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Psychometric validation of the French version of the quality of life in epilepsy inventory (QOLIE-31): Comparison with a generic health-related quality of life questionnaire

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ABSTRACT – A psychometric evaluation of a French transcultural version of the quality of life in epilepsy inventory-31 (QOLIE-31) was carried out. QOLIE-31 was compared to a generic health-related quality of life questionnaire, the Nottingham health profile (NHP). The psychometric properties of QOLIE-31, assessed in 190 adults with epilepsy, included: acceptability, test-retest reliability and validity (multi-trait analysis including internal consistency and item-to-scale correlations, construct validity using factor analysis, discriminative validity using relationship with disease characteristics, treatment effects, divergent and convergent validity using correlations with NHP scores). Both acceptability and reproducibility were good and internal consistency was high (Cronbach's α coefficient = 0.86). Factor analysis with varimax rotation identified seven factors with eigenvalues > 1, with two factors, related to cognitive function and mood, accounting for 46.5% of the variance. However, goodness of fit indices revealed that a model with four factors best fitted the data. The first factor corresponds to a generic mental dimension, the second is equivalent to the cognitive functioning dimension, the third to medication effects including social functioning, and the fourth to seizure worry. Discriminative validity was good for seizure control and treatment tolerability. Hight correlations between QOLIE-31 and pertinent NHP scales (emotional reactions, energy and social isolation) were observed. The French version of QOLIE-31 thus meets established psychometric criteria for reliability and validity.

KEY WORDS: quality of life, epilepsy, QOLIE-31, adult, seizure frequency, NHP

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There is increasing agreement that the treatment of epilepsy cannot be limited to a reduction of seizures, but should also focus on a patient's quality of life (QOL), as the disorder can have major repercussions on daily living.

There is often worry about recurrence, even in people with few or no recent seizures. Moreover, epilepsy is a social label, with legal restrictions for driving as well as occupational constraints. The potential of antiepileptic drugs to induce serious or problematic adverse effects also cannot be overlooked and must be assessed in any measurement of QOL. However, although a number of instruments have been developed to assess the health-related QOL of individuals suffering from epilepsy [1-6], to date none of them has been validated in France. The availability of such a test in different languages is particularly important for conducting multinational studies which require tests that have been consistently translated and validated and take into account the cultural specificities of the country in which they will be used. One of these tests, Quality of Life in Epilepsy (QOLIE-31), initially developed in the US, has been validated [3] and shown to be responsive to change in epileptic patients [7-10]. It has also been employed to measure QOL in a variety of different studies [11-13]. QOLIE-31 was derived from the 89 items of the QOLIE-89 [4], by excluding non-specific topics (e.g. pain) and including those subscales that appeared to be most important from reports by epileptic patients [3]. Importantly, in a large program of cross-cultural adaptation, it has been translated into a number of languages, including French [3]. In addition, it has been validated in German [14], Hungarian [15], Spanish [16] and Georgian [17].

Here, we report on the psychometric validation of the French version of this 31-item questionnaire. In addition, we have compared the results with those obtained using a health status questionnaire, the Nottingham health profile (NHP), as a measure of generic QOL [18, 19].

Methods

Quality of life measurements

In the QOLIE-31 (*annexe*), 30 items are organized into seven subscales: seizure-worry, overall QOL, emotional well-being, energy-fatigue, cognitive functioning, medication effects, and social functioning. An additional item assessing overall health status is also included [20]. Details of the scoring system are provided in the QOLIE-31 Scoring Manual [21]. The raw scores are rescaled from zero to 100 with higher values reflecting better QOL. An overall score is obtained by summing the scale scores after weighting using empirically-derived coefficients provided in the Scoring Manual.

Translation and cultural adaptation of the US version of QOLIE-31 were carried out as follows [3]. Briefly, the procedure included: 1) independent translations by two professional translators native in the target language, 2) development of a reconciled version, 3) back translation of this reconciled version into US-English by another professional translator in order to check and correct potential discrepancies with the original version, 4) cognitive debriefing by testing the translation with five epileptic patients in order to assess clarity and cultural relevance, 5) an international harmonization meeting to ensure that the various translations of the same questionnaire, including French, measured the same concepts.

The NHP contains 38 items grouped in six scales ranged from zero to 100: energy, pain, emotional reactions, sleep, social isolation and physical mobility [18]. In this study, we have used the validated French version with the weightings appropriate for the French population [19]. This instrument was chosen for two reasons. Firstly, no epilepsy-specific QOL measure is available in a validated French version, necessitating the use of a generic questionnaire. Secondly, the NHP was used in preference to the SF-36, the other widely-used generic QOL instrument, since certain items from the latter were used for the generic core in the construction of the QOLIE-31.

