Validity and reliability of the St George's Respiratory Questionnaire after adaptation to a different language and culture: the Spanish example

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ABSTRACT: We describe the adaptation into Spanish of the St George's Respiratory Questionnaire (SGRQ), a self-administered questionnaire developed by Jones *et al.* (1991) covering three domains of health in airways disease patients: symptoms, activity and impacts.

For the adaptation, the forward and back-translation method by bilinguals was used, together with professional committee and lay panel. Once tested for feasibility and comprehension, 318 male chronic obstructive pulmonary disease (COPD) patients with a wide range of disease severity completed the Spanish version of the SGRQ. The clinical status of the patients was evaluated concurrently with the measurement of health status. Lung function was assessed in the 2 months before or after the questionnaire administration.

The Spanish version of the SGRQ was acceptable and easy to understand. Cronbach's alpha reliability coefficient was 0.94 for the overall scale and 0.72 for "Symptoms", 0.89 for "Activity", and 0.89 for "Impacts" subscales. Correlation coefficients between the overall score and dyspnoea and % forced expiratory volume in one second (FEV1) were 0.59 and -0.45, respectively, and these correlations were higher than those observed between the clinical variables and the Nottingham Health Profile, a generic measure of health-related quality of life.

Results of the study suggest that the Spanish version of the SGRQ is conceptually equivalent to the original, and similarly reliable and valid. Although further studies should complete the adaptation work, results suggest that the SGRQ may already be used in Spain and in international studies involving Spanish respiratory patients. According to the present approach, it appears to be feasible to adapt a specific questionnaire on health-related quality of life in respiratory disease to another language and culture.

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Chronic obstructive pulmonary disease (COPD) is a prevalent condition associated with a high level of disability [1]. Since the goals of its treatment are mainly palliative (reducing symptoms, increasing functions, and improving the quality of life of the patient [2]), interest in assessing "health-related quality of life" (HRQL) in these patients has increased in the last decade. HRQL instruments may be useful in monitoring patients' progress or in determining the most appropriate choice of treatment. HRQL data correlate only moderately with the most widely used clinical indicator of the severity of COPD, the forced expiratory volume in one second (FEV1) [2], which has been shown to be an accurate predictor of prognosis and survival [3]. Thus, HRQL measures may provide information complementary to the assessment of COPD patients. There are, as yet, only limited data concerning the relationships between changes in spirometry following therapy and changes in health status, but the

evidence available suggests that they are poorly correlated [1]. It is, thus, appropriate to measure the changes in health status and not just the changes in spirometric values.

Until recently, generic HRQL instruments have been used in patients with COPD, but their usefulness for clinical trials may be limited because of a low level of responsiveness (sensitivity to changes). Disease-specific instruments may be more responsive to the effects of health care [4], since they focus on aspects of HRQL that are relevant to those patients [5]. Disease-specific instruments relate more closely to clinical symptoms and, as a consequence, may be more acceptable for the clinicians [2]. In recent years, several studies have reported results of HRQL instruments specific for respiratory patients. These instruments have been developed in English-speaking countries and include several health status measures for asthma patients [6–10], one for COPD patients [11, 12], and one

designed for use in both types of patients, COPD and asthma [13, 14]. Most of these measures have been shown to be reproducible, valid and responsive, although they differ from each other in several aspects. Selection of the most appropriate questionnaire depends on the patient group, the objective of the study, the hypothesis being tested, or the specific intervention to be evaluated.

Adapting a measure developed in a different language and culture may be more time-saving than developing a new one. But, if the adaptation is done by a simple translation, it is unlikely to render an equivalent measure because of the influence of language and culture in health-related issues [15]. A correct adaptation requires a broader design that takes into account not only the linguistic but the technical and conceptual aspects involved in measuring health status [16].

The main objectives of the present study were: 1) to develop a Spanish version of the St George's Respiratory Questionnaire (SGRQ) that is conceptually equivalent to the original and acceptable for use as a self-administered questionnaire; and 2) to assess the feasibility, reliability and validity of the instrument.

Given the increasing interest in multinational clinical studies measuring perceived health status, a secondary objective of this paper is to present a method to adapt such an instrument developed in a different culture.

