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ORIGINAL ARTICLE

Validity and reliability of the Turkish version of "the Dyspnea-ALS-Scale (DALS-15)"

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Abstract

Aim The aim of this study was to investigate the validity and reliability of the Turkish version of The Dyspnea-ALS-Scale (DALS-15).

Methods Forward translation, back translation, and cross-cultural adaptation were used to ensure the equivalency of translated version of the scale. Then, patients with amyotrophic lateral sclerosis (ALS) who have dyspnea or orthopnea that develops with effort or at rest were evaluated using DALS-15 via online surveys. The respiratory subscale of ALS Functional Rating Scale-Revised (ALSFRS-R) and Modified Borg Dyspnea Scale (MBDS) was used to investigate the construct validity of the Turkish DALS-15. Reliability was assessed with Cronbach's α and inter-item correlation matrix (internal consistency).

Results We have included 52 ALS patients in the study. Findings showed that Turkish version of DALS-15 was highly correlated with respiratory subscale of ALSFRS-R ($r = -0.668$; $p = < 0.0001$) and MBDS (for upright position: $r = 0.728$; $p = < 0.0001$ and for supine: $r = 0.78$; $p = < 0.0001$). The scale did not show any ceiling or floor effect. Also, DALS-15 had a high level of Cronbach's α (0.95) and internal consistency (ICC: 0.949; 95%CI: 0.92–0.96). Test-re-test reliability of the questionnaire was (ICC: 0.909; 95% CI: 0.81–0.95). The standard error of measurement value was 2.76, whereas the minimal detectable change score was 7.66 points for the translated version of the scale.

Conclusions The Turkish version of DALS-15 possesses strong psychometric properties with excellent validity and reliability. It is shown to be useful for online self-assessment, outside of the clinical settings, especially in hard times such as a pandemic.

Keywords Amyotrophic Lateral sclerosis · Dyspnea · Validation study · Reproducibility of results

Introduction

Amyotrophic lateral sclerosis (ALS) is a progressive disease characterized by degeneration of the upper and lower motor neurons of the brain and spinal cord [1]. ALS incidence is 1–2 per 100 thousand and its prevalence is around 3–8 per 100 thousand. In the later stages of the disease, patients lose their motor functions and respiratory functions due to involvement of respiratory muscles [2, 3]. Patients may lose their skills such as hand skills and walking at an early stage, while disorders such as speech, swallowing, and breathing difficulties are observed at a later period [4]. Most of the patients die within 5 to 15 years due to respiratory complications and ventilatory failure [5].

Dyspnea, which is one of the most common respiratory problems in ALS patients, is also a cardinal symptom and occurs in approximately 80% of patients [6]. Therefore, evaluation of the severity of dyspnea in ALS patients has an important place in the management of the disease and patient care [7].

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Since there may be inconsistencies in the relationship between dyspnea and diagnostic markers of respiratory functions in ALS patients, problems may occur in the detection of dyspnea by objective clinical measurements. Many patients may be suffering from dyspnea in early terms; however, they would be unaware of it since they have limited mobility or they are non-ambulatory. Moreover, some of the patients with ALS may have dyspnea in the supine position due to diaphragm dysfunction without the presence of dyspnea at rest [8].

Even though there is a wide range of scales in the assessment of dyspnea observed in pulmonary diseases, these scales are generally not suitable to for ALS patients due to various reasons [5, 9]. The most important reason is that the scales used to evaluate dyspnea are generally developed for chronic obstructive diseases, yet ALS causes a restrictive type of respiratory failure. Another reason is that the surveys include some specific activities related to dyspnea (climbing stairs, cooking, etc.) [10]. However, these activities may be already affected by neuromuscular disorders and may lead to false-positive answers or missing data when questioned in terms of dyspnea in ALS patients. Due to the important role of dyspnea in every period of ALS, evaluation with an appropriate, methodologically strong, and disease-specific dyspnea questionnaire may provide better management of the disease [11].

In 2018, "The Dyspnea-ALS-Scale (DALS-15)," a scale in which dyspnea is defined based on patients' perspective, was developed by Vogt et al. [5]. The scale fills an important gap in the field and contributes to symptom management. In addition, DALS-15 enables a more effective assessment by allowing the modification of physical limitations specific to motor function losses characterized by ALS disease [5]. It was shown to be efficient to diagnose dyspnea in patients with ALS [12].

