

Severe Traumatic Brain Injury in South America:  
The Association Between Resources and Outcomes

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Abstract

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The burden of death and disability due to traumatic brain injury is increasing in low and middle income countries. The optimal management strategies and utilization of medical resources in resource limited settings are unknown. This multinational prospective observational study evaluated the association between resources and outcomes from severe TBI in South America. 203 patients with severe TBI were treated in a designated high or low resource setting, reflecting variation in ICP monitoring technology. There were significant differences in prehospital transport, ICU admission, and use of ICP monitoring between study groups that may impact outcomes. Patients treated in a high resource setting had significant improvements in functional outcome, but not mortality, at 6 months post-injury. Multivariate regression models showed that resource setting, independent of ICP monitoring, predicted functional outcome at 6 months after

severe TBI. Understanding the characteristics that explain this variation and guiding appropriate resource allocation may improve outcomes.

## INTRODUCTION

Traumatic brain injury (TBI) is a significant 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,<sup>1</sup> and the number of TBI related deaths estimated at greater than 1.5 million.<sup>2</sup> The primary cause of TBI on a global level is road traffic crashes, which causes 50-60% of TBI, followed by falls and violence.<sup>3</sup> Accurately quantifying the global magnitude of the problem is difficult due to the absence of injury surveillance and reporting systems in many parts of the world, primarily low and middle income countries, the inability to capture minor TBI or TBI in the setting of war and civil unrest, and the lack of widely used standard definitions of injury severity and outcome in children. As a result, the magnitude of the problem may be greatly underestimated.

The World Health Organization (WHO) Global Burden of Disease 1990 Study was a milestone in collecting epidemiological data to systematically estimate worldwide mortality and disability by cause. It was found that road traffic injuries was among the ten leading causes of death worldwide, and traumatic injuries was responsible for 10% of global mortality.<sup>4</sup> In the 2004 update of the Global Burden of Disease Report, the growing impact of road traffic injuries in low and middle income countries (LMIC) was becoming evident. Among middle income countries road traffic injuries was the sixth leading cause of death and the fourth leading cause of burden of disease.<sup>5</sup> In the recent 2010 update, road traffic injuries was the eighth leading cause of death and the tenth leading cause of burden of disease worldwide.<sup>6</sup> In the period 1990-2010, there was a 46% increase in global mortality and a 33% increase in global total burden of disease attributable to road traffic injuries.<sup>7, 8</sup> By the year 2030, road traffic injuries is projected to be the fifth leading cause of death and the third leading cause of burden of disease worldwide.<sup>5</sup> Within

LMIC several factors, including population growth, economic development, and epidemiologic shift, contribute to this trend. The prevalence of road traffic injuries is increasing in the economically developing countries of Africa, Asia, and Latin America and the Caribbean. In addition, the number of armed conflicts around the globe continues to rise, particularly in the developing countries of Africa and Asia. As a result, LMIC bear a proportionally greater burden of death and disability due to traumatic injuries, especially among economically productive young adults.

The outcomes from TBI are varied. Mild TBI can result in subtle changes in memory and cognition. Moderate and severe TBI frequently results in permanent disability and long-term care, and is associated with increased mortality and reduced life expectancy among survivors.<sup>9</sup> The greatest burden of this disease is borne by the youngest and healthiest segment of the global population. Among children and adults, TBI is the leading cause of permanent disability in those under 40 years.<sup>10</sup> Given that 85% of the global population lives in LMIC, the relative direct costs of medical and long-term care coupled with the indirect costs of years of productive life lost represent significant economic and societal losses for LMIC. While the annual direct and indirect costs of TBI have been estimated for high income countries (HIC), similar equivalency estimates are tremendously difficult to make for LMIC countries. The annual direct costs of TBI in the US are estimated at US\$4 billion, while the indirect costs are estimated at US\$40 billion.<sup>11</sup>

In Latin America, the epidemiology of TBI is not well documented, and studies on the burden of disease due to TBI are limited, but the impact of TBI is evident. Death due to injuries, including TBI, is already the leading cause of death among men age 15-59 years in the low and middle income countries of Latin America and the Caribbean.<sup>5</sup> Regionally, the principal causes of TBI in adults are road traffic crashes, violence, and falls,<sup>11</sup> while the principle causes in

children are road traffic crashes and falls.<sup>12</sup> The incidence rate for TBI in adults in Latin America is as much as 1.8 times higher than that for adults in developed countries.<sup>13</sup> The incidence rate for TBI among children in Latin America is as much as 2.97 times higher than the international average.<sup>12</sup>

In the US and other high income countries, improved survival and outcomes after a moderate or severe TBI have been influenced by improved standards of prehospital care, scientific and technological advancements that guide treatment of patients with moderate and severe TBI, and targeted rehabilitation strategies for patients with TBI. Acute care guidelines for the management of trauma and TBI have been developed based on data from high income countries.<sup>14-18</sup> The WHO developed guidelines for cost-effective, feasible, and sustainable essential trauma services believed to be achievable in any setting worldwide.<sup>19</sup> There is little evidence, though, that the conclusions generated from studies conducted in high income countries can be applied to resource poor settings.

Standardized TBI management protocols may not be effective or cost-efficient in the context of resource poor settings where there is a lack of infrastructure and limited availability of emergency medical and intensive care services. Several studies have attempted to examine this problem.<sup>20-22</sup> There are fundamental differences between HIC and LMIC in regards to access to and use of resources for management of traumatic brain injury. In LMIC there is an unequal access to acute medical care, and variable availability and utilization of medical resources that is not experienced in HIC. Traumatic brain injury management guidelines developed in resource rich settings may be irrelevant to the realities of TBI management in resource limited settings, or the implementation of such guidelines may produce more harm than good.

There are several gaps in our ability to understand and treat TBI in resource poor countries. There is a marked lack of research about patient characteristics, treatment methods, outcomes, and the natural history of TBI in these settings. Rehabilitation services for survivors of TBI are essentially non-existent. There is no data on resource use and outcomes. To know when, where, and how to apply the limited resources that are available in LMIC, we must identify the most robust predictors of outcome from TBI in these settings. This study aimed to evaluate the association between resources and outcome from severe TBI in low and middle income countries in Latin America. The primary hypothesis was that greater resource availability in the acute care treatment of severe TBI is associated with improved outcome, and variations in resource availability and medical management of severe TBI are associated with mortality and functional recovery.

## METHODS

The data analyzed here are from the Latin America Pilot Traumatic Coma Data Bank, a project funded by the National Institutes of Health National Institute of Neurological Disorders and Stroke through the Fogarty International Center program *Brain Disorders in the Developing World: Research Across the Lifespan* (R01NS058302).

### Study Design and Setting

This was a prospective observational study of patients with severe traumatic brain injury. From August 2008 through December 2009 we recruited patients from four trauma hospitals in Argentina, Brazil, Colombia, and Ecuador. Site 1 is located in Rosario, Argentina. It is the only trauma center serving 1.4 million people. It has 12 intensive care unit (ICU) beds and 180 general ward beds. Approximately 25% of the population lives at the poverty level, and there is a 5% illiteracy rate. Fifty-five percent of the population are mixed race, 40% are Caucasian, and

5% are other. Site 2 is located in Campinas, Brazil. It serves 3.6 million people. It has 28 ICU beds and 470 general ward beds. Approximately 26% of the population lives at the poverty level, and there is a 6% illiteracy rate. Sixty percent of the population are Caucasian, 20% are mixed race, and 20% are Black. Site 3 is located in Barranquilla, Colombia. It serves 1.55 million people. It has 8 ICU beds and 150 general ward beds. Approximately 55% of the population lives at the poverty level, and there is a 13% illiteracy rate. Forty percent of the population are mixed race, 40% are Black, 10% are indigenous race, and 10% are Caucasian. Site 4 is located in Guayaquil, Ecuador. It serves 2.5 million people. It has 25 ICU beds and 380 general ward beds. Approximately 50% of the population lives at the poverty level, and there is a 15% illiteracy rate. Eighty percent of the population are mixed race, 10% are indigenous race, and 10% are Caucasian. Each study hospital has 24-hour availability of neurosurgery, laboratory, and computed tomography (CT) services, uses critical care physicians to treat patients with TBI in the ICU, and treats a high volume of patients with TBI.

The study protocol was approved by the University of Washington Human Subjects Institutional Review Board (IRB), and by the local ethics committee and IRB at each study hospital.

#### Study Participants

Patients were considered eligible for the study if they were age greater than 12 years, and were admitted to the study hospital within 24 hours of a severe non-penetrating traumatic brain injury, defined as a Glasgow Coma Scale (GCS) score of 8 or less on admission (GCS score range from 3 to 15, with lower scores indicating more severe injury) or a GCS motor score of 5 or less for intubated patients (GCS motor score range from 1 to 6, with lower scores indicating worse level of consciousness). Patients were also considered eligible if they were admitted

within 24 hours of a non-penetrating TBI with a non-qualifying GCS score and deteriorated to a qualifying GCS score within 48 hours after injury. Patients with a GCS score of 3 and bilateral dilated and unreactive pupils, a non-survivable injury, a pre-injury neurologic disability that would interfere with selection or follow-up, or those who were prisoners or pregnant were ineligible for study participation. In all cases informed consent for participation in the study was obtained from the patient's next of kin within 48 hours of injury.

### Study Procedures

Study hospitals were categorized as high or low resource setting based on the use of invasive intracranial pressure (ICP) monitoring in the management of severe TBI. The Integra™ Camino® Intracranial Intraparenchymal Pressure Monitor was utilized to measure intracranial pressure. Use of the Camino® ICP monitor requires a single use placement kit, a multi-use bedside monitor, a neurosurgeon or neurointensivist who is trained to gain cranial access and place the monitor, and a physician, typically a neurosurgeon or neurointensivist, who is trained to interpret the pressure information and treat elevated intracranial pressure. The use of ICP monitoring alone does not constitute a high resource environment. Rather, it was used as a proxy indicator for the presence of other advanced technologies, as well as a higher level of physician training. The hospitals in Argentina and Brazil did have available invasive ICP monitoring and were designated high resource environments. The hospitals in Colombia and Ecuador did not have available invasive ICP monitors and were designated low resource environments.

Treatment of study participants in the high resource hospitals was based on clinical observations, surveillance and clinically indicated head CT scans, and ICP measurements when available, and followed local standards of care and treatment decisions of the managing physician. Treatment of study participants in the low resource hospitals was based on clinical

observations, and surveillance and clinically indicated head CT scans, and followed local standards of care and the treatment decisions of the managing physician. There was no study-based treatment protocol implemented at any study hospital. At all hospitals, non-neurologic injuries were aggressively treated.

#### Data Collection

A trained study coordinator at each study hospital collected baseline and acute care data for each study participant (Appendix 1). Baseline data included patient demographic and pre-injury characteristics, details of the injury event, and prehospital clinical characteristics. Physiologic variables recorded upon admission included GCS score, pupillary reactivity, hypotension, and CT imaging findings. The Abbreviated Injury Scale (AIS) score, an injury severity scoring system, was recorded within the first 24 hours post-injury (AIS severity score range 0 to 6, with higher scores indicating more severe injury). Acute care data collection was initiated in the Emergency Department, and continued in the ICU and ward through hospital discharge. Detailed hospital care and treatment information included hourly vital signs and Therapeutic Intensity Level (TIL), including ICP when available, throughout the duration of ICU care, serial neurologic examination results, TBI treatments, neurosurgical and other surgical procedures and results, serial CT imaging results, and complications.

