Original article

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Psychometric validation of the French version of the side-effects and life satisfaction inventory (SEALS) in epileptic patients:

comparison with the QOLIE-31 inventory and a generic quality of life questionnaire

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ABSTRACT – A psychometric evaluation of a French version of the side-effects and life satisfaction inventory (SEALS) was carried out. SEALS was compared to the quality of life in epilepsy-31 questionnaire (QOLIE-31) and a generic, health-related quality-of-life questionnaire, the Nottingham health profile (NHP). The psychometric properties of SEALS, assessed in 190 adult subjects with epilepsy, included: acceptability, test-retest reliability and validity, multitrait analysis including internal consistency and item-to-scale correlations, construct validity using factor analysis and discriminative validity using associations with disease characteristics and treatment effects, and, correlations with NHP and QOLIE-31 scores for convergent and divergent validity. Both acceptability and reproducibility were good and internal consistency was high (Cronbach's α coefficient = 0.92). Factor analysis with varimax rotation identified five factors: the first, related to cognitive function accounted for 26.0% of the variance. Discriminative validity was good for most treatment characteristics (tolerability, seizure control, compliance) and clinical features (epilepsy type, seizure frequency and severity, depressive symptoms). Correlations with the NHP and QOLIE-31 scores were consistently strong. It was concluded that the psychometric properties of the French translation of SEALS were similar to the original English version. In addition, SEALS provides information on quality of life that is complementary to that obtained with QOLIE-31. In particular, with respect to the QOLIE-31, the SEALS provides information on cognitive and neuropsychological aspects of impairment of quality of life, whereas the QOLIE-31 has a broader scope, taking into account multiple aspects of quality of life in epilepsy.

Key words: adverse drug effects, epilepsy, quality of life, French version, psychometric validation

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In addition to good seizure control, improvement in quality of life (QOL) is an important treatment objective in epilepsy. However, the side effects of anti-epileptic medication may have profound, negative effects on QOL, particularly as regards cognitive and neurological impairment (Baker *et al.* 1996, Baker *et al.* 1997). This makes it crucial to have reliable methods of assessing those aspects of a patient's QOL affected by medication, especially those of a subtle and subjective nature. This is important not only to develop optimal protocols for seizure management but also for clinical trials of new drugs. For multinational clinical trials it is also important that any QOL measurement has been translated consistently, and validated to take into account the cultural specificities of the countries in which it is to be used.

A number of disease-specific questionnaires have been developed to assess health-related QOL in epilepsy (Brown and Tomlinson 1982, Vickrey *et al.* 1992, Baker *et al.* 1993b, Jackoby *et al.* 1994, Devinski *et al.* 1995, Cramer *et al.* 1996, Cramer *et al.* 1998, Picot *et al.* 2004) but none has so far been validated in France, with the exception of the QOLIE-31 (Cramer *et al.* 1998), which was validated simultaneously with the present study (Picot *et al.* 2004). One of these measures that deals with the psychosocial aspect of QOL in epilepsy, the Side-Effect and Life Satisfaction (SEALS) inventory, was initially developed in the UK as a 50-item, self-report questionnaire, derived from the symptoms and epileptic treatment side-effects reported by a patient population (Brown *et al.* 1982). This was later refined to a 38-item inventory (Gillham *et al.* 1996) and subsequently validated (Gillham *et al.* 2000a). SEALS has also been tested on a Japanese population (Kugoh 1996).

A large international program of transcultural adaptation of SEALS scales has been undertaken, along with another epilepsy-specific QOL measurement, the Quality of Life in Epilepsy-31 (QOLIE-31) (Cramer *et al.* 1998). Following this adaptation, we report here the results of the psychometric validation of the French version of the 38-item SEALS inventory and its comparison with QOLIE, as well as a generic QOL measure, the French adaptation (Bucquet *et al.* 1990) of the Nottingham Health Profile (NHP) (Hunt *et al.* 1985).

Methods

Quality of life measurements

The version of the SEALS inventory used in this study included 38 items organized in five subscales: cognition, dysphoria, tiredness, temper and worry (*see annexe*) (Gillham *et al.* 1996). The questions relate to the subject's feelings and behaviour over the previous week with the answers on a four-point, Likert scale: never = 0, occasionally = 1, sometimes = 2 and many times = 3. A total weighted score and a weighted score for each dimension was computed for each score, on the basis of previous factor analysis of the original version (Gillham *et al.* 1996), and the results are expressed as percentages of the maximal score. In the original study, lower SEALS scores reflected better QOL (Gillham *et al.* 1996). However, to ensure coherence with the other quality of life measures, the score values were inverted in the present study, to make higher scores reflect better QOL.

