Psychometric Validation of the Croatian Version of the Quality of Life in Epilepsy Inventory (QOLIE-31)

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ABSTRACT

The primary goals of this study were to adapt the Quality of Life in Epilepsy Inventory – 31 items (QOLIE-31) questionnaire to the Croatian language and to assess the translated questionnaire's psychometric properties. Translation/ retranslation of the English version of the QOLIE-31 was done, and all steps for cross-cultural adaptation process were performed properly by an expert committee. Later, QOLIE-31 questionnaires and previously validated Short Form-36 (SF-36) outcome instruments were given to 200 patients with epilepsy. 172 patients (86%) responded to the first set of questionnaires, and 114 of the first time respondents (66%) returned their second survey. The two measures of reliability as internal consistency and reproducibility were determined by Cronbach α statistics and intraclass correlation coefficient, respectively. Concurrent validity was measured by comparing with a SF-36 questionnaire, and measurement was made using the Pearson correlation coefficient (r). The study demonstrated satisfactory internal consistency with high Cronbach a values for all of the corresponding domains (seizure worry 0.84, medication effects 0.80, emotional well-being 0.73, energy/fatigue 0.76, cognitive functioning 0.71, social functioning 0.77, overall quality of life 0.65). The intra $class\ correlation\ coefficient\ for\ six\ domains\ of\ QOLIE-31\ question naire\ demonstrated\ excellent\ test/retest\ reproducibility$ $(ICC \ge 0.75)$, and good test/retest reproducibility (ICC 0.71) in one domain (cognitive functioning). Considering concurrent validity, three domains had excellent correlation (r=0.75-1), while 11 had good correlation (r=0.50 to 0.75), and 3 had moderate correlation (r=0.25-0.50). This study demonstrated that, if measures are to be used across cultures, the items must not only be translated well linguistically but also must be culturally adapted to maintain the content validity of the instrument at a conceptual level across different cultures. Croatian version of QOLIE-31 will be a valuable contribution to outcome measurement in epilepsy patients, particularly in the context of treatment trials, but als in a wider research context.

Key words: QoL in epilepsy, OLIE-31 questionnaire, validity, reliability, Croatia

Introduction

The chronic nature of epilepsy often results in long-term relationships among the neurologist, the patient, and the patient's family. When treating a patient with epilepsy it is important to evaluate the degree to which epilepsy affects their life. Persons with chronic health disorders are at risk of impaired health related quality of life (HRQOL)¹. Because the epilepsy has a substantial impact on health (e.g. side effects of anticonvulsant therapy, lifestyle restrictions, physical difficulties, psychosocial difficulties, perceived stigmatization) self-reported physical and mental HRQOL measures are useful in gauging the impact of epilepsy on persons with the disorder²⁻⁴.

One of the methods to define and monitor the impact of epilepsy on patient's life is to ask patients to record their feelings on questionnaires⁵. The focus of these demands is aimed at assessing »quality of life« (QOL) as a measure of outcome in clinical practice and/or drug trials, along with evaluating the allocation of health care resources. With the introduction of the health related QOL questionnaires, it is possible to understand the perception of the patient of his/her current condition and the results of the applied treatment. Health care providers and the pharmaceutical industry have been showing increasing interest in QOL, because without equally re-

fined QOL measurements, a clear and comprehensive evaluation of efficacy of new drugs – or new medical interventions – is not possible.

QOL questionnaires use a multidimensional approach; the concept of QOL assessment has led to development of generic questionnaires, designed to assess health status among patients with different health conditions and diseases, and disease-specific questionnaires to evaluate specific areas of concern to patients⁶.

There are few questionnaires designed specifically for patients with epilepsy: Liverpool Health Related Quality of Life Battery (Liverpool HRQOL); Washington Psychosocial Seizure Inventory (WPSI); Epilepsy Surgery Inventory (ESI-55); Quality of Life in Epilepsy Inventory – 89 items (QOLIE-89) and Quality of Life in Epilepsy Inventory – 31 items (QOLIE-31)⁷⁻¹¹.

There is also Quality of Life in Epilepsy Inventory – 10 items (QOLIE-10), but this questionnaire is used only for screening purposes¹².

