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ORIGINAL ARTICLE CLINICAL STUDIES

Comparing the Quality of Life after Brain Injury-Overall Scale and Satisfaction with Life Scale as Outcome Measures for Traumatic Brain Injury Research

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Abstract

It is important to measure quality of life (QoL) after traumatic brain injury (TBI), yet limited studies have compared QoL inventories. In 2579 TBI patients, orthopedic trauma controls, and healthy friend control participants, we compared the Quality of Life After Brain Injury-Overall Scale (QOLIBRI-OS), developed for TBI patients, to the Satisfaction with Life Scale (SWLS), an index of generic life satisfaction. We tested the hypothesis that group differences (TBI and orthopedic trauma vs. healthy friend controls) would be larger for the QOLIBRI-OS than the SWLS and that the QOLIBRI-OS would manifest more substantial changes over time in the injured groups, demonstrating more relevance of the QOLIBRI-OS to traumatic injury recovery. (1) We compared the group differences (TBI vs. orthopedic trauma control vs. friend control) in QoL as indexed by the SWLS versus the QOLIBRI-OS and (2) characterized changes across time in these two inventories across 1 year in these three groups. Our secondary objective was to characterize the relationship between TBI severity and QoL. As compared with healthy friend controls, the QOLIBRI reflected greater reductions in QoL than the SWLS for both the TBI group (all time points) and the orthopedic trauma control group (2 weeks and 3 months). The QOLIBRI-OS better captured expected improvements in QoL during the injury recovery course in injured groups than the SWLS, which demonstrated smaller changes over time. TBI severity was not consistently or robustly associated with self-reported QoL. The findings imply that, as compared with the SWLS, the QOLIBRI-OS appears to identify QoL issues more specifically relevant to traumatically injured patients and may be a more appropriate primary QoL outcome measure for research focused on the sequelae of traumatic injuries.

Keywords: common data elements; friend controls; Glasgow Coma Scale; health related quality of life; orthopedic trauma controls; Quality of Life after Brain Injury Overall Score; Quality of Life after Brain Injury Overall Score; Satisfaction with Life Survey; traumatic brain injury

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Introduction

In the United States, ~2,800,000 individuals are treated at hospitals annually for traumatic brain injuries (TBIs).[1] Up to 5,300,000 people in the United States are living with physical, social, cognitive, and psychological changes associated with TBI.[1–3] In these TBI survivors, health-related quality of life (HRQoL) and life satisfaction are considered important outcomes associated with rehabilitation.[4–6] QoL is defined by the World Health Organization as ''an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.''[7] Similarly, life satisfaction refers to an individual's cognitive appraisal of his or her life, overall. This global appraisal is influenced by satisfaction in those life domains or life roles that are most relevant to each individual.[8,9] QoL measures for patients with TBI represent different underlying constructs than the functional outcomes captured; for example, in the commonly utilized Glasgow Outcome Scale Extended (GOSE).[10,11] QoL is significantly altered following TBI, with prior studies showing that life satisfaction is worse shortly after TBI. Like other clinical outcomes, QoL can be expected to improve over time but can remain worse than baseline or continue to fluctuate for years after injury.[9,12–17] Reduced QoL is evident across the spectrum of severity of TBI, and even patients who experience ''mild'' TBI (mTBI) demonstrate reduced well-being.[10,18] Patients with TBI may experience reduced QoL as the result of a multitude of factors, including brain injury specifically, as well as the emotional trauma and peripheral injuries that often co-occur with TBI.[19] Indeed, a recent prospective Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) analysis indicated that patients with mTBI who had higher affective symptoms, pain interference, and insomnia post-injury developed poorer life satisfaction.[20]

Although patients with TBI commonly experience problems with QoL, there are limited data to inform QoL in the TBI population. Generic QoL measures such as the Satisfaction With Life Scale (SWLS) are commonly used in TBI research but may not measure areas of life quality that are impacted by one's injury.[9] In particular, the five-item SWLS asks about general satisfaction with one's life but does not anchor ratings to a concrete time point (such as an injury event) or cover specific domains (e.g., cognition and psychological and social functioning) of life that are commonly impacted by TBI. Consequently, the SWLS may be expected to reflect one's overall, lifetime QoL. The five-item SWLS is currently recommended as a core outcome measurement in the National Institute of Neurological Disorders and Stroke (NINDS) TBI common data elements (CDE) likely because of its brevity and widespread historical use, rather than any superiority over more disease-specific instruments such as the Quality of Life After Brain Injury (QOLIBRI) scale or its six-item short form, the QOLIBRI-Overall Scale (QOLIBRI-OS). The QOLIBRI/QOLIBRI-OS is a novel instrument that can be used with cognitively impaired populations and was specifically designed to measure QoL in individuals with TBI.[6,21–24] The instrument asks about satisfaction *since one's injury* with specific domains of life function commonly affected by TBI, including cognitive, emotional, and physical function.

One small study comparing the SWLS to the QOLIBRI scale at 3 months post-injury indicated that the QOLIBRI cognition and physical subscales successfully differentiated TBI patients from orthopedic trauma controls, suggesting that the content of the QOLIBRI may better capture issues important to brain-injured patients.[25] An additional study indicated that cognitive disability predicts life satisfaction trajectories, further highlighting the need for an outcome measure that can incorporate cognitive disability as it relates to life satisfaction and QoL after TBI.[26] In a study of patients at one time point, primarily >1 year post-injury, the QOLIBRI-OS demonstrated higher correlation to other QoL measures when compared with the SWLS.[24] However, additional study is needed on the degree to which the SWLS and QOLIBRI-OS assess QoL issues relevant to TBI and how selection between these inventories affects the information one gleans about QoL after TBI and traumatic injuries.

