Using the Saint George's Respiratory Questionnaire to evaluate quality of life in patients with chronic obstructive pulmonary disease: validating a new version for use in Brazil*

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ABSTRACT

Objective: The objective of this study was to evaluate the applicability of a modified version of the Saint George's Respiratory Questionnaire. The version evaluated elicits "agree" and "do not agree", rather than "yes" and "no", responses. The intention is to facilitate the comprehension of double-negative questions and to promote better recollection of symptoms by patients by shortening their symptom histories from 12 months to 3 months. **Methods:** A total of 30 clinically stable patients with chronic obstructive pulmonary disease were evaluated. The Saint George's Respiratory Questionnaire and the modified version of the same were administered 15 days apart. **Results:** All of the patients presented health-related alterations in their quality of life. Comparing mean scores between the two questionnaires, the greatest difference was seen in the Symptoms domain. No significant differences were found in any of the remaining domains or in the total scores. In a subsequent analysis, significant correlations between the two questionnaires were found in all domains: Symptoms ($r = 0.71$; $p < 0.001$); Activity ($r = 0.75$; $p < 0.001$); Impact ($r = 0.73$; $p < 0.001$) and Total ($r = 0.86$; $p < 0.001$). **Conclusion:** The modified version of the Saint George's Respiratory Questionnaire is as effective as the original in gauging quality of life. However, various symptoms recollection time frames should be investigated in order to determine which would be the best time frame to employ in the analysis.

Keywords: Pulmonary disease, chronic obstructive; Quality of life; Reproducibility of results; Cross-cultural comparison; Questionnaires

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INTRODUCTION

The chronic symptoms of the chronic obstructive pulmonary disease (COPD) - dyspnea, wheezing, cough, expectoration and exercise intolerance - are accompanied by anxiety and depression and are the principal factors responsible for altering the relationship between health and quality of life.[1] However, it is known that the severity of symptoms is not always directly related to the degree of airflow limitation or to the level of oxygenation at rest, which is why there has been increasing interest in the study of the quality of life in patients with COPD.[1]

The determination of quality of life can be defined as the formalized and standardized quantification of the impact of the disease on daily life activities and of the well-being of the patient.[2]The importance of standardized quality of life questionnaires is implicit in this concept, since they allow the objective comparison of the impact of interventions used in COPD through scores with numerical (absolute or percentage) expressions.

It is recommended that appropriately developed quality of life questionnaires be used. The measurement properties of such questionnaires should be those duly documented in the specific literature, including the following: responsiveness or capacity to detect changes due to interventions; discriminatory power or capacity to classify patients with different levels of quality of life; normality value score; clinically important minimum difference; and correlations with other measurements traditionally used in clinical practice.[3] The content of each questionnaire should also be adapted to the language and culture of the country in which it will be used so that the results obtained with the adapted version will reflect the objectives determined by each questionnaire author at the time of the development of the questionnaires in their countries of origin.[4] This process is called validation, and aims to maintain the measurement properties established at the time these questionnaires were outlined.

The Saint George's Respiratory Questionnaire (SGRQ) was validated for Brazil in 2000[5] and is specific for obstructive diseases. However, it has also been used to evaluate the quality of life in patients with restrictive pulmonary diseases.[6-7] During the process of developing the Portuguese version of the SGRQ (the original was written in British English), some obstacles to the coherent construction of some statements and response alternatives were encountered, mainly regarding double-negative questions, a common grammar construction in the English language that could be difficult for Brazilians to understand.[5] In clinical practice, the double-negative alternatives could contribute to make it difficult for some patients to understand the SGRQ contents. In the validation process of the Spanish version of the SGRQ, this cultural limitation was also noted, and the authors opted for a less conservative validation and developed a version without the double-negative phrases.[8]

A new SGRQ version was created for the present study, eliciting "I agree" and "I disagree", rather than "yes" and "no", responses, with the intention of facilitating the comprehension of the content of the questions (mainly of the double-negative ones) by the patients. In addition, the period of recollection of symptoms was shortened from twelve months (in the original version) to three months (part 1, questions 1 through 8), in order to focus on a shorter evaluation period, which is more appropriate for evaluating some interventions that yield results more rapidly.[9]

This study was conducted to determine whether the modified version of the SGRQ (mSGRQ), employing "I agree" and "I disagree" responses, maintains the same measurement properties of the original SGRQ, which has already been validated for use in Brazil.

