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Longitudinal Outcome of Patients with Disordered Consciousness in the NIDRR TBI Model Systems Programs

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Abstract

Few studies address the course of recovery from prolonged disorders of consciousness (DOC) after severe traumatic brain injury (TBI). This study examined acute and long-term outcomes of persons with DOC admitted to acute inpatient rehabilitation within the National Institute on Disability and Rehabilitation Research (NIDRR) TBI Model Systems Programs (TBIMS). Of 9028 persons enrolled from 1988 to 2009, 396 from 20 centers met study criteria. Participants were primarily male (73%), Caucasian (67%), injured in motor vehicle collision (66%), with a median age of 28, and emergency department Glasgow Coma Scale (GCS) score of 3. Participant status was evaluated at acute rehabilitation admission and discharge and at 1, 2, and 5 years post-injury. During inpatient rehabilitation, 268 of 396 (68%) regained consciousness and 91 (23%) emerged from post-traumatic amnesia (PTA). Participants demonstrated significant improvements on GCS ($z = 16.135$, $p \leq 0.001$) and Functional Independence Measure (FIM) ($z = 15.584$, $p \leq 0.001$) from rehabilitation admission (median GCS = 9; FIM = 18) to discharge (median GCS = 14; FIM = 43). Of 337 with at least one follow-up visit, 28 (8%) had died by 2.1 years (mean) after discharge. Among survivors, 66 (21%) improved to become capable of living without in-house supervision, and 63 demonstrated employment potential using the Disability Rating Scale (DRS). Participants with follow-up data at 1, 2, and 5 years post-injury ($n = 108$) demonstrated significant improvement across all follow-up evaluations on the FIM Cognitive and Supervision Rating Scale ($p < 0.01$). Significant improvements were observed on the DRS and FIM Motor at 1 and 2 years post-injury ($p < 0.01$). Persons with DOC at the time of admission to inpatient rehabilitation showed functional improvement throughout early recovery and in years post-injury.

Key words: cognitive function; DOC; outcome; rehabilitation; TBI

Introduction

Impaired consciousness is the clinical hallmark of severe nonpenetrating traumatic brain injury (TBI) (Levin, 1992; Ommaya and Gennarelli, 1974). Early publications regarding impaired consciousness described a course of recovery that varied with severity of TBI. Although many individuals recover consciousness quickly, some will remain with impaired consciousness for prolonged periods, or permanently. Research on long-term outcomes of persons with a disorder of consciousness (DOC), including coma, vegetative state (VS), and minimally conscious state (MCS) has been sparse.

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Existing studies vary in definition of DOC; setting (e.g., neurointensive care units vs. rehabilitation units); global region of health care provision (e.g., Europe vs. North America); study sample (e.g., children vs. adults, trauma vs. non-trauma, time since injury); length of follow-up; and outcomes evaluated (Braakman et al., 1998; Bricolo et al., 1980; Dubroja et al., 1995; Eilander et al., 2005, 2007; Estraneo et al., 2010; Fields et al., 1993; Giacino and Kalmar, 1997; Giacino et al.,1991; Heindl and Laub, 1996; Higashi et al., 1977; Katz et al., 2009; Levin et al., 1991; Luauté et al., 2010; Ng and Chua, 2005). In light of these differences, outcomes and conclusions are understandably disparate across studies. For example, mortality rates for individuals with DOC range from 5 to 65%, with earlier studies and those from acute neurosurgical units yielding the highest rates of patient death (Braakman et al., 1998; Bricolo et al., 1980; Eilander et al., 2005, 2007; Estraneo et al., 2010; Fields et al., 1993; Giacino and Kalmar, 1997; Giacino et al., 1991; Heindl and Laub, 1996; Higashi et al., 1977; Lammi et al., 2005). Rates of recovery of consciousness range from 14 to 95% (Dubroja et al., 1995; Estraneo et al., 2010; Katz et al., 2009; Lammi et al., 2005; Luauté et al., 2010). One of the major limitations of the outcome literature is the failure to clearly identify the attrition rate in follow-up, resulting in skewed proportions of patients in different outcome categories (Braakman et al., 1988; Giacino and Kalmar, 1997). The reported degree of long-term disability after emerging from a DOC is similarly variable because of these methodological considerations.

