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Study Protocol

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Trauma emergency thoracotomy for resuscitation in shock—a multi-centre evaluation of current UK practice of pre-hospital and emergency department resuscitative thoracotomy in trauma

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Abstract

Background: Resuscitative thoracotomy (RT) in traumatic cardiac arrest, in particular for penetrating trauma features within several national guidelines. However, evidence surrounding its practice is poor, consisting of predominantly small-scale observational studies. Survival is generally poor, estimated at 3–13%, with better outcomes in penetrating trauma. There is no national RT database and the Trauma Audit Research Network data misses those who have died pre-hospital. It is important that a more in-depth and accurate national picture of thoracotomy practice is developed nationally to guide future practice. Traumatic emergency thoracotomy for resuscitation in shock (TETRiS) is a multi-centre, prospective and observational evaluation of current RT practice in the UK.
Aims and objectives: The aim of TETRiS is to evaluate the pathway of care for RT patients within the UK. This will be undertaken over a period of 12 months. This project will evaluate thoracotomies undertaken both pre-hospital and in emergency departments, examining various parameters including frequency, who performs the procedure, clinical indications, time from injury to initiation, mechanism of injury, injuries identified, interventions performed and patient outcomes.
Methods: This project is being conducted as a collaboration between the National Trauma Research and Innovation Collaborative, the Pre-Hospital Trainee Operated Research Network, The Emergency Research Network and the National HEMS Research and Audit Forum (NHRAF). All UK HEMS, helicopter emergency medicine services and major trauma centre (MTCs) nationally have been recruited, with site investigators identified within each participating unit. Inclusion criteria: All patients undergoing RT, pre-hospital or in an MTC emergency department will be included.

INTRODUCTION

Background

Resuscitative thoracotomy (RT) for traumatic cardiac arrest is an accepted intervention both pre- and in-hospital. Training courses on how to carry out the procedure are run by the Royal College of Surgeons, and the procedure is incorporated into Advanced Trauma Life Support (ATLS) and European Trauma Course (ETC) courses. The European Resuscitation Council (ERC), the Royal College of Emergency Medicine (RCEM), the Faculty of Pre-Hospital Care at the Royal College of Surgeons of Edinburgh (FPHC RCSEd) have all published guidelines regarding the use of RT [1–3].

Patients in traumatic cardiac arrest at the scene of injury, in transport, or on hospital arrival have poor outcomes [4]. Survival is greatest, albeit still with low absolute numbers, in those with tamponade (compared with exsanguination) as the primary cause of arrest, or those in a low flow state rather than actual cardiac arrest [5]. Overall, very few survivors are reported in the

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literature in both penetrating and blunt trauma, with survival rates of 3–13% reported by several studies, with better outcomes for those suffering from penetrating chest injuries and shorter time to intervention and to hospital [6–9].

The evidence base for RT in both penetrating and blunt injury is comprised of a number of small-scale case series and observational studies with a large degree of heterogeneity [9]. Conclusions drawn from these studies are therefore of limited value to guide clinical practice. Nevertheless, thoracotomies are still carried out in patients suffering traumatic cardiac arrest or in low flow states who are peri-arrest with some cardiac activity.

RT for indications including proximal control of non-compressible torso, abdominal and pelvic haemorrhage may be obviated by new techniques such as resuscitative endovascular balloon occlusion of the aorta (REBOA; [10]). This has not yet been addressed in any analysis of RT and may guide and inform the use of both techniques.

Rationale

There is no complete national database of the incidence of RT, from the pre-hospital setting onwards. An informal review in 2019 [11] demonstrates that a number of air ambulance services and emergency departments cannot provide accurate numbers on how many resuscitative thoracotomies are carried out by their clinical teams, the underlying injury mechanisms, nor what the outcomes are. Patients who undergo RT and do not meet the Trauma Audit Research Network (TARN) data will not capture those who undergo RT and do not meet TARN entry criteria, e.g. those who die on scene will not be captured in the data. TARN data are also complicated by non-clinical coders potentially miscoding two separate procedures: thoracotomy and thoracostomy. This makes analysis of the TARN data challenging.

