

Validation of the Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALSAQ-40) Scale in the Portuguese Language

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ABSTRACT

The amyotrophic lateral sclerosis (ALS) is a degenerative neurological disorder that has a great impact in the quality of life of the patients. This study had the objective of validating the ALS Assessment Questionnaire in the Portuguese Language (ALSAQ-40/BR). The version of ALSAQ-40/BR, was adapted into the Portuguese language after the evaluation and re-evaluation of 20 patients with a defined ALS diagnosis. The demonstration of its reproducibility and reliability makes this instrument an additional and useful parameter which can be used in the evaluation of ALS for research or assistance.

Key words: quality of life, amyotrophic lateral sclerosis, questionnaires.

Validação da escala ALSAQ-40 em pacientes com esclerose lateral amiotrófica para a língua portuguesa

RESUMO

Esclerose lateral amiotrófica, doença neurológica, degenerativa, apresenta grande impacto na qualidade de vida dos pacientes. Este estudo teve como objetivo realizar a adaptação transcultural e validação da escala Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALSAQ-40) nestes pacientes. Foi aplicada em 20 pacientes com reteste após 30 dias. A tradução para o português e sua adequação às condições socioeconômicas e culturais da nossa população, bem como a demonstração de sua reprodutibilidade e validade, tornam este instrumento um parâmetro adicional útil que pode ser utilizado na avaliação da ELA seja em nível de pesquisa ou assistencial.

Palavras-chave: qualidade de vida, esclerose lateral amiotrófica, questionários.

The amyotrophic lateral sclerosis (ALS) is a degenerative neurological disease that represents a great impact in the quality of life (QL) of its patients. Currently, there is no effective treatment; predominantly palliative measures are being used. However, new therapeutic resources are emerging to slow the progression of the disease and extend survival¹⁻⁵. Quality of life is being able to understand the individual's perception in relationship to his/her situation

in the context of his/her culture and societal values where he/she resides, and in relationship to his/her objectives, expectations, standards and interests⁶⁻⁸. The use of questionnaires, whether generic or specific, as instruments of evaluation for QL, has been intensified in scientific research. Literature reveals that researchers are interested in the QL evaluation, due to the fact that the main objective of clinical trials is to evaluate the diverse dimensions

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of the patient's life. This includes physical, psychological, social aspects, pain, sleep and specific symptoms of the disease, besides quantifying and standardizing the changes that happen after certain interventions^{6,7,9,10}. The instruments used for measuring must be sensitive to detect changes that happen over time and amongst groups, as well as identifying the benefit of different treatments^{6,11}. The interest of measuring and monitoring the state of health and perspective of patients with diagnosis that lead to neurological conditions, such as ALS, have grown during the last few years^{3,12}. The ALS Assessment Questionnaire (ALSAQ-40) is used in England, Portugal, Norway, Greece, among other European countries to evaluate the aspects of health and the impact of treatment for patients with ALS^{3,4,5,7,13,14}. In Brazil, the QL scale mostly used is the Short Form Health Survey (SF-36)⁶, which evaluates QL, although it is not specific for ALS.

The translation of ALSAQ-40 to Portuguese and its adequacy to the socioeconomic and cultural conditions, with the objective of disseminating it within the Brazilian culture, was accomplished by Pavan et al. in 2007¹⁵.

The objective of this study is the validation of the ALSAQ-40/BR.

METHOD

Subjects

The research conducted refers to a prospective analysis with the participation of 20 subjects of both genders, taken ill by ALS. All patients attend the ER (outpatient) for Neuromuscular Diseases of Irmandade da Santa Casa de Misericórdia of São Paulo (ISCMSP). The inclusion criteria used was the defined diagnosis for ALS. Patients with a history of dementia, previously evaluated by the neurologist, were excluded.

The research was approved by the Ethics and Research Committee of the ISCMSP, protocol 240/06. All subjects or responsible legal guardians signed the consent form, in freedom and clarity, after being informed of the objective of the research.

Procedure

In the first interview, socio-demographic data was obtained: gender, age and education; data referring to time and manner of ALS evolution, as well as the application of ALSAQ-40/BR and SF-36, with the finality of comparing a generic scale against a specific. In the second interview, done 30 days after, the subjects of the research filled in the ALSAQ-40/BR again (re-evaluation).

Instrument

The ALSAQ-40/BR is comprised of 40 questions, divided into five dimensions: (1) activities in daily life (ADL) and independence (10 items); (2) physical aspects (10

items); (3) food (3 items); (4) communication (7 items) and (5) emotional aspects (10 items), involving the areas of physiotherapy, occupational therapy, speech therapy and psychology.

The questions refer to two weeks prior to the day of the application and the answers are given according to the following variables: never, rarely, sometimes, frequently and always. The score ranges from 0 to 100; the higher the score, the worse the QL^{3-5,7,14}.

