CT PRO Study Tip Sheet

PROspective comparison of a short versus long Chest Tube water seal trial for traumatic pneumothorax

Inclusion criteria

Trauma, blunt or penetrating

Traumatic pneumothorax

- hemothorax or effusion okay as long as pneumo also present

18 years or older

Any tube, any size, placed in any location, on any hospital day

Only 1 tube in place per side

Only 1st tube per side is included

Only the 1st water seal trial is included

Exclusion criteria

latrogenic pneumothorax (e.g. central line)

Placed during a thoracic operation

Previous surgery on pleural cavity on tube side

Severe ARDS (pO2/FIO2 ratio 100 or less + ARDS)

Bronchopleural fistula or major bronchial injury

Empyema

Chylothorax

Bullous emphysema

>1 tube on same side

Had a tube previously on same side as study tube during same admission

Tubes removed unintentionally

Physically clamped tubes during water seal trial

2 or more tubes on same side

Chest Tube Management

- Place tube to suction immediately after insertion
- Tube to continuous suction for minimum 24 hours after insertion
- Must stay on suction until water seal trial starts
 - short periods off suction for transport or walking okay
- No upper limit to time spent on suction
- Start water seal trial at your discretion, after 1st 24 hours (only 1st trial counts for study)
- Use water seal for either 6 hours +/- 2 (4 to 8 hours, "short") or 24 hours +/- 2 (22 to 26 hours, "long") but try to use same length of trial for all study patients (all short, or all long)
- Still include patients even if trial does not meet water seal lengths above
- Bilateral chest tubes: can do water seal trial concurrently or sequentially, you choose
- Tube must be removed at end of the water seal trial if study criteria* are met
- Your judgment regarding management and patient safety supersedes study requirements at all times

2 chest X-rays required - Must be Upright or Semi-upright

- 1. At the end of water seal trial prior to tube removal
- 2. Between 4 and 8 hours after tube removal

* Criteria for study chest tube removal:

- 1. Minimum 24 hours continuous suction prior to water seal trial
- 2. Air leak absent or resolved
- 3. Pneumothorax resolved or judged to be small and/or of minimal significance
- 4. Pneumothorax has not enlarged significantly (at study center's discretion) while on water seal, based on CXR
- 5. Chest tube fluid output of < 200 ml in the 24 hours prior to the water seal trial
- 6. Study center agrees with removal based on their usual standards of practice and their assessment of appropriateness for this patient

How to measure pneumothorax size

Measure distance in centimeters between the parietal and visceral pleura, i.e. from bottom edge of 1st rib at apex to superior edge of lung in a vertical line, on a CXR taken in semi-upright or upright position.

- If pneumothorax is not seen superiorly or the apical component is small but the lateral or basilar component is larger, use lateral/basilar measurement.
- Measure distance from inner edge of the lateral ribs to the edge of the lung at the point where this distance is widest.
- If the pneumothorax is located anteriorly or is only represented by subcutaneous air and the above rules cannot be applied, indicate N/A

DATA DICTIONARY

Prospective comparison of a short versus long chest tube water seal trial for traumatic pneumothorax

Chest tube A tube of any French (width) placed through an

incision or by Seldinger method directly through the chest wall into the pleural space, for the

purpose of treating pneumothorax

Water seal trial Period of time during which the chest tube

collection system is removed from active suction and negative pleural pressure is maintained by a column of water in the collection chamber. A trial must be continued for at least 1 hour to be

considered an eligible trial.

First water seal trial Only the first water seal trial is included in the

study. The first trial is defined as the first time the chest tube is placed on water seal for more than 1 hour with the intent of removing the tube after a period of time if no criteria for trial failure are

met.

Failure of water seal trial A trial fails in any of the following conditions: 1) if

the chest tube is placed from water seal back to suction prior to tube removal for any clinical reason (e.g. enlarging pneumothorax, clinical deterioration); 2) if the chest tube is not removed

at the end of the trial due to enlarging pneumothorax or other clinical concern

Success of water seal trial A trial is successful if the pneumothorax has not

enlarged significantly during the trial (based on provider judgment) and the chest tube is removed

at the end of the trial

Duration of water seal trial

Trials are classified as either "short" or "long" based on consecutive hours on water seal. Short trials are 6 hours, +/- 2 hours (i.e. between 4 and 8 hours long) and long trials are 24 hours, +/- 2 hours (i.e. between 22 and 26 hours long).