Data collection

All general practitioners (n = 93), neurologists (n = 4), and psychiatrists (n = 21) in the area of the French town of Béziers were invited to participate in the study. Béziers is a medium-sized town (population 70,000) close to the Mediterranean coast of France. Eligible patients were those with a diagnosis of epilepsy for at least one year, who were ≥ 16 years old and were capable of completing the questionnaires. Subjects in remission who were not receiving medication for epilepsy were excluded, as were those with concomitant conditions likely to affect cognition. All eligible and consenting patients were included between October 1996 and December 1997, at their next planned or spontaneous consultation.

Demographic data, medical history and clinical characteristics of epilepsy were documented by the physician. The presence of co-morbid anxiety and depressive disorder according to the physician's judgement was recorded. Compliance was assessed using a single question with five possible response modes on a Lickert scale. Tolerability and seizure control were appraised in the same way. In addition, a question was included on the number of medication changes in case of intolerability or bad seizure control. The subjects were asked to complete the QOLIE-31 and NHP questionnaires. At the end of the QOLIE questionnaire there were additional items relating to the pertinence and comprehensibility of the individual items. These asked questions with five possible response modes on a Lickert scale (*e.g.* did you find the questionnaire easy to understand? Very easy/Easy/Average/Difficult/Very Difficult), and patients were requested to list questions which they did not find easy to understand or pertinent. They could also provide information on why such questions were difficult to understand. Another questionnaire on epilepsy, the Side Effects and Life Satisfaction Inventory [22], was also completed in the same session and the results from this questionnaire will be published separately. To assess reproducibility, the subjects were

given a second copy of the QOLIE-31 questionnaire that they were asked to complete one week later and return to the study centre.

This study was performed within the framework of the Declaration of Helsinki guidelines for clinical research. Since participation in the study did not affect patient care, formal Ethics Committee approval was not required. No patient received remuneration for participating in the study. The study was approved by the Comité National Informatique et Liberté, which ensures that all medical information is kept confidential and anonymous.

Statistical analysis

For a given subject, a scale score was not calculated if more than 20% of the items were lacking and the overall score was not calculated if one scale score were lacking. The acceptability of the questionnaire was assessed on the basis of the completion time and the proportion of items lacking or inadequately completed. The mean standard deviation, median and range were calculated for each scale and for the overall scale. The percentage of responses on anchor points was examined for each item to detect floor or ceiling effects. Reproducibility was assessed by test-retest, using intra-class correlations between the same questionnaires completed by the same subject at an interval of seven days.

For multi-trait analysis, internal consistency of the questionnaire and its scales was analysed using Cronbach's α coefficient. For each item, the correlation with its own scale and with the other scales was calculated. It was assumed that the correlation between an item and its own scale should be ≥ 0.40 and that, to verify the discriminant validity, an individual item should show greater correlation with the score of its hypothesized scale than with the other scales. Another assumption of the multi-trait analysis is that items belonging to the same scale should show approximately the same variance. The ranges of the standard deviations were therefore calculated for each scale.

An exploratory factor analysis with varimax rotation was used to identify the questionnaire structure (construct validity). To identify the most economical structural model for the questionnaire, different goodness of fit criteria were tested, including the Akaike [23] and Schwartz [24] criteria.

Discriminative validity was assessed by investigating the capability of the instrument to differentiate between groups with expected differences in QOL. The following characteristics were chosen: the severity and frequency of seizures and the response to treatment. Comparisons were performed using non-parametric tests (Mann-Whitney test for comparing two groups; Kruskall-Wallis test for more than two groups). Whenever the Kruskall-Wallis test was significant, *post hoc* tests were made using Bonferroni's corrections to keep a familywise error lower or equal to 0.05. Convergent and divergent validity were assessed by non-parametric correlation coefficients (Spearman) with the NHP scores.

All statistical tests were two-sided, with an α-level of 0.05. Statistical analysis was performed using the 6.12 version of the SAS software on UNIX system.

Results

Subjects

Out of the 118 physicians in Béziers, 33 participated in the study. The participation rates were 30% for general practitioners, 50% for neurologists and 14% for psychiatrists, with lack of time being the main reason given for those who did not take part. Out of the 210 questionnaires filled in by the patients, 190 had sufficient data to be analyzed. Sixty seven percent (n = 127) of the valid questionnaires came from subjects being treated by neurologists, 30% (n = 58) from subjects being treated by general practitioners and 3% (n = 5) from subjects being treated by psychiatrists. The socio-demographic characteristics of these patients are detailed in *table 1*. The median age of epilepsy onset was 17 years (interquartile range: 12-29 years) with

Table 1. Socio-demographic characteristics of the 190 patients participating in the study

Characteristics	Mean ± SD N (%)
Age (years ± SD)	40.8 ± 15.5
Gender	
Male	93 (48.9%)
Female	97 (51.1%)
Employment status	
In full-time employment	67 (35.2%)
Unemployed	30 (15.8%)
Retired	21 (11.0%)
Housewife	17 (8.9%)
Student	20 (10.5%)
Receiving invalidity benefit	29 (15.3%)
Employment category*	
Self-employed/managing directors	9 (8.3%)
Managers/higher education	18 (16.7%)
Intermediate professions	14 (12.9%)
Employees	45 (40.7%)
Manual workers	19 (17.6%)
Other	3 (2.8%)
Educational level	
No formal education	6 (3.2%)
Primary	24 (12.8%)
Secondary	118 (63.1%)
Higher	39 (20.9%)

* Employment categories are expressed for 108 of the 118 subjects who were in full-time employment, retired or unemployed. Data were missing for the remaining ten subjects.

