

Reliability of the Brazilian Portuguese version of the fatigue severity scale and its correlation with pulmonary function, dyspnea, and functional capacity in patients with COPD*

Reprodutibilidade da versão brasileira da escala de gravidade da fadiga e sua correlação com função pulmonar, dispnéia e capacidade funcional em pacientes com DPOC

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Abstract

Objective: To describe the intra-rater and inter-rater reliability of the Brazilian Portuguese version of the fatigue severity scale (FSS) in patients with COPD and to identify the presence of its association with parameters of pulmonary function, dyspnea, and functional capacity. **Methods:** This was an observational cross-sectional study involving 50 patients with COPD, who completed the FSS in interviews with two researchers in two visits. The FSS scores were correlated with those of the Medical Research Council (MRC) scale, as well as with FEV₁, FVC, and six-minute walk distance (6MWD). **Results:** The mean age of the patients was 69.4 ± 8.23 years, whereas the mean FEV₁ was 46.5 ± 20.4% of the predicted value. The scale was reliable, with an intraclass correlation coefficient of 0.90 (95% CI, 0.81-0.94; p < 0.01). The FSS scores showed significant correlations with those of MRC scale (r = 0.70; p < 0.01), as well as with 6MWD (r = -0.77; p < 0.01), FEV₁ (r = -0.38; p < 0.01), FVC (r = -0.35; p < 0.01), and stage of the disease in accordance with the Global Initiative for Chronic Obstructive Lung Disease criteria (r = 0.37; p < 0.01). **Conclusions:** The Brazilian Portuguese version of the FSS proved reliable for use in COPD patients in Brazil and showed significant correlations with sensation of dyspnea, functional capacity, pulmonary function, and stage of the disease.

Keywords: Fatigue; Pulmonary disease, chronic obstructive; Reproducibility of results; Validation studies.

Resumo

Objetivo: Descrever a reprodutibilidade intra e interobservador da versão brasileira da escala de gravidade da fadiga (EGF) em pacientes com DPOC e verificar a presença de sua associação com parâmetros de função pulmonar, dispnéia e capacidade funcional. **Métodos:** Estudo observacional de corte transversal no qual 50 pacientes com DPOC responderam a EGF em forma de entrevista a dois pesquisadores em duas visitas. Os escores da EGF foram correlacionados aos da escala *Medical Research Council* (MRC), VEF₁, CVF e a distância percorrida no teste da caminhada de seis minutos (DTC6). **Resultados:** A média de idade dos pacientes foi de 69,4 ± 8,23 anos, enquanto a de VEF1 foi de 46,5 ± 20,4% do previsto. A EGF foi considerada reprodutível, com um coeficiente de correlação intraclassa de 0,90 (IC95%, 0,81-0,94; p < 0,01). Os escores da EGF mostraram correlações significantes com os da escala MRC (r = 0,70; p < 0,01), DTC6 (r = -0,77; p < 0,01), VEF₁ (r = -0,38; p < 0,01), CVF (r = -0,35; p < 0,01) e a estágio da doença pela *Global Initiative for Chronic Obstructive Lung Disease* (r = 0,37; p < 0,01). **Conclusões:** A versão brasileira da EGF mostrou-se reprodutível para uso em pacientes com DPOC no Brasil e apresentou correlações significantes com a sensação de dispnéia, capacidade funcional, função pulmonar e estágio da doença.

Descritores: Fadiga; Doença pulmonar obstrutiva crônica; Reprodutibilidade dos testes; Avaliação; Estudos de validação.

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Introduction

Fatigue is a major symptom and is present in 43–58% of patients with COPD,⁽¹⁻⁵⁾ having a major impact on the functional capacity and quality of life of COPD patients.^(6,7)

Fatigue is currently defined as a subjective, unpleasant symptom that incorporates total body feelings ranging from tiredness to exhaustion creating an unrelenting overall condition that interferes with the ability of individuals to function to their normal capacity.⁽⁸⁾ In patients with COPD, fatigue limits the motivation, concentration, and willingness to perform work and social activities,⁽⁹⁾ often leading to deep frustration and depression, as well as to a deep sense of loss of emotional control.⁽⁵⁾

The Borg scale⁽¹⁰⁾ has been routinely used in order to quantify the perception of leg fatigue during physical exertion or functional capacity tests. However, an instrument quantifying fatigue during activities of daily living should also be considered an important tool in the evaluation and treatment of patients with COPD. The fatigue severity scale (FSS),⁽¹¹⁾ previously translated into Brazilian Portuguese, has been widely used in order to assess fatigue in patients with neurological diseases,⁽¹²⁻¹⁴⁾ in the elderly,⁽¹⁵⁾ and in patients with neoplasia.^(16,17)

The FSS is a self-report scale comprising nine statements describing the severity of fatigue and the impact of fatigue on activities of daily living in the last two weeks.