Translation and cultural adaptation of the British version of SEALS were carried out as follows. 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 French version of the QOLIE-31 contains 30 items organized into seven subscales: seizure worry, overall QOL, emotional well-being, energy-fatigue, cognitive functioning, medication effects, and social functioning. An overall score is obtained by summing the scale scores after weighting using empirically derived coefficients provided in the QOLIE-31 Scoring Manual (Vickrey *et al.* 1993).

The NHP contains 38 items grouped in six scales: energy, pain, emotional reactions, sleep, social isolation and physical mobility (Hunt *et al.* 1985). NHP scores range from 0-100, with higher scores reflecting better QOL. In this study, we have used the validated French version with the weightings appropriate for the French population (Bucquet *et al.* 1990).

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. 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, and the subjects were asked to complete the SEALS, QOLIE-31 and NHP questionnaires. At the end of the SEALS questionnaire there were additional items relating to the pertinence and comprehensibility of the individual

items. To assess reproducibility, the subjects were given a second copy of the SEALS questionnaire that they were asked to complete one week later and return to the study centre. The presence of comorbid anxiety and depressive disorder, according to the physician's judgement, was recorded. Any change in the patient's medication regimen as a result of the consultation was also documented.

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 was 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 individual 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 multitrait 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 multitrait analysis is that items belonging to the same scale should show approximately the same variance. The range of the standard deviations was therefore calculated for each scale.

An exploratory factor analysis with varimax rotation was used to identify the questionnaire structure (construct validity). Discriminative validity (external construct 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, response and tolerability to treatment. Comparisons were performed using non-parametric tests (Mann-Whitney *U*-test for comparing two groups, Kruskall-Wallis test for more than two groups). Whenever the Kruskall-Wallis test was significant, *post hoc t*-tests were made using Bonferroni's corrections to keep a familywise error lower or equal to 0.05. Convergent and divergent validities were assessed by non- parametric correlation coefficients (Spearman) with the QOLIE-31 and NHP scores. All statistical tests were bilateral, with an α level of 0.05. Statistical analysis was performed using the 6.12 version of the SAS software.

Ethics

This study was performed within the framework of the Declaration of Helsinki guidelines for clinical research. Under French legislation, formal Ethics Committee approval was not required since participation in the study did not affect patient care. The study was approved by the Comité National Informatique et Liberté, which ensures that all medical information is kept confidential and anonymous.

Results

Subjects

Thirty-three of the 118 physicians in Béziers 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 participate. Out of the 210 questionnaires filled in by the patients, 190 had sufficient data to be analysed. 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) being treated by psychiatrists. Forty-nine percent of the subjects were male and the overall mean (SD) age was 40.8 ± 15.5 years. Fifty-four percent of the subjects had the equivalent of a high school education or higher (n = 103), 32.5% (n = 67) were in full-time employment, 15.8% (n = 30) were unemployed, 11.0% (n = 21) were retired, 8.9% (n = 17) were housewives, 10.5% (n = 20) were students and 15.3% (n = 29) were receiving invalidity benefit.

The median age of epilepsy onset was 17 years (interquartile range: 12-29 years), with a duration of 18 years (interquartile range: 9-28 years). Seizure type 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. The epilepsy was symptomatic in 38.8% of cases (n = 73). Of the subjects with symptomatic epilepsy, 24 (12.8%) had a history of severe head trauma, 12 (6.6%) had perinatal factors, 10 (5.3%) cerebral tumour, 8 (4.2%) infectious antecedents, 6 (3.2%) cerebrovascular disease, 6 (3.2%) chronic alcoholism and 12 (6.4%) other aetiologies or multiple causes. Almost half of the patients (47%) reported the possibility of injury during seizures. Amongst concomitant disorders, the most frequently reported was anxiety (42.1%, n = 80), followed by depression (14.2%, n= 27).

Ninety seven percent of subjects received at least one antiepileptic medication and in the opinion of the physician there was very good or good tolerance in 98% of cases with treatment compliance being assessed as very good or good in 95% of the subjects. Treatment led to the disappearance of seizures in 49% of cases and good

control in a further 27%. Within the previous 12 months, the treatment had been changed for 31% of the subjects for reasons of insufficient efficacy, and for 9% due to adverse events.

