

ORIGINAL ARTICLE

Predictors of Mortality and Functional recovery after severe traumatic brain injury: protocol for a prospective cohort study

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Abstract

Introduction: traumatic brain injury is a global public health problem due to its severity and high rates of morbimortality worldwide. Identifying predictors associated with increased mortality and unfavorable functional outcomes after the traumatic brain injury event is crucial for minimizing morbidity and mortality rates. Therefore, this study aims to establish a protocol to investigate the predictors of mortality and functional recovery after severe traumatic brain injury in Brazil.

Methods: The study will include all patients admitted for severe traumatic brain injury (Glasgow Coma Scale ≤ 8) at the State Hospital of Urgency and Emergency, which is the referral trauma hospital of Espirito Santo. The outcomes of interest are hospital mortality and functional recovery 24 months after hospital discharge. Subjects will be followed up at seventy-two hours, three months, six months, twelve months, and twenty-four months after the trauma. Morbidity will be determined by assessing: 1) the level of motor and cognitive disability, 2) functional impairment and quality of life, and 3) aspects of rehabilitation treatment. Additionally, the traumatic brain injury load, estimated by the years of life lost, will be calculated.

Discussion: the results of this study will help identify variables that can predict morbidity and mortality, as well as diagnostic and therapeutic targets for patients with severe traumatic brain injury. Furthermore, the findings will have practical implications for: 1) the development of public policies, 2) investments in hospital infrastructure 3) understanding the socioeconomic impact of functional loss in the individuals.

Study registration: the study received approval from the Ethics Committee of the Federal University of Espirito Santo under protocol number 4.222.002 on August 18, 2020.

Keywords: traumatic brain injury, mortality, functionality, predictors, protocol.

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Authors summary

Why was this study done?

Traumatic brain injury (TBI) is recognized as a significant global health problem with substantial public health costs and impacts. Therefore, prognostic studies that aims to investigate the predictors of hospital mortality and long-term functional outcomes after severe TBI are crucial for improving patient care, treatment strategies, and resource allocation. However, conducting a prospective cohort study presents many challenges that may compromise the study's integrity, reliability, and the practical application of its findings. Therefore, our study aims to report a protocol to develop a comprehensive and longitudinal assessment of morbimortality in TBI patients.

What did the researchers do and find?

In this protocol for a prospective cohort study on predictors of mortality and functional recovery following severe traumatic brain injury, it will be investigated the clinical and sociodemographic variables associated with hospital mortality and functional outcomes at 24 months post-trauma. Previous research has suggested that certain variables, such as age, injury severity, altered computed tomography findings, time to receive pre-care, and duration of mechanical ventilation, may influence the outcome after severe TBI.

What do these findings mean?

Considering that no study in Brazil has systematically followed patients from hospital admission until 2 years after injury to assess mortality and their level of functionality, such protocol serves as a structured and systematic roadmap that outlines the objectives, methods, and procedures of the study. Its significance lies in providing a clear and well-defined plan for researchers to follow, ensuring the study's transparency, reliability, and scientific rigor.

Highlights

A protocol for a cohort study to identify predictors of mortality and functional recovery after severe traumatic brain injury. Clinical and sociodemographic data will be collected prospectively and systematically. The outcomes of interest include hospital mortality and functional recovery 2 years after hospital discharge.

INTRODUCTION

Traumatic brain injury (TBI) is the leading cause of death and disability in young adults worldwide¹⁻³. TBI is considered a global public health problem due to deficiencies in the structure and function of the body and the limitations of activity resulting from brain injury⁴. It can lead to various sequelae, that can vary depending on the severity of the injury, the area of the brain affected, and the individual's overall health. Some of the main sequelae of TBI include cognitive⁵ and motor impairments⁶ emotional and behavioral changes⁷, social and vocational challenges⁸, which are long-term or permanent effects resulting from the initial injury.

