Operative versus Non-operative Treatment of Acute Unstable Chest Wall Injuries: A Multi Centered Randomized Controlled Trial

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Primary objective: To compare early surgical fixation versus conventional, non-surgical treatment of unstable chest injuries on the basis of our primary outcome measure of days spent free from a mechanical ventilator in the first 28 days following injury.

Secondary objectives:
1) To compare other important outcomes between treatment groups including days in ICU, rates of pneumonia and sepsis, need for tracheostomy, mortality, general health outcomes, objective assessment of pulmonary function, and other complications of treatment
2) To perform a cost-effectiveness analysis comparing the two treatment groups from a health care payer perspective.

Hypothesis: Our hypothesis is that the early surgical fixation of unstable chest wall injuries will significantly improve patient outcomes over conventional, non-surgical treatment.

Sites: Recruitment across multiple sites in North America

Sample Size: 206 patients in total, 103 in each treatment group

Randomization: Online randomization system (www.randomize.net)

Surgeon eligibility: The surgical fixation will be conducted by senior fracture management surgeons who have experience with rib fracture fixation. Surgeons will be considered experienced if they have met the following criteria:

a) Participated in relevant cadaver labs OR reviewed instructional videos on rib fracture fixation
   AND
b) Participated in at least 3 rib fracture fixation procedures

Treatment Arms:
1) Non-operative group:
   - Mechanical ventilation (if needed)
   - Aggressive pain management (epidural catheters, intercostal blocks, PCA…)
   - Pulmonary toilet
   - Chest physiotherapy

2) Surgical group:
   - Mechanical ventilation (if needed)
   - Aggressive pain management (epidural catheters, intercostal blocks, PCA…)
   - Pulmonary toilet
   - Surgical fixation of chest call with plates and screws within 96 hrs injury
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Inclusion criteria:
Meeting one of the following two indication for surgical fixation of chest wall injury:

Flail chest – Defined as follows:
- ≥3 unilateral segmental rib fractures; OR
- ≥3 bilateral rib fractures; OR
- ≥3 unilateral fractures combined with sternum fracture/dissociation

OR

Severe deformity of the chest wall (Diagnosed by CT scan) – Defined as follows:
- Severe displacement of 3 or more ribs (by minimum 15mm each); OR
- Marked loss thoracic volume/caved in chest (>25% volume loss in involved lobe(s)); OR
- Overriding of 3 or more rib fractures (by minimum 15mm each); OR
- Two or more rib fractures associated with intra-parenchymal injury – ie ribs in the lung parenchyma

Exclusion criteria:
Anatomic location of rib fractures are not amenable to surgical fixation (e.g. fractures directly adjacent to spinal column)
Rib fractures primarily involving floating ribs (ribs 10-12)
Home Oxygen (O2) requirement
Other significant injuries that may require long term intubation:
- Severe pulmonary contusion (Defined as PaO2/FIO2 ratio <200 with radiological evidence of pulmonary infiltrates WITHIN 24 hours of THORACIC TRAUMA)
- Severe head injury/Traumatic brain injury – (GCS ≤ 8 at 48 hrs post injury. If unable to assess full GCS due to intubation or other causes, GCS motor ≤4 at 48 hrs post injury)
- Upper airway injury requiring long term intubation and mechanical ventilation (e.g. tracheal disruption)
- Acute quadriplegia/quadraparesis
- Head and neck burn injuries, or inhalation burn injuries

Dementia or other inability to complete follow-up questionnaires; Medically unstable for OR (e.g. haemodynamic instability, acidosis, coagulopathy, etc.)* or unlikely to survive 1 year follow-up, in the opinion of the attending physician; Lack of informed consent from patient or substitute decision maker

Follow-up: Patients will be seen daily until discharged from the ICU. They will be followed up at 1, 2, 6 weeks and 3, 6, 12 months post injury.

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