Questionnaire acceptability

The acceptability of SEALS was satisfactory with a mean duration of completion of 10 minutes (range: 5-14 min). Eighty three percent of the subjects found SEALS interesting or very interesting, and 87% found it easy to understand. The questions most frequently causing problems of comprehension were item 30 (12 subjects), item 10 (9 subjects), item 22 (8 subjects), item 6 (8 subjects) and item 8 (6 subjects). Certain questions, namely items 22 (5 subjects), 31 (5 subjects) and 34 (5 subjects) were felt to be irrelevant. In addition, 21% of subjects thought that certain questions should be removed, namely item 30 (8 subjects), item 22 (5 subjects) and item 12 (4 subjects). For most items, the proportion of missing data was less than 4%, with the exception of two items: item 8 (have you felt satisfied?) and item 30 (have you found it easy to enjoy yourself?) from the dysphoria subscale for which the proportion of missing data was 5.3% and 7.4%, respectively. Even though only 69% of the patients provided data for all items, sufficient information was obtained to calculate the scores for all the scales in 95.3% of cases (181/190).

SEALS items and scores

The mean scores obtained for SEALS questionnaire are given in *table 1*. Median scores did not differ markedly from the mean scores. All of the scales showed adequate variability with all scales showing the absolute minimum of zero and three scales the maximum of 100. The floor-effect ranged from 7% (item 9: have you thought a lot about problems you may have?) to 55% (item 19: have you got on as well as you would like with people close to you?), and was high for most items, corresponding to a high proportion of optimal responses. In contrast, the ceiling-effect was generally low, ranging from 2% (item 19) to 54% (item 9). The domain with the worst responses was worry (24%-54%).

SEALS scores were not affected by gender or age *(table 2)*, but educational level was associated with higher scores for cognition ($p = 0.02$), dysphoria ($p = 0.03$), tiredness ($p = 0.03$) and overall score ($p = 0.01$). Employment status was also associated with cognition ($p = 0.006$), worry ($p = 0.003$) dysphoria ($p = 0.02$) and the overall score ($p = 0.001$) *(table 2)*. Subjects with higher education had significantly better scores in all domains than subjects with no formal education and significantly better scores for dysphoria and global score than those with only primary or secondary level education (*post hoc t*-test with Bonferroni's correction). Subjects in full employment and students had higher scores on all scales, apart from tiredness, than those who were unemployed or on invalidity benefit *(table 2)*. A *post hoc t*-test with Bonferroni's correction show that subjects on invalidity benefit were always significantly more affected than employed subjects. Students also had better scores than those on invalidity benefit.

Reliability

Reliability after one week was good, intraclass correlations ranging from 0.67 (worry) to 0.78 (cognition) and 0.79 for the overall score *(table 1)*. 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 had remained stable. For the latter group ($n = 123$) the overall correlation was 0.80, whilst for those subjects whose medication had been changed ($n = 23$) it was 0.75. This was mostly due to the worry subscale (0.71 *versus* 0.42, respectively).

Multitrait analysis

Good internal consistency was shown by a Cronbach's α coefficient of 0.92 for the overall score. For the individual scales the coefficient ranged from 0.65 (worry) to 0.91 (cognition) and only in the former case was it < 0.7. The correlation of an individual item was always higher with the scale on which it loaded than with the other scales (data not shown). The SDs of the items within a given scale were homogenous *(table 1)*.

Factor analysis

An exploratory factor analysis with varimax rotation *(table 3)* led to the identification of five factors which

Table 1. Mean, median, internal consistency and intraclass correlations of subscale and overall scores of SEALS.

Scale	No. of items	N	Mean (SD)	Median (range)	Items SD (range)	Cronbach's α factor	Intraclass correlation
Cognition	17	187	57.5 (22.8)	58.0 (6.0-100.0)	1.0-1.2	0.91	0.78
Dysphoria	8	182	72.1 (17.0)	74.4 (36.0-100.0)	0.8-1.0	0.73	0.69
Tiredness	5	188	58.7 (24.0)	62.1 (0.0-100.0)	1.0-1.1	0.70	0.74
Temper	4	181	59.8 (25.3)	58.4 (0.0-100.0)	0.9-1.1	0.75	0.73
Worry	4	182	34.6 (25.8)	29.3 (0.0-100.0)	0.9-1.1	0.65	0.67
Overall score	38	187	58.5 (16.8)	59.5 (23.0-96.5)		0.92	0.79

Table 2. SEALS scores as a function of gender, age educational level, employment status and profession.

