Validation of the Brazilian Portuguese version of the University of California San Diego Shortness of Breath Questionnaire in patients with interstitial lung disease

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ABSTRACT

Objective: To investigate the reliability, internal consistency and validity of the Brazilian Portuguese version of the University of California San Diego Shortness of Breath Questionnaire (UCSD SOBQ) in patients with interstitial lung disease (ILD). **Methods:** Patients with ILD completed the questionnaire at three different time points, one week apart, with the assistance of two independent assessors. Intra- and inter-rater reliability were analysed via the intraclass correlation coefficient (ICC). Internal consistency was assessed with the Cronbach's alpha coefficient. For the validity analysis, associations between variables were assessed with Spearman's or Pearson's correlation coefficient. **Results:** Thirty patients with ILD (idiopathic pulmonary fibrosis, connective tissue disease-associated pulmonary fibrosis, sarcoidosis, asbestosis or non-specific interstitial pneumonia) were included (15 men; mean age, 59 ± 10 years; DL_{CO}: 46 [33-64] % predicted). UCSD SOBQ scores showed excellent agreement and internal consistency in the intra-rater analysis (ICC: 0.93 [0.85-0.97]; Cronbach alpha: 0.95) and in the inter-rater analysis (ICC: 0.95 [0.89-0.97]; Cronbach alpha: 0.95), as well as correlating significantly with dyspnoea (as assessed by the Medical Research Council scale; r = 0.56); Medical Outcomes Study 36-item Short-Form Health Survey domains bodily pain, general health, vitality and physical functioning (−0.40 ≤ r ≤ −0.74); six-minute walk distance (r = −0.38); and quadriceps muscle strength (r = −0.41). **Conclusions:** The Brazilian Portuguese version of the UCSD SOBQ is valid, is reliable and has internal consistency in patients with ILD in Brazil.

Keywords: Lung diseases, interstitial; Dyspnea; Surveys and questionnaires.

INTRODUCTION

Interstitial lung diseases (ILDs) are characterised by chronic alveolar inflammation, diffuse parenchymal lung fibrosis and, as a consequence, a deficit in gas exchange.[1-3] These impairments directly impact dyspnoea, exercise capacity, muscle function, physical activity, health-related quality of life, anxiety, depression and disease prognosis.[4-8]

Currently available medical treatments can slow down disease progression but do not appear to impact survival.[9] Consequently, measures of health status and symptom perception play an important role in assessing the effects of ILD, as well as treatment efficacy. Among the typical symptoms, dyspnoea related to activities of daily living is the most commonly reported by patients with ILD and significantly contributes to the perception of poorer health status.[10,11] Despite its prevalence and relevance, dyspnoea in patients with ILD has received little attention in clinical trials and studies exploring

disease progression. This literature gap likely reflects the limited availability of information concerning dyspnoea perception in this group of patients and the absence of robust data pointing out the most valid and reliable criteria to assess their dyspnoea.

To evaluate the progression of certain respiratory diseases and the response to interventions such as rehabilitation programmes, several instruments exist, with different forms of administration, including interviews, self-report questionnaires, visual analogue scales and numeric scales.[12-14] The University of California San Diego Shortness of Breath Questionnaire (UCSD SOBQ) comprehensively assesses breathlessness experienced during activities of daily living and can be used in a wide range of chronic respiratory diseases. The UCSD SOBQ has been validated for use in patients with COPD, patients with cystic fibrosis, lung transplant recipients[15] and patients with idiopathic pulmonary fibrosis (IPF).[16] Moreover, the UCSD SOBQ has been considered a valid

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instrument to assess changes in perceived dyspnoea over time in patients with IPF.[16]

Given that dyspnoea is a major symptom of ILD and generally limits activities of daily living and quality of life in these patients, it is essential to use valid tools to assess it adequately. This study aimed to investigate the reliability, internal consistency and validity of the Brazilian Portuguese version of the UCSD SOBQ in patients with different ILDs.

METHODS

Study design and procedures

This cross-sectional study was conducted at the *Universidade Estadual de Londrina*, located in the city of Londrina, Brazil, and was approved by the local institutional review board (Protocol no. 2.484.871). Patients with a diagnosis of ILD in accordance with international guidelines[1,2] were recruited from the university hospital outpatient clinic. The medical and pharmacological management of patients remained unchanged during the study period. Patients had to be clinically stable for at least four weeks before the first interview and in the interim between completing the questionnaire the first and second time, and the second and third time. Patients were excluded if they did not have enough cognitive function to complete the questionnaire, as assessed by the Mini-Mental State Examination,[17] or presented with health status changes that could interfere with the assessments.

