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Functional Status Examination in Patients with Moderate-to-Severe Traumatic Brain Injuries

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Abstract

The assessment of functional status after traumatic brain injury (TBI) is important. The Glasgow Outcome Scale (GOS) and its revised version, the Glasgow Outcome Scale Extended (GOSE), have been used most frequently in TBI research, but there are concerns about the sensitivity of these measures. The current study evaluated the psychometric properties of the Functional Status Examination (FSE) using a sample of 448 moderately to severely injured subjects with TBI. It was shown that the FSE is significantly related to other measures of functional status including the GOSE, Short Form Health Survey, and European Quality of Life Checklist ($p < 0.001$), is sensitive to TBI severity ($p < 0.001$), and is responsive to recovery from 3 to 6 months post-injury ($p < 0.001$). In addition, there was a significant agreement ($r = 0.817$, $p < 0.001$) between the patient and significant other's assessment of functional status on the FSE at 6 months post-injury. The FSE may be a valuable measure of functional status after TBI given its strong psychometric properties, including validity, sensitivity to brain injury severity, and recovery over time.

Keywords: functional status; patient outcome assessment; psychometric properties; traumatic brain injuries

Introduction

Measurement of functional status is important in traumatic brain injury (TBI) because, among other reasons, it is needed to plan treatment, monitor treatment effectiveness, and determine success of clinical treatment trials. Several researchers have suggested that the insensitivity of outcome measures may be one of the reasons that pharmaceutical treatment trials in TBI research have uniformly failed to detect a beneficial effect.[1]

Characteristics of a model functional status measure in TBI must include validity, reliability, and sensitivity to TBI severity and change over time. It also should include multiple domains (e.g., physical, social, psychological), cover a wide range of outcomes (death through good recovery without excessive ceiling effects), and be easy to reliably administer and score. Ideally, it also should capture outcome that is meaningful to the person with TBI.

Many different functional status measures have been used for clinical and research purposes in TBI. The Glasgow Outcome Scale (GOS)[2] and the revised version, the Glasgow Outcome Scale Extended (GOSE),[3] have been used most frequently in TBI research.[4,5] Other measures include the Disability Rating Scale (DRS),[6] the Functional Independence Measure (FIM),[7,8] the Functional Assessment Measure (FAM),[9] the Community Integration Questionnaire (CIQ),[10] and the Craig Handicap Assessment and Reporting Technique (CHART).[11] However, these measures have distinct limitations, including ceiling effects (FIM, FAM, CIQ, GOS),[5,12] problems with validity and reliability (CIQ),[13] high misclassification rates (GOSE),[14,15] and difficulty detecting meaningful change (CIQ, DRS).[13,16]

The Functional Status Examination (FSE) is a measure we developed in 2001 to evaluate change in level of functioning across various areas of activities of daily life as the result of a traumatic injury. The validity and reliability of the FSE was first reported in 2001 with a sample of mostly complicated mild TBI.[17] Here, we further examine the psychometric properties of the FSE using more severely injured TBI subjects.

Methods

Subjects

We enrolled 499 patients with moderate-to-severe TBI in the Magnesium Sulfate Study from 1998 to 2004. Inclusion criteria included Glasgow Coma Scale (GCS) score upon presentation in the emergency department of 3 to 12 or intracranial surgery (e.g., craniectomy, craniotomy, or elevation of a depressed fracture with dural repair) within 8 h of injury. Subjects were excluded if they were <14 years old, could not receive the study drug within 8 h of injury, had serum creatinine concentrations >177 μmol/L, were pregnant, were prisoners, or were known to live overseas.[18] Participants were assessed with the FSE at 3 and 6 months after the injury. For this study, we analyzed data of 448 subjects with FSE

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assessment at 6 months; 405 significant others (SO) also participated in the study. Reasons for loss of subjects included inability to contact ($n=29$; 5.8% of original sample), refusal to participate ($n=9$; 1.8% of sample) and other ($n=13$; 2.6% of sample), representing a follow-up rate of 89.7% overall. Results from the clinical trial found no positive effect of magnesium sulfate on the FSE, but a negative effect was reported on the lower target range group (1.0–1.85 mmol/L).[18]

