

**Trauma Association of Canadian (TAC)
Multi-Centre Randomized Clinical Trial**

**Management of Occult Pneumothoraces in Mechanically
Ventilated Patients**

(Updated Protocol with ethics approved modifications from the original version)

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I. a. **Introduction and Background:** The term “Occult pneumothorax” (OPTX), describes a pneumothorax (PTX) that while not suspected on the basis of either clinical examination or plain radiograph, is ultimately detected with thoraco-abdominal computed tomograms (CT)¹⁻³ (Appendix A.). This situation is increasingly common in contemporary trauma care with the increased use of CT. The incidence appears to approximate 5% in injured populations presenting to hospital⁴⁻¹⁰, with CT revealing at least twice as many PTXs as suspected on plain radiographs^{5,8,10-16}. While PTXs are a common and treatable (through chest drainage) cause of mortality and morbidity, there is clinical equipoise and significant disagreement regarding the appropriate treatment of the OPTX. Based on level III evidence, some authors have recommended observation without chest drainage for all but the largest OPTXs^{6-8,14,17}, recommendations that contravene the standard dictum for ventilated patients as recommended by the Advanced Trauma Life Support Course of the American College of Surgeons¹⁸. The controversy is the greatest in the critical care unit population who require positive pressure ventilation. This is also the group for whom the highest rates of chest tube complications have been reported¹⁹, and in whom hemodynamic consequences are the greatest²⁰. Complication rates related to chest tubes in general, have been claimed in up to 21% of cases^{9,17,19,21}.

No previous studies have focused specifically on the population of mechanically ventilated patients. Prior to initiation of the OPTICC Research Program, there have been only 45 reported ventilated trauma patients that were formally randomized to treatment or observation. Furthermore, these results provided diametrically opposed conclusions. Enderson found that 8 (53%) of 15 patients had PTX progression with 3 tension pneumothoraces²¹. Brasel found that of 9 observed OPTXs, 2 progressed⁹. Brasel concluded observation was safe⁹, while Enderson felt chest tubes were mandatory²¹.

There have been a number of non-randomized retrospective and some prospective studies examining management issues related to OPTXs. Unfortunately all have significant methodological issues and have made potentially unwarranted and unjustified conclusions based on biased cohorts and

data. For instance a moderately large multi-center American Association for the Surgery of Trauma trial examined 448 pts with OPTXs in 16 trauma centers, but then immediately excluded 1/5 of the patients based on the subjective judgement of caregivers. In the 1/6 of the population receiving positive pressure ventilation (PPV). Despite a 14% failure rate in this heavily biased non-standardized or randomized population it was concluded that patients on PPV can be safely observed²². A further post-hoc analysis of this database focusing solely on pediatric patients, reported from 16 level I and II busy US trauma centers. Analyzing a cohort of 8 patients with OPTXs who were ventilated without a chest tube, they concluded that chest drainage was not required for OPTXs²³. Obviously such studies are grossly underpowered to make such conclusions. Thus, it is not surprising that an attempted meta analyses and systematic review noted the paucity of data and have concluded that further prospective randomized study was urgently required²⁴. This most recent systematic review on the subject stated; “There is, however, inadequate data to draw any definitive conclusion on safety of expectant management in patients with occult pneumothorax that undergo positive pressure ventilation”²⁴. Further, inconclusive studies are still being published every year emphasizing the frequency of OPTXs and the uncertainty with what the optimal care of this entity should be²⁵.

Given this uncertainty regarding both the “optimal” and the “safe” management of OPTXs in ventilated patients, the Occult Pneumothoraces in Critical Care (OPTICC) trial was initiated under the auspices of the Canadian Trauma Trials Collaborative (CTTC), an organization that has since evolved to become the Research Committee of the Trauma Association of Canada. This multi-center collaboration has involved cooperation between Calgary, Toronto, Quebec City, and Sherbrooke. Initial reports from OPTICC have revealed that the trial is feasible and appears to be safe²⁶. An interim report on the first 90 recruited patients revealed that OPTXs may be safely observed in hemodynamically stable patients undergoing PPV just for an operation, although one third of those requiring a week or more of ICU care received drainage, and TPTXs still occurred²⁷. Notably, complications of pleural drainage remained

unacceptably high and it was clear that the trial should continue in an attempt to delineate who should be observed and who among those observed that warrant prophylactic drainage²⁷.