In summary, it is challenging for clinicians to determine prognosis or draw patient management conclusions from the existing literature. Enhanced knowledge about the long-term outcome of individuals with DOC may help clarify the range of outcomes expected after severe TBI, and guide treatment decisions that reflect a more accurate assessment of prognosis. Therefore, the purpose of this prospective study is to characterize, using standardized measures, the neurological recovery and rehabilitation outcomes of a large cohort of individuals admitted with a DOC to acute inpatient rehabilitation as part of the multi-center National Institute of Disability Rehabilitation and Research Traumatic Brain Injury Model System Program (TBIMS). Implications for patient management and prognostication are discussed.

Methods

Participants

Participants were enrolled prospectively in the TBI Model Systems Programs (TBIMS) National Database: a multicenter, longitudinal study of TBI funded by the National Institute on Disability and Rehabilitation Research (NIDRR). Currently, there are 16 sites across the United States enrolling subjects in the database, which has been in existence since 1988. All TBIMS enrollees are ≥16 years of age, received medical care in a TBIMS-affiliated acute care hospital within 72 h of injury, and were transferred directly from acute care to an affiliated comprehensive rehabilitation program. See Gordon and associates (1993) for TBIMS inclusion and exclusion criteria. All participants provided informed consent directly or by legal proxy. This study was conducted on records selected from the TBIMS National Database.

All participants in the TBIMS database who enrolled between 1988 and March 2009 were considered for this study. Study findings are described as acute rehabilitation and post-acute rehabilitation outcomes. Inclusion criteria for this study were: 1) being unconscious upon rehabilitation admission (i.e., no prior observation of 2 consecutive days of command following from acute care record review); and 2) Glasgow Coma Scale (GCS) Motor Score <6 on rehabilitation admission (item derived from the Disability Rating Scale [DRS] assessment obtained on rehabilitation admission). Exclusion criteria included: 1) individuals with missing command following data (i.e., duration of unconsciousness) from acute care records; and 2) individuals with missing GCS Motor Scores on rehabilitation admission. For the sample assessed on post-acute rehabilitation outcomes, an additional inclusion criterion was eligibility for and completion of a 1-, 2-, and/or 5-year follow-up assessment. A subgroup analysis was performed on persons with complete follow-up data across the 1-, 2-, and 5-year follow-up intervals. Individuals with no follow-up data were excluded from follow-up analyses.

Measures

Galveton Orientation and Amnesia Test (GOAT) (Levin et al, 1979). The GOAT is a 10-item measure that assesses orientation as well as memory for events preceding and following TBI. Having two consecutive administrations of the GOAT with a score ≥76 is consistent with emergence from post-traumatic amnesia (PTA). The GOAT has been used to determine the duration of PTA in numerous studies of TBI.

Orientation log (O-Log) (Novack et al., 2000). The O-Log is a brief measure used to assess orientation, which includes questions related to place, time, and situational factors. The O-Log requires that a person obtain ≥25 points on two consecutive occasions over 72 h in order to clear PTA (Jackson et al., 1998; Novack et al., 2000).

DRS (Rappaport et al., 1982). The DRS is an 8-item scale that incorporates the GCS as well as items assessing cognitive capability for feeding, toileting, and grooming. Separate items rate need for assistance/supervision (DRS Item 7) and potential for employment (DRS Item 8). Higher scores represent a greater level of disability.

GCS (Teasdale and Jennett, 1974). The GCS is a brief screening measure of altered consciousness. There are three domains assessed: eye opening (1–4), spontaneous speech (1–5), and best motor response (1–6). The measure is scored from 3-15, with 15 being the best score.

Functional Independence Measure (FIM) (Hamilton et al., 1987). The FIM is composed of 18 items designed to operationally measure functional independence in self-care (e.g., toileting), mobility (e.g., walking, transfers), and cognition (e.g., memory, communication, problem solving). Higher scores represent a greater level of independence. Items are summed into a Cognitive subscale (5–35), Motor subscale (13–91), and overall FIM Total Score (18–126).

Supervision Rating Scale (SRS) (Boake, 1996). The SRS is a 1-item measure rated on a 13-point ordinal scale and ranked in five categories (Independent, Overnight Supervision, Part-Time Supervision, Full-Time Indirect Supervision, and

Full-Time Direct Supervision) characterizing the degree of supervision that patients receive from caregivers.