Table 2. Main seizure type and seizure frequency over the previous year

Seizure type (raw%)	Frequency in past year			
	None	≤ 1/month	> 1/month	Total
Generalised tonic-clonic (GTC)	34 (69.4%)	12 (24.5%)	3 (6.1%)	49
Absence (± GTC)	7 (46.7%)	5 (33.3%)	3 (20.0%)	15
Myoclonic (± GTC)	3 (30.0%)	2 (20.0%)	5 (50.0%)	10
Partial without GTCS	22 (34.9%)	20 (31.7%)	21 (33.3%)	63
Partial with GTCS	19 (45.2%)	12 (28.6%)	11 (26.2%)	42
Total (raw%)	**85 (47.5%)**	**51 (28.5%)**	**43 (24.0%)**	**179**

a duration of 18 years (interquartile range: 9-28 years). Ninety seven percent of the subjects were receiving antiepileptic medication. Over the previous year, 48% had experienced no seizures, 2% at least one seizure per year but fewer than one per month, and 24% had experienced more than one seizure per month. Seizure type, summarized in *table 2*, was predominantly partial (57%), of which 32% were secondarily generalized. Generalized tonic-clonic seizures accounted for 27% of cases, and absences and myoclonic seizures for 10.5% and 5.3% of cases, respectively. At the end of the consultation, medication was modified for 30 subjects (16.1%) for reasons of inefficacy or problems of side effects.

QOLIE-31 acceptability

The acceptability of QOLIE-31 was good, with a mean duration of completion of 10 minutes (range: 6-22 minutes), 57% of subjects completing all items. For most items, the proportion of missing data was less than 5%, with the exception of the overall QOL (item 1: 8%), work limitations (item 27: 8%) and problems with driving (item 20: 23%). For this last item, most of the subjects without a driving license did not respond. The two items most frequently presenting problems of comprehension were questions on the "physical" (item 29) and "mental" effects of antiepileptic medications (item 30).

Descriptive statistics

The scores obtained for the subscales of QOLIE-31 are given in *table 3*. All of the scales showed adequate variability, with five showing the minimum of zero and all, except emotional well-being, showing the maximum of 100. Median scores were not markedly different from the mean scores.

The floor-effect ranged from 2% to 42% for item 15 (embarrassment about seizures), however this was to be expected, as 48% of the subjects were seizure-free. The ceiling-effect ranged from 3% to 62% for item 20, problems with driving, although again this was expected as 36% of the subjects did not have a driving licence and, out of those patients with a licence, 31% did not drive.

Reliability

Reliability after one week was good, intraclass correlations (ICC) ranging from 0.71 (energy/fatigue) to 0.86 (seizure-worry), with an overall coefficient of 0.89. In order to see whether a change in treatment implemented during the inclusion consultation would affect reproducibility, intraclass correlations were also calculated in two subgroups of patients: those whose medication had been changed at the end of the consultation and those whose medication was unchanged. For the latter group, the overall ICC was 0.9, whist for those subjects whose medication had been changed it was only 0.85. This was mostly due to the medication effects subscale, for which the ICC was

Table 3. Mean subscale and overall scores (SD) median score (range), items variability (SD range) and internal consistency of QOLIE-31

Scale	No. of items	N = 190 (%)	Mean score (SD)	Median score (range)	SD of items: range	Cronbach's α
Seizure-worry	5	**185 (97.4%)**	58.7 (30.1)	62.7 (0.0-100.0)	33.7-39.9	0.84
Overall QOL	2	**174 (91.6%)**	64.0 (21.1)	67.5 (0.0-100.0)	22.1- 23.1	0.83
Emotional well-being	5	**187 (98.4%)**	57.6 (20.6)	60.0 (4.0-96.0)	24.6-28.1	0.83
Energy/fatigue	4	**176 (71.8%)**	51.7 (19.8)	50.0 (0.0-100.0)	24.4-27.2	0.82
Cognitive functioning	6	**187 (98.4%)**	61.7 (25.4)	64.7 (3.3-100.0)	28.3-37.5	0.82
Medication effects	3	**178 (93.7%)**	65.5 (30.1)	72.2 (0.0-100.0)	36.3-36.7	0.85
Social functioning	5	**178 (93.7%)**	69.4 (26.4)	75.0 (0.0-100.0)	31.3-40.1	0.82
Overall score	30	**159 (83.7%)**	61.9 (19.0)	65.8 (11.0-97.0)		0.86

0.47 in subjects whose medication was changed compared to 0.81 in subjects without medication changes.