Methods

The St George's Respiratory Questionnaire

The St. George's Respiratory Questionnaire (SGRQ) is a standardized self-administered airways disease-specific questionnaire developed by Jones *et al.* [13, 14]. It contains 50 items (covering 76 levels) divided into three subscales: "Symptoms" (8 items), including several respiratory symptoms, their frequency and severity; "Activity" (16 items), concerned with activities that cause or are limited by breathlessness; and "Impacts" (26 items), which covers a range of aspects concerned with social functioning and psychological disturbances resulting from airways disease.

Each item in the questionnaire has a weight attached, which provides an estimate of the distress associated with the symptom or state described. These weights were collected in 140 asthma patients and they were shown to be applicable to a wide range of patients with asthma or COPD because demographic and disease-related factors had minimal influence on them [17]. A score was calculated for each subscale of the SGRQ and also an overall score was calculated following procedures and handling of missing data recommended by the developer (P.W. Jones, personal communication). SGRQ scores range from 0–100, zero score indicating no impairment of life quality. Missing items with multiple-choice responses were treated as "No"; and for missing items with a "Yes/No" response pattern, the weight was subtracted from the total possible weight.

The questionnaire has been shown to be reproducible and valid [14]. Furthermore, in a head-to-head comparison it was shown to be more responsive to differences in disease severity than the Sickness Impact Profile (SIP), a generic instrument [13].

Table 1. – Adaptation into Spanish of the St George's Respiratory Questionnaire (SGRQ)

- 1. Translation by a bilingual (first version)
- 2. Committee of professionals (second version)
- 3. Back-translation into English and comparison with original
- 4. Panel of patients (third version)
- 6. Pilot testing in 23 COPD patients
- 7. Final version

COPD: chronic obstructive pulmonary disease.

Adaptation into Spanish of the SGRQ

We followed the same methodology used for adapting other health questionnaires by our group [16, 18–22]: the translation and back-translation method by bilinguals with consultation to a professional committee and to a lay panel. The method is summarized in table 1. A first translation was produced by a bilingual, whose mother tongue was Spanish and who was asked to keep conceptual rather than linguistic equivalence. This translation was reviewed by a committee of professionals formed by two researchers and a pneumologist, who rated the equivalence between this first forward translation and the original version, identified inadequate or ambiguous items and generated alternative expressions. Nine words or expressions used in 36 statements (including items, response choices and instructions), 41% of the total, were judged to contain one or two uncertain words, and only one phrase (1.1%) was classified as of doubtful translation. Modifications were subsequently made and a second forward translation was produced. This version was back-translated into English by a bilingual, whose mother tongue was English, to be compared with the original.

Since the adaptation of the SGRQ aimed to reflect the concerns and the usual language of the patients rather than those of the professionals, a panel of eight COPD patients was convened (aged 50-70 yrs; 6 males and 2 females; 4 out-patients and 4 in-patients). The panel was given three tasks: firstly, to respond to the questionnaire; secondly, patients were probed about their responses and asked to comment on each of the items of the translated version, encouraging them to express any difficulty they had understanding the items; finally, they were asked to identify, for those items with alternative expressions, the alternative that best conformed to their language usage. The committee of professionals and the translators took into consideration the results of these activities as well as the differences between the back-translation and the original, discussing each problematical item until a reconciled final version was reached.

The third version resulting from completion of these tasks was pilot tested with 23 COPD out-patients. It proved to be understandable and easy to complete, except for five items which contained negative expressions (English: "I cannot..."/Spanish: "No puedo..."). Also, some difficulties were encountered for response choices in a matrix format. For these reasons the final version contained no negative statements and no matrix format response choices.

Having obtained a Spanish version of the SGRQ, a translation into Catalan (language of romanic origin similar to Spanish, spoken by some eight million people living mainly in the northeastern part of Spain) was also

made. Two Catalan-Spanish bilinguals were used to obtain translations and back-translations, and also to decide the exact final wording. The close agreement between the Catalan and Spanish versions led us to include both versions in further studies of the Spanish SGRQ.

