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Validating the Persian version of the amyotrophic lateral sclerosis-specific quality of life-revised instrument

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Keywords
Amyotrophic Lateral Sclerosis; Quality of Life; Validity; Reliability

Abstract

Background: Amyotrophic Lateral Sclerosis-Specific Quality of Life-Revised (ALSSQOL-R) encompasses 50 items which assess quality of life (QOL) in patients with amyotrophic lateral sclerosis (ALS) in six major domains. This study aims to translate the ALSSQOL-R into Persian and evaluate its reliability and validity among Iranian patients.

Methods: ALSSQOL-R was translated by the standard multi-step forward-backward method. Content validity was calculated using item content validity index (I-CVI). Three items in the "intimacy" domain were deleted considering Iranian culture. Cronbach's alpha was used for all 6 dimensions to calculate the internal consistency reliability. Test-retest reliability was evaluated using intraclass correlation coefficient (ICC) with one-month interval. Concurrent validity was measured by the validated version of 36-Item Short Form Health Survey (SF-36) questionnaire.

Results: Sixty-three patients with ALS were enrolled in the study. I-CVI was 70%, promoted to 85% after modifications (acceptable). Regarding internal consistency reliability, Cronbach's alpha in all six domains was ≥ 0.70 and total Cronbach's alpha was 0.89 which is assumed as good. In terms of test-retest reliability, ICC [95% confidence interval (CI)] was 0.91 (91%) and Pearson correlation coefficient (r) was 0.90 ($P < 0.001$), all indicating an excellent reliability. The concurrent validity was established based on a strong correlation with SF-36 ($r = 0.744$, $P < 0.001$).

Conclusion: The findings show that the modified

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Persian version of ALSSQOL-R is a valid and reliable QOL questionnaire which can be used for Iranian patients with ALS in both clinical and research settings.

Introduction

Amyotrophic lateral sclerosis (ALS) is an adult-onset motor neuron disease with the incidence of 1.5-2.5 per 100000 individuals which occur slightly more in men.[1] Basically, ALS causes progressive upper and lower motor neurons degeneration; hence, the patients experience signs and symptoms of both upper and lower neurons involvement like muscle weakness and atrophy, bulbar dysfunctions, respiratory failure, increased deep tendon reflexes, and eventually these complications lead to death.[2,3]

Currently, ALS has no definite cure, and as disease progresses, patients become more and more dependent on care givers. It is always valuable to put more effort to improve patients' quality of life (QOL).[4] Thus, measuring the QOL as a quantitative scale in a patient with ALS is important because every new therapy or intervention on the patient can be assessed by its impact on the QOL. Besides, this measurement can be applied in clinical and investigatory studies. Accordingly, having a reliable and valid instrument for measuring QOL can be beneficial.[5]

According to World Health Organization (WHO) definition, QOL in chronic diseases is an individual perception which alters with patients' physical and psychological states, independency level, social relationships, and their relation to salient features of their environment.[6,7] Considering the aforesaid issues, ALS QOL is not only dependent on physical states, but it is also dependent on psychological spiritual factors and supporting team.[8] Generally, a common approach to determine patients' QOL is using an appropriate questionnaire. These instruments can assess health-related QOL (HRQOL) which relies on patients' physical and mental health, or global QOL which also consider non-health-related factors. Also, the questionnaires can be divided into generic or disease-specific types.[5,7]

Initial instruments utilized in measuring ALS QOL were Sickness Impact Profile (SIP) and the 36-Item Short Form Health Survey (SF-36),[9] which both are HRQOL instruments and mostly measure the physical status of patients and are not, therefore, able to measure the progressive nature of the disease. For this reason, 40-item and 5-item Amyotrophic Lateral Sclerosis Assessment Questionnaires (ALSAQ-40 and ALSAQ-5) were developed.[10] Still, these questionnaires are more weighted toward measuring the physical status of the patients.[11]

WHO also developed two other questionnaires to assess QOL which were used for measuring ALS QOL: the WHOQOL-100 and the WHOQOL-BREF,[12] encompassing 100 and 26 items, respectively, through which 4 main areas including physical and psychological health and social and environmental interactions were assessed. The McGill Quality of Life Questionnaire (MQOL) was another instrument used to measure QOL.[13] Both of the WHO and McGill instruments were global questionnaires. Yet, despite their strength points, they were generic scales and therefore, not regarded as ALS-specific instruments.[5]