Multitrait analysis

High internal consistency was shown by a Cronbach's α coefficient of 0.86 for the overall score and coefficients ranging from 0.82-0.85 for the subscales (*table 3*). The ranges of the SDs of the items within a given scale varied from 0.4 (medication effects) to 9.2 (cognitive functioning) (*table 3*). The main sources of this large variation were two-fold: firstly, higher SDs for memory problems (items 15 and 26) in the cognitive functioning scale; secondly, a lower SD for worry about having another seizure (item 11) in the social functioning scale and lower SDs for limitation in social activities (item 13) and leisure time (item 19) in the seizure-worry scale. Within a given scale, the correlations of the questions to that scale should be similar if the responses to the questions contain approximately the same amount of information about the concept being measured. Item-to-scale correlations ranged from 0.65 (item 20: problems with driving) to 0.82 (item 28: social limitations) in the social functioning dimension. The difference between the correlations of a given dimension was always less than 0.14 in the other dimensions.
As expected, the correlations of each item with the scale on which it was loaded were always greater than 0.70 except for items 20 (problem with driving) and 19 (problem with leisure time) for which the correlations were respectively, 0.65 and 0.66. The correlation of one item with its own scale was always greater than the correlations with the other scales, showing good discriminant validity.

Factor analysis

An exploratory factor analysis with varimax rotation of QOLIE-31 led to the identification of seven factors with eigenvalues ≥ 1 that accounted for 71% of the variance. The first factor (34% of variance) was mainly associated with the six items of the cognitive functioning and with two items of the energy/fatigue scale (worn out, tired). The second factor (12.5% of variance) appeared to be related to mood, associated with the two items of the overall QOL, two of the items of the energy/fatigue scale (pep, energy) and two from the emotional well-being scale (calm and peaceful, happy). The third factor (6.9% of variance) was identical to seizure-worry, the fourth (6.3% of variance) corresponded mainly to emotional well-being and the fifth factor (4.4% of the variance) was identical to medication effects. The sixth (4.0% of variance) and seventh (3.3% of variance) factor corresponded to social functioning.
The use of goodness of fit indices showed that a model with four factors best fitted the data. This model is numerically stable and appears to be conceptually coherent. The first factor corresponds to a generic mental dimension, including emotional well-being, energy/fatigue and overall QOL scales, the second is equivalent to the cognitive functioning dimension, the third to medication effects and social functioning, and the fourth to seizure-worry.

Discriminative validity

The influence of the seizure types, not very marked in our data, is summarized in *table 4*. Partial seizures were associated with significantly lower cognitive functioning, energy/fatigue, social functioning and global scores. If partial seizures were secondarily generalized only the seizure-worry scale decreased whilst generalized tonico-clonic seizures were associated with a higher score only for cognitive functioning. High seizure frequency was statistically associated with lower QOLIE-31 scores for each scale except for overall QOL and emotional well-being. Only seizure-free patients had significantly better scores than the others ($p < 0.05$, *post hoc* t-test with Bonferroni's correction).
Good seizure control and treatment tolerability were associated with significantly higher scores for seizure-worry, energy/fatigue, cognition, medication effects, social functioning and overall score, whilst good treatment compliance was also associated with higher scores for emotional well-being but not for seizure-worry. A change of medication for lack of efficacy was associated with significant decreased scores for all parameters except emotional well-being.
As regards socio-demographic characteristics, QOLIE-31 scores did not appear to be affected by age or sex. In contrast, higher social status/employment was associated with better scores for seizure-worry ($p = 0.0001$), energy ($p = 0.03$), cognitive functioning ($p = 0.007$), medication effects ($p = 0.0002$), social functioning ($p = 0.001$) and overall score ($p = 0.0002$). A *post hoc* t-test with Bonferroni's correction showed that subjects on invalidity benefit were always significantly more affected than employed subjects. Unemployed subjects were more affected than employed subjects regarding seizure-worry, medication effects and overall score. In addition, retired subjects had better scores than those who were unemployed, for medication effects and seizure-worry, and better scores than students and those on invalidity benefit, for seizure-worry. A higher education level was also associated with higher scores for seizure-worry ($p = 0.009$), energy/fatigue ($p = 0.01$), cognitive functioning ($p = 0.001$), medication effects ($p = 0.03$), social functioning ($p = 0.005$) and overall score ($p = 0.003$).