The overall objective of this study was to compare QOLIBRI-OS and SWLS outcomes at four time points ranging from 2 weeks to 12 months post-injury in TBI patients, orthopedic trauma controls (OTC), and healthy friend controls (FC) to inform decisions about the applicability of these inventories in TBI research. Specifically, our primary aims were twofold: (1) to compare the degree to which the QOLIBRI-OS and SWLS differentiate TBI, OTC, and FC groups at four time points (week 2, month 3, month 6, month 12) across the 1st year post-injury, and (2) to compare the degree to which ratings on these two QoL inventories change over time in the 1st year post-injury within each group (TBI, OTC, FC). Because of the particular QoL issues in the TBI population, we hypothesized that there would be bigger differences between injured (TBI, and to a lesser degree OTC) and FC groups for the QOLIBRI-OS than for the SWLS total scores at each time point, substantiating that the QOLIBRI-OS indeed captures information about HRQOL that is particularly relevant to brain-injured patients (and perhaps to the broader traumatic injury population). Because of the dynamic nature of injury recovery and the goal of the QOLIBRI-OS to measure injury-relevant QOL issues, we hypothesized that, within each injured group (TBI and OTC), the changes in QoL from 2 weeks to later time points would be larger on QOLIBRI-OS than on the SWLS. In contrast, we expected no significant change over time in QoL on any scale in FCs.

Methods

Participants

Participants were identified and enrolled in the prospective TRACK-TBI study in accordance with previously published methods.[27–29] Patients with TBI or orthopedic injury who presented to 1 of 18 participating level 1 United States trauma centers were enrolled from February 26, 2014, to June 15, 2018, and written consent was obtained from all patients or their legal representatives prior to enrollment. Eligible patients for the TBI group were those who presented to the emergency department (ED) within 24 h of head trauma warranting clinical evaluation with a non-contrast head computed tomography (CT) under American College of Emergency Medicine/Centers for Disease Control and Prevention (CDC) criteria[30] and who demonstrated signs of altered mental status. Patients with TBI were excluded if they had significant polytrauma. Patients with isolated orthopedic trauma were enrolled using the same process as that for patients with TBI. Eligible patients for inclusion were those who presented with isolated trauma to their limbs, pelvis, or ribs, and had an Abbreviated Injury Scale score of <4 for those body regions. Patients were excluded from being OTC if they had clinical findings suggestive of a brain injury such as loss of consciousness, disturbance of consciousness, seizure, post-traumatic amnesia, or retrograde amnesia. Healthy FC were adults who identified as being a family member of a study TBI participant or having been that person's friend for at least 1 year. FCs were excluded if they had a history of TBI, concussion, orthopedic injury, or significant polytrauma in the 12 months before enrollment in the study. Injured patients and FCs were excluded from all three groups if they were prisoners, pregnant, on a psychiatric hold, participating in an interventional trial, non-English or non-Spanish speaking, or had low likelihood of follow-up, major debilitating mental health disorders, neurological diseases, or significant pre-existing conditions that would interfere with follow-up. For the current analysis, we included subjects of all TBI severities, OTC subjects, and FCs with at least 1 QoL outcome.

This study received approval from the institutional review board of record at the lead site (University of California, San Francisco) and each participating institution. Reporting adhered to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement.

Primary outcome measures

Patients were assessed at 2 weeks and 3, 6, and 12 months post-injury with a comprehensive neuropsychological assessment battery comprising measures of QoL, symptoms, cognitive performance, and functional limitations. FCs were assessed four times at intervals comparable to those when injured participants were assessed. Assessments were completed in person at 2 weeks, 6 months, and 12 months, and via phone at 3 months or when otherwise necessary to avoid missing data. The primary outcomes of interest for the current study were the SWLS and the QOLIBRI-OS.[6,31] The SWLS measures general life satisfaction[32,33] and consists of five questions rated on a seven-point Likert scale, from strongly disagree (1) to strongly agree (7). The scores are summed to produce a total score ranging from 5 to 35. The six-item QOLIBRI-OS is a parallel version of the 37-item QOLIBRI scale, intended to assess QoL in domains of functioning relevant to TBI populations (e.g., cognitive, emotional, and physical function). The QOLIBRI has been validated in large international TBI populations and demonstrates good psychometric properties.[21,34–39] QOLIBRI-OS items are rated on a five-point scale from ''not at all satisfied'' (1) to ''very satisfied'' (5); the total score represents the mean item-level score. The mean item-level scores are then converted to a percentage score (0–100).[40] Higher scores on both SWLS and QOLIBRI-OS reflect better satisfaction with/quality of life.

Statistical analysis

Statistical analyses were performed using R version 3.6.2 (http://www.r-project.org). Demographic and baseline characteristics were summarized by group (TBI, OTC, FC). Sample characteristics were compared for each pair of groups using Fisher's exact tests (categorical variables) and Wilcoxon Rank Sum tests (continuous variables). The degree of association between primary outcomes (QOLIBRI-OS and SWLS total score) was computed using Pearson's correlation. SWLS and QOLIBRI-OS scores were standardized before entering the models, using their 2-week mean and standard deviation within the FC group, to allow for a common basis when comparing the two instruments. A linear mixed-effects model was conducted with standardized SWLS and QOLIBRI-OS scores at each follow-up as the outcome. The model included a random intercept; independent variables of group, time (treated as categorical), and instrument (SWLS vs. QOLIBRI-OS); all two-way interactions; the three-way interaction of instrument × group × time; and age, gender, and years of education as fixed effects. Model-estimated comparisons were reported with mean (standard error [SE]) for group differences at each time point and change over time for each group comparing SWLS and QOLIBRI-OS. *P* values for pairwise comparisons were adjusted using Tukey's method.

