

Original Article

Applicability of the 12-Item Short-Form Health Survey in patients with progressive systemic sclerosis*

Thamine Lessa Andrade¹, Aquiles Assunção Camelier², Fernanda Warken Rosa³,
Marcia Pina Santos⁴, Sérgio Jezler⁵, Jorge Luiz Pereira e Silva⁶

Abstract

Objective: To evaluate the applicability of the 12-Item Short-Form Health Survey (SF-12) as an instrument to measure health-related quality of life in a sample of patients with progressive systemic sclerosis (PSS) through the analysis of its reproducibility and its correlation with functional and clinical parameters. **Methods:** A test-retest reproducibility study for the comparative analysis of the intraclass correlation coefficients (ICCs) of the SF-12 and the SF-36. A total of 46 patients diagnosed with PSS were studied, regardless of the presence of respiratory symptoms. **Results:** The physical component summary 12 (PCS-12) score had an ICC of 0.47 (95%CI: 0.05-0.71; $p < 0.02$), whereas the mental component summary (MCS-12) score had an ICC of 0.72 (95%CI: 0.49-0.84; $p < 0.001$). The PCS-36 score had an ICC of 0.88 (95%CI: 0.78-0.93; $p < 0.001$), and the MCS-36 score also had an ICC of 0.88 (95%CI: 0.78-0.93; $p < 0.001$). **Conclusion:** The SF-12 is a reliable instrument for measuring health-related quality of life in patients with PSS, since it has been proven to be reproducible. However, this version of the SF-12 should only be used in clinical research settings.

Keywords: Quality of life; Questionnaires; Statistics; Scleroderma, systemic.

* Study carried out at the *Centro de Enfermidades Respiratórias* – CER, Respiratory Disease Center – *Universidade Federal da Bahia* – UFBA, Federal University of Bahia – Salvador (BA) Brazil.

1. Masters student in Internal Medicine at the *Universidade Federal da Bahia* – UFBA, Federal University of Bahia – Salvador (BA) Brazil.
2. PhD in Medicine from the *Universidade Federal de São Paulo* – UNIFESP, Federal University of São Paulo – São Paulo (SP) Brazil.
3. PhD student in Rehabilitation at the *Universidade Federal de São Paulo* – UNIFESP, Federal University of São Paulo – São Paulo (SP) Brazil.
4. Physical Therapy student at the *Universidade Católica do Salvador* – UCSAL, Catholic University of Salvador – Salvador (BA) Brazil.
5. Masters in Internal Medicine from the *Universidade Federal da Bahia* – UFBA, Federal University of Bahia – Salvador (BA) Brazil.
6. PhD in Internal Medicine-Pulmonology from the *Universidade Federal da Bahia* – UFBA, Federal University of Bahia – Salvador (BA) Brazil.
Correspondence to: Thamine Lessa Espírito Santo Andrade. Alameda Catânia, 181, apto. 702, Pituba, CEP 41830-490, Salvador, BA, Brasil.
Tel 55 71 3358-4025. Fax 55 71 3452-1304. E-mail: lessath@uol.com.br/aquilescamelier@yahoo.com.br
Submitted: 24 February 2006. Accepted, after review: 23 October 2006.

Introduction

Progressive systemic sclerosis (PSS) is a chronic autoimmune disease that is characterized by excessive production of collagen, endothelial cell damage, and microvascular obliteration, and usually leads to progressive cutaneous-mucosal fibrosis and visceral involvement.⁽¹⁾ Pulmonary involvement is common and results in high rates of morbidity and mortality. Interstitial lung disease (ILD) is the most common presentation, being functionally characterized by restrictive ventilatory disorder and decreased diffusing capacity of the lung for carbon monoxide (DLCO).⁽²⁾ The most common symptom of ILD is dyspnea, which contributes, among other factors, to reducing the sense of well-being.

