



The Brazilian Portuguese-language version of the Manchester Respiratory Activities of Daily Living questionnaire: construct validity, reliability, and measurement error

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Submitted: 10 December 2018.

Accepted: 31 March 2019.

Study carried out at the Universidade Federal de Santa Catarina, Florianópolis (SC) Brasil.

INTRODUCTION

Patient-reported outcomes are status reports of the health of a patient that come directly from the patient, without interpretation of the patient response by a clinician or anyone else.⁽¹⁾ They facilitate communication between patients and health care providers, as well as allowing the assessment of the impact that diseases or treatments have on the lives of patients.⁽²⁾ Patient-reported outcome measures (PROMs) are recognized assessment tools in patients with COPD. The evaluation of physical functioning by PROMs enables us to understand the impact of COPD on activities of daily living (ADLs) from the patient perspective.⁽³⁾ With the progression of the disease, patients experience limitations in activities

they choose to engage in on a day-to-day basis,⁽⁴⁾ which may lead to social isolation and increased dependency on caregivers.⁽⁵⁾ Therefore, measuring limitations in ADLs is important to the monitoring of disease progression, the planning of appropriate interventions, and the evaluation of treatment responses.⁽⁶⁾

The Manchester Respiratory Activities of Daily Living questionnaire (MRADL) is one of the physical disability PROMs for assessing ADL limitations in patients with COPD.⁽⁶⁻⁹⁾ The MRADL is a disease-specific assessment tool that is valid, reliable, and responsive to pulmonary rehabilitation,⁽¹⁰⁾ as well as being a predictor of premature death in patients with COPD.^(11,12) Although the MRADL has been translated into Portuguese and cross-culturally

ABSTRACT

Objective: To test the construct validity, reliability, and measurement error of the Brazilian Portuguese-language version of the Manchester Respiratory Activities of Daily Living (MRADL) questionnaire in patients with COPD. **Methods:** We evaluated 50 patients with COPD, among whom 30 were men, the mean age was 64 ± 8 years, and the median FEV₁ as a percentage of the predicted value (FEV₁%predicted) was 38.4% (interquartile range, 29.1-57.4%). Pulmonary function and limitations in activities of daily living (ADLs) were assessed by spirometry and by face-to-face application of the MRADL, respectively. For the construct validity analysis, we tested the hypothesis that the total MRADL score would show moderate correlations with spirometric parameters. We analyzed inter-rater reliability, test-retest reliability, inter-rater measurement error, and test-retest measurement error. **Results:** The total MRADL score showed moderate correlations with the FEV₁/FVC ratio, FEV₁ in liters, FEV₁%predicted, and FVC%predicted, all of the correlations being statistically significant ($r = 0.34$, $r = 0.31$, $r = 0.42$, and $r = 0.38$, respectively; $p < 0.05$ for all). For the reliability and measurement error of the total MRADL score, we obtained the following inter-rater and test-retest values, respectively: two-way mixed-effects model intraclass correlation coefficient for single measures, 0.92 (95% CI: 0.87-0.96) and 0.89 (95% CI: 0.81-0.93); agreement standard error of measurement, 1.03 and 0.97; smallest detectable change at the individual level, 2.86 and 2.69; smallest detectable change at the group level, 0.40 and 0.38; and limits of agreement, -2.24 to 1.96 and -2.65 to 2.69. **Conclusions:** In patients with COPD in Brazil, this version of the MRADL shows satisfactory construct validity, satisfactory inter-rater/test-retest reliability, and indeterminate inter-rater/test-retest measurement error.

Keywords: Pulmonary disease, chronic obstructive; Activities of daily living; Disability evaluation; Patient reported outcome measures; Validation studies.

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Financial support: Fernanda Rodrigues Fonseca and Alexânia de Rê are the recipients of a doctoral grant and a master's grant, respectively, from the Brazilian Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES, Office for the Advancement of Higher Education).

adapted for use in the COPD population of Brazil,⁽¹³⁾ it has yet to be validated in that population. The objective of this study was to determine the construct validity, reliability, and measurement error of the Brazilian Portuguese-language version of the MRADL in patients with COPD. We hypothesized that the total MRADL score would (in the construct validity analysis) show moderate positive correlations with five spirometric parameters: the FEV₁/FVC ratio, FEV₁ in liters, FEV₁ as a percentage of the predicted value (FEV₁%predicted), FVC in liters, and FVC%predicted.