Procedure

Trained TBIMS research assistants collected information regarding injury severity (GCS, time to follow commands [TFC]), and medical course from hospital and emergency medical service records. Demographic information such as date of birth, education, and pre-morbid functioning were collected in interviews with the subjects or family/significant others. Duration of unconsciousness (TFC) was defined as the time from injury to the occurrence of 2 consecutive days of command following as documented in medical record review. Emergence from PTA was assessed prospectively by repeated administration of the GOAT or O-Log 24-72 h apart until 2 consecutive scores were achieved at or above the threshold for clearing PTA (Hanks et al., 2008; Kalmar et al., 2008). Subjects and their families were contacted at 1, 2, and 5 years post-injury to assess the subjects' level of functioning, including completion of measures such as FIM, DRS, and SRS. If the patient was not able to provide accurate information, data were collected from family members or care providers who were familiar with the subject.

Data analysis

For descriptive purposes, continuous data are shown in quartiles (25th, 50th, 75th) and categorical data are presented as percentages. One way analysis of variance and χ^2 tests were conducted to test for clinically significant differences between participants with complete follow-up and those lost to follow-up. Mortality was evaluated with survival analysis using the Kaplan-Meier product-moment method. Change in rehabilitation outcome measures over time were assessed using repeated measures generalized linear models. Post-hoc comparisons between time points (1, 2, and 5 years) were conducted using contrasts. All analyses were conducted in SAS (Version 9.1, Cary, NC).

Results

Study population

Nine thousand twenty-eight ($n = 9028$) participants were enrolled in the TBIMS database between 1988 and 2009. Of these, 225 individuals had missing command following status from acute care records. Using chart review methodology, 8,147 participants were documented as following commands on or prior to acute rehabilitation admission. Of the 656 remaining individuals, 260 were documented as following commands or had missing scores on the GCS Motor subscale as derived from the DRS on rehabilitation admission, and were also excluded. Therefore, 396 met inclusion criteria and were used in analyses describing acute rehabilitation outcomes.

Of these 396 participants, 30 were not yet due for 1 year follow-up at the time of data extraction. Of the remaining 366, 29 (8.6%) could not be contacted or declined follow-up data collection during the study period. Typical reasons for a participant being lost to follow-up were lack of a correct phone number or address or participant refusal to provide follow-up data. Additional follow-up analyses were conducted on the subset of 337 participants with at least one post-injury follow-up ($n = 229$) plus the 108 participants with complete data at 1, 2, and 5 years post-injury. Table 1 provides demographic data, injury severity information, and time-post injury for the study sample used for analyses examining acute rehabilitation and post-acute rehabilitation outcomes and those lost to follow-up. Subjects with complete follow-up ($n = 108$) were similar to all others for acute length of stay (LOS), rehabilitation LOS, race, and gender. Subjects with

Table 1. Descriptive Information for Study Samples and Those Excluded or Lost to Follow-Up

	Sample (n = 396)	*Total Lost to Follow-up* (n = 29)	*At Least one Follow-up* (n = 337)	*Follow-up at 1, 2, 5 Years* (n = 108)
Age (quartiles)	21/28/42	24/30/49	20/27/41	19/24/35
Male	73%	86%	72%	68%
Race				
White	67%	69%	67%	73%
Black	22%	7%	23%	22%
Hispanic	8%	21%	7%	3%
Other[a]	3%	3%	3%	2%
Education				
<12 years	27%	17%	29%	27%
≥12 years	48%	39%	46%	43%
Missing	25%	44%	25%	30%
Cause of Injury				
N Motor (%)	66%	62%	66%	82%
ED GCS[b]	3/3/6	8/8/8	3/3/6	3/4/6
Rehab Admit GCS	7/9/10	6/9/10	7/9/10	8/9/10
Acute LOS	21/31/41	21/33/41	21/31/42	23/32/46
Rehab LOS	29/47/72	21/58/96	29/46/71	28/45/68

Quartiles correspond to the 25th/50th/75th percentiles.

[a]For Race, the "Other" category includes Asian, Native American, and other.

[b]GCS ED Admit denotes the Glasgow Coma Score at admission to the emergency department; chemically paralyzed patients are recoded as 3; GCS Rehab denotes Glasgow Coma Score on admission to comprehensive inpatient rehabilitation; acute LOS denotes length of stay for acute hospitalization; Rehab LOS denotes length of stay for inpatient rehabilitation.