There are few clinical conditions that cause, over a short period of time, changes in physical appearance, in the psychological sphere, and in the functional profile that are as significant as those typically caused by PSS. All of these changes result in a high degree of social inadequacy and significant impairment of the quality of life.⁽³⁾

It is known that clinical, radiological, and functional data might not express with precision the real impact of the disease on the activities of daily living of the individual.⁽⁴⁾ The evaluation of health-related quality of life through standardized questionnaires aims at codifying subjective patient perception with objective data, thereby facilitating the analysis of this outcome measure in a quantitative research environment.^(5,6)

The components of a questionnaire should be clear, simply framed, easy to apply and understand, and have appropriate administration time.⁽⁷⁾ In addition, such components need to be adapted and validated according to the cultural and linguistic characteristics of the population to be studied, these characteristics being different from those from which they originated.⁽⁸⁾ In this scenario, the 12-Item Short-Form Health Survey (SF-12) – a more concise version of the SF-36, comprising only 12 items, whose administration time ranges from 1 to 2 min – was created.⁽⁹⁾ Although the SF-12 has already been adapted for use in Brazil, it has only been administered to patients with chronic obstructive pulmonary disease (COPD).⁽¹⁰⁾

The objective of the present study was to evaluate the applicability of the SF-12 as an instrument to measure health-related quality of life in a sample

of patients with PSS, regardless of the presence of respiratory symptoms, through the analysis of its reproducibility and its correlation with functional and clinical respiratory parameters.

Methods

This was a cross-sectional study of a convenience sample comprising forty-six consecutive patients monitored between March and December of 2004 at the Federal University of Bahia Professor Edgard Santos University Hospital Outpatient Clinic for Interstitial Diseases, to which they had been referred, according to a pre-established evaluation protocol, regardless of the presence of respiratory symptoms. The diagnosis of PSS (limited and diffuse forms) was confirmed in all forty-six patients.

Individuals with environmental or occupational exposure, both recognized as potential causes of diffuse lung diseases; those with worsening of PSS-related symptoms within the past thirty days; patients with PSS accompanied by another connective tissue disease; and those with uncompensated chronic comorbidities were excluded from the study. Patients who were unable to walk on a flat surface, as well as those with presumed difficulties in reading and comprehending questionnaires, were also excluded. The study design was approved by the Ethics in Research Committee of the institution, and all participants gave written informed consent.

Patients were evaluated in two consecutive visits, with a fifteen-day interval between the two, in order to determine clinical stability, which was defined as no worsening, no new clinical symptoms, and no changes in the current treatment.

The first visit involved administering the SF-12 and the SF-36 as well as registering demographic data and clinical variables using a standardized questionnaire, in addition to determining the degree of dyspnea using the 1984 Mahler scale.⁽¹¹⁾ In that same visit, spirometry and measurement of pulmonary volumes and DLCO were performed using a Vmax 22 device (Sensor Medics Corporation, Yorba Linda, CA, USA), in accordance with the guidelines established in 2002 by the Brazilian Thoracic Society.⁽¹²⁾

The second visit included evaluating exercise capacity using the 6-minute walk test, which was performed in accordance with the norms estab-

lished by the American Thoracic Society,⁽¹³⁾ as well as second administrations of the SF-12 and SF-36.

The presence of pulmonary involvement, defined as ILD, was evaluated using the high-resolution computed tomography (HRCT) database. All patients had undergone HRCT, with a maximum interval of eighteen months between the date of the examination and the initiation of the evaluation.

The statistical analysis consisted of descriptive data analysis and distribution analysis, according to the Kolmogorov-Smirnov test, in order to justify the use of parametric tests. The Student's t-test was used to compare the means, and Pearson's correlation coefficient was used to determine the strength of the correlations among the variables. Reproducibility was evaluated according to the intraclass correlation coefficient (ICC). The continuous variables were expressed as mean, standard deviation (SD), and 95% confidence interval. A value of $p < 0.05$ was considered statistically significant.

Results

Descriptive data

Of the sixty-three patients diagnosed with PSS and regularly monitored at the Professor Edgard Santos University Hospital Outpatient Clinic for Interstitial Diseases, forty-six consecutive patients were included in the study, based on the order of the appointments, regardless of the presence of respiratory symptoms. Three patients (6.5% of the initial sample) did not return for the second visit and therefore did not complete the study protocol. Of those, one patient, who lived outside of the city, refused to return, citing transportation difficulties. The other two patients were significantly debilitated and were unable to leave home. Of the patients studied, forty-one (89.1%) were female, and five (10.9%) were male. Ages ranged from 16 to 71 years, with a mean of 43.2 ± 13.9 years. The duration of the disease ranged from 1 to 30 years, with a mean of 7.2 ± 6.5 years. The body mass index (BMI) ranged from 15 to 38 kg/m², with a mean of 24 ± 5.3 kg/m². With regard to the pattern of cutaneous involvement, the diffuse form was more frequent, occurring in 65.2% of the cases, whereas the limited form occurred in 34.8%. When the relationship between the pattern of cutaneous involvement and the presence of pulmonary involve-