The aim of the original QOLIE-31 questionnaire, developed by Cramer et al., was to facilitate – from a patient based point of view – the assessment of the outcome during the treatment of patients with a simple, practical, epilepsy-specific instrument. The QOLIE-31 is a self-completed questionnaire designed for adult epileptic patients (18 years or older). It was derived from a previously mentioned longer instrument, the QOLIE-89, created by the QOLIE Development Group in 1993. It contains seven subscales which address the following aspects: emotional well-being, social functioning, energy/fatigue, cognitive functioning, seizure worry, medication effects and overall quality of life¹¹.

The overall high performance of this questionnaire in its reliability, concurrent and discrimination validity, and responsiveness to change associated with medical treatment results in its wide use in the English-speaking countries. However, to conduct multinational epilepsy studies that include assessments of QOL requires previous rigorous translation and adaptation of the questionnaire to the culture of each country in which it is going to be used. 13 Such instruments will allow researchers to aggregate and compare QOL data across sample populations from different countries. The process is complicated not only due to wide differences in the concept of what constitutes »health« among different cultures but also due to difficulty in achieving conceptual equivalence and consistency with the original instrument¹⁴. During last few years, the validations of the Spanish, German, French, Italian, Thai and Czech versions of QOLIE-31 have been published¹⁵⁻²⁰. These validations indicate a high degree of conceptual similarity to the original version.

The main objective of presented study was to evaluate the reliability and validity of the translated and culturally adapted Croatian version of the QOLIE-31 questionnaire, with an effort to provide a common measure in reporting the quality of life of patients with epilepsy in Croatia.

Patients and Methods

The adaptation process was carried out as outlined by Beaton et al. and Ware et al.^{21,22}. In the first setting, two bilingual translators, the mother tongue of whom was Croatian, produced two independent translations, and finally a synthesis of these two translations was made. Afterwards, eight epileptic patients, ranging in age from 19 to 57 years, with different seizure types, completed the translated version of QOLIE. The next step was discussion of two neurologist with these patients about specific items of questionaire in search for problems in terms of acceptance or difficulties in comprehension. Subjects were asked to explain their opinion on item precision, clarity and appropriateness for every presented item and response. Our intention was to identify confounding, unclear, imprecise or inappropriate items. Patients were encouraged to write their comments on the questionnaire. Considering the results of the presented testing, few minor corrections of translated text were done. One translator, being unaware of the concepts studied, back--translated the adapted Croatian version into the English language. The expert committee composed of two neurologists, a translator, a physician from public health--preventive medicine department, a psychologist and a biostatistician further assessed the forward and back translations, and consensus was achieved on the final translation. The layout and the images of the final Croatian version were identical to the original instrument.

Patients included in presented study were randomly chosen from the database of Department of Neurology Epilepsy Service in Split University Hospital Centre (UHCS). UHCS is the second largest hospital in Croatia, with 1620 hospital beds, and more than 3500 employees. There is no other hospital, and also none epileptogist in private practice in the coverage area of our hospital (Split-Dalmatian County). General practitioners in Croatia would exclusively rely on specialist services at hospitals for diagnosis and follow-up of all patients with epilepsy. So, the patients included in this study were assumed to be representative for the population of epilepsy patients in Split-Dalmatian County (474.700 inhabitants).

Patients with at least 2 years of follow-up were included in the study. The reason for that criterion was to apply the instrument on patients with their treatments already established and who are thought to be stable in terms of their disease. Other eligibility criteria were good knowledge of Croatian language and ability to read and write. Exclusion criterion was any serious cognitive dysfunction and coexistence of major psychiatric disease. Before the interview, all the patients were assessed by an experienced epileptologist regarding the type, onset, duration and frequency of the seizures during previous year, including number and type of medications. Data (including age, gender, and level of education) were recorded on the previously designated questionnaire. Comorbidity was assessed by the medical record review, noting existence of other neurologic, musculoskeletal, cardiovascular, respiratory, hepatic, renal, gastrointestinal, genitourinary, metabolic, hematologic and psychiatric diseases; as well as surgical history and data about drug reactions.

