



American Association for the Surgery of Trauma

Multi-Institutional Trial Committee

New Proposal Application Form

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Title of Proposal: Mult-Center Validation of the Trauma Specific Frailty Index in Geriatric Trauma Patients.

Hypothesis: Frail status as measured by the Trauma Specific Frailty Index Reliably predicts morbidity, mortality and adverse disposition in a multicenter cohort of geriatric trauma patients.

Type of Study: **Prospective, Observational**

Background-

Define the Knowledge Gap that Study Addresses:

In the U.S., the geriatric population is the fastest growing age group. By the end of next decade, it will comprise about 20% of the total population (1). Frailty is a major health burden in older people (2,3). It is defined as a condition of reduced resistance to stressors, due to a decline in physiological reserves. Multiple studies have shown that frailty is associated with adverse health outcomes, such as mortality, in-hospital complications, readmissions, and adverse discharge disposition (4,5). The concept of frailty and frailty index has been implemented widely across surgical specialties to predict postoperative outcomes and mortality in aging patients. Fried et al demonstrated that a FI > 0.12 significantly predicted postoperative complications, whereas age, gender, and the number of co-morbidities individually were not significant predictors of postoperative complications (6). Rockwood et al reported a FI cut off > 0.40 for defining frail individuals (7). In another study by George et al reported that frail patients required additional postoperative care and support, with a noticeable increase in the intensive care unit (ICU) length of stay; cardiovascular pressure support, respiratory support, and monitoring (8). Increasing age is a known predictor of morbidity and mortality after a traumatic injury with worst outcomes seen in patients with age greater than 65 years (9). Geriatric trauma patients are a unique cohort of patients who are highly prone to develop decompensated state following the stress of traumatic event leading to adverse outcomes. We in a prospective study demonstrated that presence of frailty syndrome is a better predictor of in-hospital complications and adverse discharge disposition among geriatric trauma patients as compared to age (10,11). Most of the frailty scales that exist are extensive and time-consuming and their implementation in geriatric trauma patient is not feasible. To facilitate the clinical

implementation of frailty in trauma we at our institution developed Trauma Specific Frailty Index (TSFI), which consists of 15 variables that can reliably predict the presence of frailty and pre-frailty syndrome in geriatric trauma patients. This index was based on the Rockwood CSHA frailty, which is based on deficit accumulation. In the prospective validation study of our TSFI, we showed that 15-variable TSFI was an independent predictor adverse discharge disposition (i.e. mortality or discharge to skilled nursing facility) in geriatric trauma patients (12) as well as adverse complications and failure to rescue. Now we plan to implement TSFI at multi-institutional level to test its efficacy on a larger scale.

Study Aim(s)-

Primary Aim: The primary aim of our study is to validate the Trauma Specific Frailty Index in a multicenter cohort of geriatric trauma patients.

Secondary Aim: The secondary aim of our study is to evaluate the association of frailty and morbidity, mortality, adverse discharge disposition, and post discharge follow up in a multicenter cohort of geriatric trauma patients.

Proposed Study Population-

Inclusion Criteria:

All patients with age more than or equal to 65 years admitted to the hospital due to trauma will be enrolled in the study.

Exclusion Criteria:

Patients in whom the TSFI could not be obtained (intubated or non-responsive patients with absence of closest relative) or patients whose closest relative/proxy unable to accurately answer two or more TSFI questions (except the following questions; cancer history, coronary heart disease history, and albumin levels) will be excluded.

Outcome Measures-

Primary Outcome: Assess the sensitivity and specificity of TSFI for predicting adverse outcomes.

Secondary Outcome(s): In-hospital complications, discharge disposition, post-discharge complications, falls, and readmission

Data Collection Variables:

Patient ID, Age, Gender, Race, Mechanism of Injury, Injury Severity Scale, Abbreviated Injury Scale, Emergency Department Temperature, Emergency Department Systolic Blood Pressure, Emergency Department Diastolic Blood Pressure, Emergency Department Heart Rate, Emergency Department Respiratory Rate, Emergency Department Glasgow Coma Scale, Operative Intervention, Comorbidities (Hypertension, Stroke, Diabetes, Angina, Myocardial Infarction, Hematological Disease, High Cholesterol, Cirrhosis, Chronic Obstructive Pulmonary Disease, Asthma, Arthritis, Cancer history, Immunosuppression, Autoimmune disease, Dementia, Congestive Heart Failure, Kidney Disease),

Anticoagulant/Antiplatelet, Body Mass Index , Albumin, Trauma Specific Frailty Index Survey (Need help with grooming, Need help with managing money, Need help in doing household work, Need help with toileting, Need help with walking, Feel less useful, Felling Sad, Feel Everything is an Effort, History of Falls, Feel Lonely, Sexually active), Discharge disposition, Complications, Hospital Length of Stay, Intensive Care Unit Length of Stay, Ventilation Days, Mortality, Cause of Death.

1-year follow up for the following:

- Post discharge complications

- Post discharge mortality

- Falls recurrence

- Readmission

Planned Duration of Study: 1 Year

Center Participation Goal: 10 **Patient Recruitment Goal:** 1500

Power Analysis Performed: Yes No

Plan for Statistical Analysis: Data would be reported as means \pm SD for parametric continuous variables and as medians [interquartile range] for non-parametric continuous variables. For categorical variables, data would be reported as proportions. To assess the differences between the two groups, we will perform chi-square tests for categorical variables, student t-tests for parametric continuous variables, and Wilcoxon rank-sum tests for continuous variables. To assess the independent association between frailty and outcomes, univariate and multivariate regression analysis will be performed. All these Statistical analyses will be performed by a PhD Statistician from the College of Public Health at the University of Arizona,

Define How Findings from this Multi-Center Study Will Serve as the Foundation for Future Studies or Future Funded Research:

Validation of the Trauma Specific Frailty index in a multicenter cohort of geriatric trauma patients will establish its utility in risk assessment and discussion of prognosis and goals regarding geriatric care. It will help identify high-risk patients in need of adverse disposition early on during their hospital course and would aid the surgeon's clinical decision regarding the patient's transition of care.

Does Study Require Informed Consent, Describe Rationale:

Yes. The study involves the participants to complete the Trauma Specific Frailty Index Survey which would require the informed consent from the patient to participate in the study.

Database Development-

Do you have independent funding?: Yes No

Does your study require upload of imaging studies?: Yes No

If the cost of development of your database exceeds the allotted financial support from AAST, are you able/willing to fund the difference?: Yes No

Key References-

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