	N	Cognition	Dysphoria	Tiredness	Temper	Worry	Overall score
Gender							
Men	97	57.5	69.8	61.1	60.1	34.3	58.3
Women	93	57.5	74.2	56.3	59.4	34.8	58.6
p	–	NS	**0.08**	NS	NS	NS	NS
Age							
16-25 years	38	61.5	71.6	59.8	59.4	36.8	62.5
26-50 years	110	56.0	75.2	61.8	58.0	28.2	57.2
> 50 years	39	57.9	73.3	64.7	65.8	29.2	63.5
p	–	NS	NS	NS	NS	NS	NS
Educational level							
No formal education	28	47.4	71.3	53.8	66.2	28.2	55.1
Primary	54	58.0	75.5	63.7	57.4	25.0	58.4
Secondary	62	57.4	70.4	61.1	58.1	28.2	58.1
Higher	39	69.2	82.8	66.8	62.4	38.3	68.2
p	–	**0.02**	**0.03**	**0.03**	NS	NS	**0.01**
Employment status							
Employed	67	67.6	77.5	66.7	58.1	38.3	66.2
Unemployed	30	59.1	68.9	65.7	58.0	18.4	55.4
Retired	21	57.9	75.0	64.7	75.1	58.4	63.5
Housewife	17	48.2	77.4	56.1	49.5	25.0	55.5
Student	20	60.8	79.7	59.8	64.1	38.7	65.2
Invalid	29	41.4	66.9	53.8	54.4	15.2	45.4
p	–	**0.005**	**0.02**	**0.10**	NS	**0.003**	**0.003**

Table 3. Factor analysis with varimax rotation.
Item numbers in bold correspond to those found in the original analysis.

Our data		Data from Gilliam *et al.*, 1996 [11]	
Factor	Item number[a]	Factor	Item number
Cognition	**14,** 15, **16, 22, 23, 25, 28, 32, 33, 35, 36**	*Cognition*	5, 13, 14, 16, 18, 21, 22, 23, 24, 25, 26, 28, 32, 33, 35, 36, 38
Memory	4, **13, 21, 24, 38**		
Temper/worry	**3, 12, 29, 34,**	*Temper*	3, 12, 29, 34
	9, 17, 31	*Worry*	9, 15, 17, 31
Dysphoria	**1, 6, 8, 11, 19, 30, 37**	*Dysphoria*	1, 6, 8, 10, 11, 19, 30, 37
Tiredness	**2, 7, 20**	*Tiredness*	2, 4, 7, 20, 27

[a] Correlation factor-item > 0.40.

accounted for 50% of the variance. The first factor, which accounted for 26% of the variance, mainly consisted of 13 of the 17 items of the cognition scale *(table 3)*. This group of items represents better cognitive performance. The four remaining items of the original cognitive scale loaded on the second factor, which accounted for 8% of the variance and corresponds to memory problems. Two items from the dysphoria scale (items 1 and 6) and item 31 from the worry scale also loaded in this second factor. The third factor corresponded to both temper and worry dimensions, the fourth to dysphoria and the fifth to tiredness.

Discriminative validity: SEALS scores and epilepsy characteristics

Seizure frequency was associated with cognition, tiredness and overall score *(table 4)*. Only seizure-free patients had significantly better scores than the others (*post hoc* t-test with Bonferroni's correction). Seizure type affected only cognition (p = 0.005) and overall score (p = 0.02), and the duration of epilepsy had no effect on SEALS scores (not shown). The occurrence of injury or accidents during seizures was associated with low scores for the worry dimension (p = 0.04, not shown).

Table 4. SEALS scores (median) according to seizure frequency, control, tolerability, observance and changes in antiepileptic treatment.

	N	Cognition	Dysphoria	Tiredness	Temper	Worry	Overall score
Seizure frequency							
No. seizures	83	68.7	76.3	63.1	65.0	30.2	63.3
1/month – 1/year	51	52.8	70.3	58.1	57.0	23.3	55.4
≥ 1/month	43	53.1	70.9	65.0	58.5	30.2	54.6
p		**0.0006**	0.06	0.06	NS	NS	**0.001**
Seizure type							
Partial seizure	110	46.7	25.3	38.2	40.9	71.8	43.0
Other	79	32.3	25.9	35.3	42.1	66.7	37.0
p		**0.005**	NS	NS	NS	NS	**0.02**
Tolerability							
Very good	119	61.5	72.1	63.1	65.7	33.3	62.5
Good/poor[a]	64	50.8	78.8	61.4	57.6	19.3	55.4
p		**0.005**	NS	NS	NS	**0.002**	**0.02**
Compliance							
Very good	124	62.6	75.0	63.0	59.4	35.5	62.8
Good	49	51.7	74.5	61.8	59.4	23.3	55.0
Bad	10	19.9	50.5	50.8	37.3	9.0	30.6
p		**0.00003**	**0.01**	NS	NS	**0.008**	**0.00006**
Change for lack of efficacy							
No	127	62.7	74.3	64.6	62.5	31.2	62.5
Once	38	54.9	75.3	57.0	58.0	33.1	55.3
≥ twice	19	33.9	74.3	41.7	58.8	18.3	42.8
p		**0.002**	NS	0.02	NS	NS	**0.006**
Comorbid anxiety							
Present	78	49.1	29.2	35.9	42.0	75.4	43.5
Absent	108	38.5	24.7	40.7	40.6	65.6	37.1
p		**0.06**	**0.06**	NS	NS	**0.003**	**0.03**
Comorbid depression							
Present	26	61.7	40.6	37.7	42.3	85.2	59.8
Absent	159	38.7	25.0	38.1	40.8	66.6	38.1
p		**0.0001**	**0.02**	NS	NS	**0.0004**	**0.0001**