Results

Sample characteristics

A total of 3151 subjects ≥17 years of age were enrolled (2552 TBI, 299 OTC, and 300 FC), and outcome data at one or more time points were available for 2579 participants (Table 1). Groups did not differ significantly based

Table 1. Sample Characteristics for the Traumatic Brain Injury (TBI), Orthopedic Trauma Control (OTC), and Friend Control (FC) Groups with Follow-Up Data

	TBI (n = 2022) M (SD) or n (%)	*OTC (n = 257) M (SD) or n (%)*	*FC (n = 300) M (SD) or n (%)*	*TBI vs. OTC p*	*TBI vs. FC p*	*OTC vs. FC p*
Age, y	40.2 (17.2)	40.1 (15.2)	37.6 (15.3)	0.464	0.058	0.037
Sex, male	1376 (68.1%)	169 (65.8%)	191 (63.7%)	0.479	0.146	0.657
Race				0.953	0.185	0.332
White	1561 (77.6%)	196 (77.5%)	226 (76.1%)			
Black	330 (16.4%)	43 (17.0%)	45 (15.2%)			
Other/Unknown	121 (6.0%)	14 (5.5%)	26 (8.8%)			
Hispanic	413 (20.5%)	64 (25.2%)	53 (17.9%)	0.087	0.314	0.037
Insurance type				0.870	0.231	0.669
Insured	1082 (55.1%)	139 (56.1%)	173 (59.5%)	-		
Uninsured	418 (21.3%)	49 (19.8%)	50 (17.2%)			
Medicare/Other	464 (23.6%)	60 (24.2%)	68 (23.4%)			
Years of education	13.5 (2.9)	13.8 (2.9)	14.1 (2.5)	0.024	<0.001	0.258
Previous TBI	604 (30.4%)	58 (22.8%)	96 (32.7%)	0.011	0.456	0.010
Neurodevelopmental disorder	175 (8.7%)	19 (7.4%)	26 (8.8%)	0.554	0.913	0.641
Psychiatric history	452 (22.4%)	62 (24.1%)	66 (22.2%)	0.527	>0.999	0.614
Cause of injury			-	< 0.001	-	-
Road traffic incident	1155 (57.3%)	89 (35.9%)	-	-	-	-
Incidental fall	527 (26.2%)	90 (36.3%)	-			
Violence/assault	140 (7.0%)	2 (0.8%)	-			
Other	193 (9.6%)	67 (27.0%)	-			
TBI severity group			-		-	-
GCS 3-8	189 (9.8%)	-	-	-	-	-
GCS 9-12	78 (4.0%)	-	-			
GCS 13-15 CT+	595 (30.7%)	-	-			
GCS 13-15 CT-	1077 (55.5%)	-	-			
Loss of consciousness			-	< 0.001	-	-
No	233 (11.6%)	256 (100%)		-	-	-
Yes[1]	1693 (84.0%)					
Unknown	90 (4.5%)					
Posttraumatic amnesia			-	< 0.001	-	-
No	345 (17.1%)	256 (100%)		-	-	-
Yes[a]	1474 (73.1%)					
Unknown	197 (9.8%)					
ISS Total, Median (IQR)	12 (6, 18)	5 (4, 10)	-	< 0.001	-	-
ISS Peripheral, Median (IQR)	2 (1, 9)	5 (4, 9)	-	< 0.001	-	-
AIS Head/Neck, Median (IQR)	2 (2, 3)	0 (0, 0)	-	< 0.001	-	-
Highest level of care			-	< 0.001	-	-
Emergency department	462 (22.9%)	95 (37.0%)	-	-	-	-
Inpatient unit	775 (38.3%)	145 (56.4%)	-		-	-
Intensive care unit	785 (38.8%)	17 (6.6%)	-		-	-
Injury-related litigation[b]	318 (21.2%)	31 (16.5%)	-	0.152	-	-

AIS/ISS scores only available on patients admitted to the hospital. Statistical significance by Wilcoxon Rank Sum or Fisher's exact test as appropriate. Participants in the FC group were friends or family members of TBI group participants.

[a]Collapsed Yes and Suspected categories

[b]Collected at 12 months post-injury

CT, computed tomography; GCS, Glasgow Coma Scale; AIS, Abbreviated Injury Scale; ISS, Injury Severity Score; IQR, interquartile range.

on sex, race, insurance, psychiatric history, or developmental history. There were more Hispanic individuals in the OTC group than in the FC group (25% vs. 18%). FCs were slightly younger than the OTC group (mean difference = 2.5 years). There were statistically significant but small differences (< 1 year) among some groups in years of education. Prior TBIs were more prevalent in the FC and TBI groups than in the OTC group. TBI and OTC groups differed significantly in injury-related factors such as cause of injury and highest level of care.

Participants in the TBI group who did versus did not complete outcomes did not differ significantly based on race, ethnicity, any past psychiatric history, and depression history (Supplementary Table S1). Group completion of outcomes differed significantly based on sex, insurance status, prior TBI, history of developmental disorder, highest level of care (ED, inpatient, or intensive care unit [ICU]), Glasgow Coma Scale score (GCS), age, and years of education. Participants in the OTC group who did versus did not complete outcomes did not differ significantly based on age; sex; race; ethnicity, education; insurance status; TBI, developmental, and psychiatric history; or highest level of care. However, because the number of cases with available data was equivalent for the QOLIBRI-OS and SWLS in both the OTC and TBI groups, primary comparisons between these

instruments at any given time point were likely unbiased by patterns of attrition. All of the 300 FCs reported at least one QoL outcome.

