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Quality of life after traumatic brain injury: The clinical use of the QOLIBRI, a novel disease-specific instrument

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Abstract

Objective: To report the clinical use of the QOLIBRI, a disease-specific measure of health-related quality-of-life (HRQoL) after traumatic brain injury (TBI).

Methods: The QOLIBRI, with 37 items in six scales (cognition, self, daily life and autonomy, social relationships, emotions and physical problems) was completed by 795 patients in six languages (Finnish, German, Italian, French, English and Dutch). QOLIBRI scores were examined by variables likely to be influenced by rehabilitation interventions and included socio-demographic, functional outcome, health status and mental health variables.

Results: The QOLIBRI was self-completed by 73% of participants and 27% completed it in interview. It was sensitive to areas of life amenable to intervention, such as accommodation, work participation, health status (including mental health) and functional outcome.

Conclusion: The QOLIBRI provides information about patient's subjective perception of his/her HRQoL which supplements clinical measures and measures of functional outcome. It can be applied across different populations and cultures. It allows the identification of personal needs, the prioritization of therapeutic goals and the evaluation of individual progress. It may also be useful in clinical trials and in longitudinal studies of TBI recovery.

Keywords: *Traumatic brain injury, health-related quality of life, assessment, international, multi-centre study, QOLIBRI*

Introduction

Traumatic brain injury: A 'silent epidemic'

Traumatic brain injury (TBI) is a major cause of death and of disability, particularly in persons under 40 years of age. The number of disability cases due to TBI was estimated at ~5.3 million in the US in 1996; extrapolated to the 2006 European Community countries this suggests that in 2006 there were ~6.2 million Europeans with TBI-related disability [1, 2].

However, this 'silent epidemic' is not widely known and its importance to public health insufficiently recognized [3]. Although the incidence of TBI is high and increasing for elderly persons [4] in Western societies, worldwide it mainly affects

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adolescents and young adults in traffic accidents and comes at a time when they are making decisions about important life issues regarding independence, work and relationships. The long-term cognitive, emotional and physical impairments due to TBI and the resulting limitations of daily-life activities affect the person's self-image, coping strategies and ultimately their health-related quality-of-life (HRQoL) as well as that of their significant others [5–7]. Improving HRQoL should be the ultimate goal in the rehabilitation of patients with TBI and assessing HRQoL in this population is necessary to achieve this goal.

The World Health Organization (WHO) defines quality of life (QoL) 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' ([8], p. 153). HRQoL, a sub-set of this QoL concept, explicitly relates to those aspects of life affected by health [9, 10]. Increasingly, over the past two decades, there has been a trend to apply disease-specific HRQoL instruments in addition to generic health scales, such as the SF-36 Health Survey. This is particularly relevant to TBI as specific aspects, such as cognitive dysfunction and social disruption, are insufficiently captured by generic HRQoL measures [11–15]. No widely used and validated disease-specific HRQoL measures are as yet available for TBI.

Factors influencing HRQoL of patients with TBI

In comparison to the extensive literature on outcome after TBI, relatively few studies have reported on HRQoL and these have mainly focused on severe TBI. Three long-term studies with matched comparison groups have reported overall HRQoL to be perceived as significantly lower by people who have sustained either severe or mild/moderate TBI than by healthy controls [16–18].

Greater initial severity—as measured by the Glasgow Coma Scale (GCS), post-traumatic amnesia (PTA), length of hospital stay—and Glasgow Outcome Scale score (GOS) at discharge appear to predict poorer outcomes in terms of return to work, family and social relationships and leisure activities [18].

The relation between injury severity and HRQoL is less clear. Although coma length has been shown to predict long-term HRQoL [16], various other studies find no statistically significant relationships between initial injury severity and HRQoL [12, 15, 19–22] and one even reports slightly higher life satisfaction ratings at 1 year post-TBI, although not at 2-year follow-up, in more severely injured subjects [18].

The relationship between outcome measured by the GOS and HRQoL is also not straightforward. One study reported that severely disabled patients had a better HRQoL than those who were moderately disabled [23].

There is some evidence that pre-injury demographic variables predict subsequent health status or HRQoL, including age [24], gender [24, 25] and substance abuse [24–26], although other studies have not confirmed these findings [18, 20].

A wide variety of sequelae have been reported to be associated with lower HRQoL after TBI: inability to perform extended activities of daily life (ADL) [5, 23, 24], cognitive impairment [5, 24], sleep–wake disturbances and fatigue [27–30], deterioration in emotional status [22, 23, 31], pain [32, 33], impaired communication skills [34], low level of social participation and relationships [16, 20], loss of participation in desired everyday occupations [35] and vocational status [22, 26, 30, 36]. These sequelae have been found to be among the strongest predictors of distress for significant others [37–39]. Consistent with these findings, Vickery et al. [22] found that patients with a poor self-concept reported lower HRQoL. Steadman-Pare et al. [25] reported that the strongest long-term predictors of HRQoL after TBI are mental health, followed by self-rated health, employment, leisure, social relationships and emotional support.

The functional limitations above are associated with depression, which is also directly associated with brain lesions [40] and pituitary hormone deficiencies [41–43]. In addition, depression may also be a consequence of deterioration in function over time after injury. When combined with psycho-social factors leading to hopelessness—including the onset of disability, loss of pre-injury lifestyle, occupation and the realization of a circumscribed life requiring ongoing support—depression may have a deleterious effect. Approximately one in every five TBI-sufferers attempts suicide and the suicide rate is between 2.4–4.1-times higher than that among matched controls or general populations [44–47]. The most likely cause of these associations is neurobehavioural impairment leading to changes in personality, disability and/or mental health; associations that are comprehensively reviewed by Fleminger [48].

There is limited evidence that for a few people occurrence of a TBI may lead to improved HRQoL, consistent with the post-traumatic growth hypothesis [49]. Some patients find new personal strengths and new relationships and re-orientate their life priorities [50] and others may cease their problem drug use [51].

Overall, the evidence suggests good reasons for reporting poor HRQoL among patients with TBI [52].

A new TBI-specific HRQoL measure

To assess trauma severity and clinical outcomes after TBI there are now well-established and widely-used TBI-specific instruments available, including the Glasgow Coma Scale (GCS) [53], the Coma Remission Scale [54] and the Coma Recovery Scale [55] to measure recovery from coma, the Glasgow Outcome Scale (GOS) or its extended version, GOSE [56, 57], the Disability Rating Scale [58] and the Mayo-Portland Inventory (MPAI) [59] to index disability, the Community Integration Questionnaire (CIQ) [60] to assess social reintegration and finally the International Classification of Functioning, Disability and Health (ICF) as a framework for describing functioning and health [61].

In contrast, for TBI-related HRQoL such condition-specific tools do not exist and clinicians and researchers have most often relied on measures which explore an individual's capacity to carry out various daily functions, such as the SF-36/Rand-36/SF-12 [13, 16, 21, 24, 62–67] or the European Brain Injury Questionnaire (EBIQ) [68–76]. Increasingly, however, the limitations of such instruments have been recognized and there has been rising interest in developing condition-specific HRQoL measures which target the characteristics of a particular population, disease or condition [12, 14, 15].

In 1999, Neugebauer and von Wild organized an international and interdisciplinary consensus conference funded by the German Ministry of Education and Research. This conference recommended the development of a measure for the systematic HRQoL assessment of patients with multiple injuries [12, 14, 77]. It became apparent that no existing measure took into account specific factors likely to affect HRQoL for patients with TBI. An international and multidisciplinary Task Force on TBI-QoL was therefore established to develop a new HRQoL measure—the QOLIBRI [12, 14, 77, 78]. In setting out to develop a robust and valid multidimensional measure, the Task Force recruited a much larger and more multicultural sample than has been reported in previous studies of HRQoL in patients with TBI. The initial development, validation and psychometric analysis of the QOLIBRI scale has been described elsewere [78–82].

