LATINO

Latin American and Caribbean,
Cranial Neurotrauma Registry

A multicenter data collection to perform an analysis of effectiveness in interventions for patients with traumatic brain injury in Latin America and the Caribbean.

FUNDACIÓN MEDITECH

Foundation for the Medical/Technical Research and Education in Emergency and Disasters

Fundación para la Educación e Investigación Médica y Técnica en Emergencias y Desastres

Fundação para a Educação e Pesquisa Médica e Técnica em Emergências e Desastres

Supporting Organizations

UNIVERSITY OF CAMBRIDGE

FUNDED BY NIHR | National Institute for Health Research

UKaid from the British people

Global Health Research Group on Neurotrauma

Introduction

The study "Latin American and Caribbean Registry for Cranial Neurotrauma (LATINO-TBI)" is a capacity development project to support the study of neurotrauma in the Latin American and Caribbean region. Based on the importance of the burden of this disease in the region, the MEDITECH Foundation of Colombia, together with academic support organizations, have generated this electronic registry as a repository of institutional databases that allow understanding and analyzing the dynamics of intervention in these patients, in association with the clinical outcomes in accordance with international clinical research standards.

To participate in this project, all the institutions and interested people in starting the registry of patients with traumatic brain injury (TBI) must send an application letter expressing the desire to participate in the project and must be sent to: latino.tbi@gmail.com and copied (CC) to asistenciafundacionmeditech@gmail.com.

Once the verification of requirements has been generated, the participating entity must submit the project to an Institutional Ethics Committee (IRB), in order to comply with country-specific regulations.We already have the approval of a Colombian clinical research ethics committee, which can serve as a model for institutions that do not have this type of service. Once the local study protocol has been approved, the institutional access codes will be generated by the central research group.

The training process for local data collectors will be conducted through the project's technical and administrative group, via online, supported by video calling systems and online tutorials.

General information of the project

Objective: To develop the first large-scale repository or registry of clinical data of neurotrauma in the Latin American and Caribbean region with academic purposes of data integration and possibilities of intra-institutional and inter-institutional analysis focused on the understanding of the current dynamics of comprehensive care, from the pre-hospital management to the post-operative or general intensive care phase. Additionally, there is an analysis process focused on the optimization of care processes (comparative effectiveness analysis) that will enable better decision-making on clinical and public health policy issues in each of the participating countries.

Specific objectives:

1. To collect high quality clinical and epidemiological data to improve the evaluation of the results to develop health strategies that improve TBI care.
2. To develop new approaches in the characterization, management and follow-up of patients with TBI.

3. To identify patient profiles related to the effectiveness of specific interventions.
4. To develop quality indicators to track and improve TBI care.
5. To intensify networking activities and international collaborations, especially in Latin America and the Caribbean in the TBI context.
6. To disseminate the results of the study and the management recommendations of TBI to health professionals, government entities, and patients to improve the individual and collective medical care.
7. Dissemination of scientific articles developed with the results of the LATINO-TBI project.

Design: A cross-sectional observational analytical database study that can be prospective and/or retrospective to compare the effectiveness of interventions.

Participants: Entities or institutions that provide care services to neurotrauma patients in the Latin American and Caribbean region.

Population: The target population of this project are all patients with moderate or severe TBI who require surgical management or intensive care units.

***Data collection methods*:** The data will be registered through the project online platform: "Latin American and Caribbean Registry for Cranial Neurotrauma (LATINO-TBI)"

Analysis plan: The analysis plan can be carried out either individually, i.e. by each institution, or collectively, including the integration of joint data at the request of two or more participating entities. The Meditech Foundation supports the data analysis process at the specific request of the participating entities or the researchers registered by each institution.

Project rationale

In general, TBI is considered by the WHO as one of the leading causes of disability and death worldwide, but predominantly in regions with medium and low human development indices. These regions are mainly located in geographic areas such as Latin America and the Caribbean, South East Asia, and Africa, which makes this pathology a global public health problem (1, 2).

Traffic accidents are positioned as one of the main causes of neurotrauma followed by mechanisms associated with interpersonal violence and falls from a height (3).

Due to the above, the use of specific clinical databases of this pathology is considered of the utmost importance as a capacity development strategy to integrate knowledge and patterns of heterogeneity in management to generate public health proposals to improve the care and prognosis of patients with TBI, to reduce the high social, and economic cost associated with this health problem (4, 5).

This study will guarantee compliance with the Declaration of Helsinki for guidelines of good practices in health research and locally complies with the regulations established by law 1581 of 2012 and resolution 8430 of October 4, 1993 of the Ministry of Health of Colombia, where they include standards for scientific research in health. According to the regulations, this project is considered to be of minimal risk since it includes the analysis of anonymized secondary information (6). The project ensures data privacy and confidentiality as they will be anonymized and stored on its own server with encoded access keys.