At hospital discharge, neurologic status, duration of post-traumatic amnesia, and discharge disposition were collected. Neurologic status was based on the functional level defined by the Glasgow Outcome Scale (GOS) score. The GOS and the Extended Glasgow Outcome Scale (GOS-E) score are measures of functional level in daily life (Appendix 2).<sup>23, 24</sup> They are the most commonly used measures of functional outcome in TBI.<sup>25</sup> These measures have been previously translated into Spanish and used in TBI research in Latin America.<sup>26, 27</sup> The Galveston

Orientation and Amnesia Test (GOAT), an evaluation of cognition that assesses orientation and memory, was used to retrospectively assess the duration of post-traumatic amnesia (Appendix 2).<sup>28</sup>

Follow-up outcome data were collected at 3 and 6 months after injury. Two trained outcome examiners at each study hospital performed in-person interviews and collected functional outcome data defined by the GOS-E score and level of consciousness data defined by the impairment rating of the Disability Rating Scale (DRS) score (Appendix 2). The DRS is a measure of impairment, disability, and participation in daily life.<sup>29</sup> The GOAT was also administered at follow-up evaluation. All data were verified and entered into an Access database twice by two different data enterers, with electronic checks for discrepancies. Electronic range checks were performed on each variable. Two study monitors regularly visited each site and performed audits to assess the acute care data collection form for completeness and agreement with the medical records.

#### Outcome measures

The primary outcomes of interest were a composite outcome measure, functional status defined by the GOS-E score at 6 months after injury, and 6-month mortality. The composite outcome included 9 components: survival time (measure of survival), time to follow commands (duration of impaired consciousness), discharge GOAT (duration of impaired cognition), 3-month GOS-E (functional status), 3-month DRS impairment rating (level of impaired consciousness), 3-month GOAT, 6-month GOS-E, 6-month DRS impairment rating, and 6-month GOAT. The composite measure is sensitive to treatments with the same direction of effect on each component outcome measure. To form the composite measure, the participants were ranked from 1 (worst) to  $n$  (best) for each outcome measure, using the mean rank when there

were ties. The ranks were converted to percentiles, indicating the percent at or worse than the participant's score. For each participant, the percentiles were averaged across the different outcome measures. Secondary outcomes of interest included time to follow commands, defined as a GCS motor score of 6, and functional status defined by the GOS-E score at 3 months after injury.

#### Data Analysis

Baseline demographic, injury, treatment, and discharge variables between groups were compared using the Fisher Exact test and the Mann-Whitney test. For the composite outcome measure, the average percentiles of the two groups were tested using linear regression. Individual functional outcome measures were tested using linear regression. Mortality outcome measures and time to follow commands were tested using Cox regression. All regression analyses were performed with forward stepwise regression considering any significant effects due to age, sex, TBI severity, and other baseline variables that differed between groups. A two-sided significance level of 0.05 was used. All statistical analyses were performed using SPSS version 17.0.<sup>30</sup>

#### Power and sample size

A sample size of 576 participants was calculated to give the study 80% power to detect a difference of 0.25 standard deviations in the composite outcome between resource setting groups. Due to funding constraints, the study was concluded prior to meeting the target sample size. A *post-hoc* power calculation showed the study has 80% power to detect a difference of 0.40 standard deviations in the composite outcome between groups.

#### RESULTS

From August 2008 through December 2009, a total of 424 patients were screened and 203 patients were enrolled in the study (Figure 1). Follow-up continued through June 2010, with

no loss-to-follow-up between 3 and 6 months post-injury. Baseline demographic characteristics are shown in Table 1. Overall, severe TBI patients in this study were young (mean age 33.6 years) and male (85%). Forty percent of study participants were 20-29 years old, while 8% were age 60 years or greater. There were highly significant differences in race and socioeconomic indicators between the groups, consistent with the socioeconomic conditions of the cities in which the study was conducted. In the high resource group, 93% of study patients were identified as White and 57% of study patients were competitively employed. In the low resource group, 71% of study patients were identified as Mixed ( $p < 0.0005$ ) and 33% of study patients were competitively employed, while more were self- or family employed or engaged in uncompensated activities ( $p = 0.005$ ). The mean number of years of education was comparable between groups, and while more study patients in the high resource setting went on to at least secondary education, a greater proportion of study patients in the low resource setting went on to post-secondary vocational training or university level education.

Baseline injury and admission characteristics are shown in Table 2. The majority of study patients suffered road traffic injuries, followed by falls. Epidemiologic data from other regions of Latin America indicate that violence is a significant cause of TBI.<sup>31, 32</sup> Violence as a cause of severe non-penetrating TBI occurred in 1% of the study population. Penetrating brain injuries, such as would result from knife- or gun-related violence, were excluded in this study. Of screened patients, 8% were excluded due to penetrating injuries, but no data concerning the cause of a penetrating brain injury was collected. Between study groups there were highly significant variations in mode of transport to the hospital and direct admission to a trauma hospital. In the high resource group, 95% of study patients were transported to the hospital via ambulance, and 65% were transported directly to a trauma hospital. In the low resource group,

36% of study patients were transported to the hospital via taxi, personal vehicle, or other methods of transport ( $p<0.0005$ ), and 69% were transferred to a trauma hospital from another care setting ( $p<0.0005$ ). In both groups there were many missing values for mode of transport to the hospital, so we do not know if this represents a true difference between the groups and this finding must be carefully interpreted. Reasons for indirect transport to a trauma center for definitive care were not systematically documented.

The type and severity of TBI was similar between study patients admitted to the high and low resource hospitals. Overall mean admission GCS score was 7.6 and mean AIS head injury score was 4.1. Seventy-five percent of study patients had an AIS head injury score indicating a severe or critical injury. Initial head CT revealed a high severity of TBI, with 31% of study patients requiring surgical treatment of mass lesions, and 34% of study patients with Marshall grade III or IV diffuse brain injury (brain swelling with compressed or absent basal cisterns and midline shift up to 5mm [grade III] or brain swelling with midline shift greater than 5mm [grade IV], without mass lesions). While TBI severity was similar between groups, secondary insults may have differed. Significantly more study patients in the high resource group compared with the low resource group were hypotensive at admission to the study hospital (17% vs. 6%;  $p=0.024$ ), but there were several missing values in the high resource group. To explore a possible relationship based on admission type, we analyzed blood pressure status by direct transport to a trauma hospital and transfer from another hospital, and found no differences between the study groups (data not shown). Data on other early secondary insults was not consistently recorded.

Hospital care and discharge characteristics are shown in Table 3. There was highly significant variation in admission to the ICU between study groups. Among the high resource hospitals, greater than 25% of study patients were not treated in the ICU ( $p<0.0005$ ), and the

frequency of ICP monitor utilization was less than 50%. Given that the use of ICP monitoring requires an intensive care setting, we conducted an analysis of ICP monitor utilization by study site and ICU admission. All study patients at Site 1 were admitted to the ICU and 73% (n=43) were treated with ICP monitoring. Thirty-nine percent (n=19) of study patients at Site 2 were admitted to the ICU and 14% were treated with ICP monitoring. The use of ICP monitors at high resource hospitals was associated with the availability of ICU beds ( $p<0.001$ ).

The groups were similar in many indicators of hospital care and discharge outcomes. Overall, mean ICU LOS was 13.5 days and mean hospital LOS 21.9 days. The overall in-hospital mortality was 24%, and 15% of study patients achieved a good recovery by hospital discharge. Of patients who survived to hospital discharge, few were discharged to another formal care setting and none were discharged to a rehabilitation facility. Known cause of death through 6-month follow-up was significantly different between study groups. Twenty-four percent of deaths in the high resource group compared with 58% of deaths in the low resource group were attributed to the brain injury or neurologic complications ( $p=0.021$ ).

The results for the clinical outcomes and multivariate regression analyses are shown in Table 4. Both the composite outcome measure and the 6-month GOS-E score were significantly improved in the high compared with the low resource group. For the high resource group, the mean percentile on the composite outcome measure improved 10 percentile points ( $p=0.002$ ), while the mean GOS-E score improved 1.1 ( $p=0.009$ ). Forty-five percent of study patients treated in a high resource setting had a good functional recovery at 6 months after injury, compared with 23% of study patients treated in a low resource setting ( $p=0.004$ ; Figure 2). Between the high and low resource groups, there was a difference of 0.8 in the mean GOS-E score at 3 months that approached significance ( $p=0.054$ ). In a multivariate linear regression

model, adjusting for age, treatment in a high resource setting was predictive of improvement in the composite measure of function at 6 months after injury (unstandardized regression coefficient [ $\beta$ ] 0.09, 95% confidence interval [CI] 0.02 – 0.15,  $p=0.008$ ). In a multivariate linear regression model, adjusting for age, employment, and hypotension, treatment in a high resource setting was also predictive of improvement in functional status measured by the GOS-E at 6 months after injury ( $\beta$  1.05, 95% CI 0.22 – 1.87,  $p=0.013$ ). The cumulative rate of following commands at 6 months was 77% in the high resource group and 65% in the low resource group. When time to follow commands was analyzed by multivariate Cox regression modeling, treatment in a high resource setting was not predictive of earlier return to improved level of consciousness. By multivariate analysis, there were no differences in 3-month functional outcome or 6-month mortality between resource groups.

## DISCUSSION

This observational study is part of the first multinational prospective study to rigorously assess treatment and long-term outcomes in patients with severe TBI in Latin America. It serves to address several important gaps in our understanding of TBI in LMIC in South America. The results provide valuable epidemiologic data about risk groups, injury characteristics, and clinical course and outcomes, with important implications for targeted interventions. The study demonstrates that high quality scientific investigation is feasible in resource limited settings. The findings can be used locally in the generation of regionally relevant management guidelines and to inform public health policy regarding resource allocation.

Our primary interest in this study was to examine the impact of variable health care resources on long-term functional outcome following severe TBI. We used ICP monitoring, which is an advanced neuromonitoring technology that is considered standard of care in many

HIC, as a marker of a health care environment with greater resource availability. Hospitals that utilize one advanced technology typically dedicate resources to other advanced technologies, and to the accompanying need for specially trained physicians, nurses, and technicians. In our categorization of study hospitals to high resource or low resource, the use of ICP monitoring was the determinant. Therefore, we expected our assessment of outcomes following severe TBI would reflect the influence of ICP monitoring, among other resource-related factors.

In this study, treatment of severe TBI in a high resource setting was associated with improved functional outcome at 6 months after injury. ICP monitoring was a defined element of the high resource setting that should have varied accordingly between study groups. Among the high resource hospitals, though, only 46% of study patients were managed with ICP monitoring. There was considerable inequality in ICP monitor utilization between the high resource hospitals that was not expected. Our analysis showed that ICP monitor use was highly dependent upon ICU bed availability. Lack of an available catheter was a secondary obstacle to ICP monitoring. At one study site, a critical shortage of ICU beds significantly limited the use of ICP monitoring, and in that regard this high resource study site essentially functioned as a low resource setting. This would serve to diminish any positive effect of ICP monitoring on outcomes within the high resource group. Despite this, the high resource group had improved functional outcome at 6 months, suggesting the significant impact of other resource-related factors on outcomes.

Given the small subgroup sample sizes, a comprehensive analysis stratified by ICP monitoring was not performed, but we did explore trends related to ICP monitor use. In the setting where ICU bed availability was limited, the ICP monitored patients tended to be more severely injured than the non-ICP monitored patients (greater number of patients with CT Marshall grade type III or IV diffuse injury and critical AIS head injury score). This is likely

related to the process of ICU bed allocation in this setting, wherein patients with the most urgent need for critical care services were admitted to the ICU when a bed became available. Biased use of ICP monitoring would essentially alter the observed effect of ICP monitoring on outcomes. Moreover, it is important to consider that a lack of ICP monitoring within the high resource setting did not indicate a lack of treatment of elevated intracranial pressure. In the setting of good ICU care based on imaging and clinical examination, intracranial pressure monitoring may not provide additional value in improving outcomes.<sup>33</sup> The current study, although based on the availability of ICP monitoring, was not an assessment of ICP monitoring, and our results support that other factors in the acute management of severe TBI may have a significant effect on outcomes.

