



# Advancement of the QOLIBRI use and applications

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## ABSTRACT

**Objective:** To report the advancement of the use and applications of the QOLIBRI, a 37-item disease-specific tool of health-related quality-of-life (HRQoL) after traumatic brain injury (TBI).

**Methods:** We have performed a literature review of HRQoL in TBI involving QOLIBRI, via PubMed, since its three initial publications in 2010. We have selected 24 more studies and taken into account our respective clinical experiences on QOLIBRI use up to now.

**Results:** The QOLIBRI was initially validated in six languages: Dutch, Finnish, English, French, German, and Italian. After two assessment waves, the validation study on 795 TBI-persons showed a good reliability (Cronbach 0.86 and test-retest reliability 0.81). The QOLIBRI was related - but with an added-value- to SF-36, the Glasgow Outcome Scale extended (GOSE) and the Hospital Anxiety and Depression Scale (HADS).

Further studies have led to a comparison with the generic instrument SF-36, and the International Classification of Functioning (ICF). A 6-item Overall QOLIBRI scale (QOLIBRI - OS), and relative's proxy version (Pro-QOLIBRI) were designed and validated. Moreover, QOLIBRI was validated in Portuguese, Chinese, and Japanese. In addition, QOLIBRI was applied in studies on elderly people, mild TBI, coping and insurances.

**Conclusion:** The QOLIBRI enlightens patient's subjective perception of his/her HRQoL which supplements measures of functional outcome. 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, Functional outcome, QOLIBRI, Systematic review, Clinical use

## Introduction

Traumatic brain injury (TBI) is a major cause of death and of disability, particularly in persons under 40 years of age. Besides "objective assessments" - such as disability - conducted by professionals, assessing subjective HRQoL

is mandatory. Improving QoL should be the ultimate goal in the rehabilitation of persons with TBI. The World Health Organization (WHO) defines 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

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relation to their goals, expectations, standards and concerns.” The literature is significant in assessing HRQoL and TBI also, but limited in TBI HRQoL.

Our first question was: “Do we need a generic instrument or a TBI-disease specific one?” HRQoL is too many times confused with health status. And the generic reference SF-36 is partly a health measure more than a HRQoL instrument. Developing a TBI-specific instrument was warranted by the dimension of that external injury to the brain - more than 1 million TBI, each year, in the European Union, its specificities - the often “hidden handicap” mainly due to cognitive and, moreover, mood and behavioural disorders - and a “silent epidemic” insufficiently recognised and treated, mainly in the long-term. In addition, no widely used and validated disease-specific HRQoL measures were available for TBI until 2010. Secondly: “How to integrate the specificities of the TBI population in the measure?” Thirdly: “QoL assessment what for?”

Six years after our first publications [1-3], the requirement to publish on “Advancement of QOLIBRI use and applications” was a good opportunity to review in “Neuropsychiatry”, since behavioural disorders are the main factor of TBI disability.

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### The QOLIBRI Story

#### ■ Methods

In 1999, Neugebauer and von Wild organized an international and interdisciplinary consensus conference, which recommended the development of a measure for the HRQoL assessment of TBI persons. A Task Force on TBI HRQoL, chaired by Truelle, was created with a Steering Committee and a Methodological Centre led by von Steinbüchel. A literature review resulted in the selection of four instruments: the QOLBI (Quality of Life of the Traumatic Brain Injured), the SQLP (Subjective Quality of Life Profile), the BICRO-39 (Brain Injury Community Rehabilitation Outcome Scale), and the EBIQ (European Brain Injury Questionnaire). 148 items were extracted from these instruments, then progressively reduced, through three validation waves, to a 37-item questionnaire, the QOLIBRI (acronym for quality of life after brain injury), using a 5-point Lickert-scale from “not at all” to “very satisfied”

(Appendix). The final validation [1-3] involved 795 persons with TBI, 11 countries and 6 languages: Dutch, English, Finnish, French, German and Italian.

The inclusion criteria were: ICD-10 diagnosis of TBI; aged 15 or more at injury and aged 17-68 at recruitment; 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.

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### Results

#### ■ Statistics (1, 2)

The QOLIBRI and its 6 subscales met standard psychometric criteria (internal consistency, Cronbach=0.75–0.89, test-retest reliability, rtt=0.78–0.85), even in a subgroup of participants with lower cognitive performance. Although there is one strong HRQoL factor, a six-scale structure explaining additional variance was validated by exploratory and confirmatory factor analyses, and with Rasch modeling. The QOLIBRI was related - but with an added-value - to SF-36 (mainly with the mental component), the GOSE and the HADS.

