GEO-TBI: INCIDENCE

An international, prospective observational study on traumatic brain injury epidemiology
Study protocol

Participate on: https://geotbi.org/
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National Institute for Health Research
Global Health Research Group on Neurotrauma

Brain Injury MedTech Co-operative

Endorsed by
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Background

The epidemiology of traumatic brain injury (TBI) is unclear – it has been estimated to affect 27 to 69 million individuals every year with the bulk of the TBI burden in low-to-middle income countries (LMICs). Recent research has highlighted significant between-hospital variability in TBI outcomes following emergency surgery, but the overall incidence and epidemiology of TBI remains unclear. To address this need, the Global Epidemiology and Outcomes following Traumatic Brain Injury (GEO-TBI) registry has been established, enabling the recording of all TBI cases requiring admission irrespective of surgical treatment (https://geotbi.org/).

Objective

The *GEO-TBI: Incidence* study aims to describe TBI epidemiology and outcomes according to development indices, and to highlight best practices to facilitate further comparative effectiveness research.

Design

Multi-centre, international, registry-based, prospective cohort study.

Subjects

Any unit managing TBI and participating in the GEO-TBI registry will be eligible to join the study. Each unit will select a 90-day study period between 1st of October 2022 and 31st October 2023. All TBI patients meeting the registry inclusion criteria (neurosurgical/ICU admission or neurosurgical operation) during the selected study period will be included in the *GEO-TBI: Incidence*.

Methods

All units will form a study team, that will gain local approval, identify eligible patients and input data. Data will be collected via the secure registry platform and validated after collection. Identifiers may be collected if required for local utility in accordance with the GEO-TBI protocol.

Data

Data related to initial presentation, interventions and short-term outcomes will be collected in line with the GEO-TBI core dataset, developed following consensus from an iterative survey and feedback process. Patient demographics, injury details, timing and nature of interventions and post-injury care will be collected alongside associated complications. The primary outcome measure for the study will be 14-day mortality. Secondary outcome measures will be mortality and extended Glasgow Outcome Scale (GOSE) at the most recent follow-up timepoint.

Introduction

Traumatic brain injury (TBI) is a growing global health concern due to increasing and ageing populations in LMICs and high-income countries (HICs) respectively (1). Despite the importance of TBI epidemiology in informing health service planning, research priorities, and public health policy, this remains poorly understood. TBI is estimated to affect 27-69 million people every year, although data from LMICs is scarce (1,2).

The Global Neurotrauma Outcomes Study (GNOS) has recently demonstrated country- and hospital-level differences in the case mix, management, and outcomes of surgically treated TBI (3). Of note, outcome variability between countries was almost entirely accounted for by their human development index (HDI). Highlighting opportunities to influence outcomes by identification and replication of best practice, significant between-hospital outcome variation was described within countries (3).

To elucidate the observed differences in TBI epidemiology, case-mix and outcomes, and to pave the way for comparative effectiveness research, systematic data collection of all TBI patients is needed (4). To address this need, the Global Epidemiology and Outcomes following Traumatic Brain Injury (GEO-TBI) registry has been established. The registry is an international registry for recording TBI, with the core dataset focusing on injury mechanisms, initial presentation, interventions, and short-term outcomes. Any centre treating TBI is welcome to join the registry, and further information on protocols and documentation is available on https://geotbi.org.

The *GEO-TBI: Incidence* is the first collaborative study to run on the GEO-TBI registry. It is a multi-centre, international, prospective observational study, that aims to describe global TBI epidemiology based on real-world clinical data using the core dataset of the GEO-TBI registry via a snapshot design – all TBI patients admitted to the local hospital during a 90-day window will be included in the study. It is expected that data collection will be continued after the conclusion of the initial collection period as part of the GEO-TBI registry collaborative.

Objectives

Primary objective

1) Describe the epidemiology of TBI using primary clinical data and compare outcomes of TBI between Human Development Index (HDI) tiers.