This study aims to investigate the validity and reliability of the Turkish version of the DALS-15 questionnaire.

Materials and methods

Translation and cross-cultural adaptation

Permission was obtained from the authors of the original version of the scale for the Turkish validation. DALS-15 has been translated and culturally adapted according to published guidelines [13]. Firstly, two native speakers translated from German to Turkish. After that, the expert committee of specialist physiotherapists discussed and compared the two versions of the form in order to create the Turkish translation version. Two native speakers translated this new version from Turkish to German. These translations were examined by the expert committee and compared to the original scale. After discussing the disputes, the committee approved the Turkish version of the DALS-15 Scale. At the last stage, a preliminary test was conducted to determine comprehension of the Turkish version.

Design and participants

The medical records of all the patients who were admitted to Istanbul University Istanbul Faculty of Medicine Pulmonary Diseases Outpatient Clinic with documented physician-diagnosed ALS patients were evaluated for the eligibility. Patients over the age of 18 years and have dyspnea or orthopnea that develops with effort or at rest which is not depending on any cardiac or pulmonary disease were participated to this validation study from September 2020 to April 2021. Patients with severe cognitive impairment (a score of 24 or less in the Mini Mental State Examination) or the inability to speak or understand Turkish were excluded.

The study was approved by the Non-invasive Research Ethics Board of Istanbul University-Cerrahpaşa (approval number: A-04 and date:18.02.2020) and performed following the ethical standards as laid down in the 1964 Declaration of Helsinki. All the participants gave written informed consent before participating in the study. (Trial Registration Number: NCT04305639).

Patient-reported outcomes

The researchers contacted the patients who previously applied to the Pulmonary Diseases Outpatient Clinic, by phone and invited them to participate in the study. The volunteers received a link for Google Forms in which all of the patient-reported outcomes (PROs) were evaluated. Online assessment results of the patients were cross-checked with their medical records by researchers.

DALS-15, which was developed to assess dyspnea observed in ALS patients, is a one-dimensional scale. It can be applied very quickly and easily. The questionnaire consists of 15 questions that the patient can easily answer on his own. It expresses the patient's condition over the past 2 weeks using a 3-point Likert scale (0 = never, 1 = occasionally, and 2 = often). The total score ranges from 0 (no shortness of breath) to a maximum of 30 (severe shortness of breath). The higher the score, the more the severity of dyspnea [5].

ALS Functional Rating Scale-Revised (ALSFRS-R) is a validated instrument and Turkish validity and reliability was made in 2016 by Koç et al. [14]. It provides information in the following process of the patients' upper and lower extremities functions, bulbar functions, and respiratory functions. It consists of the following 12 subtitles: salivation, speech, swallowing, feeding, handwriting, dressing and self-care, turning and covering in bed, climbing stairs, walking,

dyspnea, orthopnea, and respiratory failure. Each item is assessed between 0 and 4 points and the patients can have a maximum 48 points [14].

Modified Borg Dyspnea Scale (MBDS) is an often used, one-sided scale to evaluate effort dyspnea and the resting dyspnea severities, which consists of 10 items to clarify the dyspnea severity [15]. The person, who has more dyspnea than ever experienced before, gets 10 points. Lately, it is used in the clinic for the assessment of the dyspnea during exercise [16].

Study protocol

One physiotherapist assessed the same patient after one week using DALS-15 for intra-rater reliability. To evaluate construct validity, ALSFRS-R and MDBS were used. All assessments were collected through a web-based survey prepared by the study team. ALSFRS-R has been validated for the online self-assessment method previously [17, 18].

Preliminary testing

Ten patients were tested using the pre-final DALS-15 version and their recommendations were presented in the result section.

Statistical analysis

Statistical Package for Social Science (IBM SPSS Statistics New York, USA) version 20.0 was used to perform statistical analyses.

The required sample size was calculated as 2–20 participants per question [19].

Descriptive statistics are reported as means ± SDs for continuous variables and as numbers and frequencies for binary and categorical variables. The statistical significance level was set at $p < 0.05$.

Shapiro Wilk test was used to determine the distribution of data and the data was normally distributed. Evidence for the construct validity of DALS-15 was determined by establishing its relationship with the respiratory subscale of ALSFRS-R and MBDS in the upright and supine position by using Pearson correlation. The cut-offs for correlation coefficient were as follows: (a) 0–0.25, no or very weak correlation; (b) 0.25–0.50, weak to moderate correlation; (c) 0.50–0.75, strong correlation; and (d) 0.75–1.00, very strong-perfect correlation [20]. Construct validity was assessed by the distribution of scores and the occurrence of the floor and ceiling effect. Floor and ceiling effects were considered if 30% of the population had the minimum or maximum score, respectively [21].