1/3 of the variance of QOLIBRI is shared with SF-36. Correlation SF-36 with GOSE disappears when controlling by 6 QOLIBRI subscales. In contrast, correlating QOLIBRI with GOSE remains stable when controlling by SF-36 M (<0.001). Thus, information is better captured by QOLIBRI, mainly on cognition and self, not on physical aspects.

A multiple regression analysis showed that the main correlation of the total QOLIBRI score was emotional state (HADS depression and anxiety), amount of help needed, outcome on the GOSE, and number of comorbid health conditions. Together these five variables accounted for 58% of the variance. By contrast, GCS, age, gender, education, administration mode, language, each accounted for less than 1% of variance.

The agreement between the 6 validated initial versions (Dutch, Finnish, French, English, German, Italian) was obtained for 5 subscales of the QOLIBRI (not for social subscale), even after adjustments for GCS, Coma length, PTA, gender, age, education, time since injury, administration mode, relation status (p<0.01)

### ■ Clinical feasibility

The completion mean time was reported at average 11 minutes for self-completion and 20 minutes for face-to-face interview (for 25 %, mainly with the more severely injured). The wording is understandable, concrete, and positive, with a goal to help a patient with limitations in communication, insight, and self-criticism. Only one refusal out of 72 consecutive cases was met in the French version validation [3].

### ■ Qualitative aspects

Beside the questionnaire itself, we ask the TBI person about his/her own problems which have not been met by the questionnaire: accommodation, art and music, spirituality, epilepsy, anosmia... and to describe moments of happiness or unhappiness. The questionnaire assists insight which enables the client (and the family) on comment: it enriches the information on one person - and their family - burden, hopes and demands [3].

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## Advancement on QOLIBRI Use and Applications

### ■ Methods

We first carried out a literature review of HRQoL in TBI involving QOLIBRI, *via* PubMed, following the initial three publications in 2010 [1-3]. Then, we selected 24 studies contributive to a real advancement with regard to those references and took into account our respective experiences on QOLIBRI use.

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## Results

### ■ Various versions of QOLIBRI

Today, QOLIBRI is validated in 9 languages: Chinese [4,5], Dutch, English, Finnish, French, German, Japanese [6], Italian, and Portuguese [7].

Lin [4] submitted "...301 persons to QOLIBRI over one year after TBI. The floor and ceiling values were under 4 % thus adequate as internal consistency (0.79-0.95), and test-retest reliability (0.81-0.89)... Effect sizes of responsiveness to changes in the GOSE over the 1-year period were clinically meaningful for all of the QOLIBRI domains except for the Emotions domain. With modifications to the Emotions domain, QOLIBRI would be suitable for use with Chinese persons with TBI in Taiwan." The same

author [5] confirmed QOLIBRI validity among 333 persons with TBI  $\geq 60$  years, who obtained lower scores for all QOLIBRI domains, except in the case of physical problems, compared with those with other soft-tissue injuries. Convergent validity and a confirmatory factor analysis were satisfactory.

Norwegian and Spanish QOLIBRI versions are in progress. In addition, versions are being developed regarding stroke and children. In a study using the Kiddy-Kindle, Villalonga-Olives [8] 3 to 5-year old migrant children perceived health was slightly higher in migrants compared to native-born German children ( $p > 0.05$ ), even though migrants had a lower socio-economic status ( $p < 0.01$ ). This could be attributed to more migrants with healthy profiles, motivation to survive and happiness to be welcomed in Germany.

A QOLIBRI Overall Scale (QOLIBRI-OS) has been validated [9] with six questions related to the headings of the 6 QOLIBRI subscales. Those 6 items can establish a Rasch scale [10]. QOLIBRI-OS demonstrated good criterion validity in Subarachnoid Hemorrhage (SAH) [11].

A QOLIBRI relative's proxy version (Pro-QOLIBRI) was developed by Formisano [12], especially in its caregiver-centred version, for example: "How satisfied are you with the ability of your son/daughter/father... to express themselves?". It was included in Italian studies. To Formisano, QoL as perceived by the caregivers was overall worse than patients' self-perceived QoL. Two factors can explain this discrepancy: the caregiver's emotional distress and the low self-awareness of the person with TBI. "There was also positive correlation between the level of satisfaction measured by Pro-QOLIBRI - but not by Pt (patient)-QOLIBRI - and the disability severity and social integration of the patients. The comparison between the Pt-QOLIBRI and Pro-QOLIBRI confirmed the usefulness of the Pro-QOLIBRI to assess patient's self-awareness, family distress and prediction of the social reintegration of survivors."