METHODS

Patient selection

Patients with a confirmed diagnosis of COPD who were referred to a public outpatient clinic specializing in COPD were considered eligible for inclusion in the study. The inclusion criteria were as follows: moderate (grade 2), severe (grade 3), or very severe (grade 4) airflow limitation and optimized medication in accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria⁽¹⁴⁾; being ≥ 40 years of age; and being a current or former smoker. Patients who had ADL limitations caused by other respiratory diseases, cardiovascular diseases, neurological disorders, musculoskeletal disorders, rheumatic diseases, or other conditions were excluded, as were those who were currently participating in a pulmonary rehabilitation program or had participated in one in the last 6 months prior to the study, those with a Mini-Mental State Examination score indicative of impaired cognition (< 24 or < 19 for literate and illiterate subjects, respectively),⁽¹⁵⁾ and those who reported a COPD exacerbation or a change in ADL limitations in the month prior to the study or during data collection. The study was approved by the Human Research Ethics Committee of the Federal University of Santa Catarina (CAAE no. 33299214.8.0000.0121). All participating patients gave written informed consent.

Study design

We carried out pulmonary function testing in accordance with the American Thoracic Society and European Respiratory Society spirometry standards,⁽¹⁶⁾ using a portable spirometer (EasyOne; ndd Medical Technologies, Inc., Zurich, Switzerland). We obtained postbronchodilator measures of the FEV₁/FVC ratio, FEV₁ in liters, and FVC in liters, using the equations devised by Pereira et al.⁽¹⁷⁾ to determine the percentages of the predicted values. The severity of airflow limitation was classified, in accordance with the FEV₁%predicted, as GOLD grade 2 ($50\% \leq \text{FEV}_1 < 80\%$), GOLD grade 3 ($30\% \leq \text{FEV}_1 < 50\%$), or GOLD grade 4 ($\text{FEV}_1 < 30\%$), assuming an FEV₁/FVC ratio < 0.7 .⁽¹⁴⁾

The MRADL was used in order to assess ADL limitations. It consists of 21 items, in four domains—mobility (7

items), kitchen activities (4 items), domestic tasks (6 items), and leisure activities (4 items). The total MRADL score ranges from 0 to 21, and a maximum score indicates no physical impairment.^(10,13) Two raters (designated raters 1 and 2) each read the MRADL instructions and items to the patients with an interval of approximately 10 min between the two administrations. Rater 1 administered the MRADL to the same patients again after an interval of 1-2 weeks.⁽¹⁸⁾ All three administrations were carried out independently in an outpatient setting.

Statistical analysis

Data normality was analyzed by the Shapiro-Wilk test. For correlation analysis between MRADL scores and spirometric variables, Spearman's correlation coefficient (r) was used. On the basis of evidence in the literature, we expected the total MRADL score to show moderate⁽¹⁹⁾ positive correlations with the FEV₁/FVC ratio, FEV₁ in liters, FEV₁%predicted, FVC in liters, and FVC%predicted. To compare the MRADL scores between the raters and between the test and retest, the Wilcoxon test was used. Inter-rater and test-retest reliability of the MRADL scores were analyzed by calculating the two-way mixed-effects model intraclass correlation coefficient for single measures—ICC(3,1)—and the corresponding 95% confidence interval. For analysis of the inter-rater and test-retest measurement errors, we calculated the agreement standard error of measurement ($\text{SEM}_{\text{agreement}}$); the smallest detectable change at the individual and group levels ($\text{SDC}_{\text{individual}}$ and $\text{SDC}_{\text{group}}$, respectively); and the limits of agreement (LoA). To visualize the total score and agreement between the MRADL measurements, Bland-Altman plots were used.⁽²⁰⁾ Values of $p < 0.05$ were considered statistically significant.

RESULTS

We evaluated 50 patients with COPD, 30 of whom were men. All eligible patients were included in the study (i.e., none were excluded). The severity of airflow limitation was stratified by the GOLD criteria: grade 2, in 15 patients (30.0%); grade 3, in 22 (44.0%); and grade 4, in 13 (26.0%).⁽¹⁴⁾ The general characteristics of the sample are presented in Table 1.