ment was evaluated, the frequency of ILD was similar (50% of the cases in each group). Dyspnea was reported by thirty-one patients (67.4%). When evaluated using the Mahler baseline dyspnea index (BDI),⁽¹¹⁾ the mean score was 7.41.

The results of the pulmonary function tests are shown in Table 1. There was a patient who was not able to perform any pulmonary function tests due to severe dyspnea. Eight patients (17.4%) did not complete the measurement of pulmonary volumes due to difficulties in properly carrying out the maneuvers. Spirometry results were considered normal in seven patients (15.6%). Restrictive ventilatory disorder was confirmed in twenty-eight patients (62.2%), and obstructive respiratory disorder was confirmed in ten (22.2%). Of the patients with obstructive respiratory disorder, five (50%) were smokers or former smokers.

Forty-one patients (89%) completed the 6-minute walk test. The mean distance covered was 454 ± 115.4 m. There were two patients who did not perform the test since they were incapable of walking freely due to the presence of plantar warts. As previously mentioned, the three remaining patients did not return for the second visit.

No difficulties in completing the two quality-of-life questionnaires were reported. No questions were left unanswered. The results of the physical component summary 12 (PCS-12) and mental component summary (MCS-12) scores and of the

Table 1 - Pulmonary function parameters of the 46 patients with progressive systemic sclerosis expressed in absolute values or in percentages of predicted.

Parameters	Mean	SD	Range
FVC (L)	2.3	0.6	0.9-3.6
FVC (%)	74.9	19.1	31-121
FEV ₁ (L)	1.8	0.4	0.9-2.6
FEV ₁ (%)	70.8	16.2	33-117
FEV ₁ /FVC (%)	82.5	9.0	60-109
TLC (L)	3.4	1.1	1.6-6.4
TLC (%)	72.1	20.1	39-110
Residual volume (%)	77.2	27.8	22-126
DLCO (mL/min/mmHg)	13.4	4.5	4.20-25.4
DLCO (%)	54.4	18.5	18-90
DLCO/AV	71.5	17.5	30-106

SD: standard deviation; FVC: forced vital capacity; FEV₁: forced expiratory volume in one second; TLC: total lung capacity; DLCO: diffusing capacity of the lung for carbon monoxide; and DLCO/AV: ratio of DLCO to alveolar ventilation.

physical component summary 36 (PCS-36) and mental component summary 36 (MCS-36) scores, as well as those of the eight SF-36 domains, are shown in Table 2. There was no statistically significant difference between the two visits in terms of the means of the quality-of-life scores.

Reproducibility

The PCS-12 had an ICC of 0.47 (95% CI: 0.05-0.71; $p < 0.02$), whereas the MCS-12 had an ICC of 0.72 (95% CI: 0.49-0.84; $p < 0.001$). The PCS-36 had an ICC of 0.88 (95% CI: 0.78-0.93; $p < 0.001$), and the MCS-36 also had an ICC of 0.88 (95% CI: 0.78-0.93; $p < 0.001$).

Construct validity

The construct validity was evaluated by determining how the PCS-12 and the MCS-12 correlated with each of the eight SF-36 domains, as well as with the PCS-36 and MCS-36 scores, using Pearson's correlation coefficient. The PCS-12 correlated significantly with the PCS-36 ($r = 0.59$; $p < 0.001$); the MCS-36 ($r = 0.45$; $p < 0.01$); physical capacity ($r = 0.62$; $p < 0.01$); pain ($r = 0.46$, $p < 0.01$); vitality ($r = 0.59$; $p < 0.001$); and social aspects ($r = 0.56$; $p < 0.001$). The MCS-12 was significantly correlated with the PCS-36 ($r = 0.45$; $p < 0.01$); the MCS-36

($r = 0.60$; $p < 0.001$); pain ($r = 0.43$; $p < 0.01$); vitality ($r = 0.46$; $p < 0.01$); general aspects of health ($r = 0.43$; $p < 0.01$); social aspects ($r = 0.40$; $p < 0.01$); emotional aspects ($r = 0.43$; $p < 0.01$); and mental health ($r = 0.66$; $p < 0.001$). The other correlations were not significant (data not shown).