Measures

Severity of brain injury. The severity of the TBI was assessed by time from injury to follow simple commands (TFC) and by the GCS motor score. TFC is a measure of coma duration and is defined as the time from injury to the ability to follow simple commands consistently.[19] The GCS motor score was assessed post-resuscitation in the ED and represents depth of coma.[20]

Neuropsychological measures. Neuropsychological data included total recall on the Selective Reminding Test[21] (a test of episodic memory and learning), and the WAIS III Processing Speed Index,[22] which were administered at 6-months post-injury. The latter is a measure of information processing speed and is calculated from the Digit Symbol and Symbol Search subtests of the WAIS III.

Functional status measures. The FSE[17] measures change in functional status specifically due to traumatic injury, including both the changes associated with TBI and peripheral injuries. This measure takes approximately 10 min to administer and covers seven areas of functioning: personal care, ambulation, mobility, major activity (work or school), homemaking, leisure and recreation, and social integration. The original FSE included three other areas of functioning (cognitive competency, standard of living, and financial independence) that were removed due to poor fit with the rest of the measure. Functional areas are evaluated using the concept of dependency to operationally define outcome at four levels: 0 = no change from pre-injury; 1 = difficulty in performing the activity although the person is still independent; 2 = dependence on others some of the time; and 3 = nonperformance, inability to perform the activity, or total dependence on others. A total score is generated by summing scores from the seven categories, yielding a range from 0 (return to pre-injury baseline in all areas) to 21 (total dependence on others or can no longer perform any activities across functional areas). Persons who die are assigned a total score of 22.

Participants who are not yet back to normal in a functional area also are asked how bothered they are by: 1) the difficulty they are experiencing, and/or 2) degree of dependency they have on others. The bothersome score for each area is rated on a 4-point scale: 0 = not at all bothered, 1 = mildly bothered, 2 = moderately bothered, and 3 = severely bothered. The total bothersome score is the sum of all ratings. Subjects who are back to normal in a functional area are assigned a bothersome score of 0 when calculating the total bothersome score. The most informed person (patient or proxy) completed the FSE at 3 months post-injury (331 were participants with TBI and 111 were SOs). At 6 months post-injury, the FSE was completed by the patient and the SO separately.

The GOSE[3] is the extended version of the GOS, a widely used measure of outcome following TBI. The revised version increased the number of outcome categories from five to eight to improve its sensitivity to outcome and to improve its reliability. The patient is classified on an eight-category scale ranging from death to upper good recovery. This measure was administered at 6 months post-injury to the participant with TBI or the person with the most knowledge about the TBI subject if the person was unable to report for themselves.

The European Quality of Life Checklist (EuroQol)[23] is a measure of current health status in five areas: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The TBI subject rated his or her health status at 6 months post-injury.

The Short Form Health Survey (SF-36)[24] is a general health measure and is designed for use in clinical practice, research, health policy evaluations, and general population surveys. It includes multi-item scales that assess limitations in physical activities, social activities, usual role activities, bodily pain, general mental health, vitality, and general health perceptions. Two aggregate scores are calculated: the Physical Component Summary and the Mental Component Summary. This measure was administered at 6 months post-injury to the person with TBI.

Measures of emotional functioning. The Brief Symptom Inventory (BSI)[25] is an abbreviated form of the Symptom Checklist 90 (SCL-90), a widely used measure of emotional functioning. It contains 53 items rated on a 5-point scale ranging from 0 for ''not at all'' to 4 for ''extremely.'' Two overall indices of distress were calculated: the Global Severity Index and the Positive Symptoms Distress Index.

The Center for Epidemiological Studies-Depression Scale (CES-D)[26] is a measure of depressive symptoms. It consists of 20 items that are rated on a 4-point scale to indicate the frequency of depressive symptoms experienced over the past week.

The symptom checklist[27,28] was administered to the participants with TBI and consists of 12 symptoms that are frequently reported in the literature as sequelae of TBI (e.g., headaches, fatigue, memory difficulty, irritability). Symptoms are rated as present if they are of new onset since the TBI or are worse than they were before the injury; the total number of new or worsened symptoms is calculated.