The internal consistency of the questionnaire was assessed by Cronbach's α coefficient and the inter-item correlation matrix. A Cronbach's α coefficient higher than 0.7 was considered to be adequate [22]. Intraclass correlation coefficient (ICC) was calculated to determine test-re-test reliability by using a two-way mixed model under consistency.

Agreement was assessed with the standard error of measurement (SEM) and minimal detectable change (MDC) with the following equations [23]:

$$SEM = SD - \sqrt{1 - ICC}$$

$$MDC = 1.96\, x \sqrt{2}\, x\, SEM$$

Results

Translation and cultural adaptation

In the preliminary testing performed face-to-face with 10 patients, the only question that the patients needed further explanation was question 10, specifically the word "isolated." However, there was no other word in Turkish to use instead. Therefore, a consensus was reached to use the word "isolated" along with an explanation "separated, lonely" ("ayrı, yalnız" in Turkish) in the brackets. Other than that, patients did not report any problem with the scale. They completed the questionnaire around 5–10 min.

PROs and testing

A total of 113 patients were contacted by phone by the investigators. However, only 52 patients met the inclusion criteria and participated in the study. Figure 1 shows the flow of patients during the study.

The mean age of participants was 57.31 ± 10.58 years and 29 of them (55.8%) were male. The average years of education were 9.35 ± 4.08 years. Four patients (7.7%) were currently smoking and 14 patients (26.9%) reported that they quit smoking (mean time: 90.40 ± 97.15 months ago). The spirometry measurements revealed that none of the smokers had airway obstruction. Only one patient was not under medication for ALS-related symptoms due to a recent diagnosis of the disease (around 2 days ago). All other patients were receiving medication for both ALS (Rilutek/Riluzole) and comorbidities such as diabetes or hypertension. The demographic and clinical characteristics of patients are presented in Table 1. Notably, there was no difference between patients with and without bulbar symptoms in terms of demographic data (i.e., age, gender, BMI) ($p > 0.05$ for all) and clinical variables such as disease duration, number of emergency visits/hospital stays, comorbidities, or symptoms

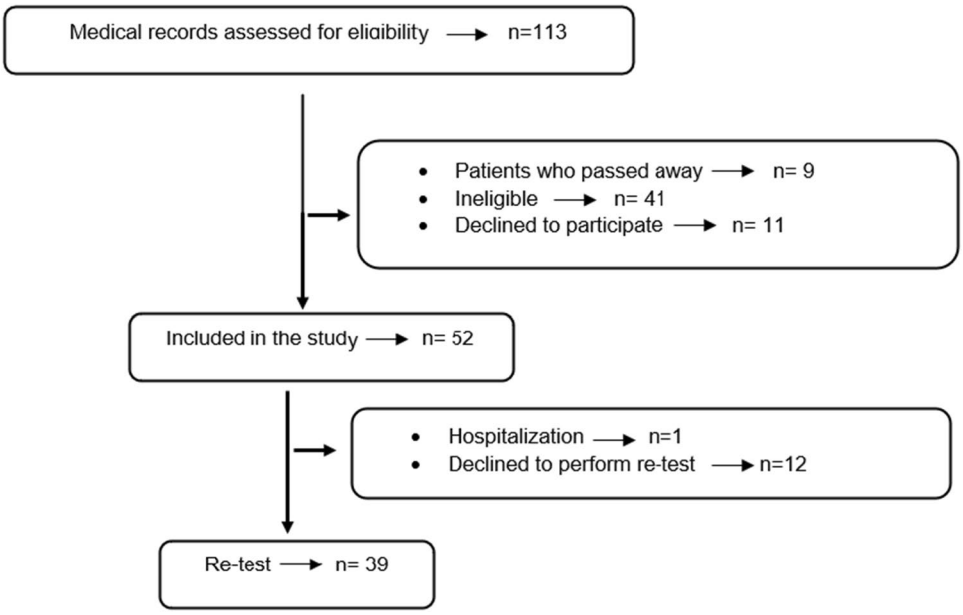

Fig. 1 Flowchart of the study population

Table 1 Demographic and clinical characteristics of study population ($n=52$)