Study design

A cross-sectional study of male COPD patients with a wide range of age and disease severity was carried out. All consecutive male patients with clinical symptoms compatible with COPD attending the out-patient clinic of respiratory departments of four hospitals and a pneumology out-patients department of a primary health care centre were recruited, until a maximum of 100 patients in each of four groups of severity was reached. Severity was defined as the proportion of observed over predicted FEV1 by the patient's age, height, and weight (%FEV1) calculated according to the norms published by Roca et al. [23] and the recommendations of the Spanish Respiratory Pathology Society [24, 25]. Patients were clinically evaluated and then administered the Spanish version of the SGRQ and other health status instruments. FEV1 and forced vital capacity (FVC) were performed in the 2 months before or after the patient interview.

To be accepted into the study, patients had to meet the following criteria: 1) a best FEV1 of less than 80% predicted, and a FEV1/FVC ratio of 0.7 or less; 2) clinical stability (that is, at least 1 month without acute exacerbation or a hospital admission); and 3) a bronchodilator test with an increase of FEV1 over basal of less than 15% and 200 mL.

Health status measures

During the clinical visit, in addition to the Spanish version of the SGRQ, patients completed two scales of dyspnoea (the Borg scale [26] and a visual analogue scale [27]), the Spanish versions of the MOS SF-36 Health Survey Mental Health Inventory [22] and the Nottingham Health Profile (NHP) [18]. The SF-36 Health Survey Mental Health Inventory (MHI) was constructed from the five items that best predicted the summary score for the 38 item MHI and has demonstrated validity in discriminating psychiatric patients from those with other medical conditions [28]. MHI scores were computed following the instructions in the SF-36 Scoring Manual [29], and ranged from 0 (worst health) to 100 (best health). The NHP is a multidimensional generic instrument containing 38 items measuring perceived distress, divided into six dimensions (Energy, Pain, Emotional Reactions, Sleep, Social Isolation and Physical Mobility). NHP scores, ranging from 0 (no perceived distress) to 100 (maximum perceived distress), were calculated simply as a count of the number of items endorsed [21]. The NHP has been shown to be appropriate for Spanish COPD patients [30].

All HRQL instruments were administered as a self-completed questionnaire. For 27% of the respondents, the questionnaires were administered by an interviewer because of the patient's inability to read or write, despite use of large type in the printed questionnaire, following

the recommendations of Kurtin *et al.* [31]. Questionnaires were randomly ordered, half of the sample responded first to the generic questionnaire, the NHP and then to the SGRQ, and the other half responded to the SGRQ before the NHP.

Analysis

Internal consistency of each scale score of the Spanish version of the SGRQ was assessed by the Cronbach's alpha coefficient [32]. Differences in values of alpha coefficient were tested by using the ALPHATST program [33, 34]. Item discrimination was also assessed across scales. Specifically, the correlations between each item and the subscale scores were calculated. Correlations between items hypothesized to be in a given subscale and the subscale itself were corrected for overlap [35] to provide estimates of the item-subscale relationship that are not spuriously inflated. Scaling success rates were computed for each subscale as the percentage of items within a scale which correlated higher or significantly higher with their hypothesized scale than with the other scales. An item correlated significantly higher with its own scale when the correlation between this item and its hypothesized scale was more than two standard errors higher than its correlation with other scales. A revised version of the Multitrait Analysis Program was used to perform the previous analyses described [36].

Construct validity of the questionnaire was assessed following four approaches. Firstly, the correlations between clinical measures and SGRQ were analysed. It was hypothesized that the SGRQ would be highly correlated with clinical indicators of severity of COPD (dyspnoea and %FEV1). Secondly, the pattern of relationships between the overall SGRQ score and pulmonary function and symptoms was compared, with that of a generic HRQL measure, the NHP. Thirdly, convergent and discriminant validity of health constructs assessed by the SGRQ and by the NHP were examined. Convergent validity refers to the extent to which different ways of measuring a similar concept intercorrelate with one another, whilst discriminant validity involves demonstrating that a measure does not correlate too strongly with measures that are intended to assess different traits [37]. Finally, the proportion of variance of each SGRQ subscale score explained by several independent variables to assess their hypothesized contents and to provide information about the underlying nature of each scale was computed.