Internal consistency

The internal consistency and the homogeneity of the SF-12 were evaluated by determining how each question on the SF-12 correlated with the PCS-12 and MCS-12 scores using Pearson's correlation coefficient. The results are shown in Table 3.

Discriminatory power

The patient sample was divided into two subgroups, according to several variables clinically relevant to PSS, and different cut-off points were adopted. The variables studied for the evaluation of the discriminatory power were as follows: gender; BMI; pattern of cutaneous involvement; pulmonary involvement (ILD or non-ILD); dyspnea; BDI; pulmonary function; and distance covered on the 6-minute walk test. The two subgroups were then compared in terms of the mean PCS-12 and MCS-12 scores for each variable.

Table 2 - Scores of the physical and mental domains of the 12-Item and the 36-Item Short-Form Health Survey and scores of the other domains of the 36-Item Short-Form Health Survey in the two visits.

Domain	V1	V2	V1-V2 mean difference	p ^a
	Mean \pm SD			
PCS-12	37.3 \pm 9.0	38.1 \pm 8.9	-0.7 \pm 10.6	NS
MCS-12	41.1 \pm 10.8	42.8 \pm 11.3	-1.8 \pm 10.4	NS
PCS-36	38.3 \pm 18.9	37.4 \pm 16.9	-0.1 \pm 4.5	NS
MCS-36	46.4 \pm 20.3	44.3 \pm 19.7	-0.8 \pm 7.0	NS
Physical capacity	37.1 \pm 23.8	39.4 \pm 24.2	1.5 \pm 11.8	NS
Physical aspect	25.5 \pm 45.4	16.2 \pm 34.0	5.8 \pm 20.2	NS
Pain	45.0 \pm 22.1	45.9 \pm 19.9	-2.3 \pm 19.1	NS
General health aspects	43.1 \pm 20.4	42.9 \pm 20.7	0.09 \pm 14.2	NS
Vitality	40.8 \pm 20.4	43.0 \pm 19.8	-1.7 \pm 13.0	NS
Social aspects	57.2 \pm 28.6	55.4 \pm 27.8	2.6 \pm 21.6	NS
Emotional aspects	33.3 \pm 40.4	23.2 \pm 38.1	9.3 \pm 34.3	NS
Mental health	57.5 \pm 23.9	56.5 \pm 23.7	-0.9 \pm 14.9	NS

V1: visit 1; V2: visit 2; SD: standard deviation; NS: not significant; PCS-12: physical component summary 12; MCS-12: mental component summary 12; PCS-36: physical component summary 36; and MCS-36: mental component summary 36. ^ap = V1 vs. V2.

Table 3 - Correlation of the twelve questions on the 12-Item Short-Form Health Survey with the physical component summary 12 and the mental component summary 12.

SF-12	PCS-12	MCS-12
Question 1	0.45 ^a	0.40 ^a
Question 2	0.47 ^a	NS
Question 3	0.61 ^b	NS
Question 4	-0.57 ^b	NS
Question 5	-0.71 ^b	NS
Question 6	NS	-0.63 ^b
Question 7	NS	-0.51 ^b
Question 8	0.61 ^b	NS
Question 9	NS	0.60 ^b
Question 10	0.41 ^a	0.44 ^a
Question 11	NS	0.71 ^b
Question 12	NS	NS

SF-12: 12-Item Short-Form Health Survey; PCS-12: physical component summary 12; MCS-12: mental component summary 12; and NS: not significant. ap < 0.01; bp < 0.001.

For the pulmonary function parameters, forced vital capacity (FVC) and DLCO were used (with cut-off points of 50 and 40% of predicted, respectively), since both are clinically relevant markers.⁽¹²⁾ Since there are no clinically significant cut-off points for the 6-minute walk test or for BDI in PSS, the median was adopted for identifying subgroups with different exercise capacities and different degrees of dyspnea. The median distance covered (435 m) was used in the evaluation. The same criterion was used for the BDI (median, 8). In addition, since there is no clinically defined cut-off point for BMI in collagenosis, we used the value that identified populations with different mortality rates for COPD⁽¹⁴⁾: BMI equal to 21 kg/m². The other variables, such as gender, pattern of cutaneous involvement, presence of dyspnea, and pulmonary involvement, are dichotomous.

