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Development of a Severe TBI Consensus-Based Treatment Protocol Conference in Latin America

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Abstract

Background: Severe TBI (sTBI) is a significant global health problem disproportionately affecting Low and Middle Income Countries (LMICs). Management of intracranial hypertension in sTBI is crucial to survival and optimal recovery. High Income Country practitioners routinely use Intracranial Pressure (ICP) monitors although their utility has been questioned. ICP monitors are usually unavailable in LMICs. No consensus based/tested protocols or literature exists for sTBI treatment without ICP monitoring.

Methods: Investigators developed serial SurveyMonkey surveys for Latin American neurointensivists and neurosurgeons to determine current practice. These clinicians had extensive, routine, ongoing experience in sTBI without ICP monitoring. Surveys were administered and analyzed before/during/after a 2015 Buenos Aires consensus conference. Investigators identified areas of convergence blinded from colleagues' responses. A 47 clinician task force, representing 15 countries, who routinely manage sTBI patients without monitors developed consensus-based treatment guidelines during a three-day facilitated conference.

Results: Elements were added to the protocol at an 80% agreement threshold. Follow-on surveys resolved remaining elements to 97% agreement. The protocol addresses both tapering (upon improvement) and neuroworsening. Staged treatment options were identified, plus unique clinical practice issues. This process introduced a research method to a large, multi-disciplinary group of LMIC clinicians. This paper describes the process used to develop an LMIC-specific protocol which is transferrable to other diseases/injuries. The protocol is being tested in 5 LMICs.

Conclusions: We derived consensus-based guidelines for sTBI treatment without ICP monitoring, and introduced a research method to a large, multi-disciplinary group of LMIC clinicians naive to such methods.

Keywords

intracranial hypertension; intracranial pressure monitoring; severe traumatic brain injury; neurocritical care; global health

INTRODUCTION

Traumatic brain injury (TBI) is a major and growing global public health problem, causing both death and permanent disability. Worldwide, the number of people who sustain a TBI is estimated at greater than 10 million annually (1). The number of TBI related deaths is estimated at greater than 1.5 million annually (2). CRASH trial investigators reported the TBI burden was greatest in LMIC countries (3). Latin America has the highest incidence of intracranial injury worldwide due to high rates of road traffic crashes and to violence (1, 4). WHO projects that trauma will be a leading cause of death by the year 2020 (5). TBI accounts for about 85% of all trauma-related fatalities (6).

Management of intracranial hypertension (ICH) in patients with severe traumatic brain injury (sTBI) is crucial to their survival and optimal recovery. The evidence-based Guidelines for the Management of Severe Traumatic Brain Injury (7) as well as the European Brain Injury Consortium Guidelines for Management of Severe Head Injury in Adults (8) recommend use of ICP monitors to assess and manage intracranial hypertension, but there is no access to this technology in most countries. In addition, despite the above recommendations, actual employment of monitors is incomplete in high-income countries (HICs) where the technology is readily available. ICP monitoring has been estimated at 77.4% in the US (9), 44.5% in Australia and New Zealand (10), 63% in Canada (11), and 37% in Europe (12). Although actual figures are lacking, it is clear that the majority of sTBI cases worldwide are being managed without ICP monitoring. Notably, there are no

guidelines for sTBI treatment under these conditions and the only relevant literature on amenable protocols is based on the BEST-TRIP trial (13).

We conducted the BEST TRIP randomized trial, comparing outcomes between sTBI patients managed using ICP monitoring and those managed using a rudimentary protocol based on imaging and clinical exam (ICE). The ICE protocol was developed by three clinicians from Bolivia who were PIs at the initial clinical sites. Surprisingly, the results of the BEST TRIP trial showed no difference in outcome based on management approach. In reviewing the results of the BEST TRIP trial with site investigators, our colleagues expressed interest in improving the ICE protocol approach to sTBI management in the absence of ICP monitoring. The proposal was to develop such a protocol based on the collective experience of a larger, more representative group of clinicians whose practice routinely involved sTBI management in the absence of ICP monitoring (or used in very few cases) and to test this new protocol for feasibility, efficiency, and efficacy. This study was submitted through the Fogarty International Center (FIC) and funded jointly by FIC and the National Institute of Neurological Disorders and Stroke.

