Thrombolytic Care During Inter-Hospital Transfer

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Study Protocol

Inclusion Criteria

Transfer population: Include all patients transferred to UIHC via air ambulance after receiving rtPA for acute ischemic stroke.

Control population: All patients presenting directly to comprehensive stroke center (UIHC) and receive rtPA for acute ischemic stroke.

Exclusion Criteria
Prisoners, non-english speaking and pregnant patients, patients unable to consent for us to collect the data or do not have a family member who is able to consent.

Enrollment and Consent process

1) Patients will be identified when the principal investigator (PI) receives a page that a code stroke patient who received rtPA has arrived or for the control population, the patient receives rtPA in the comprehensive stroke center Emergency Department.
2) Within 24 hours of the patient's arrival, the patient and/or legally authorized representative will be approached by the PI for consent to access their medical record.
3) The PI will discuss the study, including the risks and benefits with the patient and/or legally authorized representative
4) The patient/legal authorized representative will be informed that the decision whether to participate will not affect the clinical care he/she (the person he/she is representing) receives.
5) Once all of the questions have been answered, the informed consent will be handed to the patient and/or legally authorized representative to review.
6) They will have up to 24 hours to decide if they would like to take part in the study.
7) Consent will be shown by the signing of the consent document.
8) After consent is obtained, the PI will begin to collect the patient's data needed for the study and the survey data will be linked to the actual patient.

Data Collection Includes:
Age, date of birth, height, weight, sex, transferring hospital, onset of symptoms, initial NIHSS, initial heart rate/systolic blood pressure, time to rtPA administration, rtPA dose, stroke protocol adherence, time to flight, flight time, medications administered in flight, National Institutes of Health Stroke Scale (NIHSS) in flight, time rtPA infusing in flight, comprehensive stroke center ED arrival time, time rtPA completed, comprehensive stroke center NIHSS, medications administered in comprehensive stroke center ED, intubation, adverse events, time to admission, Operating room intervention, stroke protocol

adherence, 24 hour follow-up CT, Intensive Care Unit and hospital length of stay, discharge disposition and NIHSS, in-hospital mortality, 90-day Modified Rankin Scale.

Statistical Analysis Plan

The primary outcome was percentage of participants with an rtPA protocol violation, with secondary outcomes of time to rtPA administration and in-hospital mortality. We characterized each outcome through descriptive statistics (mean, median, and interquartile range) for each treatment arm. Differences between each group were evaluated using t-tests for continuous measurements and chi-squared tests for categorical variables with exact p- values. Our hypothesis was that inter-hospital transfer results in significantly more rtPA protocol violations compared to presenting directly to a comprehensive stroke center. All analyses were completed using SAS software, version 9.3 of the SAS System for Microsoft (SAS Institute Inc, Cary, NC).