In the initial visit, all participants underwent a comprehensive clinical assessment. Lung function assessment was performed in accordance with internationally accepted guidelines,[18-21] including whole-body plethysmography and DL_{CO} measurement with a Vmax plethysmograph (CareFusion, Hochberg, Germany). Exercise capacity was assessed by the six-minute walk test. The test was performed twice, and the highest six-minute walk distance was recorded.[22,23] Quadriceps muscle strength was assessed by the maximal voluntary isometric contraction of the dominant limb, with the use of a strain gauge sensor (EMG System do Brasil, São José dos Campos, Brazil). Participants were instructed to perform a maximal voluntary isometric contraction for six seconds, with 90° of hip and knee flexion.[24] Dyspnoea-related limitations in activities of daily living were assessed with the Medical Research Council (MRC) scale,[13] and health-related quality of life was assessed with the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36).[25,26] Furthermore, participants completed the UCSD SOBQ at three different time points (during the initial visit and two additional visits), with a maximum interval of 7 days between visits. This time frame is considered long enough for participants not to fully recall their previous responses and avoid significant changes in health status.[27]

Two investigators administered the questionnaire for the evaluation of intra- and inter-rater reliability.

Investigator 1 applied the questionnaire in the first and third visits, whereas investigator 2 applied it during the second visit. A comparison of the UCSD SOBQ scores across the three time points was performed (i.e., inter- and intra-rater reliability). Furthermore, the convergent criterion validity of the UCSD SOBQ was assessed via its correlations with anchors (i.e., the MRC scale and the SF-36).

Questionnaires

Approval to use the UCSD SOBQ was obtained from the original author and from the Mapi Research Trust (Request no. 89588), which had translated the original questionnaire to Portuguese and adapted it for use in Brazil. Therefore, the translation and cross-cultural adaptation of the UCSD SOBQ was out of the scope of the present study.

The UCSD SOBQ[15] is a 21-item questionnaire that evaluates dyspnoea during activities of daily living of varying intensity (e.g., brushing one's teeth and walking uphill). Participants were asked to indicate the perceived severity of breathlessness on a six-point scale ranging from 0 (not at all) to 5 (maximal or unable to do because of breathlessness). When participants did not usually perform an activity mentioned in the UCSD SOBQ, they were instructed to estimate the degree of breathlessness to perform that activity. Three additional questions about limitations due to shortness of breath, fear of harm from overexertion and fear of shortness of breath are included for a total of 24 items. The total score ranged from 0 to 120 and was calculated by the sum of all items, in which a higher score translated to a greater limitation caused by dyspnoea.[15] The Brazilian Portuguese version of the UCSD SOBQ is available upon request to the Mapi Research Trust at https://eprovide.mapi-trust.org.

The MRC scale was used to assess dyspnoea-related limitations in activities of daily living. Scores range from 1 to 5, with higher scores indicating greater impairment.[13] The SF-36 comprises 36 questions covering eight domains of health status: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. Measurements of the eight domains were transformed linearly to scores ranging from 0 (the worst possible condition) to 100 (the best possible condition).[25]

A quiet room was used for the administration of the questionnaires. Given that illiteracy is not an uncommon characteristic among Brazilians (mainly the elderly) and the considerable variation of scores when questionnaires are self-administered in comparison with when they are interviewer-administered, completion of the questionnaires at all time points in the present study was facilitated by a researcher using an interview approach.[28]

Statistical analysis

Continuous variables were described as mean ± standard deviation or median [IQR] depending on

data distribution. The intraclass correlation coefficient (ICC) was used to investigate the reliability of the questionnaire. The ICC was selected in accordance with McGraw & Wong.[29] The "two-way mixed effects, single measurement, absolute agreement" was used to investigate intra- and inter-rater agreement. Reliability was classified as poor (ICC < 0.5), moderate (0.5 ≤ ICC < 0.75), good (0.75 ≤ ICC < 0.9) or excellent (ICC ≥ 0.9).[30] Absolute reliability of the data was determined by the standard error of measurement (SEM). The SEM was calculated on the basis of intra-assessor reliability by the following equation: $SEM = SDX\sqrt{1 - ICC}$. A lower SEM translated to a more reliable measurement.[31] Internal consistency was tested using Cronbach's alpha. Values ranging from 0.70 to 0.95 represent acceptable internal consistency for the instrument.[32] Agreement between tests (intra- and inter-rater agreement) was assessed by Bland-Altman analysis.[33] Ceiling and floor effects were calculated by estimating the proportion of patients whose scores lay within the 10% best UCSD SOBQ scores (ceiling effect) or the 10% worst UCSD SOBQ scores (floor effect).[34]