Damages of traumatic brain injury (TBI) can be categorized into primary and secondary⁹. Primary damages are related with the mechanical impact on the brain, while secondary damages arise due to neurochemical and immunoexcitotoxic processes over time^{10,11}. Tissue damage is due to excitotoxicity, intracellular calcium overload and oxidative stress¹², neuroinflammation with activation of astrocytes and microglia and increased production of local immune mediators^{13,14}. At the same time, several neuroprotective¹⁵ and anti-inflammatory mechanisms¹⁶ are activated to minimize damage¹⁷.

Despite the complexity of the physiological damages caused by TBI, certain factors have been identified in previous prognostic studies^{1,18,19} as being associated with acute mortality and long-term functional recovery, such as the initial Glasgow Coma Scale (GCS) score, age of the patient, presence of intracranial hemorrhage, and the extent of diffuse axonal injury. Prognostic studies are statistical models that combine two or more variables from patient data to predict clinical outcome and influence therapeutic strategies²⁰.

Identifying predictors of outcome after TBI can benefit clinicians and researchers in optimizing neurofunctional rehabilitation, designing and analyzing clinical trials, and providing accurate prognosis information to aid patient decision-making. However, conducting a prospective prognostic study presents several challenges, including patient recruitment and retention, data collection, long-term follow-up, data standardization, and generalizability of findings. Therefore, the aim of this study is to establish a feasible protocol for conducting a prospective observational cohort study on predictors of outcome after severe traumatic brain injury (TBI).

METHODS

Study Design

A protocol for an observational, prospective cohort study.

Study Location

The State Hospital for Urgency and Emergency (HEUE), Vitória, Espírito Santo.

Study Population and Eligibility Criteria

All patients admitted for severe TBI on admission (Glasgow Coma Scale ≤ 8) at the State Hospital for Urgency and Emergency (HEUE) during the study period will be included. Predictive variables and outcomes will be prospectively collected from admission until hospital discharge/death and by telephone at 3, 6, 12, and 24 months after trauma (Figure 1).

Inclusion criteria will be age ≥ 18 years, TBI diagnosis and GCS score 8 or lower during hospitalization. Exclusion criteria will be age ≤ 18 years old, hospitalization for chronic sequelae of TBI, significant decompensated pre-morbid conditions (Figure 2).