There are several characteristics of a high resource setting that may contribute to improved outcomes following severe TBI. A traumatic brain injury is the cumulative result of the primary injury that occurs at the time of impact, and secondary injury due to a cascade of cellular events initiated by the primary event and evolving over a course of hours to days. Secondary insults are discrete and often preventable events that occur independent of the primary injury, and contribute to the secondary brain injury. Brain damage from the primary injury is irreversible. Therefore, acute treatment of TBI focuses on minimizing secondary injury by preventing secondary insults, particularly hypoxemia, systemic hypotension, and intracranial hypertension. These secondary insults have been found to independently predict poor outcome in TBI.<sup>34-40</sup>

In HIC, aggressive treatment of severe TBI occurs in a specialized intensive care setting with advanced interventional and supportive care. The findings of this study revealed the realities of critical care in resource limited environments. In both the high and low resource settings,

several patients with severe TBI were not initially managed in the ICU due to a lack of available ICU beds. In these cases, early management of severe TBI occurred in the emergency department or other acute care setting until an ICU bed became available and an undefined triage process occurred. In hospitals where ICU beds were not always available, patients with more severe injuries and a greater indication for ICU management were generally admitted to the ICU earlier than those with less severe injuries. In some cases, patients with severe TBI received the entirety of their acute care treatment in a non-intensive care setting.

The effect of delayed ICU admission on outcomes may be consequential. Similar to ICP monitoring, intensive care unit bed scarcity would undoubtedly impact the utilization of other available critical care monitoring and interventions. The group of patients not initially admitted to the ICU we have termed ‘orphan’ patients and are the subject of separate investigation. In this study, despite a large number (28%) of patients in the high resource setting not admitted to the ICU, 6-month functional outcome was improved for those patients treated in a high resource setting. It may be that there is a subgroup of patients with less severe injury characteristics who do not require ICU level care, and in whom outcome from their TBI is dependent upon high quality basic acute hospital care. Additionally, high quality ICU care may be a significant driver of the improved outcomes in the high resource group, but it cannot completely explain the difference.

Advanced monitoring and interventions, enhanced content expertise of treating physicians, and a higher level of nursing care define ICU care, but there is great heterogeneity in ICU care that is commonly attributed to differences in available technologies and trained physicians and nurses. In HIC, where there is less variability in available technologies, variations in the intensive care setting that are associated with differential outcomes include ICU

organization, staffing with critical care specialists, dedicated critical care teams, and sub-specialization of units.<sup>41-49</sup> Among LMIC, resource constraints are most often identified as the source of variability in ICU and hospital outcomes. Poor outcomes in resource limited environments are attributed to lesser access to technological resources, decreased education and training, diminished intensity of care per patient, and reduced nurse-to-patient ratios with associated increased workload.<sup>50-52</sup> Economic development status alone, though, may not fully explain disparities in outcomes. The characteristics of treatment, such as the timing of readily available interventions, and variable implementation of appropriate treatment guidelines may partially explain differences in outcomes in resource-limited settings.<sup>53</sup> There is also evidence that ICU and hospital organizational factors, independent of allocation of resources, may impact outcomes.<sup>54</sup>

Detailed data on the intensity level of brain-specific and other treatments was collected throughout the ICU stay for each study patient, or throughout the duration of care in an alternative acute care setting for those patients not admitted to the ICU. In a separate analysis, the data will be examined to identify specific process of care variables and acute treatment characteristics that may explain the variations in outcomes from severe TBI between resource settings. Resource-based variations in both ICU care and acute non-ICU care between the study hospitals may account for some of the observed difference in outcome between the resource groups. This will also allow us to better understand how the current management guidelines for severe TBI are utilized in variable resource settings, and assist in the development of guidelines relevant to treatment of severe TBI in South America. As this study focused on the acute care treatment of severe TBI, detailed data on hospital and ICU organizational characteristics were not collected. Based on informal discussions with the principal investigators at each study site,

between study hospitals there was wide variation in the critical care team structure, equipment availability, nursing ratios, and patient care intensity, but we did not systematically assess these characteristics between study groups. Future investigation to identify both resource-based and organizational features of hospital care that influence outcomes from TBI and other injuries will be valuable for informing institution and system level health policy in LMIC.

The emergency management of TBI employs the acute care principles of stabilizing the primary injury, minimizing secondary injury, and preventing secondary insults. In HIC, emergency management of the trauma patient begins in the prehospital setting. Prehospital care delivered by trained personnel in an organized emergency medical services system has been shown to reduce mortality and improve outcomes following TBI.<sup>55-59</sup> In resource poor settings in LMIC, the development of prehospital trauma services and the training of layperson first responders have been shown to reduce mortality from trauma.<sup>60-63</sup> In this study, the variation in transport to the hospital via ambulance that we observed between the high and low resource groups may explain some of the variation in outcomes from severe TBI. Among the high resource settings, one study site is the single trauma center in a municipality with a systematic organization of trauma services,<sup>64</sup> while the other study site is one of several trauma centers in a city with a developing trauma system and implemented prehospital trauma transport services.<sup>65</sup> This is evident in the high ambulance transport rate in the high resource setting. The prehospital trauma services in Colombia and Ecuador are less developed, and the lower ambulance transport rate in the low resource setting reflects this.

In many LMIC, though, transport in an ambulance does not equate to resuscitation. The services provided by prehospital emergency transport vehicles can vary from life support provided by physicians to ‘scoop and run’ assistance provided by minimally trained technicians.

Organized trauma transport services that provide prehospital resuscitation may minimize secondary insults and decrease the severity of injury, thus contributing to improved outcomes following a severe TBI. Prehospital care without resuscitation may result in secondary insults that worsen the severity of injury and contribute to poor outcomes, or the most severely injured patients may not survive to reach the hospital. In this study, prehospital care varied in both the high and low resource settings, ranging from physician-staffed trauma transport or trained emergency technicians to ambulance services providing minimal life support or other transport without medical attention. An interesting finding was the number of patients in the high resource group who were hypotensive upon admission to the study hospital. This finding was not related to status as a direct transport from the injury site or transfer from another hospital. The majority of these patients were from a study site with great variation in prehospital resuscitation, but we cannot explain this finding from the data at hand.

We did not collect detailed data about prehospital care, thus we cannot draw conclusions about the influence of prehospital resuscitation on severe TBI outcomes in this study. Such information, though, is critical in developing optimal treatment strategies for severe TBI, and other traumatic injuries, in LMIC. Given the global epidemiological trend toward increasing burden of death and disability due to injury, trauma system development in LMIC is essential. Prehospital trauma care has been identified as one of the most cost-effective interventions to reduce death and disability from traumatic injuries.<sup>66, 67</sup> Simple interventions during the prehospital phase of TBI care have great potential to make a significant impact on outcomes from TBI.

While we did observe a difference in 6-month functional outcome between study groups, mortality did not vary between patients treated in the high resource compared to the low resource

setting. A review of the timing of and causes of death, though, provides additional insight into the possible influence of resource-based variations in acute care on outcomes from severe TBI in LMIC. Most deaths occurred in the acute care setting prior to hospital discharge, with greater than 60% of deaths occurring in the first 14 days post-injury. Early deaths occurring within 7 days post-injury were predominantly due to the primary brain injury or neurologic complications. Deaths occurring after 7 days post-injury were primarily due to systemic complications. Neurologic deaths were not reported after 14 days post-injury. The observed variation in death due to the primary brain injury and neurologic complications between high and low resource groups (24% vs. 58%, respectively) support that the early course of treatment is critical for survival from the initial injury, and suggest that variations in care during this time period may impact long-term outcomes. Intensive care treatment in the high resource setting that decreased death due to severe TBI may have likewise decreased disability due to severe TBI that is reflected in improved functional outcome. As previously indicated, a detailed analysis of specific processes of ICU care and treatment characteristics between resource groups will be important to identify those acute care factors that may explain the improved outcome seen in the high resource setting.

Finally, a comment about an important finding that deserves attention: The overwhelming majority of patients suffering a severe TBI in this study are young males in motorized vehicles, particularly motorcycles. This finding is consistent with regional trauma estimates from the Global Burden of Disease study, and with data from other TBI studies in Latin America.<sup>5, 11-13</sup> Severe TBI in adults greater than 60 years old was uncommon, as was injury due to falls, which occur most commonly in children and the elderly. Children under 12 years were excluded from this study. Violence as a cause of severe TBI was rare among the study population, but this was

influenced by study design and the exclusion of penetrating brain injuries. These data should serve as a call to action in targeting the group at highest risk of severe TBI in these communities and throughout the LMIC of South America. We did not collect data on the use of helmets or seatbelts among study participants injured in motor vehicle crashes, and more thorough investigation of the risk factors for road traffic injuries is warranted. Nor did we collect information about the use of alcohol or drugs at the time of injury, which are known risk factors for TBI. These should be high priority areas for epidemiologic investigation and public policy initiatives.

There are several important methodological limitations of this study. The observational nature of the study, without the introduction of any study-specific protocols, provides for a systematic understanding of the prevalent practice patterns in resource constrained environments in South America, and lends to the identification of areas where appropriate interventions may prove beneficial. Observational studies are often the only means of answering important questions about prognostic factors, the natural history of disease and disease trends, and resource utilization. Well-designed observational studies can capture the clinically important data on heterogeneous populations of patients that represent disease and treatment in the ‘real world.’ This study was carefully designed and conducted, but systematic bias can lead to erroneous results. Selection bias was minimized in this study through targeting a high participation rate to achieve a representative sample of the population. Less than 10% of patients screened declined to participate in the study, but no specific data on reasons for decline was gathered. The screening interview was performed in Spanish by host country study examiners, but a linguistic barrier, and possible associated cultural differences, may have hindered participation, particularly in the low resource settings, as several indigenous dialects are spoken in the host

countries of this study. This must be considered when interpreting the generalizability of the study results. The multinational setting, though, does improve our ability to generalize the findings to diverse populations of severe TBI patients in South America.

Another source of selection bias may exist in the choice of study hospitals. Potential study hospitals and research teams were assessed to determine the feasibility of conducting clinical research, and selection was influenced by demonstrated success with a pilot project. While all the hospitals in this study are busy trauma centers with large TBI populations, it is not clear to what extent the study hospitals are representative of trauma centers throughout Latin America. The hospitals range from public hospital to university medical center, they represent different health systems, and, as demonstrated by our findings, there is considerable variability between them. The small number of hospitals in each group, with several important differences between them, was a limitation of this study. The small study sample size, which resulted from early termination of recruitment, was a further limitation that may influence the generalizability, as well as the significance, of the study findings.

Information bias, in the form of measurement error or misclassification, was minimized by the use of standardized data gathering and reliable measures. The injury severity measures (GCS, Marshall CT grade, and AIS score) are discriminative classifications with good inter-observer reliability that are commonly used in TBI studies.<sup>68-70</sup> As well, the functional status and cognitive measures (GOS, GOS-E, DRS, GOAT) have been shown to be reliable assessment tools for use in a broad spectrum of head injury severity.<sup>28, 71-73</sup> Prior to initiation of the study, a comprehensive training program for the host country study teams was developed, that included multiple training sessions to address patient screening, informed consent, acute care data collection, and in-hospital assessments. Outcome examiners were trained in the use of the

functional status and cognitive measures and assessed for proficiency. Follow-up outcome assessments were double-checked and any errors in administration, scoring, or coding were discussed with the examiner to provide ongoing training. Additionally, quarterly inter-rater reliability tests were conducted. Data audits were performed monthly and the medical chart reviewed for consistency with the data collection forms. At the end of patient enrollment in December 2009, there was an error rate of less than 1%. Despite careful planning, a level of information bias may exist in this observational study, though we believe it to be minimized through methodical study design.

