Title

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Journal

Journal of neurotrauma, 36(16)

ISSN

0897-7151

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Publication Date

2019-08-01

DOI

10.1089/neu.2018.6198

Peer reviewed

JOURNAL OF NEUROTRAUMA 36:2423–2429 (August 15, 2019)

DOI: 10.1089/neu.2018.6198

Functional Status Examination versus Glasgow Outcome Scale Extended as Outcome Measures in Traumatic Brain Injuries: How Do They Compare?

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Abstract

Outcome measures are essential components of natural history studies of recovery and treatment effects after traumatic brain injury (TBI). The Glasgow Outcome Scale (GOS) and its revised version, the Glasgow Outcome Scale Extended (GOSE), are well accepted and widely used for both observational and intervention studies, but there are concerns about their psychometric properties and aptness as outcome measures for TBI. The present study compares the Functional Status Examination (FSE) with the GOSE to assess outcome after TBI in a sample of 533 participants with TBI from the Magnesium Sulfate study and the Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) study by evaluating the sensitivity of each measure to severity of brain injury and recovery of function over time. The results indicate that both measures are strongly correlated with TBI severity. At three months, the correlation strengths between injury severity and each outcome measure do not differ ($p = 0.88$ for Glasgow Coma Scale [GCS], $p = 0.13$ for computed tomography [CT] abnormalities) but at six months, the FSE is more strongly related to TBI severity indices than is the GOSE ($p = 0.045$ for GCS, $p = 0.014$ for CT abnormalities). In addition, the FSE generally shows significantly more improvement over time than the GOSE ($p < 0.001$). Detailed, structured administration rules and a wider score range of the FSE likely yields more sensitive and precise assessment of functional level than the GOSE. The FSE may be a valuable alternative to the GOSE for assessing functional outcome after TBI.

Keywords: outcome assessment; psychosocial outcome; quality of life; traumatic brain injury

Introduction

Outcome measures play a critical role in studies of natural history of recovery and treatment effects. In the area of traumatic brain injury (TBI), the Glasgow Outcome Scale (GOS)[1] and its revised version, the Glasgow Outcome Scale Extended (GOSE),[2] has been the primary end-point for both observational and intervention studies. While its brevity, face validity, and wide use are highly attractive, the GOS and GOSE have noted weaknesses. These include the large range of functioning included at the different levels of the scale and high misclassification rates likely because of insufficient test instructions leading to erroneous ratings of outcomes.[3–5] Further, the GOSE score reflects only the worst outcome with all else ignored.

In addition, the GOSE score is not on an interval scale, making normal-theory-based statistical procedures problematic. The score is often dichotomized into favorable and unfavorable outcome, which may cause a further loss of information; also, peripheral injuries affect function, and studies should decide whether or not to include their effects. The GOSE interview is worded so that it works with either decision, but that makes it easy to overlook the need to specify whether effects of peripheral injuries are being taken into account, increasing variability as each study participant or each examiner makes his or her own decision. Very few articles

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even indicate which approach was taken when reporting GOSE as an outcome, making comparisons within and across samples problematic.

When treatment effects of large and expensive studies rest on such measurement properties, the cost to science and to patients who might have benefited if the study had shown a positive effect is high. The majority of acute treatment trials in TBI have yielded negative results.[6] A critical question is whether psychometric properties of the outcome measure, more specifically the GOS and the GOSE, might be partially responsible for this.

The Functional Status Examination (FSE) was developed to assess a broad range of everyday functioning using a structured interview format to improve the accuracy of administration and rating of functional status after TBI. The measure has strong psychometric properties including good validity, test-retest reliability, and close correspondence between patient and significant other report, allowing use of a proxy.[7,8] The present study compares the psychometric properties of the FSE and the GOSE and assesses the sensitivity of the two measures to severity of injury and recovery of function after injury.