Spearman's correlation coefficient was used to verify correlations of UCSD SOBQ scores at all time points with other questionnaires and clinical outcomes. The MRC scale and the SF-36 were used as anchors in the validation of the UCSD SOBQ. It was hypothesized that the UCSD SOBQ would show at least moderate correlation with the MRC scale and the Physical Health component of the SF-36. The magnitude of this correlation was expected to be at least moderate (r > 0.39).[35] Statistical significance was set at p < 0.05. All statistical analyses were performed with the Statistical Analysis System, version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Thirty patients were evaluated and included in the analysis. There was no attrition after inclusion. Of the 30 patients included in the analysis, 18 had IPF, 5 had connective tissue disease-associated pulmonary fibrosis, 4 had particle-induced pulmonary fibrosis, and 3 had non-specific interstitial pneumonia. The clinical characteristics of the patients are described in Table 1.

There were no differences in total UCSD SOBQ scores across the three visits (visit 1: 39 ± 23, visit 2: 42 ± 24 and visit 3: 37 ± 21; p = 0.07). As can be seen in Figure 1, the UCSD SOBQ showed excellent reliability, agreement and internal consistency on the intra-rater test-retest (visit 1 vs. visit 3; ICC: 0.93 [0.85-0.97]; Δ1.34 [95% CI: −20 to 23]; Cronbach's alpha: 0.95) and on the inter-rater test-retest (visit 1 vs. visit 2; ICC: 0.95 [0.89-0.97]; Δ−1.03 [95% CI: −22 to 20]; Cronbach's alpha: 0.95). In addition to the overall internal consistency analysis, we tested Cronbach's alpha by deleting one item at a time and obtained similar results (0.955 < α < 0.961). The proportion of patients whose scores lay within the top 10% UCSD SOBQ scores (ceiling effect), i.e., more severe

shortness of breath, was = 0% (i.e., no patients). The proportion of patients whose scores lay within the bottom 10% UCSD SOBQ scores (floor effect), i.e., less severe shortness of breath, was = 3%. The SEM for the total score was 4.9 (9%) for (intra-rater) test-retest reliability.

UCSD SOBQ scores showed a moderate positive correlation with MRC scale scores (r = 0.56, p = 0.0019) and a significant negative correlation with different SF-36 domains (physical functioning, bodily pain, general health and vitality), ranging from −0.40 to −0.74 (Table 2). In addition, the UCSD SOBQ was significantly correlated with quadriceps muscle strength adjusted by body weight and the six-minute walk distance in metres (r = −0.41, p = 0.03; r = −0.38, p = 0.03, respectively). Correlations with pulmonary function variables were all non-significant (−0.12 < r < 0.25, p > 0.05 for all).

DISCUSSION

The present study results indicate that the Brazilian Portuguese version of the UCSD SOBQ has excellent internal consistency and is a reliable instrument to assess dyspnoea in patients with ILD. Furthermore,

Table 1. Clinical characteristics of the patients.

Variable	n = 30
Sex, men (%)	15 (50)
Age, years	59 ± 10
BMI, kg/m^2	27.4 ± 5.3
Pulmonary function	
FVC, % of predicted	73 [59-80]
FEV$_1$, % of predicted	73 [58-84]
FEV$_1$/FVC	84 [79-87]
TLC, % of predicted	72 [65-89]
DL$_{CO}$, % of predicted	46 [33-64]
Exercise capacity	
6MWD, m	469 ± 100
6MWD, % of predicted	86 ± 17
Peripheral muscle strength	
Quadriceps muscle strength, N	350 [234-530]
Quadriceps muscle strength, N/kg	5.4 [3.6-7.1]
Health-related quality of life (SF-36 domains)	
Physical functioning, score	40 [25-60]
Role-physical, score	25 [0-75]
Bodily pain, score	51 [41-62]
General health, score	47 [35-52]
Vitality, score	60 [45-70]
Role-emotional, score	67 [0-100]
Social functioning, score	74 [50-100]
Mental health, score	72 [56-76]
Dyspnoea	
MRC scale, score	3 [2-4]
UCSD SOBQ, score	37 [22-52]