Analysis of variance (ANOVA) was used to examine the correlation between QOLIE-31 and demographic and clinical variables (age, gender, level of education, type, duration and frequency of seizure(s) during previous year, duration of epilepsy, type and number of medications), as well as to assess construct validity under the hypothesis that duration

of epilepsy, number of medications, type and frequency of seizures would be significantly related to QO-LIE-31 domains. Patients were divided into five groups according to seizure frequency: no seizure during last year, <3 seizures during last year, 4–10 seizures during last year, 1–2 seizure/month, >3 seizure/month. The hypothesis was that higher seizure frequency would correspond with worse quality of life. Values less than 0.05 were considered statistically significant (adjusted for multiple testing).

After the interview and a description of study, the first package was given during their regular control visits to 200 outpatients, which comprised a written short description of the study, consent form, Croatian version of QOLIE-31 questionnaire and Short Form-36 (SF-36) questionnaire. Questionnaires were administered in face-to-face interviews to check the comprehensibility of the instruments.

The SF-36 Health Survey is a multi-purpose, short-form health survey that consists of 36 questions. It represents a theoretically based and empirically verified operationalization of two general health concepts – physical and psychological, and their two general manifestations – functioning and well-being. The Croatian version of SF-36 questionnaire was licensed to »Andrija Štampar« School of Public Health^{23,24}. Previously mentioned QOLIE-89 questionnaire is an QOL measure for people with epilepsy that includes SF-36 as a generic core, while QOLIE-31 is a subset of disease targeted items from QOLIE-89¹⁰.

Hundred and seventy two patients (86%) have completed the first set of questionnaires. The same set of questionnaires – without the consent form, but with an addressed and stamped return envelope – were mailed to the same 172 patients 3–5 weeks after the first one. Hundred and fourteen of the above mentioned first-time respondents (66%) returned their second survey.

Sociodemographic and clinical characteristics of these 114 patients are shown in Table 1.

The average response time between the first and second assessments was 26 days.

The two measures of reliability – internal consistency and reproducibility – were determined by Cronbach α statistics and intraclass correlation coefficient (ICC), respectively.

Concurrent validity was measured by comparing with an already translated and validated SF-36 questionnaire. Although the SF-36 is not a gold standard for health sta-

TABLE 1 SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE STUDY PARTICIPANTS (N=114)

| Characteristics | Number | Percent |
|-------------------------------------|--------------|------------|
| Mean age (yr) | 36.8±8.9 (ra | nge 18–71) |
| Gender | | |
| Male | 60 | 53% |
| Female | 54 | 47% |
| Mean duration of epilepsy (yr) | 11.3 (ra | nge 2–31) |
| Type of seizure | | |
| Simple partial | 17 | 15% |
| Complex partial | 51 | 45% |
| Primary generalized | 40 | 35% |
| Other | 6 | 5% |
| Number of seizures during last year | r | |
| None | 49 | 43% |
| 1–2 | 44 | 39% |
| ≥3 | 21 | 18% |
| Number of medications | | |
| 1 | 79 | 69% |
| ≥2 | 35 | 31% |
| Level of education | | |
| Primary schoool | 14 | 13% |
| Industrial or trade school | 31 | 27% |
| Secondary school | 33 | 29% |
| 2-year higher degree | 11 | 10% |
| University | 25 | 21% |
| Employment status | | |
| Student | 39 | 34% |
| Employed | 43 | 38% |
| Unemployed/retired | 32 | 28% |

tus assessment in epilepsy, we decided to use it as a standard for HRQOL, because it was the only appropriate instrument translated (and validated) in the Croatian language. A possible objection is that we have evaluated only a convergent validity – instead of a concurrent validity. However, the core SF-36 questionnaire has documented responsiveness in many other diseases besides epilepsy.

Measurements were made by using the Pearson correlation coefficient (r). Only the internal consistency of the domains was evaluated for the second part of the study by using Cronbach α statistics. Statistical Package for Social Sciences for Windows, version 10.0 (SPSS Inc., Chicago, IL, USA) was used for data processing. Values of p<0.05 were considered statistically significant.