The aim of the current report is to focus on the clinical application of the QOLIBRI, its potential use and added value. This study explores associations with clinical parameters which are likely to be of particular interest and relevance to clinical teams working with patients at various stages of their treatment and rehabilitation and highlights conceptual and design features of the instrument which relate directly to its clinical utility.

Methods

Participants

The study sample was the QOLIBRI validation study sample [80] with convenience sample participants drawn from Belgium, Finland, France, Italy, the Netherlands, the UK and the USA. Participants from Australia and Germany were randomly drawn from participating hospital trauma records.

The inclusion criteria were: ICD-10 diagnosis of TBI; age 15 or more at injury and 17–68 years at recruitment to the study; 3 months to 18 years after injury, capacity to give informed consent; and adequate cognitive and behavioural functioning to understand, answer and cooperate. Exclusion criteria were: GOSE <3; spinal cord injury; pre-traumatic or current psychiatric disease; ongoing addiction; and terminal illness. Nine hundred and twenty-one participants were recruited altogether. Due to missing data the current study is based on the 795 participants for whom GCS and GOSE data were available.

Measures

HRQoL was assessed by the QOLIBRI. This consists of two parts with a total of 37 items across six sub-scales [81]. The first part assesses level of satisfaction within four domains: cognition (seven items), self (seven items), daily life and autonomy (seven items) and social relationships (six items). The second part asks respondents how 'bothered' they are in relation to two domains: emotions (five items) and physical problems (five items). The items of the QOLIBRI English version are presented in the Appendix. The completion mean time was reported at 11 minutes for self-completion and 20 minutes for face-to-face interview, although this is likely to vary by disability level.

The QOLIBRI total scores were obtained by simple summation of 37 item scores (graded 1–5), after reversal of 10 'bothered' items in order to have a 'satisfaction global score'. Then, the maximum score is $37 \times 5 = 185$. Afterwards, the QOLIBRI scores are presented on a 0 (worst possible score on the QOLIBRI) to 100 (best possible score) scale (although this is a percentage scale it is more common among HRQoL instruments to describe this as a 0–100 point scale).

Probable anxiety and depression were identified by the Hospital Anxiety and Depression Scale (HADS) [83] using the cut-points recommended by the developers; viz., 10/11 for probable anxiety or depression [84]. Because correlation between the two scales has been reported as evidence of real coincidence between anxiety and depression [85], cases were coded as those who did not meet the criteria for either probable anxiety or depression, those who met the criteria for either alone and those who met the criteria for a dual diagnosis of both anxiety and depression (cothymia).

Functional outcome was examined with the GOSE which is the extended version of the GOS [56, 57]. The GOSE assigns functional outcome to one of eight levels: dead (1), vegetative (2), lower severe disability (3), upper severe disability (4), lower moderate disability (5), upper moderate disability (6), lower good recovery (7) and upper good recovery (8). There were, obviously, no cases in the study in the range 1–2. Scoring of the GOSE was based on the overall interviewer impression and missing data imputed using a computer algorithm developed by the author (L. Wilson) of the GOSE.

The injury date, main site of brain damage, GCS scores (24-hour) and length of post-traumatic amnesia (PTA) were extracted from the medical records. Brain damage site was coded into those with no lesion, frontal lesion (left and/or right), posterior (left, right, posterior fossa, peri-ventricular) and diffuse injury. PTA was coded in <1 day, 1–7 days, 8–28 days and 29 + days. GCS scores were coded into three levels: severe (GCS score 3–8), moderate (9–12) and mild (13–15).

Finally, two health and socio-demographic questionnaires asked for details of health complaints (or co-morbid conditions) and socio-demographic details. The number of health complaints in this paper was classified into 0, 1–2, 3–5, 6–10 and ≥11. Socio-demographic information included gender (male/female), age, education attainment (primary/secondary/trade certificate/college diploma or degree/university degree), partner status (single/partnered/post-partnered (defined as those who were separated, divorced or widowed), labour-force participation (working full-time, part-time or self-employed/unable to work/unemployed/out of the labour-force—including students, homemakers and those who were retired) and the extent of caregiver support.

Procedure

After receiving the participant's (or his/her representative's) informed consent, the interviewer (a psychologist or trained interviewer) determined if the participant was able to respond to the self-report questionnaires independently. If yes, the questionnaires were completed in the clinic or sent and returned by mail. If no, participants completed the questionnaire in a face-to-face interview or by telephone. Administration mode was partly a function of local data collection protocol. Subject to this caveat 71.3% self-completed the questionnaire (30.2% at the clinic or hospital and 41.1% by mail), 27.1% completed it in a face-to-face interview and 1.6% over the telephone. Those with severe disability (GOSE score 3–4) were significantly more likely to have had the questionnaire administered in a face-to-face interview, those with a moderate disability (GOSE score 5–6) were more likely to complete it through the mail and those with a good recovery (GOSE 7–8) to complete it over the telephone ($\chi^2 = 59.76$, df = 6, $p < 0.01$).

This study was approved by the local ethics committees.

Statistical analyses

Missing data for categorical variables were not imputted and list-wise deletion was used during data analyses; for categorical variables missing data varied between 0.1–8.8% of cases, the exception was PTA with 16.7% missing. For scale scores (e.g. the HADS) missing data was imputed using horizontal mean imputation for up to 1/3 of items. Where >1/3 of items were missing list-wise deletion was used.

Categorical data are presented as counts or percentages and chi-square (χ^2) was used for the analysis. Continuous variables are reported as means and standard deviations (SD). Examination of skewness revealed that all QOLIBRI scales were statistically skewed. Therefore, all statistical analyses were carried out on square-root transformed data although non-transformed means and SDs are presented for easy reader interpretation.

To compare between mean transformed scores on the QOLIBRI scales, the paired *t*-test was used. For differences between known groups QOLIBRI scale scores (transformed) were analysed with analysis of variance (ANOVA) and where omnibus statistical significance was reported differences between known groups were examined using the post-hoc Tukey HSD (honestly significantly difference) test.

Pearson correlations were used to report relationships between scale scores. Receiver operating curve analysis (ROC) was used to examine the sensitivity and specificity of the QOLIBRI total score and to identify appropriate cut-points for suggested clinical follow-up. Relative risks were calculated to quantify the risk findings from the ROC analyses.

Consistent with Rothman [86] and Perneger [87], the test value for the study was set at $p = 0.05$.

Descriptive values (e.g. percentages) are reported to 1-decimal place, standard deviations to 2-decimal places and statistical values to 2-decimal places. Data analysis was carried out in SPSS Version 15.0 [88].

Results

Population characteristics

There were six language groups and corresponding countries: Finnish ($n = 157$, 19.7% of sample), German ($155 = 19.5\%$), Italian ($139 = 17.5\%$), French (France and Belgium; $148 = 18.6\%$), English (Australia, UK, USA; $97 = 12.2\%$) and Dutch ($99 = 12.5\%$).

Table I shows the injury and socio-demographic details of participants. Almost three-quarters of participants were middle-aged males. Almost half of the participants were partnered and the commonest education attainment was holding a trade qualification. Almost two-thirds were living independently and just under half were working. The mean time at interview since TBI was just under 5 years (the range was 3–214 months). The most common lesion sites were frontal and diffuse and the highest proportion of cases persisted in PTA for a month or more post-TBI. Finally, 58% were classified with a severe brain injury according to the GCS.