Convergent and divergent validity: correlations between QOLIE-31 and NHP

Fairly strong correlations were identified between QOLIE-31 and NHP scales of close content, indicating convergent validity (*table 5*). In particular, QOLIE-31 emotional well-being correlated with NHP emotional re-

Table 4. Relationship between clinical characteristics and QOLIE-31 scores (median scores)

	N	Seizure-worry	Overall QOL	Emotional well-being	Energy/fatigue	Cognit. funct.	Medication effects	Social funct.	Global score
Partial seizures									
Yes	114	61.6	67.5	60	50	60.4	72.2	67	60.0
No	75	62.6	67.5	60	55	74.7	72.2	81	69.4
p		NS	NS	NS	**0.05**	**0.001**	NS	**0.03**	**0.04**
Secondarily generalized (in partial seizures)									
always/often	44	48.3	65.0	58	50	53.4	66.6	70	58.0
Rarely/never	67	72.3	72.5	60	50	61.6	72.2	66	64
p		**0.02**	NS	NS	NS	NS	NS	NS	NS
Tonic-clonic generalized seizures									
Yes	72	61.3	67.5	60	55	73.3	72.2	80	68.3
No	117	62.3	72.5	60	50	61.9	72.2	70	63.8
p		NS	NS	NS	NS	**0.01**	NS	NS	NS
Seizure frequency									
No seizure	85	75.3	72.5	60	60	73.6	77.8	81.0	71.2
< 1/month	50	50.0	65.0	60	45	53.3	69.4	69.3	55.2
≥ 1/month	42	48.0	67.5	52	50	61.6	58.3	61.0	55.5
p		**0.0001**	NS	NS	**0.0009**	**0.0004**	**0.06**	**0.001**	**0.002**
Seizure control									
No seizures	89	76.0	72.5	62	60.0	72.7	72.5	80.0	70.5
Good	49	58.3	65.0	60	50.0	56.2	65.0	70.0	64.7
Bad	45	42.3	62.5	56	42.5	50.7	67.5	59.0	54.7
p		**0.0001**	NS	NS	**0.0004**	**0.0008**	**0.03**	**0.003**	**0.0004**
Anxiety disorder									
Yes	78	49.3	60.0	52	45	57.7	55.5	70.0	56.0
No	108	70.1	72.5	64	55	66.9	80	78.1	69
p		**0.001**	**0.002**	**0.0006**	**0.02**	NS	**0.0003**	**0.09**	**0.004**
Depressive disorder									
Yes	26	62.6	27.5	32	37.5	53.0	48.6	48.0	41.1
No	159	62.3	72.5	64	55	66	72	76.8	68.3
p		NS	**0.0001**	**0.0001**	**0.0001**	**0.01**	**0.03**	**0.002**	**0.0001**
Tolerability									
Very good	117	66.7	72.5	60	55	66.9	55.5	78.7	69.1
Good/bad	63	50.3	67.5	60	50	58.0	25	68.7	60.2
p		0.06	NS	NS	**0.03**	**0.05**	**0.06**	**0.0001**	**0.03**
Compliance									
Very good	123	65.3	72.5	60	52.5	66.9	76.3	80.0	69.1
Good	48	54.6	67.5	60	50.0	64.3	55.5	65.6	57.7
Bad	10	40.3	56.2	38	35.0	27.2	47.2	49.5	45.3
p		NS	NS	**0.007**	**0.02**	**0.003**	**0.03**	**0.008**	**0.001**
Change for lack of efficacy									
No	125	70.3	72.5	60	55.0	71.1	79.2	80.0	69.1
Once	37	48.0	72.5	64	50.0	59.9	66.7	62.5	61.2
≥ twice	19	42.3	55.0	48	35.0	39.7	41.7	60.0	43.1
p		**0.001**	**0.06**	NS	**0.0004**	**0.0004**	**0.0008**	**0.004**	**0.0008**

NS: not significant.

actions (r = -0.80, $p = 0.0001$), QOLIE-31 energy/fatigue with NHP energy (r = -0.68; $p = 0.0001$), emotional reactions (r = -0.59, $p = 0.0001$) and social isolation (r = -0.52, $p = 0.0001$), QOLIE-31 QOL with NHP emotional reactions (r = -0.65, $p = 0.0001$) and QOLIE-31 social functioning with NHP social isolation (r = -0.52; $p = 0.001$). In contrast, weak correlations were found between scales of dissimilar contents, suggesting discrimi-

Table 5. Correlation (Spearman's coefficient) between QOLIE-31 and NHP scores. Correlations ≥ 0.60 are shown in bold. All associations were statistically significant ($p < 0.05$)

QOLIE-31	NHP					
	Energy	Pain	Emotion	Sleep	Isolation	Mobility
Seizure-worry	-0.31	-0.25	-0.35	-0.39	-0.32	-0.35
Overall QOL	-0.37	-0.17	**-0.65**	-0.24	-0.48	-0.25
Emotional well-being	-0.45	-0.29	**-0.80**	-0.40	-0.49	-0.35
Energy/fatigue	**-0.68**	-0.43	-0.59	-0.30	-0.52	-0.43
Cognitive functioning	-0.49	-0.31	-0.52	-0.35	-0.40	-0.40
Medication effects	-0.24	-0.22	-0.38	-0.22	-0.35	-0.26
Social functioning	-0.40	-0.33	-0.46	-0.32	-0.52	-0.48
Overall score	0.57	-0.39	**-0.69**	-0.40	**-0.60**	-0.49

nant validity e.g. QOLIE-31 medication effects and NHP pain (r = -0.22; $p = 0.005$). The two very specific dimensions of the QOLIE-31 (seizure-worry and medication effects) showed no correlations > 0.4.