Confounding presents the area for greatest bias in this study. There are well known independent predictors of outcomes in severe TBI, and the design of the study analyses considered control for both known predictors and potential confounders. Age, TBI severity as measured by GCS score, GCS motor score, pupil reactivity, or CT classification, and secondary insults resulting from either hypotension or hypoxia are known to independently predict mortality and functional outcome following severe TBI.<sup>74</sup> Known predictor variables were designated, *a priori*, for inclusion in the regression analyses. From the univariate analysis, variables that were found to differ between resource groups were included in the regression models to control for their potential confounding effect, with a few notable exclusions.

The distribution of race differs significantly between resource settings, but this variable was not included in the regression model. In our designation of a high resource setting, we used the availability of ICP monitoring as the indicator upon which to base that designation, with the understanding that ICP monitoring, as a proxy for resource availability, was an indirect indicator of environments that differed in socioeconomic and other factors known to be associated with resources, such as race. In this study, there is a tight association between race and resources that

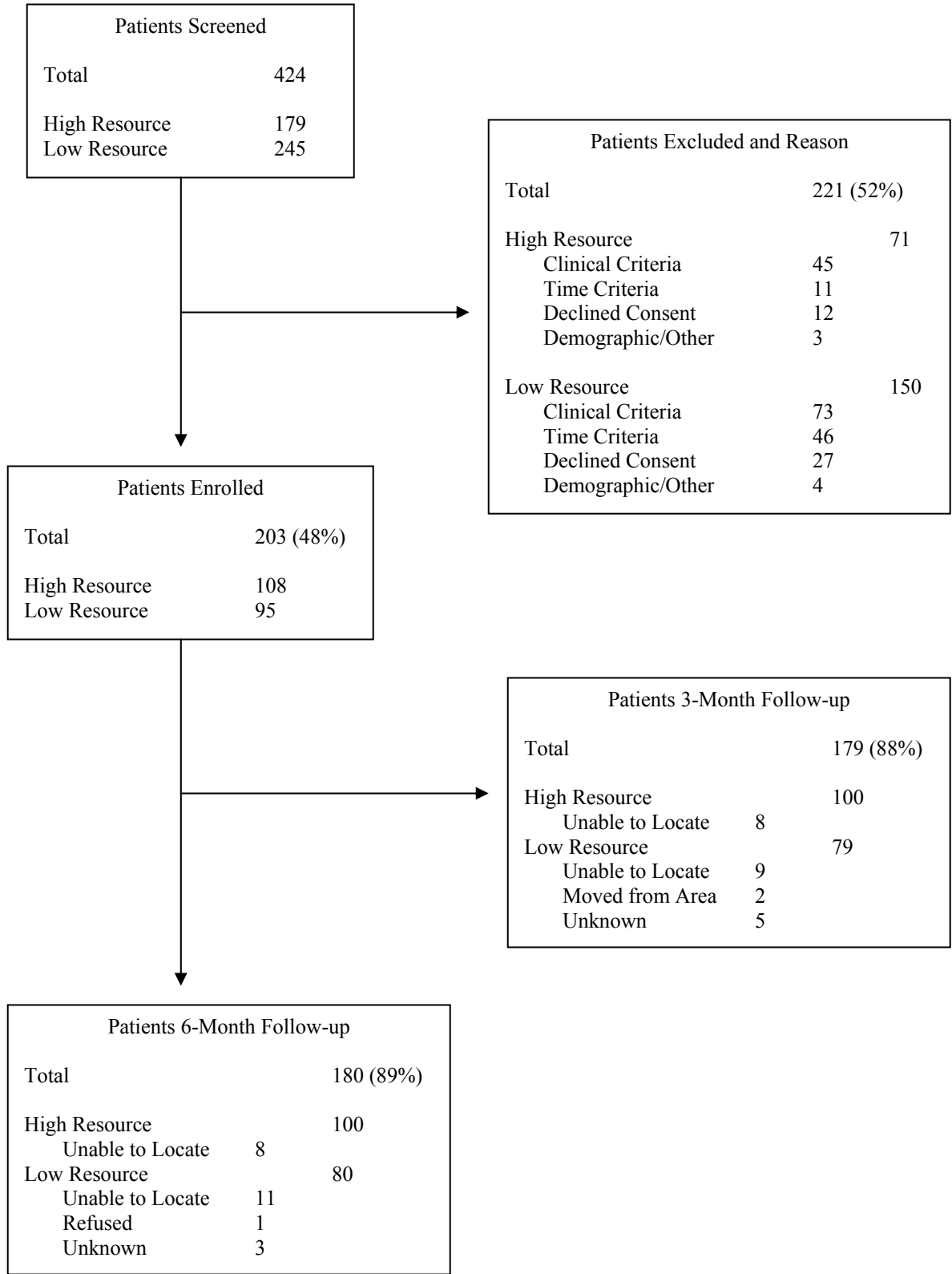
was introduced in the selection of study settings (*i.e.* the racial composition of the cities), and that cannot be separated in the analysis of the effect of resources on outcomes through controlling for race.

Similarly, by study design, ICP monitoring is a variable that differed between groups. The availability of ICP monitoring, though, did not equate to utilization, as demonstrated by the significant variation in ICP monitor use between the two high resource hospitals. For all study outcomes except time to follow commands, when ICP monitoring was included in the regression models the effect of being treated in a high resource setting did not change. This suggests that ICP monitoring alone is not likely predictive of improved outcomes. More likely, it is a complex association of multiple resource-based elements that affect outcomes from severe TBI. Intracranial pressure monitoring did predict a later return to following commands, and when adjusted for this effect the relative likelihood of following commands at any given time was improved in the high resource group. This finding may be related to variable treatment based on ICP measurements, such as increased depth or duration of sedation. Intracranial pressure monitoring may be causally related to improved outcome in the high resource group, but small sample sizes precluded a detailed subgroup analysis of outcomes by ICP monitoring within the high resource group.

The findings from this study highlight several important topics in the management of severe TBI in resource poor settings. Our data supplement the existing epidemiologic profile of TBI in Latin America. Severe traumatic brain injury in South America primarily affects young adults, resulting in many years of productive life lost. Prevention efforts should target motorized vehicles, especially motorcycles, to reduce road traffic injuries. Variation in outcomes from severe TBI is associated with resources, but the optimal distribution of resources is not known.

Adequate prehospital trauma care has great potential to improve outcomes from traumatic injuries, and trauma system organization should be a priority for LMIC. Advanced medical technologies in the acute care setting may improve outcomes from severe TBI, but in resource limited environments processes of acute care and hospital organization may have a greater impact and further research is needed to guide resource allocation.

**Figure 1. Sample Selection and Follow-up.**



**Table 1.** Baseline Demographic Characteristics.

	<b>High Resource (N=108)</b>	<b>Low Resource (N=95)</b>	<b>P Value†</b>
<b>Age (yr.) – no. (%)</b>			
Mean (SD)	32.8 (16.2)	34.6 (16.1)	0.284
<20	16 (15)	14 (15)	0.108
20-29	47 (43)	35 (37)	
30-39	14 (13)	18 (19)	
40-49	16 (15)	7 (7)	
50-59	5 (5)	14 (15)	
60-69	6 (5)	3 (3)	
70+	4 (4)	4 (4)	
<b>Male Sex – no. (%)</b>	89 (82)	84 (88)	0.242
<b>Race – no. (%)</b>			
White	101 (93)	11 (12)	<0.0005
Mixed	4 (4)	65 (71)	
Black/Indigenous/Other	3 (3)	16 (17)	
Unknown		3	
<b>Education Years – no. (%)</b>			
Mean (SD)	8.9 (3.4)	8.7 (3.4)	0.524
0-6 years	16 (15)	28 (34)	<0.0005
7+ years	88 (85)	54 (66)	
Unknown	4	13	
<b>Education Level* – no. (%)</b>			
None	5 (5)	8 (9)	0.077
Primary	52 (49)	40 (44)	
Secondary	43 (40)	27 (30)	
Vocational	3 (3)	10 (11)	
University	4 (4)	5 (6)	
Unknown	1		
<b>Literate – no. (%)</b>	101 (94)	87 (95)	1.000
Unknown	1	3	
<b>Primary Activity – no. (%)</b>			

	<b>High Resource (N=108)</b>	<b>Low Resource (N=95)</b>	<b>P Value†</b>
Student	15 (14)	11 (12)	<b>0.005</b>
Employed competitively	62 (57)	30 (33)	
Self-employed	19 (18)	33 (36)	
Unemployed/Other	12 (11)	18 (19)	
Unknown		3	

\*Category defined as any education within a given level. Number of years comprising primary and secondary education varies between countries and does not correspond with the US education system.

†Statistical significance calculated by Fisher Exact test or Mann-Whitney test, excluding unknown values.

SD=standard deviation.

**Table 2.** Baseline Injury and Admission Characteristics.

	<b>High Resource (N=108)</b>	<b>Low Resource (N=95)</b>	<b>P Value†</b>
<b>Mechanism of Injury – no. (%)</b>			
Road Traffic Incident	83 (80)	81 (89)	0.375
Fall	14 (13)	7 (8)	
Violence/Other	7 (7)	3 (3)	
Unknown	4	4	
<b>Mode Transport to First Hospital – no. (%)</b>			
Ambulance	80 (95)	25 (64)	<0.0005
Car/Taxi/Other	4 (5)	14 (36)	
Unknown	24	56	
<b>Transport Direct to Study Hospital – no. (%)</b>	70 (65)	29 (31)	<0.0005
<b>Admission GCS Score</b>			
Mean (SD)	7.9 (3.6)	7.3 (2.8)	0.411
Unknown	1		
<b>Normal Pupils – no. (%)</b>	61 (77)	50 (69)	0.114
Unknown	29	23	
<b>First Head CT Marshall Grade* – no. (%)</b>			
Diffuse Injury Type I	3 (3)	7 (7)	0.246
Diffuse Injury Type II	32 (30)	21 (22)	
Diffuse Injury Type III	27 (25)	33 (35)	
Diffuse Injury Type IV	4 (4)	5 (5)	
Evacuated Mass Lesion	38 (35)	25 (26)	
Non-evacuated Mass Lesion	3 (3)	4 (4)	
Unknown	1		
<b>AIS Head Severity Score – no. (%)</b>			
Mean (SD)	4.1 (0.8)	4.1 (0.9)	0.800
1-2 Minor/Moderate	2 (2)	1 (1)	0.098
3 Serious	22 (20)	25 (27)	
4 Severe	46 (43)	27 (29)	
5 Critical	38 (35)	39 (42)	
Unknown		3	

	<b>High Resource (N=108)</b>	<b>Low Resource (N=95)</b>	<b>P Value†</b>
<b>Hypotension at Admit – no. (%)</b>	16 (17)	6 (6)	<b>0.024</b>
Unknown	16	1	

\*Evacuated mass lesion on first head CT indicates a mass lesion that was subsequently surgically removed. Non-evacuated mass lesion on first head CT indicates a mass lesion that was not subsequently surgically removed.

†Statistical significance calculated by Fisher Exact test or Mann-Whitney test, excluding unknown values.

GCS=Glasgow Coma Scale; SD=standard deviation; CT=computed tomogram;  
AIS=Abbreviated Injury Scale.