We thus propose to continue to study the need for chest drainage in all sized OPTXs with the only exclusion of "minuscule" size (< 2 cuts on high-resolution scans), as well as the practicalities of carrying out such a study. This study will also consider the potential effects of OPTXs on pulmonary mechanics and potential influences on the known risks of ventilator- induced lung injury inherent with mechanical ventilation.

I. b. **Foothills Medical Centre Experience:** We initially retrospectively reviewed the prior experience with OPTXs at Foothills Medical Centre during the period from June 30 2002 to July 1 2003^{2,3}. This review confirmed that there was no standard approach to managing OPTXs in the critically ill population. Seventeen patients (35% of all OPTXs identified in the series) were mechanically ventilated, of whom only 13 (76%) underwent chest tube insertion³. There were no complications related to observation of these OPTXs although there was an overall 22% rate of complications or ineffective chest tubes in the ventilated group³. We subsequently have extensively reviewed the literatures, which motivate a randomized controlled study to address this clinical dilemma.

I. c. **Trauma Association of Canadian (TAC) – Canadian Trauma Trials Collaborative (CTTC):** TAC (formerly CTTC) is a voluntary association of interested trauma specialists from across Canada with a professed interest in participating in prospective multi-center clinical trials. The original single site pilot OPTICC study has been updated to facilitate a Canada-wide prospective multi-center trial.

II. Hypotheses

- a. **Primary Hypotheses or Outcome Variables:** In ventilated patients with occult PTXs, the rate of respiratory distress will not differ between those treated with tube thoracostomy tubes and those not treated but closely monitored (observed).
- b. **Secondary Hypotheses or Outcome Variables:** Observation of OPTXs in ventilated patients will not increase the rates of;
 - i. Emergency chest drainage
 - ii. Death
 - iii. Tracheostomy
 - iv. Acute Respiratory Distress Syndrome (ARDS)
 - v. Ventilator associated pneumonia (VAP)
 - vi. Intra-abdominal hypertension (IAH) & the Abdominal Compartment Syndrome (ACS)

Nor increase the lengths of;

 - vii. Mechanical ventilation
 - viii. Intensive care stay
 - ix. Hospital stay

III. **Overview of Study Design:** This study has been carried out as a pilot study in Calgary, Toronto, Quebec city, and Sherbrook, and now been proposed for a larger multi-center randomized controlled study involving the participating academic critical care units across Canada, who care for multisystem trauma patients. Adult patients without respiratory distress who have PTXs detected on computed tomography (CT) which are not seen on plain radiographs will be screened for eligibility, **IF** they are undergoing PPV or are expected to undergo PPV within 24 hours of admission. A log of all eligible patients will be kept and will constitute a measure of incidence data for OPTXs in this setting. Those patients, who do not have respiratory distress, do not already have a drainage catheter in situ, who do not have obvious PTXs on CXR but who have any sized OPTXs will be considered eligible for the study. Patients will be randomized to either observation or chest tube drainage by the study team or an investigator once eligibility has been determined. Randomization will be done *via* an online randomization portal in any computer with Internet access. A block of 4 randomly generated numbers will be used to assign the patients to the allocated group. Informed consent to include the patients' data in the study analysis will be obtained from the patient prior to patient discharge. Standard chest drainage or observation will be performed as per the usual unit procedures.

Time Windows for Enrollment: The patient will be expected to be enrolled within six hours of the diagnosis of an OPTX if already undergoing positive-pressure ventilation (PPV), or within 6 hours of commencing PPV if not

ventilated at the time of enrollment. If not ventilated at the time of enrolment but are expected to undergo PPV for an operation, this operation should occur within 24 hours of hospital admission.