Discussion

The French version of the QOLIE-31 inventory showed good psychometric properties and comparable to those of similar studies in other countries (*table 6*). In particular, we found a mean overall score (SD) of 61.9 (19.0), as compared to 63 (16) in the original US study [3], and 61.77 (17.33) in the Spanish study [16], whilst the Cronbach's factors for the overall scores were 0.86 in the present study and 0.93, 0.94 and 0.92 in the US [3], German [14] and Spanish studies [16], respectively (*table 4*). The scores and Cronbach's α-factors for the individual items were also similar to those found previously in other languages (*table 6*). In the Hungarian study, generally lower score values were reported but the trends were similar to the other studies (*table 6*) [15].

Acceptability appeared satisfactory, given that, the patients had to complete three different questionnaires within the same session. The lack of relevance for those with no driving license accounted for the fairly high proportion of missing data for the driving problem item. The two items most frequently raising problems of comprehension were on the "physical" and "mental" effects of antiepileptic medications, suggesting that the wording of these items could be improved. Reproducibility was also good, and again similar to previous studies (*table 6*). Additional analyses showed that the main source of fluctuation was related to changes in treatment at the end of the study consultation.

Factor analysis suggested that the QOLIE-31 inventory could be summarized by four dimensions: the first corre-

Table 6. Results from the validation of QOLIE-31 in US English [3], Spanish [16], German [14], Hungarian [15] and Georgian [17]

	French	US English	Spanish	German	Hungarian	Georgian
Mean score ± SD						
Seizureworry	58.7 ± 30.1	58 ± 26	51.5 ± 29.7	NA	54.0 ± 28.5	NA
Overall QOL	64.0 ± 21.1	67 ± 18	68.3 ± 16.9	NA	55.5 ± 19.32	NA
Emotional well-being	57.6 ± 20.6	67 ± 19	61.8 ± 19.1	NA	58.3 ± 18.5	NA
Energy/fatigue	51.7 ± 19.8	55 ± 12	60.9 ± 20.7	NA	49.7 ± 17.7	NA
Cognitive functioning	61.7 ± 25.4	60 ± 23	60.3 ± 23.8	NA	59.3	NA
Medication effects	65.5 ± 30.1	55 ± 31	60.3 ± 29.1	NA	57.4 ± 31.1	NA
Social functioning	69.4 ± 26.4	67 ± 21	66.4 ± 28.0	NA	56.88 ± 23.6	NA
Overall score	61.9 ± 19.0	63 ± 16	61.77 ± 17.3	NA	NA	NA
Cronbach's α						
Overall score	0.89	0.93	0.92	0.94	NA	0.71-0.82
Range for subscales	0.71-0.86	0.77-0.85	0.55-0.83	0.76-0.90	NA	0.71-0.82
Test-retest						
Overall score	0.86	0.89	0.90	0.79	NA	NA
Range for subscales	0.82-0.85	0.64-0.89	0.62-0.84	0.59-0.78	NA	NA

NA: data not available.

sponding to a psychological dimension (overall QOL, emotional well-being and energy/fatigue) and the second to cognition. The other two corresponded to more specific dimensions: one to medication effects and social functioning and the other to seizure-worry. This differs slightly from previous studies, where medication and social functioning were also found to be single factors [3, 14], but in both these studies a similar heterogeneous factor was identified consisting of overall QOL, emotional well-being and energy/fatigue.

Discriminative validity was also good and in agreement with other studies. QOLIE-31 scores were found to be influenced by seizure frequency [3, 14] and treatment characteristics [3, 14]. QOLIE-31 scores also varied significantly with social/employment status, unemployed and disabled subjects having particularly low scores. Similar results were found in the Hungarian study between subjects who were employed and those on a disability pension [15]. We also found that educational level had a positive, significant effect on QOLIE-31 scores, in agreement with the Georgian study [17]. Nonetheless, it should be pointed out that the causal nature of these relationships is not addressed by any these studies, and remains unclear.

Expectations related to convergent validity were met, with high correlations between QOLIE-31 and NHP scores for scales of similar content and low correlations for those of dissimilar content that were epilepsy-specific.

QOLIE-31 was designed to assess QOL in a broad spectrum of adult patients suffering from epilepsy. It was derived from QOLIE-89 [4], to give a more rapid test. It was found to have similar responsive indices to the longer version [7, 10] and to be sensitive to change [7, 10]. An even more abbreviated form, QOLIE-10, has also been validated [2]. However, subsequent studies have concluded that QOLIE-31 is preferable to QOLIE-10, when time and resources are available [8]. In addition, QOLIE-31 has been validated in several other languages.