### ■ Correlations with other outcome data

Azouvi [13] conducted a longitudinal multi-centre cohort study on 504 severe TBI. Out of them 85 completed the assessment 4 years after injury. While disability appeared to be much more strongly influenced by the injury itself and its cognitive and somatic consequences, satisfaction with life was much more strongly

related to emotional state and cognition but not with injury severity.

Cappa, *et al.*'s recent meta-analysis [14] also showed that, while measures of injury severity were most significantly associated with measures of global outcome, they were most poorly associated with measures of satisfaction with life.

In a Norwegian series [15], QOLIBRI predictors were: employment status ( $p=0.05$ ), GOSE ( $p=0.05$ ), Rivermead post-concussion questionnaire ( $p<0.001$ ) and HADS ( $p<0.001$ ). Symptom pressure and global functioning in the sub-acute phase of traumatic brain injury and psychological distress in the post-acute phase are also significant for HRQoL.

In a Finnish study, Siponkoski and von Steinbüchel [16] demonstrated that QOLIBRI was related to depression, amount of help needed, anxiety, as in the initial validation studies [1-3], and - in contrast with them - also with education level and age at injury. QoL was not associated with time since injury. A paradoxical relationship was found with injury severity, milder injuries being associated with lower satisfaction.

Gerber [17] conducted a cohort study of a convenience sample of 63 community residents with Acquired Brain Injury (ABI) 4 years after injury. Disability rating scale (DRS) scores explained significant variance in Community Integration Questionnaire (CIQ) and QOLIBRI.

Correlations also showed that cognitive skills and Activities in Daily Living (ADL / IADL) functioning are strongly related to CIQ and the Daily life and autonomy QOLIBRI sub-scale. The CIQ Total was not correlated with QOLIBRI Total, although there were some significant correlations between the CIQ social sub-scale and QOLIBRI. Lesser degree of disability is a key predictor of greater CI and QoL.

### ■ Rehabilitation

Patel [18] showed that "compared with severe TBI, QOLIBRI scores were 11.7 points higher in mild TBI and 17.3 points higher in moderate TBI. In addition, survivors who received post-discharge rehabilitation had higher QOLIBRI scores by 11.4 points than those who did not. Survivors with private insurance had QOLIBRI scores that were 25.5 points higher than those with workers' compensation and 16.8 points higher than those without insurance."

Sasse [19] did a study on 141 persons with TBI who responded to Freiburg questionnaire of

copied with illness. She extracted two factors for coping: the Trivialisation/Resignation strategy was negatively correlated with all aspects of QoL in QOLIBRI, while relationships with the Action/Distract strategy were positive and significant for two domains: self and social - related QoL. These two factors for coping also showed significant associations with anxiety, depression, recovery, cognitive status, mood states and trauma severity.

For Chiang [20], employment status was the most crucial associated factor for QoL, measured by SF-36 and QOLIBRI, in individuals with mild TBI at the 1-year follow-up.

Tazopoulou [21] recruited, in residential facilities, 27 persons with cerebral anoxia, on average 8 years post-injury. Only 20 went through the whole study. Over three consecutive 2 month periods, they were assessed four times to evaluate: baseline observations (T1-T2), adjustment of their medication (T2-T3); and the effect of psychotherapy, support group and intensive physical and artistic or cultural activities (T3-T4).

Taken together, all the therapeutic interventions, except medication adjustment, improve social participation (MPAI-4) and life satisfaction (QOLIBRI). Exercise (mainly WII) improves social participation. Support group reduces anxiety and depression.

### ■ Comparison between QOLIBRI and SF-36

For von Steinbüchel [22], "psychometric performances" were generally higher, and more homogenous for the QOLIBRI than for the SF-36 subscales...The QOLIBRI can be recommended as the preferred instrument."

For Wilson [23], "Cross-walking with the SF36-Mental component suggests bands of average and poor HRQoL on the QOLIBRI Total and on the QOLIBRI-OS. The results indicate that, even in a sample in which most participants were followed up many years after injury, poor HRQoL is a feature of more than one third of patients with TBI."