- Trials with a duration falling outside of these parameters should still be included and have the length of the trial documented, providing that no water seal trial failure criteria are met.
- Trials are measured in hours, rounded to the nearest full hour (e.g. 2 hours 1 minute through 2 hours 30 minutes is rounded to 2 hours; 2 hours 31 minutes through 2 hours 59 minutes is rounded to 3 hours)
- A minimum of 1 hour on water seal is required to be counted as a water seal trial.

Pneumothorax

Air in the pleural space after a traumatic injury mechanism (excludes pneumothorax due to procedures, barotrauma from positive airway pressure, or spontaneous bleb rupture)

Hemopneumothorax

Both air and blood in the pleural space after a traumatic injury mechanism

Hemothorax

Blood in the pleural space after a traumatic injury mechanism (may include combined blood and serous pleural fluid)

Size of pneumothorax

The size of a pneumothorax should be determined by measuring the distance in centimeters between the parietal and visceral pleura, i.e. from the bottom edge of the 1st rib at its apex to the superior edge of the lung in a vertical line, on a chest xray taken in the semi-upright or upright position. See photo example #1.

- If the pneumothorax is not seen superiorly or the apical component is small but the lateral or basilar component is larger, measure the distance from the inner edge of the lateral ribs to the edge of the lung at the point where this distance is widest. See photo example #2.
- If the pneumothorax is located anteriorly or is only represented by subcutaneous air and the above rules cannot be applied, indicate N/A

Photo #1

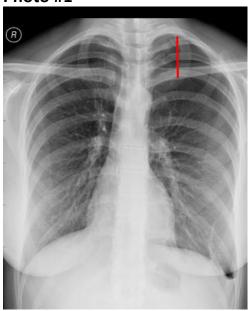
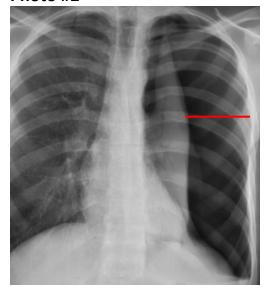


Photo #2



Recurrent pneumothorax

Pneumothorax diagnosed after index chest tube removal, if the chest xray taken at the end of the water seal trial shows absent or miniscule pneumothorax

Worsening pneumothorax

Pneumothorax diagnosed after index chest tube removal that is both larger than the pneumothorax present on the chest xray taken at the end of the water seal trial, and that requires some additional observation, radiological followup, or intervention.

Chest xray

Plain radiograph of the chest taken in an anterior to posterior or posterior to anterior direction

Removal of chest tube

Intentional complete withdrawal of the chest tube from the patient by a health care provider. The study does not specify removal upon a particular point in the respiratory cycle, or with/without Valsalva maneuver.

Occlusive dressing

A dressing covering the chest tube incision after the tube has been removed, and which is covered with an adhesive dressing such that it is deemed "air-tight". The chest tube site may or may not be sutured closed depending on provider preference.

24-hour suction minimum

Chest tubes must be placed directly to suction after initial insertion and remain on suction for a minimum of 24 consecutive hours prior to a water seal trial. The "24 hour" length is literal, and should NOT be interpreted as "1 calendar day". For example, a tube placed at 1pm on Thursday may not be placed to water seal prior to 1pm on Friday, even though a "calendar day" has passed since placement.

Positive pressure ventilation

Mechanical ventilation or Bipap

Clamping trial

Physically clamping or occluding a chest tube by an external device for a period of time between when the chest tube is on suction and the time it is put to water seal or removed, such that air is prevented from escaping through the chest tube. This does not include temporary clamping for a few seconds while the tube is being physically removed from the chest.