However, Amyotrophic Lateral Sclerosis-Specific Quality of Life (ALSSQOL)[14] and its revised version (ALSSQOL-R)[15] are global and developed to evaluate QOL status in patients with ALS, which embraced other dimensions possibly affecting the QOL rather than mere concentration on patients' physical status. This instrument can also be employed in different visits and can trace the QOL changes over the time. This can demonstrate the effect of changes in patient's treatment, interventions, and other possible variables affecting QOL. Considering this questionnaire report, the clinician can also set the priority of intervention for the patient.[5] The validity and reliability of ALSSQOL-R have been proved in different studies and it can be used in both clinical setting and research projects.[5,11,15,16] Considering the lack of a Persian (Farsi) version of ALSSQOL-R instrument in Iran, this study was an attempt to translate the ALSSQOL-R into Persian and to determine whether such a version can be reliable and valid in Iranian ALS population.

Materials and Methods

Patients: The current prospective observational study was conducted between September 2018 and May 2020. Consecutive adult patients admitted for ALS clinic at the Department of Neurology of Firoozgar Hospital affiliated to Iran University of Medical Sciences, Tehran, Iran, in a period from September 2018 until March 2020, were invited to the study. Patients who were unable to speak Persian, or with severe cognitive or neurologic deficits were excluded.

Data collection: This study was approved by Ethics Committee of Vice Chancellor for Research and Technology, Iran University of Medical Sciences (Code: IR.IUMS.FMD.REC.1398.230).

Participants signed the informed written consent. The inclusion criteria were: 1) those in whom the clinical diagnosis of ALS was affirmed with electrodiagnostic patterns of ALS, 2) those who were living in Iran and were Persian speaker, and 3) those who signed the informed consent. The exclusion criteria were: 1) patients unwilling to participate in the study at the beginning or in the middle of study, 2) the final stages of the disease, 3) those who were not able to understand questions due to dementia, and 4) patients with severe psychological problems such as major depression, bipolar disorder, or schizophrenia. Definite ALS diagnosis had been made by revised El Escorial electrodiagnostic criteria[17] and Awaji criteria.[18]

Questionnaires

ALSSQOL-R: The ALSSQOL-R[19] is a QOL assessment questionnaire encompassing 50 items in 6 domains: 1) negative emotion (12 items), 2) interaction with people and the environment (11 items), 3) intimacy (7 items), 4) religiosity (4 items), 5) physical symptoms (6 items), and 6) bulbar function (5 items). Forty-six items are used for scoring and each question's score ranges between 0 (worse) and 10 (best). The questionnaire results in a total score (ranging from 0 to 460) and average total score (ranging from 0 to 10). Compared with original questionnaire, items 41, 44, 47, and 50 are not included in the total score calculation. The questionnaire takes 10-25 minutes to be filled and can be completed in an interview or filled by patients themselves. To assess test-retest reliability, fifteen participants, representing the total group characteristics, answered the ALSSQOL-R for the second time (retest) after one-month interval from the first administration. The ALSSQOL-R questions were asked from patients by 2 neurology residents in a private room. Enough time was allocated to each patient and those with physical limitations responded to questions by nodding or blinking. There was no intubated patient among our cases. Retest was conducted in a situation similar to that of the first administration.

SF-36: The nationally-validated SF-36 was used to evaluate the concurrent validity of the revised scale. SF-36 is a generic QOL instrument which assesses the HRQOL and contains 36 items in 8 domains (4 physical and 4 mental components), resulting in a score between 0 and 100. This questionnaire is found valid and reliable in patients with ALS.[20] The Persian version of this scale is also available and reported valid and reliable in Iranian patients.[21,22] The SF-36 instrument was administered to the participants of the study exactly after ALSSQOL-R administration.

Translation of ALSSQOL-R: A standard multi-step forward-backward method was used to translate the scale into Persian. Two proficient and independent translators translated the ALSSQOL-R into Persian. Then, the Persian version was translated to English (backward translation) by two different translators. Both translation and back-translation were compered and evaluated by a team including three neurologists, one statistical specialist, and one more translator. The Persian translated version of the scale was then reported.

Content validity: In the second step, the final Persian version was reviewed by 15 individuals including neurologists, nurses, and physicians who were in contact with patients with ALS. The team commented on four dimensions of the questionnaire including relevance, clarity, comprehensiveness, and brevity. Besides, content validity index (CVI) was employed to evaluate the validity of the questionnaire. According to the grading and comments of the designated 15-member medical team, three items (47, 48, and 49) were removed from the original version. After this modification, the calculated CVI in all four aforesaid dimensions was reported acceptable. Considering the original questionnaire guideline, the items 41, 44, 47, and 50 were not calculated in final scoring. Therefore, the final Persian questionnaire was narrowed down to 47 questions, out of which 44 items were used in scoring. Thus, the highest total score in Persian ALSSQOL-R was 440 comparing to 460 in the original scale. CVI was calculated to assess the content validity of Persian ALSSQOL-R. CVI was used for quantitative evaluation.