The results presented here support the reliability and validity of the French translation of this inventory, and suggest that observed differences in item and scale scores are due to real and relevant differences and not ascribable to inadequate translation. The availability of a validated epilepsy-specific, health-related QOL tool will not only benefit clinical studies within France but should also aid larger, multinational studies. □

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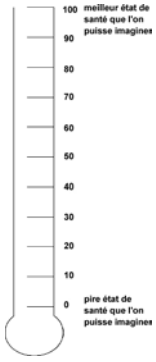
Annexe
QOLIE-31 Questionnaire (version 1.0)

Item	Scale	US-English	French
1	**OQL**	Overall, how would you rate your quality of life?	Dans l'ensemble sur une échelle de 10 à 0, quelle est, selon vous, votre qualité de vie ?
		[Circle one number on a scale from 10 (best possible QOL) to 0 (worst possible QOL, as bad as or worse than being dead)]	*[Entourez un seul chiffre sur l'échelle de 10 (Meilleure qualité de vie possible) à 0 (Pire qualité de vie possible (comparable à la mort ou pire)]*
		These questions are about how you feel and how things have been for you during the past 4 weeks.	**Les questions qui suivent portent sur comment vous vous êtes senti(e) au cours de ces 4 dernières semaines.**
		For each question please indicate the one answer that comes closest to the way you have been feeling.	*Pour chaque question, veuillez entourer la réponse qui vous semble la plus appropriée.*
		How much of the time during the past 4 weeks ...	*Au cours de ces 4 dernières semaines, y a-t-il eu des moments où ...*
		(Circle one number on a scale ranging from 1 [all of the time] to 6 [none of the time]).	*(En permanence = 1 ; Très souvent = 2 ; Souvent = 3 ; Quelques fois = 4 ; Rarement = 5 ; Jamais = 6)*
2	**E/F**	Did you feel full of pep?	Vous êtes-vous senti(e) dynamique?
3	**EWB**	Have you been a nervous person?	Vous êtes-vous senti(e) très nerveux(se)?
4	**EWB**	Have you felt so down in the dumps that nothing could cheer you up?	Vous êtes-vous senti(e) si découragé(e) que rien ne pouvait vous remonter le moral?
5	**EWB**	Have you felt calm and peaceful?	Vous êtes-vous senti(e) calme et détendu(e)?
6	**E/F**	Did you have a lot of energy?	Vous êtes-vous senti(e) débordant(e) d'énergie?
7	**EWB**	Have you felt downhearted and blue?	Vous êtes-vous senti(e) triste et abattu(e) ?
8	**E/F**	Did you feel worn out?	Vous êtes-vous senti(e) épuisé(e) ?
9	**EWB**	Have you been a happy person?	Vous êtes-vous senti(e) heureux(se) ?
10	**E/F**	Did you feel tired?	Vous êtes-vous senti(e) fatigué(e) ?
11	**SW**	Have you worried about having another seizure?	Vous vous êtes fait du souci à l'idée d'avoir une autre crise ?
12	**CF**	Did you have difficulty reasoning and solving problems (such as making plans, making decisions, learning new things)?	Vous avez eu des difficultés pour réfléchir et résoudre des problèmes (par exemple : faire des projets, prendre des décisions, ou apprendre des choses nouvelles) ?
13	**SF**	Has your health limited your social activities (such as visiting with friends or close relatives)?	Votre santé a limité votre vie sociale et vos relations avec les autres (par exemple : rendre visite à des amis ou parents proches) ?
14	**OQL**	How has the quality of your life been during the past 4 weeks (that is, how have things been going for you)?	Comment a été votre qualité de vie au cours de ces quatre dernières semaines (c'est-à-dire comment les choses se sont-elles passées pour vous ?)
		(Circle one number on a ladder scale ranging from 1 = very well : could hardly be better, to 5 = very bad : could hardly be worse)	*(Entourez un seul chiffre sur l'échelle ci-dessous :* *[Très bonne, aurait difficilement pu être meilleure = 1 ; Très mauvaise : aurait difficilement pu être pire = 5])*
15	**CF**	In the past 4 weeks, have you had any trouble with your memory?	Au cours de ces quatre dernières semaines, avez-vous eu des problèmes de mémoire ?
		[Circle one number between 1 and 4 :. 1 = yes, a great deal : 4 = no, not at all]	*(Entourez un seul chiffre: [Oui beaucoup = 1 ; Oui assez = 2 ; Seulement un peu = 3 ; Non pas du tout = 4])*
16	**CF**	**Circle one number for how often in the past 4 weeks you have had trouble remembering or how often this memory problem has interfered with your normal work or living.**	**La question suivante porte sur la fréquence avec laquelle vous avez eu des problèmes pour vous souvenir des choses, ou la fréquence avec laquelle ces problèmes de mémoire ont perturbé votre travail ou votre vie de tous les jours, au cours de ces 4 dernières semaines.**
		[Trouble remembering things people tell you (Circle one number on a scale from 1 = All of the time to 6 = none of the time)]	Problèmes pour vous souvenir de ce que les gens vous ont dit ? *(Entourez un seul chiffre : [En permanence = 1 ; Très souvent = 2 ; Souvent = 3 ; Quelques fois = 4 ; Rarement = 5 ; Jamais = 6])*
		The following questions are about concentration problems you may have had.	**Les questions suivantes portent sur les problèmes de concentration que vous pouvez avoir.**
		[Circle one number for how often in the past 4 weeks you had trouble concentrating or how often these problems interfered with your normal work or living. (Circle one number on a scale from 1 = all of the time to 6 = none of the time)]	Avec quelle fréquence avez-vous eu des problèmes de concentration ? Avec quelle fréquence ces problèmes ont-ils perturbé votre travail ou votre vie de tous les jours, au cours de ces 4 dernières semaines. *[En permanence = 1 ; Très souvent = 2 ; Souvent = 3 ; Quelques fois = 4 ; Rarement = 5 ; Jamais = 6]*
17	**CF**	Trouble concentrating on reading	Problèmes de concentration pour lire
18	**CF**	Trouble concentrating on doing one thing at a time	Problèmes pour vous concentrer sur une seule chose à la fois