Current health and functional status

As Table II shows, most participants reported they were in good health. This may be explained by both impaired functioning after TBI and by health complaints, as shown by the fact that 70% of participants reported at least three health complaints (see Table II). Although not shown in Table II, self-reported health complaints involving >30% of participants were a lack of energy (43.3%), a lack of physical strength (37.3%), sleep disorders (37.2%), vision problems (35.8%), headache or migraine (35.7%), nervousness (36.1%), back pain (33.8%), restricted movements (32.3%) and depression (30.6%).

Table II also shows GOSE scores, revealing that the most commonly reported levels were lower moderate disability and upper moderate disability.

Regarding participants' mental health status, based on the HADS 19.2% reported moderate or severe anxiety symptoms and 16.7% reported depressive symptoms. The estimates in Table II show the proportions for those meeting the criteria for anxiety and depression only and the proportion meeting the dual diagnosis criteria. The table also

Table I. Characteristics of participants.

	Category	%[a]
Gender	Male	72.1%
Age	Years (mean, SD)	39.0 (13.3)
Education attainment	Primary	5.7%
	High/Secondary	25.0%
	Trade certificate	29.5%
	College diploma/degree	23.4%
	University degree	11.9%
Partner status[b]	Single	40.6%
	Partnered	47.2%
	Post-partnered	12.1%
Living arrangements	Living independently	58.3%
	Supported by partner, family or carer	34.0%
	Living in sheltered accommodation[c]	7.8%
Labour-force participation[d]	Working	44.1%
	Unable to work	10.2%
	Unemployed	15.0%
	Out of the workforce	30.8%
Time since injury (interviewed)	Months (mean, SD)	59.9 (46.7)
Lesion site[e]	No lesion	14.9%
	Frontal	32.6%
	Posterior	20.6%
	Diffuse	31.8%
PTA[e]	<1 day	19.3%
	1–7 days	23.9%
	8–28 days	20.2%
	29 + days	36.6%
Glasgow Coma Scale classification[e]	Mild (13–15)	32.1%
	Moderate (9–12)	9.6%
	Severe (3–8)	58.4%

[a]Base number of participants = 795. Percentages are valid percentages, after excluding missing cases and 'other' responses. Missing: gender ($n = 0$), age (0), education (89), partner status (52), living arrangements (74), labour force (96), time since injury (3), lesion site (10), PTA (133), GCS (0).
[b]Partnered = married or *de facto*; Post-partnered = separated, divorced, widowed.
[c]Sheltered housing, community housing, nursing home or hospital ward.
[d]Working = fulltime, part-time, self-employed; Unable to work = temporarily, permanently; Out of the labour-force = homemaker, student, voluntary work, retired.
[e]Data from the medical record.

shows that 53.7% of participants also needed a carer for at least one activity of daily living.

The QOLIBRI total scores are presented graphically in Figure 1. This shows that the most commonly obtained scores fell within the band with 71–75% of maximum satisfaction and that the data were skewed with a tail towards the lower scores, indicating poor HRQoL for these participants.

Age and gender

Table III breaks the QOLIBRI scale scores down by age group and gender. The scales with the highest

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Table II. Current health and functional status of participants.

	Category	%[a]
Self-reported health status	Excellent	7.1%
	Very good	23.6%
	Good	43.2%
	Fair	22.4%
	Poor	3.7%
Number of health complaints	0	8.2%
	1–2	21.1%
	3–5	31.3%
	6–10	30.4%
	≥11	8.9%
GOSE scores	3; Lower severe disability	3.6%
	4; Upper severe disability	14.3%
	5; Lower moderate disability	29.7%
	6; Upper moderate disability	24.8%
	7; Lower good recovery	15.5%
	8; Upper good recovery	12.1%
HADS anxiety & depression delineation	Symptoms did not meet criteria	71.5%
	Anxiety only (cut-point: 11+)	11.8%
	Depression only (cut-point: 11+)	9.4%
	Dual diagnosis (anxiety & depression)	7.4%
Carer status (needing help)[c]	0; Does not need help	46.3%
	1; Help needed with 1 ADL task	20.1%
	2; Help needed with 2 ADL tasks	13.8%
	3; Help needed with 3 ADL tasks	9.6%
	4/5; Help needed with 4/5 ADLs	10.2%

[a]Percentages are valid percentages, after excluding missing cases.
[b]t-test compared with US population norms (50.00 (SD = 10)), t-value range from −7.86 (95% CI: −3.75–2.24) for Vitality to −17.35 (95% CI: −8.36 to −6.66) for Role physical (all $p < 0.01$).
[c]ADLs were personal needs, mobility, daily activities, transportation and management of personal affairs.
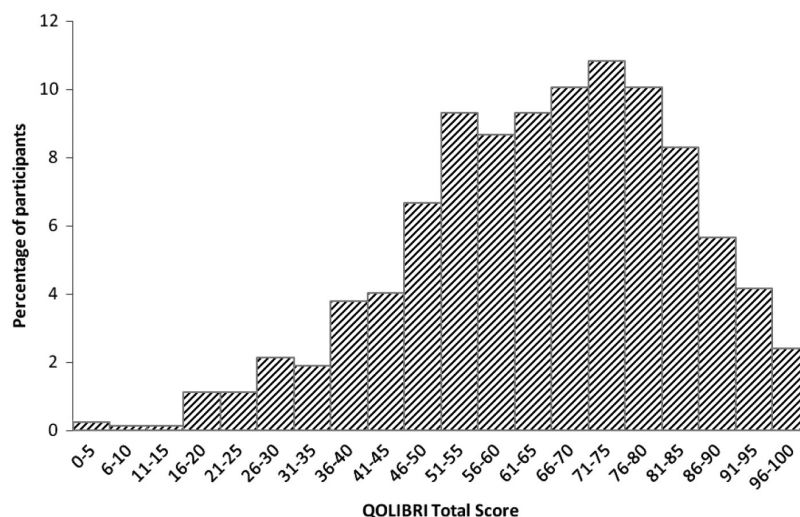
Figure 1. QOLIBRI total score: distribution of mean scores on 0–100 scale.

scores were Emotions, Physical and Daily Life & Autonomy. Lower levels of life satisfaction were reported on the Social, Cognition and Self-perception scales (all statistically significantly different, paired t-test values −2.10 to 43.39, $p < 0.04$ for all tests). The mean scores show that, regardless of clinical outcomes, QOLIBRI scores systematically varied by age on four scales and the QOLIBRI total score with those aged 35–54 obtaining the lowest QOLIBRI scores.

Table III. QOLIBRI scale scores, by gender and age group.