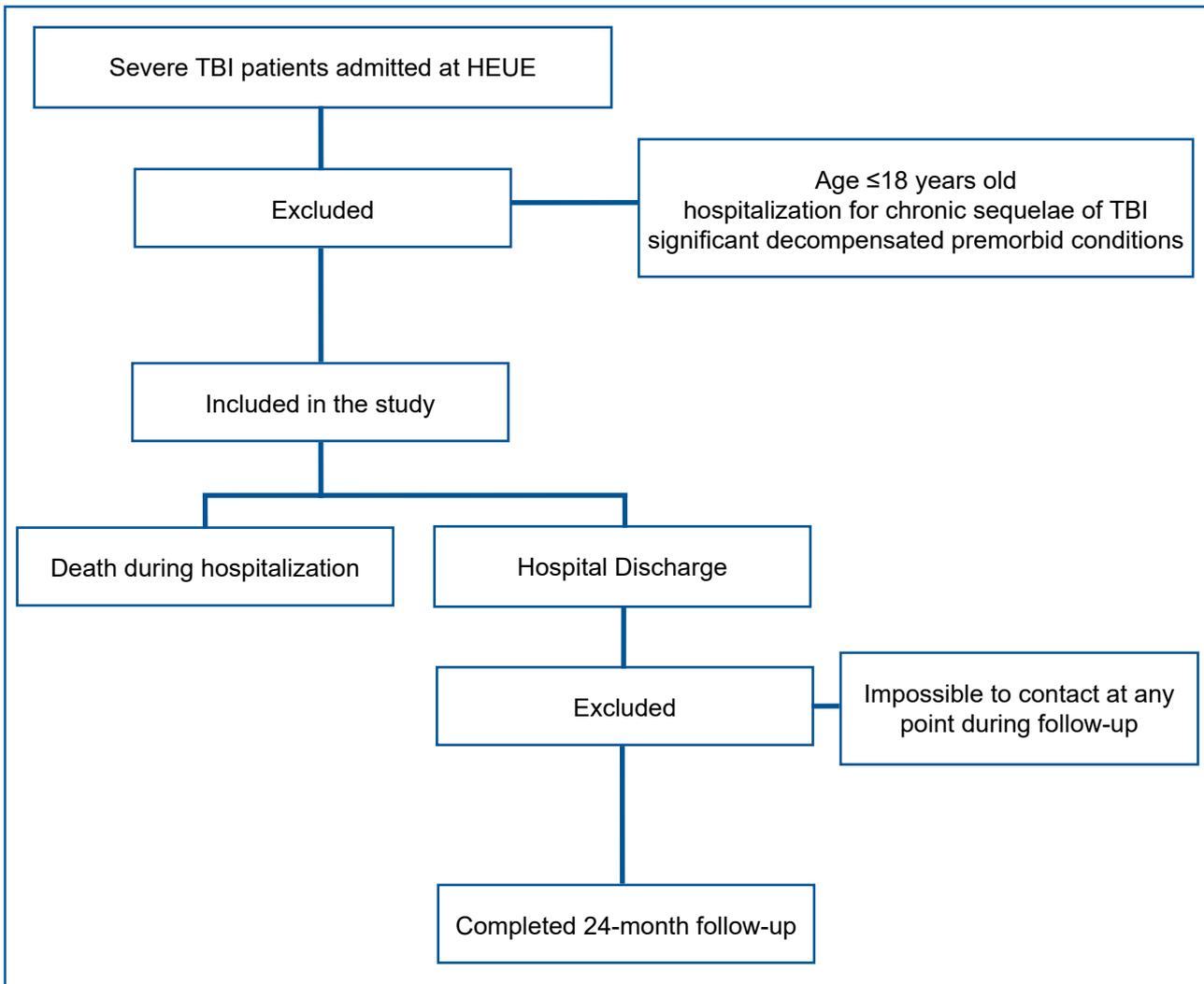


Figure 1: Flow chart of the study

TBI= Traumatic Brain Injury; IC= Informed Consent; GOS-E= Glasgow Outcome Scale Extended.

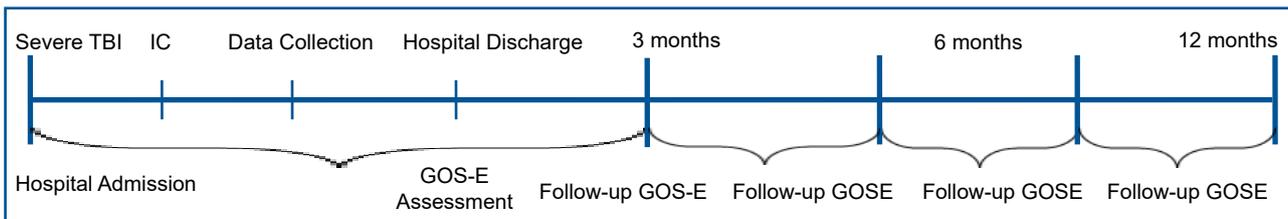


Figure 2: Study Design

HEUE= State Hospital of Urgency and Emergency; TBI= Traumatic Brain Injury.

