Safety of therapeutic anticoagulation in TBI patients

Kazuhide Matsushima, MD
LAC+USC Medical Center
University of Southern California

Background

- Traumatic brain injury (TBI)
  - higher incidence of venous thromboembolism (VTE)
- Therapeutic anticoagulation (TAC)
  - VTE, atrial fibrillation, mechanical valve, etc.
- Dilemma between bleeding risks of TAC versus thromboembolic complications

Bleeding or Thromboembolism?
Hypothesis

TAC would be safely initiated without serious adverse events in a selected group of TBI patients

Methods

- Multicenter prospective observational study
- Once qualified patient identified, collect data prospectively
- No generalized protocol regarding TAC
  - Indications
  - Timing
  - Type of TAC
  - Repeat head CT after TAC

Methods

- **Inclusion criteria**
  - ≥ 18 years
  - CT-proven TBI
  - TAC within 30 days after injury

- **Variables**
  - Demographics
  - TAC data (indication, type, timing)
  - Endpoint outcomes (Progression of TBI)
Outcomes

- **Primary outcome**
  Clinically significant progression of TBI following ACT

- **Secondary outcome**
  Progression of hemorrhagic TBI on repeat head CTs, Major complications (hemorrhagic/thromboembolic)

Methods Analysis Plan

- **Descriptive analysis**
  - Primary and secondary outcomes
  - Identify the risk factors associated with TBI progression after TAC
    - Univariate analysis
    - Multivariate analysis

Progress / Needs

- **Progress**
  - A single center retrospective study done
  - Pending IRB approval for prospective part

- **Needs for participating centers**
  - IRB approval
  - Prospective data collection
  - Approx. 10-15 cases/year at each center
Goals / Timeline

- Protocol development: January 2016
- IRB submission: March 2016
- Data collection: April 2016 - March 2017
- Analysis completed: June 2017

- Goal: abstract submission to the EAST 2018