**Table 3.** Hospital Care and Discharge Characteristics.

	<b>High Resource (N=108)</b>	<b>Low Resource (N=95)</b>	<b>P Value†</b>
<b>Admitted to ICU – no. (%)</b>	78 (72)	90 (95)	<b>&lt;0.0005</b>
<b>ICP Monitor – no. (%)</b>	50 (46)	0 (0)	<b>&lt;0.0005</b>
<b>ICU LOS – days</b>			
Mean (SD)	14.7 (10.4)	12.1 (7.5)	0.181
Unknown	1	5	
<b>Hospital LOS – days</b>			
Mean (SD)	22.4 (16.6)	21.3 (14.9)	0.846
Unknown	2	3	
<b>In-hospital Mortality - no. (%)</b>	22 (21)	26 (28)	0.247
Unknown	2	3	
<b>Discharge Disposition – no. (%)</b>			
Home	62 (58)	54 (59)	0.573
Acute care hospital	20 (19)	10 (11)	
Dead	22 (21)	26 (28)	
Other	2 (2)	2 (2)	
Unknown	2	3	
<b>Discharge GOS Score – no. (%)</b>			
Mean (SD)	3.1 (1.4)	2.8 (1.4)	0.146
1 Dead	22 (21)	26 (29)	0.621
2 Vegetative State	6 (6)	7 (8)	
3 Severe Disability	32 (30)	24 (27)	
4 Moderate Disability	28 (26)	22 (24)	
5 Good Recovery	18 (17)	11 (12)	
Unknown	2	5	
<b>6-Month Cause of Death – no. (%)</b>			
Neurologic injury/complication	6 (24)	15 (58)	<b>0.021</b>
Systemic injury/complication	19 (76)	10 (38)	
Other	0 (0)	1 (4)	
Unknown		5	

†Statistical significance calculated by Fisher Exact test or Mann-Whitney test, excluding unknown values.

ICU=intensive care unit; ICP=intracranial pressure; LOS=length of stay; SD=standard deviation; GOS=Glasgow Outcome Scale.

**Table 4.** Clinical Outcomes and Multivariate Regression Analyses.

	<b>High Resource (N=108)</b>	<b>Low Resource (N=95)</b>	<b>P Value</b>	<b>Regression Coefficient (95% CI)‡</b>	<b>Hazard Ratio (95% CI)‡</b>
<b>PRIMARY OUTCOMES</b>					
<b>Composite Measure – percentile</b>					
Mean (SD)	55 (23)	45 (23)	<b>0.002†</b>		
			<b>0.008¶</b>	0.09 (0.02, 0.15)	—
<b>6-Month GOS-E Score – no. (%)</b>					
Mean (SD)	4.9 (2.9)	3.8 (2.7)	<b>0.009†</b>		
1 Dead	25 (25)	31 (39)			
2 Vegetative State	6 (6)	1 (1)			
3 Lower Severe Disability	9 (9)	13 (16)			
4 Upper Severe Disability	7 (7)	3 (4)			
5 Lower Moderate Disability	3 (3)	4 (5)			
6 Upper Moderate Disability	5 (5)	10 (13)			
7 Lower Good Recovery	9 (9)	8 (10)			
8 Upper Good Recovery	36 (36)	10 (13)			
Unknown	8	15			
			<b>0.013¶</b>	1.05 (0.22, 1.87)	—
<b>Cumulative 6-Month Mortality – %</b>					
	24%	35%	0.146§	—	0.68 (0.40, 1.15)
<b>SECONDARY OUTCOMES</b>					
<b>Cumulative Following Commands* – %</b>					
	77%	65%	0.071§	—	1.37 (0.97, 1.94)
<b>3-Month GOS-E Score – no. (%)</b>					
Mean (SD)	4.3 (2.6)	3.5 (2.5)	0.054†		
1 Dead	24 (24)	30 (38)			
2 Vegetative State	6 (6)	2 (3)			
3 Lower Severe Disability	13 (13)	13 (16)			
4 Upper Severe Disability	17 (17)	10 (13)			
5 Lower Moderate Disability	6 (6)	3 (4)			

	<b>High Resource (N=108)</b>	<b>Low Resource (N=95)</b>	<b>P Value</b>	<b>Regression Coefficient (95% CI)‡</b>	<b>Hazard Ratio (95% CI)‡</b>
6 Upper Moderate Disability	4 (4)	4 (5)			
7 Lower Good Recovery	8 (8)	9 (11)			
8 Upper Good Recovery	22 (22)	8 (10)			
Unknown	8	16			
			0.082¶	0.68 (-0.09, 1.44)	—

\*Cumulative percentage of patients with GCS motor score of 6 at 6 months post-injury.

†Statistical significance calculated by Fisher Exact test or Mann-Whitney test, excluding unknown values.

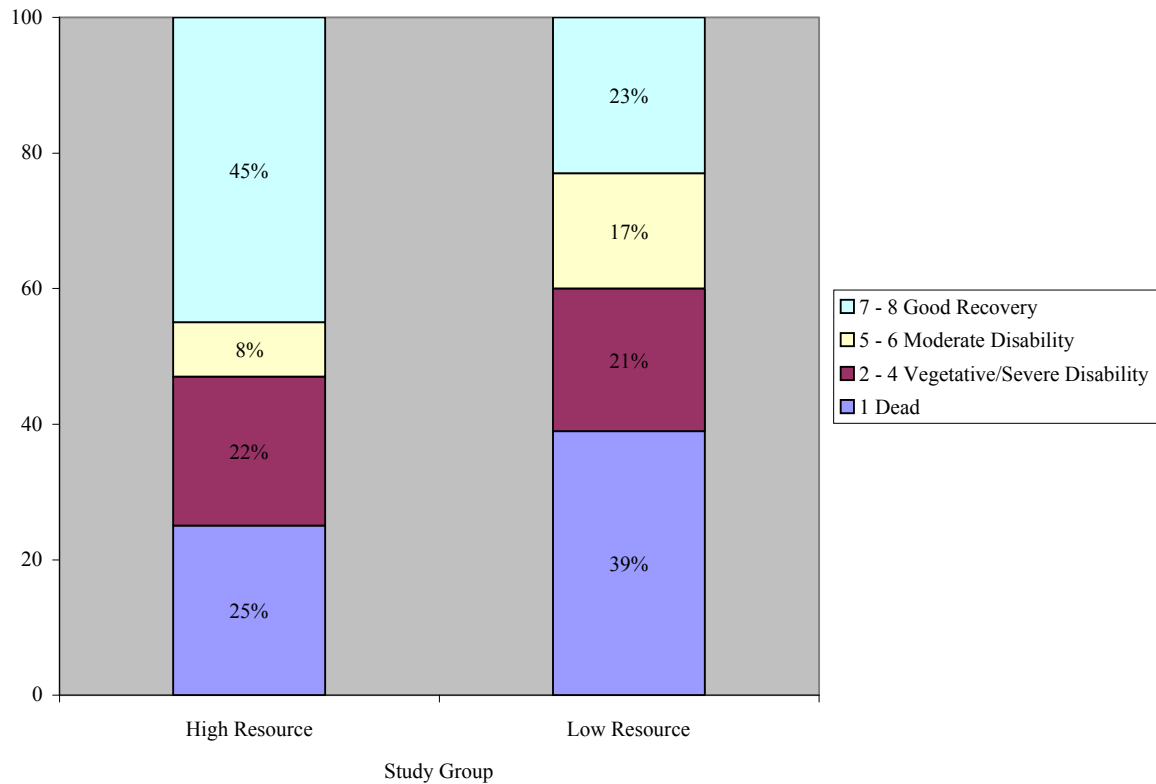
¶Statistical significance calculated by linear regression.

§Statistical significance calculated by Cox regression. All multivariate regression models were adjusted for any significant effects due to age, sex, education, employment, direct admission, admission GCS score, admission GCS motor score, and hypotension.

‡Unstandardized regression coefficient indicates the effect of high resource on the respective outcome in units of the outcome measure. Hazard ratio indicates the relative likelihood of the outcome in the high resource group.

CI=confidence interval; SD=standard deviation; GOS-E=Extended Glasgow Outcome Scale.

**Figure 2.** 6-Month Extended Glasgow Outcome Scale Score by Study Group.



Graph shows the variation in Extended Glasgow Outcome Scale (GOS-E) functional outcome score at 6 months post-injury between patients treated in a high resource compared with a low resource setting (Mann-Whitney  $p=0.004$ ). The proportion of patients in each functional outcome group is indicated. GOS-E scores 2 (vegetative state), 3 (lower severe disability), and 4 (upper severe disability) are considered unfavorable outcomes and grouped together.

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**APPENDIX 1**  
Data collection forms.

## Screening Form

- Fill in this form for all TBI patients with GCS $\leq$ 8 at admission (or motor GCS  $\leq$ 5 for intubated patients) and also
- For all patients with GCS  $\geq$ 9 and/or motor GCS = 6 at admission and then deteriorate to total GCS  $\leq$ 8 or motor GCS  $\leq$ 5) during the first 48 hours since injury.
- When filling out this form, an ID number is assigned to the patient.
- Once opened, fill in ALL the form.

ID: \_\_\_ / \_\_\_ \_\_\_ \_\_\_  
 (Center N<sup>o</sup> / N<sup>o</sup> entry into the study)

Patient Initials: \_\_\_ \_\_\_  
 (first last name and first name)

Area: \_\_\_  
 1: ED 2: ICU 3: Ward (general Hospital)

Day: \_\_\_ / \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  
DD MM AA AA  
 (Date and time you begin to fill this form)

Time: \_\_\_ : \_\_\_

### PATIENTS SELECCTION ( Ai/ Aii/ B)

#### Ai . Patients selection for the study

Code: 1. No 2. Yes 8. Not applied 9. Unknown  
 (if the answer of one of these question is like 1: NO, this patient is not chosen for the any of the studies (Randomized or observational) fill in only the screening form)

1.	Have 24 hs passed from Injury to hospital admission?	—
2.	Is the patient 13 years old or older?	—
3.	Was the patient excluded because of <b>pregnancy</b> ? <i>(no pregnancy test required, only clinical judgment)</i>	—
4.	Was a <b>penetrating TBI injury</b> exclude? <i>(Foreign object in the brain parenchyma)</i>	—
5.	Was excluded that the patient is a prisoner?	—
6.	Was it decided to actively treat the patient?	—
7.	Were <b>GCS=3 and fixed and dilated pupils</b> excluded?	—
8.	Pre-existing neurological disability that would not allow selection/follow up?	—
9.	Other reasons for excluding the patient, short description	..... .....

**A.ii. Only for Centers in Bolivia: about GCS after admission and previous to the randomization process.**

Codes: 1. No 2. Yes 9. Unknown

Only patients with a **GCS motor  $\leq 5$**  at admission and remain like this can be randomized. If after admission and before randomization, the patient improves with a **motor GCS =6**, cannot be selected for the randomized study. Choose option **1. NO** and evaluate him later to include in the observational study (see also explanation grid).

1.	<p>1- Does the patient stay with <b>GCS m <math>\leq 5</math></b> post initial resuscitation and previous to randomization?  <i>If the answer is:</i>  <b>1. No</b>, evaluate to include him in the observational study  <b>2. Yes</b>, evaluate resources availability in your hospital before interviewing the patient relatives  <b>9. Unknown</b>, ex: if you have previously excluded the patient and you may not know his evolution later.</p>	—
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**B. Resources availability at Hospital**

Code: 1. No 2. Yes 9. Unknown

(In **Bolivia Centers** there must be beds available in ICU, ICP fiberoptic and monitors in order to enrol the patient into the **randomized study**. Otherwise, evaluate to include him in the observational study).

1.	Are there available beds in ICU?	—
2.	Are there ICP monitors available?	—
3.	Are there any catheters for ICP monitoring available?	—

**PATIENT ENROLMENT ( Ci/Cii)**

**Ci. . Enrolment for the study (about the interview and the Consent Form, IC)**

The codes for the answer at the end of each question.

