



**EAST MULTICENTER STUDY
DATA COLLECTION TOOL**

Multicenter Study: _____

Enrolling Center: _____

Enrolling Co-investigator: _____

Demographics / Injury Variables:

Gender: _____ Age: _____ Height(cm): _____ Weight(kg): _____ BMI: _____

BCVI screening protocol in place at institution at time of patient presentation (select one)

- Denver Criteria
- Expanded Denver Criteria
- Memphis Criteria
- Universal Screening
- Other (free text): _____

Level of trauma activation (Circle One): HIGHEST / LOWEST / NOT ACTIVATED

Mechanism of initial injury (Circle One): BLUNT / PENETRATING / BOTH

ISS: _____ AIS Head: _____ AIS Neck: _____ AIS Chest: _____

GCS in Field: _____ GCS on arrival: _____

Traumatic Brain Injury (Circle One): YES / NO

Extended Denver Criteria present (place a check next to all that apply):

- Le Fort II or III displaced midface fracture
- Mandible fracture
- Complex skull fracture (e.g., involving frontal bone and orbit)
- Base of skull fracture (sphenoid, petrous temporal, clivus, and occipital condyle fractures)
- Scalp degloving
- Cervical spine fracture, subluxation, or ligamentous injury at any level
- Severe traumatic brain injury with Glasgow coma scale <6
- Near hanging with hypoxic-ischemic (anoxic) brain injury
- Clothesline type injury or seat belt abrasion with significant swelling, pain, or altered mental status
- Traumatic brain injury with thoracic injuries
- Upper rib fractures
- Thoracic vascular injuries
- Blunt cardiac rupture

Total Number of Extended Denver Criteria Present (Type 0 if none): _____

Imaging, Diagnosis, and Treatment Variables:

Outside Imaging before Arrival (Circle all that apply): 0, CT Head

- 1, CT C Spine
- 2, CTA Neck
- 3, CT Chest
- 4, CT Abdomen/Pelvis
- 5, None
- 6, Other (Type): _____

- 0, CT Head
- 1, CT C Spine
- 2, CTA Neck
- 3, CT Chest
- 4, CT Abdomen/Pelvis
- 5, None
- 6, Other (Type): _____

Imaging Obtained on arrival (Circle all that apply):

Total cost of CT scans obtained upon arrival (Do not include outside images): _____

BCVI present (circle one): YES / NO *****(If no, skip to Hospital Outcomes/Clinical Course Section)**

BCVI Diagnosis/Treatment and Complications:

Laterally (circle one): RIGHT / LEFT

Artery Injured (select one):

- Vertebral Artery
- Common Carotid Artery
- Internal Carotid Artery
- External Carotid Artery

Biffi scale/grade (check one):

- grade I
- grade II
- grade III
- grade IV
- grade V

Diagnostic Modality (select one):

- CTA Neck
- MRA Head/Neck
- Carotid US
- DSA
- Other (free text): _____

Timing of diagnosis? (check one, include details for timing if indicated):

- Upon arrival
- After admission HD# _____

Did patient experience any BCVI related symptoms (Circle One): YES / NO

If yes, diagnosis was made (select one):

- BEFORE patient experienced clinical change
- AFTER clinical change prompted further evaluation

Was there a delay to diagnosis of BCVI (Circle one): YES / NO.

Reason for delay: _____

Management/Intervention upon BCVI diagnosis (select all that apply):

- Anticoagulation
- Antiplatelet
- Endovascular Therapy
- Surgery
- Serial Imaging
- Other: _____

Rationale for the management/intervention/treatment chosen (Free Text): _____

Patient experienced stroke (Circle one): YES/NO

Hospital Day: _____

NIH Stroke Scale Score: _____

Distribution of stroke – include laterality: _____

Hospital Outcomes/Clinical Course:

Hospital LOS (days): _____

ICU LOS (days): _____

Ventilator Days: _____

Mortality: YES / NO

Hospital Readmission: _____

Number of days from injury to mortality:

Discharge Disposition/Destination (Check one that best applies):

