

**ORIGINAL RESEARCH**

# Traumatic Brain Injury—Practice Based Evidence Study: Design and Patients, Centers, Treatments, and Outcomes



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**Abstract**

**Objectives:** To describe study design, patients, centers, treatments, and outcomes of a traumatic brain injury (TBI) practice-based evidence (PBE) study and to evaluate the generalizability of the findings to the U.S. TBI inpatient rehabilitation population.

**Design:** Prospective, longitudinal, observational study.

**Setting:** Ten inpatient rehabilitation centers.

**Participants:** Patients (N=2130) enrolled between October 2008 and September 2011 and admitted for inpatient rehabilitation after an index TBI injury.

**Interventions:** Not applicable.

**Main Outcome Measures:** Return to acute care during rehabilitation, rehabilitation length of stay, FIM at discharge, residence at discharge, and 9 months postdischarge rehospitalization, FIM, participation, and subjective well-being.

**Results:** The level of admission FIM cognitive score was found to create relatively homogeneous subgroups for the subsequent analysis of best treatment combinations. There were significant differences in patient and injury characteristics, treatments, rehabilitation course, and outcomes by admission FIM cognitive subgroups. TBI-PBE study patients were overall similar to U.S. national TBI inpatient rehabilitation populations.

**Conclusions:** This TBI-PBE study succeeded in capturing naturally occurring variation in patients and treatments, offering opportunities to study best treatments for specific patient impairments. Subsequent articles in this issue report differences between patients and treatments and associations with outcomes in greater detail.

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Traumatic brain injury (TBI) inpatient rehabilitation has been studied largely as an undifferentiated “black box,” with comparisons being made between patients who received rehabilitation and those who did not, between those who received it early and

those who received it late, or between those who received intensive treatment and those whose program was less intense.<sup>1-6</sup> However, Chesnut et al<sup>7</sup> observed that knowing time spent without knowing what impairments were being treated or what

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methods of treatment were used may be too blunt an instrument to identify important sources of variance in rehabilitation outcomes. This assumption is supported by results of a stroke rehabilitation comparative effectiveness study: average time spent in physical therapy (PT) and occupational therapy (OT) per day did not increase the percentage of variance explained in outcomes, but average time spent in specific PT and OT activities per day did.<sup>8</sup>

High<sup>9</sup> reviewed effectiveness studies of acute rehabilitation after TBI that described (1) gains made during rehabilitation; (2) effects of early intervention; and (3) effects of intensity of rehabilitation efforts. His conclusions were consistent with those of an NIH Consensus Conference and the evidence-based review of Chesnut et al: persons with TBI unequivocally make functional gains during inpatient rehabilitation, including gains in ambulation, independence, and cognition.<sup>7,9,10</sup> However, it was less clear how much these gains can be attributed to specific rehabilitation therapies and interventions and how much should be attributed to age, natural recovery as modified by brain injury severity, and patient preinjury characteristics. Also, there was insufficient evidence to inform what the timing of interventions should be, what type and intensity of interventions are most appropriate, and for whom specific interventions are most effective.

Inpatient TBI rehabilitation practice remains highly variable, which, in part, reflects lack of empirical evidence of how the complex interweaving of rehabilitation treatments from different professionals, in conjunction with patient prognostic factors (eg, comorbidities and injury severity), influences recovery. Understanding what treatment factors and processes lead to better outcomes, and for which patient subgroups, would allow development of more effective TBI rehabilitation. However, the information required to gain this understanding is very complex and requires capturing detailed information on injury type and severity; the types, timing, and amounts of interventions received; and how these factors affect outcomes across diverse types of patients. A necessary first step in deciphering the content of the “black box” is to develop a comprehensive index of patient prognostic factors that allows for standardized assessment of patient differences in illness and injury severity after TBI. Second, a standard taxonomy of TBI inpatient rehabilitation treatments for each discipline would allow researchers to capture reliably the targets of treatments; the types, intensities, and durations of rehabilitation activities performed; as well as other treatment process factors. We can then identify variance in outcomes, along with those patient and treatment factors that are associated with that variance. The evidence gleaned may be used to inform delivery of future treatment by patient characteristics, design of randomized controlled trials, guide clinical pathways development, or stimulate development of new and innovative treatment approaches.

