Study Title:	Pediatric PROspective Observational Vascular Injury Trial
Short Title:	Pedi PROOVIT
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Abstract

Background

Pediatric major vascular injury (MVI) occurs in about 2% of pediatric trauma patients, but is becoming more common as the rate of penetrating injuries continues to rise. The rarity of the condition and the wide diversity of possible injury patterns makes it challenging to standardize diagnosis and treament. A multicenter registry is needed to study these injuries to improve our understanding of these patients. The feasibility of a multicenter vascular trauma registry has been established with the PROspective Observational Vascular Injury Trial (PROOVIT) registry, housed by the American Association for the Surgery of Trauma (AAST). We aim to establish a similar registry for pediatric patients, and ultimately merge the two registries to be even more comprehensive.

Objectives

The primary objective is to determine incidence, etiology, management, and long-term outcomes of pediatric MVI. We will aim to do this by developing a pediatric multicenter database. There are several secondary objectives which revolve around using the data to generate hypotheses for future study and ultimately develop evidence-based practice strategies for pediatric patients with MVI.

Study Design:

This is a prospective multicenter observational study that will be conducted at the hospitals within the University of Texas System. Pediatric Trauma Association member hospitals will also enroll, and our goal is to have as many centers as possible participating.

Study Measures:

Data will be collected thorugh prospective chart review. The data collection sheet divides pediatric MVI by anatomic location and There will be no prescriptive changes to the patients' care. No PHI will be recorded and no specimens will be obtained.

1 Background Information and Rationale

1.1 General Information

This is a prospective database, modeled after the AAST PROOVIT study, to collect information regarding pediatric major vascular injuries. Type and mechanism of injury as well as management of injury will be recorded. Additionally, we will follow patients after their index hospitalizations as outpatients for follow-up data.

1.2 Background Information

As of 2020 penetrating injury is the most common cause of death for pediatric patients. With this shift in demographic, management of pediatric major vascular injuries (MVI) is becoming more important. It takes an integrated, skilled, and confident team to manage these injuries in smaller and smaller patients. Overall the rate of MVI in children is still low (2% of pediatric trauma patients). In order to collect enough data to inform decision making and perform statistical review, a multicenter database will be necessary. We have modeled our database after the American Association for the Surgery of Trauma's (AAST) Prospective Observational Vascular Injury Trial (PROOVIT) database and have collaborated with its creator to plan to begin our own pediatric-specific data collection.

We hypothesize that vascular surgery is not performed in a standard fashion across centers when it comes to pediatric trauma patients. Further data collection is necessary to address discrepancies in practice and improve the quality of care of this subset of trauma patients.

2 Study Objectives

2.1 Primary Objective

We want to determine the incidence and clinical and anatomic characteristics of pediatric major vascular injuries.

2.2 Secondary Objectives

We also plan to assess outcomes, both short term and long term based on the patient anatomy, type of injury, types of surgeons, and types of interventions.
We'll assess current practices in long term surveillance and anticoagulation or antiplatelet therapy.
We'll determine the vessel and patient size that should prompt microvascular surgery consultation.

3 Ivestigational Plan

3.1 General Description of Study

The study will be entirely chart review but data will be collected in a prospective manner. Patients will be identified based on injury pattern on admission to a Level 1 urban trauma center.

3.2 Study Duration

We anticipate that the current study will last 10 years, but we will hope to expand the database and continue data collection indefinitely.

3.3 **Study Population**

3.3.1 Inclusion Criteria

The study population will be pediatric trauma patients (age 0-17) with a vascular injury. Any mechanism can be included.

3.3.2 Exclusion Criteria

1. Exclusion criteria- age >18
2. Patients in custody of child protective services or the juvenile detention system

4 Study Procedures

4.1 Data collection

The data will be collected from the electrical medical record. All data will be stored on REDCap and on encrypted facility computers. The study is observational and data will be collected prospectively as the patients are cared for in the hospital at the initial admission. We will ultimately collect follow-up data at their scheduled follow-up appointments. There will be no additional time required for patient participation as it is all chart-review based. No additional laboratory tests will be drawn for the study as this is a purely observational study. All of the information is detailed in our data collection form. It includes type of injury, method of management, and outcomes of injury

4.2 Data Handling and Record Keeping

Linking log will be only identifiable information, connecting the study ID to the patient MRN. Each site will have their own linking log, which will not be shared with the lead site. Human subjects will not be identifiable directly via their record IDs.

4.3 Quality control and assurance

Data verification will be at the level of the individual centers. We will collect data in real time prospectively and verification will be by the surgical and medical teams and the research coordinators at each site. We do not plan to have ongoing third party monitoring.

5 Statistical Considerations

Statistical evaluation will vary depending on the outcomes being assessed. Initially, we plan to gather data in a multi-institutional way to build a database that can be queried in the future. We will assess for efficacy and safety

5.1 Primary Outcomes

Primary outcomes we will be functional outcome of vascular injuries, which will vary depending on the vascular territory involved in the injury (i.e. rate of amputation, stroke)

5.2 Secondary outcomes

Secondary outcomes will be need for re-interventions or changes in management strategy, and long term outcomes including

6 Regulatory and Ethical Considerations

6.1 Waiver of Consent

We have requested a waiver of consent as this is a purely observational study. Patient privacy will be maintained by using a study-specific record number for each patient. Each site will maintain a linking

log with only the patients MRN and this will only be accessible by the site study team. Institutions will be assigned a coded number. The master list of institutions and coded institutional IDs will be kept by the lead site (UTHealth Houston) and will not be released to other sites. For published information (manuscripts, abstracts, presentations, etc), no cell containing a value of 1 to 5 will be reported directly to ensure that patient confidentiality is maintained.

7 Data and Safety Monitoring

There are no adverse events anticipated as this is a purely observational study based on chart review.

8 Publication

We plan to use our collected data in a database manner, with ability to query it and answer various questions regarding vascular traumatic injuries in children. Participating centers will be able to request access to the entire registry containing only deidentified data for their own research as well. We plan to publish in Journal of Pediatric Surgery, Journal of Trauma, and other journals as the study goes on. Results will not be returned to research subjects.

9 References:

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- Barmparas G, Inaba K, Talving P, David JS, Lam L, Plurad D, et al. Pediatric vs adult vascular trauma: a National Trauma Databank review. J Pediatr Surg. 2010;45(7):1404- 12. doi: 10.1016/j.jpedsurg.2009.09.017
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