Secondary objectives

2) Examine differences in patient demographics, mechanisms of injury, and baseline clinical characteristics alongside indications, means and outcomes of TBI management.
3) Establish an international benchmark as a basis to compare outcomes in future clinical audits, epidemiological and intervention effectiveness research.
4) Compare the settings and resources of TBI management with regard to development indices.
5) Demonstrate the feasibility of collaborative registry data collection in an international setting and encourage ongoing prospective data collection.
6) Expand and empower the international network of neurotrauma professionals to conduct collaborative TBI research.

Roles, responsibilities and authorship

Central study team

A team of lead investigators from the NIHR Global Health Research Group on Neurotrauma will be responsible for co-ordinating the *GEO-TBI: Incidence* study.

Local study team

Each participating institution will form a local study team consisting of the senior study lead, data collectors, optional additional members and an independent data validator. The validator will work independently to the rest of the local team and will perform local data validation after its collection as outlined on p. 7 under *Data capture and validation*. Local teams may consist of a mix of surgeons, physicians, research associates and/or trainees.

Authorship

Fully named authors on the byline of publications resulting from this study will be those that satisfy the International Committee of Medical Journal Editors guidelines for authorship. In addition, 'on behalf of the Global Epidemiology and Outcomes following Traumatic Brain Injury Registry Collaborators' will be listed on the byline – the local study lead, additional members of the local study team and independent data validator at each participating site will be listed as PubMed citable collaborator status authors on all publications resulting from this study. Individuals that contribute significantly to the study in other ways will also be listed as PubMed citable collaborator status authors and will be acknowledged on all manuscripts under the following headings based on their contributions.

Data ownership, processing and storage

Data ownership remains with the participating centres in accordance with the GEO-TBI protocol. As per the GEO-TBI protocol, data is processed on behalf of the participating unit by Orion MedTech CIC (a not-for-profit organisation) independently of the central study team. Data will be collected and stored on a secure online platform (https://orion.net). Anonymised aggregate data will be shared with the central study team to enable analysis as outlined in the Data Sharing Agreement. Collection of identifiable data is supported by the platform, but not required in order to participate to *GEO-TBI: Incidence* or the GEO-TBI registry in general. If identifiable data is decided to be collected by the participating units, any identifying data will be kept strictly confidential and accessible only for local use. A detailed explanation is available in the GEO-TBI registry protocol (https://geotbi.org/documents).

Local collaborators will be given access to their own data after completion of the study to enable comparison of local practice with regional or international standards. Named collaborators will be able to request access to the entire data set or a subset of the data to perform post-hoc analyses to answer a defined research question. The study dataset will also be included in the aggregated core registry data reports and benchmarking.

Methods

Inclusion criteria

Centre inclusion criteria

Any hospital or clinic worldwide offering acute TBI treatment (surgical and/or non-surgical) and participating in the GEO-TBI registry will be eligible to join the study.

Patient inclusion criteria

All adult and paediatric patients admitted to the participating institution with a traumatic brain injury during the selected 90-day inclusion period are eligible for inclusion in the *GEO-TBI: Incidence* study. The inclusion criteria are the GEO-TBI core registry criteria:

- Clear history of recent head injury leading to TBI

AND at least one of:

- Neurosurgical admission with TBI
- Intensive care unit (ICU) admission with TBI
- Neurosurgical procedure(s) for TBI

Patient exclusion criteria

Patients receiving elective (planned admission) procedures or admission.

Data set

The GEO-TBI registry core dataset (Appendix 1) will be collected on all patients admitted to the participating unit due to TBI during in the study period. The collected data consists of 3 sub-sections – injury/admission data, operative data and outcome data. The dataset was formed via an international iterative consensus-based approach comprising an initial face-to-face meeting between a network of neurotrauma professionals from LMICs and HICs, an international survey to ensure usefulness and feasibility of the dataset in a variety of healthcare settings, and a final consensus meeting to define the final dataset. A publication outlining this process and the registry protocol is currently under peer review.

Each institution lead will be asked to fill out a questionnaire on resources available for neurotrauma care and rehabilitation in their healthcare setting. Finally, the data will be validated by the local independent validator as described on p. 7 under *Data capture and validation*.