Home

LTAC

SNF

Inpatient Rehab

Hospital

EAST MULTICENTER STUDY DATA DICTIONARY

Multi-Center Study of Universal CTA Necks for Major Blunt Trauma Patients – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
-------------	---------------------------

Standard Study Questions

Enrolling Institution Name of Institution where patient was treated

Enrolling Co-investigator Name of investigator entering patient data

Demographics/Injury variables:

Gender Gender of patient enrolled

Age Age of patient enrolled (in years)

Height (cm) Indicate height of patient enrolled (in centimeters)

Weight (kg) Indicate Weight of patient enrolled (in kg)

BMI Auto calculated from Height and Weight. (kg/cm²)

BCVI screening protocol in place at time of patient presentation: Drop down menu – select one of the following (Denver, extended Denver, Memphis, Universal, Other). If other, free text description of protocol in place.

Level of Activation Single choice for level of activation (Highest/Lowest/Not activated).

Mechanism of Injury Single choice for mechanism of injury (Blunt/Penetrating/Both)

ISS Numerical value for calculated ISS
(ISS = Injury Severity Score)

AIS Head Numerical Value for AIS body region = Head
(AIS = Abbreviated Injury Score)

AIS Neck Numerical Value for AIS body region = Neck
(AIS = Abbreviated Injury Score)

AIS Chest Numerical Value for AIS body region = Chest
(AIS = Abbreviated Injury Score)

Field GCS Numerical value for highest GCS calculated in the field (3-15)

Arrival GCS Numerical value for highest GCS calculated upon hospital arrival (3-15)

TBI Select one – yes or no. Indicate if TBI was present on arrival.

Extended Denver Criteria Present

Checkbox – select all that apply if finding was present on initial assessment. Can select one, more than one, or none. Options include:
Le Fort II or III displaced midface fracture
Mandible Fracture
Complex Skull Fracture (e.g., involving frontal bone and orbit)
Base of Skull Fracture (sphenoid, petrous temporal, clivus, and occipital condyle fractures)
Scalp Degloving
Cervical Spine Fracture, subluxation, or ligamentous injury at any level
Severe TBI with GCS <6
Near hanging with hypoxic-ischemic (anoxic) brain injury
Clothesline type injury or seat belt abrasion with significant swelling, pain, or altered mental status.
Traumatic brain injury with thoracic injuries
Upper rib fractures
Thoracic vascular injuries
Blunt cardiac rupture

Imaging and diagnosis:

Imaging obtained at Outside Hospital

Checkbox – select all imaging modalities that were obtained prior to arrival at enrolling facility, if applicable. Options Include:
CT Head
CT C-Spine
CTA Neck
CT Chest
CT Abdomen/Pelvis
None
Other: Free text any other modality

Imaging obtained upon arrival

Checkbox – select all imaging modalities that were obtained upon arrival. Options Include:
CT Head
CT C-Spine
CTA Neck
CT Chest
CT Abdomen/Pelvis
None
Other: Free text any other modality

Cost of initial CT imaging?

Free text. Integer value of cost from CT scans on initial arrival (Do not include OSH images).

BCVI present?

Select one based on whether patient has BCVI diagnosis – YES / NO.

Timing of CTA Neck and BCVI diagnosis

Laterality of BCVI

Select one – Right vs. Left side of BCVI

Artery Injured

Select one – Vertebral artery, Common carotid, external carotid, internal carotid.

Biffi Scale/Grade of BCVI

Checkbox – Select one of the grades (I-V) using Biffi scale.