Internal consistency reliability: For internal consistency, Cronbach's alpha was calculated. Value of 0.70 is acceptable. Thus, Cronbach's alpha was calculated for all 6 dimensions of the questionnaire. Cronbach's alpha of the whole scale was also calculated.

Test-retest reliability: Reproducibility was estimated using test-retest method for which 15 patients were retested through ALSSQOL-R in a one-month interval after the first administration. Intraclass correlation coefficient (ICC) with 95% confidence interval (CI) as well as Pearson correlation coefficient (r) was run to evaluate test-retest reliability.

Concurrent validity: Concurrent validity of the Persian version of ALSSQOL-R was measured by the validated version of SF-36 questionnaire which

was administered to participants simultaneously.

Content validity was measured by calculating the Item-CVI (I-CVI). The expected value for I-CVI was higher than 79%, while the value between 70% and 79% required modification, but when the value was less than 70%, the item was removed from the scale.[23] Internal consistency reliability was evaluated using the Cronbach's alpha coefficient (α). This measure is considered "acceptable" when the value is beyond 0.70, $0.80 \leq \alpha < 0.90$ is assumed as "good", and $0.90 \leq \alpha$ is assumed as "excellent".[24] Test-retest reliability was evaluated by ICC. ICC values less than 0.50 were indicative of poor reliability, values between 0.50 and 0.75 indicated moderate reliability, values between 0.75 and 0.90 indicated good reliability, and values greater than 0.90 indicated excellent reliability.[24] In the same way, Pearson correlation coefficient was run. Also, concurrent validity was determined using Pearson correlation coefficient. Pearson correlation coefficients of 0.40 or higher and ideally larger than 0.60 are assumed acceptable. Data were analyzed using the SPSS software (version 24, IBM Corporation, Armonk, NY, USA), where a two-tailed probability value of < 0.05 was assumed significant.

Results

A total of 64 patients (37 men, 27 women) were enrolled in the study. The participants were 29-77 years old with a mean age of 58.9 ± 16.0 years.

Content validity: The baseline I-CVI was 70% and after modification in translation and removing 3 items, CVI promoted to 85%, ranging from 82% to 89% for each item, which was acceptable (beyond 79%).

Internal consistency reliability: Cronbach's alpha reports are presented in table 1 for six main dimensions, separately and in whole. Cronbach's alpha is ranging between 0.70 in "bulbar function" domain and 0.87 in "interaction with people and the environment" domain. Cronbach's alpha in each domain compared to the original study[19] is depicted in table 2. In this study, Cronbach's alpha was "good" ($0.80 \leq \alpha < 0.90$) in "negative emotions" and "interactions with people and environment" domains. Also, Cronbach's alpha was "acceptable" ($0.70 \leq \alpha < 0.80$) in other subscales. The total calculated alpha for all items was 0.89 (good) and was accepted.

Table 2. Cronbach's alpha in each domain compared to the original study

Domain	Cronbach's alpha in this study	Cronbach's alpha in the original study
Negative emotions	0.85	0.91
Interaction with people and the environment	0.87	0.87
Intimacy	0.70	0.81
Religiosity	0.75	0.92
Physical symptoms	0.71	0.71
Bulbar function	0.70	0.83

Test-retest reliability: The mean score out of 440 for the test was 276.33 ± 59.34, and for retest was 268.80 ± 67.62. ICC with 95% CI was 0.91 (91%), indicating an excellent reliability (greater than 0.90). In the same way, the correlation between test and retest using Pearson correlation coefficient was 0.90 which was statistically significant ($P < 0.001$) and was interpreted as "strong correlation" ($r > 0.90$). Thus, the reliability of questionnaire was confirmed.

Concurrent validity: Comparing the validated SF-36 scale with our questionnaire, Pearson correlation was 0.74, indicating a strong positive linear relationship, which was statistically significant ($P < 0.001$). Thus, the concurrent validity was confirmed.