Percent back to normal[29] is a self-report rating scale used to assess the degree to which the person feels they have returned to normal. The person with TBI chooses a number from 0 (0% back to normal) to 100% returned to the way they were before the injury.

An estimate of current happiness also was obtained by asking participants to rate their happiness by choosing a number from 0 (not at all happy) to 100 (extremely happy).[30] Measures of emotional functioning, current happiness, the symptom checklist, and percent back to normal ratings were obtained at 6 months post-injury.

Statistical analysis

Unless otherwise specified, the data analysis described below used the total FSE score obtained from the participant with TBI. If that was missing, the SO score was used ($n=69$) at 6 months post injury. Data were analyzed using non-parametric methods due to the skewness caused by inclusion of the large number of those who died ($n=105$).

Sensitivity. We examined the sensitivity of the FSE by assessing its relationship to brain injury severity indices using Spearman's rank correlation, Kruskal-Wallis analysis and the Mann-Whitney test. TFC was classified into four groups (< 24 h, 1 to 6 days, 7 to 28 days and ≥29 days) and GCS motor score formed two groups (≤ 4 and ≥5). TBI subjects who expired before following commands consistently were placed in the ≥29 day group.

Responsivity. Responsivity was evaluated by examining change from 3 to 6 months post-injury on the FSE. Change was examined descriptively with and without the exclusion of expired subjects and formally tested using Wilcoxon signed rank tests. Both indices of absolute change and meaningful change were examined. We defined meaningful change as a difference of ≥4 points between the two time periods. Change scores that fell between −3 and 3 were counted as representing no change in the analysis of meaningful change. Change also was presented in relation to brain injury severity indices.

Validity. Convergent validity was assessed by comparing the FSE with other measures thought to assess similar constructs using Spearman's rank correlation. These measures were the GOSE, the SF-36, the EuroQol, and the neuropsychological measures. Participants who were too impaired neurologically to be assessed on the neuropsychological measures were assigned a score equal to 1 point worse than the worst observed score. Expired subjects were assigned a score of 2 points worse than the worst observed score. Correlations between the FSE and SF-36 or EuroQol were calculated with patient responses only. Correlations between the FSE and the GOSE and between the FSE and neuropsychological measures were calculated with and without the inclusion of expired subjects.

To evaluate discriminant validity, or measures expected to have less of a relationship, Spearman's rank correlation compared the FSE with emotional health, post-traumatic symptoms, and percent back to normal rating. These correlations were calculated with patient responses only.

Patient and SO concordance. For pairs that completed the FSE independently, the level of the scores (bias) was evaluated by a paired *t* test and the association between patients' and SOs' assessment of functioning on the FSE was evaluated via Spearman's rank correlation. Patient and SO median total FSE scores also were examined descriptively in relationship to brain injury severity indices.

Bothersome rating. The total bothersome score was compared with the total FSE score and with an index of current happiness, percent back to normal rating, and brain injury severity indices using Spearman's rank correlation. TFC groups also were compared using the Kruskal-Wallis Test and GCS motor groups were examined with Mann-Whitney analysis.

Results

Demographic information and results of the brain injury severity indices and the FSE are shown in Table 1. On average, participants of this study were young men with a high school education. There was a significant and systematic relationship between the FSE and brain injury severity. For example, subjects who were able to follow commands consistently within a day of injury had an average total FSE score of 5, indicating a low level of functional disability. The average FSE score reflected increased difficulty in functional status as time to follow commands increased.

Absolute change from 3 to 6 months post-injury was significant ($p < 0.001$) in surviving subjects (Table 2). The majority (70%) improved over time, but 15% stayed the same and 15% reported more difficulty with functional status at 6 months than at 3 months post-injury. Meaningful change (defined as a difference of ≥4 points on the total FSE score between 3 and 6 months post-injury) also was significant ($p < 0.001$) and is summarized in Table 2. This more stringent approach also shows significant improvement, with 35% reporting improved functional status of at least 4 points and 5% reporting worse functional status at 6 months, compared with at 3 months. Absolute and meaningful change analyses remained significant ($p < 0.001$) when expired participants were included (data not shown). Change from 3 to 6 months on the FSE showed little relationship to TBI severity.