EAST MULTICENTER STUDY DATA COLLECTION TOOL

Prospective comparison of a short versus long chest tube water seal trial for traumatic pneumothorax ("CT Pro Study")

Variables to be collected

*If patient has 2 eligible chest tubes (i.e. 1 on each side), data should be completed on two separate forms. Make sure to identify the patient as the same patient for sub analysis purposes (e.g. ID# 1A and ID# 1B)

Patient Number:

The following sheets are for annotation. All data will be entered electronically at each site into the AAST data collection tool for secure/encrypted electronic sharing with the coordinating site.

| 1. | PATIENT DAT | <u>A</u> | | | | |
|----|---|------------------|---------|--|--|--|
| | Age Sex Mechanism of injury (check one) | | | | | |
| | Blunt | Penetrating | | | | |
| | Injury Severity Score (ISS) | | | | | |
| d. | Abbreviated Injury Scale (AIS) – enter number 1-5 | | | | | |
| | Head | Chest | Abdomen | | | |
| | | | | | | |
| e. | Number of rib fractures on the side of the chest tube | | | | | |
| f. | Breathing DURING water seal trial (check one) | | | | | |
| | Spontaneous | Positive pressur | re Both | | | |
| | | | | | | |
| ø. | Hospital length of stay (#calendar days) | | | | | |

| h. | Status upon hospit | al discharge | (check one) | | | |
|----|---|---------------|--------------------|-----------------------------|-----------------|--|
| | Alive | Dead | | | | |
| | | | | | | |
| | | | | | | |
| 2. | CHEST TUBE DA | ATA | | | | |
| a. | Location of chest | tube placeme | ent (check one) | | | |
| | ED Opera | ting room | ICU | Patient care ward (non-ICU) | Radiology suite | |
| | | | | | | |
| b. | Duration of chest | tube (# calen | dar days) | _ | | |
| 0 | | | | | | |
| C. | Side of chest tube | (check one) | | | | |
| | Left | Right | | | | |
| | | | | | | |
| d. | Breathing at time | of tube remo | oval (check one) | | | |
| | Spontaneous | Positive p | ressure | | | |
| e. | e. Indication for placement (check one) | | | | | |
| | Pneumothorax Onl | y | Pneumothorax | with | | |
| | | | hemothorax/effu | ısion | | |
| | | | | | | |
| f. | Size of chest tube in French units | | | | | |
| g. | Method of tube pl | acement (che | eck one) | | | |
| | Over a wire/Sel | | Direct pleural en | try/open | | |
| | (e.g.pigtail) |) | | | | |
| h. | ☐ Duration of suction | n prior to wa | ater seal trial (# | calendar days) | | |
| | | F 1- 10 | (| | | |
| i. | Actual duration of (*Please be specific | | , , | | | |

| j. Water seal tri | al outcome (check or | ne) | | | | | | | |
|---------------------------------|---|--|--|--|--|--|--|--|--|
| Chest tube removed | Chest tube placed back to suction | Chest tube continued on water seal, removal criteria NOT met | Chest tube continued on water seal, removal criteria MET | | | | | | |
| | | | | | | | | | |
| 3. RADIOLOGY | Y DATA | | | | | | | | |
| _ | | ter seal trial prior to chest ictionary for measurement in | | | | | | | |
| b. Size of pneum | othorax* after chest t | tube removal centim | eters | | | | | | |
| c. Number of CX remaning hospit | , | ason, after chest tube remo | oval during | | | | | | |
| 4. COMPLICAT | ΓIONS | | | | | | | | |
| | r pleural drain reinse ng index hospital say | ertion (ipsilateral to study (check one) | chest tube) | | | | | | |
| Yes | No | | | | | | | | |
| | | | | | | | | | |
| | If answer "YES" to propose for pneumothorax? | revious question, was reinse | rtion primarily | | | | | | |
| | Yes | No | | | | | | | |
| | | | | | | | | | |
| ii. Wit | ii. Within 30 days of discharge (check one) | | | | | | | | |
| Yes | No | | | | | | | | |
| | | | | | | | | | |
| | If answer "YES" to perfor pneumothorax? | revious question, was reinse | rtion primarily | | | | | | |
| | Yes | No | | | | | | | |
| | | | | | | | | | |

| b. | Thoracic surgical intervention, other than chest tube, (ipsilateral to study chest tube) after chest tube removal (i.e. VATS or thoracotomy) i. During index hospital stay (check one) | |
|---|--|----|
| | Yes | No |
| | | |
| ii. Within 30 days of discharge (check one) | | |
| | Yes | No |
| | | |
| c. | Readmission within 30 days for recurrent pneumothorax (ipsilateral to study chest tube) (check one) | |
| | Yes | No |
| | | |