QOLIBRI scale	Age group	Male			Female			All		
		n	M	SD	n	M	SD	n	M	SD
Cognition	17–24 years	94	62.68	21.39	37	63.61	15.97	131	62.94	19.95
	25–34	160	64.29	20.78	54	64.19	20.98	214	64.26	19.95
	35–44	126	60.23	22.02	46	58.85	23.12	172	59.86	19.95
	45–54	103	56.35	23.31	51	59.21	19.19	154	57.30	19.95
	55–69	89	60.49	22.31	34	62.04	27.43	123	60.92	19.95
	All	572	61.11	21.96	222	61.51	21.37	794	61.22	19.95
Self	17–24	94	62.16	21.14	37	59.48	21.20	131	61.40	21.11
	25–34	160	65.27	20.68	54	61.43	22.39	214	64.30	21.14
	35–44	127	59.28	22.97	46	56.37	25.22	173	58.50	23.55
	45–54	103	57.21	22.56	51	53.89	20.51	154	56.11	21.89
	55–69	89	58.00	22.63	34	55.67	22.50	123	57.36	22.53
	All	573	60.85	22.07	222	57.44	22.41	795	59.90	22.21
Daily life and autonomy	17–24	94	68.38	21.81	37	71.14	17.12	131	69.16	20.57
	25–34	159	69.08	21.16	54	68.94	22.95	213	69.04	21.57
	35–44	127	66.73	22.67	46	61.66	26.42	173	65.38	23.75
	45–54	103	62.51	22.46	51	61.96	23.31	154	62.32	22.67
	55–69	89	63.27	24.01	34	66.86	23.89	123	64.27	23.93
	All	572	66.36	22.37	222	65.87	23.21	794	66.22	22.60
Social relationships	17–24	94	63.53	22.10	37	66.89	18.86	131	64.48	21.22
	25–34	160	63.77	22.15	54	62.65	21.96	214	63.49	22.05
	35–44	127	60.90	23.32	46	69.11	22.47	173	63.10	23.32
	45–54	103	61.12	23.36	51	63.81	23.91	154	62.01	23.50
	55–69	89	64.30	22.89	33	69.94	24.77	122	65.82	23.45
	All	573	62.70	22.70	221	66.06	22.48	794	63.64	22.68
Emotions	17–24	93	73.71	25.06	36	65.03	29.34	129	71.29	26.50
	25–34	160	74.59	23.55	54	66.39	23.46	214	72.52	23.74
	35–44	126	70.78	24.27	46	70.11	31.65	172	70.60	26.35
	45–54	102	70.25	23.91	51	68.63	23.86	153	69.71	23.82
	55–69	89	73.26	24.09	34	74.89	24.70	123	73.71	24.17
	All	570	72.62	24.09	221	68.77	26.55	791	71.54	24.84
Physical problems	17–24	93	71.80	21.89	37	65.88	23.58	130	70.12	22.45
	25–34	160	72.05	21.76	54	67.15	21.77	214	70.81	21.82
	35–44	127	70.95	21.75	46	60.00	27.67	173	68.04	23.88
	45–54	103	61.32	23.84	51	60.56	24.13	154	61.07	23.86
	55–69	89	69.00	24.62	34	69.01	25.68	123	69.00	24.81
	All	572	69.36	22.88	222	64.23	24.56	794	67.93	23.46
QOLIBRI total	17–24	94	66.37	17.73	37	65.32	15.39	131	66.07	17.05
	25–34	160	67.74	16.81	54	64.98	17.37	214	67.04	16.95
	35–44	127	64.23	18.39	46	62.27	21.22	173	63.71	19.14
	45–54	103	60.98	18.76	51	60.97	17.48	154	60.98	18.29
	55–69	89	64.08	19.37	34	65.43	20.72	123	64.45	19.67
	All	573	64.95	18.17	222	63.62	18.42	795	64.58	18.24

Statistics: ANOVA (transformed data): Cognition: $F_{model} = 2.15$, $p = 0.06$; $F_{age} = 2.68$, $p = 0.03$, $F_{gender} = 0.15$, $p = 0.70$. Self: $F_{model} = 3.96$, $p < 0.01$, $F_{age} = 3.99$, $p < 0.01$, $F_{gender} = 3.17$, $p = 0.08$. Daily life and autonomy: $F_{model} = 2.06$, $p = 0.07$, $F_{age} = 2.57$, $p = 0.04$, $F_{gender} = 0.01$, $p = 0.97$. Social relationships: $F_{model} = 1.17$, $p = 0.32$, $F_{age} = 0.64$, $p = 0.64$, $F_{gender} = 3.48$, $p = 0.06$. Emotions: $F_{model} = 1.28$, $p = 0.27$, $F_{age} = 0.82$, $p = 0.51$, $F_{gender} = 2.86$, $p = 0.09$. Physical problems: $F_{model} = 5.10$, $p < 0.01$, $F_{age} = 4.64$, $p < 0.01$, $F_{gender} = 5.73$, $p = 0.02$. QOLIBRI total: $F_{model} = 2.29$, $p = 0.04$, $F_{age} = 2.65$, $p = 0.03$, $F_{gender} = 0.58$, $p = 0.45$.
Note: F_{model} is the overall F for each ANOVA.

Only one of the scales (Physical) statistically significantly varied by gender with males obtaining scores higher than females. Regarding differences, the scales with the largest differences between age groups were the Physical problem scale (11-points differences for males and 10-points for females), the Daily Life and autonomy scale (7-points for males and 9-points for females) and the Emotions scale (5-points for males and 10-points for females).

QOLIBRI sub-scales and socio-demographic variables

The relationship between key socio-demographic variables and the QOLIBRI are presented in Table IV. These data and the transformed analyses suggest that Cognition, Daily life, Physical and the QOLIBRI overall scales were sensitive to education attainment. Post-hoc Tukey HSD analysis showed

Table IV. QOLIBRI scale scores by demographics and self-reported health status.

		n	Cognition M	SD	Self M	SD	Daily life and autonomy M	SD	Social relationships M	SD	Emotions M	SD	Physical problems M	SD	QOLIBRI total M	SD
Education attainment	Primary	42	52.00	23.23	50.37	24.52	54.46	22.48	62.60	23.99	67.38	25.76	58.04	23.08	56.79	19.29
	High/Secondary	185	60.40	22.40	62.01	21.20	66.83	21.94	64.30	23.00	69.88	25.02	69.06	23.41	64.92	18.04
	Trade certificate	218	62.06	21.92	60.76	21.76	66.53	22.13	64.58	21.87	72.49	24.21	67.82	24.11	65.21	18.28
	College	173	61.42	21.61	59.83	22.72	64.88	24.02	64.09	23.38	72.91	25.37	67.43	22.95	64.62	18.72
	University degree	88	66.31	20.84	60.58	23.17	72.94	21.32	64.84	22.49	77.12	22.32	74.57	21.98	68.74	17.61
			$F=2.49$, $p=0.03$		$F=1.78$, $p=0.11$		$F=4.20$, $p<0.01$		$F=0.05$, $p=0.99$		$F=1.7$, $p=0.13$		$F=3.06$, $p<0.01$		$F=2.43$, $p<0.03$	
Partner status	Single	302	62.97	20.64	61.78	21.11	67.01	21.30	61.54	21.44	72.68	24.18	71.25	21.60	65.65	16.98
	Partnered	351	60.34	23.23	59.84	22.61	66.66	23.99	67.97	22.50	72.64	24.19	66.43	24.92	65.15	19.21
	Post-partnered	90	60.26	21.62	56.61	23.22	63.40	22.74	59.88	24.57	68.22	27.09	66.58	23.20	62.03	18.91
			$F=1.13$, $p=0.32$		$F=1.85$, $p=0.16$		$F=1.02$, $p=0.36$		$F=8.78$, $p<0.01$		$F=0.94$, $p=0.39$		$F=3.06$, $p=0.05$		$F=1.33$, $p=0.26$	
Living arrangements	Independent	420	64.41	21.36	62.62	21.34	71.95	20.60	66.53	22.18	74.95	23.76	72.26	22.14	68.32	17.39
	Supported	245	55.21	22.19	55.83	22.54	56.78	23.48	60.76	23.26	68.51	24.60	61.27	24.10	59.07	18.51
	Sheltered	56	62.44	20.54	58.50	23.47	62.84	20.46	61.98	22.52	65.27	26.20	69.73	23.11	63.06	17.67
			$F=14.27$, $p<0.01$		$F=7.51$, $p<0.01$		$F=38.74$, $p<0.01$		$F=5.24$, $p<0.01$		$F=8.82$, $p<0.01$		$F=17.40$, $p<0.01$		$F=21.35$, $p<0.01$	
Labour-force participation	Working	308	65.68	21.05	66.04	19.96	73.93	21.42	69.47	20.45	77.59	22.36	74.57	21.99	70.66	17.17
	Unable to work	71	55.48	25.65	51.83	26.14	54.84	24.41	55.48	24.97	64.64	25.58	56.41	25.69	56.05	20.47
	Unemployed	105	57.01	20.55	56.73	21.22	61.05	19.94	60.17	23.10	66.64	26.86	65.44	22.13	60.67	17.02
	Out of workforce	215	58.94	21.58	56.29	22.51	62.30	22.24	62.01	23.86	68.94	25.00	65.28	23.34	61.78	17.90
			$F=8.30$, $p<0.01$		$F=14.04$, $p<0.01$		$F=25.16$, $p<0.01$		$F=10.35$, $p<0.01$		$F=10.54$, $p<0.01$		$F=16.00$, $p<0.01$		$F=21.43$, $p<0.01$	
Self-reported health status	Excellent	55	73.83	21.17	77.13	21.23	80.11	20.13	74.09	20.79	77.48	24.83	81.95	19.23	77.07	18.07
	Very good	184	70.97	19.61	69.61	19.80	78.62	18.64	71.22	21.59	82.24	18.15	80.68	16.76	74.97	15.16
	Good	337	60.86	19.37	60.80	17.37	66.44	18.24	63.58	20.94	71.55	24.41	69.42	20.62	64.95	14.44
	Fair	175	52.53	19.72	48.07	20.85	53.44	21.91	56.53	20.74	63.16	24.10	52.48	23.37	53.96	15.69
	Poor	29	31.55	21.96	23.40	22.52	33.04	26.35	35.57	25.32	40.18	26.40	37.11	19.45	32.92	16.07
			$F=41.15$, $p<0.01$		$F=63.67$, $p<0.01$		$F=61.80$, $p<0.01$		$F=25.54$, $p<0.01$		$F=29.06$, $p<0.01$		$F=62.52$, $p<0.01$		$F=81.35$, $p<0.01$	