All of the patients completed all of the items on the MRADL. As shown in Figure 1, the total MRADL score correlated moderately with four of the five spirometric variables evaluated. Some of the MRADL domain scores also showed moderate correlations with spirometric variables: the kitchen activities domain score correlated with the FEV₁/FVC ratio ($r = 0.45$; $p < 0.01$), FEV₁ in liters ($r = 0.38$; $p < 0.05$), FEV₁%predicted ($r = 0.43$; $p < 0.01$), and FVC%predicted ($r = 0.29$; $p < 0.05$); the domestic tasks domain score correlated with the FEV₁/FVC ratio ($r = 0.41$; $p < 0.01$), FEV₁ in

Table 1. General characteristics of the sample.

Characteristic	(N = 50)
Age (years), mean \pm SD (95% CI)	64 \pm 8 (62-66)
BMI (kg/m ²), mean \pm SD (95% CI)	24.6 \pm 5.0 (23.2-26.1)
Smoking history (pack-years), median (IQR)	48 (32-80)
FEV ₁ /FVC ratio, median (IQR)	0.46 (0.38-0.56)
FEV ₁ (L), median (IQR)	1.07 (0.79-1.43)
FEV ₁ (% predicted), median (IQR)	38.4 (29.1-57.4)
FVC (L), median (IQR)	2.26 (1.96-2.90)
FVC (% predicted), median (IQR)	64.8 (56.3-72.9)

BMI: body mass index; and IQR: interquartile range.

liters ($r = 0.30$; $p < 0.05$), FEV₁%predicted ($r = 0.45$; $p < 0.01$), and FVC%predicted ($r = 0.38$; $p < 0.05$); and the leisure activities domain score correlated with FEV₁ in liters ($r = 0.30$; $p < 0.05$), FEV₁%predicted ($r = 0.31$; $p < 0.05$), and FVC%predicted ($r = 0.29$; $p < 0.05$). All of the MRADL scores are shown in Table 2, as are the inter-rater and test-retest values for ICC(3,1), SEM_{agreement}, SDC_{individual}, and SDC_{group}. As can be seen in Table 2, no inter-rater or test-retest differences were observed for the MRADL scores ($p > 0.05$ for all). The inter-rater and test-retest LoA for the total MRADL score are plotted in Figure 2. The respective inter-rater and test-retest LoA values for the MRADL domain scores were as follows: for the mobility domain score, -1.19 to 1.03 and -1.32 to 1.36 ; for the kitchen activities domain score, -1.00 to 1.08 and -1.24 to 1.20 ; for the domestic tasks domain score, -0.92 to 0.84 and -0.91 to 1.19 ; and for the leisure activities domain score, -1.21 to 1.09 and -1.41 to 1.17 .

DISCUSSION

In this study, we assessed the Brazilian Portuguese-language version of the MRADL, evaluating its construct validity, reliability, and measurement error using repeated measurements. To our knowledge, this is the first study to describe the measurement properties of this version of the MRADL.

As expected, moderate correlations were observed between the total MRADL score and spirometric variables, four of our five hypotheses being accepted. Therefore, we rated the construct validity of the instrument for use in patients with COPD in Brazil as satisfactory according to the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN),⁽²¹⁾ considering the relationship its total score showed with the FEV₁/FVC ratio, FEV₁ in liters, FEV₁%predicted, and FVC%predicted. In addition, the MRADL scores for the kitchen activities, domestic tasks, and leisure activities domains also correlated with most of the spirometric variables. In other validation studies, similar correlations have been observed between the ADL limitation and lung function constructs: the total COPD Activity Rating

Scale score has been shown to correlate positively with the FEV₁ in liters, FEV₁%predicted, and FVC in liters⁽²²⁾; the total London Chest Activity of Daily Living scale score has been shown to correlate negatively with the FVC in liters⁽²³⁾; and the total Functional Performance Inventory score has been shown to correlate positively with the FEV₁%predicted.⁽²⁴⁾