Table 1. Cronbach's alpha of the Persian version of Amyotrophic Lateral Sclerosis-Specific Quality of Life-Revised (ALSSQOL-R)

Domain (number of items)	Number of items on questionnarrie	Cronbach's alpha
Negative emotions (13 items)	11, 12, 13, 17, 18, 19, 21, 22, 25, 28, 31, 32, 34	0.85
Interaction with people and the environment (11 items)	14, 15, 16, 20, 26, 27, 30, 33, 36, 37, 40	0.81
Intimacy (5 items)	39, 42, 43, 45, 46	0.70
Religiosity (4 items)	23, 29, 35, 38	0.75
Physical symptoms (6 items)	1, 2, 7, 8, 9, 10	0.70
Bulbar function (5 items)	3, 4, 5, 6, 24	0.70
Total (44 items)	Scorable questions*	0.89

*Scorable questions are all questions of Persian Amyotrophic Lateral Sclerosis-Specific Quality of Life-Revised (ALSSQOL-R) except 41, 44, and 47 questions

Discussion

The ALSSQOL-R is regarded as a comprehensive QOL instrument for its capability of assessing all areas of care including functional and psychosocial aspects of the disease.[23] The developed translated questionnaire of ALSSQOL-R is valid and reliable to assess the QOL in Iranian ALS population. ALSSQOL-R has not been widely evaluated so far and to the best of our knowledge, this is the first study in which the ALSSQOL-R questionnaire is validated. Previously, Shamshiri et al. conducted a study on 21 Iranian ALS cases and found that ALSAQ-40 was valid and reliable in Iranian patients.[25] However, ALSAQ-40 is distinct from HRQOL scale and different from this version of the questionnaire (ALSSQOL-R).[25] The current research was also innovatory by enrolling 63 patients with ALS which is 3 times larger sample size than those reported in the literature.

Considering Iranian culture, our team decided to remove three items in the "intimacy" domain, as a result of which the CVI promoted to 85% (ranging from 82% to 89% for individual item). These values indicate an acceptable content validity for the translated scale. In a similar study conducted in Korean context, the most unanswered items were items 48 and 49 which were also removed from the Persian version. The Korean authors reported that Asian patients were conservative in their sexual relationships and therefore, they did not tend to answer these items.[16]

Regarding internal consistency reliability, the current modified Persian version of ALSSQOL-R acknowledges quite satisfactory reliability since the Cronbach's alpha calculated for each item was "acceptable" or "good" and for the scale in whole was 0.89 which is assumed as "good".

In addition, the current questionnaire indicates an excellent level of test-retest reliability, since when the test-retest was performed in a period of 4 weeks, ICC (95% CI) was 0.91 (91%). The retest was not conducted in the original study of the ALSSQOL-R. However, these values were also calculated in another study.[16]

According to concurrent validity, the modified Persian version of ALSSQOL-R scores are correlated ideally with the Persian SF-36 scores ($r = 0.74$, $P < 0.05$), demonstrating the verified concurrent validity of Persian ALSSQOL-R questionnaire. This means that compared to the well-established test (SF-36), the current questionnaire is a valid test which is able to assess the QOL in these patients well. In this study, the mean of total score was higher than the values reported in original study and the Korean study.[16]

One of the important items, which plays an important role in Iran and perhaps in many other countries, is the financial difficulties for patients with ALS. Considering the variety of medical problems with progressive nature in patients with ALS along with limitations in health insurance coverage, patients and their care givers suffer from direct and indirect cost hardships.[26,27] Evidence shows that socioeconomic status (SES) contributes significantly to QOL in patients with ALS by influencing the possibility of obtaining optimum care even in highly-socialized health systems.[3] The original ALSSQOL-R seems inadequate in this regard because financial issues are not included and some patients' problems are being missed during neurology visits. Therefore, it was suggested to introduce internally-generated questions assessing patients' SES into the Iranian version of the questionnaire.

It is also worth mentioning that pseudobulbar affect (PBA) is common among patients with ALS[28,29] which makes them incapable of expressing their feelings which in turn restrains collecting information for ALSSQOL-R. Therefore, physicians need to allocate more time and energy in each visit to tackle these constraints. Regardless of this issue, allocating 15 minutes for filling a questionnaire such as ALSSQOL-R before each visit can definitely help the physicians to assess more aspects of the disease in each patient and to compare them with previously-filled questionnaires.[30] And last but not the least, it is worth mentioning that a newer brief version of ALSSQOL-R including 20 items is developed recently which is yet to be validated in Iran.[31]

Conclusion

Modified Persian version of ALSSQOL-R is a valid and reliable QOL questionnaire among Iranian patients with ALS and it would be useful to be applied as a QOL instrument in both clinical and research settings.

Conflict of Interests

The authors declare no conflict of interest in this study.

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