Statistics: ANOVA$_{adj}$.
For full definitions of coding see the notes to Tables I and II.

that the statistically significantly group was those who had achieved primary school level education only; they obtained significantly lower Cognition scores when compared with those with trade of university qualifications ($p = 0.05$ and $p < 0.01$, respectively). For Daily life primary school-level attainment was significantly lower than all other education attainment levels ($p < 0.04$ for all comparisons) and for Physical primary school attainers obtained scores that were significantly below those of university attainers ($p < 0.01$). Finally, on the QOLIBRI total scale there were statistically significant differences between primary school attainers and those with trade and university qualifications, the latter having higher scores ($p = 0.04$ and $p < 0.01$).

There were also significant differences by partnership status on the Social and Physical scales. When compared with those who had never partnered, those with a partner obtained scores that were significantly higher on the Social scale (Tukey HSD, $p < 0.01$). Similarly the partnered obtained scores that were statistically significantly higher than the post-partnered ($p < 0.01$). On the Physical scale those who were single obtained scores significantly higher than those with a partner ($p = 0.04$). There were no other significant differences by relationship status.

There were statistically significant differences on all QOLIBRI scales by participants' living arrangements. Across all QOLIBRI scales the highest scores were obtained by those living independently and for all scales these scores were statistically higher than those obtained by those living at home with the support of their family or a caregiver (Tukey HSD, $p < 0.01$ for all comparisons). There were no statistically significant differences on the QOLIBRI scales between those living at home with family or caregiver support and those living in sheltered accommodation, other than the Physical Problems scale (Tukey HSD, $p = 0.03$).

There were also statistically significant differences on all QOLIBRI scales by labour-force participation. On all scales those who were working obtained scores which were statistically significantly higher than those of any other group. For the Cognition, Self, Social relationships and Emotions scales there was no statistically significant difference between those who were unable to work, who were unemployed or who were out of the workforce. For the Daily living and autonomy and the QOLIBRI total score, those out of the labour-force obtained scores significantly higher than those unable to work (Tukey HSD, $p = 0.04$ and $p = 0.05$, respectively) and on the Physical problems scale those who were unemployed obtained scores significantly higher than those who were unable to work.

QOLIBRI sub-scales and functional outcome

Figure 2 shows QOLIBRI scores by GOSE classifications. As shown, there were statistically significant differences between the QOLIBRI scales at all levels of GOSE functional outcome. Across the GOSE, there were different patterns among the QOLIBRI scales, suggesting that different scales are differentially sensitive to different levels of functioning. The increasing breadth of the 95% CIs with lower levels of GOSE is a function of the smaller numbers of cases in these GOSE classification levels (at GOSE level 3 there were 29 cases). A possible concern, however, is with the non-monotonicity by GOSE level 3 scores, but as shown in the Tukey HSD post-hoc tests there was no statistically significant difference between QOLIBRI scores on any of the QOLIBRI scales by GOSE level 3 vs. levels 4 and 5. In general, the Tukey HSD post-hoc analyses suggest that the QOLIBRI scales, although monotonic with the exception above, are not particularly sensitive to different levels of functional outcome, except at the more disabled (e.g. level 4) and good recovery levels (levels 7 and 8).

Mental health

Figure 3 shows the relationship between the QOLIBRI scales and the mental health of participants as assessed by the HADS, using the cut-points for the delineation of probable anxiety and depression. As shown, all scales were statistically significantly sensitive to participants' mental health status. Cognition and Physical were more sensitive to anxiety than to depression, but the other QOLIBRI scales were equally sensitive to the two mental health states. The data in Figure 3 suggests there are three distinct bandwidth scores for mental health: those who do not meet the HADS criteria for probable anxiety or depression, those who meet the criteria for one or the other and those who meet the criteria for dual diagnosis.

Receiver operating curve (ROC) analysis was used to explore the optimum cut-points delineating probable anxiety and depression. For identification of those meeting the HADS cut-points of anxiety, depression or both, the optimum cut-point was 60 on the QOLIBRI total scale. This provided an area under the curve (AUC) of 0.83, sensitivity of 0.75 and specificity of 0.75. For persons with a TBI obtaining a QOLIBRI overall score <60, the relative risk (RR) of probable anxiety, depression or dual diagnosis was 3.12 (95% CI: 2.64–3.69). For those with dual diagnosis only, the optimum cut-point was 40 on the QOLIBRI overall scale. The AUC = 0.86, sensitivity = 0.94, specificity = 0.58 and the RR = 12.34 (95% CI: 7.70–19.78).

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Figure 2. QOLIBRI scale scores by GOSE classification; SD = severe disability; MD = moderate disability; GR = good recovery. Statistics ANOVA $F = 9.55$–38.77, all $p < 0.001$.

A feature of all the tables and figures is that the standard deviations were typically ~20% of the QOLIBRI scale range. This implies that within the known groups analysed or within the bandwidths described there was considerable variation in QOLIBRI scores. For example, consider the variation in data on the GOSE presented in Figure 2. The implication is that within these classifications some cases obtained scores on the QOLIBRI indicating a higher HRQoL than might be expected for their level of disability and others a lower HRQoL than might be expected for their level of disability and others a lower quality-of-life. Two case studies illustrate this and their scores on each of the QOLIBRI scales are shown in Figure 4.