Patients and Methods

Subjects

Participants for this project were survivors from two prospective, longitudinal studies of TBI, the Magnesium Sulfate Study[9] and the Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) study (https://tracktbi.ucsf.edu/transforming-research-and-clinical-knowledge-tbi).

The Magnesium Sulfate Study was a randomized, controlled trial that enrolled 499 patients with moderate to severe TBI from 1998 to 2004. Inclusion criteria included Glasgow Coma Scale (GCS) score of 3–12 on presentation in the emergency department (ED) or intracranial surgery (e.g., craniotomy, or elevation of a depressed skull fracture with dural repair) within 8 h of injury. Subjects were excluded if they were age <14 years (see Temkin and associates[9] for full inclusions/exclusions). Demographic characteristics are presented in Table 2. Participants were assessed at three and six months after the injury.

The TRACK-TBI study is an 18-center prospective, observational cohort study; 170 participants were enrolled at the University of Washington site from 2014 to September 2017 and were administered the FSE as a site-specific measure. Inclusion criteria consisted of adult patients arriving to the ED less than 24 h of injury with a history of TBI and clinical indication for obtaining computed tomography (CT). Exclusions included being in custody, pregnant, non-survivable physical trauma, debilitating mental health disorders, neurological disease, or non-English speaking. For further details of inclusion/exclusion criteria, see TRACK-TBI Study Protocol: https://tracktbi.ucsf.edu/researchers. Twenty-eight percent of subjects were discharged home from the ED, and 72% were admitted to the hospital. Demographic and injury characteristics are presented in Table 2. Outcome evaluations occurred at two weeks, three months, six months, and 12 months post-injury.

Measures

Severity of brain injury. Brain injury severity was evaluated by the initial post-resuscitation GCS[10] score collected in the ED and by the presence or absence of acute intracranial CT abnormalities. The GCS is a measure of coma depth. The CT abnormalities were obtained from the radiology report for participants in the Magnesium Study. For the TRACK study, they were coded by a central reader (EY) according to the NINDS Common Data Elements for TBI (https://commondataelements.ninds.nih.gov/TBI.aspx#tab=Data_Standards). The CTs were considered positive if there was an acute intracranial abnormality.

Functional status measures

The FSE[7] measures change in functional status specifically from TBI. The measure can be administered in relation to changes from TBI only or both the changes associated with TBI and peripheral injuries. The Magnesium Sulfate study collected changes related to the entire traumatic injury. The FSE covers seven areas of functioning: personal care, ambulation, mobility, major activity (work or school), homemaking, leisure and recreation, and social integration, and takes about 10 min to administer. The original FSE had three other areas of functioning (cognitive competency, standard of living, and financial independence) that were removed because of weak fit with the rest of the measure.

Functional areas are evaluated using the concept of dependency to operationally define outcome at four levels for each area: 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 = non-performance, inability to perform the activity, or total dependence on others. Table 1 gives an example of the structured interview used to rate major activity (work). Contact the primary author (dikmen@uw.edu) about obtaining the measure.

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 have died are assigned a total score of 22. The most informed person (patient or proxy) completed the FSE and the GOSE at three months and six months post-injury in the Magnesium Sulfate study.

For the TRACK-TBI study, patients enrolled at the University of Washington were administered the FSE at two weeks, three months, six months, and 12 months post-injury. Participants were asked about all injury-related effects, similar to the procedure used in the Magnesium Sulfate study. They were also asked about function, considering the effect of TBI alone. Total scores summing all injury-related effects were used in this project for consistency with the Magnesium Sulfate study.

The GOSE[2] is the extended version of the GOS, a widely used measure of outcome after TBI. The revised version increased the number of outcome categories from five to eight to attempt to improve its sensitivity to outcome and reliability. Domains covered include independence within the home, independence outside the home (shopping and travel), work/school, social and leisure activities, family and friendships, and other current problems that affect daily functioning.