For a procedure whose efficacy has yet to be fully established, and whose evidence base at present consists mainly of case series, it is imperative that accurate and comprehensive data are collected across the whole patient pathway. As case numbers are likely to be relatively few this project should be carried out at a national level, across multiple sites, with central organization. By reviewing the incidence, injury mechanisms, timelines, location, clinical injuries and outcomes of those patients undergoing RT we can aim to develop a clear national picture of current RT practice within the UK, from which to inform further areas for development, evaluation and research.

Project objectives

The overall aim of TETRiS is to evaluate the current processes of care within the UK for patients undergoing emergency RT for traumatic injury, pre-hospital or in the emergency department. The secondary aim is to evaluate current practice with established national guidelines, which as discussed are based on a limited evidence base.

The specific objectives are to identify:

- the population demographics (age, gender and injury mechanism);
- who is carrying out the thoracotomy (professional background and experience);
- location of the thoracotomy: (pre-hospital or ED);
- time elapsed from injury to resuscitative thoracotomy;
- clinical indications for thoracotomy;
- injuries that are found at thoracotomy;
- interventions carried out during thoracotomy;
- patient outcomes.

METHODS AND ANALYSIS

Inclusion criteria

1. Any adult or paediatric trauma patient with traumatic injuries undergoing RT pre-hospital by a helicopter emergency medicine services (HEMS) critical care team, or in the major trauma centre (MTC) emergency department

Exclusion criteria

1. Non-traumatic cardiac arrest.
2. Thoracotomy within an operating theatre, intensive care unit (ITU) or ward

Project design

This project is being co-ordinated by the National Trauma Research and Innovation Collaborative (NaTRIC). NaTRIC was established in 2018 and is the first trainee-led, multidisciplinary, trauma research collaborative in the UK. The project is being launched in conjunction with the pre-hospital and emergency medicine trainee research collaboratives—PHOTON (the Pre-Hospital Trainee Operated Research Network) and TERN (The Emergency Research Network), with additional input from the National HEMS Audit and Research Forum (NHRAF).

Regional HEMS provide pre-hospital critical care interventions to those sustaining severe traumatic injuries. The HEMS team can deliver a number of advanced pre-hospital interventions including rapid sequence induction of anaesthesia, blood transfusion and RT. MTCs provide a 24-h consultant led trauma service, capable of delivering advanced resuscitative interventions, and are often the default triage hospital within regional trauma networks for those patients in traumatic cardiac arrest or with penetrating torso and abdominal injuries transferred by non-critical care pre-hospital teams.

Through utilization of these research collaboratives, all UK Major Trauma Centres (MTCs) and Helicopter Emergency Medicine Services (HEMS) have been invited to participate ahead of the project commencement. This has seen every UK HEMS service and almost every MTC sign up to participate. The data collection period is running from the 1st February 2022 to 1st February 2023.

Resuscitative thoracotomies undertaken in the pre-hospital setting by HEMS and within the emergency departments of MTCs within the UK and Northern Ireland will be included in this project.

Sample size

This project is designed to evaluate current pathways of care, therefore, no minimum sample size is required to show effect.

Timescale

Patient enrolment will run from 1st February 2022 until 1st February 2023. Retrospective data collection will be permitted for those sites who do not have the formal service evaluation registration in place prior to the commencement date.

The project will end following the death or hospital discharge of the final patient, or until 30 days have elapsed since the hospital admission date of the final patient. Two months will be anticipated for subsequent data queries, follow-up and completion of the data set.

Patient identification

Local site investigators will decide the most appropriate local measures for identifying and enrolling patients who meet the inclusion criteria.

Patient consent

No formal consent process is required due to the service evaluation nature of the project. The data to be collected are routinely collected and de-identified data.

Data collection

Project data will be collected and managed using REDCap (Research Electronic Data Capture; Vanderbilt, Nashville, USA), hosted at Queen Mary University of London. REDCap is a secure, web-based application designed to support data capture. Anonymised data will be analysed centrally, by amalgamation of the individual, de-identified site data. Only members of the working group will have access to the full anonymised, data set. Individual sites will only have access to patients they have enrolled. Patients will be included for analysis if >70% of the data for an individual patient is available. See Appendix 1 for the full data points to be collected.