Relationship between QoL and injury group (TBI, OTC, FC)

The correlation between QOLIBRI-OS and SWLS total score was moderate to large and increased somewhat over time ($r = 0.56$, 0.67, 0.67, and 0.70 from 2 weeks to 12 months).

Figure 1a (SWLS), Figure 1b (QOLIBRI-OS), and Supplementary Table S2 depict the observed mean (and 95% confidence interval) for both QoL inventories by injury group (TBI, OTC, FC). Table 2 presents the model-estimated mean group differences for standardized QOL scores and p values for comparing the two instruments. The majority of group comparisons in SWLS were not significant, with the exception of lower life satisfaction in TBI versus FC at 2 weeks and 3 months (mean difference = -0.26 and -0.25, respectively). In contrast, QOLIBRI-OS reflected significantly lower QoL in the TBI group than in either the OTC (mean difference range -0.24 to -0.34) or FC group (mean difference range -0.30 to -1.04) at all four time points. OTCs also reported lower QoL on the QOLIBRI-OS than FCs at 2 weeks and 3 months (mean difference = -0.78 and -0.41, respectively), with these groups not significantly different at 6–12 months. The hypothesis that the QOLIBRI-OS would detect bigger differences between injured and FC groups than the SWLS was supported, as evidenced by significant QOLIBRI-OS versus SWLS differences in the between-group effect sizes for all TBI–FC comparisons (2 weeks through 12 months) and two OTC–FC comparisons (2 weeks, 3 months; see Table 2, right column).

Table 3 presents the model-estimated mean change from 2 weeks to later time points in standardized QoL ratings separately for each group (see also Fig. 1, right

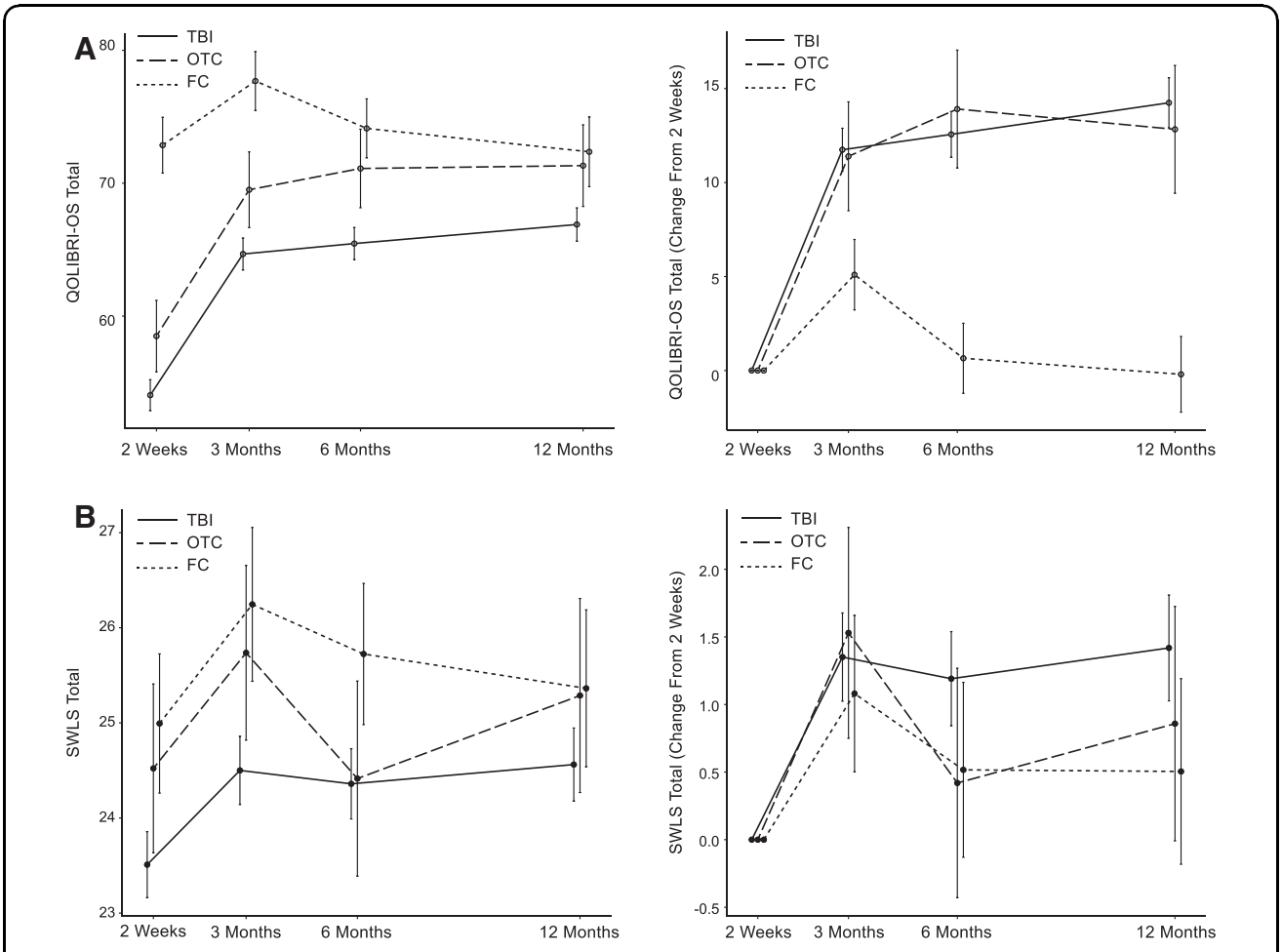

FIG. 1. Mean (95% confidence interval) of the Quality of Life After Brain Injury-Overall Scale (QOLIBRI-OS) **(A)** and Satisfaction with Life Scale (SWLS) **(B)** total scores from 2 weeks to 12 months post-injury for the traumatic brain injury (TBI), orthopedic trauma control (OTC), and friend control (FC) groups. The left panel displays observed total scores on each inventory, while the right panel displays observed change scores from 2 weeks.

