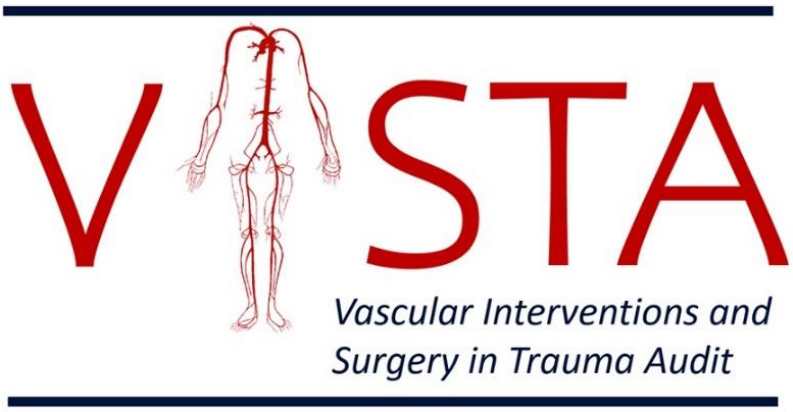

Vascular Interventions and Surgery in Trauma Audit

(VISTA)

A multi-centre evaluation of incidence, contemporary management and outcomes of vascular trauma in the United Kingdom

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National Trauma Research and Innovation Collaborative (NaTRIC)

Vascular and Endovascular Research Network (VERN)

The Circulation Foundation

Conflicts of Interest

No conflicts of interest

Funding

The Circulation Foundation has generously awarded £3,000 to the project

1. Summary and Synopsis

Short title	VISTA
Methodology	Multi-centre, prospective, audit of current practice
Objectives / aims	**Primary objective:** 1. To determine the incidence of vascular trauma and its distribution across the UK **Secondary objectives:** 2. To record the contemporary approaches to the management of vascular trauma and how this compares to current, available guidelines (AAST, EAST). 3. To compare regional and national approaches to the management of vascular trauma across the multiple centres in the UK involved 4. To describe the outcomes of vascular trauma in the UK
Number of participants	All eligible patients within the 6 month audit period.
Inclusion and exclusion criteria	**<u>Inclusion Criteria:</u>** All patients (children and adults) with radiological or surgically proven vascular trauma in the UK, inside and outside of major trauma centres. Vascular trauma is defined as one, or more, named extracranial vessel injury (laceration, intimal tear, thrombosis, transection) **<u>Exclusion Criteria:</u>** Trauma patients without vascular injury
Study duration	6 months

2. Introduction

2.1 Background

Vascular trauma kills and for patients who survive, there is significant associated morbidity, including major limb loss. These primarily young, healthy patients consume significantly more hospital resources compared with trauma patients without vascular injury, requiring up to a third of all blood transfusions and their overall inpatient stay is six times longer (Perkins et al, 2012). Whilst international guidelines exist for the management of vascular trauma (AAST, 2020; EAST, 2015), there are no UK specific guidelines despite trauma being the leading cause of death in the first four decades of life and the commonest cause of limb loss in the young population (Department of Transport, 2021; ONS, 2021; Owens-Williams, 2020).

Whilst the Trauma and Audit Research Network (TARN) collects data pertaining to traumatic vascular injury; this is sub-optimal with many pertinent, contemporary specifics absent making focused analysis of this group challenging (TARNb, 2021). The data collected is not of sufficient granularity to allow understanding of what, when and how vascular intervention occurs nor its impact on patient outcomes – survival, limb salvage. We aim to address this with VISTA.

2.2 Rationale

There is no complete national database recording the incidence, specific management and outcomes of patients with vascular trauma of any cause. Existing databases, such as TARN, capture trauma data but do not capture the vascular specifics with any granularity, prohibiting detailed evaluation of the current incidence, prevalence or management options. The National Vascular Registry (UK) collect data on vascular procedures performed for vascular patients but excludes those with traumatic vascular injury.

Accurate and comprehensive data collected across the whole patient pathway is critical to understand the current incidence, contemporary management, and outcomes associated with vascular trauma in the UK. As case numbers are likely to be small, this audit has to be conducted at a national level, across multiple centres with a central organisation. By reviewing the incidence, timelines, location of management, approaches to intervention (open, endovascular and hybrid) and outcomes of patients with confirmed vascular trauma, we aim to describe the current

national burden and management of vascular trauma, from which to inform future areas for development, research, and education.