Participation, roles, responsibilities and authorship issues

The principal investigators of the Meditech Foundation will coordinate the access of the investigators of the participating institutions through the creation of a user to enter the data into the platform. They will also conduct an ongoing assessment and continuous monitoring of the instruments and data collected there.

Each institution can form local research teams to collaborate in data collection. However, each institution will be represented by a local principal investigator who will be responsible for the data processing and registration of their own institution. Local researchers will have continuous access to their own data during and after the study, with which they will be able to evaluate local practices and interventions and buy it, if they wish, with the other institutions that are part of the registry and that authorize the use of the data collected here.

Researchers publishing the results from this study will be those who comply with the authorship guidelines of the International Committee of Medical Journal Editors (ICMJE). In multicenter studies, the local study leader will be included as a co-author in all publications resulting from this study. People who contribute significantly to the study in other ways will also be included in PubMed's list of authors with citable contributor status and will be recognized in all manuscripts. Designated contributors will have the ability to request access to the entire dataset or a subset of the data for further analysis to answer defined research questions.

Methods

Guidelines for the selection of registration centers:

Any institution of any level of complexity located in the Latin American and Caribbean region with an influx of patients with traumatic brain injury may submit its application to enter the study as a data collection center. The compilation may be carried out by specialists, surgeons in training, general practitioners, medical students and other qualified personnel who have obtained satisfactory training on the use of the platform. All of this, under the supervision of the local principal investigator of each center.

Inclusion criteria:

- Adult patients (≥ 14 years)
- Patients diagnosed with mild, moderate, or severe traumatic brain injury with intensive care unit (ICU) management criteria.
- Patients treated at health centers located in the Latin American and Caribbean region.
- Patients diagnosed with moderate or severe traumatic brain injury who also have other extracranial trauma may be included in the study.

Exclusion criteria:

- Pediatric patients (≤ 14 years)
- Patients with mild head trauma.

Data collection instruments:

The data collection instruments were categorized into the following sections:

1. Demographic data
2. Pre-hospital care
3. Emergency room
4. Surgical procedures
5. ICU admission
6. Stay in ICU (initial 15 days)
7. Discharge data
8. Follow-up at 3, 6 and 12 months

Study duration:

The time of use of the registry is unlimited and each center can define its cut-off date for data analysis, semi-annual, or annual. As described below, follow-up can be extended up to 12 months for each patient.

Data collection:

Data registration will be done through an online platform. The data will be entered in each center through the principal investigator. Each quarter, a random sample of 10% of the data entered may be requested to assess whether the recorded information meets quality

standards. The central data of the platform is stored on its server, and only the data of each center will be available for use. If each center authorizes it, a comparative inter-institutional analysis will be carried out. All data within the platform is anonymized. Only the principal investigator of the center will correlate the identifier code of the platform with the clinical history of each patient. Platform updates will be previously consulted with each of the participating centers. A repository of diagnostic images from each center will be included as an option for subsequent consultations.

Statistical analysis:

Sample calculations and calculations of statistical power will be explained for each center according to its average patient admissions per month. The data analysis will be exploratory, considering the complexity of this disease, and associations will be sought through standardized techniques to analyze descriptive statistics, including inferential methods. Multiple variables will be considered to perform prognostic analysis. The variables included in the TBI - LATINO platform are grouped into 6 basic modules as follows:

1. DEMOGRAPHIC ASPECTS: Study Hospital, Platform Identification Code, Age, Gender, Date of Injury, Time of Injury, Type of Trauma, Mechanism of Trauma and Related Causes.

2. EMERGENCY DEPARTMENT ASPECTS: Date of Admission to the Emergency Department, Time of Emergency Care, Respiratory Rate, Heart Rate, Systolic Blood Pressure, Pulse Oximetry, Motor Glasgow Coma Scale, Verbal Glasgow Coma Scale, Coma Scale of Glasgow Ocular, Pupillary Reactivity Data, Reactive Right Pupil, Reactive Left Pupil, Intubated in the emergency room, Prehospital Intubation, Sedation Inducer in the emergency room, Which Inducer of Sedation In the emergency room, Muscle relaxant in the emergency room, Which Muscle Relaxer in the emergency room, Use of Intravenous Fluids in the emergency room, Normal Saline Solution in the emergency room, How many milliliters of Normal Saline Solution in the emergency room, Ringer's Lactate in the emergency room, How many milliliters of Ringer's Lactate, 3% Saline Solution in the emergency room, How many milliliters of 3% Saline Solution, 7.5% Saline Solution in the emergency room, How many milliliters of Solution 7.5% Saline, 23% Saline Solution in the emergency room, How many milliliters of 23% Saline Solution, Colloid Solutions in the emergency room, How many milliliters of colloid solutions, Transfusion of Blood Products in the emergency room, Red Blood Cell Transfusion in the emergency room, Platelet Transfusion in the emergency room, Plasma Transfusion in the emergency room, How many milliliters of blood products in the emergency room, Arterial gases in the emergency room, PH in the emergency room, Oxygen Saturation in the emergency room, Excess Base in the emergency room, Lactate in the emergency room, PCO2 in the emergency room.

