Study Title: Multi-Center Study of Universal CTA Necks for Major Blunt Trauma Patients

1.0 Study Background and Significance

Trauma patients are at risk for blunt cerebrovascular injury (BCVI), which is defined as damage to the carotid or vertebral artery after a non-penetrating injury[2]. Studies show that 1-2% of all trauma cases and up to 9% of severe head trauma cases result in BCVI[2,5]. Although seemingly rare, untreated BCVIs cause strokes in up to 50% of the cases[3]. Stroke is the major cause of functional impairment and death associated with BCVI[5]. Early detection is important, as anticoagulant therapy and endovascular treatment reduce the incidence of stroke in patients with BCVI[4,8]. One study shows that untreated BCVIs in the carotid artery have a mortality of 23-28% and result in neurological deficits in 48-58% of patients[8]. These rates decrease in the instance of untreated vertebral artery injury to a mortality of 8% and a 14-24% occurrence of permanent morbidity[8]. The relative cerebrovascular risk associated with precise injury patterns have not been identified[10]. Without this information, the diagnostic screening test for BCVI with the best risk-benefit profile has not been established[10].

A 2020 study showed even the most up-to-date, expanded Denver BCVI criteria would have missed nearly 20% of BCVI in trauma patients had they not been universally screened using CT Angiography of the neck (CTA neck)[7]. A study comparing BCVI screening techniques to universal CTA neck screening showed that the Denver criteria, expanded Denver criteria, and Memphis criteria do not detect 42.5%, 25.3%, and 52.7% of BCVIs diagnosed with universal CTA, respectively[1].

In comparison to alternative diagnostic modalities, CTA neck is more effective for identifying BCVI than ultrasound and it is more cost effective than digital subtraction angiography (DSA)[8,9]. Studies show that CTA imaging is accurate for diagnostics and few associated risks, including renal dysfunction and allergic reactions to contrast dye[9,6].

A retrospective chart review in addition to concurrent implementation of a universal screening protocol with CT angiography was recently performed at our institution. Universal screening was found to prevent one stroke for every fifteen trauma patients with BCVI when compared to the previously instated screening methods in place at our Level 1 trauma center.

Based on these studies, a prospective multicenter study will be conducted with the following aims:

Primary Aim: To evaluate if there is a reduction in BCVI related morbidity/mortality with implementation of universal CTA neck screening in all major blunt trauma patients across multiple centers.

Secondary Aim: To evaluate if existing guidelines should be modified to include universal CTA neck screening for all trauma patients.

2.0 Subject Population

We will prospectively collect data on all adult patients who underwent a CTA head/neck and sustained any blunt trauma presenting to University Medical Center in New Orleans (UMCNO) from September 1, 2022-August 31, 2025. Patients below 18 years of age, members of vulnerable populations (pregnant women, prisoners), and patients who did not have a CTA neck during their hospital stay will be excluded from the study. The PI and sub-PIs will have access to the information from the trauma registry.

Patients will not be contacted, and a HIPAA waiver of consent will be requested as this study only involves chart review.

This study is a chart review and involves no therapeutic intervention.

3.0 Study Procedures

Study Design:

This is a prospective, multi-center study evaluating timing of CTA neck in patients diagnosed with BCVI at participating sites. Dr. Smith, the PI, has access to patient data at UMCNO through the Trauma Registry. Identification of patients will be through their medical record numbers (MRN) obtained through our trauma registry database. The PI is requesting access to patient MRNs to obtain additional information from the electronic medical record for completion of the data collection process.

Participating centers will acquire individual IRB approval for access to information in the electronic medical record of any patient found to meet inclusion criteria from respective trauma registry. A data collection tool will be provided to participating centers after signing a data use agreement. The information collected will then be uploaded to a REDCAP database.

All information will be obtained from chart review and patients will not be contacted as part of the study.

Data Collection:

The patient's MRN will be used to access electronic medical record and collect information needed to complete the study. No other confidential information will be accessed, and patients will be assigned a unique ID to minimize the risk to loss of confidentiality. All files will be password protected. The master list of code numbers assigned to each subject will be stored in a separate database only accessible by the PI. Data collection documents will be available to the principal investigator or key subject personnel on the research team. Coded data will be archived in the PI's office computer as a password-protected file for 3 years. The data will be deleted from the PI's hard drive 3 years after study completion.

Participating institutions will utilize the trauma registry from their respective center to obtain MRNs of patients meeting the set inclusion criteria. Remainder of the data collection will be

carried out using our provided data collection tool and electronic medical records. Patients will not be contacted to obtain information and will have no time commitment. To minimize the risk of privacy loss to subjects, patient data will only be shared between researchers using HIPAA protected email sending encrypted files only to those granted access to the trauma registry. Only the PI and other members of the research team that have been granted access will have access to the database.

Outcomes Measured:

The primary outcome measured will be to compare the morbidity and mortality of BCVIs in trauma patients who underwent universal screening CTA necks on arrival (Universal CTA Cohort) and compare to those patients found to have a BCVI that did not get universal imaging on arrival (Non-universal CTA cohort). Each cohort can then be assessed as to whether BCVI present, whether ischemic stroke present.

