bleeding requiring a thoracotomy
    - Open thoracostomy: Extra-pleural position requiring 2<sup>nd</sup> chest tube placement
  - No difference in all other secondary outcomes including ventilator days, ICU/Hospital LOS, and need for video-assisted thoracostomy
  - Two deaths (one from each group) that were not related to chest tube placement.

## Limitations

- All chest tubes were placed in patients who were stable and not in extremis
- Pain scores *could* have been due to a difference in anesthesia/analgesia management
- Trial did not reach planned sample size (4-year trial, which led to changes in local practice over the time period at individual institutions)
- Ultimately decided to stop enrollment at the beginning of the COVID-19 pandemic when most clinical research stopped at participating institutions.
- NOTE: This study was partially funded by Cook Medical, LLC (Bloomington, Indiana, USA); however, the sponsor had no role in the study design, data collection, data analysis, and the content of the manuscript.

## Authors Take Home Points

- Findings of this small multi-center, randomized control trial are consistent with previous single-center trials that 14Fr pigtail catheters are adequate for draining traumatic hemothorax *in stable patients* presenting the ED/Trauma Bay.
- Patients reported a better tube-insertion experience including less pain with pigtail catheters compared open thoracostomy.