Grade I	Luminal irregularity with <25% narrowing
Grade II	Dissection or intramural hematoma with 25% or greater narrowing, intraluminal thrombus or raised intimal flap
Grade III	Pseudoaneurysm
Grade IV	Occlusion
Grade V	Transection with extravasation

Diagnostic Modality for BCVI	Checkbox – Select one of the diagnostic modalities: CTA Neck, MRA Head/neck, Carotid US, DSA, Other (free text explanation if other).
Timing of Diagnostic Imaging	Checkbox – Select one of the scenarios: Diagnostic imaging ordered on arrival/initial assessment, or diagnostic imaging was ordered after admission.
Hospital Day of Imaging	If imaging ordered after admission, enter hospital day which it was done
BCVI symptoms present?	Select one – YES/NO. Did patient experience any symptoms
Diagnosis relative to symptoms -	Drop down menu – If patient experienced clinical symptoms, was BCVI diagnosis made prior to symptom onset or did symptoms prompt the workup leading to diagnosis?
Delay in Diagnosis of BCVI?	Drop down menu – yes or no.
Reason for Delay in Diagnosis?	Free text entry for reason of delay in diagnosis.
Management of BCVI?	Checkbox – Select all that apply – Anticoagulation, Antiplatelet, Endovascular therapy, Surgery, Serial imaging, Other. If other, free text any intervention.
Rationale for management?	Free text – enter briefly the decision-making process for why the selected modality was chosen for the management of a patient’s BCVI (Examples include: the severity of the injury, protocol in place at institution, clinical experience/prior success with that modality, clinical evidence for certain situations, etc.)

Complications

Stroke?	Drop down menu – yes or no. Select yes if patient suffered stroke.
Timing of Stroke?	Free text – enter as integer, number of days from admission to stroke diagnosis . (Day of admission = hospital day #1)
Severity of Stroke?	Free text – enter as integer, NIHSS score.
Distribution of Stroke	Free text – laterality and arterial distribution of stroke

Hospital Course and Outcomes

Mortality	Drop down menu. Yes or No. Did patient expire during initial hospitalization?
-----------	---

Time to in-hospital mortality?	Free text – enter as integer, number of days from admission to expiration. (Day of admission = hospital day #1)
Hospital LOS (days)	Free text entry for number of consecutive days patient hospitalized at initial admission (Day of admission = hospital day #1) LOS = Length of Stay
ICU LOS (days)	Free text entry of number of consecutive days patient required ICU admission (ICU = Intensive Care Unit, LOS = Length of Stay) - Day of admission = hospital day #1
Duration of Mechanical Ventilation (days)	Free text entry for total number of days patient required mechanical ventilation (Day of admission = hospital day #1)
Disposition?	Drop down – select discharge disposition of patient. Options include: Home, LTAC (Long Term Acute Care), SNF (Skilled Nursing Facility), Inpatient Rehab, Hospital, Other.

PROTOCOLS

kuali

IRB Certificate of Determination

From: LSUHSC-NO Institutional Review Board (Federal Wide Assurance FWA00002762)

To: Smith, Alison

Date: Wednesday, August 17th 2022

Re: Protocol ID: 4575

Protocol Version: 3

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

Submission Type: Initial

The LSUHSC-NO IRB reviewed the **Initial** submission of the above-referenced protocol and found the study to meet the **Exempt** review criteria. The IRB made the following determinations:

IRB Review Action: APPROVAL

Effective Date: Wednesday, August 17th 2022

This protocol is approved until Saturday, August 16th 2025. To continue research beyond this date, a *Renewal* application must be submitted and approved by no later than this date. Please consult the [LSUHSC IRB website](#) for submission deadlines for *Renewal* applications.

Approval comments (if any) to note:

The LSUHSC-NO IRB has determined the above referenced human subjects research study to be exempt under 45 CFR 46.104(d), Category 4iii.

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens.

The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

Waiver of HIPAA Authorization is granted.

Approved attachments associated with the submission (if any) include:

Attachments

Protocol	IRB_Protocol	MC_BCVIProposal_v1.pdf
Data Collection Instruments	DATA_CollectionTool	BCVIData_MultiCenterStudyOfUni.pdf

As the Principal Investigator, you are responsible for complying with, and assuring all study staff comply with, all federal regulations and HRPP policies and procedures, including post-approval study requirements, pertaining to human subjects research. HRPP policies and procedures, post-approval study requirements, and other information are available at the [LSUHSC IRB website](#).

Please note: Effective June 2020, the LSUHSC-NO IRB moved into the KualI system which impacted the numbering for studies. For studies approved prior to that date, the Protocol ID may not match the previous IRB number for the same study.