Pre-hospital

Due to the clinical and time pressures on the clinical team data collection points can be completed retrospectively by the clinical team and/or the site investigator, using the routinely collected pre-hospital data and clinician review/confirmation. Patients who have undergone pre-hospital RT will be assigned a unique hospital identifier by the treating team. If patients are transported to hospital, then ongoing data collection will be conducted through liaison with the relevant in-hospital site investigator for that hospital.

Table 1. Project evaluation points

Project intervention	Pre-hospital	ED	In-hospital
Resuscitative thoracotomy	x	x	
Timelines	x	x	
Transfusion requirements	x	x	
Clinical observations	x	x	
Ultrasound findings	x	x	
Indication for thoracotomy	x	x	
Procedures performed during thoracotomy	x	x	
Operative findings/interventions			x
Complications (ARDS/MOF/sepsis/residual pneumothorax)			x
Complications related to procedure			x
ITU length of stay			x
Hospital length of stay			
Outcomes (mortality)	x	x	x

ITU, intensive therapy unit; ARDS, acute respiratory distress syndrome; MOF, multi-organ failure. x = point at which intervention/data point will be evaluated.

In-hospital

On-going data collection following either a RT performed within the Emergency Department (ED) or one brought into the ED following a pre-hospital thoracotomy will be conducted by the local TETRiS site investigator, with the support TETRiS working group.

Local site investigators will have a file stored on their trust server with password-protected access, which will have the original patient ID noted against their unique study identifier. This will be the only location where the link between the original patient ID and the project ID will be located. Patient data will be uploaded in a pseudo-anonymised manner directly on to REDCap. This can be done both by the HEMS MTC teams.

Patient follow-up

Patients will be followed up to 30 days, discharge, or death, whichever is earliest.

Schedule of assessment

For a specific patient group, RT is already a standard of care both in-hospital and pre-hospital and will be carried out by the clinical team prior to inclusion in the project, according to local standard operating procedures. No new intervention is under assessment.

The only intervention to determine inclusion criteria is a RT for traumatic injuries. All of the following assessments will be made through routine clinical practice or clinician assessment. (Table 1, schedule of assessments).

Statistical considerations

Data will be reported as means with standard deviations (SD) for normally distributed data and medians with interquartile ranges (IQR) for non-normally distributed data. If comparisons between groups are made, Student's *T*-Tests and Mann–Whitney *U* Tests will be used

for normally and non-normally distributed data respectively. Pearson's chi-squared test will be used to compare categorical data. A *P*-value of <0.05 will be considered statistically significant.

ETHICS AND DISSEMINATION

Ethics

According to the HRA decision tool and 'defining research' definitions, this project meets the criteria for service evaluation. It is designed to define the current system and pathways of care, rather than directly derive new systems of care due to its results. It involves an existing intervention, which is undertaken by the clinical team caring for the patient in accordance with local protocols, rather than introducing a new intervention or protocol of care. There is no allocation to interventions or randomization, data are routinely collected, and the clinical team have chosen the intervention before the evaluation has occurred. It is a hypothesis generating audit and evaluation, evaluating practice against current national guidelines and defining current practice. As such there is no need for REC review. Each site will need to register the project locally with their research and development or audit office and obtain local approvals for a service evaluation project.

Confidentiality

Patient data will be anonymised at the point of enrolment by the local site teams, and data entered on to REDCap will be under a unique project identified. Age and gender will be the only potential identifiable data uploaded, and identification has been minimised as much as is possible for a rare occurrence. Sites will not be analysed individually, which further minimises the risks of identifying patients. In addition, date and time of injury will not be uploaded, as due to the rarity of this procedure, this may lead to accidental de-anonymization of patients.

Patient & Public involvement

A Patient and Public Engagement event will be held prior to the commencement of the project. A patient representative has been consulted on the rationale for and design of this project.

The project will be registered with the INVOLVE open-access database, which registers healthcare projects involving members of the public as partners in the research process (http://www.invo.org.uk).

Dissemination

A manuscript summarizing the project will be drafted by the working group following completion of the project for publication in a peer-reviewed journal and at academic conferences. The results will also be presented locally, regionally and nationally at suitable conferences.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of Surgical Protocols and Research Methodologies* online.

CONFLICT OF INTEREST STATEMENT

None declared.

FUNDING

There is no financial support or funding for this project.

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