All other aspects of the patients care will be as per the usual unit standard as interpreted by the attending critical care physician. Patients will be prospectively followed throughout the critical care unit and hospital stay until discharge and all patients will be followed up by a site investigator 30 - 60 days after hospital discharge. For statistical analysis, the primary outcome will consist of an analysis of the occurrence of a composite endpoint defined by episodes of clinical distress. In practical translation to clinical care however, it is recognized that each cohort of patients (drained or observed) is at greatest risk of different potential benefits and complications. Those subjected to drainage are protected against tension pneumothorax, but are subject to chest drainage complications. Those observed are potentially protected against primary chest tube complications but are risk of tension pneumothoraces and the potential complications of emergent chest tube placement. Therefore the most meaningful data expected to guide clinical care will be accurate **event rates of complications** arising from the different treatment strategies which will provide data for clinicians to apply to their own patient population to determine best practices. The secondary outcomes will be the need for emergency chest drainage, in-hospital death, tracheostomy, ARDS, VAPS, IAH, ACS, length of ventilation, length of ICU stay, length of hospital stay.

(See Appendix B: Flow diagram of study)

IV. Patient Selection Criteria

a. Inclusion criteria

- 1) Age \geq 18 years
- 2) Occult pneumothorax identified on chest or abdominal CT scan
- 3) No chest drain in-situ
- 4) No hemothorax which warrants drainage in the judgment of attending clinician
- 5) No respiratory distress in the judgment of the attending clinician

b. Exclusion criteria

- 1) Not undergoing PPV and not expected to require PPV within 24 hours of admission
- 2) Not expected to survive
- 3) "Minuscule" OPTX, which are < 2 cuts on high-resolution scans
- 4) PTX obvious to the clinical team on plain CXR (not occult)
- 5) Respiratory distress in the judgment of the attending clinician
- 6) Pre-existing chest drain in-situ

V. Definitions:

- a. Obvious pneumothorax (Obvious PTX) – air in the pleural space, demonstrated by a visible pleural stripe on plain AP supine chest radiograph. Subtle signs of PTX such as the deep sulcus sign, double diaphragm sign, unusually distinct cardiac apex, visualized pericardial fat tags, depressed diaphragms, paramediastinal lucencies, or “crisp” mediastinal silhouettes²⁸⁻³⁴; in the absence of a visible pleural line will NOT be considered obvious.
- b. Occult pneumothorax (OPTX) – air in the pleural space documented as present on computed tomography of the chest or abdomen, but without an obvious PTX as defined above. For study purposes the determination of “occult” will be made by the treating clinical team at the time of potential treatment allocation. In the event of retrospective reporting by radiologists with benefit of all imaging, who report that a PTX was not occult and was visible on the original CXR, the PTX will still be considered as “occult” for study purposes.
- c. **Composite Respiratory distress:** acute changes from a “stable” baseline requiring;
 - urgent placement of a chest drain
 - acute increase by 0.2 in the FiO₂
 - pharmacologic paralysis for the purpose of improving ventilator synchrony
 - hand-bagging
 - prone ventilation
 - documentation of an adverse respiratory event in the medical record by the attending medical team
- d. Intra-abdominal hypertension (IAH) - IAH is defined by either one or both of the following:
 - 1) An IAP \geq 12 mmHg, recorded by a minimum of three standardized measurements conducted 4-6 hours apart.
 - 2) An APP \leq 60 mmHg, recorded by a minimum of two standardized measurements conducted 1-6 hours apart³⁵.
- e. Abdominal Compartment Syndrome (ACS) – ACS is defined as the presence of BOTH³⁵:
 - 1) An IAP \geq 20 mmHg with or without APP $<$ 50 mmHg recorded by a minimum of three standardized measurements conducted 1-6 hours apart AND;
 - 2) Single or multiple organ system failure which was not previously present
- f. Abdominal Perfusion Pressure (APP) = mean arterial pressure (MAP) – IAP³⁵.