6MWD: six-minute walk distance; SF-36: Medical Outcomes Study 36-item Short-Form Health Survey; MRC: Medical Research Council; and UCSD SOBQ: University of California San Diego Shortness of Breath Questionnaire.
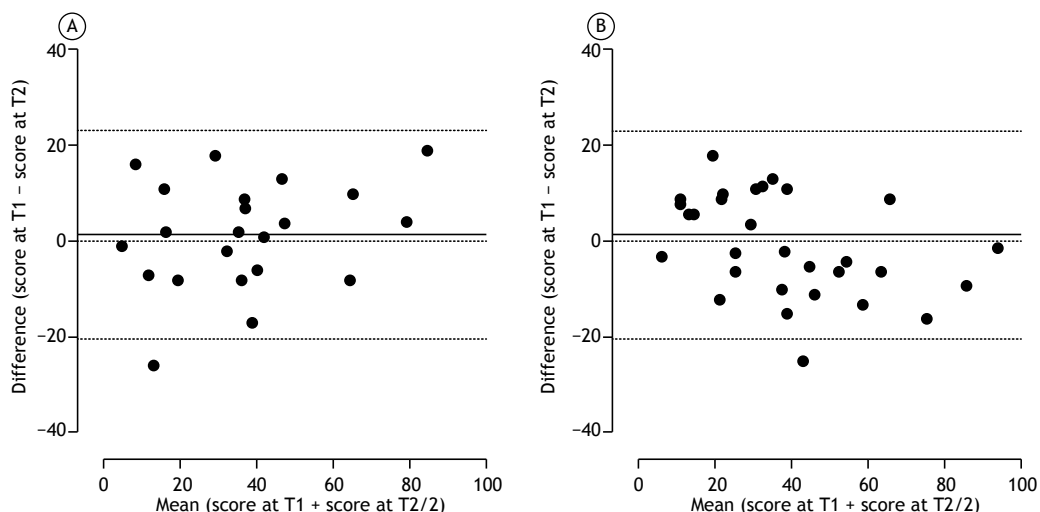
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Figure 1. Bland-Altman plots showing the level of agreement between two different applications of the University of California San Diego Shortness of Breath Questionnaire (at time point 1 [T1] and time point 2 [T2]). In A, intra-rater agreement. In B, inter-rater agreement.

UCSD SOBQ scores were significantly correlated with the questionnaires used as anchors (the MRC scale and the SF-36). Moreover, the UCSD SOBQ showed good reliability and agreement when applied by the same rater and by different raters. All of these features provide a good scientific basis for using the UCSD SOBQ to assess dyspnoea in patients with ILD.

Eakin et al.[15] observed excellent internal consistency when they initially validated the UCSD SOBQ. Likewise, the values of Cronbach's alpha in the present study also showed excellent internal consistency. Importantly, neither intra-rater reliability nor inter-rater reliability was investigated in previous validation studies of the UCSD SOBQ.[15,16] Our results expand the current knowledge on the metric properties of the UCSD SOBQ, confirming excellent reliability of the UCSD SOBQ in patients with ILD. Moreover, the reliability found in the present study was excellent in both intra- and inter-rater assessments. The difference in UCSD SOBQ scores across the three evaluation time points was less than five points, which is the minimal clinically important difference for this questionnaire.[36,37] In addition, there was no statistically significant difference across the three evaluation time points (p > 0.05). Therefore, only one assessment is sufficient to identify the impact of dyspnoea on activities of daily living. These findings demonstrate that the UCSD SOBQ can be applied by different assessors. This facilitates its application in clinical settings such as pulmonary rehabilitation programmes.

The development study of the UCSD SOBQ[15] found a correlation with dyspnoea as assessed by modified Borg scale ratings of perceived breathlessness (r = 0.45) that is somewhat weaker than the correlation with the MRC scale scores found in the present study (r = 0.56). A likely explanation for the differences between the aforementioned results is the tool used as an anchor for dyspnoea measurements. The correlation

Table 2. Correlation of University of California San Diego Shortness of Breath Questionnaire scores with Medical Research Council scale and Medical Outcomes Study 36-item Short-Form Health Survey scores.