Pearson correlation coefficients are reported because they are robust whatever the underlying probability distribution, and because no major discrepancies between parametric and distribution-independent tests were found. Convergent and discriminant validity of SGRQ were examined by the multitrait multimethod matrix [38]. Multiple regression analysis was carried out with each SGRQ subscale score as the dependent variable. The stepwise method was used to identify those independent variables statistically related with the dependent variable (p<0.05). Residuals from parametric regression were examined for normality of distribution around the regression by plotting the cumulative frequency distribution of the residuals against the cumulative frequency distribution for the normal distribution

Symptoms Activity Impacts Overall 46.4 (21.6) 53.9 (26.2) 36.5 (22.6) 43.4 (21.4) Scorest Items n 50 26 8 16 29 Levels n 16 31 76 Patients with missing items % 12 4 10 22 0 - 100Theoretical range 0 - 1000 - 1000 - 100Observed range 0 - 1000 - 1000 - 952 - 9694 87 91 Scaling success % 100 Items which correlated closely % 31 37 56 35 Items which correlated significantly closely % 44 52 54 63 9 0 2 With best possible score ("Ceiling") % 4 With worst possible score ("Floor") % 3 4 0 0 Item-convergent validity* 0.30 - 0.630.41 - 0.660.12 - 0.65Item-discriminant validity# 0.23 - 0.410.23 - 0.630.14 - 0.66Cronbach's alpha coefficient A11 0.72 0.89 0.89 0.94 Self-administered 0.74 0.89 0.88 0.94 Interviewer-administered 0.66 0.90 0.90 0.95 p-value‡ 0.3259 0.1331 0.6162 0.3354

Table 2. - Results of item scaling tests and reliability of the SGRQ subscales in COPD patients

Results

Three hundred and thirty five patients who met the inclusion criteria were identified. Fourteen patients refused to participate and three were excluded because of invalid responses. Complete quality of life data were available from 318 patients, whose mean dyspnoea in general was 3.4 cm (SD=2.5) on a 10 cm visual analogue scale, and whose average %FEV1 was 44% (SD=18%). Table 2 presents SGRQ mean scores as well as estimates of dispersion, internal consistency, and other important instrument characteristics. The proportions of missing data for the SGRQ subscales ranged 4-12%. Very few patients achieved the worst possible score ("floor effect"), ranging among the different subscales 0–4%. Also, few patients had the best possible score ("ceiling effect"), ranging 0-9%. Internal consistency of the total score (Cronbach's alpha=0.94) was higher than that of the subscales (ranging 0.72–0.89). No differences in internal consistency were found between self- and interview-administered SGRQ.

In general, SGRQ overall and subscale scores had a higher correlation with dyspnoea ("Activity" r=0.56; and "Impacts" r=0.56), and moderate to high with %FEV1 ("Activity" r=-0.53; and "Impacts" r=-0.37) (table 3). Correlations between "Symptoms" and these two clinical indicators were lower (r=0.43 and r=-0.29, respectively). Correlations between most of the NHP scores and these clinical indicators were lower than those found for the SGRQ scores, whereas correlations with the SF-36 MHI were higher for the NHP scores (table 3). "Impacts" was the subscale which showed the greatest correlation with the SF-36 MHI.

Most of the expected relations for convergent and discriminant validity were confirmed (table 4). Correlation coefficients for "Activity" and "Impacts" scores of the SGRQ with the two dimensions of NHP addressing similar concepts (Energy and Physical Mobility) were higher (range r=0.70–0.72) than correlations with noncomparable NHP

dimensions (Pain, Emotional Reactions, Sleep and Social Isolation) (range r=0.29–0.52).

Finally, multiple regression models with overall and subscales SGRQ scores as the dependent variable and dyspnoea, %FEV1, and the SF-36 MHI score as independent variables were built. The partial correlation coefficients for each model are represented in fig. 1. Dyspnoea was the component accounting for the highest proportion of the variance in all the models (r^2 =0.17–0.36). These three independent variables (dyspnoea, %FEV1, and mental health) accounted for about half of the variance of the "Activity" and "Impacts" subscale scores (r^2 =0.52 and r^2 =0.49, respectively) as compared with about a quarter of the variance of the "Symptoms" subscale.