Case reports

Case 1. A 38-year-old electrician had a very severe TBI in a motor vehicle incident. Fourteen years after the injury he still has left hemiparesis, dysarthria and severe problems in executive functions, memory, slowness, uncontrollable laughter and poor behavioural control. Today, he needs a great deal of help from his parents on a daily basis.

He was offered support and services immediately after his injury. Multi-professional rehabilitation started at the hospital and is still ongoing. His social outcome is optimal considering his restrictions and he has reached the goals in life he has set for himself. Last year he managed to move into his own apartment in the same house that his parents live in. He has met a girlfriend and is engaged to get married. He regularly participates in social and leisure activities, including music, sports and the activities of the local brain injury association. In the QOLIBRI open-ended questions he wrote: 'I have learnt to speak and walk, I got home from the hospital. I live in my own apartment. I'm happy
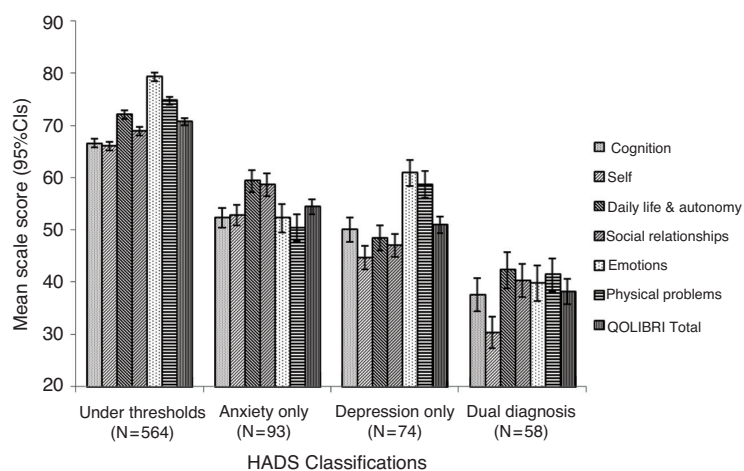
Cognition	Under thresholds > Anxiety, Depression, Dual diagnosis (p=0.01); Anxiety, Depression > Dual diagnosis (p=0.01).
Self	Under thresholds > Anxiety, Depression, Dual diagnosis (p=0.01); Anxiety, Depression > Dual diagnosis (p=0.01).
Daily life& autonomy	Under thresholds > Anxiety, Depression, Dual diagnosis (p=0.01); Anxiety > Depression, Dual diagnosis (p<0.01).,
Social	Under thresholds > Anxiety, Depression, Dual diagnosis (p=0.01); Anxiety > Depression, Dual diagnosis (p<0.01).
Emotions	Under thresholds > Anxiety, Depression, Dual diagnosis (p=0.01); Anxiety, Depression > Dual diagnosis (p=0.03).
Physical	Under thresholds > Anxiety, Depression, Dual diagnosis (p=0.01); Depression > Dual diagnosis (p<0.01)
QOLIBRI	Under thresholds > Anxiety, Depression, Dual diagnosis (p=0.01); Anxiety, Depression > Dual diagnosis (p<0.01).

Figure 3. QOLIBRI scores by anxiety and depression (HADS). Statistics ANOVA $F = 49.99–114.19$, all $p < 0.001$.
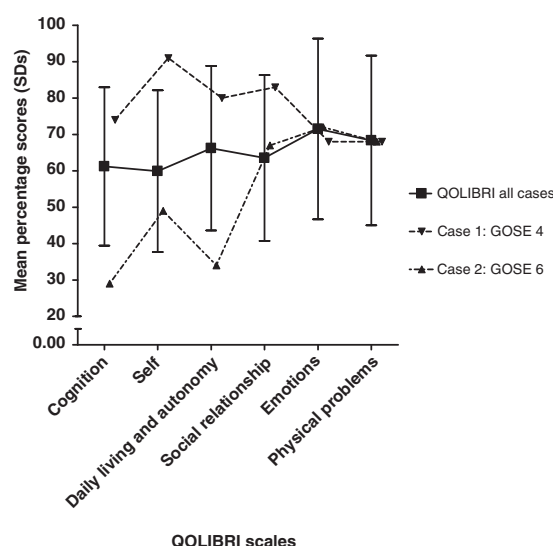
Figure 4. Six QOLIBRI sub-scales mean scores and standard deviations in two illustrative cases. Case 1: GOSE 4 and high QoL: case 2: GOSE 6 and lower QoL.

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because my parents have been able to support me. I met my companion. My friends disappeared. Some people do not understand me'.

On the GOSE he was rated 4 (severe disability: upper level). However, according to the QOLIBRI, he rated his HRQoL quite high, obtaining an overall QOLIBRI score of 74%.

Case 2. A 42-year-old secretary was injured 8 years earlier in a fall. Neuropsychological assessment revealed problems with fatigue, attention, memory, slowness of cognitive processing, executive functions and emotional reactions. She is independent at home and is able to perform everyday tasks.

Her functioning was not assessed after the injury and she did not receive any rehabilitation. Her post-traumatic personality changes led to problems with her family and friends. Her self-esteem is low and she is constantly faced by goals she is unable to reach. She participates in social and leisure activities much less than before the injury. She returned to her previous work 6 months after the injury but was no longer able to perform as previously. However, she tried to continue at work for years. Her functional status was assessed only 8 years after the accident and then a 4 hour per day work trial was organized. She wrote: 'After the accident I felt stupid and I performed slowly. Then started the typical demands that are placed upon present day workers: more work, courses, more, more! I did not have enough strength, and due to my many absences from work I was sent for an examination'. The GOSE rating was 6 (moderate disability: upper level). On the overall QOLIBRI her self-rated HRQoL was low at 45%.

Consistent with the case study information, Figure 4 shows that case 1 obtained a Self score above 1-SD above the usual QOLIBRI Self score, indicating a very positive and unusual outcome, whereas his scores on Emotions and Physical problems scale were almost identical with the generally obtained outcomes. In contrast, case 2 reports a very poor satisfaction on Cognition and Daily living and autonomy; both of which were well below the usual TBI outcomes. Similarly, her Self score was ~0.5 SD below the mean score, yet she obtained scores on Emotions and Physical problems scales that were typically generally obtained. Perhaps importantly she did not receive rehabilitation and it may be that professional support targeting these three areas of her life would have benefited her.

Discussion

The development and validation of the QOLIBRI, a disease-specific instrument for measuring HRQoL after TBI has been comprehensively described [78–82]. This paper describes preliminary clinical experience with the QOLIBRI and how QOLIBRI scores may be interpreted in clinical situations. QOLIBRI scores were examined by various socio-demographic indicators—especially by age, gender and education, since any variations would have importance in how a clinician or researcher interpreted participant scores—and also by known indicators of functional outcome, health status and mental health.

The results show that (contrary to prevailing clinical judgement) assessment of HRQoL in TBI patients is feasible and a valid approach. The QOLIBRI is the first disease-specific scale for assessing HRQoL in TBI patients. According to experience, it can be completed by either self-assessment or personal/telephone interview within 10–20 minutes in most cases.

It was further found that demographic factors (age, gender, education), as well as living situation and particularly mental health were all associated with perceived HRQoL.

The participants reported highest level of satisfaction in the Emotions, Physical problems and Daily living and autonomy scales. Lower levels of satisfaction were reported on the Social relationships, Cognition and Self scales. The highest scores were obtained by the youngest participants aged 17–34. Participants living independently without the help of family members or other caregivers were significantly more satisfied than participants needing help. People who were working obtained higher scores on all QOLIBRI scales than people not working. Those results were expected and coherent with the literature.