VI. Informed consent/Ethical Issues: As true clinical equipoise exists, two physician and regained capacity consent will be sought. At the present time, evidence-based medical review does not allow a determination of the correct therapy for this condition. As such complete clinical equipoise exists. Based on analogy to overt pneumothoraces, it might be assumed that placement of a chest tube is the closest approximation to a “standard of care” that exists. Thus the intervention in this study is the avoidance of an invasive procedure. It is impractical to consider approaching next of kin (if available) to consent for avoiding an invasive procedure for which the indications are essentially unknown. For this reason we would wish to proceed with the trial understanding that the treatment will be randomly allocated, but will be completely “standard” notwithstanding whichever treatment arm is allocated, given that there is no current standard of practice. From this regard, consent will not be required to randomize this treatment, but will be required in order to ethically include the patient in a research analysis. All participating patients will receive the institutional standard of care regarding all other treatments other than chest tube placement. Refusal or withdrawal from the study will not affect any care delivered to the patient.

VII. Stratification and Randomization: Patients will not be stratified in this study. An online randomization portal will be used to allocate patients randomly as receiving or not receiving chest drainage.

Planned Post-Hoc Analyses: A planned post-hoc analysis will be carried out to compare and potential differences in characteristics and outcomes in patient who are undergoing PPV at the time of enrollment (**ICU-group**) compared to those who are subjected to PPV after the time of enrollment for an operative procedure only (**Operation-Group**)

VIII. Description of Treatment Groups

- a. Chest drainage group: This group will have an intra-pleural catheter placed with the intent of draining the intra-pleural air collection. The size and nature of the catheter, manner of placement, and timing of removal will be at the discretion of the attending clinician.
- b. Closely monitored group: This group will not have an intra-pleural catheter placed on the basis of the OPTX. Intra-pleural catheters may be placed after enrollment at the attending clinician’s discretion. After enrollment this decision will constitute an outcome variable, and will require full documentation as to the indications and rationale.

IX. Baseline and Follow-Up Data Collection

a. Baseline Independent variables

- 1) **Demographic data:** age, gender, pre-existing and co-morbid medical conditions including not limited to respiratory, cardiac,

- endocrine, and neurological diseases will be collected.
- 2) **Admission injury severity data:** Mechanism of injury, Injury Severity Score, anatomic injury scores, revised trauma score, Glasgow Coma score, and APACHE II scores, PTX size on CT scan, presence or absence of hemothorax, number of rib fractures, presence or absence of flail chest.
 - 3) **Physiologic and laboratory data:** mean arterial pressure, heart rate, $\text{FiO}_2/\text{PaO}_2$ ratio, mean airway pressure, positive end-expiratory pressure (PEEP) requirements, continuous intra-abdominal pressure, white blood cell count, lactate level, base deficit, and arterial blood gasses.

b. Primary Outcome variable

- 1) Episodes of respiratory distress (see V. Definitions)

c. Secondary dependent variables

- 1) **Respiratory outcomes:** requirement for chest drainage, mean airway pressure, $\text{FiO}_2/\text{PaO}_2$ ratios, requirement for tracheostomy, days of intra-pleural drainage, confirmed ventilatory associated pneumonia, confirmed acute respiratory distress syndrome, hemothoraces, bacteriologically proven empyema.
- 2) **Global Outcome variables:** death, ventilator days, ICU days, hospital days, organ dysfunction and failure, transfusion requirements, IAH, ACS.

X. Statistical Issues: The previous but limited literature on OPTXs in mechanically ventilated trauma patients suggests that there will be a failure of conservative management in 0.42 of the observed patients²¹. In the absence of better data regarding rates of respiratory distress in these patients this can be assumed to represent an event rate. A rate of 0.15 in the treated patients will be assumed. Thus the study will be powered as a trial of equivalence with an event rate difference of 0.25 between studies and controls. In order to detect a difference of 0.25 in the outcome rate, with an alpha of 0.05, and a Power of 90% ($B = 0.10$), there will need to be approximately 40 in each group. While it is possible that this study might provide this number of patients, the basic goal is to provide further methodological and statistical assistance with the planning of a future multi-center prospective randomized trial.

Based on the interim report of the first 90 recruited patients in the study²⁷, the event rate in the treated group was 0.30, which is higher than we expected. Thus, larger sample sizes are needed to increase the power to detect the difference of event rates. We estimate that 150 patients per group may be required to detect the event rate difference.