Results

Most of the patients accepted the questionnaire quite well, and none of the items were found embarrassing. The time needed to complete the questionnaire was approximately 18 minutes (11–40); median time for questionnaire completion was 16 minutes. Six patients reported

difficulty with understanding the meaning of item No. 28 ("social limitations") and three patients had similar difficulties with the item No. 29 ("physical effects of anti-epileptic medication").

Disease duration, frequency of seizures and number of medications had a significant inverse relationship with QOLIE-31 scores (p<0.05). Age, gender difference, type of seizure and level of education were not associated with QOLIE-31 scores (p>0.05).

Table 2 shows the distribution of scores for the seven QOLIE-31 domains according to the second part of the study, with mean scores ranging from 55 to 84. In all of the domains of QOLIE-31 questionnaire the percentage of patients with floor effect was less than 2%. The percentage of patients with ceiling effect was found to be high in the seizure worry, medication effect, cognitive and social functioning domains of QOLIE-31 questionnaire. On two of the seven scales, >30% of the subjects scored 100 (the maximum value), indicating that a moderate proportion of the patients in our population had a good QOL – or the questionnaire was unable to discrimi-

nate between these subjects. The standard deviations were large for all scales, indicating large variations in the sample on most scales.

For comparison purposes the QOLIE-31 domain scores were analyzed by distribution in quartiles (Table 3). It was observed that 50% of the patients in role-physical and role-emotional domains of SF-36 questionnaire scored 100, demonstrating that the spread in the distribution of the responses was weak in these domains.

In Table 4 the internal consistency reliability scores according to the second part of the study are shown. The calculated Cronbach α of internal consistency for two domains (seizure worry 0.84, medication effects 0.80) was very satisfactory (Cronbach $\alpha\!=\!0.80\!-\!0.89$), and for other five domains (overall quality of life 0.65, emotional well-being 0.73, energy/fatigue 0.76, cognitive functioning 0.71, social functioning 0.77) was good (Cronbach $\alpha\!=\!0.50\!-\!0.79$).

The domains in SF-36 questionnaire demonstrated very satisfactory (three domains) or good (five domains) internal consistency reliability.

| Domain/subscale (No of items) | Domain means (SD) | % with floor effect | % with ceiling effect |
|-------------------------------|-------------------|---------------------|-----------------------|
| Seizure worry (5) | 76.2 (25.6) | 0.9 | 35.7 |
| Overal QOL (2) | 72.6 (21.1) | 0.9 | 11.3 |
| Emotional well-being (5) | 77.1 (22.1) | 0.0 | 18.3 |
| Energy/fatigue (4) | 54.8 (23.4) | 1.7 | 5.2 |
| Cognitive functioning (6) | 62.4 (31.2) | 0.9 | 32.2 |
| Medication effect (3) | 75.8 (19.9) | 1.7 | 25.2 |
| Social functioning (5) | 84.4 (28.9) | 0.9 | 21.8 |

| Quartiles | Seizure worry | Overal QOL | Emotional well-being | Energy/ Fatigue | Cognitive functioning | Medication effects | Social Functioning | |
|--------------|-------------------|--------------------|-------------------------|--------------------|-----------------------|--------------------|-------------------------|------------------------|
| QOLIE-31 do | mains | | | | | | | |
| 100% | 100 | 100 | 96 | 96 | 100 | 100 | 100 | |
| 75% | 100 | 96 | 80 | 84 | 100 | 100 | 80 | |
| 50% | 90 | 84 | 76 | 76 | 75 | 65 | 60 | |
| 25% | 76 | 72 | 68 | 64 | 60 | 60 | 40 | |
| 0% | 50 | 44 | 24 | 28 | 24 | 45 | 25 | |
| Quartiles | Physical function | Role- -physical | Role- -emotional | Bodily pain index | Vitality | Social functioning | Gen. health perceptions | Mental health index |
| SF-36 domain | s | | | | | | | |
| 100% | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| 75% | 90 | 100 | 100 | 90 | 75 | 100 | 75 | 76 |
| 50% | 80 | 100 | 100 | 77.5 | 65 | 87.5 | 60 | 64 |
| 25% | 72 | 50 | 50 | 57.5 | 50 | 62.5 | 40 | 56 |
| 0% | 22 | 0 | 0 | 22.5 | 15 | 25 | 15 | 20 |

The test/retest reproducibility correlations are presented in Table 5. The intraclass correlation coefficient of six domains of QOLIE-31 questionnaire demonstrated excellent test/retest reproducibility (ICC \geq 0.75), and good

test/retest reproducibility (ICC $\geq 0.40)$ in one domain (cognitive functioning). All of the domains of SF-36 questionnaire demonstrated excellent test/retest reproducibility.