Table 2. Model-Estimated Standardized Mean Differences (M_{diff}) on QOLIBRI-OS and SWLS among TBI, OTC, and FC Groups

		SWLS		*QOLIBRI-OS*		*QOLIBRI-OS vs. SWLS*
		M_{diff}[a] *(SE)*	p *value*[b]	M_{diff}[a] *(SE)*	p *value*[b]	p *value*
TBI vs. OTC	2 weeks	-0.18 (0.08)	0.064	**-0.25 (0.08)**	**0.007**	0.387
	3 months	-0.20 (0.08)	0.051	**-0.27 (0.08)**	**0.003**	0.343
	6 months	-0.05 (0.09)	0.839	**-0.34 (0.09)**	**<0.001**	**<0.001**
	12 months	-0.10 (0.09)	0.458	**-0.24 (0.09)**	**0.019**	0.123
TBI vs. FC	2 weeks	**-0.26 (0.08)**	**0.002**	**-1.03 (0.08)**	**<0.001**	**<0.001**
	3 months	**-0.25 (0.08)**	**0.004**	**-0.68 (0.08)**	**<0.001**	**<0.001**
	6 months	-0.16 (0.08)	0.089	**-0.42 (0.08)**	**<0.001**	**<0.001**
	12 months	-0.12 (0.08)	0.281	**-0.30 (0.08)**	**<0.001**	**0.024**
OTC vs. FC	2 weeks	-0.07 (0.10)	0.768	**-0.78 (0.10)**	**<0.001**	**<0.001**
	3 months	-0.05 (0.11)	0.865	**-0.41 (0.11)**	**<0.001**	**<0.001**
	6 months	-0.11 (0.11)	0.542	-0.08 (0.11)	0.749	0.728
	12 months	-0.02 (0.11)	0.983	-0.07 (0.11)	0.823	0.668

Bolded p values indicate statistically significant differences.

[a]M_{diff} symbol (negative) is the estimated mean group differences for standardized QoL scores based on the mean (M) and standard deviation (SD) of week 2 from the FC group. Difference represents: TBI-OTC; TBI-FC; OTC-FC.

[b]p values were adjusted using Tukey's method for comparing a family of three groups.

FC, friend control; OTC, orthopedic trauma control; QOLIBRI-OS, Quality of Life After Brain Injury-Overall Scale; SWLS, Satisfaction With Life Scale; TBI, traumatic brain injury; SE, standard error.

column, for an illustration of observed mean changes over time in original scale units). Supporting our hypothesis, changes in QoL were larger for both injured groups for the QOLIBRI-OS (standardized mean change = 0.60–0.75) than the SWLS (standardized mean change = 0.05–0.21, QOLIBRI-OS vs. SWLS $p < 0.001$ for all TBI and OTC comparisons). Within the TBI group, both inventories detected significant improvements in QoL across time, with these changes larger for the QOLIBRI-OS (mean standardized change = 0.66) than for the SWLS (mean standardized change = 0.19). For OTCs, change in QoL was significant from 2 weeks to all three follow-up time points for the QOLIBRI-OS, whereas the SWLS only detected significant change from 2 weeks to 3 months. FC, not expected to change in QoL over time, showed a significant but temporary improvement in QoL on both inventories from 2 weeks to 3 months (QOLIBRI-OS mean change = 0.24, SWLS mean change = 0.18), with 6-month and 12-month ratings reverting to comparable levels as those at 2 weeks. However, the QOLIBRI-OS and SWLS did not differ significantly in the degree of 2-week to 3-month QoL changes that they detected within the FC group ($p = 0.518$).

Because TBI and OTC groups differed statistically on highest level of care (ED discharge, non-ICU admit, ICU), a sensitivity analysis was conducted to evaluate the contribution of this variable to the QoL outcome. Level of care was unrelated to SWLS at any time point and was only related to QOLIBRI-OS at the 2-week time point, when individuals discharged from the ED reported the highest QOLIBRI-OS scores. The TBI versus OTC group differences were re-computed adjusting for level of care and were confirmed to have no meaningful effect on the effect sizes or conclusions.

Table 3. Model-Estimated Standardized Mean Change (M_{diff}) on the QOLIBRI-OS and SWLS from 2 Weeks (W) to 3, 6, and 12 Months (M)

		SWLS		*QOLIBRI-OS*		*QOLIBRI-OS vs. SWLS*
		M_{diff}[a] *(SE)*	p *value*[b]	M_{diff}[a] *(SE)*	p *value*[b]	p *value*
TBI	3M vs. 2W	**0.19 (0.03)**	**<0.001**	**0.60 (0.03)**	**<0.001**	**<0.001**
	6M vs. 2W	**0.18 (0.03)**	**<0.001**	**0.66 (0.03)**	**<0.001**	**<0.001**
	12M vs. 2W	**0.21 (0.03)**	**<0.001**	**0.73 (0.03)**	**<0.001**	**<0.001**
OTC	3M vs. 2W	**0.20 (0.07)**	**0.037**	**0.62 (0.07)**	**<0.001**	**<0.001**
	6M vs. 2W	0.05 (0.08)	0.923	**0.75 (0.08)**	**<0.001**	**<0.001**
	12M vs. 2W	0.13 (0.08)	0.336	**0.71 (0.08)**	**<0.001**	**<0.001**
FC	3M vs. 2W	**0.18 (0.07)**	**0.030**	**0.24 (0.07)**	**0.001**	0.518
	6M vs. 2W	0.09 (0.07)	0.518	0.04 (0.07)	0.920	0.603
	12M vs. 2W	0.08 (0.07)	0.683	-0.01 (0.07)	0.999	0.397

Bolded p values indicate statistically significant differences.