The study uses a comparative effectiveness approach. In Phase I of this two-phase study, sites that had participated in the BEST-TRIP trial continued to use the ICE protocol from that study. New sites were recruited that continued treatment as usual at their center, with individual clinicians making their own decisions about how to manage their patients, with no formal guidance from a shared common or institutional protocol. Participating sites were in Argentina, Bolivia, Colombia, Ecuador, and Venezuela. Phase I of the study completed recruitment in July, 2015.

Following Phase I completion, the consensus-development process described below was used to develop a new protocol. Upon ratification by the group, it was adopted as standard operating procedure for sTBI management by all sites for Phase II of the study. During this phase (now ongoing) we are collecting data from all sites to allow before/after comparison of outcomes between the new protocol and the ICE protocol in the BEST-TRIP sites and between the new protocol and no protocol in the other sites. In addition, we will also compare outcome from the two groups within each Phase in an attempt to determine if differences should be attributed to the actual individual protocols or if “protocolization” alone might be responsible.

There are two approaches to addressing ICP monitoring in sTBI. One is to advocate strictly for adoption. Another is to recognize the lack of rigorous evidence supporting such a restrictive approach and to work to optimize care for the numerous patients not afforded such monitoring, regardless of the etiology of this situation. Beyond medical considerations, requirements for ICP monitoring include personnel as well as financial considerations. Neurosurgeons are required to place the monitors, which is particularly relevant in systems where the majority of acute management is performed by critical care physicians, and neurosurgical consultation can be a limited resource. As well, most of the less invasive monitoring systems are quite expensive. For example, in Bolivia, a LMIC, a single use intra-parenchymal ICP monitoring catheter costs over \$1000 (not including tariffs and other obstacles to acquisition). This is prohibitive to patients and their families (initially

responsible for such costs). It also presents serious concerns to the hospitals and health care systems in terms of prioritizing the resource investment, pitting ICP-monitoring-system acquisition against more fundamental items with wider applicability to trauma management in general (such as EMS system improvements, ICU capacity expansion, and the purchase and upkeep of imaging systems, ventilators, etc.). This situation could worsen in disaster or war/terrorism scenarios.

Given the BEST TRIP results and these realities, we proposed that development of a protocol for treatment of sTBI without ICP monitoring provided a vital step toward improving outcomes for the large number of sTBI patients who will be treated in this way for the near future. This paper describes the process used to develop the consensus-based protocol. This may be useful to others developing a protocol or guidelines where the literature base is minimal and the best evidence comes from the collective experience of skilled clinicians.

MATERIALS AND METHODS

Protocol Development Process

Few reports address TBI outcomes in LMIC centers that do not monitor ICP; no literature describes these centers' management approaches for ICH, their efficacy, or how they were developed and refined. Currently ICH is assessed and managed in LMICs through repeated neurological examination and serial CT imaging, with little guidance as to when to perform serial imaging and no protocols for overall management of imaging or exam evolution.

Protocol development required the following steps, described in more detail below:

- Develop a survey to determine current practice.
- Find and invite primarily LMIC Latin American clinicians with extensive, routine, ongoing experience in sTBI without ICP monitoring to participate in the study.
- Serially survey clinicians to describe their current sTBI treatment practice and find areas of convergence blinded from colleagues' responses.
- Use survey responses to initiate and shape the conference deliberations.
- Employ a modified Delphi and nominal group process (14, 15) to shape the treatment guidelines.

Based on study team (RC, WV) experience with guideline development in high income countries, we began with web-based surveys and then used an audience response system (ARS) at an in-person conference to derive consensus on protocol elements. Application of this process introduced a completely new research approach to the conference attendees.

Preconference Surveys

Preconference polling was conducted using SurveyMonkey [<https://www.surveymonkey.com/>]. A survey development team (PH, WV, SL, GP, NG, RC) drafted an initial English version of *How do you treat your severe TBI Patients* SurveyMonkey

instrument (SMI) at a February 25, 2015 meeting Buenos Aires, Argentina. The group (including physicians who used ICP monitoring when treating patients clinically) brainstormed questions based on collective experience with previous LMIC studies and their practice with monitored patients. The items were posed to collect information on routine practice, so far as possible without injecting biases based on the survey writers' high-resource experience. In the absence of Class 1 or Class 2 evidence, we asked practitioners who work in low resource environments to define their practice in their own terms, prior to attempting consensus. We wished to avoid bias caused by applying educated guesses or estimates of such parameters derived from literature or experience derived from realities based entirely on ICP-monitored situations. Then a Spanish version was circulated among the survey development team for content and clarity.