Characteristics and outcome measures	($n=52$) Mean ± SD/ n(%)	Characteristics and outcome measures	($n=52$) Mean ± SD/ n(%)
Age (years)	57.31 ± 10.58	ALSFRS-R, total	27.0 ± 11.77
Gender (F/M)	23(44.23%)/ 29 (55.77%)	ALSFRS- R, respiratory subscale	8.37 ± 3.1
BMI (kg/m^2)	25.63 ± 5.29	MBDS (upright position)	2.62 ± 2.84
Time since initial symptom (months)	29.42 ± 27.48	MBDS (supine position)	3.29 ± 3.18
Time since diagnosis (months)	25.04 ± 30.29	DALS-15 scores	
Smoking		Initial assessment	14.25 ± 9.16
		Re-test	15.72 ± 9.18
Yes	4 (7.7%)	Comordities	
No	32 (61.5%)	Hypertension	20 (38.5%)
		Diabetes mellitus	2 (3.8%)
Quitted	14 (26.9%)	Disease-related symptoms	
Number of emergency service visits in the last year	1.98 ± 3.49	Presence of dyspnea at rest	24 (46.2%)
Number of hospital stays in the last year	1.0 ± 1.62	Presence of dyspnea on exertion	28 (53.8%)
		Presence of dyspnea in supine	28 (53.8%)
		Absence of effective cough	25 (48.1%)
		Failure to clear airway	33 (63.5%)
		Speech problems	31 (59.6%)
		Swallowing problems	27 (51.9%)

F/M female/male, *BMI* body mass index, *ALSFRS-R* Revised Amyotrophic Lateral Sclerosis Functional Rating Scale, *MBDS* Modified Borg Dyspnea Scale, *DALS-15* Dyspnea-ALS Scale

($p > 0.05$ for all), except the absence of effective coughing ($p = 0.02$) as expected. In addition, no difference was observed in both ALSFRS-R, total ($p = 0.056$), ALSFRS-Respiratory subscale ($p = 0.101$), MBDS (upright position) ($p = 0.835$), MBDS (supine position) ($p = 0.197$), and DALS-15 ($p = 0.516$) scores between patients with and without bulbar symptoms.

Validity

a. Construct validity

In the absence of a gold standard measure, construct validity of DALS-15 was investigated using ALSFRS-R and MDBS (upright and supine). Pearson correlation revealed a significant correlation between DALS-15 and other PROs ($p < 0.05$). The validity of DALS-15 was considered "good"

based on correlation coefficient which was higher than 0.5 for all PROs [24]. The results are presented in Table 2.

b. Content validity

Floor and ceiling effects were assessed to determine content validity of DALS-15 in the first assessment. None of the participants achieved the minimum score of 0 (zero) in the first assessment, whereas only one patient (2.6%) achieved a score of 0 (zero) in the re-test. Thus, there was no floor effect. A maximum score of 30 was achieved by 5 (9.9%) and 3 (7.7%) patients in the first and last assessments, respectively. The results suggested no ceiling effect.

Reliability

The DALS-15 was confirmed to exhibit strong internal consistency with a Cronbach's α value of 0.95 and an ICC value of 0.949 (95%CI, 0.92–0.96). The inter-item correlation matrix did not show any low or negative inter-item correlation.

The mean time between the first assessment and re-test was 7.81 days. The mean score of global rating of change scale was − 0.17 suggesting that the patients were feeling slightly worse compared to the time of first assessment. Table 3 shows the distribution of global rating of change scores. Test-re-test reliability of the questionnaire was 0.91 (ICC: 0.909, 95% CI: 0.81–0.95).

Table 3 Distribution of global rating of change scale ($n = 30$)

Score of change		*N*	%
− 2	much worse	2	6,7
− 1	worse	4	13,3
0	same	21	70
1	better	3	10
+ 2	much better	-	-

Agreement

The SEM value was 2.76, whereas the MDC was 7.66 point for the Turkish version of DALS-15.

Discussion

This study shows that the Turkish version of DALS-15 is a valid and reliable tool to detect dyspnea in patients with ALS. The questionnaire exhibits strong and very strong correlations with ALSFRS-R and MBDS, respectively, promising to be a highly valid measurement. Also, there is no ceiling or floor effect, which suggests items are excellently distributed. It also represents high reliability with strong Cronbach's α and ICC values for both internal consistency and reproducibility.

