

Form "EAST Multicenter Study Proposal"

Study Title Effect of Regional Anesthesia on Delirium in Geriatric Patients After Blunt Thoracic Trauma

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My Multicenter Study proposal is... Retrospective

Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined Patients 65 and older will soon account for 20% of the US population, and are an increasing proportion of patients admitted after traumatic injury. Rib fractures are identified in at least 10% of patients admitted after blunt traumatic injury. The cornerstone of treatment of rib fractures is adequate pain management in order to facilitate participation in respiratory therapy and prevent development of pulmonary complications. However, narcotic pain medications, as well as uncontrolled pain, are known precipitating factors for delirium in the elderly. Delirium is increasingly associated with poor outcomes in the elderly including functional decline, longer length of stay, and increased mortality. Regional anesthesia techniques including epidural and paravertebral catheters provide excellent pain control for patients with multiple rib fractures, and have been shown to decrease the usage of opioid narcotics. The association of regional anesthesia and prevalence of delirium has yet to be investigated.

Primary aim Our primary aim is to investigate the association between the use of regional anesthesia and development of delirium in geriatric trauma patients with rib fractures.

Secondary aims Our secondary aim is to examine the association between use of regional anesthesia and the occurrence of pulmonary complications, ICU and hospital lengths of stay, in-hospital mortality, and discharge disposition in geriatric trauma patients with rib fractures.

patients 65 years and older

mechanism: blunt trauma

Inclusion Criteria 3 or more rib fractures

admission to the intensive care unit

severe head injury (AIS 3+)

severe spine injury (AIS 3+)

Exclusion Criteria

history of dementia

Therapeutic Interventions

Retrospective cohort study from 1/1/2011-12/31/2015. Therapeutic intervention monitored will include use of regional anesthesia (epidural and paravertebral catheters), placement of which was at the discretion of the attending intensivist and attending pain service anesthesiologist.

Primary Outcome

Delirium positive ICU days (measured by CAM-ICU)

Pulmonary complications (pneumonia, empyema, aspiration, ARDS)

ICU length of stay

Secondary Outcomes

In-hospital mortality

Discharge disposition

Demographics (age, sex, race, ethnicity, comorbidities, BMI)

Outpatient medications (current use of aspirin, plavix, coumadin, direct thrombin inhibitor, factor Xa inhibitors)

Trauma variables (mechanism of injury, injury severity score, maximum chest AIS, presence of flail segment, hemopneumothorax, sternal fracture, chest tube placement)

ICU variables (admission date, discharge date, length of ICU stay, daily CAM-ICU scores, daily RASS scores, daily pain scores, intubation, number of ventilator days)

List specific variables to be collected & analyzed

Pain service data (consult to pain service, placement of epidural or paravertebral catheter, date of catheter placement, date of catheter removal, reason for no regional anesthesia if pain service was consulted)

Complication data (presence of pneumonia, empyema, aspiration, ARDS)

Surgical data (type of thoracic operation, need for laparotomy)

Hospital data (admission date, discharge date, hospital length of stay, discharge disposition, in-hospital mortality)

Data will be collected retrospectively from patients admitted to participating centers from 1/1/2011-12/31/2015. See associated data collection document for patient-specific information of interest.

Outline the data collection plan and statistical analysis plan succinctly

To assess the risk of delirium and pain we will use univariate and multivariable methods. Since multiple observations will be collected per patient, we will account for clustering using mixed effects models. In univariate analyses, we will examine the relationship between covariates of interest and the risk of delirium using generalized linear mixed models (GLMM) with Poisson distribution, log link and robust standard errors to estimate risk ratios (RRs) and 95% confidence intervals (95% CIs) of delirium by regional anesthesia use during ICU stays. To evaluate the relationship between regional anesthesia use and pain scores, we will use GLMM with ordinal family, log link and robust standard errors to estimate RRs and 95% CIs. We will also evaluate using survival analysis methods to account for varying times in ICU length of stay and right-censoring. Multivariable models will be developed by fitting all covariates initially and using a manual stepwise procedure to remove variables not associated with the outcomes and that do not change the primary estimates of interest by more than 10% by their removal to achieve the most parsimonious models. Individual covariates will be considered statistically significant at $p < 0.05$.

Outline consent procedures here, if applicable

NA- retrospective cohort study

Succinctly outline a risk/benefit analysis

The use of regional anesthesia to control pain in elderly trauma patients with multiple rib fractures may provide better pain management without the systemic side effects of narcotic pain medications, to which these patients are particularly susceptible. If we can reduce the use of systemic pain medications in this population, we may in turn reduce their post-injury complication rates and improve outcomes for this vulnerable group of patients.

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**Include a brief listing of
key references**

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