Variable	r	p
MRC scale	0.56	0.0019
SF-36 domains		
Physical functioning	−0.74	< 0.0001
Role-physical	−0.29	0.11
Bodily pain	−0.48	0.007
General health	−0.40	0.02
Vitality	−0.40	0.02
Role-emotional	−0.26	0.16
Social functioning	0.08	0.67
Mental health	−0.06	0.72

MRC: Medical Research Council; and SF-36: Medical Outcomes Study 36-item Short-Form Health Survey.

with the MRC scale scores is possibly better because the MRC scale is designed to evaluate the degree of dyspnoea during activities of daily living, whilst the Borg scale was developed to assess dyspnoea on exertion. Since dyspnoea is strongly related to quality of life in patients with respiratory disorders, it is not surprising that previous studies have investigated associations between these two outcomes.[16,38] Interestingly, others have reported similar correlations between the UCSD SOBQ and health-related quality of life as assessed by the SF-36 (i.e., −0.70 < r < −0.78).[16,38] The SF-36 was chosen for the present study because it had previously been translated to Portuguese. It has been widely used in patients with ILD due to the lack of a specific questionnaire for this population.[39]

Dyspnoea is the cardinal symptom of ILD and significantly affects patient overall health status. In other respiratory diseases, dyspnoea has a negative impact on the performance of physical activities of daily living.[40] Because the UCSD SOBQ is an instrument

that evaluates the impact of dyspnoea on physical activities, we also investigated the correlation of the UCSD SOBQ with other clinical outcomes. Correlation values between the UCSD SOBQ and exercise capacity in the present study were similar to those observed in the validation study.[15,16] Moreover, we also found a significant correlation between the UCSD SOBQ and muscle strength (quadriceps muscle strength) that has not been demonstrated in previous studies.

No significant correlations were found between UCSD SOBQ scores and pulmonary function ($-0.12 < r < 0.25$, $p > 0.05$ for all) in the present study. Swigris et al. investigated associations between UCSD SOBQ scores and pulmonary function and found similar results in patients with IPF.[16] On the other hand, Eakin et al. evaluated patients with different respiratory diseases (COPD patients, cystic fibrosis patients and lung transplant recipients), which differ from ILDs in terms of lung function impairment.[15,16] Although lung function impairment is associated with dyspnoea, this correlation seems to be stronger in obstructive diseases.[15,16] Yet, the severity of lung function impairment does not appear to be a decisive factor downplaying dyspnoea in ILDs.[15]

The present study has some limitations. The low prevalence of patients with ILD and the single-centre nature of the study limited participant recruitment, resulting in a somewhat limited sample size. Notably, the reliability and validity analysis results are in line with a previous validation study in patients with IPF.[16] Therefore, sample size and composition in the present study are unlikely to have compromised the reliability of the results. Furthermore, although the UCSD SOBQ was developed to be self-administered, it was interviewer-administered in the present study. This was an a priori criterion carefully used in our study because we anticipated illiterate patients, who are not uncommon in Brazil.[28] Finally, since there is

considerable variation of scores when questionnaires are self-administered in comparison with when they are interviewer-administered, we attempted to reduce bias by standardising the application method.[28] Whether or not the self-administered UCSD SOBQ is also valid and reliable in patients with ILD in Brazil remains to be confirmed.

In conclusion, although the present study was conducted in a relatively small sample, the Brazilian Portuguese version of the UCSD SOBQ was found to be a valid and reliable instrument to assess dyspnoea related to activities of daily living in patients with ILD. Furthermore, our results demonstrate that different assessors can apply the questionnaire, thus facilitating its use in clinical settings such as pulmonary rehabilitation programmes.

AUTHOR CONTRIBUTIONS

HS: conception and design of the study; data acquisition, analysis, and interpretation; drafting of the manuscript; and final approval of the version to be published. LCM and CLZ: drafting of the manuscript; critical revision of the manuscript for important intellectual content; and final approval of the version to be published. WFA, AFLG and TG: data acquisition; critical revision of the manuscript for important intellectual content; and final approval of the version to be published. ALR: substantial contribution to the study design; data acquisition and interpretation. MR: critical revision of the manuscript for important intellectual content; and final approval of the version to be published. FP: data analysis and interpretation; critical revision of the manuscript for important intellectual content; and final approval of the version to be published. CAC: conception and design of the study; data analysis and interpretation; critical revision of the manuscript for important intellectual content; final approval of the version to be published; and guarantor of the article.

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