Managing severe TBI without ICP monitoring - guidelines development and testing- R01 NS080648

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Introduction

Globally, Traumatic Brain Injury (TBI) is a primary cause of death and disability. According to the World Health Organization (WHO) Traumatic brain injury is the leading cause of death and disability in children and young adults around the world and is involved in nearly half of all trauma deaths. Optimizing injury management within the capabilities of treatment facilities where the majority of injuries occur is critical.

Our 15 year experience in Latin American middle and low income (LMIC) countries revealed Intracranial Pressure Monitoring (ICP) is rare. Considering LMICs globally, it is highly unlikely that severe TBI patients currently admitted to hospital will have ICP monitoring and it is unlikely that this situation will change in the foreseeable future. Clearly, the management of severe TBI is focused on controlling ICP with or without direct monitoring.

Specific aims of the study:

Specific Aim #1: To conduct a prospective observational 2 phase study of treatment with 6-month outcomes for patients with severe TBI in 2 sets of centers – one with prior exposure to TBI treatment protocols (Prior Exposure Group) and one without (No Prior Exposure Group) – to determine the effects of treating according to a rudimentary protocol (Phase I).

Hypothesis #1: For Phase I, patients treated in centers with prior protocol exposure will have significantly lower mortality and better neurobehavioral functioning measured 6 months post-injury.

Specific Aim #2: To conduct a systematic consensus process to derive guidelines for treatment of severe TBI using centers and clinicians who treat these patients without ICP monitors.

Specific aims # 3: To introduce the guidelines into both sets of centers (Phase II) and compare the influence of its use on outcomes to those observed during Phase I.

Hypothesis #2: Outcomes will be significantly better for Phase II patients than those for Phase I patients in each group.

Hypothesis #3: The improvement in outcomes from Phase I to Phase II will be significantly greater in the No Prior Exposure Group than in the Prior Exposure Group.

Specific Aim #4: To extend the existing efforts to establish capacity for ongoing research about brain disorders in the developing world, by conducting this new level of research both in centers in which we have been working, and in centers that do not have previous research experience.

In accomplishing these aims, we will create and test guidelines for the treatment of severe TBI in the absence of ICP monitoring that could be used immediately to improve outcomes for the vast majority of such patients on a global basis. We will validate in LMICs a new, systematic and innovative technology and process to accomplish consensus that was derived in a high income country (HIC).

Study design

This is an observational study in Latin America with two phases (each phase will last 12 - 18 months). In the first phase, sites will use their current standard of care (for 7 sites, clinician preference, for the other 6 a protocol developed for a completed study that has been adopted as standard of care in those hospitals) Also, during the first phase, we will develop consensus-based guidelines . All 13 sites will adopt the recommended consensus-based guidelines at the end of the Phase I and will enter the second observational phase

Setting.

The study will be conducted in 14 Hospital in 4 countries (Bolivia, Ecuador, Colombia and Venezuela)

Inclusion criteria

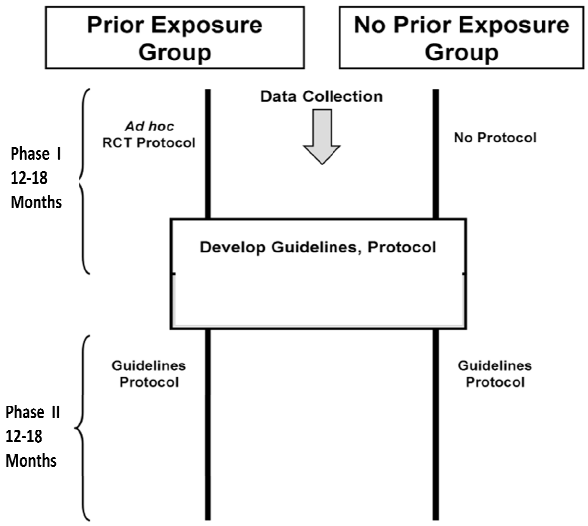
- Non-penetrating TBI
- Post-resuscitation Glasgow Coma Scale score (GCS) ≤ 8, and GCS Motor score ≤ 5, or Deterioration to those values within 24 hours of injury
- Age 13 years or older
- Consent to participate signed by Legally Authorized Representative (LAR)

Exclusion criteria

- GCS Motor of 1 with bilateral fixed, dilated pupils prior to consent
- Prisoner

Outcomes /Phases I and II

During Phases I and II, patient outcomes will be assessed at hospital discharge with the Glasgow coma Scale and Galveston Orientation and Amnesia Test. 6 months post-injury in addition to these measure, a battery of neuropsychological tests and functional status measures will be administered.


Prior Exposure Group
No Prior Exposure Group
Data Collection
Ad hoc RCT Protocol
No Protocol
Phase I 12-18 Months
Develop Guidelines, Protocol
Guidelines Protocol
Guidelines Protocol
Phase II 12-18 Months