[a] poor, n = 3; good n = 61.

Good seizure control was associated with significantly higher SEALS scores for cognition, tiredness, and overall score, whilst treatment tolerability was associated with a positive effect on cognition, worry and overall score. There was a particularly strong association between SEALS scores, cognition and overall score and, to a lesser extent, worry and dysphoria

As expected, underlying anxiety or depression was associated with poorer scores not only on the worry score ($p = 0.004$ and $p < 0.001$, respectively), but also on dysphoria ($p = 0.04$ and $p = 0.02$, respectively), cognition ($p = 0.04$ and $p < 0.001$, respectively) and overall scores ($p = 0.02$ and $p < 0.001$, respectively) (*Annexe 1*).

Convergent and divergent validity of SEALS with QOLIE-31

The SEALS cognition score correlated well with all scales of QOLIE-31, particularly cognition, and to a lesser extent energy, social functioning and emotional well-being *(table 5)*. SEALS dysphoria correlated well with the non-specific psychological dimensions of QOLIE-31, namely emotional well being, energy/fatigue and overall QOL and to a lesser extent to cognition and social functioning *(table 5)*. In contrast, there was a weak correlation between SEALS and the epilepsy-specific dimensions of QOLIE-31, namely seizure worry and medication effects *(table 6)*.

Correlation between SEALS and the NHP

SEALS cognition and overall scores had correlations of > 0.4 with all of the NHP domains except pain, and this was particularly strong for energy, emotion and isolation. SEALS dysphoria correlated best with the NHP emotion and isolation domains that reflect mood disorder, and

Table 5. Non-parametric correlation coefficients and *p* values between SEALS and QOLIE-31 scores. Correlations ≥ 0.60 are shown in dark grey and correlations between 0.4-0.59 are shown in light grey.

QOLIE 31	SEALS					
	Cognition	**Dysphoria**	**Tiredness**	**Temper**	**Worry**	**Overall score**
Seizure worry	0.48	0.34	0.37	0.31	0.48	0.56
	0.0001	*0.0001*	*0.0001*	*0.0001*	*0.0001*	*0.0001*
Overall QOL	0.43	0.50	0.27	0.37	0.32	0.55
	0.0001	*0.0001*	*0.0003*	*0.0001*	*0.0001*	*0.0001*
Emotional well-being	0.58	0.53	0.37	0.50	0.54	0.71
	0.0001	*0.0001*	*0.0001*	*0.0001*	*0.0001*	*0.0001*
Energy/ fatigue	0.62	0.50	0.43	0.18	0.27	0.63
	0.0001	*0.0001*	*0.0001*	*0.0201*	*0.0004*	*0.0001*
Cognitive functioning	0.78	0.45	0.45	0.15	0.32	0.72
	0.0001	*0.0001*	*0.0001*	*0.04*	*0.0001*	*0.0001*
Medication effects	0.48	0.26	0.24	0.19	0.48	0.49
	0.0001	*0.0005*	*0.0015*	*0.001*	*0.0001*	*0.0001*
Social functioning	0.59	0.46	0.38	0.20	0.37	0.62
	0.0001	*0.0001*	*0.0001*	*0.008*	*0.0001*	*0.0001*
Overall score	0.80	0.60	0.47	0.31	0.49	0.84
	0.0001	*0.0001*	*0.0001*	*0.0001*	*0.0001*	*0.0001*

Table 6. Non-parametric correlations between SEALS and NHP. Correlations between -0.4 and -0.60 are shown in light grey and those ≤ -0.60 are shown in dark grey.