Inviting LMIC neurointensivists and neurosurgeons to participate

A PI (WV) with extensive professional ties across Latin America solicited colleagues and used a feed-forward referral strategy to extend the invitations to over 100 clinicians throughout the region. The invitees were experienced neurointensivists and neurosurgeons actively practicing in primarily LMICs in Latin America with extensive, routine, ongoing experience in managing sTBI without ICP monitoring. Most had no academic appointment. This direction is counter to the practice in HICs where most sTBI research originates and toward which most management recommendations are directed.

Conducting the surveys

In June, 2015 the initial survey was sent to clinicians not participating in Phase I data collection. After accessioning was completed in July, a slightly revised survey, incorporating questions about what respondents would change in the ICE protocol, was sent to Phase I sites in July. In addition to questions about their practice treating sTBI without an ICP monitor, questions were asked about how many sTBIs the respondent had treated, whether their ICU had a sTBI management protocol, what percent had an ICP monitor, and reasons for not monitoring ICP. These questions were asked to determine who would be appropriate clinicians to invite to the in-person conference. At some sites, Internet access was either limited or problematic, and therefore hard copy documents were circulated and then returned for hand entry by the surveyor (PH). Initial survey (n=51 completed) responses showed considerable variability in practice, including widespread lack of within-hospital sTBI treatment protocols (<60% used step-by-step protocol, excluding those sites using a protocol as part of the RCT and Phase 1 of the current study). **See** Table 1.

Initial survey respondents and newly identified colleagues were invited to respond to a next stage survey in October, 2015 (n=63 completed). Clinicians reported their use of treatment agents as First Level (most favorable perceived risk:benefit ratio), Second Level (intermediate perceived risk:benefit ratio), and Third Level (least favorable perceived risk:benefit ratio). There were many differences between clinicians who reported treating fewer than 10% of patients without ICP monitoring and others. Table 2 displays results for inquiries about use of mannitol and hypertonic saline. Other questions probed reasons for monitoring, use of a protocol, hyperosmotic treatments, clinical examinations, wake up tests, tapering therapy, etc.

Conducting the Consensus Conference

Results from the October, 2015 survey were used to inform and shape discussion at the CBG in Buenos Aires, Argentina November 14–16, 2015. Results were also key in identifying clinicians who had extensive experience managing sTBI without ICP monitoring and also broadly represented Latin American countries. Study site PIs or their designees were also invited.

A Research Advisory Group (RAG) of 10 clinicians selected for diverse geography and leadership skills met with the investigators for a half-day just prior to the meeting. The RAG helped formulate the discussion items, identified additional topics that should be included, and were introduced to the consensus process so that they could support their colleagues in the days ahead. This process was new to all of the participants.

A team of three local (Buenos Aires) group process facilitators were included in the meeting to both learn the sTBI medical terms and to coach the team in the ways of respectful debate and consensus building. Facilitators from [business name] emphasized the need to avoid incendiary unproductive verbal confrontations.

Jone Howard, live ARS polling system owner, (Electronic Meeting Services, Gig Harbor, WA), demonstrated the software at the planning session. She also became more familiar with both the medical terms and consensus conference aims.

In addition to the pre-meeting session and inclusion of the RAG, several components were key to the successful execution of the consensus process.

1. Social events were held off site to build team, elements felt to be critical to clinical practice and research globally. A dinner was held at a downtown restaurant the evening before the CBG to renew old friendships from prior studies and bring new investigators into the fold. Participants stayed at the same city center hotel and took breakfast and lunch together plus two evening meals, building the bonds necessary for forthright discussion and debate.
2. The PIs displayed redacted results from the October survey to reveal points of modest or strong agreement and areas of broad diversity in practice and belief. These displays gave clinicians a sense of their standing in relation to colleagues around the protocol elements. Never did the displays reveal the countries, hospitals or names behind the data.
3. Survey results were parsed by the PIs (RC, WV) to generate “Si” (yes/agree) or “No” (disagree) statements bound for the protocol being shaped element by element. It was agreed that no less than 80% voted support was needed from the 39 invited clinicians on site.
4. A highly capable team of Spanish/English translators with a strong background in medical/scientific work provided simultaneous translations.
5. Each of the 39 on-site clinicians (excluding PIs and the survey development group) used credit card sized, Wi-Fi, instant polling clickers to register anonymous votes. After ~15 seconds, histograms displayed the percent

agreement. The ARS operator (JH) harvested text from the rapidly changing, mostly Spanish PowerPoint slides presented by the discussion leaders (RC, WV) to pose clean, succinct language for further polling.