Duration of study

Local study teams can select any 90-day period between the 1st of October 2022 and the 31st of October 2023 as their data input period. From the date of their injury, teams must follow patients up for a minimum of two weeks. For example, if a team selects the the 1st of March 2023 as their start date then they must include all patients who meet the inclusion criteria between then and the 30th of April 2023. Functional outcomes at the date of last follow-up will also be included as a secondary measure.

Outcome measures

Primary outcome

The primary outcome measure for the study will be 14-day mortality. The GNOS study demonstrated this as a useful and feasible outcome measure for data collection in a comparable setting comprising both LMICs and HICs (3).

Secondary outcomes

Glasgow Coma Scale (GCS) at hospital discharge.

Intracranial infections during the admission.

Length of stay in hospital and intensive care.
GOSE at latest follow-up.

Data capture and validation

Data capture

Collected data will be stored exclusively on a secure web-based registry system within the Orion described earlier (https://orion.net). The platform enables the secure data collection, validation and storage in a standard (SQL) format and is compliant with NHS security standards (including the Information Governance toolkit). The feasibility of data collection was confirmed in an internal pilot.

Data validation

Data validation will occur by two mechanisms:

- Web-based forms in the registry will contain fixed options at the point of data entry to maximise the likelihood of accurate and complete data capture from the outset.
- A local data validator independent of the local study team will be appointed at every participating site. After the 90-day study period chosen by the local team has ended, the data validator will be asked to retrospectively identify all patients admitted to their hospital during the 90-day period and complete the Data Validation Form (Appendix 2).

Statistical analysis

Epidemiology

The overall mortality after surgically and non-surgically managed TBI is not well known. Studies with differing methodologies suggest highly varying estimates of the worldwide yearly TBI incidence. Extrapolating data from road traffic injuries, Dewan et al. suggest that between 64-74 million TBIs occur yearly with the highest incidence in Northern America and Europe, whereas the absolute TBI burden was found to be highest in resource-poorer regions (2). A review based on the Global Burden of Disease Study 2016 suggested a TBI incidence of 27 million/year, but noted that this is probably an underestimate, as the results were derived predominantly from hospital-based sources (1). Indeed, 70-90% of treated TBI (presenting to secondary care) is of mild severity, which probably represents 17-30% of all mild TBI (5,6). A survey study showed that the incidence of TBI varied from <1% in China to almost 15% in Mexico suggesting a broad range of incidence rates across both LMICs and HICs (7). There is a consensus that the incidence of TBI is likely increasing – in HICs due to population ageing (8), and in LMICs due to increasing motorisation leading to

more road traffic injury-related TBIs (9). The Lancet Neurology Commission on TBI reported that an international consensus is needed on standardised epidemiological monitoring of TBI to allow the measurement of its incidence and mortality as well as comparison of access to care (10). The GEO-TBI collaborative is a step to this direction.

Standard of care

Mortality

Data on TBI outcomes in relation to development indices is scarce. Data from GNOS confirmed previous reports indicating that most surgically managed TBIs in HICs are severe, but mild-to-moderate TBI is more prevalent in the medium and low HDI tier countries (3). Furthermore, the pathologies varied in relation to the HDI tiers, patient age and injury mechanisms. Surgeries in very high and high HDI tier countries were conducted more commonly due to acute subdural haematomas, whereas epidural haematomas and skull fractures were more common in medium and low HDI tier countries, respectively. Correspondingly, patients were oldest in higher HDI countries and youngest in low HDI countries – falls were the most common cause of injuries in HICs, whereas road traffic accidents and violence were the prominent mechanisms in medium and low HDI tiers, respectively (3), which corresponds with research discussed under *Epidemiology* (pp. 7-8). Most between-country variation in TBI surgery outcomes was explained by HDI (3).

In GNOS, fourteen-day mortality following emergency surgery for severe TBI was 33% in very high HDI tier countries, 31% in high HDI tier, 43% in medium HDI tier and 27% in low HDI tier countries (3), which is in line with previous research suggesting a long-term mortality of 30% in HICs, but in contrast to earlier results indicating a mortality of 51% in LMICs for severe TBI (11). The mechanism behind this difference is unclear – it is possibly related to country-level differences in patient selection for surgery and pre-hospital management of TBI. This highlights the rationale for the *GEO-TBI: Incidence* study to help elucidate the basis for this discrepancy.