DALS-15 was created by Vogt et al. [5] in order to fill the gap in the assessment and optimize symptom management of patients with ALS. The authors also concluded that DALS-15 is easy, quick, and short tool to use for diagnosing dyspnea. In the original article, the validity of DALS-15 was evaluated with the respiratory subscale of expanded version of ALSFRS (ALSFRS-EX). Similarly to our results, there was a strong relationship between DALS-15 and ALSFRS-EX. On the other hand, the correlation between MBDS in upright and supine position and the Turkish version of DALS-15 was significantly higher than the original article representing a very strong relationship. However, one should bear in mind when interpreting these results that the patient population in the original article was somewhat different compared to current study. The mean disease duration of the patients, mean age, and the mean value of respiratory subscale of ALSFRS-EX were slightly higher than our population.

Additionally, both studies (i.e., present study and the original study by Vogt et al. [5]) reported that DALS-15 does not have floor or ceiling effect, suggesting that DALS-15 has a good content validity. This also shows that the items of the questionnaire are excellently distributed for diagnosing the patients with dyspnea symptoms.

In the original article [5], reported Cronbach's α value and the ICC for reliability were 0.88 and 0.982 suggesting a high reliability. The current study also showed that the Turkish version of the questionnaire had high internal consistency with a Cronbach's α value of 0.95 and reproducibility with an ICC value of 0.909. It was found in the current study that the SEM of DALS-15 was 2.76

Table 2 Results of construct validity ($n = 52$)

PROs		ALSFRS-R (respiratory subscale)	MBDS (upright position)	MBDS (supine position)
DALS-15 (first assessment)	*r*	-0.668	0.728	0.780
	p	< 0.0001*	< 0.0001*	< 0.0001*
DALS-15 (re-test)	*r*	-0.579	0.633	0.722
	p	< 0.0001*	< 0.0001*	< 0.0001*

*$p < 0.05$. *ALSFRS-R* Revised Amyotrophic Lateral Sclerosis Functional Rating Scale, *MBDS* Modified Borg Dyspnea Scale, *DALS-15* Dyspnea-ALS Scale

(90.2%) and MDC was 7.66 (25.53%), whereas Vogt et al. [5] reported that the SEM and MDC were 1.16 (3,8%) and 3.21 (10.7%), respectively. We believe that the small difference in ICC might lead to a higher SEM and MDC in our study compared to the values reported in the original study.

The main strength to state in our study is that we have used online surveys to evaluate patients since there was a global pandemic. Our results showed that DALS-15 is a valid tool to use in online settings. As stated in the "Methods" section, ALSFRS-R is a valid assessment for online use [17] and the DALS-15 may also be used for self-assessment since it reflects patients' perspectives. This study has also one limitation which is that the 13 participants were lost during the re-test period. One patient was hospitalized and unable to fill the questionnaire and 12 participants refused to perform re-test. However, the number of participants was still adequate to perform reliability analysis[19].

Conclusion

The Turkish version of DALS-15 possesses strong psychometric properties with excellent validity and reliability. Therefore, it may be used to diagnose dyspnea in patients with ALS by clinicians and researchers, even in the outside of the clinical environment. Turkish version of DALS-15 is shown to be useful for online self-assessment in especially hard times such as pandemic.

Abbreviations DALS-15: The Dyspnea-ALS-Scale; ALS: Amyotrophic lateral sclerosis; ALSFRS-R: The ALS Functional Rating Scale-Revised; MBDS: Modified Borg Dyspnea Scale; ICC: Intraclass correlation coefficient; SEM: Standard error of measurement; MDC: Minimal detectable change; F/M: Female/male; BMI: Body mass index; PROs: Patient-reported outcomes; ALSFRS-EX: The ALS Functional Rating Scale-Extension

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10072-021-05516-4.

Declarations

Ethical approval The study was approved by the Non-invasive Research Ethics Board of Istanbul University- Cerrahpaşa (approval number: A-04 and date:18.02.2020) and performed following the ethical standards as laid down in the 1964 Declaration of Helsinki. The study was approved by the Non-invasive Research Ethics Board of Istanbul University- Cerrahpaşa (approval number: A-04 and date:18.02.2020) and performed following the ethical standards as laid down in the 1964 Declaration of Helsinki.

Conflict of interest The authors declare no competing interests.

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