The comparison of the mean PCS-12 scores only revealed statistical significance when they were compared in terms of the presence of dyspnea (presence of dyspnea 34.4 ± 8.1; absence of dyspnea 43.4 ± 7.9; p < 0.001) and BDI (BDI ≤ 8; 34.1 ± 6.9 and BDI > 8; 41.2 ± 9.9; p < 0.009). The differentiation of the PCS-12 regarding gender, BMI, pattern of cutaneous involvement, pulmonary involvement, pulmonary function, and distance covered was not significant, and neither were any

of the mean MCS-12 scores (data not shown). A box plot of the PCS-12 scores in relation to the presence of dyspnea is shown in Figure 1.

Suggestion for sample size calculation

We have built a table to be used as a basis for planning future studies that will use the SF-12 as an outcome measure for the evaluation of quality of life in outpatient clinics for ILDs. In this table, the various sample sizes were obtained by estimating the size of the effect to be detected, considered as the variation in the score for each domain after an intervention (which ranged from 1 to 10 points for each score), taking into account the standard deviation obtained in this study. The suggestions for sample size calculation are described in Table 4.

Discussion

Although PSS is a chronic and severely incapacitating disease, little attention has been given to the objective evaluation of quality of life of individuals with this disease. The SF-12, which has been used worldwide, has only recently been validated for use in Brazil.⁽¹⁰⁾ There are no studies in the literature that have used the SF-12 in individuals with PSS.

The results found in the present study demonstrate that the SF-12 is reproducible, the ICCs of its domains (PCS-12 and MCS-12) having ranged from 0.47 to 0.72, with confidence intervals of

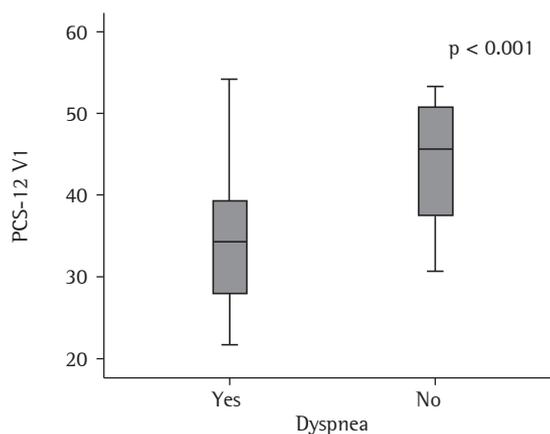


Figure 1 - Box plot of the physical component summary 12 score by the presence or absence of dyspnea in visit 1 (PCS-12 V1).

Table 4 – Suggestion for sample size calculation using two 12-Item Short-Form Health Survey subscales in progressive systemic sclerosis.

Size of the effect (Range of variation in the questionnaire scores)	Sample size necessary to detect the differences suggested by the questionnaire scores			
	SF-12			
	PCS-12 SD = 10.56		MCS-12 SD = 10.42	
	E/SD	n	E/SD	n
1	0.09	1571	0.10	1571
2	0.19	394	0.19	394
3	0.28	176	0.28	176
4	0.37	100	0.38	100
5	0.47	64	0.47	64
6	0.57	45	0.57	45
7	0.66	26	0.67	34
8	0.75	21	0.76	26
9	0.85	17	0.86	21
10	0.94	17	0.96	17

SF-12: 12-Item Short-Form Health Survey; PCS-12: physical component summary 12; MCS-12: mental component summary 12; E: size of the effect; SD: standard deviation of the means of the differences between visits 1 and 2. Values calculated using a two-tailed test with an alpha error of 5%, a power of 80%, and parametric distribution.