- XI. Enrollment Issues:** Our previous review of OPTXs over a 12 month period (June 30 2002 – July 1 2003) revealed 57 OPTXs in trauma patients (ISS > 12) entered into the institutional trauma registry. Seventeen of these patients were ventilated³. We are now carrying out a prospective surveillance project to detect ALL OPTXs in traumatized patients, including those with an ISS less than 12, who are presumably much more common. Thus, while the recruitment of patients into a study typically much less than the number of eligible patients, we believe there will be a much larger number of eligible patients identified. With this rationale, we would anticipate recruitment of 10 – 20 patients per year at the FMC.

Appendices

Appendix A. Illustrative Figures.

Appendix B. Flow Diagram of Study

Appendix A. Illustrative Figures.

Occult Pneumothoraces can occur when the chest radiograph is clearly abnormal

Figure A.1.

Antero-superior supine chest radiograph of blunt trauma victim revealing left posterolateral rib fractures and parenchymal opacity due to pleural fluid and pulmonary contusion. No obvious pneumothorax visible.

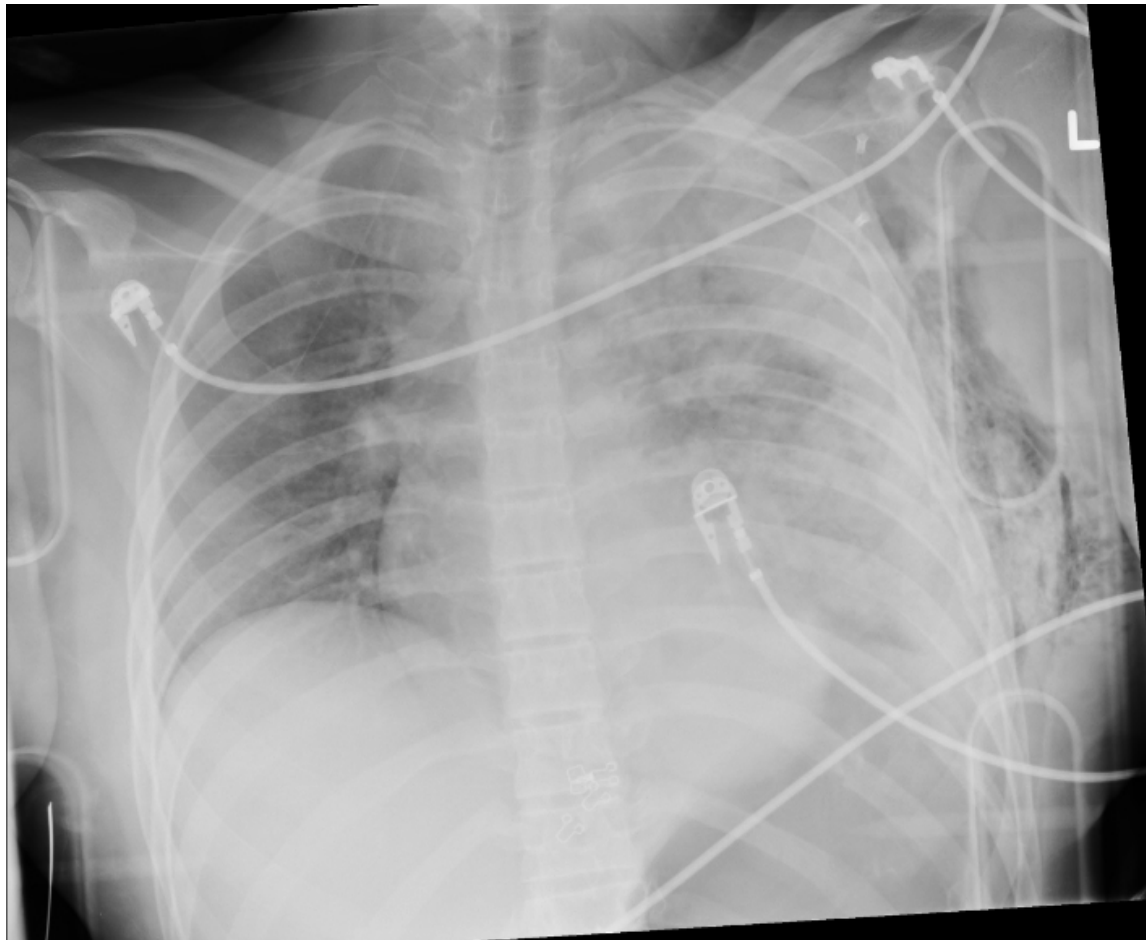
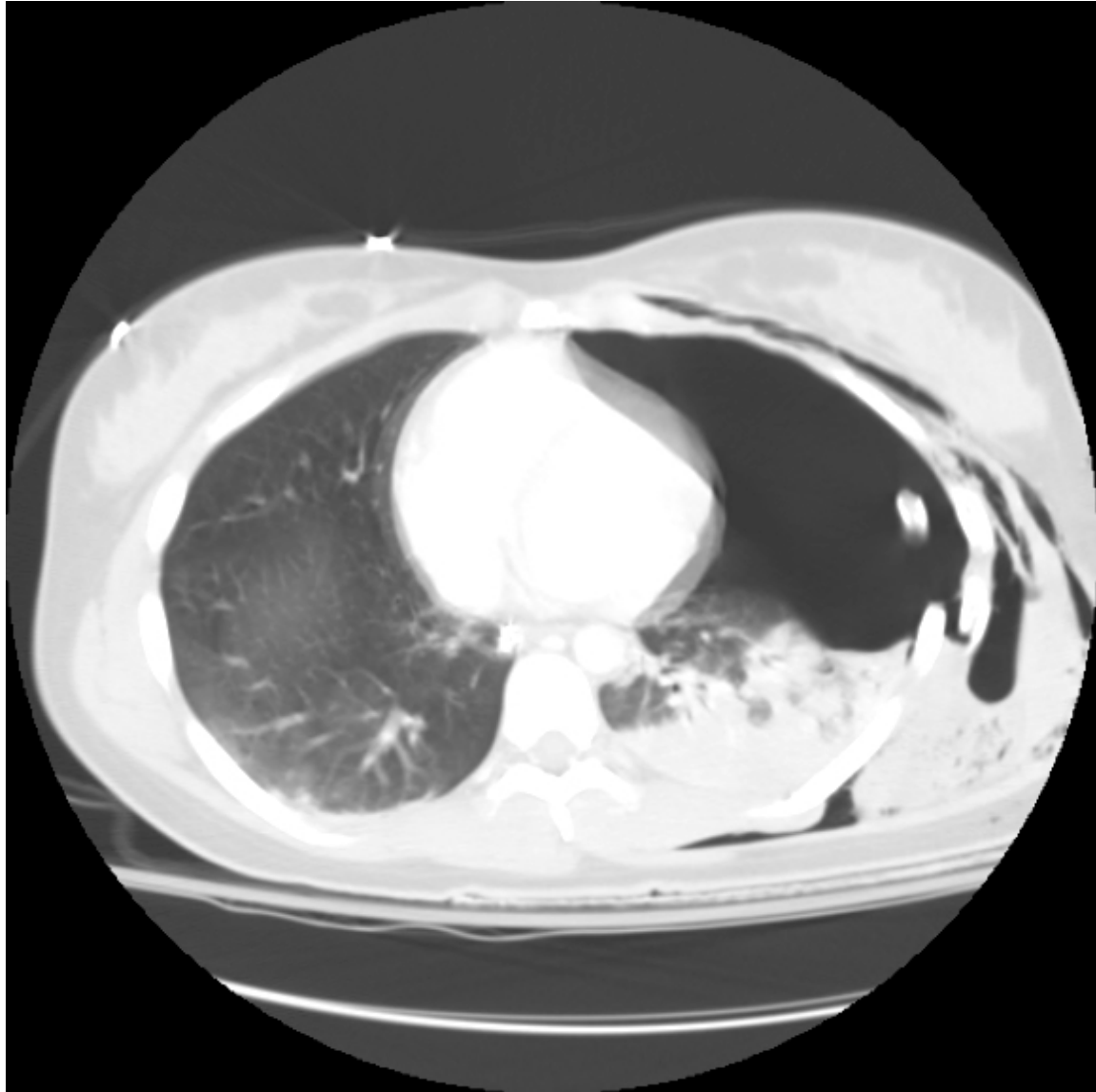


Figure A.2.