The researchers hypothesized that the FSS would show good reliability, internal consistency, and validity, i.e., that it would correlate with lung function, perception of dyspnea, and the six-minute walk distance (6MWD). They also hypothesized that patients with fatigue would have more severe clinical and functional limitations (severity of airway obstruction, disease stage, dyspnea, and functional exercise capacity).

The objective of the present study was to evaluate the intra-rater and inter-rater reliability of the FSS and determine whether the degree of fatigue correlated with lung function, perception of dyspnea, and functional exercise capacity in patients with COPD.

Methods

This was a cross-sectional study evaluating clinically stable patients with COPD staged in

accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria⁽¹⁸⁾ and with no medication changes for at least three months before the beginning of the study. Patients were selected from among those treated at a university medical center between October and December of 2011. We excluded those who had been involved in any type of physical activity before the beginning of the study, those who had any extrapulmonary disease causing functional limitation and fatigue (such as severe cardiovascular disease), and those who had difficulty understanding the scale items (as determined by the interviewers on the basis of subjective criteria).

The present study was approved by the local research ethics committee, and all participants gave written informed consent.

The FSS comprises nine statements, and, for each item, patients are instructed to choose a score ranging from 1 to 7, 7 representing the highest level of agreement with a given statement. The total FSS score is obtained by calculating the mean of all items, a score ≥ 4 indicating the presence of fatigue.⁽¹¹⁾

In order to determine the reliability of the FSS, the scale was administered by two interviewers on two different occasions, two weeks apart. The evaluations were designated interview 1 (I1, intra-rater reliability assessment) and interview 2 (I2, inter-rater reliability assessment). The interviews were conducted independently by two raters, with a 30-min interval between interviews.⁽¹⁹⁾ Although the patients were literate, we followed the methodology used in other studies^(13,14); that is, the interviewers read the questions aloud and marked the answers given by patients.

Additionally, we assessed the degree of dyspnea—using the Medical Research Council (MRC) scale,⁽²⁰⁾ previously translated into Brazilian Portuguese and validated for use in Brazil⁽²¹⁾—the 6MWD,⁽²²⁾ and lung function parameters (FVC and FEV₁).⁽²³⁾

Data analysis was performed with the Statistical Package for the Social Sciences, version 16.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive statistics (frequency, mean, standard deviation, median, and interquartile range) were calculated for demographic, anthropometric, and clinical characteristics, depending on the type of variable and the

data distribution. The intraclass correlation coefficient (ICC) and its 95% CI were used in order to assess inter-rater reliability at I1 and I2, and the Wilcoxon test was used in order to determine whether there were differences between I1 and I2. The intra-rater reliability at I1 and I2 and inter-rater reliability were visually assessed by Bland & Altman plots. Bland & Altman plots display the differences, the overall mean and variance are calculated, and the 95% CI is constructed around the mean, a normal distribution of the data being assumed. We used Spearman's test in order to determine the association of the FSS score with the degree of dyspnea as assessed by the MRC scale score, 6MWD, disease severity, FEV₁, and FVC. The level of statistical significance was set at $p < 0.05$.

Results

Our study included 50 patients. Of those, all were literate and 28 (56%) were male. No significant differences were found between the genders regarding any of the study variables. All patients were using bronchodilators. General, sociodemographic, and clinical data are shown in Table 1.

There were no significant differences in FSS scores between I1 and I2 in the intra-rater reliability assessment ($p = 0.76$) or in the inter-rater reliability assessment ($p = 0.67$).

Intra-rater and inter-rater ICCs were significant for the FSS (0.90 [0.81-0.94]; $p < 0.01$; and 0.95 [0.92-0.98]; $p < 0.01$, respectively). Cronbach's alpha coefficient was 0.90.

The test-retest reliability of the FSS was demonstrated by Bland & Altman plots between I1 and I2, as well as between the two raters (Figure 1).

The correlations of FSS scores with disease severity (GOLD criteria), SpO₂, FEV₁, FVC, MRC scale scores, and 6MWD are shown in Table 2.

The median FSS score was 5.33 (range, 1-7). The prevalence of fatigue in the study sample was 60% ($n = 30$); consequently, it was possible to divide the sample into two groups: patients with fatigue ($n = 30$) and patients without fatigue ($n = 20$). When compared, the groups showed significant differences regarding FSS scores, spirometric parameters (FEV₁, FVC, and FEV₁/FVC), GOLD stages, MRC scale scores, and 6MWD (Table 3).