Item	Scale	US-English	French
		The following questions are about problems you may have had with certain activities.	**Les questions suivantes portent sur les problèmes que vous rencontrez peut-être pour faire certaines activités**.
		Circle one number for how much during the past 4 weeks your epilepsy or antiepileptic medication has caused trouble with .... *[Circle one number on a scale from 1 = a great deal to 6 = not at all]*	Dans quelle mesure, au cours de ces quatre dernières semaines, l'épilepsie ou vos médicaments anti-épileptiques ont-ils posé problème pour les activités suivantes.*(Enormément = 1; Beaucoup = 2; Assez = 3; Seulement un peu = 4; Pas du tout = 5]*
19	**SF**	Leisure time (such as hobbies, going out)	Loisirs (par exemple : passe temps, sorties)
20	**SF**	Driving	Conduire
		The following questions relate to the way you feel about seizures.	**Les questions suivantes portent sur ce que vous ressentez par rapport à vos crises.**
21	**SW**	How fearful are you of having a seizure during the next months?	Avez-vous peur d'avoir une crise au cours des quatre prochaines semaines ?
		[Circle one number on a scale from 1 = very fearful to 4 = not fearful at all]	*[Très peur = 1; Assez peur = 2; Pas très peur = 3; Pas peur du tout = 4]*
20	**SW**	Do you worry about hurting yourself during a seizure?	Etes-vous inquiet(ète) à l'idée de vous faire mal au cours d'une crise ?
		[Circle one number on a scale from 1 = worry a lot to 3 = don't worry at all]	*[Très inquiet(ète) = 1; Un peu inquiet(ète) = 2; Pas inquiet(ète) du tout = 3]*
23	**SW**	How worried are you about embarrassment or other social problems resulting from having a seizure during the next month?	Etes-vous inquiet(ète) en pensant à l'embarras ou aux autres problèmes vis-à-vis des autres qu'occasionnerait une crise au cours des quatre prochaines semaines ?
		[Circle one number on a scale from 1 = very worried to 4 = not worried at all]	*[Très inquiet(ète) = 1; Assez inquiet(ète) = 2; Pas très inquiet(ète) = 3; Pas inquiet(ète) du tout = 4]*
24	**ME**	How worried are you about medications you are taking will be bad for you if taken for a long time?	Etes-vous inquiet(ète) à l'idée que les médicaments que vous prenez finissent par vous faire du mal à la longue ?
		For each of these problems, circle one number for how much they bother you (on a scale of 1 to 5 where 1 = not at all bothersome, and 5 = extremely bothersome).	**Pour chacun des problèmes ci-dessous, entourez le chiffre qui indique dans quelle mesure il vous gêne**. Pour cela, utilisez l'échelle de 1 à 5 sur laquelle : 1 = pas gênant du tout et 5 = extrêmement gênant.
25	**SW**	Seizures	Crises
26	**CF**	Memory difficulties	Problèmes de mémoire
27	**SF**	Work limitations	Limites dans le travail
28	**SF**	Social limitations	Vie sociale ou relations limitées avec les autres
29	**ME**	Physical effects of antiepileptic medication	Effets physiques des médicaments anti-épileptiques
30	**ME**	Mental effects of antiepileptic medication	Effets psychologiques des médicaments anti-épileptiques
31		**How good or bad do you think your health is?** On the thermometer scale below, the best imaginable state of health is 100 and the worst imaginable state is 0. Please indicate how you feel about your health by circling one number on the scale. Please consider your epilepsy as part of your health when you answer this question. (Thermometer scale 100 = best imaginable health state to 0 = worst imaginable health state [as bad as or worse than being dead])	**La question suivante porte sur votre état de santé actuel**, tel que vous le ressentez et en tenant compte de votre épilepsie dans cette évaluation. Pour cela, entourez sur le thermomètre le chiffre correspondant.  100 correspond au meilleur état de santé que l'on puisse imaginer et 0 au pire état de santé que l'on puisse imaginer.

SW: seizure-worry ; OQL : overall quality of life : EWB : emotional well-being ; E/F : energy/fatigue ; CF : cognitive functioning ; ME : medication effects ; SF : social functioning.

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