Incidence of TBI in individual unit catchment areas during a consecutive 90-day period will be determined. To account for case mix and interventions, a logistic regression model will be constructed. In the model, patient-, institution- and country-level confounders are adjusted for. Patient-level confounders include age, GCS, pupillary reactivity, major extracranial injury; the hospital in which the patient is managed is the institution-level confounder; and country-level confounders include the country and its HDI tier.

Time from injury to imaging

The UK National Institute of Clinical Excellence (NICE) guidelines for investigation of suspected clinically significant acute head injuries suggests that such patients should be assessed on arrival in the emergency department, and a CT head should be conducted within 1 hour of arrival (12). A large European dataset showed that a shorter time from TBI leading to GCS 9-12 to CT head scan was associated with reduced time to intervention and ED stay times, but not with mortality or worse outcomes (13).

Time from injury to intervention

Mortality after trauma craniotomy increases sharply, if the procedure is conducted more than four hours after injury (14,15). In GNOS, the median delay from injury to intervention was 8 hours. The median delays from injury to admission, admission to operation and injury to operation were highest in low HDI tier countries, and lowest in high HDI tier countries with significant HDI tier-related variation. Importantly, even in the very high HDI tier, the time from injury to surgery exceeded 4 hours in half of such cases – in the low HDI tier, the minimum times in all of the above categories were 4 hours or longer.(3)

Infections

Post-craniotomy infection rates in recent large studies have been reported to be 5-7% (16,17). In GNOS, the surgical site infection rate was 3%, though the 14-day follow-up period is probably not sufficient to characterise the total incidence of surgical site infections.

GOSE

As the GOSE is not a sufficient measure of neurological outcome after the 14-day follow-up proposed in the *GEO-TBI: Incidence* study. On the other hand, long-term follow-up may be altogether infeasible in certain settings. Therefore, the GOSE will be measured at the most recent available follow-up as a secondary outcome. GOSE scores typically increase within the first year after moderate-to-severe TBI patients (18), but seem to plateau in longer-term follow-up (19).

Analysis

Statistical advice was provided by the MRC Biostatistics Unit, University of Cambridge. We plan to stratify the countries in which the participating units are situated in relation to their HDI index (very high, high, medium and low) as defined by the United Nations (20) and successfully applied in the GNOS and the GlobalSurg studies (3,21,22). The HDI is a tri-dimension composite measure

comprising life expectancy index, education index and gross national income index, that consist of life expectancy at birth, expected and mean years of schooling, and GNI per capita, respectively.

Participating centres will be stratified based on their country into four groups based on their Human Development Index (HDI) rank, similar to the approach successfully used by the GlobalSurg studies (16, 17). The Human Development Index is calculated for each country based on life expectancy at birth, years of schooling, years of schooling and gross national income (GNI) per capita (http://hdr.undp.org/en/composite/HDI).

Limitations

The GNOS highlighted disparities in case-mix and outcomes after emergency surgery for TBI, but it was not designed to assess the epidemiology of TBI, an area deficit of robust information. Data on TBI epidemiology may be used to inform different stakeholders, such as patients, care providers and policymakers, and to eventually guide data-driven decision-making and funding allocation. Indeed, the unavailability of data may impede funding opportunities as reports are commonly required by international funding providers and universities. Furthermore, the *GEO-TBI: Incidence* will form a basis for ongoing auditing and research intiatives as part of the GEO-TBI registry, and aims to provide insight to guide comparative effectiveness research. However, the methodology of the *GEO-TBI: Incidence* will not allow for evaluation of TBI that does not result in a hospital admission.

All data and results must be interpreted in the context of the participating units' healthcare setting – for example, long-term follow-up may not be feasible in all settings. The epidemiological representativeness of the data depends on case ascertainment into the online registry. As such, the dataset was formed following an international consensus of neurotrauma care providers and it was kept sufficiently concise, while still capturing the most pertinent variables.