3. Project Objectives

The aim of VISTA is to determine the incidence contemporary management and outcomes for vascular injury in the United Kingdom. The specific objectives are:

- To evaluate the demographics of patients sustaining vascular trauma and describe their distribution across the UK.
- To characterise the different patterns of vascular injury and the mechanisms associated with them.
- To describe the current interventions and surgical procedures used to treat vascular injury.
- To quantify the clinical outcomes of patients who have sustained vascular trauma
- To determine care pathways for the patient with vascular trauma.
- To inform future national audit and data collection in relation to vascular trauma.
- To highlight key areas for future research in vascular trauma.

4. Study Population

4.1 Inclusion Criteria

- All patients (children and adults) with radiologically or surgically proven vascular trauma (named, extra-cranial vessel injury) in the United Kingdom, inside and outside of major trauma centres.
- Vascular trauma is defined as a named, extracranial vessel injury i.e. laceration, transection, intimal tear, thrombosis.

4.2 Exclusion Criteria

- Trauma patients without vascular injury.

5. Project Design

The project will be a 50/50 collaborative between the National Trauma Research and Innovation Collaborative (NaTRIC) and the Vascular and Endovascular Research

Network (VERN), both of which are trainee-led, multidisciplinary research collaboratives in the UK.

Through NaTRIC and VERN, all Major Trauma Centres in the UK will be invited to participate through email and social media prior to the study commencement date. A protocol will be disseminated to all participating sites with opportunities for clarifications being provided before each institution confirms its participation in the collaborative.

Registration:

The VISTA audit team will support each eligible hospital site to register. Registration is via the online VISTA site registration form. The VISTA project needs to be registered at each participating site prior to data collection. It also requires local Cauldicott Guardian approval and is the responsibility of the local principal investigator to ensure this is complete prior to data collection.

5.1 Project Setting

All Major Trauma Centres in the UK, along with hospitals with a dedicated 24-hour vascular surgery service are suitable for enrolment.

5.2 Number of Patients to be Enrolled

We aim to enrol all patients meeting the inclusion criteria within the 6 month study period. As this is a national audit, no minimum sample size is required.

5.3 Timescale

Data collection will run for a total period of 6 months (March 2022 to September 2022).

Data collection for each patient recruited will end at:

1. Death

   OR
2. Discharge from hospital

   OR
3. 30 days from date of admission if still an inpatient

5.4 Patient Identification

Members of the study team at each site will review all cases within the previous 24 hour period to establish if any vascular injury was diagnosed and intervened on. The treating clinical team can also directly notify the local PI or other study team members that a patient has undergone intervention. Members of the study team should liaise

with their local TARN coordinators on at least a fortnightly basis to ensure that cases are not missed.

5.5 Consent

As this is a national audit with the use of data that is routinely recorded as part of clinical care, no formal consent process is required. No change to patients' clinical care will occur as a result of their inclusion in VISTA.

5.6 Co-Enrolment with Clinical Studies and Projects

Patients in VISTA are eligible for co-enrolment in other projects but this should be documented as part of the recruitment process.

5.7 End of Project

The end of the project is defined as the point at which the final patient dies, is discharged from hospital or reaches day 30 of their inpatient stay.

5.8 Data Collection

Data will be collected and managed using the REDCap (Research Electronic Data Capture) (Vanderbilt, Nashville, USA) electronic data capture tool (hosted at Queen Mary University of London). REDCap is a secure, web-based application designed to support data capture. Data collection will be conducted by the local site team with source data entered directly into REDCap, following anonymisation by the local PI, or designated team member. The local PI will have a password-protected file stored on the trust server which will have the original patient ID and the project ID. This will be the only location where the link between original and project IDs are stored. Anonymised data will be analysed by the central committee, by amalgamation of the individual site data. Patients will be included if 80% or more of data for individual patients is available. The full data points to be collected are listed in Appendix A.

6. Project Procedures

There is no new intervention under assessment in this project. The project will describe vascular trauma in the UK, illustrate the current range of procedures being utilised to manage vascular trauma, and associated outcomes .

7. Statistical Considerations

7.1 Sample Size

This is a national audit, therefore a sample size calculation has not been undertaken. Based on the median number of vascular injuries being intervened on over 8 years using data from the Trauma Audit and Research Network (TARN), a 6 month observation period is estimated to capture vascular trauma data on approximately 450 cases.