The patient is classified on an eight-category scale from death (1), vegetative state (2), lower and upper severe disability (3,4), lower or upper moderate disability (5,6), or lower or upper good recovery (7,8). The scale classification is based on the worst outcome obtained across the domains assessed. As with the FSE, for this project, outcome was evaluated in relationship to all injury-related effects including any effects of peripheral injuries sustained in the same event. The measure can be viewed in the Wilson and colleagues[2] article.

Data analysis

The relationship of the FSE and GOSE to brain injury severity was assessed at three and six months post-injury. Brain injury

Table 1. Functional Status Examination Work Category

<table>
<tr><td colspan="4">Work
This section is about being self-employed, family-employed, or employed competitively by someone else.</td></tr>
<tr><td colspan="4">Are you currently working?</td></tr>
<tr><td>NO, NOT WORKING DUE TO INJURY</td><td colspan="3">YES</td></tr>
<tr><td rowspan="4">Explain.</td><td colspan="3">Compared to your pre-injury work, are you currently earning less money (at least 25% less), or are you in a job which has less responsibility due to the injury? Have you received a demotion? Have you reduced your work hours by 25% or more? Is someone taking over any of your previous job duties?</td></tr>
<tr><td>YES</td><td colspan="2">NO</td></tr>
<tr><td rowspan="3">Explain.</td><td colspan="2">Are you having difficulty on the job now due to the injury? Is it taking you longer to get things done? Are problems with fatigue, concentration, memory, how you feel, or pain making your job harder? Are you having more trouble getting along with people at your job? Have you reduced your hours by < 25%, or are you taking more days off from work due to your health? Do any other problems make work more difficult?</td></tr>
<tr><td>YES</td><td rowspan="3">NO, SAME AS BEFORE</td></tr>
<tr><td>Explain.</td></tr>
<tr><td>CODE 3</td><td>CODE 2</td><td colspan="2">CODE 1</td><td>CODE 0</td></tr>
</table>

(If code is higher than 0), how much do these difficulties bother you in your day-to-day life?	None = 0	Mild = 1	Moderate = 2	Severe = 3
(If code is 0), how long after the injury did it take before you returned to normal in this area?	_____ Months			

Code without other system injuries included: _____

severity indices included the total GCS score (ungrouped) as well as the presence or absence of CT abnormalities. The relationships between the brain injury severity and outcome measures were examined by Spearman rank correlation. There were 100 participants who died before the first evaluation, and because no functional measure can detect change in death, analyses were run without the inclusion of those who died.

The Choi test of equality of two correlations[11] when both involve a common variable assessed whether one measure is more closely related to severity than the other. Because the presence of CT abnormality is dichotomous, the Mann-Whitney U test[12] was used to assess significance of correlations involving that severity index.

Change from three to six months post-injury on the FSE and GOSE was also examined. To account for scale differences between the FSE and GOSE, change scores were standardized by dividing the difference between the individual's scores at the two times by the standard deviation of the difference on that measure. This puts the change on both measures on the same scale—with a standard deviation of 1. The average of these values is the effect size for the change.

Wilcoxon signed rank tests compare the standardized FSE change with standardized GOSE change. The average of the standardized change scores for a measure is the effect size (Cohen d for correlated measures) for the change. Additional analyses of change were conducted using TRACK-TBI data only to explore change on the FSE and GOSE over a broader range of time. Standardized change from two weeks to three months, two weeks to six months, two weeks to 12 months, three months to six months, three months to 12 months, and six months to 12 months were compared using the Wilcoxon signed rank tests.

Results

Table 2 presents the demographic and severity characteristics of the included participants from each study. The studies are combined to provide a broad range of demographic characteristics and severity of head injury.

The GOSE and FSE were highly correlated with each other (Spearman correlation = -0.86 at three months and –0.87 at six months when considering only survivors). Table 3 summarizes the relationship of the FSE and GOSE to GCS and the presence of CT abnormalities. Both measures had moderate to strong correlations with each measure of severity. At three months, there was no reliable difference between the correlations ($p = 0.88$ for GCS, $p = 0.13$ for CT abnormalities), while at six months, the FSE was more strongly related to the severity measures ($p = 0.045$ for GCS, $p = 0.014$ for CT abnormalities).