The study evaluating the measurement properties of the original MRADL demonstrated that its total score is accurate in discriminating patients with an FEV₁%predicted $< 60\%$ from healthy controls (without lung diseases or respiratory symptoms).⁽¹⁰⁾ The authors of that study found that the FEV₁/FVC ratio was one of the predictors of the total MRADL score, explaining 2% of its variance.⁽¹⁰⁾ Determining the FEV₁/FVC ratio is fundamental to establishing a diagnosis of COPD, whereas determining the FEV₁ is a necessary part of assessing the severity of airflow limitation.⁽¹⁴⁾ Lung function should be considered a primary endpoint in clinical research on the efficacy of medications for the treatment of COPD.⁽²⁵⁾ In the absence of other widely accepted, validated clinical markers, spirometric variables have been used as global markers of pathophysiological changes in COPD,⁽²⁶⁾ underscoring the relevance of the relationship between lung function and ADL limitation.

In the present study, we determined the ICC(3,1), SEM_{agreement}, SDC_{individual}, SDC_{group}, and LoA values for the use of the MRADL in patients with COPD in Brazil. The inter-rater and test-retest reliabilities of the MRADL (total and domain scores) were rated against the COSMIN criteria⁽²¹⁾ and were found to be satisfactory, because the ICC(3,1) values were higher than 0.7 for all of the domain scores, except the test-retest ICC(3,1) for the kitchen activities domain score, which was exactly 0.70. However, the inter-rater and test-retest measurement errors of the MRADL scores would be rated as indeterminate in accordance with the COSMIN guideline for systematic reviews of PROMs,⁽²¹⁾ given that the minimal important change value does not yet exist for the classification of SDC and LoA values. In another study, the observed inter-rater and test-retest ICC values (0.92 for both) were shown to be similar to the test-retest value for the total score on the MRADL administered by post, whereas the