TABLE 4 INTERNAL CONSISTENCY RELIABILITY (CRONBACH α) (N=114)

| QUOLIE-31 domain | α | SF-36 domain | α |
|-----------------------|------|----------------------------|------|
| Seizure worry | 0.84 | Physical functioning | 0.79 |
| Overal QOL | 0.65 | Role-physical | 0.77 |
| Emotional well-being | 0.73 | Role-emotional | 0.78 |
| Energy/fatigue | 0.76 | Bodily pain index | 0.86 |
| Cognitive functioning | 0.71 | Vitality | 0.74 |
| Medication effect | 0.80 | Social functioning | 0.78 |
| Social functioning | 0.77 | General health perceptions | 0.82 |
| | | Mental health index | 0.81 |

 ${\bf TABLE~5} \\ {\bf TEST-RETEST~REPRODUCIBILITY~AS~DETERMINED~BY~INTRACLASS~CORRELATION~COEFFICIENT~(N=114)} \\$

| QOLIE-31 domain | ICC | SF-36 domain | ICC |
|-----------------------|------|----------------------------|------|
| Seizure worry | 0.85 | Physical functioning | 0.84 |
| Overal QOL | 0.77 | Role-physical | 0.75 |
| Emotional well-being | 0.76 | Role-emotional | 0.83 |
| Energy/fatigue | 0.78 | Bodily pain index | 0.83 |
| Cognitive functioning | 0.71 | Vitality | 0.79 |
| Medication effect | 0.81 | Social functioning | 0.80 |
| Social functioning | 0.79 | General health perceptions | 0.78 |
| | | Mental health index | 0.83 |

| QUOLIE-31 domain | SF-36 domain | Pearson r | p |
|-----------------------|----------------------------|-----------|-----------|
| Seizure worry | Role-emotional | 0.47 | p=0.003 |
| | Social functioning | 0.57 | p = 0.000 |
| | General health perceptions | 0.66 | p=0.000 |
| Overal QOL | Vitality | 0.59 | p=0.000 |
| | Social functioning | 0.42 | p = 0.004 |
| | General health perceptions | 0.77 | p=0.000 |
| Emotional well-being | Role-emotional | 0.71 | p = 0.000 |
| | Mental health index | 0.55 | p=0.000 |
| Energy/fatigue | Physical functioning | 0.59 | p=0.000 |
| | Vitality | 0.73 | p=0.000 |
| | General health perceptions | 0.65 | p=0.000 |
| Cognitive functioning | Social functioning | 0.40 | p=0.008 |
| | Mental health index | 0.66 | p=0.000 |
| Medication effect | Physical functioning | 0.82 | p=0.000 |
| | Vitality | 0.63 | p = 0.000 |
| | General health perceptions | 0.59 | p=0.000 |
| Social functioning | Social functioning | 0.83 | p=0.000 |

Concurrent validity according to the comparison with the SF-36 questionnaire is shown in Table 6. Correlations were found to be statistically significant among related domains and generally demonstrated good in 11 domains (r=0.50-0.75) to moderate correlation in 3 domains (r=0.25-0.50). Three domains (overal QOL vs. general health perception, medication effect vs. physical functioning and social functioning vs. social functioning) had excellent correlation (r=0.75-1).

Discussion

In general assessment of epilepsy patients in Croatia, quality of life measures are underutilized. Currently, outcome assessment is focused on efficacy – e.g. reduction of seizures. The objective of this study was to investigate the validation of the translated and adapted QOLIE-31 questionnaire in 114 Croatian epilepsy patients.