Table 4 presents the percent of cases improving by at least one point and the standardized change in the functional status measures (effect size) from three to six months in the Magnesium Sulfate and TRACK-TBI combined sample. The FSE reflected significantly more improvement over that interval than did the GOSE. Similar

Table 2. Demographic Information and Severity

	Magnesium Sulfate Study	*TRACK-TBI study*
n	363	170
Age M (SD)	32.5 (16)	40 (16.8)
Years of education M (SD)*	11.5 (2.5)	13.8 (2.6)
Male n (%)	279 (77)	118 (69)
Glasgow Coma Scale n (%)		
3 to 8	193 (59)	19 (12)
9 to 12	108 (33)	3 (2)
13 to 15	28 (8)	137 (86)
CT intracranial abnormalities n (%)	363 (100)	33 (28)

TBI, traumatic brain injury; SD, standard deviation; CT, computed tomography.

*n for years of education = 344 for Mag.

results were seen within the TRACK-TBI study, with the FSE reflecting significantly more improvement from two weeks to three months, two weeks to six months, two weeks to 12 months, three months to six months, and three months to 12 months. The GOSE reflected significantly more improvement between six and 12 months (Table 5).

Discussion

Our results indicate that both the FSE and the GOSE are sensitive to severity of brain injury and to recovery of function over time. At six months post-injury, however, the FSE is related more strongly to severity of brain injury than is the GOSE. In addition, the FSE generally shows significantly more improvement over time than the GOSE. General improvement in functioning is expected over the first year after injury. Sensitivity to change may reflect the ability of FSE to detect improvement or deterioration, clinically important diagnostic constructs, and potentially be responsive to the effects of an intervention.

Consistent with the consensus understanding regarding recovery of function after TBI, the FSE shows decreasing rate of recovery over time with a large effect size for change (in the direction of improvement, on average) between two weeks and three months, a medium effect size between three and six months, and a small-medium effect size between six and 12 months. The GOSE indicates a similar pattern, except that in the TRACK-TBI study, the change indicated for GOSE between three and six months is small.

More recent work has indicated that some TBI survivors may deteriorate rather than continue to improve, especially longer after their injury.[13–16] The FSE captures almost double the number of cases with a worse score at 12 months compared with six months post-TBI, compared with the GOSE. Further investigation of the TRACK-TBI cohort, aimed at capturing longer-term follow-up, may resolve whether this is just fluctuation or if the FSE is able to better detect early indications of deterioration.

Important strengths and weaknesses of the two scales must be noted. The GOSE takes less time to administer, is widely accepted—including by the U.S. Food and Drug Administration (FDA)—and has been used as the primary end-point for assessing global outcome in TBI clinical trials. Consequently, it is also a core measure currently for all types of TBI studies in the NINDS TBI Common Data Elements https://www.commondataelements.ninds.nih.gov/TBI.aspx#tab=Data_Standards).

Table 3. Relation of Functional Status Examination Total and Glasgow Outcome Scale Extended Overall Score to Severity (Glasgow Coma Scale Total Score, Computed Tomography Abnormality)

	3 months post-injury						
	Total FSE ALL score				*GOSE overall*		
	n	*median*	*r*	p	*median*	*r*	P
GCS total			–0.481	< 0.001		0.514	< 0.001
3–8	193	15			4		
9–12	96	11			5		
13–15	132	5			6		
CT abnormal			0.395	< 0.001		–0.389	< 0.001
No	77	3			6		
Yes	350	13			5		
	6 months post-injury						
	Total FSE ALL score				*GOSE overall*		
	n	*median*	*r*	p	*median*	*r*	P
GCS total			–0.428	< 0.001		0.396	< 0.001
3–8	202	12			5		
9–12	101	8			6		
13–15	131	2			7		
CT abnormal			0.393	< 0.001		–.0343	< 0.001
No	74	1			7		
Yes	372	11			6		

FSE, Functional Status Examination; GOSE, Glasgow Outcome Scale Extended; GCS, Glasgow Coma Scale; CT, Computed tomography.