NHP	SEALS					
	Cognition	**Dysphoria**	**Tiredness**	**Temper**	**Worry**	**Overall score**
Energy	-0.50	-0.31	-0.42	-0.16	-0.18	-0.51
	0.0001	*0.0001*	*0.0001*	*0.03*	*0.02*	*0.0001*
Pain	-0.36	-0.18	-0.23	-0.12	-0.12	-0.35
	0.0001	*0.02*	*0.003*	*ns*	*ns*	*0.0001*
Emotion	-0.60	-0.54	-0.36	-0.38	-0.42	-0.69
	0.0001	*0.0001*	*0.0001*	*0.0001*	*0.0001*	*0.0001*
Sleep	-0.40	-0.34	-0.24	-0.17	-0.35	-0.44
	0.0001	*0.0001*	*0.002*	*0.03*	*0.0001*	*0.0001*
Isolation	-0.54	-0.45	-0.20	-0.24	-0.25	-0.57
	0.0001	*0.0001*	*0.009*	*0.003*	*0.001*	*0.0001*
Mobility	-0.41	-0.21	-0.34	-0.19	-0.21	-0.42
	0.0001	*0.008*	*0.0001*	*0.002*	*0.008*	*0.0001*

SEALS tiredness correlated with NHP energy. SEALS temper and worry correlated best with NHP emotion.

Discussion

The French version of the 38-item SEALS inventory showed satisfactory psychometric properties. The mean overall score was similar to that reported for the English version (Gillham *et al.* 2000a) and scores did not vary according to gender and age, unlike that which is observed with generic quality of life measures, such as the NHP (Hunt *et al.* 1985) or the SF-36 (Jenkinson *et al.* 1993). Similar relationships between SEALS scores and gender and age were reported in the British and Japanese studies (Gillham *et al.* 1996, Kugoh 1996). Higher SEALS scores were associated with higher education levels and employment status, as is observed for many other health-related, quality of life measures.

It is perhaps interesting to note that the validation of the UK version of SEALS (Gillham *et al.* 2000a) used a study population where subjects with poor seizure control were over-represented, and it was suggested that further validation with a sample population with good seizure control might be desirable. In the subjects used in the present study, seizure control was estimated as good or very good in 76% of cases showing that the psychometric properties

of the SEALS inventory are comparable in different clinical study populations.

The psychometric properties of the French version of SEALS are, generally speaking, consistent with those of the original English version (Gillham 1996, Gillham 2000a). Internal consistency was good, with a Cronbach's α factor of 0.92 for the overall score and with the scores for all the subscales, except worry, being ≥ 0.7. For the worry subscale, Cronbach's α factor was 0.65, which is low but consistent with other studies where values of between 0.65-0.7 have been reported (Gillham *et al.* 2000a, Kane *et al.* 1996).

With respect to the factor analysis, we identified five factors after varimax rotation as did Gillham *et al.* (1996). However, our analysis suggested that the worry and temper scales from the analysis by Gillham *et al.* (1996) could correspond to one dimension only, whereas the initial cognition scale could be subdivided into two dimensions, the first related to intellectual performance, and the second to memory problems.

Inasmuch as this questionnaire focuses on the side effects of medication and is therefore likely to be used mainly during international clinical trials, acceptability was a crucial factor. The results in this regard were good, with 87% of the subjects finding the inventory interesting or very interesting. The wording of some of the items may have caused problems of comprehension (see annexe), for instance in items 30 and 22 the word "*to enjoy yourself*" has been translated by the French "*prendre plaisir*". In retrospect this might be too strong to convey the original concept and it might be better replaced with "*s'amuser*". In addition, items 6 and 10 might be too abstract in their current translation. Item 6: in the original is "*have you felt awake...*"; this is translated by "*avoir l'esprit vif*" which might be more suitably replaced with "*se sentir éveillé*". As for Item 10, "*Have you been even-tempered?*" is translated by "*Avez-vous été d'humeur égal?*", whereas "*Avez-vous été calme/serein?*" might be better. Reproducibility of the SEALS inventory was good with Pearson's and intraclass correlations factors for the overall scores of 0.83 and 0.79, respectively. Part of variability in the answers after a one-week interval was found to be due to those subjects whose medication had been changed after the study consultation, which affected their replies to the worry subscale.

Regarding discriminative validity, the most significant parameters likely to influence the SEALS scores were seizure frequency and treatment characteristics, especially compliance or a change of medication in the previous year due to lack of efficacy, disability and anxiety.