The results from this study do not constitute norms because of the variable sampling methods in time and place. The observed standard deviations of the QOLIBRI scale ranges, varying from 15–29%, is typical of HRQoL instruments where population norms have been published, such as for the AQoL [89], the EQ5D [90], SF-36 [91, 92] or the WHOQOL-BREF [93]. The statistically significant differences of up to 11% of the QOLIBRI scale scores observed by age group and gender on QOLIBRI scores (Table III) may have important clinical implications and should alert clinicians and researchers to the fact that such criteria may need to be age- and gender-specific. This advice is not unique to the QOLIBRI and differences by age and gender have been reported elsewhere for other QoL or health status instruments [90–93]. Whether differences in QOLIBRI ratings may also have been caused by method effects (e.g. translation artifacts), different health care service provision and support or other cultural factors (such as

differences in the underlying populations in which TBIs occur) remains uncertain.

The finding that there were across the QOLIBRI scales no significant difference between those supported at home and those living in sheltered accommodation was surprising. Generally, the expectation is that people move into sheltered accommodation when their condition deteriorates to the point where family and caregivers can no longer cope—typically caused by behavioural disorders. The findings in Table IV may suggest that the professional care provided by sheltered accommodation offsets the attractions of living at home with family care. If this is the case, given that family care is less expensive than institutional care, it would suggest that more resources may be needed to support at home care for patients with TBI, although this clearly needs further research.

Return to work following a TBI has been intensively studied ever since English's [94] seminal paper and work status is one of the most consistent predictors of TBI HRQoL [23, 25, 26, 36]. A key issue is whether a person returns to work at the same occupational level, whether he/she returns to full or part-time work, in a normal environment or in a sheltered work centre. Those with a severe TBI-related impairment may not necessarily express much distress if their impairment has no specific meaning in their situation, such as the use of a wheelchair for a job which does not require walking autonomy. In contrast, a mild disability such as subtle limitations in executive functions may prevent return to a demanding job causing a low perceived HRQoL, as in Case #2 above. In the present study 43% of participants returned to work, which is comparable to other studies reporting on severely injured patients. Although no information on the level of work was collected, elsewhere it has been reported that many return to work at a lower level or part-time work, frequently involving lower income [5, 16, 23, 24, 36].

For mental health the QOLIBRI scale scores were extremely sensitive to anxiety and depression classification on the HADS. Although the QOLIBRI does not assess anxiety or depression, the ROC analysis of the data in Figure 3 suggests that low scores on the QOLIBRI overall scale should alert clinicians to the possibility that those scoring <60 may meet the HADS criteria for probable anxiety or depression. Similarly, those with scores <40 may meet the criteria for a dual diagnosis. On the basis of these findings it would seem prudent for clinicians to recommend that patients with TBI with scores below these thresholds are screened for their mental health status and treated if they meet clinical criteria for anxiety, depression or a dual diagnosis, consistent with the guidelines espoused by Wagner and Vickery [95].

The observed variability in QOLIBRI ratings within and between the GOSE categories is of importance and of great relevance, as the implication is that different perspectives on outcome are captured by the two approaches. Regarding the modest sensitivity of the QOLIBRI by functional outcome (Figure 2), whether this is a function of the QOLIBRI scales *per se* or of the GOSE is unknown. Although the GOSE was developed to overcome perceived insensitivity of the GOS, it is possible that the revised version is still relatively insensitive to subtle changes in functional status [57]. If the GOSE is insensitive to functional outcome classification in the mid-ranges (levels 5, 6 and 7), then this may explain the findings presented in Figure 2; viz., that the QOLIBRI scales appear to be not particularly sensitive to disability levels. In this sense, it is possible that the GOSE may not be an appropriate criterion for assessing the sensitivity of HRQoL or life satisfaction scales, although this is in need of further research.

Alternatively, those with lower GOSE scores, indicating poorer functional outcome, obtained QOLIBRI scores that were non-monotonic and not statistically different to those with somewhat better recovery. This is consistent with at least one other report suggesting that more severely disabled patients had a better HRQoL than those who were moderately disabled [23]. This could be explained by the 'disability paradox' [96, 97] based on anosognosia and better support provided to severely injured people when compared to those moderately injured.

The two case studies (Figure 4) illustrate the possible gap between HRQoL and functional outcome; a person with severe disability (from an external perspective) could report a rather good HRQoL, as in case #1, whilst the opposite is also possible, as in case #2. The extent to which these assessments are influenced by the environment, rehabilitation and support is unknown, although the literature suggests they may be important [25, 75]. The results for accommodation (Table IV) might suggest these have a major role to play.

Finally on this topic, it may be that the non-monotonic QOLIBRI scales scores for those at GOSE level 3 may indicate that at this level of disability participants lack the necessary insight to provide reliable assessments of their own condition and that for those with this level of disability proxy reports might be preferred. This is speculation and needs further research.

The discordance between QOLIBRI and GOSE ratings raises the fundamental question of what

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clinically the most relevant outcome measure is: functional outcome assessed by professionals or the quality-of-life perceived by the patient. The authors submit that both perspectives are relevant and would encourage the further development of a multidimensional approach to outcome assessment for use in clinical studies.

As shown in Tables III and IV and in Figure 4, observed standard deviations varied between 15–29% of the QOLIBRI scale ranges, which is typical of HRQoL instruments as noted above. There are, however, two important consequences in addition to those reported above. The first relates to the required sample size needed in clinical trials. Where a large difference as a result of the intervention is expected, the sample could be quite small; but where smaller gains are expected the sample size would need to be carefully calculated. The second clinical consequence is in relation to using the QOLIBRI at the individual patient level. The large standard deviations suggest that reliable change scores [98] at the patient level would need to be very large, requiring improvements of ~30% of the QOLIBRI scale range.

Figure 4 shows a third method of interpreting individual patient scores for the identification of those who need professional clinical help. The scores obtained by cases 1 and 2 show that on some QOLIBRI scales these scores were outside the normal range of expected scores. Patients obtaining such scores should be carefully monitored and, where warranted, interventions targeted at these areas, such as the provision of further rehabilitation. Figure 4 presents QOLIBRI mean scores and standard deviations; elsewhere it has been argued that the threshold for changes in HRQoL in chronic disease is ~0.5 SD [99]. By these criteria, case 2 shown in Figure 4 should be identified by her treating clinician as being in need of further health-care intervention.

The previous two papers regarding the development of the QOLIBRI's descriptive system and psychometric validity are complemented by the findings reported in this paper regarding its sensitivity to known groups (Tables III and IV). It assesses life satisfaction rather than health function and is sensitive to functional outcome (Figure 2) and mental health (Figure 3). Importantly, this paper has shown that these relationships can provide guidelines for clinicians and researchers relating to the collection of data for those who are cognitively impaired, follow-up rehabilitation, screening for mental health conditions and the interpretation of the meaning of differences or gains in QOLIBRI scale scores, including advice for handling difficulties at the individual patient level. Together these findings suggest that the QOLIBRI is a valid life satisfaction outcome measure in TBI which may have a useful role in clinical practice or research.

Limitations

One important limitation of any HRQoL measure is the complexity of the HRQoL concept. It is very difficult to define and then capture self-perceptions, view of the future, individuality and the experience of intimacy. And in so doing it is very difficult not to be intrusive. The authors wished to accommodate both what may be measured in a well-validated multiple-choice questionnaire via a 5-point scale and important qualitative information and statements provided by the responder during and after completing the questionnaire.