*In the centers of Bolivia, remember that **the relatives patient must sign and accept the consent form n° 1** within 24 hours since injury for the randomization study (or 48hs since injury in case of neuroworsening).*

*In all the centers of the study, remember that **the patient relatives must sign and accept the consent form N° 2** within 48 hours since injury for the observational study..*

1.	<b>1. Only for Centers in Bolivia:</b>	
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	<p><b>What happened with the interview and/or the relatives decision about Consent Form N°1 (randomized study)?</b></p> <p>1: The interview was done and they accept to participate into the study.  2: The interview was done and they didn't accept to participate into the study.  3: The interview was done but they didn't answer in time.  4: The interview wasn't done: more than 24 hours have passed since injury and no possibility of doing the interview because there are no patients relatives.  5: The interview wasn't done: more than 24 hours have passed since injury and no possibility of doing the interview because of lack of staff of the study.  6: The interview wasn't done: this patient was first selected for the observational study (ex: improve his motor GC:6, there are no bed or ICP fiberoptic/monitors available).  7: The interview wasn't done: doesn't fulfil the inclusion/exclusion criteria for any of the studies.  8: Other facts:  .....  .....</p> <p><i>If the answer is YES:</i>  1, go on with the randomization to assign the patient and ICP or not ICP group,  2, 3, 4 or 5 evaluate the possibility of including him in the observational study,  6, do the interview for the consent form N°2,  7, only fill in the screening form.  8, write down 8 and describe on the line provided.</p>	<p>_____</p>
<p>2.</p>	<p><b>2. For all the centers of the study:</b>  <b>What happened with the interview and/or the relatives decision about the Consent Form N°2 (observational study)?</b></p> <p>1: The interview was done and they accept to participate into the study.  2: The interview was done and they didn't accept to participate into the study.  3: The interview was done but they didn't answer in 48 hs.  4: The interview wasn't done: more than 48 hours have passed since injury and no possibility of doing the interview because there are no patients relatives.  5: The interview wasn't done: more than 48 hours have passed since injury and no possibility of doing the interview because of lack of staff of the study.  6: In Bolivia, this patient has already been selected for the randomized study.  7: The interview wasn't done: doesn't fulfil the inclusion/exclusion criteria for any of the studies.</p>	<p>_____</p>

	<p>8: Other facts</p> <p>.....</p> <p>.....</p> <p><i>If the answer is:</i></p> <p>1, fill in and close the screening form and go on with the acute care forms.</p> <p>2, 3, 4, 5 or 7: only fill in and close the screening form,</p> <p>6, go on with randomization to assign the patient an ICP/not ICP group.</p> <p>8, write down 8 and describe on the provided line</p>	
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**C.ii. Data and Time of the interview of the Consent Form and the decision of the relatives**

**Code:** dd/mm/year hh:mm

08/08/888 88:88, if the interview wasn't done

1.	<p>Only for the <b>centers in Bolivia</b></p> <p><b>Interview</b> for getting the Consent Form N°1 for the randomized study</p>	<p>__ / __ / ____</p> <p>__ : __</p>
2.	<p>Only for <b>centers in Bolivia</b></p> <p>Relatives <b>decision</b> about the Consent Form CI N°1, randomized study</p>	<p>__ / __ / ____</p> <p>__ : __</p>
3.	<p>For all centers</p> <p><b>Interview</b> for getting the Consent Form N°1 for the observational study</p>	<p>__ / __ / ____</p> <p>__ : __</p>
4.	<p>For all centers</p> <p>Relatives <b>decision</b> about Consent Form N°2 for the observational study</p>	<p>__ / __ / ____</p> <p>__ : __</p>

**PREVIOUS TRANSFER AND ENROLMENT (T/ E)**

**D. Transfer before enrolment**

	<p>1: The patient wasn't transferred before enrolment</p> <p>2: Yes, the patient was transferred to a non study hospital before enrolment</p> <p>3: Yes, the patient was transferred to a study hospital before enrolment</p> <p>8. Not applied</p> <p>9. Unknown</p> <p><i>If the answer is:</i></p> <p>1: go on with the evaluation of the patient for the study</p> <p>2: The patient was transferred to a non study hospital before the consent form. Fill in and close the screening form.</p> <p>3: The patient was transferred to a study hospital before the consent form, let the PI know about this hospital, fill in and close the screening form.</p>	<p>_____</p>
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	<p>8: Ex.: the patient was not selected for the study (doesn't fulfil the criteria 9: Ex: the patient wasn't selected for the study and you know his later evolution.</p> <p>If the patient was transferred to another hospital after signing the consent form, close the acute care forms and remember the relatives that they'll be interviewed at 3 and 6 months post injury. In the form "Hospital discharge" write down this. This patient <b>CANNOT BE ENROLLED AGAIN IN ANOTHER STUDY HOSPITAL</b> where only a screening form will be filled in (see Section E, question 1) and he'll be immediately excluded.</p>	
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**E. Enrolment previous to Hospital admission**

The codes for the answers are at the end of each question.

1.	<p><b>1. Is the patient enrolled in another study?</b> 1: NO (leave the following question blank) 2: YES, but not in this study. 3: YES, in this study 9: Unknown</p> <p>If the answer is : <b>1 and 2:</b> go on with the patient evaluation for the study <b>3:</b> this patient <b>CANNOT BE ENROLLED AGAIN IN YOUR HOSPITAL</b>. Even if the result of the <b>PREVIOUS INTERVIEW</b> was negative, fill in only the screening form and exclude him immediately. The data of hospitalization in your institution <b>ARE NOT USEFUL</b> for the study. The follow up staff from the study hospital could ask for seeing the patient for the follow up. See also section F, question 3. <b>9:</b> can go on with the patient evaluation for the study in your hospital</p>	_____
2.	<p><b>2. Has the patient already been enrolled in another study?</b> (Name and brief description of the study. Leave it blank if the patient hasn't been previously enrolled in another study)</p>	<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

**EVOLUTION SINCE INJURY (F/ G/ H)**

**F. Previous data to hospital admission**

The codes for the answers are at the end of each question.

1.	<p><b>Day and time of Injury (dd/mm/year) (hh:mm)</b> If date or hour of injury is only suspected, consider the maximum time possible from injury and check only suspicion (the patient can be chosen for the study if you suspects that less than 24 hs have passed from injury to hospital admission)</p> <p>If completely unknown, Code 09/09/9999 99/99 (the patient can not be entered into study)</p>	<p style="text-align: center;">____ / ____ / _____           : ____</p> <p>Only suspicion <input type="checkbox"/></p>
2.	<p><b>Day and time of call to emergency? (dd/mm/year) (hh:mm)</b> If unknown, Code 09/09/9999 99/99</p>	<p>____ / ____ / _____           : ____</p>

	If not applied, 08/08/8888 88/88	
<b>3.</b>	<p><b>Was the patient transported from another hospital?</b></p> <p>1. No (and leave the next question blank)</p> <p>2. Yes, from another not study hospital</p> <p>3. Yes, from another study hospital and the interview on the consent form was already done (the result doesn't matter)</p> <p>4. Yes, from another study hospital but the interview of the consent form wasn't done.</p> <p>9. Unknown</p> <p><i>If the answer is:</i></p> <p><i>1, 2, 4 and 9: go on with the patient evaluation for this study.</i></p> <p><i>3. THE PATIENT RELATIVES CANNOT BE INTERVIEWED, fill in the screening form.</i></p>	_____
<b>4.</b>	<p><b>Previous to hospital, admission day and time in the first center where the patient was admitted after injury: (dd/mm/year) (hh:mm)</b></p> <p><i>Code 09/09/9999 99/99if unknown.</i></p>	____ / ____ / _____ ____ : ____
<b>5.</b>	<p><b>Day and time at hospital study admission (dd/mm/year) (hh: mm).</b></p> <p><i>This data cannot be unknown</i></p>	____ / ____ / _____ ____ : ____
<b>6.</b>	<p><b>How the patient was transported to the first hospital?</b></p> <p>1. Ambulance</p> <p>2. Taxi</p> <p>3. Fire men</p> <p>4. Car</p> <p>5. Helicópter</p> <p>6. Other: _____</p> <p>9. Unknown</p>	_____
<b>7.</b>	<p><b>O2 extra deliver during transfer between injury and the first center where assisted?</b></p> <p>1. No</p> <p>2. Yes</p> <p>9. Unknown</p>	_____
<b>8.</b>	<p><b>Fluids supply during transfer between injury and the first center where assisted?</b></p> <p>1. No</p>	_____

	2. Yes 9. Unknown	
<b>9.</b>	<b>Cause of Injury</b> The first two digits describe the patient (riding a bicycle, motor cycle, driving a car or as a pedestrian) and the following digits to describe if another vehicle was involved in the accident (car, motor cycle, etc.). If another car wasn't involved, the second two digits are filled in as 88: not applied, 99 if unknown.  01. Motor vehicle (not motor cycle) 02. Motor cycle 03. Bicycle 04. Pedestrian 05. Home 06. Work 07. Fall from a height 08. Fall 09. Robbery/Strike 10. Accidental Strike or with an object 11. Sport 12. Other_----- 13. Gunshot wound 88. Not applied 99. unknown	____ / ____
10-23	<b>GCS, intubation, endotracheal tube, alcohol, drugs pupils, date and time</b>	Fill in the grid at the end of this form

**Questions 24 – 26 are coded as :1. No 2. Yes 9. Unknown**

<b>24.</b>	<b>Hypotension during transfers prior to hospital admission?</b>	___
<b>25.</b>	<b>Hypoxia during transfers prior to hospital admission?</b>	___
<b>26.</b>	<b>Cardio respiratory arrest during transfers prior to hospital admission?</b>	___

**G-First examination at Hospital Study Admission**

<b>27.</b>	<b>Age of patient (years)</b> Codes: 999: unknown (cannot enter patient into study, fill in only screening form) 222: unknown but suspect > or = 13 years old (can enter patient into study).	____ _
<b>28.</b>	<b>Gender</b> 1. Male 2. Female	____
<b>29.</b>	<b>Hypotension at Hospital admission?</b> 1. No	____

	2. Yes 9. Unknown	
<b>30.</b>	<b>Hypoxia at hospital admission?</b> 1. No 2. Yes 9. Unknown	_____
<b>31</b>	<b>Cardio respiratory arrest at study hospital admission?</b> 1. No 2. Yes 9. Unknown	_____
<b>32-45</b>	<b>GCS, intubation, endotracheal tube, alcohol, drugs pupils, date and time</b>	Fill in the grid at the end of this form

**H- After hospital admission and until the interview for the consent form or exclusion time**

<b>46-59</b>	<b>GCS post initial resuscitation or hospital admission</b> <i>See rules of the grid at the end of this form.</i>	Fill in the grid at the end of this form
<b>60.</b>	<b>Has the patient died before the interview for the consent form or at exclusion time ?</b> 1. No (leave the following question blank) 2. Yes 9. Unknown	_____
<b>61.</b>	<b>Day and time of patient expiration (dd/mm/year)</b> (hh:mm) If day is unknown. Code : 09/09/9999 If time is unknown. Code 99:99	____ / ____ / _____ ____ : ____
<b>62.</b>	<b>Time of ventilation with Ambu or “T” Tube after admission into the study hospital</b> (code 888 Not applied ; 999 unknown )	____ : ____ Hours          Minutes
<b>63.</b>	<b>Hypotension before enrolment or exclusion time</b> (previous episodes suffered during transport and admission are excluded) 1. No 2. Yes 9. Unknown	_____
<b>64.</b>	<b>Hypoxia before an attempt to enrol or exclusion time</b> (previous episodes suffered during transport and admission are excluded) 1. No 2. Yes 9. Unknown	_____
<b>65.</b>	<b>Was a CT Scan done?</b> 1. No – go to question # 70 and don’t fill in # 66-69 2. Yes	_____

	9. Unknown – go to question # # 70 and don't fill in # 66-69	
66.	<b>Day and time of the first CT Scan (dd/mm/year)</b> (hh:mm) If day is unknown. Code: 09/09/9999 If time is unknown. Code: 99:99	____ / ____ / ____ ____ : ____
67.	<b>Marshall Classification</b> 1. ID type I 2. ID type II 3. ID type III 4. ID type IV 5. Evacuated Mass lesion 6. Not evacuated Mass Lesion 9. Unknown	_____
68.	<b>Periencephalic cisterns status</b> 1. Normal 2. Compressed 3. Absent 9. Unknown	_____
69.	<b>Midline shift</b> (Code 00 for no midline shift ; 99 unknown)	_____
70.	<b>Has the patient undergone neurosurgery before an attempt to enrol or exclusion time?</b> 1. No 2. Yes 9. Unknown (if the patient was enrolled into the study, make sure to report this in the neurosurgery form )	_____
71.	<b>Has the patient suffered from other injuries?</b> Coded as: 1. No 2. Yes 9.Desconocida  a. Abdominal b. Thoracic c. Upper extremities d. Low Extremities e. Spine f. Spinal Cord  <i>If the patient was later enrolled into the study , the associated injuries will be scored in the AIS Score within 24 hours since injury.</i>	a. _____ b. _____ c. _____ d. _____ e. _____ f. _____

72.