The correlations between overall scores from SEALS and QOLIE-31 were acceptable. However, the different dimensions did not necessarily correlate well, suggesting that they capture different sorts of information. The cognition subscale of SEALS showed good correlations with all the subscales of QOLIE-31 and, in particular, the cognitive functioning subscale, whilst the SEALS dysphoria subscale was linked to the non-specific, psychological aspects of QOLIE–31, emotional well-being, energy/fatigue and overall QOL. On the other hand, the tiredness, worry and temper SEALS scores did not match particular QOLIE-31 scales well, and the QOLIE-31 seizure worry and medication effect scales were not well assessed by the SEALS. The mismatch between the QOLIE-31 medication subscale and the SEALS is at first sight paradoxical, since the SEALS is supposed to measure medication effects. This difference may be explained by the different sorts of information tapped by the two scales. In the SEALS, items generally relate to the neuropsychological impact of antiepileptic drugs (and also to the impact of epilepsy itself). In fact, the quality of life variables measured by the SEALS are only implicitly related to antiepileptic drug treatment and it is difficult to assign them specifically to treatment side-effects rather than to the global impact of the pathology on cognitive function. On the other hand, the QOLIE-31 explicitly asks questions on the physical, mental and functional impact of antiepileptic drug treatment, and it is these variables that are captured in the medication subscale. For example, the question in the QOLIE-31 "*How worried are you about medications you are taking will be bad for you if taken for a long time?*" may generate similar information to the "Worry" dimension of the SEALS, which is well-correlated between the two scales.

Good correlations were also found between certain SEALS dimensions and pertinent NHP scores, for example, SEALS cognition and NHP energy, emotion and isolation. Once again, the concepts measured by the tiredness, worry and, particularly, temper SEALS subscores were not well correlated with any of the NHP scores.

The SEALS inventory was designed to assess adverse cognitive and behavioural effects of antiepileptic medications (Brown *et al.* 1982, Gillham *et al.* 1996, Gillham *et al.* 2000a). However, although it is nominally a measure of the impact of "side-effects" and "life satisfaction" on quality of life, in fact it indiscriminately captures information on the neuropsychological impact of epilepsy and its treatment. To measure specifically and exhaustively the impact of adverse events with antiepileptic drugs on quality of life, the Adverse Events Profile (Baker *et al.* 1993a) may be a more appropriate instrument, and scores on this measure are well correlated with the QOLIE-31 (Gilliam *et al.* 2004).

Nonetheless, the SEALS complements other QOL instruments such as the Liverpool Life Satisfaction Inventory (Baker *et al.* 1993b) that is concerned with how a subject feels, whereas SEALS measures how mood states manifest in behaviour (Gillham *et al.* 2000a). In particular, with respect to the QOLIE-31, the SEALS provides information on cognitive and neuropsychological aspects of impairment of quality of life, whereas the QOLIE-31 has a broader scope, taking into account multiple aspects of quality of life in epilepsy. The former instrument is well-

suited for studies specifically addressing cognitive function, whereas the latter is more appropriate for general quality of life studies in epilepsy.
The SEALS is easy to administer and complete, and its reliability and responsiveness have been verified in several clinical trials (Brodie *et al.* 1995, Kane *et al.* 1996, Bryant-Comstock *et al.* 1999, Steiner *et al.* 1999, Gillham *et al.* 2000b). In one of these studies it was concluded that not only is SEALS an effective tool for clinical trials but also it is a better predictor of trial completion than seizure counts (Gillham *et al.* 2000b).
SEALS is available in a number of languages (Gillham *et al.* 2000a) but to our knowledge, until now, it has only been validated in UK English (Gillham *et al.* 2000a) and Japanese (Kugoh 1996). The results presented here demonstrate that the psychometric properties of the French translation of SEALS are acceptable and are close to those of the original English version. The SEALS inventory provides complementary information to other general and epilepsy-specific questionnaires. This opens the way for the use of this instrument in international clinical trials. □