Secondary outcomes will include any complications from contrast/imaging risks, complications related to delay to diagnosis, costs associated with imaging, and treatment of BCVIs.

Variables Collected:

1. Gender
2. Age
3. Height
4. Weight
5. Body mass index
6. BCVI screening tool in place at time of patient enrollment
7. Injury severity score
8. AIS head
9. AIS neck
10. AIS chest
11. Traumatic brain injury
12. GCS in the field
13. GCS on arrival
14. Mechanism of injury (blunt or penetrating)
15. Imaging performed on arrival to UMCNO (CT head, CT c spine, CTA neck, CT chest, CT abdomen/pelvis)
16. Outside imaging performed (CT head, CT c spine, CTA neck, CT chest, CT abdomen/pelvis)

17. Extended Denver criteria present (YES/NO):
    A. Le Fort II or III displaced midface fracture
    B. Mandible fracture
    C. Complex skull fracture (e.g., involving frontal bone and orbit)
    D. Base of skull fracture (sphenoid, petrous temporal, clivus, and occipital condyle fractures)
    E. Scalp degloving
    F. Cervical spine fracture, subluxation, or ligamentous injury at any level
    G. Severe traumatic brain injury with Glasgow coma scale <6
    H. Near hanging with hypoxic-ischemic (anoxic) brain injury
    I. Clothesline type injury or seat belt abrasion with significant swelling, pain, or altered mental status
    J. Traumatic brain injury with thoracic injuries
    K. Upper rib fractures
    L. Thoracic vascular injuries
    M. Blunt cardiac rupture
18. CTA neck obtained during initial assessment (Yes/No)
19. CTA neck obtained later during ED course (Yes/No)
20. CTA neck obtained after admission (Yes/No)
21. Time from admission to CTA neck (in hours)
22. When BCVI was diagnosed (Before/After Clinical Change, if present)
23. Time from injury to diagnosis of BCVI (in hours)
24. Delay to diagnosis of BCVI (Yes/No)
25. Reason for delay (lack of recognition, unable to obtain CT scan due to patient instability or surgery)
26. Treatment when BCVI diagnosed (conservative management, endovascular, surgery)
27. Biffl grade of BCVI
28. Artery injured – Artery in which BCVI diagnosed.
29. Stroke (Yes/No)
30. NIHSS score/severity of stroke
31. Timing of stroke (hospital day)

32. Distribution of stroke – laterality and arterial distribution
33. Cost of initial CT scans
34. In-hospital mortality (Yes/No)
35. Time to in-hospital mortality (in days)
36. Hospital length of stay (in days)
37. ICU length of stay (in days)
38. Ventilator days (in days)
39. Discharge destination (home, LTAC/SNF, IPR, Death)

Statistical Analysis:

Continuous variables will be compared using Student's t-test and the Mann Whitney U test. The Chi-squared tests or Fisher's exact test will be used to compare categorical variables. All variables with a p value <0.2 on univariate analysis will be entered into a multivariable logistic regression analysis to identify independent risk factors for increased length of stay. Data will be reported as adjusted odds ratios with 95% confidence intervals. Statistical significance will be set at $p<0.05$.

An *a priori* power analysis was conducted using retrospective data from our institution. A total of 640 patients (320 in each cohort) will give the study an adequate power of 80%.

4.0 Risks

The risk for these subjects is minimal as this study is a prospective chart review of data within the electronic medical record. Loss of privacy during data collection and use of the patient's medical record number is the main risk to patients. To minimize these risks, only the study PI will have access to the patient's PHI. All files will be stored electronically as password protected files only accessible to research personnel as encrypted data on facility-maintained computers. All subjects included in the chart review will be assigned a coded subject ID number and kept in a password protected folder on the PI's office computer that is only accessible to the PI. Key research personnel and the PI will have access to the database and data collection sheet which will include coded data using an assigned subject ID number. Files will be archived in the PI's office computer for a period of 3 years as a password protected file. Data will be permanently deleted at the completion of 3 years post-study completion.

For this minimal risk study, provisions for monitoring data will include the study team reviewing the data on a bi-monthly basis to ensure that the study is proceeding as planned and no additional risks have been identified.

5.0 Benefits

There will be no direct benefits to the subject for participating in this research study. However, the knowledge gained from the study may benefit society in general. Developing a better understanding of the importance of prompt recognition and treatment for BCVI can help to reduce the mortality and morbidities that result from BCVI.

6.0 Remuneration

There will be no payment to the subject for participating in this research study as it is retrospective chart review.

7.0 Academic or Extra Credit

None

8.0 Costs

There will be no costs to the subject for participating in this research study as it is retrospective chart review.

9.0 Alternatives

This does not apply.

10.0 Consent Process and Documentation

This study is a chart review in nature and fits the criteria for expedited research given that the risk to subjects is minimal and a waiver of consent will be requested. The only risk to subjects is related to potential loss of privacy due to data collection. All collected data will be pre-existing in the patient's electronic medical record when collected and will therefore not impact the care of subjects involved. The risk to the patients is minimal with no direct impact on their medical care.

11.0 References

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