complete follow-up ($n = 108$) were significantly younger (26.2 years ± 15.5 vs. 28.4 years ± 13.5, $p < 0.002$), more likely to be unmarried (68.5% vs. 54.7%, $p < 0.035$), and more likely to have been injured in a motor vehicle accident (81.4% vs. 59.7%, $p < 0.001$). Compared to subjects with complete follow-up ($n = 108$), subjects completely lost to follow-up (N = 29) were similar in race (68.9% vs. 73.2%, p < .07) and education (39% vs. 43%, p < 0.65) and more likely to be male (86.2% vs. 68.5%, p < 0.06). Further, compared to subjects with complete follow-up (n = 108), subjects completely lost to follow-up ($n = 29$) were significantly older (35.8 years ± 15.0 vs. 28.7 years ± 13.5, $p < 0.02$), had lower GCS scores upon admission (4.0 ± 1.7 vs. 7.0 ± 15.8, $p < 0.05$), greater rehabilitation LOS (77.9 ± 53.7 vs. 53.4 ± 40.9, $p < 0.01$) and were less likely to have been injured by or in a motor vehicle (62.1% vs. 81.4%, $p < 0.03$).

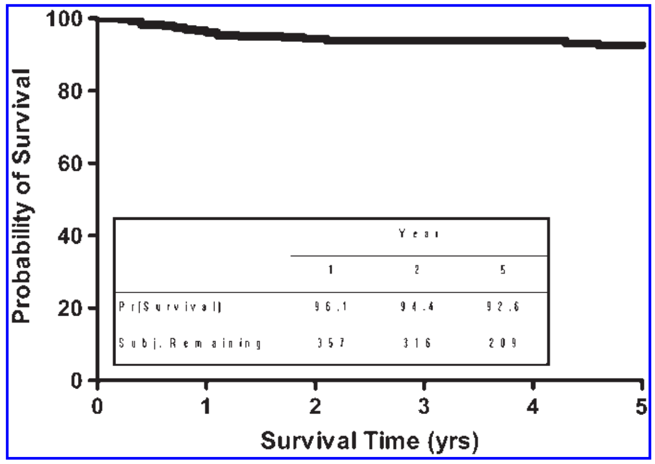

FIG. 1. Survival probability for cases entered from inception of TBI Model System in 1988 through March 31, 2009.

Inpatient rehabilitation outcomes

Consciousness and cognition. Of the 396 participants, 268 (68%) returned to consciousness during inpatient rehabilitation as evidenced by following commands across 2 consecutive days (median of 24 days post-rehabilitation admission). Significant differences on total GCS ratings were observed between rehabilitation admission (quartiles: Eye 3/4/4; Motor 3/4/5; Verbal 1/1/2) and rehabilitation discharge (quartiles: Eye 4/4/4; Motor 5/6/6; Verbal 1/4/4) for the sample ($z = 16.135$, N-Ties = 354, $p \leq 0.001$). Ninety-one (23%) of these subjects also emerged from PTA during inpatient rehabilitation, as was evidenced by 2 consecutive days of GOAT or O-Log scores in target range. Significant improvement in FIM scores were observed across the Cognitive- (quartiles: Admission 5/5/5, Discharge 5/11/19), Motor (quartiles: Admission 10/12/13; Discharge 13/30/58), and Total Scale scores (quartiles: Admission 15/18/18, Discharge 19/43/77; $z = 14.313$, N-ties = 274, $p \leq 0.001$; $z = 15.327$, N-ties = 315, $p \leq 0.001$; $z = 15.584$, N-Ties = 324, $p \leq 0.001$; respectively).

Discharge placement. Upon discharge, 264 (68%) participants had a community discharge (returned to a private residence or group home).

Post-acute rehabilitation outcomes

Mortality. A Kaplan-Meier product-moment survival analysis of study participants is presented in Figure 1. Among study participants, 28 deaths were observed; on average 2.1 years from discharge (0.5/1.0/2.0 years). Thirteen deaths occurred within 1 year of discharge. Survival rates at 1, 2, and 5 years were 95.3%, 92.2%, and 89.0%, respectively. Subjects dying had significantly longer acute LOS than did survivors (29/38/58 vs. 21/29/39, $p < 0.001$). No significant differences between survivors and those who died were observed for rehabilitation LOS, Emergency Department GCS, or rehabilitation admission GCS.

Late recovery of consciousness. Of the 128 who did not regain ability to follow commands during acute rehabilitation, 78 had 1-year follow-up, 47 had 2-year follow-up, and 34 had 5-year follow-up (because of variable follow-up and pending follow-up intervals). Across the follow-up intervals, 59% of participants regained the ability to follow commands on the DRS (Motor Item) at 1-year follow-up, 66% regained the ability at 2-year follow-up, and 74% regained the ability at 5-year follow-up. A similar trend was observed for the percentage of patients who did not regain ability to follow commands during inpatient rehabilitation among the 108 with consistent follow-up across the 5-year intervals. Approximately 54% (20/37) regained command following ability by 1-year follow-up, 64% (24/37) regained it at 2-year follow-up, and 76% (28/37) regained it at 5-year follow-up.

