Study Title: Prospective, Observational Trial of Blunt Cerebrovascular Injury Management and Stroke Formation

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Background/Significance:

Scant research exists examining optimal therapy for patients with blunt cerebrovascular injury (BCVI). While medical therapy for BCVI is standard as it is associated with decreased rate of stroke, the optimal medical therapy overall and for each grade of injury is unknown. Patients with BCVI are often followed with serial radiographic imaging with unclear durations necessary between scans. Indications for and results with endovascular intervention (EI) in BCVI are similarly unclear. Complicating matters is the fact that BCVI is not a stagnant lesion, and injury grade can change over time. BCVI are comprised of both carotid and vertebral artery injuries, and practices may differ by vessel injured. Finally, risk factors associated with stroke development are unknown.

Given the large amount of unknowns in ideal management of BCVI, a multicenter trial is a critical need. The long-term goal of this prospective, multicenter, observational trial is to define rates of stroke development and risk factors for stroke formation. A secondary goal is to define the current practices in use for management of patients with BCVI; this would include medical therapy, radiologic imaging, use of diagnostic angiography and use of EI. Achieving these specific goals of this proposed trial will further our understanding for optimal treatment in patients with BCVI.

Primary Aim:

The primary aim of this study is to determine rates of stroke for BCVI overall and by grade of injury and predictors of BCVI related stroke formation.

Secondary Aims:

A secondary aim of this study is to determine rates of endovascular interventions for BCVI overall and by grade of injury.

A second aim of this study is to determine rates of diagnostic angiography for BCVI overall and by grade of injury.

A secondary aim of this study is to determine timing of follow-up radiographic imaging for BCVI overall and by grade of injury.

A secondary aim of this study is to determine rates of utilization of medical therapies for BCVI overall and by grade of injury.

Inclusion Criteria:

1. Age 18 years and greater
2. Traumatic injury
3. Blunt injury mechanism
4. Presence of BCVI (either internal carotid or vertebral artery injury)

Exclusion Criteria:

1. Age less than 18 years
2. Non-traumatic internal carotid or vertebral artery pathology
3. Penetrating injury mechanism

Therapeutic Interventions:

This is a prospective observational trial only. Patients will be managed according to the discretion of the treatment team at each individual institution. No alterations in patient care will occur because of this trial.

Primary Outcome:

BCVI related stroke

Secondary Outcomes:

Rates of diagnostic angiography

Rates of endovascular interventions

Timing of follow-up radiographic imaging

Rates of medical therapies

Variables:

1. Hospital geographic location
2. Hospital trauma yearly volume (patients/year)
3. Hospital urban environment
4. Hospital academic affiliation
5. Institution BCVI screening guidelines used.
6. Who is the team managing carotid injuries at your institution?

7. Who is the team managing vertebral injuries at your institution?
8. Do you have an institutional protocol for carotid injury management?
9. Do you have an institutional protocol for vertebral injury management?
10. Age
11. Race
12. Gender
13. Mechanism of Injury
14. Injury Severity Score
15. AIS Head
16. AIS Face
17. AIS Neck
18. AIS Spine
19. AIS Thorax
20. AIS Abdomen
21. AIS Lower Extremity
22. AIS Upper Extremity
23. Admission Systolic Blood Pressure
24. Admission Diastolic Blood Pressure
25. Admission Heart Rate
26. Admission Respiratory Rate
27. Admission oxygen saturation
28. Admission Eye GCS
29. Admission Voice GCS
30. Admission Motor GCS
31. Admission hemoglobin
32. Admission WBC
33. Admission lactate
34. Admission platelets
35. Admission INR
36. Admission Creatinine
37. First medical therapy for the BCVI
38. Time to first medical therapy for the BCVI (hours)
39. Repeat 28-29 for all medical therapy given
40. If the first medical therapy for the BCVI was not started within 1 day after diagnosis of the BCVI, what was the reason why?
41. Complication occurring with medical therapy for the BCVI.
42. Was a diagnostic angiography performed?
43. Time to diagnostic angiography (hours)
44. Indication for diagnostic angiography.
45. Grade of injury at the time of diagnostic angiography.
46. Was an endovascular intervention performed?
47. What type of endovascular intervention was performed?
48. Indication for endovascular intervention.
49. BCVI related stroke

50. Time until diagnosis of BCVI related stroke (hours)
51. Mortality during initial hospitalization
52. Cause of mortality during hospitalization
53. Hospital length of stay (days)
54. Glascow Outcomes Scale score
55. BCVI vessel injured
56. What was the radiologic modality used at BCVI imaging occurrence #1?
57. Time to BCVI imaging occurrence #1 (hours)
58. BCVI grade at imaging occurrence #1.
59. Presence of luminal stenosis at the time of imaging occurrence #1.
60. Estimated percentage luminal stenosis (0-100%) at the time of imaging occurrence #1.
61. Presence of intimal flap at the time of imaging occurrence #1.
62. Presence of intraluminal thrombus at the time of imaging occurrence #1.
63. Presence of pseudoaneurysm at the time of imaging occurrence #1.
64. Size of pseudoaneurysm (largest mm diameter) at the time of imaging occurrence #1.
65. Repeat 49-57 for each imaging occurrence

Data Collection and Statistical Analysis:

This is a prospective, observational trial. Collected variables will include those listed in the data dictionary, and the data points will be entered into the data collection form on the central data collection tool. The coordinating center team at the University of Maryland will maintain the database and evaluate the data for quality. The University of Maryland team will also be responsible for communication with participating centers. The University of Maryland team will also provide the statistician for data analysis.

For the statistical analysis we are proposing to perform univariate analysis for rates of the collected variables, focusing on the primary and secondary aims of medical therapy, diagnostic angiography, endovascular interventions, radiographic follow-up, and stroke formation. We will also examine radiographic lesion characteristics. Stratification may be performed by injury grade and by vessel injured (vertebral or carotid). We are then proposing examining risk factors for stroke development with bivariate analysis for the association of collected variables with stroke formation and subsequent binary logistic regression to determine factors influencing stroke development; the analysis for stroke formation may also undergo stratification by grade of injury and vessel injured. Other secondary outcome measures include radiographic lesion evolution and functional outcome.

Consent Procedures:

Informed consent will not be obtained as this is a prospective observational trial and there will be no alteration in patient care.

Risk/Benefit Analysis:

The optimal treatments for specific grades of BCVI are unknown, as are the benefits and risks of each specific treatment for individual grades of BCVI. Better delineating the optimal management of BCVI may be beneficial to future patients with BCVI by improving our treatment efficacy. The risk to patients in this trial is minimal as this is a prospective observational trial without alteration in patient care. The major risk to patients is loss of confidentiality, which we will guard against.

References:

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