It is likely that an interaction of interventions and patient factors influences outcomes: that is, what is optimal treatment for

**Table 1** Participating rehabilitation centers

| Facility   | Location                      |
|--|-------------------------------|
| Wexner Medical Center*                                 | Columbus, OH                  |
| Carolinas Rehabilitation, Carolinas HealthCare System* | Charlotte, NC                 |
| Mount Sinai Medical Center*                            | New York, NY                  |
| National Rehabilitation Hospital Shepherd Center       | Washington, DC<br>Atlanta, GA |
| Intermountain Medical Center                           | Salt Lake City, UT            |
| Rush University Medical Center                         | Chicago, IL                   |
| Brooks Rehabilitation Hospital                         | Jacksonville, FL              |
| Loma Linda University Rehabilitation Institute         | Loma Linda, CA                |
| Toronto Rehabilitation Institute                       | Toronto, ON, Canada           |

\* TBI Model Systems center.

one patient subgroup may have no or very limited impact on another group with different needs or abilities to benefit. In rehabilitation, multiple interventions are provided daily by professionals from varied disciplines, backgrounds, and experiences and nested within rehabilitation facilities with varied customs, cultures, and physical environments. Relatively small effects of a single intervention may be magnified when used in combination with other interventions.<sup>11</sup> Interventions that seem effective when studied in isolation may be antagonistic when provided together. In current TBI rehabilitation practice, the large variation in treatments delivered and outcomes produced, between as well as within facilities, affords an opportunity to compare the relative effectiveness of combinations and intensities of interventions among patients with TBI.

Practice-based evidence (PBE) study methodology provides an efficient, comprehensive means of implementing comparative effectiveness research.<sup>11</sup> The 5-year TBI rehabilitation project described in this article and in other articles in this supplement used PBE research methodology to isolate specific components of rehabilitation treatments, as has been done in previous PBE rehabilitation inpatient treatment studies.<sup>8,12-14</sup> The specific aims of the TBI-PBE project were (1) to identify individual patient characteristics, including demographic data, severity of brain injury, and severity of illness (complications, comorbidities), that may be associated with significant variation in treatments selected and in outcomes of acute rehabilitation for TBI; (2) to identify medical procedures and therapy interventions, alone or in combination, that are associated with better outcomes, controlling for patient characteristics; and (3) to determine whether specific treatment interactions with age, severity/impairment, or time are associated with better outcomes.

In this introductory article, we first provide an overview of the study design, centers, and methods. Second, we briefly describe the primary measures and variables used to describe patients who sustained TBI, with an emphasis on stratification by admission FIM cognitive scale score groups, and the results in our sample. Third, we provide an overview of the point-of-care (POC) forms incorporating our treatment taxonomy used to capture information on treatments and the most common treatments used by each discipline. Fourth, we describe inpatient rehabilitation outcomes for our sample. Fifth, for the purposes of evaluating generalizability, we compare the project's U.S. subsample with the U.S. rehabilitation population of persons with TBI.

#### **List of abbreviations:**

|            |                                     |
|------------|-------------------------------------|
| <b>CSI</b> | <b>Comprehensive Severity Index</b> |
| <b>GCS</b> | <b>Glasgow Coma Scale</b>           |
| <b>LOS</b> | <b>length of stay</b>               |
| <b>OT</b>  | <b>occupational therapy</b>         |
| <b>PBE</b> | <b>practice-based evidence</b>      |
| <b>POC</b> | <b>point-of-care</b>                |
| <b>PT</b>  | <b>physical therapy</b>             |
| <b>PTA</b> | <b>posttraumatic amnesia</b>        |
| <b>SLP</b> | <b>speech-language pathology</b>    |
| <b>TBI</b> | <b>traumatic brain injury</b>       |

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