The Scale of the Quality of Life - SF-36 was selected due to the fact that it is already a validated scale in the Portuguese language, through the evaluation of reliability and reproducibility⁶. It is a generic, multidimensional questionnaire, formed by 36 items subdivided into 8 scales or components: (1) functional capacity (10 items); (2) physical aspects (4 items); (3) pain (2 items); (4) overall state of health (6 items); (5) vitality (4 items); (6) social aspects (2 items); (7) emotional aspects (3 items) and (8) mental health (5 items). The final score ranges from 0 to 100; the higher the score, the better the QL^{6,11,16}.

Statistical analysis

For the validation of the instrument, the proposed norms of the Instrument Review Criteria (SAC)¹⁷ was followed with analysis of internal consistency, reliability or stability of the instrument and reproducibility^{10,17}.

The measure of reliability and internal consistency of the instrument was obtained through Chronbach's Alpha Coefficient, which can range from 0 to 1.0; between 0 and 0.6 the reliability is considered unsatisfactory; between 0.6 to 0.7 reliability satisfactory and, between 0.7 to 1.0 high reliability¹⁰.

The reproducibility of the scale was verified through Wilcoxon's test, compared to the results obtained between the evaluation and re-evaluation, with the intention of verifying possible differences amongst the results given. The level of reproducibility can only be 'acceptable' or 'not-acceptable'.

The level of significance adopted was that of 0.05 for all of the statistical tests. The program used for statistical analysis was the Statistical Package for Social Sciences (SPSS), in its 13.0 version.

RESULTS

The social demographics of the individuals who participated in the research can be observed on Table 1.

The level of reliability of ALSAQ-40/BR and SF-36 obtained in Chronbach's Alpha Coefficient is demonstrated on Table 2 and on Table 3 Chronbach's Alpha Coefficient for each dimension. As the value of Chronbach's Alpha Coefficient is statistically significant, we can infer that the data presented offer high consistency and reliability.

The values observed in the evaluation and re-evalua-

tion was statistically similar, with a level of reproducibility in the questionnaire ALSAQ-40/BR of 85%, considered 'acceptable'.

DISCUSSION

ALS presents considerable consequences for the patients. This way, the perception of the state of health and the impact of QL¹, as well as the evolution of the disease and the benefits of the treatment, are being broadly recognized as a topic of research in clinical and epidemiological studies^{8,18}.

The evaluation criteria currently used for individuals with ALS is relatively limited, because throughout its generic measurements, such as the SF-36, there are specific aspects of the disease that are not measured, that are not capable of saying exactly, what the health professional must do, however, they are capable of showing whether the patients can execute determined activities they normally perform and how they feel while practicing them⁶.

Table 1. Socio-demographics of 20 patients with amyotrophic lateral sclerosis.

Socio-demographics data	(average ± SD)
Sex F : M	1 : 1
Age	54.10 ± 16.80
Education L : I	17 : 3
Time of disease (years)	1.97 ± 1.13

SD: standard deviation; F: Female; M: Male; L: Literate; I: Illiterate.

Table 2. Analysis of internal consistency of the ALSAQ-40/BR and SF-36 through Chronbach's Alpha Coefficient.

Aspect	Chronbach's Alpha Coefficient	p*
ALSAQ-40/BR	0.903	< 0.001*
SF-36	0.789	< 0.001*

ALSAQ-40/BR: amyotrophic lateral sclerosis assessment questionnaire – Brazilian version; SF-36: short form health survey; *data statistically significant for p≤0.05

Table 3. Analysis of internal consistency of the 5 dimensions of ALSAQ-40/BR through Chronbach's Alpha Coefficient.

Dimension of ALSAQ-40/BR	Chronbach's Alpha Coefficient	p*
Food	0.858	< 0.001*
Communication	0.915	< 0.001*
DLA	0.941	< 0.001*
Physical mobility	0.871	< 0.001*
Emotional	0.739	< 0.001*

ALSAQ-40/BR: amyotrophic lateral sclerosis assessment questionnaire – Brazilian version; DLA: daily life activity; *data statistically significant for p≤0.05

Problems such as difficulty in communication, self-perception, physical abnormalities or discomfort are rarely present in the generic evaluations, being that these aspects are the ones that offer a higher impact in the QL of the patients with ALS⁷. This is how the use of the specific scale of QL justifies itself to the disease.

Green et al.² observed that ALSAQ-40 was specifically developed to be used in patients with ALS/Neuro-motor Diseases and has proven to be a valid instrument for the evaluation of QL among the patients. The original scale contained 78 items, however, afterwards, studies indicated that 40 items evaluated the main complaints of these patients⁴.

The development and validation of ALSAQ-40 was done by Jenkinson et al.⁵, in England and the United States, in a study comprised of 75 ALS patients. The result was compared to the application of SF-36 and turned to be sensitive, reliable and reproducible, which is in agreement with the results found and with the characteristics of this study.

The transcultural adaptation of ALSAQ-BR/40 to the Brazilian language (ALSAQ-40/BR), described by Pavan et al in 2007¹⁵, revealed that this one remained equivalent to the original as far as the cultural concepts.

The homogeneity of the items of the instrument, or, its accuracy demonstrated by the values of reliability are statistically high (p=0,903) (Table 2), a value similar to the one found by Jenkinson et al.^{4,5} in 1999 and 2000 which suggest that the values of Chronbach's Alpha higher than 0.9 mean that the measurement is appropriate for individual analysis.