Comparison of the FSE to other functional status measures and to neuropsychological measures is summarized in Table 3. There are significant relationships between all the functional status measures ($p < 0.001$), especially between the FSE and the GOSE, SF-36 physical aggregate score, and mobility, self-care, and usual activities scales of the EuroQol. There is a moderate relationship between the FSE and the mental aggregate score of the SF-36 and for pain and anxiety/depression scales of the EuroQol, indicating less of an association of the FSE with parts of functional status measures having to do with mental health and pain. Both neuropsychological measures examining episodic memory and information processing speed are significantly ($p < 0.001$) and strongly related to the FSE. Inclusion of expired subjects showed stronger relationships between the FSE and GOSE (−0.93), episodic memory (−0.85), and information processing speed (−0.86) measures (data not shown).

Correlations between the FSE and measures of emotional functioning were moderate in strength, ranging from 0.35 (CES-D)

Table 1. Demographics and TBI Severity by Total FSE

n	*448*	*Total FSE*	*Spearman's rank correlation*
Mean age (SD)	34.5 (18)		
% male	75		
Mean education in years (SD)	11.5 (2.5)		
Time to follow commands consistently			
Mean days (SD)	37.4 (49)		
Time to follow command groups	*n* (%)	Median (25th, 75th percentiles)**	0.692**
< 24 h	112 (27)	5 (2, 12)	
1 to 6 days	88 (21)	9 (5, 15)	
7 to 28 days	70 (17)	13 (8, 17)	
≥ 29 days	145 (35)	22 (20, 22)	
GCS Motor in ED		**	−0.335**
≤ 4	299 (67)	17 (9, 22)	
≥ 5	146 (33)	8 (3, 15)	

** $p < 0.001$.

TBI, traumatic brain injury; FSE; Functional Status Examination; SD, standard deviation; ED, emergency department.

Table 2. FSE Change from 3 to 6 Months Post-Injury

	Improved	*Stayed the same*	*Worsened*	*p*
Total change*, *n* (%)	223 (70)	47 (15)	49 (15)	< 0.001
TFC group				
< 24 h	69 (68)	12 (12)	20 (20)	
1 to 6 days	59 (74)	8 (10)	13 (16)	
7 to 28 days	45 (73)	9 (14)	8 (13)	
≥ 29 days	29 (67)	9 (21)	5 (12)	
Meaningful change^ *n* (%)	112 (35)	192 (60)	15 (5)	< 0.001
TFC group				
< 24 h	36 (36)	58 (57)	7 (7)	
1 to 6 days	32 (40)	45 (56)	3 (4)	
7 to 28 days	25 (40)	34 (55)	3 (5)	
≥ 29 days	13 (30)	29 (67)	1 (2)	

*3 month-6 month; expired not included.

^Improved by 4 or more points, stayed the same ±3 points, worsened by 4 or more points.

FSE, Functional Status Examination; TFC, time from injury to follow simple commands.

Table 3. Total FSE and Other Measures

	Total FSE
Functional status measures	
GOSE (expired removed)	–0.834**
SF-36 PCS	–0.693**
SF-36 MCS	–0.223**
EuroQol	
Mobility	0.623**
Self-care	0.570**
Usual activities	0.639**
Pain	0.414**
Anxiety/depression	0.332**
Neuropsychological measures	
Total recall on SRT^	–0.571**
PSI index^	–0.609**
Emotional functioning measures	
CES-D Total	0.352**
BSI-Global Severity Index	0.472**
BSI-Positive Symptom Distress Index	0.418**
Symptoms	
Total new or worse symptoms	0.514**
Percent Back to Normal	
Overall	–0.616**

Spearman's rank correlation: **$p \leq 0.001$.

^with untestable due to central nervous system = 1 worse than worst observed.