Linguistic adaptation of QOLIE-31 questionnaire was done, and its reliability and validity for Croatian patients were evaluated. In the first part of the study, the construction validity and reliability were found to be satisfactory. Some minor corrections were made in the structure of questions. As Croatian patients with epilepsy are not allowed to drive unless they have been seizure-free for the past 2 years after stopping medication (which means that practically none of the patients included was allowed to drive), the item regarding driving (Question 20, Social function subdomain) was modified into more general - or more broader - question about transportation problems: »...troubles in order to inability for driving and for necessity to use public transportation«. Item 28 (Social limitations) was also slightly modified, because the structure of the question may not reflect the main issue in the way it is desired to ask and may lead to misunderstandings for Croatian patients. The stem of the question has been thought to be difficult to understand for our patients, and its perception in its original form might be influenced by cultural differences. Consenquently, the stem has been changed as »Limitations in social activities - like visiting friends, relatives, etc. « for a precise understanding.

Generally, the Croatian version of QOLIE-31 questionnaire was well accepted by the participants. The wide range of score distribution among patients enrolled in this study has shown that each patient can interpret his (or her) social and medical condition in his/her individual way, indicating that this questionnaire can respond to a variety of patient-perceived outcomes.

The fact that on two scales more than 30% of the subjects scored the maximum value, indicating that a moderate proportion of the patients in our population had a good QOL, is hard to explain. The possible explanation was that all patients included in the study were from the Dalmatian coastal area, the region of Croatia with outstanding life conditions. Namely, the first comparative research on the quality of life of Croatian citizens in comparison to citizens of 27 European Union countries, organised by the United Nations Development Programme

(UNDP) and European Foundation for the Improvement of Living and Working Conditions (EuroFoundation) have shown that life satisfaction, feeling of happiness and the number of satisfied and happy respondents is the highest exactly in Split-Dalmatian County. In spite of economic difficulties, the level of optimism and expectations for the future in Split-Dalmatian County is among the highest in Europe; it is higher only in Scandinavian countries²⁵.

The presence of evident ceiling effect for the seizure worry, cognitive functioning and medication effect domains may be explained by the trust of the patients to their treatment in our hospital, and consenquently their biased answers – since the neurologists who performed the study were mainly the same who regularly have treated them from the moment of first diagnosis of epilepsy.

The mean of the Cronbach α values obtained from Croatian version of QOLIE-31 questionnaire was found to be slightly lower than the mean of the Cronbach α of the original version, except in domains of seizure worry and medication effects. This tendency has been observed in some other linguistic adaptations of questionnaires, particularly for the overall QOL domain.

Majority of scales show very good internal consistency, with a Cronbach's alpha greater than 0.8, except for Overall QOL, which was slightly lower in comparison with other domains. This can probably be explained by the small number of items (two) in the scale. The tendency for slightly lower internal consistency in comparison with the original version for some domains could be interpreted as to be due to undetected cultural differences (American vs. Croatian) rather than the incorrect translation of the original questionnaries. The two function questions with the lowest internal consistencies were questions 12 and 18.

Test-retest reproducibility as determined by intraclass correlation coefficient in patients who were re-examined was very satisfactory for every domain, supporting the temporal stability of the questionnaire.

Our study also showed strong and significant correlations between corresponding scales of the Croatian version of QOLIE-31 and items of the corresponding SF-36 measures, and lower correlations with noncorresponding items, supporting the construct validity. Comparing QO-LIE-31 with SF-36 questionnaire might not be the ideal way to evaluate the validity of the QOLIE-31 questionnaire in this particular patient population, because SF-36 Health Survey is a multi-purpose short-form health survey, while QOLIE-31 is specifically targeted questionnaire²⁶. However, SF-36 was the only available adapted health-related QOL questionnaire in the Croatian language. The value of general and specific population norms has also been demonstrated for the SF-36, and some of the initial descriptive studies using the SF-36 were performed primarily to validate scale scores²⁷. One reason has been the lack of practical measurement tools appropriate for widespread use across diverse populations, and the SF-36 was constructed to provide a basis for such

comparisons of results. Some publications have reported descriptive data for patients with epilepsy^{28,29}.

In spite of the slightly lower precision in comparison with the original, the Croatian version came out to be a valuable instrument, suitable as a generic measure of QOL for patients with epilepsy and a good tool for population surveys, where it can be easily administered.