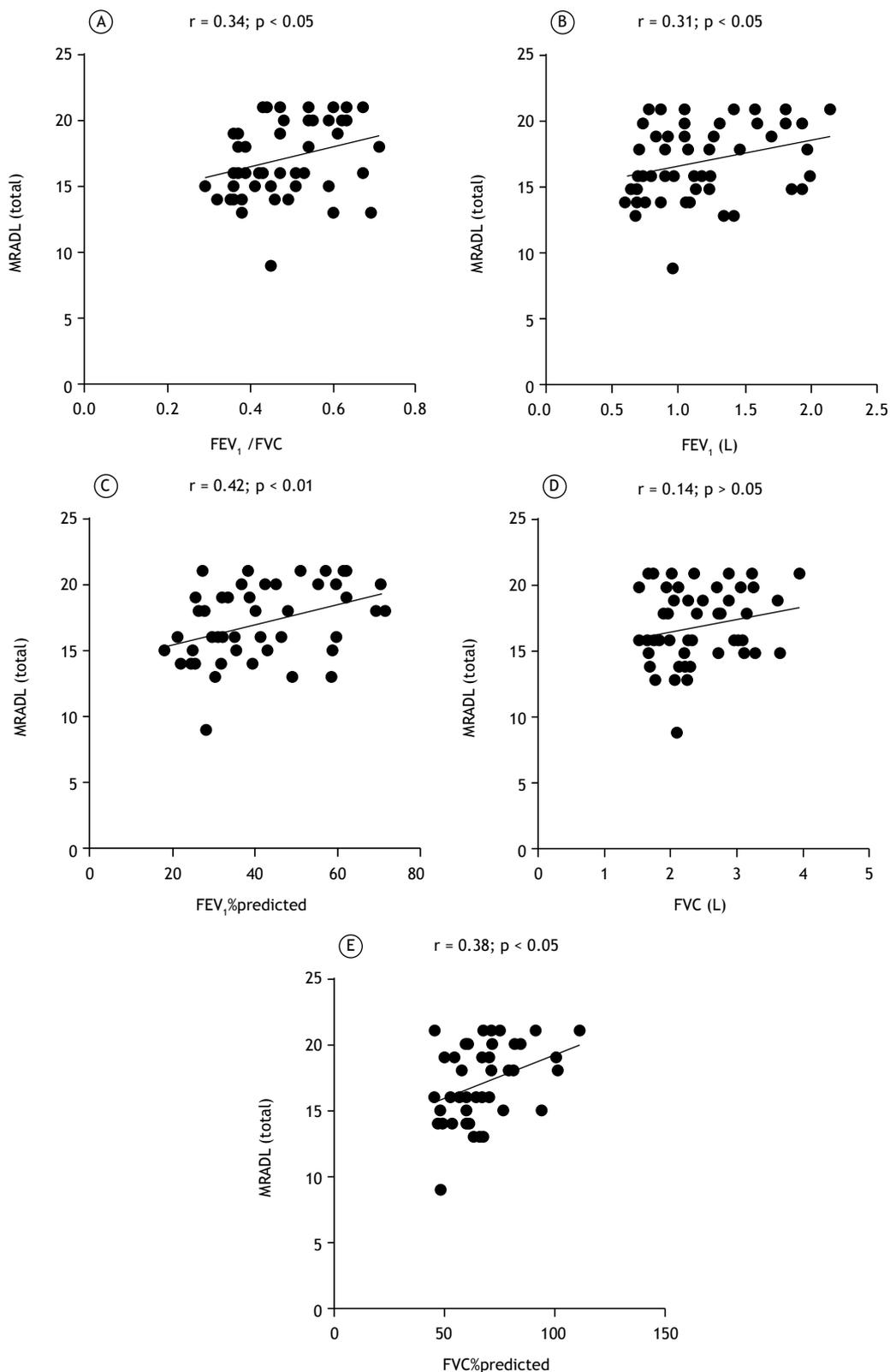


Figure 1. Correlations of the total score on the Manchester Respiratory Activities of Daily Living questionnaire (MRADL) with the FEV_1/FVC ratio (in A); FEV_1 in liters (in B); FEV_1 as a percentage of the predicted value ($FEV_1\%$ predicted, in C); FVC in liters (in D); and $FVC\%$ predicted (in E).

Table 2. Scores, reliability, and measurement error of the Brazilian Portuguese-language version of the Manchester Respiratory Activities of Daily Living questionnaire.

MRADL domain	Rater 1 ^a		Rater 2		ICC(3,1)		SEM _{agreement}		SDC		Score Rater 1 ^b		ICC(3,1)		SEM _{agreement}		SDC	
	Median (IQR)	Median (IQR)*	Median (IQR)	Median (IQR)*	Value (95% CI)	Value (95% CI)	Individual	Group	Individual	Group	Median	Group	Value (95% CI)	Value (95% CI)	Individual	Group		
Total	16 (15-20)	17 (15-20)	7 (6-7)	4 (3-4)	0.92 (0.87-0.96)	0.80 (0.67-0.88)	1.03	0.40	2.86	0.40	17 (15-20)	0.40	0.89 (0.81-0.93)	0.97	2.69	0.38		
Mobility	7 (6-7)	7 (6-7)	4 (3-4)	5 (3-5)	0.80 (0.67-0.88)	0.76 (0.61-0.86)	0.57	0.22	1.57	0.22	7 (6-7)	0.22	0.75 (0.59-0.85)	0.49	1.37	0.19		
Kitchen activities	4 (3-4)	4 (3-4)	3 (2-4)	3 (2-4)	0.76 (0.61-0.86)	0.95 (0.91-0.97)	0.43	0.17	1.18	0.17	4 (3-4)	0.17	0.70 (0.53-0.82)	0.45	1.25	0.18		
Domestic tasks	4 (3-6)	4 (3-6)	3 (2-4)	3 (2-4)	0.95 (0.91-0.97)	0.80 (0.67-0.88)	0.38	0.15	1.04	0.15	4 (3-6)	0.15	0.93 (0.88-0.96)	0.80	2.21	0.31		
Leisure activities	3 (2-4)	3 (2-4)	3 (2-4)	3 (2-4)	0.80 (0.67-0.88)	0.80 (0.67-0.88)	0.51	0.20	1.42	0.20	3 (3-4)	0.20	0.73 (0.57-0.84)	0.76	2.11	0.30		

MRADL: Manchester Respiratory Activities of Daily Living questionnaire; ICC(3,1): two-way mixed-effects model intraclass correlation coefficient for single measures; SEM_{agreement}: agreement standard error of measurement; and SDC: smallest detectable change. Test. ^aRetest. *p > 0.05 vs. rater 1 (test, not retest) for all domain scores and for the total score.