7.2 Method of Analysis

Data will be reported as means with standard deviations (SD) for normally distributed continuous data and medians with interquartile ranges (IQR) for non-normally distributed continuous data. Categorical data will be presented as frequencies and percentages. Where comparisons between groups are made, the T-Test and Mann-Whitney U Tests will be used for normally and non-normally distributed continuous data, respectively. Categorical data will be analysed using Pearson's Chi-squared test. Statistical analysis and graph design will be performed using SPSS. A p-value of <0.05 will be considered statistically significant.

8. Ethics

This project meets the service evaluation criteria according to the NHS Health Research Authority decision tool, as it is designed to define the current system and pathways of care. It describes interventions already in use, which are undertaken by the clinical team caring for the patient, in accordance with their own local existing protocols. As there is no introduction of new intervention nor protocol of care, there is no allocation to interventions or randomisation. Data is already routinely collected via the National Vascular Registry (NVR) and TARN, and the clinical team have chosen the intervention before the evaluation has occurred. It is a project to define current clinical practice and audit against any current gold standards and guidelines. Whilst each contributing site will need to register the project with their audit department, no formal Research Ethics Committee approval is required.

8.1 Confidentiality

Patient data will be anonymised at the point of enrolment into the project and upon data entry into REDCap. Age, sex, time of injury, location of injury and geographical location of

intervention will be the only potentially identifiable data uploaded to REDCap. Sites will not be analysed individually which further minimises the risk of individual patient identification.

9. Public Involvement

The project will be openly advertised on social media and in medical society newsletters/ journals. There is an open mailbox through which any member of the public can contact the central VISTA committee team to learn more about the project and ask questions. A lay summary has been created and will be published on The Circulation Foundation website. Subsequent publications from the VISTA audit aim to have Open-Access status.

10. Data Handling and Record Keeping

10.1 Data Management

Cases will be identified by the local study team as described. The case will be given a project ID, allocated by REDCap and this will be used for all data entry. The local investigating team will capture all appropriate data information in accordance with this protocol from the original patient records and clarify any uncertainties with the treating clinical team and/or local study lead.

Project data will be collected, stored and managed using REDCap. This secure service will provide:

1. An interface for validated data entry
2. Audit trails for tracking data manipulation and export procedures
3. Automated export procedures for data downloads to statistical packages including SPSS
4. Procedures for importing data from external sources

Any major revisions to the study protocol will be authorised by the project management group and updated versions distributed to all investigating sites promptly via email. All versions will be stored in a study master file which will be stored in accordance with information governance policies and will also be held securely in digital format on REDCap.

10.2 Source Data

All source data should be collected directly into REDCap in hours with no paper forms being utilised to further ensure confidentiality. Out of hours, paper forms can be utilised and should be transferred into the REDCap database at the earliest possible opportunity. All times will be recorded in Coordinated Universal Time (UTC) to avoid confusion over transitions between BST and GMT during the data collection period. Recruited sites should also have a local, secure database with local identifiers and the TARN ID for each case recruited. The site Principal Investigator is responsibility for ensuring it is stored securely.

10.3 Confidentiality

The investigators will preserve the confidentiality of participants taking part in accordance with the Data Protection Act (2018), the General Data Protection Regulation (2018), NHS Caldicott Principles, The UK Policy Framework for Health and Social Care Research. Data access will be granted to the regulatory authority to permit monitoring, audit and inspections.

Any paper files will be stored in locked cabinets in a restricted access office at the local investigating sites. A password protected Excel Spreadsheet will be used on a password protected database at participating sites which will contain the link between the patient ID and project ID. Any electronic records created during project analysis will not contain person identifiable data and will be stored on REDCap to which access will be granted to the named project investigators.

10.4 Record Retention and Archiving

Data will be stored, retained and archived in accordance with local information governance policies. Data may be used for analysis not described in this protocol subject to approval from the central audit site.

11. Safety Reporting

Safety reporting of adverse events will not occur due to the nature and design of this project as a service evaluation.

12. Monitoring and Auditing

The project committee will monitor the project in conjunction with NaTRIC via the Centre for Trauma Sciences. Monitoring will be conducted to ensure data integrity and compliance to the

protocol. Remote visits and central monitoring of data via the REDCap database may be performed alongside on-site visits if the current COVID restrictions allow. Monitoring will include source data verification, query resolution and review protocol compliance and the core committee (consisting of current UK vascular trainees) will be responsible for this.