Conclusion

Self report measures are commonly used in clinical practice and in research studies. Most existing questionnaires were developed in English and it is not clear how many have been adapted to other languages. For any health-related quality of life questionnaire to be used across cultures, the items must not only be translated well linguistically but must also be culturally adapted to maintain the content validity of the instrument at a conceptual level across different cultures. This may necessitate several validation studies to ensure and improve consistency in the content and face validity between source and target versions of a questionnaire, due to difficulty in detecting subtle differences in the living habits of different cultures. Following this first step, it is also

essential to assess whether the adapted questionnaire has retained the content validity of the original questionnaire. This second step requires an assessment of the measurement properties of the new questionnaire.

To improve the QOL of persons with epilepsy, the International Commission on Outcome Measurement in Epilepsy has recommended further research into the HRQOL among persons with epilepsy⁴. Indeed, epileptologist should be cautious to report patient outcome studies based on translated QOLIE-31 questionnaire without proper evaluation in terms of reliability and validity. Although the sample size was relatively small, we suggest that Croatian version of QOLIE-31 will be a valuable contribution to outcome measurement in epilepsy patients, particularly in the context of treatment trials, but also in a wider research context. Further studies are needed to assess its responsiveness to change.

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PSIHOMETRIJSKA VALIDACIJA HRVATSKE VERZIJE »QUALITY OF LIFE IN EPILEPSY INVENTORY« (QOLIE-31)

SAŽETAK

Osnovni ciljevi prikazanog istraživanja bili su prilagodba hrvatske verzije upitnika QOLIE-31 (Quality of Life in Epilepsy Inventory - 31 items) te procjena njegovih psihometrijskih svojstava. Stoga je izvršen prijevod, a zatim i unatražni prijevod izvorne engleske verzije QOLIE-31, nakon čega je ekspertno tijelo izvršilo sve radnje neophodne za međukulturalnu prilagodbu upitnika. U slijedećem su koraku QOLIE-31 upitnici te već ranije validirani SF-36 (Short Form-36) upitnici podijeljeni pacijenatima s epilepsijom (N=200). Od njih 200, 172 ispitanika (86%) ispunilo je i vratilo upitnike, nakon čega im je upućen i drugi komplet istih upitnika. 114 pacijenata vratilo je i drugi komplet upitnika. Dvije mjere pouzdanosti, u vidu unutarnje konzistencije i reproducibilnosti upitnika ispitane su Cronbachovim α-koeficijentom, kao i koeficijentom intraklasne korelacije. Konkurentna valjanost testa određena je usporedbom s SF-36 upitnikom primjenom Pearsonovog koeficijenta korelacije (r). Prikazanim je istraživanjem potvrđena zadovoljavajuća unutarnja konzistencija upitnika s visokim vrijednostima Cronbach-α koeficijenta za sve odgovarajuće domene (strepnja zbog napadaja 0,84, učinci lijekova 0,80, emocionalna dobrobit 0,73, energija /umor 0,76, kognitivno funkcioniranje 0,71, socijalno funkcioniranje 0,77, ukupna kvaliteta života 0,65). Koeficijenti intraklasne korelacije u šest domena ukazali su na izvrsnu reproducibilnost u retestiranju (ICC \geq 0,75), te na zadovoljavajuću reproducibilnost u samo jednoj domeni (ICC 0,71 - kognitivno funkcioniranje). U pogledu konkurentne valjanosti u tri je domene utvrđena izvrsna korelacija (r=0,75-1), u 11 domena korelacija je bila zadovoljavajuća (r=0,50 to 0,75), dok je u preostale tri domene korelacija bila umjerena (r=0,25-0,50). Prikazano istraživanje ukazuje na činjenicu da primjena istih upitnika u različitim civilizacijskim sredinama zahtjeva ne samo primjeren lingvistički pristup već i kulturološku prilagodbu u cilju održavanja sadržajne valjanosti upitnika na pojmovnoj razini među različitim kulturama. Hrvatska će verzija QOLIE-31 predstavljati značajan doprinos u procjeni uspješnosti liječenja bolesnika s epilepsijom, i to ne samo u kontekstu istraživanja lijekova, već i u širem smislu istraživanja epilepsije.