METHODS

A convenience sample comprising 30 patients with COPD was recruited from the COPD Outpatient Clinic of the Pulmonary Rehabilitation Center of the Federal University of São Paulo between January and September of 2002. The following inclusion criteria were used: a diagnosis of COPD in accordance with the guidelines established in the II Brazilian Consensus on COPD[3]; clinical stability during the study and up to 30 days before the beginning of the evaluations, defined by determining the clinical stability and adherence to the current treatment by means of a standardized questionnaire of symptoms; variation of ± = 10% of the forced expiratory volume in one second between visits; variation of ± = 2% in oxygen

saturation measured through digital pulse oximetry between visits. Patients scoring < 25 on the Minimental questionnaire,[10] which measures cognitive capacity, were excluded, as were those who presented other concomitant pulmonary diseases or comorbidities (severe or uncontrolled), as well as those who opted to discontinue their participation in the study.

The patients were evaluated during two visits to the outpatient clinic, fifteen days apart. A two-day variation (before or after the scheduled visit) was tolerated for re-evaluation. The following evaluations were applied during each visit: spirometry (Koko PFT System), according to the standards of the Brazilian Society of Pulmonology and Phthisiology; pulse oximetry (Healthdyne Technologies - model 920m), with the patient breathing room air and at rest; standard clinical stability questionnaire; Minimental questionnaire for the evaluation of cognitive capacity. The body mass index (BMI) was obtained by calculating the ratio between weight (kg) and height (m^2). This index was used in the nutritional diagnosis. Values under 22 kg/m^2 indicated malnutrition, values between 22 and 27 kg/m^2 indicated healthy physical condition, and values above 27 kg/m^2 indicated overweight status.[11]

One of the following versions of the SGRQ was administered during each visit: the original, previously validated Portuguese version (SGRQ), containing "yes" and "no" responses and the modified version (mSGRQ), which contains the "I agree" and "I disagree" alternatives (Annex 1). One version was used in the first visit and the other was used in the subsequent visit. The order of application was randomized so that neither the patient nor the interviewer had any option. The questionnaires were applied in a quiet environment, in isolation, and the patient answered the questions without interference. For illiterate patients, the interviewer read the questions and answer alternatives aloud, verbatim (without explanations). The application of both versions of the questionnaires was timed.

Written informed consent was obtained from all patients. The protocol was approved by the ethics and research committee of the university.

The variables were expressed as mean ± standard deviation. All continuous variables were analyzed in order to check the distribution of normality according to the Kolmogorov-Smirnov test. Nonparametric tests were used for the variables with normal distribution. The 95% confidence interval was calculated to evaluate the mean differences between the two versions of the questionnaire. The Wilcoxon test was used to compare two means from variables with normal distribution. Spearman correlation coefficient was used to measure the correlation between two minimally ordinal variables. The level of statistical significance adopted was 5%.

RESULTS

A total of 36 patients with COPD were evaluated for inclusion in the study protocol. Of those, 6 patients were excluded: 3 due to exacerbation of the disease, 2 because they did not return for the second visit and 1 for presenting a score of < 24 score on the Minimental questionnaire, resulting in a sample comprised of 30 patients who completed the study.

Of the 30 patients with COPD, 10 (33.3%) were female. Mean age was 64.3 ± 7.5 years old. The BMI ranged from 16 to 33.6 kg/m2 (mean, 25.6 ± 4.1 kg/m^2), and 3 patients (10%) were considered malnourished (BMI < 22 kg/m^2), 13 (43.3%) were considered healthy (BMI between 22 and 27 kg/m^2), and 14 patients (46.6%) were considered obese (BMI > 27 kg/m^2). All of the patients were former smokers and presented a mean 58.6 ± 38.4 pack-years of exposure to tobacco.

Patient cognition was evaluated using the Minimental questionnaire, and the minimum score required for inclusion was 25 points. All but 2 (6.6%) of the patients scored above 25, and those 2 both scored exactly 25. The mean Minimental score was 28 ± 1.6 points. There were 5 patients who did not know how to read (16.6%), and the questionnaires were read to them by the study interviewers.

Throughout the study, all 30 patients consistently met the criteria for clinical stability, as assessed using the symptoms questionnaire and analyzing spirometry and pulse oximetry measurements (Table 1).

Drug therapy remained unaltered for all the patients during the 15-day interval between the applications of the questionnaires.