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Annexe. SEALS questionnaire

Choix de réponse: ***De nombreuses fois, quelques fois, de rares fois, jamais***	**Response choice:** ***Many times, sometimes, occasionally, never***
Au cours de la semaine dernière:	**In the last week:**
1 - Avez-vous été enthousiaste à l'idée de faire des choses?	1 - Have you felt enthusiastic about doing things?
2 - Vous est-il arrivé d'avoir envie de vous endormir pendant la journée?	2 - Have you felt like nodding off to sleep during the day?
3 - Avez-vous été irritable avec les autres?	3 - Have you been irritable with people?
4 - Vous êtes-vous senti(e) trop fatigué(e) pour faire quoi que ce soit le soir?	4 - Have you felt too tired to do anything at all in the evening?
5 - Avez-vous laissé les autres choisir à votre place?	5 - Have you let other people make up your mind for you?
6 - Avez-vous eu l'esprit vif même quand vous étiez tout(e) seul(e)?	6 - Have you felt alert even when on your own?
7 - Vous êtes-vous endormi(e) sans le vouloir pendant la journée?	7 - Have you fallen asleep during the day without meaning to?
8 - Avez-vous été satisfait(e) / content(e)?	8 - Have you felt satisfied?
9 - Avez-vous beaucoup pensé à vos problèmes éventuels ?	9 - Have you thought a lot about problems you may have?
10 - Avez-vous été d'humeur égale?	10 - Have you been even tempered?
11 - Avez-vous montré envers les autres autant d'affection que vous le souhaitiez?	11 - Have you been as affectionate towards other people as you would have like?
12 - Avez-vous été mêlé(e) à des disputes ou à des querelles à la maison?	12 - Have you been involved in rows or arguments at home?
13 - Avez-vous été obligé(e) de faire des listes ou de noter certaines choses que vous deviez faire pour ne pas les oublier?	13 - Have you had to make lists or notes to remind you to do things?
14 - Avez-vous dû renoncer à faire quelque chose parce que vous aviez du mal à vous concentrer?	14 - Have you had to give up something because of difficulty concentrating?
15 - Vous êtes-vous fait du souci pour votre avenir?	15 - Have you been worrying about your future?
16 - Avez-vous eu du mal à vous joindre aux autres quand vous étiez en leur compagnie ?	16 - Have you found it difficult to join in when you have been with other people?
17 - Etes-vous resté(e) éveillé(e) plus tard que d'habitude?	17 - Have you stayed awake later than usual?
18 - Avez-vous manqué de volonté pour faire certaines choses?	18 - Have you felt you couldn't be bothered to do things?
19 - Vous êtes-vous entendu(e) aussi bien que vous le souhaitiez avec les personnes qui vous sont proches?	19 - Have you got on as well as you would like with people close to you?
20 - Vous êtes-vous endormi(e) avant d'aller vous coucher?	20 - Have you fallen asleep before going to bed?
21 - Avez-vous prévu de faire quelque chose que vous avez ensuite oublié?	21 - Have you planned to do something, but then forgotten?
22 - Avez-vous eu du mal à prendre du plaisir dans ce que vous avez fait?	22 - Have you found it difficult to enjoy yourself?
23 - Avez-vous eu du mal à suivre le fil d'une émission de télévision, d'un article de journal, etc. ...?	23 - Have you found it difficult to follow the story of a TV programme, newspaper article, etc.?
24 - A-t-on dû vous dire deux fois la même chose parce que vous l'aviez oubliée la première fois?	24 - Has anyone had to tell you something twice because you forgot it the first time?
25 - Avez-vous dû faire les choses très lentement pour pouvoir les faire correctement?	25 - Have you had to do things very slowly in order to get them right?
26 - Vous est-il arrivé de ne pas avoir les idées claires?	26 - Have you felt fuzzy headed or vague?
27 - Etes-vous allé(e) vous coucher plus tôt que d'habitude?	27 - Have you gone to bed earlier than you usually do?
28 - Avez-vous eu du mal à suivre ce que disaient les autres?	28 - Have you had difficulty following what people were saying?
29 - Vous êtes-vous mis(e) à crier pour un rien?	29 - Have you shouted or yelled for very little reason?
30 - Vous a-t-il été facile de prendre du plaisir dans ce que vous avez fait?	30 - Have you found it easy to enjoy yourself?
31 - Vous êtes-vous fait du souci pour l'avenir de votre famille?	31 - Have you been worrying about your family's future?
32 - Avez-vous eu l'impression d'avoir l'esprit qui fonctionne au ralenti?	32 - Have you felt slowed up?
33 - Avez-vous évité d'avoir des contacts avec les autres?	33 - Have you avoided mixing with people?
34 - Vous êtes-vous mis(e) en colère?	34 - Have you lost your temper?

Choix de réponse: ***De nombreuses fois, quelques fois, de rares fois, jamais***	**Response choice:** ***Many times, sometimes, occasionally, never***
35 - Avez-vous eu l'impression d'avoir l'esprit qui fonctionne au ralenti même en compagnie des autres?	35 - Have you felt slowed up or dulled in the company of other people?
36 - A-t-il fallu que les autres prennent des décisions à votre place?	36 - Have other people had to make decisions for you?
37 - Avez-vous été d'humeur à bavarder?	37 - Have you had a lot to say people?
38 - Avez-vous oublié où vous aviez mis certaines choses?	38 - Have you forgotten where you've put things?