Median scores for each measure in severity subgroups are shown for descriptive purposes. There are no significant differences between measures at 3 months ($p = 0.881$ for GCS, $p = 0.129$ for CT abnormalities). At 6 months, the FSE is more highly related to severity than the GOSE is ($p = 0.045$ for GCS, $p = 0.014$ for CT abnormalities).

Table 4. Change from 3 to 6 Months Post-Injury—Magnesium Sulfate and TRACK-TBI Studies Combined

n (%)	Improve	No change	Worsened	Mean change	SD of change	Effect size
FSE	263(63)	86 (21)	67 (16)	1.97[a]	3.90	0.50[c]
GOSE	156 (38)	204 (49)	56 (13)	–0.42[b]	1.13	–0.37[c]

TBI, traumatic brain injury; FSE, Functional Status Examination; GOSE, Glasgow Outcome Scale Extended.

[a]$p < 0.001$ paired Wilcoxon signed rank test comparing change from 3 to 6 months post-injury on the FSE.

[b]$p < 0.001$ paired Wilcoxon signed rank test comparing change from 3 to 6 months post-injury on the GOSE.

[c]$p < 0.001$ paired Wilcoxon signed rank test comparing whether there is more change on one measure compared with another.

Change calculated as 3 month–6 month. Subjects who died not included.

The FSE takes a little longer to administer. It has important advantages over the GOSE, however. The FSE is highly structured and is able to gather information needed to rate disability level accurately across various domains of everyday life function. The levels are well defined and the inquiries are well structured, with little room for classification errors regarding the level of disability. This is not the case with the GOSE, for which there is no one standard structured interview and scoring rubric.

Also, multiple areas of functioning contribute to the FSE score on an ordinal scale, enabling one to sum items into a total score with more continuous, interval-like measurement properties amenable to common methods for statistical interrogation. GOSE items, on the other hand, are scaled in variable ways and yield a total score that depends only on the worst item-level score; theoretically, this reduces the information and sensitivity of each score to differences between patients' outcomes. In addition, the ordinal scaling of the GOSE total score limits the feasibility of conducting more

Table 5. TRACK-TBI Only Functional Status Examination Compared with Glasgow Outcome Scale Extended All Ratings and Time Points

Change from 2 weeks to 3 months

n (%)	Improve	No change	Worsened	Mean change	SD of change	Effect size
FSE	79 (86)	6 (7)	6 (7)	5.91[a]	5.16	1.14[c]
GOSE	61 (67)	25 (28)	5 (5)	–1.08[b]	1.10	–0.98[c]

Change from 2 weeks to 6 months

n (%)	Improve	No change	Worsened	Mean change	SD of change	Effect size
FSE	80 (90)	8 (9)	1 (1)	7.53[a]	5.37	1.40[c]
GOSE	63 (71)	17 (19)	9 (10)	–1.28[b]	1.38	–0.93[c]

Change from 2 weeks to 12 months

n (%)	Improve	No change	Worsened	Mean change	SD of change	Effect size
FSE	64 (86)	5 (7)	5 (7)	8.44[a]	5.94	1.42[c]
GOSE	54 (73)	15 (20)	5 (7)	–1.57[b]	1.49	–1.05[c]

Change from 3 months to 6 months

n (%)	Improve	No change	Worsened	Mean change	SD of change	Effect size
FSE	63 (54)	40 (35)	13 (11)	1.88[a]	3.60	0.52[c]
GOSE	33 (28)	56 (48)	27 (23)	–0.12	1.04	–0.12[c]