Approval

This study, as well as the GEO-TBI registry, will measure current practice and will not introduce any changes to current patient care. Being a part of the GEO-TBI registry, local approvals for the reporting of anonymised aggregate data will already in place as part of the registry enrollment process.

Support and funding

This study is endorsed by the World Federation of Neurological Surgeons (WFNS). Funding for the administrative costs of this study are being provided by the National Institute of Health Research (NIHR) Global Health Research Group on Neurotrauma.

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Appendix 1. The Global Epidemiology and Outcomes following Traumatic Brain Injury (GEO-TBI) Case Report Form.

Demographic data	
Name	Surname, forename
Date of birth	dd.mm.yyyy
Sex	Male/female
Unique patient ID number	CHI number/NHS number/National patient identifier
Hospital	Choose from participating hospitals
Injury data	
Date and time of injury	dd.mm.yyyy, hh:mm
Mechanism of injury	Select one: Fall: level/<2m/≥2m Vehicle collision: car/motorcycle/pedestrian/bicycle/other Assault: firearm/blade/blunt Blast Not otherwise specified: occupational/recretional/self-harm/other/unknown
Primary intracranial injury	Select one: Scalp injury Fracture of skull vault Base of skull fracture Compound fracture of skull Concussion Diffuse brain injury Focal brain injury or contusion Extradural haematoma Acute subdural haematoma Chronic subdural haematoma Traumatic subarachnoid haemorrhage Injury to cranial nerve Unspecified injury to head No secondary intracranial injury
Secondary intracranial injury	
Presence of major extracranial injury	Yes/No
Initial GCS *	Eye, Verbal, Motor: 1–4, 1–5, 1–6, respectively
Pupil reactivity *	Left, right: Yes/No/Unassessable
Focal neurological deficit	Yes/No/Unassessable
ASA grade	I–V
Secondary transfer	Yes/No

sRR prior to resuscitation	Millimetres of mercury, option for unknown
SpO2 prior to resuscitation	%, option for unknown
Imaging data	
No imaging performed	Tick if no imaging
	If imaging performed:
Date of initial CT head	dd.mm.yyyy
Imaging pathology present	Select if present: Extradural haematoma Subdural haematoma Contusion Fracture Intraventricular blood Traumatic subarachnoid haemorrhage
Midline shift on initial CT	Millimetres
Obliteration of basal cisterns	Select one: Normal Compressed Absent
Admission data	
Date and time of hospital admission	dd.mm.yyyy, hh:mm
Pre-hospital intubation	Yes/No
Treatment	Non-operative management only If operatively managed, select if conducted: Washout or debridement (including penetrating injury) ICP monitoring EVD Burrhole(s) Fracture elevation Craniotomy Craniectomy Posterior fossa decompression Other surgical procedure
Intracranial infection during admission	Yes/No

Intubation †	Yes/No If Yes: Dates of intubation & extubation or tracheostomy (dd.mm.yyyy) Extubation Tick one: Independent ventilation/tracheostomy/terminal
Intensive care unit admission	Yes/No If Yes: Dates of ICU admission & discharge dd.mm.yyyy
In-hospital mortality	Yes/No If No: Glasgow Coma Scale on hospital discharge Eye, Verbal, Motor: 1–4, 1–5, 1–6, respectively
Date of hospital discharge	dd.mm.yyyy
Outcome data	
Date of assessment	dd.mm.yyyy
GOSE	1–8

* Initial GCS and pupil status: after resuscitation, pre-intubation or at presentation if not intubated.
† Intubation other than solely for surgery. For example, if the patient was only intubated for intraoperative anaesthesia (e.g. surgery of subdural and epidural haematomas causing only mild neurological impairment). If the patient was kept intubated postoperatively, they should be recorded as intubated.

Appendix 2. Data validation form

To ensure the epidemiological quality of the GEO-TBI data, the local data validator is requested to fill the below fields using an alternative information source such as hospital records, theatre logbooks or institutional reports.

Centre name:	
Number of admissions due to TBI during the year:	
Number of operations due to TBI during the year:	
Source of information:	