Data Collection

The outcomes of interest (i.e., dependent variable) will be:

- **Mortality:** dichotomous outcome, categorized as yes or no, collected at hospital discharge, 3, 6, 12 and 24 months after the trauma.
- **Functional recovery:** categorical variable, assessed at hospital discharge, 3, 6, 12 and 24 months after trauma, using the Glasgow Outcome Scale Extended (GOS-E). The GOS-E is a globally used scale to assess functional outcomes in patients affected by traumatic brain injury (TBI), especially severe cases. It is applied through a structured interview, which can be conducted in person or over the phone, with the patient or a close family

member if the patient cannot comprehend or communicate sufficiently well²¹⁻²². GOS-E scores range from 1 to 8: full recovery (8 points); good recovery (7 points); upper moderate disability (6 points); lower moderate disability (5 points); upper severe disability (4 points); lower severe disability (3 points); persistent vegetative state (2 points); and death (1 point)²³. For analysis purposes, patients will be classified into 4 groups: good recovery (7 and 8 points), moderate disability (5 and 6 points), severe disability (3 and 4 points), and vegetative state (2 points).

The following predictive variables (independent variables) will be collected:

- **Age:** continuous variable, defined based on

participants' date of birth and reported in years.

- Sex: dichotomous variable categorized as male or female.
- Cause of injury: categorical variable presented as motor vehicle accident, fall, gunshot, physical aggression, and pedestrian vs. auto.
- Level of Consciousness on admission to the emergency room: obtained by the Glasgow Coma Scale (GCS) score.
- Level of Injury severity: obtained by calculating the Injury Severity Score (ISS).
- Probability of survival (Ps): Obtained by calculating the Trauma and Injury Severity Score (TRISS), which varies from 0 to 100%.
- Pupillary response: categorical variable classified as isochoric, miotic, anisochoric, and mydriatic.
- Computed Tomography (CT) lesions by Marshall CT classification: categorized into Lesion Type I, II, III, and IV.
- Performing Decompressive Craniectomy: dichotomous variable (yes or no).
- General vital signs: Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Heart Rate (HR), Respiratory Rate (RR), Temperature, and Glycemia.
- Days of Mechanical Ventilation; Days in ICU; Total days of hospitalization.
- Level of Education: years.

Data Analysis

Descriptive statistics will be performed using means and standard deviation (SD) for continuous variables and proportions for categorical variables. For the mortality outcome, a binomial logistic regression analysis will be conducted for each variable individually with the aim of identifying potential predictors. Variables considered statistically significant were analyzed in a final binomial logistic regression model, with significance at " $p \leq 0.05$ ".

In patients who survived the trauma, the functional recovery will be assessed at 3, 6, 12 and 24 months post-injury using multinomial logistic regression (GOSE 2 vs. 3-4, 5-6, 7-8). Significance will be considered at " $p \leq 0.05$ ". The magnitude of the association between hospital mortality/functional outcome and predictor variables will be measured by the odds ratio (OR), and the respective 95% confidence interval will be reported for each predictor. The analyses will be conducted using the Statistical Package for the Social Sciences (SPSS) version 21 (IBM Corp., Chicago, IL).

Ethical and Legal Aspects of the Research

This study was approved by the Research Ethics Committee of the Health Sciences Center of the Federal University of Espirito Santo and all volunteers should sign the Informed Consent Form, agreeing to participate in the study. The study has been authorized by SESA since October 2019. The STROBE recommendations will be used to ensure an adequate description of the method and results of this observational study.

DISCUSSION

The outcome of traumatic brain injury (TBI) is influenced by a combination of factors, some of which can be modified and others that cannot²⁴. These factors include age, sex, level of education, cause of injury, level of injury severity, pre-existing health conditions, time to receive definitive care, and the quality of clinical treatment^{1,18,19,25,27,28}. Identifying the key variables associated with TBI outcomes is crucial in reducing mortality and morbidity. This process plays a vital role in risk assessment, optimizing resource allocation, and improving clinical treatment approaches.

At the end of the study, it will be possible to identify clinical and functional variables that can be considered predictors of mortality and functional recovery in patients with severe TBI 2 years after trauma. Thus, it will be possible to identify the epidemiological profile and the number of patients disabled by motor, cognitive or psychiatric problems caused by severe TBI in a period of 2 years after trauma. This information will serve as the basis for public health planning and management in our state. As the follow-up of patients will be carried out systematically through telephone contact from the first days after discharge and periodically, it is intended to minimize losses for follow-up as much as possible.