Table 3. – Pearson correlation coefficients between clinical variables and HRQL scores

	Dyspnoea (Borg scale)	% FEV1	SF-36 MHI
SGRQ			
Symptoms	0.43	-0.29	-0.40
Activity	0.56	-0.53	-0.45
Impacts	0.56	-0.37	-0.55
Overall score	0.59	-0.45	-0.54
NHP			
Energy	0.50	-0.34	-0.55
Pain	0.23	0.03*	-0.44
Emotional reactions	0.31	-0.12*	-0.65
Sleep	0.21	-0.09*	-0.42
Social Isolation	0.21	-0.15	-0.44
Physical Mobility	0.48	-0.33	-0.51
Overall score	0.45	-0.24	-0.66

All p-values are <0.01, except those marked with *: (NS: p>0.05). HRQL: health-related quality of life; SGRQ: St George's Respiratory Questionnaire; NHP: Nottingham Health profile; FEV1: forced expiratory volume in one second; SF-36 MHI: short-form-36 Mental Health Inventory.

^{†:} mean, and sp in parenthesis; *: range of correlations (corrected for overlap [35]) between items and their hypothesized scale; #: range of correlations between items and other scale; ‡: test of differences in alpha coefficients between self- and interview-administered SGRQ [33, 34]. SGRQ: St George's Respiratory Questionnaire; COPD: chronic obstructive pulmonary disease.

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	SGRQ			NHP					
	Symptoms	Activity	Impacts	Energy	Pain	Emotion	Sleep	SO	PM
Symptoms	(0.72)								
Activity	0.57	(0.89)							
Impacts	0.64	0.79	(0.89)						
Energy	0.50	0.71	0.72	(0.74)					
Pain	0.27	0.39	0.47	0.49	(0.84)				
Emotion	0.39	0.41	0.52	0.54	0.48	(0.78)			
Sleep	0.28	0.41	0.46	0.44	0.53	0.56	(0.78)		
SO Î	0.30	0.29	0.36	0.37	0.23	0.57	0.28	(0.51)	
PM	0.45	0.72	0.70	0.70	0.55	0.47	0.39	0.35	(0.71)

Table 4. – Multitrait-multimethod matrix: showing correlations between different SGRQ subscales and NHP dimensions

Values in parentheses represent internal Cronbach's alpha coefficient. SO: Social Isolation; PM: Physical mobility. For further abbreviations see legend to table 3.

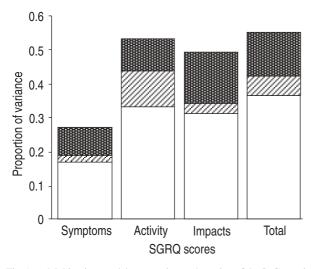


Fig. 1. — Multivariate models comparing each section of the St George's Respiratory Questionnaire (SGRQ) with clinical indicators and other measures.

Members : Mental Health Inventory (MHI); **ZZZZ* : forced expiratory volume in one second (%FEV1); **_____: dyspnoea (visual analogue scale).

Discussion

In this study, we found the Spanish version of the SGRQ to be acceptable and easy to administer to male COPD patients. The SGRQ questionnaire showed acceptable to high internal consistency, and the scores were moderately to highly correlated with a range of established measures of respiratory disease activity. The results presented are consistent with previous reports with the original SGRQ instrument, and suggest that the Spanish version is conceptually equivalent to the original and similarly reliable and valid. All the subscale scores may be used for comparing groups because the Cronbach's alpha coefficient of subscales are above 0.7 [39], while the total score is very reliable and would allow for individual comparisons (suggested standard, alpha=0.90, 0.95) [39]. Overall, results suggest that the SGRQ may be used in Spain and in international studies involving Spanish-speaking respiratory patients.

The SGRQ correlated more closely with dyspnoea and %FEV1 than the Nottingham Health Profile (NHP), a generic measure of health status. This is consistent with a similar finding with the original version of the SGRQ, when it was compared with the Sickness Impact Profile

(SIP) [13]. Disease specific measures include symptoms and functional limitations or changes in these domains that are of particular concern to patients with a given condition. Disease specific measures are located closer to symptoms and physiological variables on the conceptual continuum of patients' outcomes [40].