Change from 3 months to 12 months

n (%)	Improve	No change	Worsened	Mean change	SD of change	Effect size
FSE	59 (59)	29 (29)	12 (12)	2.74[a]	4.14	0.66[c]
GOSE	41 (41)	46 (46)	13 (13)	–0.48[b]	1.11	–0.43[c]

Change from 6 months to 12 months

n (%)	Improve	No change	Worsened	Mean change	SD of change	Effect size
FSE	33 (32)	48 (47)	21 (21)	0.85*	2.87	0.30[c]
GOSE	36 (35)	54 (53)	12 (12)	–0.35[b]	.94	–0.37[c]

TBI, traumatic brain injury; FSE, Functional Status Examination; GOSE, Glasgow Outcome Scale Extended.

[a]$p < 0.001$, *$p \leq 0.01$ paired Wilcoxon signed rank test comparing change from time 1 to time 2 post-injury on the FSE.

[b]$p < 0.001$ paired Wilcoxon signed rank test comparing change from time 1 to time 2 post injury on the GOSE.

[c]$p < 0.001$ Paired Wilcoxon signed rank test comparing whether there is more change on one measure compared with the other.

commonly used and potentially more powerful statistics available for continuous outcomes.[17]

While the FSE has not been used as a primary outcome measure for an FDA-regulated registration study, it has the desirable administration characteristics and meets the FDA definition of a clinical outcome that could be used to demonstrate clinical benefit. Although the FSE was developed as a research tool, it may also be a useful tool for clinicians because it provides extensive information about functional status changes across everyday life activities capturing not only areas of dependency and details about the type and amount of assistance received, but also details about activities that are currently limited as well as types of difficulty experienced.

A limitation of the present study is that, in the Magnesium Sulfate study, answers to the FSE were used to ensure the GOSE score was accurate, because the primary end-point of that study was a composite that included the GOSE. Because of this, outcome examiners were trained to return to the GOSE if answers to the FSE cast doubt on responses to items in the GOSE. Thus, the GOSE benefitted from the clarity of the FSE with respect to ensuring correct classification of outcome in the Magnesium Sulfate study.

This was not done in the TRACK-TBI study, although the GOSE scoring was extensively curated based on internal consistency and answers to structured interview questions about work status and living situation. The GOSE curation required much time and many queries to the sites. Yet, the FSE administered at six months showed closer relationship to severity of the TBI, and it more clearly reflected recovery over most time periods compared with the GOSE.

Another limitation is the exclusion of participants who died. Both measures give deaths the worst score, so this should have little impact on the comparison of the measures. The inclusion of 105 deaths, 100 of which occurred before three months, would have put a large number of persons in the ''no change'' category whose functional status could not change regardless of the sensitivity of the instrument.

The different scales of the instruments make interpretation of the relative number who change by at least one point difficult. The effect sizes for the change on the measures can be compared and the test to compare the scaled change values is valid despite the differences in range. Some may consider the use of rank-based methods to be a limitation, but the ordinal nature of the GOSE makes use of normal-theory methods questionable, itself a limitation of the GOSE.

Another limitation is the combining of data from two studies. The studies were conducted more than 10 years apart and have different distributions of TBI severity. Thus, relationships of the measures to severity might be confounded by the time and study-specific characteristics. This is mitigated, however, by the same investigators overseeing both studies at the site and the examination of the same individuals for both measures.

Conclusions

The FSE holds promise as an alternative to the GOSE for assessing functional outcome in the first year after TBI. The FSE interview is more detailed, more clearly structured, and better worded than the GOSE, leading to more accurate answers and less time needed for subsequent queries, data curation, and need for reclassification. The FSE has a broader range of scores, is more sensitive to TBI severity, and generally demonstrates greater recovery through six months after TBI than the GOSE.

Acknowledgments

This study was supported by the following grants: W81XWH-14-2-0176, R01 NS19643, U01NS086090. Amy J. Markowitz, JD, provided editorial support.

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Author Disclosure Statement

No competing financial interests exist.

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