SEM and LoA values were shown to be lower (1.55) and higher (-0.69 to 0.54), respectively.⁽²⁷⁾ However, the authors of that study used different parameters of reliability and measurement error (the one-way random effects model ICC and consistency SEM).⁽²⁷⁾

In a previous systematic review,⁽⁶⁾ the lack of detailed information about the measurement properties of tools designed to assess ADL limitations in patients with COPD was one of the main problems identified. A few studies have been conducted to determine the measurement properties of disease-specific PROMs for ADL limitations in patients with COPD in Brazil.^(28,29)

Our study has some limitations. First, the construct validity analysis was limited to the hypothesis of a relationship between ADL limitations and lung function. Our results support that hypothesis, except for the fact that we identified no significant correlation between the total MRADL score and FVC in liters. It is known that the FVC may not be discriminative; in patients with obstructive lung disease, it is usually reduced to a lesser degree or even normal. It is also known that the FVC value in liters may be nonspecific, because it is not corrected for age, height, gender, or ethnicity (i.e., by a reference equation). In addition, the absence of a correlation between the total MRADL score and FVC in liters could also be due to a type II error, despite the fact that our sample size was within the limits of what is considered satisfactory.⁽³⁰⁾ Additional studies could test other hypotheses related to the construct validity of the instrument. Furthermore, the adequacy of the MRADL measurement error can only be attested to when studies on interpretability provide its minimal important change value. Nevertheless, the present study is unprecedented in that it details the measurement properties of the Brazilian Portuguese-language version of the MRADL.

In conclusion, the Brazilian Portuguese-language version of the MRADL has sufficient construct validity for use in patients with COPD in Brazil, given that our findings support our hypotheses about the specific relationship between ADL limitations and lung function. In addition, this version of the MRADL is sufficiently reliable; that is, it is able to distinguish ADL limitation between patients with COPD, even when applied by different raters on the same occasion and when applied twice within a short period of time. Furthermore, the present study provides inter-rater and test-retest measurement error parameters, which refer to the systematic and random error of the scores of patients with COPD that is not attributed to true changes in ADL limitations, for this version of the MRADL. To date, the measurement error of the MRADL for Brazilians with COPD is considered indeterminate. Further studies should be conducted to evaluate other measurement properties of the instrument in this population.

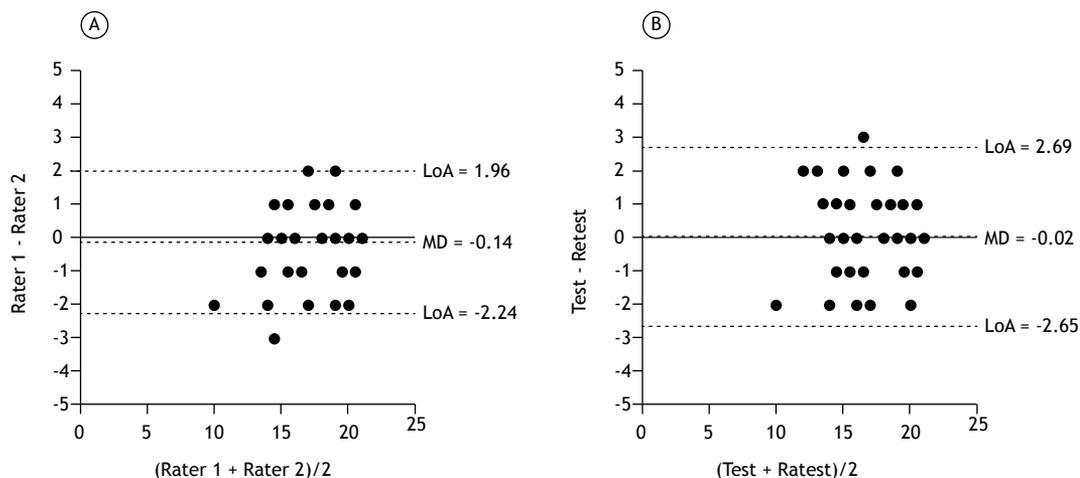


Figure 2. Bland Altman plots of the total score on the Manchester Respiratory Activities of Daily Living questionnaire, showing the inter-rater reliability (A) and test-retest reliability (B). LoA: limit of agreement; and MD: mean difference.

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