Potential for independence and productivity. In the first 5 years post-injury, potential for living without in-house supervision (DRS Item 7, scores of 0–2) and potential for competitive or sheltered-workshop employment (DRS Item 8, scores of 0–2) were analyzed with available follow-up data. Using the three follow-up intervals (1, 2, 5 years) as a basis for analysis, 66 participants (19.6%) were found to be capable of living without in-house supervision and 63 participants (18.7%) demonstrated employment potential either in competitive or sheltered workshop environments at one or more of the follow-up intervals.

Longitudinal outcome across standardized measures ($n = 108$ with complete follow-up data). Functional changes across outcome scales were analyzed for the 108 participants with complete follow-up at 1, 2, and 5 years post-injury (see Table 2 for descriptive statistics across scales). Significant change was observed from discharge to 1-year follow-up in the DRS Total Score ($F = 170.7$, $p < 0.001$), FIM (Cognitive [$F = 222.4$, $p < 0.001$], Motor [$F = 148.5$, $p < 0.001$], and SRS [$F = 20.5$, $p < 0.001$], respectively). Significant change was also observed from 1 year to 2 years post- injury in the DRS Total ($F = 29.2$, $p < 0.001$), FIM (Cognitive [$F = 23.3$, $p < 0.001$], Motor [$F = 18.4$, $p < 0.001$], and [$F = 5.6$, $p < 0.020$] SRS. However, more robust change from the 2-year to the 5-year follow up was observed for the Cognitive FIM ($F = 7.9$, $p < 0.01$), and SRS ($F = 5.6$, $p < 0.02$), than for the DRS ($F = 3.9$, $p < 0.052$) or Motor FIM ($F = 3.9$, $p < 0.052$). Figure 2 shows percent change for this subsample. Analyses were repeated for individuals with inconsistent follow-up with similar trends in change over time observed (data not shown).

Table 2. Descriptive Information for Participants with Three Completed Follow-Ups Through 5 Years Post-Injury for $N = 108$ Participants

	Timeline			
Measure	*Discharge*	*1 yr*	*2 yr*	*5 yr*
DRS (quartiles)	10/15/22[1]	3/7/13[2]	2/5/11[3]	2/5/11[3]
% change	0.0	−44.1	−10.6	−3.9
FIM_Cog	05/10/19[1]	13/25/31[2]	16/27/32[3]	19/27/33[4]
% change	0.0	75.8	7.3	5.6
FIM_Mot	13/25/51[1]	25/77/89[2]	29/81/90[3]	32/82/90[3]
% change	0.0	73.5	6.1	3.2
SRS	—	3/7/10[1]	2/6/8[2]	2/4/8[3]
% change	—	0.0	−10.8	−8.6

DRS, Disability Rating Scale; FIM_Cog, Cognitive subscale of the Functional Independence Measure; FIM_Mot, Motor subscale of the Functional Independence Measure; FIM_Tot, Total Functional Independence Measure Score; SRS, Supervision Rating Scale. Scores annotated with distinct numbers are significantly different from one another.

Discussion

It has been our experience that there has been a perception that patients with prolonged post-traumatic DOCs have a poor prognosis and may not benefit from rehabilitation services (Murray et al., 1993). Current insurance regulations in many regions require that a patient demonstrate signs of responsiveness to be eligible for acute inpatient rehabilitation (Center for Medicare and Medicaid Services, 2004). The results of this study show substantial recovery among patients with DOC admitted to inpatient rehabilitation relatively early after TBI, with two-thirds of subjects regaining command following ability (i.e., study definition of consciousness) during their rehabilitation stay and one-fourth emerging from PTA (regaining orientation). Importantly, significant recovery continues for 2 years post-injury, and to a more modest degree for as long as 5 years post-injury. The vast majority of subjects in this study were living at annual follow-up intervals (1–5 years post-injury) indicating greater life expectancy than had been anticipated from previous studies.