6. When consensus was not reached in the initial polling, discussion was prompted. Papers were cited. Personal experiences were related. Guidelines from other sources were noted and web searches were conducted for relevant data to support or refute arguments. In some cases the issue was simply re-voted. In other cases edits were made to better state the issue before re-voting. One topic took six iterations to reach consensus. There was frequently applause after multiple attempts to reach the 80% agreement threshold led to consensus.
7. Minority and (in some cases) majority voters were invited to reveal their identity to support their votes. The impact of the facilitator work was apparent when a clinician said, "I disagree with what you said." All had been coached to separate the person—"I disagree with *you*"—from their statements about the content of comments—"What you said."
8. The 39 clinicians, with occasional participation from three Rosario, Argentina based investigators, were divided into four ad hoc smaller groups for extended discussions about critical protocol areas, e.g. tapering SICH therapy, MAP management, and transfusion threshold. Facilitators supported the small group discussions but the discussion leaders made no attempt to steer the dialogue. New colleagues got to know each other better and fresh professional relationships developed. Small group results were presented with clever and humorous discussion summaries.
9. Live Internet conferencing employing split-screen viewing was used to further include four clinicians who were unable to travel to Buenos Aires. They were respected colleagues of many at the in-person event and extended the conversation to Brazil, Costa Rica, and El Salvador. They listened and talked but did not vote.
10. Failure to reach consensus was accepted in some cases as an accurate representation of the unsettled state of a particular treatment. In other cases the treatment element was so important it was tabled for later discussion or further post conference, online survey iterations.
11. The newly formed RAG met with the small team immediately following the CBG to map out next steps including identification of points needing further clarification via post-conference surveys, circulation of the protocol, follow-on data collection regarding use of the protocol elements, and interest in participation in further studies.
12. Two post conference surveys completed days after the clinicians dispersed brought three additional treatment guideline elements to agreement.
 - Maintain Hemoglobin level at or above 10mg/DL: Consensus was not reached. Five days later, November 24, they were surveyed again and consensus was reached (89.5%) for a hemoglobin level of Hb $\geq$ 7mg/DL, acknowledging that

other factors, such as altitude, could be considered in deciding when transfusion was appropriate.

- Ideal body temperature range: Consensus was reached (maintain <37.5 C) at 82.4% agreement.
- Steroid use counter-indicated: Consensus was reached (do not use) at 84.4% agreement.

RESULTS

Initial plans called for the draft protocol to be presented for approval prior to disbanding the conference. The challenges of dual languages, terminology differences within and between countries, disparate professional cultures, and widely varying governmental structures prolonged the time needed to produce a clean Spanish protocol captured from the ARS voting files and post-conference surveys. In addition extreme range of altitude influences on treatment (sea level to over 4000m) became a separate element.

The RAG members were surveyed again December 4 seeking assurance that the protocol fairly represented the discussions and repeated polling to consensus—100% agreed. Three suggestions for further clarification of the language were registered and considered for edits prior to again surveying the 39 voters. It was clear that, with time, further nuances in meaning occurred to the clinicians. The study group noted that the protocol, as adopted and approved by the University of Washington IRB, would undergo further tests for clarity and effectiveness in the second phase of the study.

The points of possible ambiguity were addressed in a final Spanish language version of the survey to the 39 CBG voting members December 15, four weeks after the conference conclusion. The final vote was 38 of 39 responding “Si” (97.4%) to the question: “*El protocolo adjunto ¿refleja los votos emitidos durante y después de la conferencia Vote, por favor.*” Roughly translated: “Does the attached protocol reflect the votes during and after the conference?” Comments included spelling corrections and further comments about nuances in treatment reflecting the broad sweep of clinical and cultural realities across Latin America.

The protocol publication has been submitted and Phase II of the study is underway in five South American countries, as planned.

DISCUSSION

Additional questions invited comments about the conference. Response rates approached 100%, which we believe represents newly formed professional alliances, strong endorsement of the process, and appreciation of the speed to resolve differences. There was 100% agreement to be a point of contact for others in respective countries to support the study. Conferees rated elements of the process on a 4-point scale (4=strongly support) with 82% to 97% marking the highest value on all but travel arrangements (70%). Personal investment in the process was strong even for those enduring the rigors of 24 to 36 hours in transit. The written comments were highly complementary.