Discussion

The results of the present study show that the Brazilian Portuguese version of the FSS is reliable for use in the evaluation of fatigue in patients with COPD. In addition, FSS scores

Table 1 – Characteristics of the patients evaluated ($n = 50$).^a

Variable	Mean, SD
Age, years	69.4 ± 8.23
BMI, kg/m ²	25.7 ± 4.54
FVC, % of predicted	65.9 ± 20.4
FEV ₁ , % of predicted	46.5 ± 20.4
FEV ₁ /FVC	65.9 ± 25.3
SpO ₂ , %	92.4 ± 3.13
MRC scale score ^b	3 (2-3)
GOLD stage, I/II/III/IV ^c	5/15/14/16
6MWD, m	357.2 ± 92.6
6MWD, % of predicted	77 ± 22
EGF ^b	5.33 (3.50-6.00)

BMI: body mass index; GOLD: Global Initiative for Chronic Obstructive Lung Disease; 6MWD: six-minute walk distance; MRC: Medical Research Council; and EGF: *escala de gravidade da fadiga* (Brazilian Portuguese version of the fatigue severity scale). ^aValues expressed as mean ± SD, except where otherwise indicated. ^bValues expressed as median (interquartile range). ^cValues expressed as n of patients.

Table 2 – Correlations of fatigue severity scale scores with the study variables.

Variable	r	p
GOLD stage	0.37	0.01
SpO ₂	-0.38	0.03
FEV ₁ , % of predicted	-0.38	0.01
FVC, % of predicted	-0.35	0.01
FEV ₁ /FVC	-0.30	0.03
MRC scale score	0.69	< 0.01
6MWD, m	-0.77	< 0.01
6MWD, % of predicted	-0.54	< 0.01

GOLD: Global Initiative for Chronic Obstructive Lung Disease; MRC: Medical Research Council; and 6MWD: six-minute walk distance.

Table 3 – Differences between the groups of patients with and without fatigue as assessed by fatigue severity scale scores.^a

Variable	Group		p
	With fatigue (n = 30)	Without fatigue (n = 20)	
EGF ^b	6.0 (4.6-7.0)	3.0 (1.0-4.0)	< 0.01
Age, years	70.1 ± 7.9	68.4 ± 8.8	0.42
Female/male gender ^c	15/15	7/13	0.30
BMI, kg/m ²	25.20 ± 4.94	26.50 ± 3.84	0.33
FVC, % of predicted	62.40 ± 21.90	71.00 ± 17.21	0.04
FEV ₁ , % of predicted	40.18 ± 16.30	56.00 ± 22.60	< 0.01
FEV ₁ /FVC	58.00 ± 22.00	76.45 ± 26.30	0.01
SpO ₂	92.10 ± 3.17	92.90 ± 3.00	0.27
MRC scale score ^b	3 (1-4)	2 (0-4)	< 0.01
GOLD stage, I/II/III/IV ^c	1/7/10/12	4/8/4/4	< 0.01
6MWD, m	323.1 ± 78.2	408.4 ± 90.5	< 0.01
6MWD, % of predicted	68.80 ± 18.70	89.40 ± 21.15	< 0.01

EGF: *escala de gravidade da fadiga* (Brazilian Portuguese version of the fatigue severity scale); BMI: body mass index; MRC: Medical Research Council; GOLD: Global Initiative for Chronic Obstructive Lung Disease; and 6MWD: six-minute walk distance. ^aValues expressed as mean ± SD, except where otherwise indicated. ^bValues expressed as median (interquartile range). ^cValues expressed as n of patients.

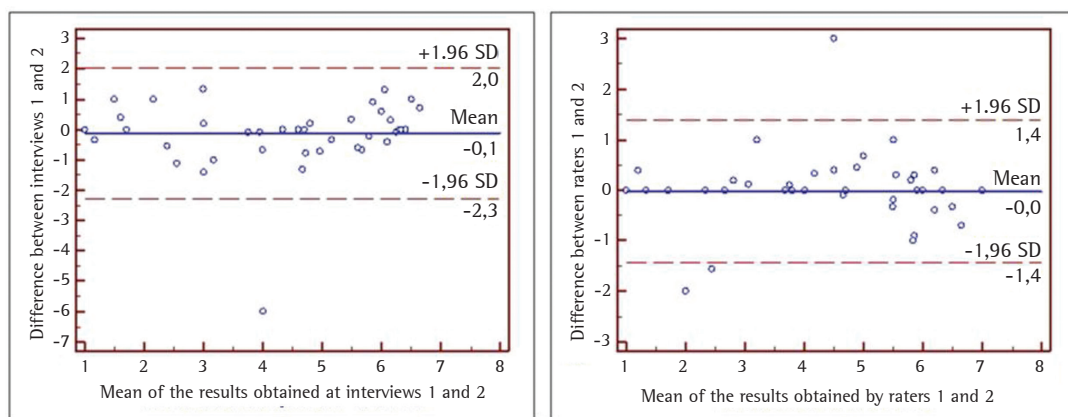


Figure 1 – Bland & Altman plots comparing the results obtained at interviews 1 and 2 (left), as well as comparing the results obtained by interviewers 1 and 2 (right).

correlated strongly and significantly with the degree of dyspnea and the 6MWD, and the FSS scores allowed us to divide the sample into two groups of patients (with and without fatigue) and detect differences between the two groups in terms of the parameters evaluated.