0.05 to 0.71 and 0.49 to 0.84, respectively. All of the results were statistically significant, which confirms the SF-12 reproducibility, and, according to the analysis of the confidence intervals, similar to those reported in the literature, evaluated through the superposition of these intervals. However, the SF-12 has a slightly lower tendency toward reproducibility. In a study that evaluated 233 individuals with rheumatoid arthritis, the 95% confidence interval was 0.64 to 0.87 for the ICC of the PCS-12 and 0.60 to 0.83 for the ICC of the MCS-12.⁽¹⁵⁾ In a study of patients with cerebral vascular accident, the ICC of the SF-12 was 0.80 ($p < 0.05$).⁽¹⁶⁾ In the 2004 Proyecto Latinoamericano de Investigación en Obstrucción Pulmonar (Latin American Project for the Investigation of Pulmonary Obstruction),⁽¹⁷⁾ which was carried out in the city of São Paulo and evaluated the SF-12 in a sample of patients with COPD, the ICC of the PCS-12 was found to be 0.69 and the ICC of the MCS-12 was found to be 0.63. All of these ICC values are within the confidence interval for the patients with PSS evaluated in the present study. The SF-36, which, in the present study, was adopted as the gold standard for the SF-12 and had already been used in other studies on PSS, has proven to have good reproducibility, with an ICC that ranged from 0.77 to 0.88.

However, we observed that, on average, the PCS-12 presented lower reproducibility than did the PCS-36, which implies the need that a larger sample should be allocated to the study of this domain in the design phase of future studies (Table 4). The ICCs found for the SF-12 indicate, however, that it should be used only in clinical trials with an appropriate sample design, rather than being administered individually in medical appointments.

Despite the low prevalence of PSS, our sample is derived from the largest Brazilian cohort study and portrays a heterogeneous group of patients with different disease spectra, including with various degrees of pulmonary involvement.⁽¹⁸⁾ The frequency of ILD, evaluated by HRCT, was high (50%). This percentage, however, was lower than that reported in most publications in which HRCT was also used as an evaluation method. These studies reported frequencies that ranged from 39 to 91% of the cases.⁽¹⁹⁾ Differences in these percentages may result from the methodological diversity of the studies, including sample bias, since only patients with respiratory symptoms were selected, which increases the probability of the appearance of this type of complication.⁽²⁰⁾ In addition, we should also consider the clinical, demographic, and immunogenetic differences among the populations. Most of these

studies evaluated, almost exclusively, Caucasian patients. There is evidence that race-related factors can influence the expression of autoantibodies, the clinical form of the disease, the pattern of visceral involvement, and the prognosis.^(21,22)

From a functional point of view, restrictive ventilatory disorder, which is characterized by a decrease in total lung capacity or inferred by a decrease in FVC, is the pattern most commonly described in patients with PSS.⁽²³⁾ In the present series, mild restrictive ventilatory disorder occurred in most patients. This finding might be explained by the methodology of the study, which systematically evaluated the patients, regardless of the presence of respiratory symptoms, thereby increasing the probability of identifying functional alterations early, when the pulmonary disease is still incipient and subclinical.

A decrease in DLCO occurred in most patients, including in those cases with no apparent pulmonary involvement (absence of ILD). A decrease in DLCO can result from interstitial involvement and can also be secondary to pulmonary vascular disease caused by PSS, which could explain this functional abnormality in patients with normal HRCT scans. The evaluation of pulmonary arterial hypertension was not within the scope of this study.

The means found for both questionnaires show a decrease in quality of life in all domains evaluated, with a greater impact on the physical domain. The PCS scores were lower than the MCS scores on both questionnaires. One possible explanation for this finding is that the disease has a greater impact on physical capacity than on mental health, this being the most likely explanation, since it reflects what has been identified in other studies.^(3,24-27) Another possible explanation is that the MCS subscale has less discriminatory power.

There was a significant correlation between the SF-12 and the SF-36, which demonstrates an association between these two instruments. However, the strength of the correlation (the ICC) was lower than that reported in international studies, but similar to that found in a Brazilian sample of patients with COPD.⁽¹⁰⁾ This indicates the need to improve these scales through further studies.

Internal consistency evaluates how each item correlates with the overall score measure of each questionnaire.⁽²⁸⁾ The evaluation of internal consistency of the SF-12 revealed that those questions

that did not have a statistically significant correlation with the PCS-12 had a common denominator in that they addressed emotional and subjective aspects, which are probably more accurately assessed in the mental domain. Another possibility is that the correlation of those questions, although weak, was not identified due to limitations in the sample size, not excluding the possibility of a type II error. With regard to the questions that did not present a statistically significant correlation with the MCS-12, all of them addressed aspects related to physical capacity and pain, which are certainly more accurately assessed in the physical domain.