Moreover, open-ended questions give the clinician useful information about issues such as values and important topics in patients' lives. For that reason, in all language groups, during the developmental process after completing the first version of the questionnaire, the participant was asked: 'Would you assess your HRQoL in other areas important to you, which were not mentioned in the questionnaire (such as religion [100], pets [101] and accommodation)?' and secondly the question, 'Would you tell me examples of the happiest and unhappiest moments after injury?' gives useful information concerning participation and social integration: family, hobbies and moments of success or distress.

Many patients with TBI have significant problems with communication, insight, anosognosia and denial, all of which may affect the understanding of questions and the validity of responses.

Although this study has not examined these, they can be assessed and their importance judged. For example, anosognosia can be measured by the PCRS [102] or by comparing the patient's and the significant other's responses or to the pre-traumatic situation [103–105]. This was done in the French, German and Italian samples.

A major limitation of this study is that clinical conclusions from the data are restricted by the approaches to recruitment. The primary aim of this convenience sample was to investigate psychometric properties and validate the QOLIBRI scale across a wide range of settings. It was deliberately chosen to recruit participants from different settings and at variable times after injury. Consequently the sample was 'scale-oriented', rather than 'patient-focused'. The study was not designed to assess specific cohorts or at fixed time periods after injury. Thus, interpretation of clinical findings and comparisons between groups should be done with caution. Notwithstanding this caveat, the results do provide insight and permit general conclusions.

In addition, this study was an organizational challenge since it involved sampling participants from across six different language groups and 14 research centres. As shown, there were differences in the recruitment strategies between the centres which may have affected the results. It is also possible that there were language differences attributable to either different health cultures or translation differences among the items.

QOLIBRI: Clinical use and further development

Because HRQoL is perceived by patients themselves, consistent with the WHO definition [8], it should preferably be assessed via self-report. Although clinicians may be well aware of the physical impairments, limitations and restrictions in patients' health-related functioning, the literature suggests they have less insight when it comes to the social, personal and intimate aspects of peoples' lives [106]. The TBI-specific QOLIBRI meets this need through capturing the patient subjective perspective and providing evidence which can be used alongside objective clinical indicators.

At an individual level, an ideal clinical tool would be a brief questionnaire that could be presented to the patient for rapid self-completion in less than 20 minutes. It would meet the requirements of clinicians overwhelmed by the accumulation of measures. The QOLIBRI is reasonably short at 37 items and it is at least as easy to understand and complete as generic HRQoL tools which have been used in patients with TBI such as the SF-36 or EBIQ [13, 16, 66, 74–76]. In addition the QOLIBRI poses questions in a positive fashion, with a unidirectional 5-point response option. Thus, items do not focus only on disabilities which help patients to identify not only weaknesses but also their strengths and the impact on their own life situation. This is in line with recent research arguing that rehabilitation is more effective when it enhances strengths and facilitates adjustment than when it tries to compensate for deficiencies [7].

The QOLIBRI may be given as soon as the patient is aware enough to respond appropriately. However, the value of HRQoL assessment increases with time since injury. Since the QOLIBRI is a multidimensional questionnaire, beyond the QOLIBRI total score the six sub-scale scores provide additional information, as illustrated by Figure 4. Similarly, a very detailed profile can be constructed by examining responses to individual items. A further step can be added with open-ended questions. These three further steps from the total score enrich significantly the HRQoL profile of one patient with TBI.

Improving patients' HRQoL is one of the main and ultimate goals of TBI rehabilitation. On an individual level asking patients for their subjective opinion is crucial to prioritizing therapeutic goals, taking into account their personal needs, values and hopes and improving goal attainment. It also facilitates the therapeutic alliance, thus helping the participant to build a new life via a new ego-identity, in his/her own cultural, social and environmental context [3, 21, 33, 107].

In addition, QOLIBRI data allow those responsible for the care of patients with TBI to assess individual progress or regression—through the patients' subjective perception. This perception can assist with assessing and comparing programmes of service delivery and their cost-effectiveness. This can influence policy-making in the field of rehabilitation. Further, HRQoL assessment has much to contribute to clinical trials for drugs or psychotherapies and to epidemiological studies.

The authors' experience, through the validation process, is that the QOLIBRI can provide a rapid yet comprehensive screening of patient limitations and needs [79], thus obtaining the necessary data for these purposes. Moreover, the main admission criteria intuitively designed in TBI re-entry French facilities (ADEF-residences) were behavioural problems, autonomy and help needed, co-morbidity and disability: they are very similar to the five main factors of HRQoL measured by the QOLIBRI at a mean time of 5 years since injury and explaining 59% of the variance; depression, amount of help needed, co-morbidity, anxiety and GOSE [81, 108].

The QOLIBRI is now considered ready for more routine use in clinical studies on TBI. Determination of the added value, its position in relation to other outcome measures and influences of cultural and language differences can only be accomplished in prospective studies of consecutive cohorts with assessments at fixed pre-determined times.

Conclusion

The evidence presented in recent publications on the development and psychometric validity of the QOLIBRI combined with the clinical experience reported in this paper demonstrate it as a valid instrument for assessing patient reported outcomes in TBI for both clinical practice and research.

The QOLIBRI is a unique TBI-specific measure of HRQoL. It provides information about patients' subjective views of their own lives and complements traditional measures of disability and recovery. This paper has shown how it may be used at the clinical level, including discussion of when it is appropriate to use it, how it may be interpreted and how scores may assist clinicians with decision-making.

It captures life satisfaction rather than health function and is sensitive to disability and mental health, demographic and socioeconomic factors. Importantly, it captures a different perspective on outcome than is provided by GOSE assessments performed by professionals.

Although more studies are needed, particularly on use of a proxy version mainly in severely impaired patients with TBI and pre–post studies to investigate its responsiveness, the findings from this study suggest that clinicians and researchers may find the QOLIBRI a useful instrument for eliciting the patient perspective in TBI recovery, rehabilitation and research.

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Appendix

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The items of the questionnaire are presented below:

Part I: How satisfied are you with . . . ,

(A) Your thinking abilities?

   (1) your ability to concentrate, for example when reading or keeping track of a conversation

   (2) your ability to express yourself and understand others in a conversation

   (3) your ability to remember everyday things, for example where you have put things

   (4) your ability to plan and work out solutions to everyday practical problems, for example what to do when you lose your keys

   (5) your ability to make decisions

   (6) your ability to find your way around

   (7) your speed of thinking

(B) The view of your self?

   (1) your level of energy

   (2) your level of motivation to do things

   (3) your self-esteem, how valuable you feel

   (4) the way you look

   (5) what you have achieved since your brain injury

   (6) the way you perceive yourself

   (7) the way you see your future

(C) Your independence and how you function in daily life?

   (1) the extent of your independence from others

   (2) your ability to get out and about

   (3) your ability to carry out domestic activities, for example cooking or repairing things

   (4) your ability to run your personal finances

   (5) your participation in work or education

   (6) your participation in social and leisure activities, for example sports, hobbies, parties

   (7) the extent to which you are in charge of your own life

(D) Your social relationships?

   (1) your ability to feel affection towards others, for example your partner, family, friends

   (2) your relationships with members of your family

   (3) your relationships with your friends

   (4) your relationship with your partner or with not having a partner

   (5) your sex life

   (6) the attitudes of other people towards you

Part II: How bothered are you by . . .

(A) Your emotions?

   (1) feeling lonely, even if you are with other people

   (2) feeling bored

   (3) feeling anxious

   (4) sad or depressed

   (5) feeling angry or aggressive

(B) Your physical problems?

   (1) slowness and/or clumsiness of movement

   (2) any other injuries you sustained at the same time as your brain injury

   (3) pain, including headache

   (4) problems with seeing or hearing

   (5) the effects of your brain injury