[a]M_{diff} symbol represents mean change in life quality/satisfaction (positive = improvement) from 2 weeks to later time points (e.g., 3 months vs. 2 weeks = 3months – 2 weeks).

[b]p values were adjusted using Tukey's method for comparing a family of four time points.

QOLIBRI-OS, Quality of Life After Brain Injury Scale-Overall Scale; SWLS, Satisfaction with Life Scale; TBI, traumatic brain injury; FC, friend control; OTC, orthopedic trauma control; SE, standard error.

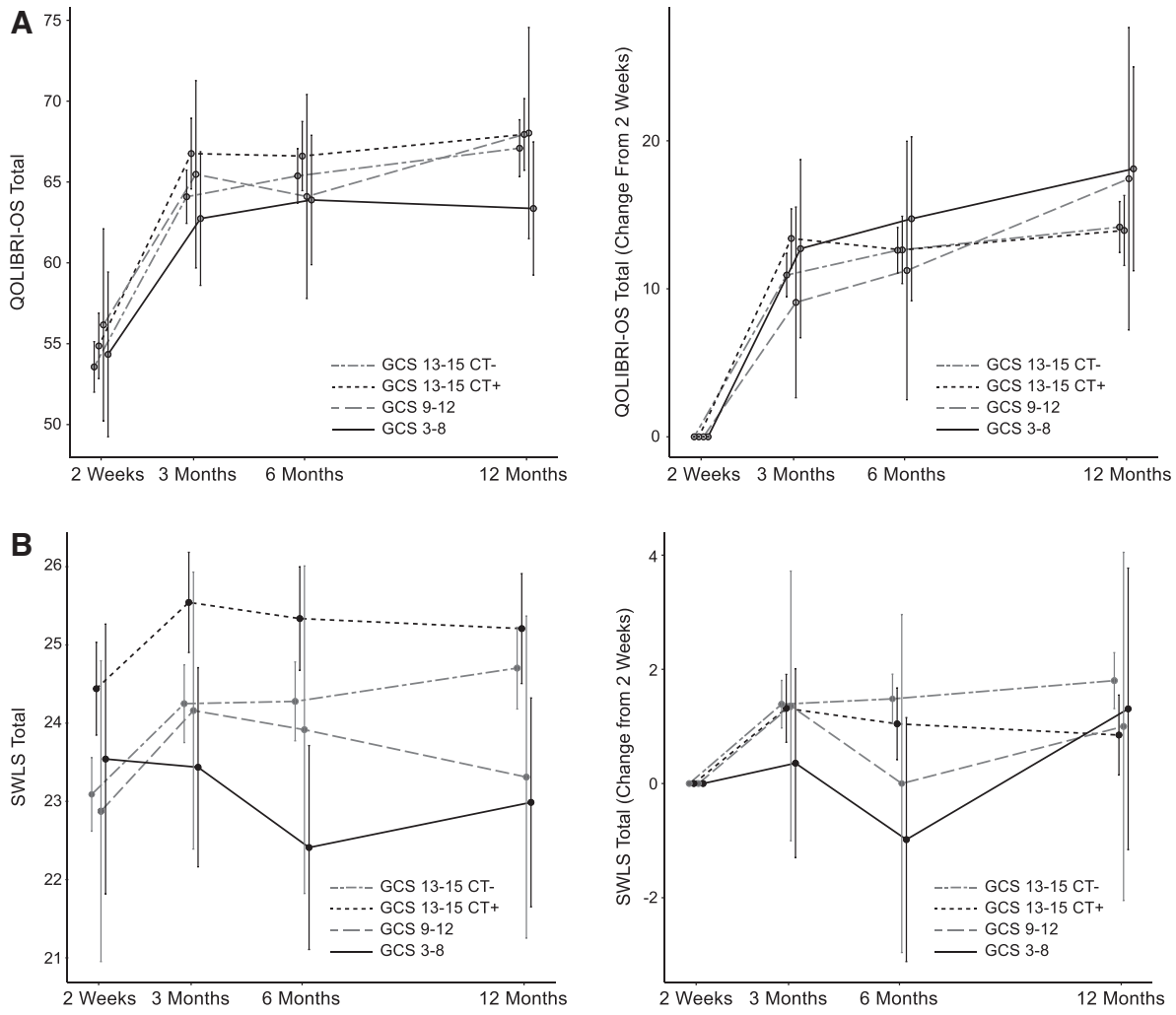

FIG. 2. Mean (95% confidence interval) of the Quality of Life After Brain Injury-Overall Scale (QOLIBRI-OS) **(A)** and Satisfaction with Life Scale (SWLS) **(B)** total scores from 2 weeks to 12 months post-injury, stratified by traumatic brain injury (TBI) severity. The left panel displays observed total scores on each inventory, while the right panel displays observed change scores from 2 weeks.