This study has several notable strengths that contribute to its reliability. Firstly, the data collection will be carried out prospectively, ensuring the accuracy and trustworthiness of patient information. Secondly, the study will be benefited from a large sample size obtained from a referral trauma hospital, which enhances the generalizability of the findings. Importantly, the participating reference center treats a significant proportion of severe TBI cases in the covered geographical areas during the study period. This suggests the inclusion of a representative sample of severe TBI cases within the region. Additionally, this study stands out as one of the few in Latin America that will have prospectively assessed predictors of hospital mortality in severe TBI patients. The scarcity of similar studies in the region highlights the uniqueness and importance of this research, providing valuable insights into the significance of considering regional disparities when devising and implementing TBI management strategies worldwide.

Author Contributions

All authors contributed to the manuscript.

Jessica Vaz Gonçalves: Participated in data collection, data analysis, statistical analysis and writing of the text. Ramon da Silva Pereira: Participated in the study design, statistical analysis, discussion of results and final version of the text. Rodrigo Miranda Groberio: Participated in the study design, data collection phase and revision of the text. Lucas Rodrigues Nascimento: Participated in the general orientation of the research, definition of the study design and final revision of the text. Walter Gomes da Silva: Participated in the general orientation of the research, definition of the study design, statistical analysis, discussion of results and final version of the text. Hellen Siler Vasconcellos: Participated in the general orientation of the research, definition of the study design, statistical analysis, discussion of results and final version of the text.

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Conflicts of Interest

The authors declare that they have no conflicting interests.

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Resumo

Introdução: traumatismo cranioencefálico é um problema global de saúde pública devido à sua gravidade e altas taxas de morbimortalidade em todo o mundo. Identificar preditores associados ao aumento da mortalidade e desfechos funcionais desfavoráveis após o evento do traumatismo cranioencefálico é primordial para minimizar as taxas de morbidade e mortalidade. Portanto, este estudo tem como objetivo estabelecer um protocolo para investigar os preditores de mortalidade e recuperação funcional após traumatismo cranioencefálico grave no Brasil.

Métodos: este estudo tem como objetivo investigar os preditores de mortalidade e recuperação funcional em pacientes com traumatismo cranioencefálico, além de fornecer uma visão geral do traumatismo cranioencefálico no estado do Espírito Santo. O estudo abrangerá todos os pacientes internados por traumatismo cranioencefálico grave (Escala de Coma de Glasgow ≤ 8) no Hospital Estadual de Urgência e Emergência, o hospital de referência para traumas no Espírito Santo. Os desfechos de interesse incluem mortalidade hospitalar e recuperação funcional após 24 meses da alta hospitalar. Os participantes serão acompanhados em setenta e duas horas, três meses, seis meses, doze meses e vinte e quatro meses após o trauma. A morbidade será determinada pela avaliação de: 1) nível de incapacidade motora e cognitiva, 2) comprometimento funcional e qualidade de vida, e 3) aspectos do tratamento e reabilitação. Além disso, a carga de traumatismo cranioencefálico, estimada em anos de vida perdidos, será calculada.

Discussão: os resultados deste estudo ajudarão a identificar variáveis que podem prever a morbidade e a mortalidade após traumatismo cranioencefálico grave. Além disso, as descobertas terão implicações práticas para: 1) o desenvolvimento de políticas públicas, 2) investimentos em infraestrutura hospitalar e 3) compreensão do impacto socioeconômico da perda funcional nesses indivíduos.

Registro do estudo: o estudo recebeu aprovação do Comitê de Ética da Universidade Federal do Espírito Santo sob o número de protocolo 4.222.002 em 18 de agosto de 2020.

Palavras-chave: traumatismo cranioencefálico, mortalidade, funcionalidade, preditores, protocolo.

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