Jenkinson et al.³, through the use of the SF-36 scale in patients with ALS, concluded that this scale supplies reliable data for the group studied. However, in the dimensions related to the function, the results do not demonstrate good reliability, which also justifies the need for specific instruments³. In this study, the index for Chronbach's Alpha Coefficient for the ALSAQ-40/BR revealed to be higher than the SF-36.

In this study, the reproducibility analysis in only 6 of the 40 questions of the questionnaire evaluated, did not reach the level of significance adopted, resulting in a level of 85%, which is considered, in the procedures of validation, a sufficient satisfactory result according to the criteria of Guillemin in 1995¹⁹, which considers as significant, results higher than 2/3, in the evaluation of reproducibility.

The reproducibility and validation of ALSAQ-40/BR, make this instrument a useful, additional parameter which can be used in the evaluation of the results for research or assistance of ALS patients.

In conclusion, the sample allowed for validation of the ALSAQ-40/BR in the Brazilian population.

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REFERENCES

- Norquist JM, Fitzpatrick R, Jenkinson C. Health-related quality of life in amyotrophic lateral sclerosis: determining a meaningful deterioration. *Qual Life Res* 2004;13:1409-1414.
- Green C, Kiebert G, Murphy C, et al. Patients' health-related quality-of-life and health state values for motor neuron disease/amyotrophic lateral sclerosis. *Qual Life Res* 2003;12:565-574.
- Jenkinson C, Hobart J, Chandola T, Fitzpatrick R, Peto V, Swash M. Use of the short form health survey (SF-36) in patients with amyotrophic lateral sclerosis: tests of data quality, score reliability, response rate and scaling assumptions. *J Neurol* 2002;249:178-183.
- Jenkinson C, Levvy G, Fitzpatrick R, Garratt A. The amyotrophic lateral sclerosis assessment questionnaire (ALSAQ-40): tests of data quality, score reliability and response rate in a survey of patients. *J Neurol Sci* 2000;180:94-100.
- Jenkinson C, Fitzpatrick R, Brennan C, Swash M. Evidence for the validity and reliability of the ALS assessment questionnaire: the ALSAQ-40. *Amyotrophic Lateral Scler Other Motor Neuron Disord* 1999;1:33-40.
- Ciconelli RM, Ferraz MB, Santos W, Meinão I, Quaresma MR. Translation to the Portuguese language and validation of the generic questionnaire for the quality of life SF-36 (Brasil SF-36). *Rev Bras Reumatol* 1999;39:143-150.
- Jenkinson C, Fitzpatrick N, Brennan C, Bromberg M, Swash M. Development and validation of a short measure of health status for individuals with amyotrophic lateral sclerosis/motor neuron disease: the ALSAQ-40. *J Neurol* 1999; 246 (Suppl 3):S16-S21.
- Faden R, Leplege A. Assessing quality of life. Moral implications for clinical practice. *Med Care* 1992;30(Suppl 5):S166-175.
- Carr AJ, Thompson PW, Kirwan JR. Quality of life measures. *Br J Rheumatol* 1996;35:275-281.
- World Health Organization Quality of Life. General guidelines for methodologies on research and evaluation of traditional medicine. WHO/EDM/TRM/2000.
- Vitorino DMF, Martins FLM, Souza AC, Galdino D, Prado GF. Use of the SF 36 in clinical rehearsals involving fibromyalgia patients: determination of minimum criteria for clinical improvement. *Neurosciences* 2004;12:147-151.
- Norquist JM, Jenkinson C, Fitzpatrick R, Swash M. Factors which predict physical and mental health status in patients with amyotrophic lateral sclerosis over time. *Amyotroph Lateral Scler Other Motor Neuron Disord* 2003;4: 112-117.
- Jenkinson C, Norquist JM, Fitzpatrick N. Deriving summary indexes of health status from the amyotrophic lateral sclerosis assessment questionnaires (ALSAQ-40 and ALSAQ-5). *J Neurol Neurosurg Psychiatry* 2003;74:242-245.
- Jenkinson C, Fitzpatrick N. Reduced item set for the amyotrophic lateral sclerosis assessment questionnaire: development and validation of the ALSAQ-5. *J Neurol Neurosurg Psychiatry* 2001;70:70-73.
- Pavan K, Marangoni BEM, Zinezzi MO, et al. Adaptation of the transcultural questionnaire of the evaluation of the amyotrophic lateral sclerosis (ALSAQ-40) in the Brazilian culture and language. *Med Reabil* 2007;26:73-76.
- Ware JE Jr, Snow KK, Kosinski M, Gandek B. SF-36 Health Survey. Manual and interpretation guide. Boston: The Health Institute, N Engl Med Center, 1993.
- Scientific Advisory Committee of the Medical Outcomes Trust – SAC Instrument Review Criteria 1995.
- Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Ann Intern Med* 1993;118:622-629.
- Guillemin F. Cross-cultural adaptation and validation of health status measures. *Scand J Rheumatol* 1995;24:61-63.