Regarding the severity of COPD, according to the classification of the Brazilian Society of Pulmonology and Phthisiology, 3 patients (10%) were classified as grade I (mild), 11 (37%) as grade II (moderate), 13 (43%) as grade III (severe) and 3

TABLE 1

Characteristics of pulmonary function and arterial oxygen saturation by pulse oximetry of patients with chronic obstructive pulmonary disease who completed the Saint George's Respiratory Questionnaire in the "yes"/"no", and "I agree"/"I disagree" versions administered fifteen days apart (clinical and functional stability)

Variable	First Visit	Second Visit	p
SpO_2 (%)	93.7 ± 2.7	93.6 ± 2.2	0.9
FEV_1 (%)	51.8 ± 20.3	51.1 ± 20.8	0.48
FVC (%)	83.0 ± 20.3	80.1 ± 18.0	0.09
FEV_1/FVC	12.4 ± 12.4	12.5 ± 12.5	0.31

SpO_2: arterial oxygen saturation by pulse oximetry; FEV_1: forced expiratory volume in one second; FVC: forced vital capacity.

(10%) as grade IV (very severe). Only 2 patients presented = 88% oxygen saturation by pulse oximetry, at rest and on room air, and were classified as hypoxic.

The mean and standard deviation values for score and mean response time on the two SGRQ versions are expressed in percentages and are displayed in Table 2. Response times ranged from 9'10" to 24'10" for the original version of the SGRQ, and from 9'20" to 30'20" for the mSGRQ.

The entire sample studied presented some health status alteration (normal values are lower than 10%).

Spearman's correlation coefficient (r) was used to evaluate the strength of the correlation between the two questionnaires, since it was assumed that the two questionnaires would represent different evaluations. All of the domains, as well as the overall score, presented significant correlations: Symptoms ($r = 0.71$, $p < 0.001$); Activity ($r = 0.75$, $p < 0.001$); Impact ($r = 0.73$, $p < 0.001$); and Total ($r = 0.86$, $p < 0.001$). The dispersion of the total score between the SGRQ and the mSGRQ can be seen in Figure 1.

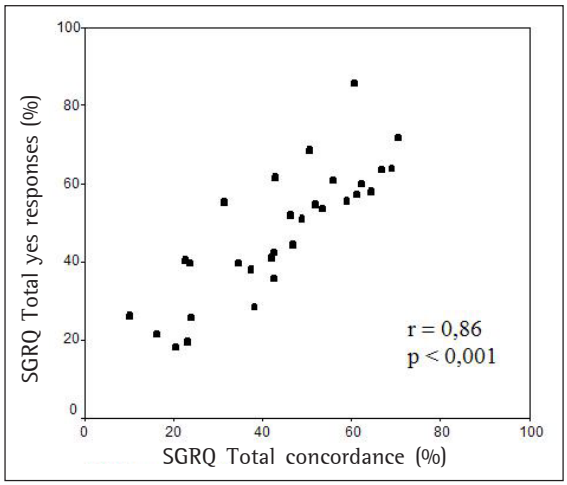

Figure 1 - Dispersion of the total score between the two SGRQ questionnaires in the 30 patients with COPD

DISCUSSION

The mSGRQ presents questions on symptoms recollection over a three-month period (rather than a twelve-month period as in the original version previously validated for use in Brazil)[5] and offers "I agree" and "I disagree" response alternatives to facilitate the comprehension of the double-negative questions in the original version. In the sample studied, which comprised patients with moderate or severe COPD, the mSGRQ presented quality of life measurement properties that were similar to those presented by the SGRQ. The correlations

TABLE 2

Scores and score response times on the two versions of the Saint George's Respiratory Questionnaire

Domains and response time	Mean ± SD		Mean differences		
	SGRQ	mSGRQ	SGRQ - mSGRQ	95% CI	p
Symptoms (%)	53.9 ± 20.1	44.1 ± 21.2	9.8 ± 15.86	4.4 - 16.4	0.02
Activities (%)	59.2 ± 19.1	60.7 ± 21.6	-1.4 ± 12.47	-6.3 - 3.4	0.83
Impact (%)	39.5 ± 20.0	34.5 ± 17.7	5.0 ± 13.72	-0.4 - 10.2	0.17
Total (%)	47.9 ± 16.7	44.0 ± 16.9	3.85 ± 9.6	0.2 - 7.6	0.18
Time (min and sec)	14'84" ± 3'51"	13'24" ± 4'10"	-	-	0.41

SD: standard deviation; SGRQ: Saint George's Respiratory Questionnaire; mSGRQ: modified Saint George's Respiratory Questionnaire; 95% CI: 95% confidence interval

between the two questionnaires in the Symptoms, Activity and Impact domains, as well as in the overall score, were statistically significant and similar to the reproducibility values found in the original validation study (which evaluated identical versions administered during two different visits).[5] This result can be considered noteworthy because this study applied the same method of patient recruiting and analysis used in the original study that validated the SGRQ for use in Brazil. However, since this study was carried out in the same center, there might be some limitation regarding the applicability of the results and conclusions in other populations. The application time of the two versions was similar, which indirectly shows that the understanding of the statements was also similar. Therefore, this study might imply that the mSGRQ should be the version of choice, both in the research environment and in health care facilities that use this questionnaire, since the quantification of quality of life has also been used outside the academic environment.