FSE, Functional Status Examination, GOSE, Glasgow Outcome Scale Extended; SF-36, Short Form Health Survey; PCS, Physical Component Summary; MCS, Mental Component Summary; EuroQol, European Quality of Life Checklist; SRT, selective reminding test; PSI, processing speed index; CES-D, Center for Epidemiological Studies-Depression Scale; BSI, Brief Symptom Inventory,

to 0.47 (Global Severity Index of the BSI). Correlations with total new or worse symptoms were also moderate in strength. There was a strong relationship between the FSE and Percent Back to Normal rating (Table 3).

The patients' and SOs' assessment of functioning on the FSE were significantly and strongly correlated (Table 4). There was no significant difference between the patient and SO scores on average (mean difference = –0.434; 95% confidence interval –0.889 to 0.021; $p = 0.06$). In addition, when broken down independently by brain injury severity index, average total FSE scores showed close agreement between TBI patients and their SOs except in the case of the most severely brain-injured group. For example, while the medians were identical for the milder TFC groups, the median total FSE score of the patient was 12, while the median total FSE score reported by their SOs was 14 in the group that took ≥29 days to follow simple commands consistently, suggestive of some lack of awareness in the more severely injured patients. The same pattern occurred but was much more pronounced when the summary was not restricted to TBI patient/SO pairs who were both able to complete the FSE independently (i.e., when responses for all subjects and SOs in this category are included, regardless of whether their partner also was able to provide a response). In this case, the median patient score was 12, while the median SO score was 18, likely reflecting SO report of more functional difficulties in TBI patients who were too impaired to take the measure and thus did not provide a response. The correlation between the patients' and SOs' assessment (0.817) increased with the inclusion of expired subjects (0.939; data not shown).

The total bothersome score is summarized in Table 5. The median bothersome score was 6, indicating an average level of being mildly to moderately bothered by functional status difficulties. Fifty-nine participants were not bothered at all (31 reported functional status back to normal; the remaining 28 still had functional status difficulties but were not bothered by them). A quarter of the sample had a moderately worse average bothersome score ranging from a total of 12 to 21. The bothersome rating was significantly related to brain injury severity and to the total FSE score ($p < 0.001$). It was also significantly related to the Percent Back to Normal rating and to current happiness ($p < 0.001$). The most common functional status areas reported to be moderately or severely bothersome were major activity (e.g., work or school) and leisure and recreation (51% and 50%, respectively). The least common functional status area to be moderately or severely bothersome was personal care (21%).

Discussion

In this study, we examined the convergent and discriminant validity of the FSE, its sensitivity to brain injury severity, its

Table 4. TBI Participant Versus SO Total FSE Scores (Expired Omitted)

Total patient FSE Spearman's rank correlation	*Total SO FSE* 0.817**			
			Restricted to patient–SO pairs	
	Total patient FSE	*Total SO FSE*	*Total patient FSE*	*Total SO FSE*
TFC group medians (25th, 75th percentiles)				
(*n*)	(255)	(270)	(215)	(215)
< 24 h	5 (2, 11.67)	5 (2, 10)	5 (2, 11.7)	5 (1.6, 10)
1 to 6 days	8 (5, 12)	9 (4, 15)	8 (3.5, 11.75)	8 (4.25, 14)
7 to 28 days	12.5 (7.75, 16.1)	13 (8.25, 16.75)	13 (8, 16)	13 (9, 16)
≥ 29 days	12 (4.5, 15.1)	18 (12.83, 20)	12 (3, 15.17)	14 (7, 16)
GCS motor score medians (25th, 75th percentiles)				
(*n*)	(271)	(299)	(230)	(230)
1–4	11 (4.75, 15)	14 (6.25, 18)	11 (4.33, 15)	11 (5.5, 15.46)
5–6	6 (2, 12)	7 (3, 13)	6 (2, 12)	7 (2.5, 11)

**$p < 0.001$.

TBI, traumatic brain injury; SO, significant other; FSE, Functional Status Examination; GCS, Glasgow Coma Scale.