Computed tomographic scan of previous patient revealing an large occult left sided pneumothorax



Note: As this OPTX extends posterior to the mid-coronal line of the thoracic cavity, this would be defined as a LARGE OPTX in this study, and this patient would still be eligible.

Figure A.3.

Occult Pneumothoraces can also occur though when the chest radiograph appears unremarkable

Antero-superior supine chest radiograph of blunt trauma victim revealing no obvious pneumothorax.

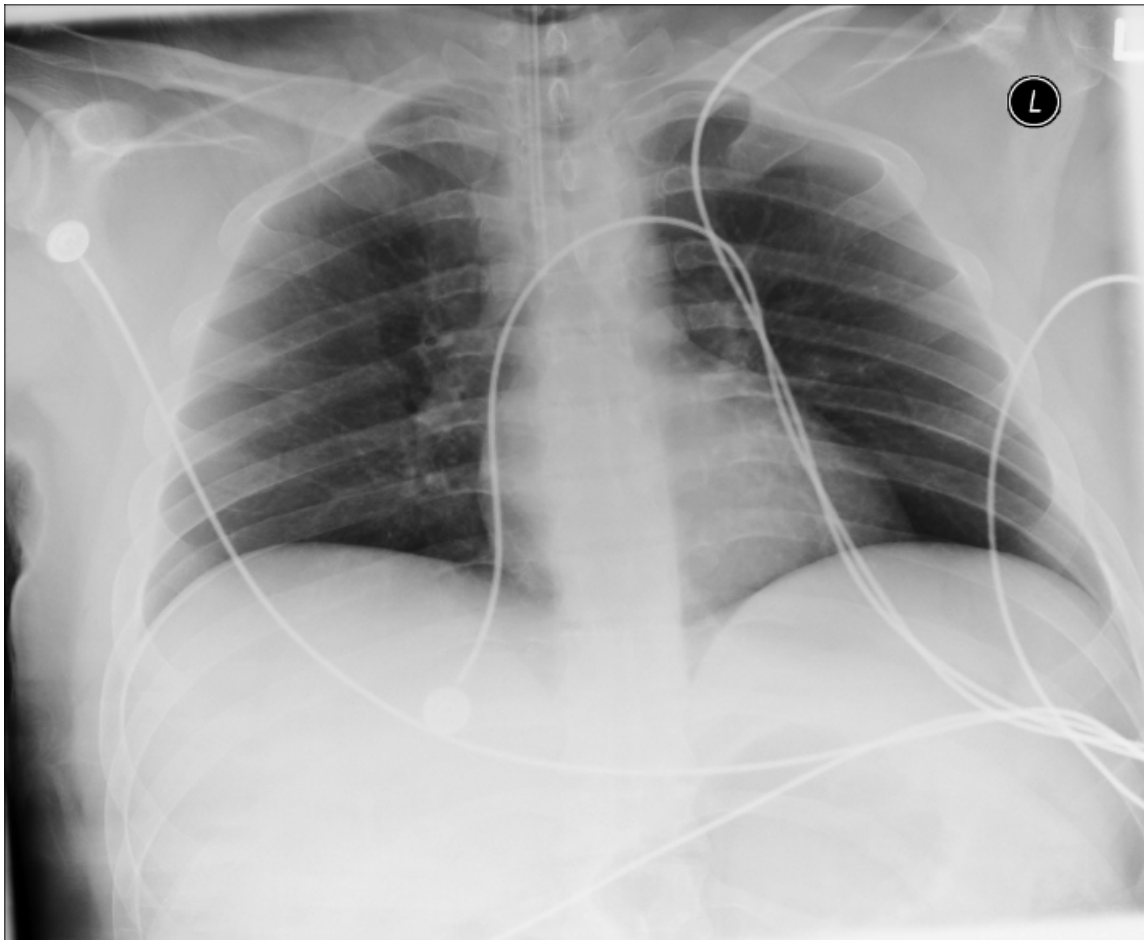


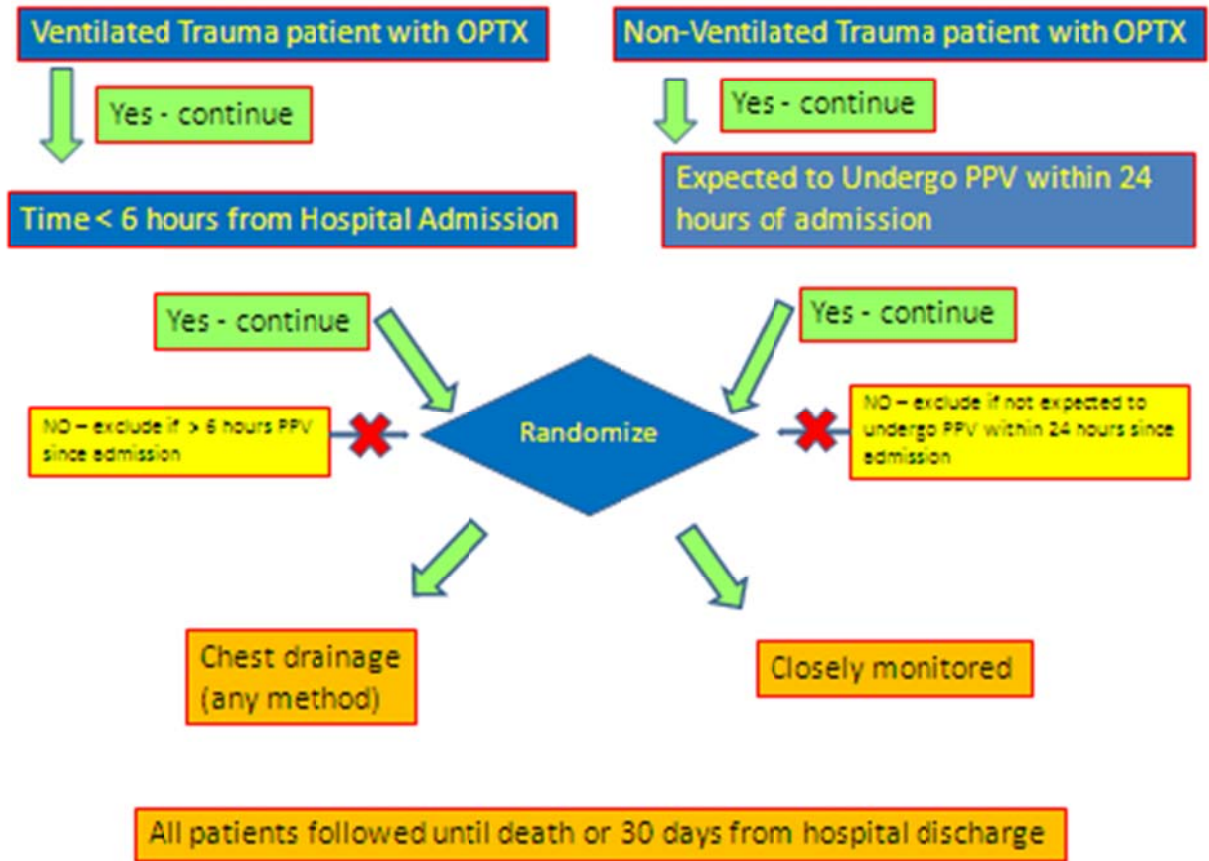
Figure A.4.

Computed tomographic scan of previous patient revealing an large occult left sided pneumothorax



Note: As this OPTX does not extend posterior to the mid-coronal line of the thoracic cavity, this would be defined as a MEDIUM OPTX in this study, and thus this patient would be eligible.

Appendix B. OPTICC Study Over-view Flowchart



XIII. References

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