Comparisons between the subscales of the SGRQ and the NHP dimensions showed a consistent pattern. Energy and Physical Mobility, the two NHP dimensions frequently impaired in COPD patients [30], whose content is comparable with that of the SGRQ subscales, correlated considerably more closely with "Activity" and "Impacts". On the other hand, since the "Impacts" subscale covers aspects concerned with psychological disturbances, it was the Emotional Reactions NHP dimension which correlated most closely with this subscale. The SGRQ "Symptoms" subscale scores were found to have the lowest correlations with NHP scores. This is consistent with the conclusion of the developers of the SGRQ, that the patients' well-being may be better judged from assessments of disturbances to daily life than from the symptoms severity [13].

The increasing use of health status measures developed in the United States or the UK in countries with different languages and cultures has generated more attention to the principles and methods of adapting instruments [18]. The cross-cultural adaptation of the SGRQ into Spanish followed a systematic methodology designed to maximize the conceptual equivalence of the adapted version. This method has yielded an instrument which is highly reliable, showing a pattern and level of correlations with clinical indicators and other measures similar to those of the original. Although the level of correlation or statistical similarity that should be accepted as evidence of equivalence is difficult to establish [41], our results suggest the conceptual equivalence of the Spanish version. As happens with the original questionnaire, the "Activity" and "Impacts" subscale scores correlate highly with dyspnoea, whilst "Activity" scores correlate more closely with %FEV1 and "Impacts" correlate more closely with mental health (anxiety in the original study) [14]. The low level of correlation found between "Symptoms" and dyspnoea may be due to the fact that the subscale contains items other than dyspnoea (i.e. frequency of cough, sputum production, wheeze and chest trouble). A low level of correlation between "Symptoms" and dyspnoea was also found in the original study with a population of patients that included some asthma patients.

Although the SGRQ has shown a high level of testretest reproducibility, and the Spanish version has shown a good internal consistency, a comparison of the reliability of the two versions is not possible, since test-retest reproducibility does not explore the same property as internal consistency. We have not assessed test-retest reproducibility, whereas internal consistency was not reported by the developers of the original questionnaire.

The level of data incompleteness (4-12%) may indicate only a moderate level of acceptability, but there are no reference values published from the original SGRQ. However, it may be explained in part by the sociodemographic status of this group of patients, whose mean age was 65 (sp=9.6) yrs, and 44% of whom had not completed primary education. The majority of "Symptoms" data incompleteness was due to two items which could be skipped if the patient did not present that problem, and may reflect some difficulties for a self-administered response. A possible explanation of the remaining missing items is that the SGRQ was designed to be used with either COPD or asthma patients, but in our study only COPD patients were included. Some items may be less suitable for COPD patients than for asthma patients (e.g. how many severe or very unpleasant attacks of chest trouble have you had?). This hypothesis will be tested in a study of patients with asthma, which is currently under way [42].

Overall, the results presented here give considerable support to the conceptual and scalar equivalence of the Spanish version of the SGRQ. At the same time, however, one should be aware of differences to the protocol and design of the studies of the original British instrument. The fact that our study sample was restricted to male COPD patients with negative bronchodilator test limits the comparability of results with those reported by the original developers of the SGRQ, based on a mixed population of patients, some with asthma, others with COPD [13]. Thus, although both studies selected a wide range of ages and disease activity, the differences of sex and disease in the study sample along with the differences in clinical measures or in instruments used to assess them, make comparison difficult.

The original version of the SGRQ achieved an acceptable ability to quantify change over an extended time period in an observational study [14], and to quantify improvements in health following therapy [43]. Clearly, additional longitudinal studies are needed to determine whether the Spanish version of the SGRQ is responsive enough to register within-patient change over time, or to reflect a change after a health intervention.

Results of the present study suggest the feasibility of adapting a specific instrument of health-related quality of life of respiratory disease patients to be used in settings different from that where the instrument was originally developed. This should facilitate the use of patient-based outcomes in the evaluation of respiratory patients.

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