It is known that there are questionnaires that are even shorter than the SF-12, such as the SF-8.⁽²⁹⁾ This shorter set of questions is formed by choosing those with greater strength of correlation with their main domains. The present study provides theoretical basis for the future development of shorter versions of the SF-12 for use in Brazil.

Several clinical markers, such as dyspnea, exercise capacity, and pulmonary function, correlate with a sense of quality of life in diseases involving the respiratory tract. Most studies show that, when the presence of pulmonary involvement is evaluated, dyspnea correlates better with quality of life than do any other symptoms or clinical markers.⁽³⁰⁾

The analysis of the variables considered in the present study showed that only dyspnea was a significant marker of worsening of quality of life in patients with PSS. Therefore, the adoption of measures aimed at improving the quality of life of such patients should, among other things, prioritize the reduction of the intensity of dyspnea.

The presence of pulmonary involvement, characterized by ILD on HRCT, did not correlate with worse quality of life in our study. The high sensitivity of tomography to identify mild forms of ILD, with few repercussions in the clinical and functional evaluation, can explain this finding. This observation is corroborated by the absence of correlation between the pulmonary function parameters (FVC and DLCO) and the scores on the physical and mental domains of the two questionnaires. The Scleroderma Lung Study⁽²⁷⁾ showed a correlation between decreased FVC and worse quality of life. However, the correlation coefficient described was considered too weak ($r = 0.31$). The population evaluated in that study also differed from that of the present study in that it included patients with a more severe spectrum of

pulmonary involvement, i.e., patients with at least one respiratory symptom, alveolitis, and altered pulmonary function parameters.

The present study was carried out in a tertiary health care facility and therefore may not represent all of the patients with PSS. Future studies should seek to include patients from primary and secondary health care facilities in an attempt to obtain a more representative sample and therefore be able to generalize the results.

We can conclude that the SF-12 is a reliable instrument for measuring health-related quality of life in patients with PSS, since it has been proven to be reproducible. Dyspnea was the principal clinical marker of decreased quality of life. The authors suggest, however, that this version of the SF-12 should only be used in clinical research settings.

