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Version 1

Global NeuroSurg 1 Study: Determining the Global Outcomes of Traumatic Brain Injury in low-, middle-, and high- income countries: A prospective, international cohort study V.1



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We use this protocol and it's working

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Abstract

Background

Every year, there are about sixty-nine million new cases of Traumatic Brain Injury (TBI) worldwide. However, there are wide variations in the management of TBI across low-, middle-, and high-income countries which affect TBI outcomes worldwide.

Aim

This study aims to provide a comprehensive global picture of the management and outcomes of TBI in high-, middle-, and low-income countries.

Objectives

Primary objectives

- To determine the mortality rates after TBI in low-, middle-, and high-income countries.
- To determine the functional outcomes after TBI in low-, middle-, and high-income countries.

Secondary objectives

- To compare the mortality rates of TBI in HICs vs. LMICs.
- To compare the functional outcomes of TBI in HICs vs. LMICs.
- To determine the factors associated with mortality following TBI.
- To determine the pattern of TBI management in low-, middle-, and high-income countries.
- To determine TBI associated complications.
- To form of an international network of neurosurgery researchers to facilitate future research efforts.

Study Design

A multicenter, international, prospective cohort study

Duration

One year (from the 1st of June 2019 to the 31st of May 2020)

Follow up: 90 days

Study Setting

The study will be conducted in self-selected registered centers worldwide. Any hospital receiving and managing TBI patients is eligible to participate in Global NeuroSurg-1; There is no minimum patient number per center; all consecutive cases must be included.

Eligibility Criteria

The study will include TBI patients who meet the following criteria:

- [1] TBI defined as WHO ICD-11 codes from NA07.0 to NA07.9.
- [2] patients with mild, moderate, and severe TBI
- [3] Age ≥ 18 years old
- [4] both genders

Data Collection Method

We will collect anonymous data on patient demographics, TBI etiology and severity, clinical and surgical management, and the 30-day and 90-day mortality rate. All data will be submitted to the secure Redcap system of the Oregon Clinical & Translational Research Institute, Oregon Health and Science University.

Sample Size

A total sample size of 1153 patients will allow detecting a mortality rate of 25% with a 5% wide 95% confidence interval. The sample size was calculated using R software version 3.4.1 (The R Foundation for Statistical Computing).

Statistical analysis plan

The human development index (HDI) is a composite score of life expectancy, education, and income indices published by the United Nations (<http://hdr.undp.org/en/statistics>).

Participating centers will be classified into three tertiles according to the HDI rank. We will test the differences between HDI tertiles by using the Pearson chi-square test for categorical variable and Kruskal–Wallis test for continuous variables. Binary logistic regression analysis will be conducted to evaluate the predictors of 30-day mortality. The odds ratios (OR) and the corresponding 95% confidence intervals will be calculated for each variable. First, variables from the univariate analysis with $P < 0.05$ will be selected for inclusion in the multivariate model. Then variables that are independently contributing to the mortality will be selected and examined. All analyses will be conducted by STATA software (version 15) for windows.

Ethics and dissemination

Study ethical approval will be acquired from all participating centers. All collected data will be kept confidential and will be used only for this study.

Attachments



[GNS Protocol version...](#)

398KB