### ■ Comparison between QOLIBRI and International Classification of Functioning (ICF)

While ICF refers to limitations and restrictions related to a health problem and is useful in monitoring outcome and in defining the goals of rehabilitation, HRQoL refers to how someone

feels about these limitations and restrictions. An international consensus conference selected 143 ICF categories for the comprehensive ICF core set for TBI and 23 ICF categories for the brief core set.

In Koskinen's study [24], on 55 TBI persons, 2.7 years after injury, functional outcome - based on GOSE and ICF - was compared to their HRQoL. QOLIBRI was linked to 42 and the GOSE to 57 out of 143 two-level ICF categories. Based on the ICF brief core set for TBI, 17 out of the 23 (78%) most relevant ICF two-level categories were represented, confirming the appropriateness of these two measures (GOSE and QOLIBRI) for the evaluation of persons with TBI. At the less-detailed one-level ICF classification, all but one of the main chapters is covered by using both the QOLIBRI and the GOSE.

To summarize, the results of the linking procedure showed that both the QOLIBRI and the GOSE as short outcome scales can capture a wide range of problems encountered after TBI. QOLIBRI and GOSE capture important domains that are not sufficiently documented, e.g., interpersonal relationships, social activities, self and the environment.

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## Discussion

### ■ Ethical aspects

The individual approach, e.g., "medicine of the subject" is - unfortunately! - A rather decreasing practice, in contrast with the increasing time devoted to the "Evidence-Based Medicine" e.g. the unavoidable and necessary contribution of technology and scientific references. This trend is reflected in the scientific literature. The place of methodology is increasing logically supporting the scientific dimension of the studies. In contrast, the clinical impact of the study and, moreover, the individual approach is often reduced. For instance, the case reports - showing the complexity but also the interest of the qualitative data - are rarely published.

Thus, we need a questionnaire, validated, short and feasible, applicable to one person with TBI, enabling him/her to make comments, ask questions, e.g., qualitative data which complement quantitative ones: the QOLIBRI [3]. In addition, the Pro-QOLIBRI [9] is useful for assessing the relative's feeling, being able to compare it with the person with TBI's opinion, and the QOLIBRI-OS [12] mainly for epidemic studies and facilities' assessment.

How to capture individuality, insight, intimacy, while avoiding intrusion? The QOLIBRI requires an informed and written consent, in research and also in clinical practice. In both our experiences, refusal is under 3% for a person with TBI as is for their relative's proxy.

When the proxy version is submitted to the relative, the agreement of the person with TBI is also requested. Nevertheless, we have met family associations that were reluctant to assess QoL. They mainly represent the most severely injured and, therefore, the most distressed families. Thus, assessing their QoL seemed shocking and intrusive to them. That initial opposition is decreasing, with the consciousness that it is an opportunity for person with TBI and family to express their point of view.

### ■ Cross-cultural aspects

To validate new versions, we used forward and backward translations *vs* English version, made by native-speakers of both languages and skilled in TBI. They confronted their results and submitted their synthesis to persons with TBI. This work improved the item wording, generally moving from literal translation to more meaningful wording for the patient, taking into account the culture of the new language version. This was a hard but fascinating challenge with Asian countries (China Mainland-Tianjin and Beijing-, Hong Kong, Taiwan, Indonesia, Japan). For instance, negative formulations were avoided in the translations for these countries. Therefore, the so-called "bothered" part of the QOLIBRI was not acceptable as is and required significant changes. For a few items, it appeared necessary to divide the question into two sentences. The first was general, conceptual and not intrusive. The second one was more targeted and compatible in sense of decency, understanding and answering the questions, especially in sex and spirituality and in the emotion and social domains [25].

### ■ Generic or TBI-specific HRQoL instruments?

The choice of QOLIBRI has to be confronted with other instruments, as far as "there is still a lack of consensus about preferred HRQoL instruments and study designs in the TBI field... influenced by a range of factors, e.g., availability in own language, availability of normative population values, user fees, and instrument length." [22]

Polinder [26] made a systematic and extensive review on functional outcome and HRQoL



instruments, from 1991 to 2013. She used the Consensus Based Standards for the Selection of Health Status Measurement Instruments (COSMIN), with regard to three quality domains, i.e., reliability, validity, and responsiveness. 49 studies measuring TBI QoL were selected, including 29 with SF-36.

### ■ Two generic instruments stand out as relevant for their use in TBI

WHOQOL-BREF meets the three required qualities, a good interpretability and a short time to fill-out. SF-36 is the more widely used measure, which meets the same qualities except for the responsiveness to detect a change in a treatment effect, and for the ceiling and floor effects. Both instruments are not sensitive enough to take into consideration the specificities of TBI, especially cognitive, emotional and behavioural problems.