The sample of patients had good cognition, as per the Minimental questionnaires. Since the patients had been referred to a tertiary care center, they presented with moderate or severe COPD and altered quality of life, as evidenced by the descriptive pulmonary function and quality of life data. It was not possible to evaluate, in isolation, the correlations between the two questionnaires applied to illiterate patients since the sample was not powerful enough (only 5 patients). This aspect has also been analyzed in the previous validations of specific questionnaires for obstructive pulmonary disease in Brazil.[5,12]

In the present study, the mean overall scores, as well as the scores for the Activity and Impact domains, were not statistically significant between the two SGRQ versions. Since one of the criteria used is the minimum clinically significant difference, which is four points in the case of the SGRQ,[13] we calculated the 95% confidence interval for the difference between the mean scores of each SGRQ version. The 95% confidence interval surpassed the threshold of clinical difference in the Total score, Activity domain score and Impact domain score, revealing the high variability of these questionnaires. It is important to mention that no intervention was performed between the two evaluations. We recommend that validation studies be used to calculate the minimum sample number necessary when making this kind of evaluation. It is not possible to suggest a minimum number needed to detect the four-point difference in this study since the two versions were considered different. The modification in the types of response, using "I agree" and "I disagree" rather than "yes" and "no", did not alter the quality of life measurement properties.

The criteria for COPD clinical stability usually involve spirometry findings and clinical history,[14] both of which were evaluated in this study. A period of one month without exacerbations prior to the study period was used as an inclusion criterion in order to rule out any consequent interference with the scores evaluated.[15] It is known that other measurements, such as inspiratory capacity, correlate more strongly with COPD symptoms, mainly dyspnea, which is one of the most important determinants of altered quality of life.[16] It is also well known that COPD symptoms are the greatest determinants of altered quality of life and, since patients with mild COPD are oligosymptomatic, often constitute the main motivation for patients to seek treatment at the health care facility.[17] Assuming clinical stability, however, we noticed that there was significant variability in the Symptoms domain and that the 95% confidence interval of the mean score difference between the two versions was above four points in percentage, leading us to the conclusion that the two questionnaires evaluated this aspect of quality of life in distinct ways. Since the recollection time was shortened from twelve months to three months from one version to the other, we concluded that this part of the questionnaire has undergone a real change from the statistical and clinical points of view. It is therefore recommended that researchers choose between the three- and the twelve-month recollection period on a case-by-case basis, depending on the objective of their study.

We concluded that the mSGRQ has quality of life measurement properties for use in patients with moderate and severe COPD that are similar to those possessed by the original Brazilian SGRQ. However, researchers should choose the best time frame for symptoms recollection to be used in each study.

Anexx 1 - The Saint George's Respiratory Questionnaire modified to three months (mSGRQ)

Before completing the questionnaire:
Put an "x" in the box next to the response that better describes your state of health:
Very good ( )1 Good ( )2 Moderate ( )3 Poor ( )4 Very Poor ( )5

PART 1

Among the alternatives below, check the one that best identifies your respiratory problems in the last 3 months. Note: Mark only one alternative for each question.

Over the last 3 months:	most days	several days per week	a few days per month	only when I had a respiratory	nunca
1. I coughed					
2. I was congested					
3. I had shortness of breath					
4. I had wheezing episodes					

5. Over the last 3 months, how many attacks of severe respiratory problems have you had?

More than 3	3	2	1	None

6. How long did the worst attack last? (Go to question 7 if you did not have any severe attacks)

1 week or more	3 or more days	1 or 2 days	less than 1 day

7. Over the last 3 months, in a typical week, how many good days (with few respiratory problems) did you have?

None	1 or 2 days	3 or 4 days	almost all days	1	all days

8. If you experience wheezing, is it worse in the morning?

No 0	Yes 1

PART 2

Section 1
Mark only 1 alternative to describe your respiratory disease:

It is my greatest me problem	it causes me a lot of problems	it causes me a few problems	it does not cause any problem

If you have ever held a paying job, mark one of the alternatives: (go to section 2 if you don't work)

My respiratory disease forced me to stop working
My respiratory disease interferes (or has interfered) with my regular job or has forced me to change jobs
My respiratory disease does not affect (or has not affected) my work