Areas for improvement in future work were informed by conversations with the RAG, post meeting surveys, and conversations with the study team. **See** Table 3 for a collapsed summary of those queries.

Conclusion

By using this consensus-process approach, we accomplished two things. We derived consensus-based guidelines for the treatment of sTBI without ICP monitoring. Further, we introduced a research method to a large, multi-disciplinary group of LMIC clinicians who had not had previous exposure to such methods.

Assurances

The ongoing study is conducted in accordance with the ethical principles expressed by the World Medication Association Declaration of Helsinki as amended (2013). The study was approved by the University of Washington IRB and by the IRBs for each of the clinics where patients provided informed consent. Authors report on competing interests.

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Table 1

Compares selected treatment frequencies if clinicians have a step-by-step sTBI protocol or not. Responses from study sites using the ICE protocol are excluded from this table (45 respondents analyzed).

Paralytics	Never	Rare	Routine
Protocol	12%	52%	36%
No Protocol	6%	83%	11%
Mannitol by bolus			
Protocol	4	40	56
No Protocol	6	17	78
Hypertonic Saline by infusion			
Protocol	32	24	44
No Protocol	39	39	22
Hypertonic Saline by bolus			
Protocol	4	20	76
No Protocol	12	29	59
Hyperventilate PaCO₂ 6–10 mg below normal			
Protocol	56	32	12
No Protocol	29	59	12

Table 2

Compares low frequency of ICP monitoring (33 respondents) to more frequent monitoring (27 respondents) by treatments.

Mannitol fixed schedule	First Level Treatment	Second Level Treatment	Third Level Treatment	Not Used
<10% Monitor	63.4%	36.4	15.2	12.1
=>10% Monitor	48.1%	14.8	7.4	29.6
Hypertonic Saline fixed schedule	First Level Treatment	Second Level Treatment	Third Level Treatment	Not Used
<10% Monitor	60.6%	24.2	12.1	3.0
=>10% Monitor	37.0%	33.3	7.4	22.2
Mannitol continuous	First Level Treatment	Second Level Treatment	Third Level Treatment	Not Used
<10% Monitor	0.0%	12.5	12.5	75
=>10% Monitor	0.0%	7.7	3.8	88.5
Hypertonic saline continuous	First Level Treatment	Second Level Treatment	Third Level Treatment	Not Used
<10% Monitor	15.6%	12.5	15.6	56.3
=>10% Monitor	23.1%	26.9	0.0	50.0

Table 3

Issues raised during the conference and in the several surveys.

General Issues calling for attention	Possible Approaches
1 Travel to Buenos Aires from distant cities without direct flights was exhausting. Visa issues compounded travel for some. Information from Initial Post Survey (IPS) and Personal communications.	Efforts to find a meeting venue closer to the geographic center were not successful. Seek a balance between costs, access for study leaders, and rigors of travel for visiting clinicians.
2 Sitting, conferring, voting and eating needed physical activity as a balance. - IPS	One clinician suggested a 3 to 5K morning run.
3 The ARS instant response technology could work only as quickly as English to Spanish translations could proceed. The owner/operator's skill with the technology and extensive experience working with clinicians was a fair trade-off with monolingual limitations.	Provide estimates of wait time so that participants can make best use of down time.
4 Newfound colleagues with similar clinical, political and fiscal interests wish to work together across country boundaries. – IPS.	Facilitate special interest groups with survey and other support.
5 Members new to the study without working relationships with others wanted time with study leaders. – IPS.	Link new members with a veteran mentor. Provide new member meeting time with study leadership.
6 Greater involvement and buy-in from neurosurgeons was desired. –IPS	Target communication of results to Latin American neurosurgeons.
7 Concern was expressed that the consensus work may not reach as far as needed. – IPS.	Publish as widely as possible to reach neurointensivists and others called upon to treat sTBI in low resource environments.
Clinical Practice Issues	Possible Approaches
1 Listen and respond to the clinical concerns unique to high altitude practice. - IPS	Be explicit in the protocol about tailoring to unique conditions, e.g. high altitude.
2 Fresh blood for neurotrauma anemia treatment may be needed for more urgent uses in countries where violence is escalating. -IPS	“Transfusion trumps anemia” – attend to life threatening trauma before later concerns.