In comparison, QOLIBRI has excellent validity and reliability, low ceiling and floor effects, a short time to fill-out. However its responsiveness was not determined in the long-term, and there was no control group to determine normal scores. QOLIBRI-OS meets the same qualities, a fair responsiveness and a very short time to fill-out. The Pro-QOLIBRI caregiver-centred has good psychometric qualities and reflect the fact that “TBI is a family affair”, which requires a systemic approach.

Polinder [26] suggested assessing TBI HRQoL by SF-36 and QOLIBRI in parallel. However, it doubles time devoted to QoL assessment, thus reducing its availability for the clinician. Moreover, SF-36 is more a health evaluation than a QoL one.

### ■ QOLIBRI and objective instruments

In research and in clinical practice, QOLIBRI, as a subjective assessment of patient's HRQoL, complements objective assessments made by professionals regarding initial severity (GCS), mood (HAD), disability (GOSE) community integration CIQ)...

A special spot is reserved to ICF, which is not a questionnaire but a conceptual reference usable in rehabilitation. As QOLIBRI, ICF is not referred to diagnosis. However, QOLIBRI is subjective, with positive questions (“How satisfied are you with...”) while ICF is objective, via professionals and with rather negative statements e.g. limitations.

As example of clinical use of ICF and QOLIBRI [24], the lack of initiative is usually interpreted

by professionals as a limitation in executive functions, and in contrast expressed as a lack of motivation by the person with TBI. Second example, the QOLIBRI question “attitude of others towards you...” often leads to very low satisfaction while that question is rarely asked by professionals.

### ■ Are there convergent results in various studies on QOLIBRI?

QOLIBRI appeared much more strongly related to mood and social participation (help needed, return to work), but not with injury severity. QOLIBRI is correlated with SF-36 and GOSE although that, compared to them, it has an added-value.

Therefore, QOLIBRI is recommended during the rehabilitation process, mainly in the long-term.

### ■ Limitations

Capturing such a complex concept - QoL - is an ambitious and questionable challenge, particularly in the case of a person with TBI! On the one hand, building a questionnaire with answers' quantification is an endeavour to scientific approach. On the other hand, the QOLIBRI questionnaire can assist insight allowing the person with TBI to make comments, and questions e.g. qualitative data reflecting an individual approach [3].

Methodological limitations were mentioned in the previous paragraph.

The interpretability of a questionnaire implies a face to face interview if a short previous mental state' assessment shows severe impairments, particularly in language, via MMSE or preferably BNIS (Barrow neurological Institute Screening of Higher Cerebral Functions) [27].

In addition, young or older ages and a low education level decrease the feasibility of the QOLIBRI. In such situations, self - and proxy - reports should be considered as complementary sources of information. Thus, with such a complex notion, methodology, study design and measurement specificities are especially difficult to achieve.

Finally, don't forget “Elephants remain in the room!”: pre-traumatic story, personality, hierarchy of personal needs and values and their evolution in the long-term of a vulnerable life. This emphasizes the importance of qualitative data provided by comments made by the patient during and after the questionnaire. Recurring

exchanges between patient and professional, especially psychologist, are also key to the process.

Another hard but significant challenge is to take into account languages specificities, reflecting socio-cultural differences. This is developed in the discussion section.

#### ■ QOLIBRI: What for?

Our ultimate goal is the QoL of the person with TBI and family, via their subjective but unavoidable opinion on their QoL. It is therefore to identify problems and needs of one individual in order to re-prioritize goals of life projects and promote therapeutic alliance, and assess individual progress.

The other goals are an epidemiology of that disability and of its various causes, assess and compare programmers of service delivery, continuum of care and specific networks, medications, their cost-effectiveness and influence on disability policy making.

What further targets? A child version, a version adapted to stroke; cohort controlled studies and case studies, with an evaluation at different phases, especially in the long-term, in facilities and in the community; cross-cultural studies; clinical trials; medico-legal applications.

#### Conclusion

What is the impact of the QOLIBRI in our therapeutic approach, in the long-term?

A short, TBI-specific HRQoL tool which... complements the objective assessments, such as disability assessment; promotes the co-construction of recovery and community re-entry for one person with TBI and family; helps to evaluate efficacy and efficiency of therapeutic strategies; evaluates via the national, social, cultural context and values the rehabilitation programs to be promoted.

QOLIBRI is available free of charge for the scientific community around the world.

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