Relationship between QoL and TBI severity group

Figure 2 and Supplementary Table S3 depict the observed mean (and 95% confidence interval) of QoL by TBI severity group (GCS 13–15 CT-, GCS 13–15 CT+, GCS 9–12, GCS 3–8). Model-estimated mean differences in standardized QoL scores for pairwise comparisons among these four groups are presented in Table 4. QOLIBRI-OS showed no statistically significant differences among TBI severity strata over time. SWLS showed more separation than the QOLIBRI-OS comparing TBI severity strata, with the GCS 13–15 CT+ group showing significantly higher life satisfaction than either the GCS 13–15 CT- group (2 weeks and 3 months, standardized mean difference = 0.23–0.24) or the GCS 3–8 group (3–12 months, standardized mean difference = 0.33–0.43). The GCS 13–15 CT-, GCS 9–12, and GCS 3–8 groups were not significantly different in SWLS ratings.

Discussion

In this large, longitudinal study of TBI compared with controls across the injury spectrum, the TBI-specific QOL measure, QOLIBRI-OS, manifests larger differences in QoL between TBI and healthy individuals when compared with the SWLS across the 1st year post-injury. Similarly, differences in QoL between orthopedically injured and healthy individuals were stronger for the QOLIBRI-OS than for the SWLS from 2 weeks to 3 months post-injury. These findings imply that, as compared with the SWLS, the QOLIBRI-OS detects QoL issues that are more relevant to the traumatically

Table 4. Model-Estimated Standardized Mean Differences (M_{diff}) on the QOLIBRI-OS and SWLS Total Scores by TBI Severity Strata

	GCS 13-15 CT- vs. GCS 13-15 CT+	*GCS 13-15 CT- vs. GCS 9-12*	*GCS 13-15 CT- vs. GCS 3-8*	*GCS 13-15 CT+ vs. GCS 9-12*	*GCS 13-15 CT+ vs. GCS 3-8*	*GCS 9-12 vs. GCS 3-8*
	M_{diff}[a] (p)[b]	M_{diff}[a] (p)[b]	M_{diff}[a] (p)[b]	M_{diff}[a] (p)[b]	M_{diff}[a] (p)[b]	M_{diff}[a] (p)[b]
QOLIBRI-OS						
2 weeks	-0.11 (0.394)	-0.13 (0.877)	0.06 (0.967)	-0.02 (> 0.999)	0.18 (0.575)	0.20 (0.779)
3 months	-0.18 (0.062)	0.06 (0.983)	0.12 (0.771)	0.24 (0.446)	0.30 (0.060)	0.05 (0.991)
6 months	-0.09 (0.646)	0.14 (0.845)	0.04 (0.985)	0.23 (0.549)	0.13 (0.692)	-0.10 (0.953)
12 months	-0.07 (0.813)	0.05 (0.992)	0.14 (0.644)	0.12 (0.911)	0.21 (0.300)	0.09 (0.997)
SWLS						
2 weeks	**-0.24 (0.004)**	0.14 (0.867)	0.04 (0.993)	0.38 (0.135)	0.28 (0.181)	-0.09 (0.965)
3 months	**-0.23 (0.009)**	0.13 (0.865)	0.16 (0.521)	0.36 (0.126)	**0.39 (0.005)**	0.04 (0.997)
6 months	-0.18 (0.080)	0.14 (0.845)	0.25 (0.143)	0.32 (0.254)	**0.43 (0.002)**	0.11 (0.935)
12 months	-0.09 (0.623)	0.29 (0.361)	0.24 (0.196)	0.38 (0.139)	**0.33 (0.030)**	-0.05 (0.993)

Bolded *p* values indicate statistically significant differences.

[a]*Mdiff* symbol (negative or positive) represents difference in each comparison of TBI severity strata. Difference represents: the second severity strata in each column subtracted from first severity strata (e.g., GCS13–15 CT- minus GCS 13–15 CT+).

[b]*p* values were adjusted using Tukey's method for comparing a family of four time points.

CT, computed tomography; GCS, Glasgow Coma Scale, QOLIBRI-OS, Quality of Life After Brain Injury Scale-Overall Scale; SWLS, Satisfaction with Life Scale; TBI, traumatic brain injury.

injured population. As the first disease-specific scale for assessing HRQOL in TBI, these results are not surprising and are likely because the QOLIBRI-OS was designed to inquire about QoL in domains known to be affected by TBI, whereas the SWLS focuses on general life satisfaction.[21] These findings support using the QOLIBRI-OS as a measure of HRQOL in TBI and traumatic injury studies, consistent with similar work in other patient populations that has recognized the importance of disease-specific QoL metrics.[41,42]

In addition, the QOLIBRI-OS identified greater changes from 2 weeks through 1 year of follow-up in injured individuals when compared with the SWLS. In fact, the small changes observed in SWLS ratings for the TBI and OTC group were comparable with the small and unexpected improvement in life satisfaction observed in uninjured FC from 2 weeks to 3 months (standardized mean change = 0.18, vs. 0.19–0.20 for the injured groups). These findings may imply that the small improvement in SWLS reported by the TBI and OTC groups was the result of non-injury factors. Across TBI and OTC groups, health-related QoL as reported on the QOLIBRI-OS improved much more dramatically from 2 weeks to 3 months post-injury, with minimal changes after 3 months. This pattern of change aligns with the well-documented natural history of clinical recovery from TBI and further supports the QOLIBRI-OS as indexing injury-relevant outcomes.[28,43–46] Given the dynamic nature of recovery from traumatic injuries and relatively minimal changes in SWLS ratings over time in the injured groups, these findings also suggest that the SWLS does not measure the impact of injury on QoL and may instead reflect something else, such as one's innate sense of well-being.