**Results from initial lab, after hospital admission and before an attempt to enrol or exclusion time**

Fill in 9 for missing data in the provided spaces.

- a. GB: \_\_\_\_\_ cel/mm<sup>3</sup>
- b. GR: \_\_\_\_\_ cel/mm<sup>3</sup>
- c. Platelet: \_\_\_\_\_ cel/mm<sup>3</sup>
- d. TP: \_\_\_\_\_ . \_\_\_\_\_
- e. KPTT: \_\_\_\_\_ . \_\_\_\_\_
- f. RIN: \_\_\_\_\_ . \_\_\_\_\_
- g. Fib: \_\_\_\_\_ mg/dl
- h. Hcto: \_\_\_\_\_ . \_\_\_\_\_ %
- i. Hb: \_\_\_\_\_ gr/dl
- j. Na+: \_\_\_\_\_ mEq/l
- k. K+: \_\_\_\_\_ . \_\_\_\_\_ mEq/l
- l. Ca+: \_\_\_\_\_ . \_\_\_\_\_ mg/dl
- m. Alcholemia: \_\_\_\_\_ . \_\_\_\_\_ gr/l
- n. EAB: pH: \_\_\_\_\_ . \_\_\_\_\_
- o. PaO<sub>2</sub>: \_\_\_\_\_ mmHg
- p. PaCO<sub>2</sub>: \_\_\_\_\_ mmHg
- q. HCO<sub>3</sub>: \_\_\_\_\_ meq/l
- r. %SatHb: \_\_\_\_\_
- s. Glicemia: \_\_\_\_\_ mg/dl

## PRE-INJURY PATIENT FORM

ID: \_\_\_ / \_\_\_ / \_\_\_ / \_\_\_  
(Center N<sup>o</sup> / N<sup>o</sup> entry into the study)

Patient Initials: \_\_\_ \_\_\_  
(first last name and first name)

Day: \_\_\_ / \_\_\_ / \_\_\_ / \_\_\_  
D D M M y y y y

1. How old are you (Years)? (code 999 if unknown) \_\_\_\_\_
2. What is your gender? \_\_\_\_\_
  1. Male
  2. Female
3. What is your nationality? \_\_\_\_\_
  1. Argentinean
  2. Bolivian
  3. Brazilian
  4. Colombian
  5. Ecuadorian
  6. Other: \_\_\_\_\_
  9. Unknown
4. What is your race? \_\_\_\_\_
  1. White
  2. Black or African American
  3. Asian
  4. Native Hawaiian (or other Pacific Islander)
  5. American Indian
  6. Mixed
  7. Other: \_\_\_\_\_
  9. Unknown
5. What is your ethnic group? (Ask about ethnic group if race is American Indian, otherwise code 88) \_\_\_\_\_
  1. Aymara (Bolivia)
  2. Quechua (Argentina, Bolivia)
  3. Guarani (Argentina, Bolivia, Brazil)
  4. Wayuu (Colombia)
  5. Arhuacos (Colombia)
  6. Toba (Argentina)
  7. Tupi (Brazil)
  8. Mixed

- 9. Other: \_\_\_\_\_
- 88. Not applicable, race is not American Indian
- 99. Unknown

6. Based on culture, language, religion, behavior and/or ancestry, which one of the following best defines your immigrant group? \_\_\_\_\_
- 1. African
  - 2. English
  - 3. Portuguese
  - 4. Italian
  - 5. Spaniard
  - 6. German
  - 7. Polish
  - 8. Japanese
  - 9. Chinese
  - 10. Korean
  - 11. Syrian/Lebanese
  - 12. Jewish (Ashkenazi/Sephardi)
  - 13. None of the above, (record the other culture that best defines your immigrant group): \_\_\_\_\_
  - 88. Not applicable, (no one culture/language/religion/behavior defines your immigrant group)
  - 99. Unknown

7. What is his/her mother tongue?  
*Code each as: 1: No 2: Yes 9: unknown*
- a. Spanish \_\_\_\_\_
  - b. Portuguese \_\_\_\_\_
  - c. Italian \_\_\_\_\_
  - d. English \_\_\_\_\_
  - e. Germany \_\_\_\_\_
  - f. Aymara \_\_\_\_\_
  - g. Quichua \_\_\_\_\_
  - h. Guarany \_\_\_\_\_
  - i. Other: .....

8. Do you speak and understand any Spanish (Portuguese)? \_\_\_\_\_
- 1. No
  - 2. Yes
  - 9. Unknown

9. Are you very fluent in Spanish (Portuguese), that is, able to hold a conversation in Spanish (Portuguese) with no or very little difficulty? \_\_\_\_\_
- 1. Can't understand and follow

2. Quite difficult
3. Has some difficulty
4. Slightly difficult
5. No difficulty
9. Unknown

10. What language do you speak at home? \_\_\_\_\_
1. Only other language
  2. Other language more than Spanish (Portuguese)
  3. Both equally
  4. Spanish (Portuguese) more than other language
  5. Only Spanish (Portuguese)
  9. Unknown
11. What is your current marital status? \_\_\_\_\_
1. Never married
  2. Currently married
  3. Separated
  4. Divorced
  5. Widowed
  6. Cohabiting
  9. Unknown
12. Who did you live with just prior to the injury? \_\_\_\_\_
1. Alone
  2. Adult family members
  3. Children/adolescent(s)
  4. Roommates/friends
  5. Other patients/residents/personal care attendant
  6. Others: \_\_\_\_\_
  9. Unknown
13. What was your residence just prior to the injury? \_\_\_\_\_
1. Private residence
  2. Nursing home or institution
  3. Hotel
  4. Hospital
  5. Rehabilitation Center
  6. Homeless
  7. Other: \_\_\_\_\_
  9. Unknown
14. Are you able to both read and write a short, simple statement on your everyday life and understand it? \_\_\_\_\_
1. No
  2. Yes

9. Unknown
15. What hand do you use to write with? Or, if you do not write, then \_\_\_\_\_  
 what leg do you play soccer with?  
 1. Right  
 2. Left  
 3. Both  
 9. Unknown
16. What is the highest level of education that you have completed? \_\_\_\_\_  
 1. None  
 2. Primary  
 3. Secondary  
 4. Tertiary (e.g., Teachers, Technicians)  
 5. University  
 6. Post graduate (e.g., Masters, Doctoral)  
 7. Other: \_\_\_\_\_  
 9. Unknown
17. How many years of school, including higher education have you \_\_\_\_\_  
 completed? (code 99 for unknown) \_\_\_\_\_  
 (code 88 not applicable)
18. What is your main activity prior to the injury? \_\_\_\_\_  
 1. Full-time student  
 2. Part-time student  
 3. Self- or family-employed  
 4. Employed competitively (employed by someone else)  
 5. Homemaker  
 6. Unemployed  
 7. Retired  
 8. Volunteer work  
 77. Other: \_\_\_\_\_  
 99. Unknown
19. What is your second main activity prior to the injury? \_\_\_\_\_  
 1. Full-time student  
 2. Part-time student  
 3. Self- or family-employed  
 4. Employed competitively (employed by someone else)  
 5. Homemaker  
 6. Unemployed  
 7. Retired  
 8. Volunteer work  
 77. Other: \_\_\_\_\_  
 88. Not applicable. Only one activity is identified

99. Unknown

20. During the last 12 months, what has been your main occupation? \_\_\_\_\_

1. Legislator, senior official or manager
2. Professional (engineer, doctor, teacher, clergy, etc)
3. Technician or Associate Professional (inspector, finance dealer, etc)
4. Clerk (secretary, cashier, etc)
5. Service or sales worker (cook, travel guide, shop salesperson, etc)
6. Agricultural or fishery worker (vegetable grower, livestock producer, etc)
7. Craft or trades worker (carpenter, painter, jewelry worker, butcher, etc)
8. Plant/machine operator or assembler (equipment assembler, sewing-machine operator, driver, etc)
9. Elementary worker (street food vendor, shoe cleaner, etc)
10. Armed forces (government military)
88. Not applicable, has not worked in last 12 months
99. Unknown

21. Thinking over the past year, can you tell me what has been your family's average earnings? (Please tell me the amount per week, per month or per year, whichever is easiest for you). *Code earnings amount on 1<sup>st</sup> line (if refuse or unknown leave the first line blank and complete with code refuse or unknown in the time frame and currency) Fill in time frame on 2<sup>nd</sup> line and code for currency on third line* \$ \_\_\_\_\_

1. Per week \_\_\_\_\_
2. Per month \_\_\_\_\_
3. Per year \_\_\_\_\_
7. Refused \_\_\_\_\_
- 9 Unknown \_\_\_\_\_

Code for currency \_\_\_\_\_

1. Boliviano
2. Argentine Peso
3. Colombian peso
4. Real
5. US Dollar
6. Other: \_\_\_\_\_
7. refused
9. Unknown

22. Thinking over the past year, can you tell me what has been your own average earnings? (Please tell me the amount per week, per \_\_\_\_\_

\$ \_\_\_\_\_  
\_\_\_\_\_

month or per year, whichever is easiest for you). *Code earnings amount on 1<sup>st</sup> line (if refuse or not applicable because he didn't work for money or unknown leave the first line blank and complete with code refuse or not applicable or unknown in the time frame and currency) Fill in time frame on 2<sup>nd</sup> line and code for currency on third line.* \_\_\_\_\_

1. Per week
2. Per month
3. Per year
7. Refused
- 8 Not applicable
9. Unknown

Code for currency \_\_\_\_\_

1. Boliviano
2. Argentine peso
3. Colombian peso
4. Real
5. US Dollar
6. Other: \_\_\_\_\_
7. refused
8. Not applicable
9. Unknown

23. What is the main reason you are not working for pay? \_\_\_\_\_

1. Homemaker/caring for family
2. Looked but can't find a job
3. Doing unpaid work/voluntary activities
4. Studies/training
5. Retired/too old to work
6. Ill health
7. Other: \_\_\_\_\_
88. Not applicable, working for pay
99. Unknown

24. Have you ever been hospitalized for a prior traumatic brain injury? \_\_\_\_\_

1. No
2. Yes
9. Unknown

25. In the 3 months before your injury, how often did you use alcoholic beverages (beer, wine, spirits, etc.)? \_\_\_\_\_

1. Never
2. Once or twice

3. Monthly
4. Weekly
5. Daily or almost daily
9. Unknown

26. *Ask if question 25 was coded as 2 or higher. If question 25 = never then code = 8 here* \_\_\_\_\_

In the 3 months before your injury, how often did your use of alcoholic beverages lead to health, social, legal or financial problems?