3. DIAGNOSTIC IMAGES: emergency epidural hematoma CT, epidural hematoma greater than 30 cc in the emergency room, emergency subdural hematoma CT, subdural hematoma greater than 10 mm in the emergency room, Subdural hematoma less than 10 mm in the emergency room, emergency intracerebral hematoma CT, intracerebral hematoma greater than 50 cm in the emergency room, Intracerebral hematoma smaller than 50 cm in the emergency room, baseline CT scan of subarachnoid hemorrhage in the emergency room, CT scan of the emergency midline deviation, Midline deviation greater than 5 mm in the emergency room, Midline deviation less than 5 mm in the emergency room, Compromise of the basal cisterns in the emergency room.

4. SURGERY ROOM ASPECTS: Date of Admission to Surgery, Time of Surgical Procedure, Duration in hours of the procedure, Use of Intravenous Fluids in surgery, Normal Saline Solution in surgery, How many milliliters of Normal Saline Solution in surgery, Ringer's Lactate in surgery, How many milliliters of Ringer's Lactate, Saline solution at 3% in surgery, How many milliliters of Saline Solution at 3%, Saline solution at 7.5% in surgery, How many milliliters of Saline Solution at 7.5%, Saline Solution at 23% in surgery, How many milliliters of Saline Solution at 23%, Colloid Solutions in surgery, How many milliliters of colloid solutions, Transfusion of Blood products in surgery, Transfusion of Red Blood Cells in surgery, Platelet transfusion in surgery, Plasma transfusion in surgery, How many milliliters of blood products in surgery, Arterial gases in surgery, pH in surgery, Oxygen saturation in surgery, Excess base in surgery, Lactate in surgery, PCO2 in Surgery, Findings in Surgery, Decompressive Craniectomy, Ventriculostomy, Drainage of Hematomas.

5. INTENSIVE CARE UNIT ASPECTS: Date of Admission to ICU, Time of Admission to ICU, Day of hospitalization in ICU, Use of Intravenous Fluids in ICU, Normal Saline Solution in ICU, How many milliliters of Normal Saline Solution in ICU, Lactate of Ringer in ICU, How many milliliters of Ringer's Lactate, 3% Saline Solution in ICU, How many milliliters of 3% Saline Solution, 7.5% Saline Solution in ICU, How many milliliters of 7.5% Saline Solution, 23 Saline Solution % in emergencies, How many milliliters of 23% Saline Solution, Colloid Solutions in ICU, How many milliliters of colloid solutions, Transfusion of Blood Products in ICU, Transfusion of Red blood cells in ICU, Platelet transfusion in ICU, Plasma transfusion in ICU, How many milliliters of blood products in ICU, Arterial gases in ICU, pH in ICU, Oxygen saturation in ICU, Excess base in ICU, Lactate in ICU, PCO2 in ICU, FiO2 in ICU: Sedation in ICU, What sedation medication in ICU, Inotropic support in ICU, What inotropic support in ICU, Anticonvulsant management in ICU, What anticonvulsant management in ICU, Clinical seizure in ICU, How many clinical seizures in ICU, Neuro-monitoring in ICU, Measurement of PIC in ICU, ICU greater than 20mmHg in ICU, Central Venous Catheter in ICU, Central Venous Pressure greater than 15 cm, Urine volume in 24 hours, Systolic blood pressure less than 90 mmHg, Hemoglobin less than 6 g/d ,

Serum glucose greater than 180 mg/dl, Serum glucose less than 40 mg/dl, Serum sodium greater than 160 meq, Serum sodium less than 120 meq, Serum potassium greater than 6meq, Serum potassium less than 2meq, nutritional support in ICU, INR in ICU, INR greater than 1.5, Platelet count greater than 50,000 in ICU, CT control in ICU .

6. ASPECTS OF HOSPITAL DISCHARGE: Date of Hospital Discharge, Total days of hospitalization, Neurological examination at hospital discharge, Glasgow Functional Outcome Scale at discharge and follow-up at 3, 6 and 12 months.

Ethical aspects

The development of this study must be governed by the criteria of good research practices as well as comply with the data processing regulations of each country. The inclusion of patients must follow all the guidelines suggested by the research ethics committees of each center. The main researchers may verify the veracity of the information provided at any time, as well as the prior signing of the informed consent by the patient or their legal representative.

The centers must guarantee the understanding of the study purposes by the patient, the data processing must be carried out by assigning a unique registration number within the project and avoiding the identification of the patient.

Support and funding

The project does not have specific funding. However, the Meditech Foundation and Universidad El Bosque have provided support and approval of the LATINO project.

References

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