Table 5. Total Bothered Score

		Correlation
(*n*)	(321)	
Median bother score (25th, 75th)	6 (2, 12)	
Not bothered at all *n* (%)	59 (18)	
Functional status is back to normal	31	
Functional status is not back to normal	28	
(*n*)	(265)	
Current happiness		–0.475**
% back to normal		–0.661**
TFC group medians (25th, 75th percentiles)		0.218**
(*n*)	(295)	
< 24 h	4.0 (0, 9.5)	
1 to 6 days	6.0 (1.4, 12.6)	
7 to 28 days	7.0 (4, 12)	
≥ 29 days	8.1 (4, 14.75)	
p	*	
GCS motor score medians (25th, 75th percentile)		–0.194**
(*n*)	(318)	
≥ 5	4.7 (1, 9.75)	
≤ 4	7.0 (3, 14)	
p	**	
Total FSE		.736**

Spearman's rank correlation: * $p < 0.01$; ** $p \leq 0.001$.

TFC, time from injury to follow simple commands; GCS, Glasgow Coma Scale; FSE, Functional Status Examination.

responsiveness to recovery, and patient and SO concordance using data from participants with moderate or severe TBI. The results indicate that the FSE is significantly related to other measures of functional status, especially measures of independence in daily activities. The FSE is sensitive to TBI severity and is responsive to recovery from 3 to 6 months post-injury. The patient and SO assessments of functional status are significantly and strongly correlated. Finally, how much the subject is bothered by the limitations on the FSE is strongly related to the total FSE score, to TBI severity, to current happiness, and to Percent Back to Normal rating. There is less of a relationship between the FSE and measures of emotional functioning, mental health, and pain, supporting the assumption that the constructs measured by the FSE are more related to functional status or independence in everyday activities than to emotional well-being.

Further research comparing the FSE with other measures of functional status is needed to determine whether the FSE provides a better estimate of functioning than other measures, such as the GOSE. The FSE may have less of a ceiling effect given its broader range of coverage and lower threshold for endorsement than the GOSE, but this will need further investigation. These findings are consistent with results we reported in 2001[17] using a smaller and more mildly injured sample of subjects with TBI. That study found strong correlations between the GOSE and the FSE and between the SF-36 physical aggregate score and the FSE. There was also a close correspondence between the report of functioning by the patient and by the SO on the FSE. In addition, the FSE was significantly related to TBI severity indices and showed significant change from 1 to 6 months post-injury. These previous results, in conjunction with the current findings from a more severely injured cohort, suggest the FSE is a valuable measure of functional status following TBI, across a broad range of severity from concussion to coma.

The close correspondence between the report of functional status by the patient and by the SO indicates a proxy can be used if needed. This allows the evaluation of those who are too impaired to provide their own responses, thereby reducing bias from nonrandom missing data. This is a valuable characteristic—especially when examining functional status of severely injured subjects, given that a portion of them would be expected to be unable to provide their own assessment.

The inclusion of the bothersome rating on the FSE is a unique aspect of this functional status measure. No other measure determines both level of functioning and the patient's perspective as to the degree to which functional limitations bother him or her. In the future, patient-reported outcomes are expected to become increasingly important for determining optimal patient treatment.[31] The results of this study provide some preliminary information about the subjective aspect of functional status and its relationship to objective measurements of injury severity and to other patient-reported outcomes.

Potential limitations of this study include the representativeness of the data and the age of the data since information was collected on a randomized clinical trial approximately 20 years ago. However, although the clinical trial enrolled participants with specific inclusion and exclusion criteria, it was granted permission to enroll under waiver of consent, had <2% refusal of consent before randomization, and only 7% loss to follow-up over the 6-month follow-up period.[18] In addition, while treatment for TBI has undergone significant change over the past 20 years, we do not believe the relationships between outcome measures and their relationships to severity of injury and recovery should be affected.

In conclusion, the FSE covers multiple domains, provides detailed information about changes in the patient's functioning, and captures a wide range of outcomes. It can be used for both clinical and research purposes. Study results suggest that the FSE may be a valuable measure of functional status after TBI because it has strong psychometric properties, including validity, sensitivity to brain injury severity, and responsivity to change. In addition, given the strong correlation between patient and SO report on the FSE, use of a proxy may be warranted when the patient is unable to report for themselves.

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Author Disclosure Statement

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