There were few differences over time in SWLS and QOLIBRI across TBI subgroups differing in acute indicators of TBI severity. Overall, QoL was poorest in the most severely injured group (GCS 3–8) and was best in TBI patients with GCS 13–15; however, the direction of effect within the GCS 13–15 subgroups (i.e., better QoL in CT+ than in CT- participants) was opposite to what one would expect from these groups based on TBI injury severities alone. However, most TBI severity group differences were small in magnitude and non-significant, and those few comparisons that were significant were for the SWLS, which as described, was not associated with TBI and did not pick up on expected changes over time. Taken together, the data support assertions that there is not a consistent or strong relationship between TBI severity and QoL. This is consistent with prior findings suggesting minimal to no relationship between QoL and other self-report (e.g., symptom) outcome measures and TBI severity.[47–51] This phenomenon is likely multifactorial and could be secondary to differing levels of baseline resilience, degree of social support, anchoring, and adjustment effects that differentially impact TBI severity subgroups, or the ''disability paradox'' in which those who are more severely injured may have anosognosia and/or receive better support than those with mild injuries, and therefore, report QoL that is higher than might be expected.[52–56] Future studies are needed to evaluate the specific components that drive reductions in QoL in each TBI subgroup to determine identifiable features and potential interventions.

Our results suggest implications for future research and clinical considerations. In clinical practice, our findings support the idea that all individuals with TBI, even those with relatively mild TBI, may have sustained concerns about QoL as a result of injury and therefore should be offered long-term follow-up, including neuropsychological assessments and necessary rehabilitation. Additionally,

future TBI research studies should include the QOLIBRI-OS. As a newer instrument, QOLIBRI-OS was not included as a core measure in the NINDS TBI CDE, which favored the SWLS given its long history of use in TBI studies.[33] Our findings indicate that QOLIBRI-OS may be more appropriate than SWLS in measuring TBI-related QoL problems, and therefore, should be considered as a higher priority QoL outcome measure than the SWLS in a future revision of the TBI CDE.

Limitations

Our sample represents individuals with TBI at 18 level 1 trauma centers, and therefore, may not be applicable to individuals seen in non-academic, community settings, or those who do not seek clinical care. The samples differed at baseline when comparing highest level of care in OTC and TBI. This is likely because it is common for individuals with TBI to be admitted to ICUs for serial neurological examinations, whereas individuals with non-severe orthopedic injuries are more often discharged or admitted to non-ICU inpatient units. However, given the finding of essentially no relationship between level of care and QoL, this difference between groups is not likely to be a meaningful confound in this study. We also acknowledge that there was attrition over time that was not missing completely at random. However, because attrition was the same across the two instruments, conclusions drawn about the characteristics of the QOLIBRI-OS versus the SWLS can be made without concern for differential bias related to attrition across the two inventories. Lastly, we used the QOLIBRI-OS, whose advantage of brevity must be weighed against the benefits of completing the more detailed, full-length QOLIBRI scale. In particular, the QOLIBRI would allow for richer characterization of subdomains of QoL in this population. That we found dramatic group and time-related differences even for the ultra-short QOLIBRI-OS inventory highlights its superiority compared with the similarly brief SWLS for the purpose of assessing injury-related QoL in TBI and OTC populations.

Conclusion

The QOLIBRI-OS demonstrates greater differentiation of injured subjects from FCs than the SWLS. Additionally, the QOLIBRI-OS identifies more changes over time in individuals with TBI and OTC than the SWLS. Finally, TBI severity does not robustly predict QoL after an injury on either the QOLIBRI-OS or the SWLS. Our findings underscore the importance of the QOLIBRI-OS in describing injury-related QoL issues in individuals with TBI and other traumatic injuries.

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Authors' Contributions

Natalie Kreitzer, Sonia Jain, Jacob S. Young, Xiaoying Sun, and Lindsay D. Nelson contributed to the design of the study, analysis and interpretation of data, and drafting of the manuscript. Murray B. Stein, Michael A. McCrea, Harvey S. Levin, and Joseph T. Giacino contributed to the execution of the TRACK-TBI study, acquisition of data, and drafting of the manuscript, and critically reviewed and approved the final manuscript. Amy J. Markowitz and Geoffrey T. Manley contributed to the design of the study, execution of the TRACK-TBI study, andacquisition of data, and critically reviewed and approved the final manuscript. Opeolu Adeoye, Neeraj Badjatia, Kim Boase, Jason Barber, Yelena Bodien, M. Ross Bullock, John D. Corrigan, Karen Crawford, Ramon Diaz-Arrastia, Sureyya Dikmen, Ann-Christine Duhaime, Richard Ellenbogen, V. Ramana Feeser, Adam R. Ferguson, Brandon Foreman, Raquel Gardner, Etienne Gaudette, Dana Goldman, Luis Gonzalez, Shankar Gopinath, Rao Gullapalli, J Claude Hemphill, Gillian Hotz, C. Dirk Keene, Frederick K. Korley, Joel Kramer, Chris Lindsell, Joan Machamer, Christopher Madden, Alastair Martin, Thomas McAllister, Randall Merchant, Pratik Mukherjee, Laura B. Ngwenya, Florence Noel, Amber Nolan, David Okonkwo, Eva Palacios, Daniel Perl, Ava Puccio, Miri Rabinowitz, Claudia Robertson, Jonathan Rosand, Angelle Sander, Gabriella Satris, David Schnyer, Seth Seabury, Mark Sherer, Sabrina Taylor, Nancy Temkin, Arthur Toga, Alex Valadka, Mary Vassar, Kevin Wang, John K. Yue, Esther Yuh, and Ross Zafonte contributed to the execution of the TRACK-TBI study and acquisition of data, and critically reviewed and approved the final manuscript.

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Supplementary Material

Supplementary Table S1
Supplementary Table S2
Supplementary Table S3

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