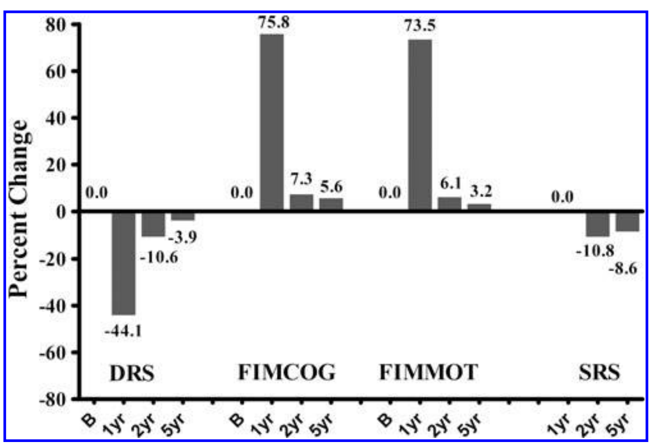

FIG. 2. Percent change in rehabilitation indices across follow-up intervals for subjects with complete follow-up ($n = 108$).

Surprising numbers of participants recovered the ability to live independently and to work, at least at the sheltered workshop level. These improvements in participants (reduced need for supervision, improved vocational capacity) might be expected to result in decreased caregiver burden and improved quality of life. Although data regarding outpatient rehabilitation services received by participants were not available, results indicate that many participants recovered to the point that they could participate in additional rehabilitation services after discharge from inpatient rehabilitation.

These findings extend the work of recent investigations with substantially smaller sample sizes, diverse patient groups, and different inclusion/exclusion criteria (Estraneo et al., 2010; Luauté et al., 2010). Although our study did not compare and contrast the outcomes of different DOC diagnoses or etiologies, similar observations were made with regard to early recovery for a substantial cohort with additional late recovery observed. Luauté and colleagues (2010) reported that those with recovery of consciousness at 5-year follow-up had a higher proportion of subjects with cognitive gains (establishment of a yes/no response and verbalizations) than with motor gains (locomotion and dependence for activities of daily living). Our study also showed modest but significant gains in cognitive domains relative to those in motor domains on the FIM between the 2- and 5-year follow-up interval. In contrast, the mortality rate of this study was lower than in recent investigations; however, sample selection factors may influence these comparisons (Estraneo et al., 2010; Luauté et al., 2010).

Although these data demonstrate a large number of cases of recovery of consciousness during the inpatient rehabilitation stay, they do not demonstrate a causal relationship, *per se*, in which rehabilitation hastens this recovery or improves the ultimate outcome. Such an analysis would require a comparison to unconscious patients cared for in less intensive clinical settings. Despite this limitation, two points are worth noting. First, the relatively positive prognosis and prolonged interval of survival and recovery intuitively suggest the importance of minimizing secondary complications (e.g., infections, skin breakdown, etc.) which could undermine the ultimate functional outcome as consciousness returns, and raise the concern about whether such potential complications are as aggressively managed in lower levels of care even if the time course of return of consciousness is unchanged. Second, TBIMS centers admit relatively few TBI patients from nursing facilities and sub-acute facilities at a later date, suggesting that few patients who regain consciousness in an alternate setting are secondarily referred to inpatient rehabilitation.

This study has several limitations. First, it was conducted on a sample of subjects admitted to acute inpatient rehabilitation despite their responsiveness status. These patients may have differed in subtle ways from other unresponsive patients not receiving inpatient rehabilitation, which may limit generalization to a broader sample of nonresponsive patients. Reliance on markers of responsiveness sometimes abstracted from clinical records may have also introduced some imprecision in the data. The lack of DOC measures to denote greater information about neurobehavioral recovery of patients in VS versus those in MCS is another study limitation. Longitudinal information for these two distinct diagnostic groups would have provided valuable information about recovery trajectory and comparison to recent investigations. However, sensitive measures that can distinguish between VS and MCS are not widely used in acute care institutions and the rate of referral misdiagnosis between VS and MCS is high (Schnakers et al., 2009) suggesting that the more important message for acute care providers is the considerable recovery potential present in the DOC population in general. Finally, missing data caused by loss of participants to follow up or inability to locate a subject at a particular assessment point may also limit generalization, although differences in the sample who contributed data versus those with missing or unavailable data suggested modest sample differences.

Conclusion

Overall, the evidence of substantial and ongoing recovery among patients admitted to inpatient rehabilitation in a minimally responsive state attests to the importance of further research to identify those with the greatest potential for recovery, and to assess the impact of different care systems at different time points on their long-term outcomes. These findings also signal the need to revisit current practices governing authorization of rehabilitation services for patients with DOC.

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