References

- Arroliga AC, Podell DN, Matthay RA. Pulmonary manifestations of scleroderma. *J Thoracic Imaging*. 1992;7(2):30-45.
- Minai OA, Dweik RA, Arroliga AC. Manifestations of scleroderma pulmonary disease. *Clin Chest Med*. 1998;19(4):713-31.
- Del Rosso A, Boldrini M, D'Agostino D, Placidi GP, Scarpato A, Pignone A et al. Health-related quality of life in systemic sclerosis as measured by the Short Form 36: relationship with clinical and biologic markers. *Arthritis Rheum*. 2004;51(3):475-81.
- Jones PW, Quirk FH, Baveystock CM. The St. George's Respiratory Questionnaire. *Respir Med*. 1991;85(Suppl B):25-31; discussion 33-7.
- Kaplan RM, Atkins CJ, Timms R. Validity of a quality of well being scale as an outcome measure in chronic obstructive pulmonary disease. *J Chronic Dis*. 1984;37(2):85-95.
- Guyatt GH, Berman LB, Townsend M, Pugsley SO, Chambers LW. A measure of quality of life for clinical trials in chronic lung disease. *Thorax*. 1987;42(10):773-8.
- Bell MJ, Bombardier C, Tugwell P. Measurement of functional status, quality of life and utility in rheumatoid arthritis. *Arthritis Rheum*. 1990;33(4):591-601.
- Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol*. 1993;46(12):1417-32.
- Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: Construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34(3):220-33.
- Camelier A. Avaliação da qualidade de vida relacionada à saúde em pacientes com DPOC: estudo de base populacional com o SF-12 na cidade de São Paulo-SP. [thesis]. São Paulo: Universidade Federal de São Paulo, 2004.
- Mahler DA, Weinberg DH, Wells CK, Feinstein AR. The measurement of dyspnea. Contents, interobserver agreement, and physiologic correlates of two new clinical indexes. *Chest*. 1984;85(6):751-8.
- Sociedade Brasileira de Pneumologia e Tisiologia. Diretrizes para testes de função pulmonar. *J Bras Pneumol*. 2002;28(Supl 3):S1-S238.
- ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS Statement: Guidelines for the Six-Minute Walk Test. *Am J Respir Crit Care Med*. 2002;166(1):111-7.
- Celli BR, Cote CG, Marin JM, Casanova C, Montes de Oca M, Mendez RA et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. *N Engl J Med*. 2004;350(10):1005-11.
- Marx RG, Menezes A, Horovitz L, Jones EC, Warren RF. A comparison of two time intervals for test-retest reliability of health status instruments. *J Clin Epidemiol*. 2003;56(8):730-5.
- Bohannon RW, Maljanian R, Landes M. Test-retest reliability of short form (SF-12) component scores of patients with stroke. *Int J Rehabil Res*. 2004;27(2):149-50.
- Platino [Homepage on the Internet]. Buenos Aires: Proyecto Latinoamericano de investigación en obstrucción pulmonar; [cited 2005-09-20]. Available from: <http://www.platinoalat.org/>.
- Jezler SFO, Santiago MB, Andrade TL, Araújo Neto C, Braga H, Cruz AA. Comprometimento do interstício pulmonar em portadores de esclerose sistêmica progressiva. Estudo de uma série de 58 casos. *J Bras Pneumol*. 2005;31(4):300-6.
- Marie I, Dominique S, Levesque H, Ducrotté P, Denis P, Hellot MF et al. Esophageal involvement and pulmonary manifestations in systemic sclerosis. *Arthritis Rheum*. 2001;45(4):346-54.
- Warrick JH, Bhalla M, Schabel SI, Silver RM. High resolution computed tomography in early scleroderma lung disease. *J Rheumatology*. 1991;18(10):1520-8.
- Reveille JD, Fischbach M, McNearney T, Friedman AW, Aguilar MB, Lisse J et al. Systemic sclerosis in 3 US ethnic groups: a comparison of clinical, sociodemographic, serologic, and immunogenetic determinants. *Semin Arthritis Rheum*. 2001;30(5):332-46.
- Tan FK. Systemic sclerosis: The susceptible host (genetics and environment). *Rheum Dis Clin North Am*. 2003;29(2):211-37.
- Steen VD, Owens GR, Fino GJ, Rodnan GP, Medsger TA. Pulmonary involvement in systemic sclerosis (scleroderma). *Arthritis Rheum*. 1985;28(7):759-67.
- Hurst NP, Ruta DA, Kind P. Comparison of the MOS short form-12 (SF12) health status questionnaire with the SF36 in patients with rheumatoid arthritis. *Br Rheumatol*. 1998;37(8):862-9.
- Georges C, Chassany O, Mouthon L, Tiev K, Marjanovic Z, Meyer O et al. Quality of life assessment with the MOS-SF36 in patients with systemic sclerosis. [Article in French] *Rev de Med Interne*. 2004;25(1):16-21.
- Danieli E, Airò P, Bettoni L, Cinquini M, Antonioli CM, Cavazzana I, et al. Health-related quality of life measured by the Short Form 36 (SF-36) in systemic sclerosis: correlations with indexes of disease activity and severity, disability, and depressive symptoms. *Clin Rheumatol*. 2004;24(1):48-54.
- Khanna D, Clements PJ, Furst DE, Chon Y, Elashoff R, Roth MD, et al. Correlation of the degree of dyspnea with health-related quality of life, functional abilities, and diffusing capacity for carbon monoxide in patients with systemic sclerosis and active alveolitis: results from the Scleroderma Lung Study. *Arthritis Rheum*. 2005;52(2): 592-600.

28. Haywood KL, Garrot AM, Fitzpatrick R. Quality of life in older people: a structured review of generic self-assessed health instruments. *Qual Life Res.* 2005;14(7):1651-68.
29. Lefante JJ, Harmon GN, Ashby KM, Barnard D, Webber LS. Use of the SF-8 to assess health-related quality of life for a chronically ill, low-income population participating in the Central Louisiana Medication Access Program (CMAP). *Qual Life Res.* 2005;14(3):665-73.
30. Jones PW. Health status measurement in chronic obstructive pulmonary disease. *Thorax.* 2001;56(11):880-7.