Section 2
The answers below refer to activities that have typically caused you shortness of breath in the last few days. Mark each alternative below with an "x", indicating the response "I agree" or "I disagree", according to your case:

Sitting or lying down	I agree	I disagree
Taking a shower or getting dressed	I agree	I disagree
Walking around inside the house	I agree	I disagree
Walking on level ground	I agree	I disagree
Climbing up a flight of stairs	I agree	I disagree
Going up steep slopes	I agree	I disagree
Doing sports or playing games that involve physical exertion	I agree	I disagree

Section 3
Here are a few more statements about your cough and shortness of breath in the last few days. Mark each option below with an "x", selecting the response "I agree" or "I disagree", according to your case:

My cough causes me pain	I agree	I disagree
My cough makes me feel tired	I agree	I disagree
I have shortness of breath when I speak	I agree	I disagree
I have shortness of breath when I lean forward	I agree	I disagree
My cough or shortness of breath disturbs my sleep	I agree	I disagree
I get exhausted easily	I agree	I disagree

Section 4
Here are some statements about other effects caused by your respiratory disease in the last few days. Mark each option below with an "x", selecting the response "I agree" or "I disagree", according to your case:

My cough or shortness of breath embarrasses me in public	I agree	I disagree
My respiratory disease is inconvenient for my family, friends or neighbors	I agree	I disagree
I am afraid, or even panic, when I cannot breathe	I agree	I disagree
I feel that my respiratory disease is out of my control	I agree	I disagree
I do not expect any improvement in my respiratory disease	I agree	I disagree
My disease has physically debilitated me, which makes me need help from others	I agree	I disagree
Doing exercises is risky for me	I agree	I disagree
All I do seems to demand great effort	I agree	I disagree

Section 5
Here are some statements about your medication. If you are not taking any medication, go to section 6. Mark each alternative below with an "x", selecting the response "I agree" or "I disagree", according to your case:

my medication is not helping me much	I agree	I disagree
I am embarrassed to take medication in public	I agree	I disagree
my medication causes unpleasant side effects	I agree	I disagree
my medication interferes considerably with my day-to-day activities	I agree	I disagree

Section 6
The next items refer to the activities that can be affected by your respiratory disease.
Mark each alternative below with an "x", selecting the response "I agree" if at least one part of the sentence is applicable to your case. Otherwise, select "I disagree".

It takes me a long time to bathe or get dressed	I agree	I disagree
It takes me a long time (or I am unable) to take a shower or a bath	I agree	I disagree
I walk slower than do other people or I have to stop for a rest	I agree	I disagree
It takes me a long time to perform tasks such as household chores, or I have to stop for a rest	I agree	I disagree
When I go up a flight of stairs, I do it very slowly or I have to stop and rest	I agree	I disagree
If I am in a hurry or walk faster, I have to stop and rest or go more slowly	I agree	I disagree
Because of my respiratory disease, I have difficulty in performing activities such as: going up steep slopes, carrying objects while climbing stairs, dancing, etc.	I agree	I disagree
Because of my respiratory disease I have difficulty in activities such as: lifting heavy weights, jogging, walking fast (8 km/h) or swimming	I agree	I disagree
Because of my respiratory disease, I have difficulty in activities such as: heavy manual labor, running, swimming fast or engaging in very tiring sports	I agree	I disagree

Section 7
We would like to know how your respiratory disease typically affects your day-to-day activities.
Mark the response "I agree" or "I disagree" with an "x":
(Remember that "I agree" is only applicable to your case when you are unable to do this activity due to your respiratory disease)

I am not able to do sports or play games that involve physical exertion	I agree	I disagree
I am not able to go out of the house to have fun	I agree	I disagree
I am not able to go out to do my shopping	I agree	I disagree
I am not able to do household chores	I agree	I disagree
I am not able to get out of bed or out of a chair	I agree	I disagree

The next list describes a series of other activities that your respiratory problem might prevent you from doing. (You do not need to select any of the activities, our intention is merely to remind you of the activities that might be affected by your shortness of breath).

Go out for a walk or walk your dog
Do household chores or gardening
Have sexual intercourse
Go to church, bars or entertainment locales
Go out in bad weather or stay in places where there is cigarette smoke
Visit family and friends or play with the kids
Please indicate any other important activity that your respiratory disease might prevent you from doing.
_____

Mark with an "x" only the response that best defines the way in which you are affected by your respiratory disease:

It does not prevent me from doing any of the things I would like to do	(0)
It prevents me from doing one or two things that I would like to do	(1)
It prevents me from doing most of the things that I would like to do	(2)
It prevents me from doing everything that I would like to do	(3)

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