14. Finance and Funding

This project has been awarded funding from the Circulation Foundation UK.

15. Dissemination of Project Results

Data will be submitted for presentation at national and international academic conferences. Further, a manuscript will be prepared for peer reviewed publication.

A writing team, including those involved with the design, implementation and dissemination of the VISTA audit and those contributing to data analysis will be responsible for both presentation(s) and publication(s). For both presentation(s) and publication(s) a collaborative authorship model will be used. Criteria to qualify for collaborative authorship are defined as:

1. Had a significant role in the set up and management of the VISTA audit; including audit department registration, creation of a data collection team and engagement with VISTA committee to ensure timely upload of data (with validation as required)

OR

2. Captured sufficient data to warrant authorship – this would be the equivalent of collecting baseline and follow up data on approximately 12 patients, although it is appreciated individuals may participate in only baseline data collection or only follow up data capture. Data collection is expected to be complete (>95% variables completed) and submitted within 7 months of starting data collection

OR

3. (for principal investigators) provide oversight and support as detailed in sections 8 and 9.

AND

4. Review and approve any resultant manuscript(s) for submission to a peer-reviewed journal.

The corresponding author will take primary responsibility for communication with the journal throughout the submission process.

The anticipated number of audit team members per centre is: 1 PI + 2 other team members (1 vascular/ trauma-interested surgical trainee, 1 radiology trainee). If centres include more than 2 additional team members, it is expected that allied healthcare professionals and/or medical students are included.

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Appendix 1

Data Field	Specifics	Clarification of Specific Field
Patient Demographics	Sex Age Ethnicity Comorbidities	**Comorbities List:** Smoking status – active, ex-smoker (>3 months), never smoker Diabetes Hypertension Previous MI Previous stroke Chronic kidney disease Peripheral vascular disease Previous traumatic vascular injury?
Injury Data	Type of injury – blunt vs penetrating Mechanism of injury Injury sustained Any associated injuries? Abbreviated injury scale Injury severity score Observations on arrival in ED Blood gas result on arrival in ED Prehospital intervention? Grade of shock on arrival in ED ED intervention?	**Type of Injury:** Laceration Transection Thrombosis Intimal tear **Prehospital and ED Intervention:** Tourniquet Blood products Thoracostomy/ Thoracotomy/ Clamshell Tranexamic Acid
Site Data	Location of presenting hospital – rural or urban? Transferred out? Transfer destination (vascular centre, MTC) Time from presentation to transfer Reason for transfer Any delay? Why?	
Management Data	Method of diagnosis – imaging vs surgery What modality of imaging? Time from presentation to intervention Intervention performed (subcategories + free text to record exact procedure) Most senior grade of surgeon Primary operator speciality Rationale for no intervention	**Intervention Performed:** Endovascular Open surgery Hybrid Start and end time of surgery
Operative Findings	Record anatomical level of injury Confirm injury sustained – named vessel, tear/laceration/ transection/ rupture Materials used in repair	**Materials Used in Repair:** Stent? Covered? Uncovered? Graft? Autologous? Synthetic? Shunt?

	Primary amputation?	
Outcome Data	Total length of stay Length of critical care stay Death at 30 days Amputation rate at 30 days Complications Return to theatre Discharge destination	**Complications List:** Sepsis – record source Anastamotic leak ARDS DIC Pneumonia – hospital acquired, ventilator associated, aspiration Compartment syndrome Delirium In hospital cardiac arrest VTE Organ failure – record which or if multiple Fat embolism Stroke **Return to Theatre:** Rationale? Record procedure performed, time from first surgery (end time) to further surgery (start time), most senior grade surgeon, primary operator speciality, operative findings **Discharge Destination List:** Home (own) Home (with relatives/ carers) Nursing home Rehabilitation hospital Alive at 30 days, still in hospital Transferred to other acute hospital – rationale? Mortuary
Follow up Data	Mortality Major limb amputation Functional status	**Functional Status:** Ability to walk Return to work/ study Living independently

Key

Information in red can be obtained from TARN – data already collected

Whilst injuries are recorded by TARN, the level of injury and pattern of that vascular injury is not recorded in sufficient detail. The operative intervention is also recorded with TARN but not with sufficient granularity – rationale not clear, no accurate recording of operative findings, unclear why multiple surgeries performed etc. Reason for vascular intervention not clear.