1. Never
2. Once or twice
3. Monthly
4. Weekly
5. Daily or almost daily
8. Not applicable: never used alcoholic beverages in question above
9. Unknown

27. In the 3 months before your injury, how often did you use nonprescription, recreational drugs (Cannabis, Cocaine, Amphetamine type stimulants, inhalants, sedatives or sleeping pills, hallucinogens, opioids)? \_\_\_\_\_

1. Never
2. Once or twice
3. Monthly
4. Weekly
5. Daily or almost daily
9. Unknown

28. *Ask if question 27 was coded as 2 or higher. If question 27 = never then code = 8 here* \_\_\_\_\_

In the 3 months before your injury, how often did your use of nonprescription, recreational drugs lead to health, social, legal or financial problems?

1. Never
2. Once or twice
3. Monthly
4. Weekly
5. Daily or almost daily
8. Not applicable: never used non prescription recreational drugs in question above
9. Unknown

29. Have you ever been hospitalized for a psychiatric disorder? \_\_\_\_\_

1. No

- 2. Yes (what/when?): \_\_\_\_\_
- 9. Unknown

30. Have you ever attempted suicide at anytime before this injury? \_\_\_\_\_
- 1. No
  - 2. Yes (when?): \_\_\_\_\_
  - 9. Unknown

31. *The next set of questions (31a – 31g) are each coded as*
- 1. *No*
  - 2. *Yes*
  - 9. *Unknown*

- a. Do you have a history of stroke? \_\_\_\_\_
- b. Cognitive disorder? \_\_\_\_\_
- c. Movement disorder? \_\_\_\_\_
- d. Dementia? \_\_\_\_\_
- e. Demyelinating disorder? \_\_\_\_\_
- f. Seizures? \_\_\_\_\_
- g. Other neurological disorder? \_\_\_\_\_

32. *The next set of questions (32a – 32j) are each coded as*
- 1. *No*
  - 2. *Yes*
  - 8. *Not applicable*
  - 9. *Unknown*

- a. Do you have a history of cardiovascular disease? \_\_\_\_\_
- b. Respiratory? \_\_\_\_\_
- c. Renal? \_\_\_\_\_
- d. Metabolic? \_\_\_\_\_
- e. Endocrine? \_\_\_\_\_
- f. Psychiatric? \_\_\_\_\_
- g. Gastrointestinal? \_\_\_\_\_

h. Gynaecological? \_\_\_\_\_

i. Allergic? \_\_\_\_\_

j. Other disease? \_\_\_\_\_

## AIS Form

*(Complete only in the first admission)*

ID:    /                 
*(Center N<sup>o</sup> / N<sup>o</sup> entry into the study)*

Patient Initials:        
*(first last name and first name)*

Day:       /       /              
D D    M M    A A A A

*Complete this form based on the first 24 hours post injury. Record the highest severity score per body region. If injury to a particular body part is not reported fill in '0'.*

		Severity Score
1.	Head	_____
2.	Face	_____
3.	Neck	_____
4.	Thorax	_____
5.	Abdomen	_____
6.	Spine	_____
7.	Upper Extremity	_____
8.	Lower Extremity	_____
9.	External and Other	_____

## IN HOSPITAL CRITICAL AREA (CA) FORM

Fill in a form for each Critical Care Admission (ICU, Emergency or any other area while the patient is in hospital for critical care, mechanical ventilation included)

During this admission, all Acute Care, TIL and Nursing Forms (Vital Signs) must filled in only if the reason is due to neurological injury.

If the patient is admitted again for a not neurological reason, no TIL and Vital Form are recorded.

For each admission, remember to fill in the data from ICP monitor in the attached grid.

---

ID: \_\_\_ / \_\_\_ \_\_\_ \_\_\_  
(Center N° / N° entry into the study)

Patient Initials: \_\_\_ \_\_\_  
(first last name and first name)

Area: \_\_\_  
(1: Emergency, 2: ICU, 3: Hospital)

Critical Care Admission Date: \_\_\_ / \_\_\_ / \_\_\_\_\_

Critical Care Discharge Date: \_\_\_ / \_\_\_ / \_\_\_\_\_

**1. Is this admission primary related to the traumatic neurological reason?** \_\_\_\_\_

- 1. No
- 2. Yes
- 9. Unknown

**2. What's the main reason for admission in Critical Care?** Short description:

.....  
.....

**3. Total number of days with mechanical respiratory assistance :**

\_\_\_ \_\_\_

**4. Tracheostomy during this admission?** \_\_\_\_\_

- 1, No, go to question 6, leave #5 blank
- 2. Yes
- 9. Unknown, go to question 6, leave #5 blank

**5. Date of tracheostomy:**

\_\_\_ / \_\_\_ / \_\_\_

**6. Needed dialitic treatment?** \_\_\_\_\_

- 1. No
- 2. Yes
- 9. Unknown

**7-25. ICP monitoring, fill in the attached grid.**

## HOSPITAL DISCHARGE FORM

ID: \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  
(Center N<sup>o</sup> / N<sup>o</sup> entry into the study)

Patient Initials: \_\_\_ \_\_\_  
(first last name and first name)

1.	Hospital discharge date	___ / ___ / ___ ___ ___
2.	GOS score at hospital discharge (1-5; 9 if unknown)	
3.	Date and time able to follow commands consistently (GCSm 6) (code 08/08/8888 88:88 if patient not following commands consistently when discharged; code 09/09/9999 99:99 if unknown; leave date and time blank if S expired without following commands)	___ / ___ / ___ ___ ___ ___ : ___
4.	Select the code that best describes the amount of time that elapsed from injury until the patient follows commands consistently 1. Within 1 hour 2. Between 1 and 5 hours 3. Between 6 and 24 hours 4. 25 hours to 3 days 5. 4 to 6 days 6. 7 to 13 days 7. 14 to 20 days 8. 21 to 28 days 9. 29 to 59 days 10. 60 to 89 days 11. 90 or more days 12. Patient expired before following commands 99. Unknown (describe situation) : _____ _____ _____ _____	_____
5.	Physiotherapy ICU 1. No – go to question # 9 (leave 6-7 blank) 2. Yes 9. Unknown – go to question # 9 (leave 6-7 blank)	_____
6.	Type of ICU physiotherapy Each of the following coded as: 1. No 2. Yes, professional only 3. Yes, professional and family 9. Unknown a. Respiratory b. Motor	a. _____ b. _____
7.	Average total daily minutes of all ICU physiotherapy (code 999 if unknown)	___ ___ ___

8.	Physiotherapy post ICU 1. No – skip to question # 12 (leave 9-10 blank) 2. Yes 9. Unknown – skip to question # 12 (leave 9-10 blank)	_____
9.	Type of post ICU physiotherapy Each of the following coded as 1. No 2. Yes 9. Unknown a. Respiratory  b. Motor  c. Other: _____	a. _____  b. _____  c. _____
10.	Average total daily minutes of all post ICU physiotherapy (code 999 if unknown)	____ _
11	Discharge referral 1. Home 2. Acute care hospital 3. Rehabilitation Institute 4. Non rehabilitation Institute 5. Death 6. Discharge voluntary 7. Other: _____ 9. Unknown	_____
12.	<u>Protocol violation</u> <hr/> <hr/> <hr/>	

## APPENDIX 2

Definitions of outcome scales used.

**Glasgow Outcome Scale.** A measure of functional outcome for prediction of long-term disability following traumatic brain injury (28).

1 = DEAD

2 = VEGETATIVE STATE

Unable to interact with environment, no meaningful responsiveness, non-sentient state

3 = SEVERE DISABILITY

Conscious, able to communicate and follow commands, unable to live independently or perform activities of daily life

4 = MODERATE DISABILITY

Able to live independently and perform activities of daily life, unable to return to work or school, does not have capacity to regain pre-injury level of social or occupational activity

5 = GOOD RECOVERY

Able to return to work or school, capacity to regain pre-injury level of social and occupational activity, may have minor residual physical or neuropsychological deficits

**Extended Glasgow Outcome Scale.** Sub-divisions, evenly spread across the range of disability among conscious survivors, allow more sensitive measures of recovery (29).

1 = DEAD

2 = VEGETATIVE STATE

Unable to interact with environment, no meaningful responsiveness, non-sentient state

3 = LOWER SEVERE DISABILITY

Conscious, able to communicate and follow commands, requires 24-hour assistance with all activities of daily life

4 = UPPER SEVERE DISABILITY

Conscious, able to communicate and follow commands, requires partial assistance up to 16 hours daily, able to perform some activities of daily life

5 = LOWER MODERATE DISABILITY

Able to live independently and perform activities of daily life, unable to return to work or able to work only in a sheltered non-competitive setting, unable to return to school, unable to or rarely participates in social activity, constant disruption in interpersonal relationships

6 = UPPER MODERATE DISABILITY

Able to live independently and perform activities of daily life, able to work in reduced capacity, able to return to school in reduced capacity, significant reduction in participation in social activity, frequent disruption in interpersonal relationships

7 = LOWER GOOD RECOVERY

Able to return to work or school, some reduction in participation in social activity, occasional disruption in interpersonal relationships, injury-related physical or neuropsychological deficits inhibit return to normal life

8 = UPPER GOOD RECOVERY

Able to return to work or school, no reduction in participation in social activity, no disruption in interpersonal relationships, no injury-related physical or neuropsychological deficits that inhibit return to normal life

**Disability Rating Scale Impairment Rating.** A measure of level of consciousness following traumatic brain injury (36).

Arousability – Eye Opening

- 0 = Spontaneous eye opening with sleep/wake rhythms
- 1 = Eye opening to verbal stimulation and/or mild sensory stimulation
- 2 = Eye opening to painful stimulation
- 3 = Absence of eye opening to any stimulation

Awareness – Communication Ability

- 0 = Normal awareness of surroundings, can express basic facts about location and situation, and basic details of life
- 1 = Able to hold attention and answer questions, but answers may be delayed and/or indicate disorientation or confusion
- 2 = Able to talk with intelligible articulation, but speech inappropriate and meaningless, and typically random or exclamatory, sustainable conversation not possible
- 3 = Able to make sounds, but not recognizable words, conversation not possible
- 4 = Absence of sounds or signs of communication

Responsivity – Motor Response

- 0 = Obeys simple commands with movements not associated with reflex motor activity
- 1 = Movement of limb away from source of painful stimulation when delivered at multiple points, or attempt to remove source of painful stimulation
- 2 = Active withdrawal of limb away from painful stimulation, not a reflex response
- 3 = Flexion of limb to painful stimulation
- 4 = Extension of limb to painful stimulation
- 5 = Absence of motor response to any stimulation

**Galveston Orientation and Amnesia Test.** A measure of cognitive outcome predictive of long-term recovery following traumatic brain injury (37).

76 – 100 = NORMAL

No evidence of disorientation or confusion, including anterograde and retrograde post-traumatic amnesia

75 – 66 = BORDERLINE

Evidence of mild cognitive impairment, some disorientation and/or confusion, mild anterograde and/or retrograde post-traumatic amnesia

<66 = IMPAIRED

Evidence of significant cognitive impairment, disabling disorientation and/or confusion, severe anterograde and/or retrograde post-traumatic amnesia