For instruments (such as scales and questionnaires) to be considered suitable for use in clinical practice or research in countries other than those in which they were originally developed, it is necessary to evaluate their reliability.⁽¹¹⁾ Reliability is defined as the ability of an instrument to show little or no variability

when it is used by different researchers or at different time points.

The absence of a statistically significant difference in test-retest reliability, together with the high ICC and excellent internal consistency (Cronbach's alpha coefficient = 0.90), demonstrate the reliability of the FSS in patients with COPD.

The reliability of the FSS was visually assessed by analyzing Bland & Altman plots, which showed that the bias ratio (difference between I1 and I2) was nearly zero. This showed good concordance between the interviews and between the two raters.

Regarding the FSS test time, there was no statistically significant difference between I1 and I2 (5 ± 3 min and 3 ± 2 min, respectively), although the test time was shorter at I2. We believe that this minimal difference is due to the fact that the patients had a better understanding of the questions. The FSS test time was shorter in the present study than in a study in which the FSS was administered to patients with Parkinson's disease in Brazil.⁽¹³⁾ We believe that this difference is due to the fact that the cognitive status is more severely impaired in patients with Parkinson's disease.

Regarding construct validity, the FSS score correlated strongly and significantly with the degree of dyspnea as assessed by the MRC scale score ($r = 0.69$) and with the 6MWD ($r = -0.77$), as well as having correlated moderately with disease stage, SpO_2 , and the spirometric parameters FEV_1 , FVC, and FEV_1/FVC .

Some studies have investigated the prevalence of fatigue and the association between fatigue and functional and clinical parameters in patients with COPD using, however, scales or questionnaires other than the FSS, including the fatigue impact scale,⁽²⁴⁾ the multidimensional fatigue inventory,⁽²⁵⁾ the chronic respiratory disease questionnaire,⁽²⁶⁾ and the functional assessment of chronic illness therapy-fatigue scale.⁽²⁷⁾

Only one study⁽²⁰⁾ used the FSS, showing that the presence of fatigue was correlated with age ($r = -0.31$), the degree of dyspnea as assessed by the MRC scale score ($r = 0.27$), and the quality of sleep ($r = 0.37$). Our results showed a stronger correlation between FSS scores and MRC scale scores. This might be due to the fact that our study sample comprised a large number of patients with advanced disease.

In a study validating the MRC scale for use in Brazil,⁽²¹⁾ the results showed a weak correlation between MRC scale scores and the 6MWD ($r = -0.33$). The MRC scale is an instrument that assesses the limitations imposed by dyspnea,⁽²⁹⁾ being therefore less sensitive in identifying fatigue than is the FSS.

Our results confirm that fatigue is a common symptom in patients with COPD, affecting 60% of the study sample. There were no differences between the groups of patients with and without fatigue regarding age, gender, body mass index, or SpO_2 . Most of those with fatigue had advanced COPD (GOLD stages III and IV) and a higher

degree of dyspnea, as well as having shown more severely impaired lung function and lower 6MWD (Table 3). The median FSS score in the present study was 5.33, being higher than those found by other authors using the FSS in patients with COPD (median score, 3.91)⁽²⁷⁾ and in patients with Parkinson's disease (median score, 4.6).⁽¹¹⁾ The fact that the FSS score was highest in our study can be explained by the presence of a high number of patients with advanced disease.

Our sample size was larger than was that in another study validating the FSS,⁽¹³⁾ as well as being larger than was that in studies validating other scales or questionnaires, such as the Saint George's Respiratory Questionnaire,⁽²⁹⁾ the MRC scale, and the Pulmonary Functional Status and Dyspnea Questionnaire - Modified version.⁽²¹⁾ This demonstrates the reliability and external validity of the FSS.

The FSS is a simple instrument that is useful for the assessment of fatigue, which is a very common symptom in patients with COPD. More specifically, the FSS can contribute to the evaluation of the effectiveness of a clinical (physical and pharmacological) intervention for COPD patients with fatigue. In addition, the identification of an association between fatigue and the main clinical and functional features of patients with COPD, such as the presence of dyspnea and decreased functional exercise capacity, can lead to interventions that are more specific in the rehabilitation process.

The results of the present study showed that the Brazilian Portuguese version of the FSS is reliable for use in patients with COPD in Brazil and correlated strongly with the degree of dyspnea and the 6MWD.

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