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Transculturally adapted Spanish SRI questionnaire for home mechanically ventilated patients was viable, valid, and reliable

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Abstract

Objective: To validate the Spanish Severe Respiratory Insufficiency (SRI) questionnaire, the first health-related quality-of-life questionnaire specific for patients receiving home mechanical ventilation (HMV).

Study Design and Setting: This multicenter prospective study enrolled 115 patients (53 males, age 62 ± 13 years) receiving HMV, recruited from five hospitals. Patients were scheduled for two visits during which sociodemographic and clinical data were recorded, and both the Spanish SRI and the SF-36 questionnaires were administered. Viability was assessed by recording timing and the response rate in the questionnaire. Reliability was assessed using intraclass correlation coefficient (ICC) and Cronbach alpha coefficient. Validity was studied by factor analysis, by a correlation test between the SRI and SF-36 questionnaires, and by establishing several simple, plausible, ad hoc hypotheses.

Results: The SRI was administered in 10 ± 5 minutes with ⩾96% responses for most items. Cronbach alpha coefficient was >0.7 for all scales except social relationships. ICCs were above 0.8 for all scales. Criterion validity obtained high correlations with SF-36, especially in psychosocial well-being and physical functioning scales. Factor analysis explained 60% of the variability. All ad hoc hypotheses were fulfilled.

Conclusion: The Spanish version of the SRI questionnaire has good psychometric properties, similar to those of the original questionnaire.

Keywords: Health-related quality of life; Home mechanical ventilation; Transcultural adaptation; Validation; Spanish; German

1. Introduction

Health-related quality-of-life (HRQL) questionnaires have become an important tool in the management of patients with chronic diseases to assess the impact of these diseases on patients' daily life. In the past few decades, several generic or disease-specific questionnaires [1] have been developed as multidimensional tools to record several aspects of the impact of the disease in patients' lives that are not otherwise studied in clinical practice.

Patients with chronic respiratory failure who receive home mechanical ventilation (HMV) delivered noninvasively via a mask constitute a heterogeneous group. Patients with diseases such as chest wall deformities, neuromuscular diseases, or chronic obstructive pulmonary disease (COPD) may benefit from this well-established treatment [2]. Because these patients' severe chronic respiratory failure is caused by a disease that progresses over several years or decades, and they normally suffer from end-stage lung disease with severe limitations in daily living [3], an evaluation of HRQL in patients receiving HMV is desirable [4]. Nonetheless, until very recently there were no specific

A free sample of the SRI questionnaire together with the instructions for recoding and interpreting it can be obtained from the corresponding author of this manuscript on request.

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questionnaires developed for this group of patients. Most of the questionnaires used were nonspecific, or specific for COPD [5,6]. Several of the conditions that are important for the daily life of patients receiving HMV were not addressed by these questionnaires leading to an incomplete assessment of HRQL [7]. Therefore, the SRI questionnaire was developed as a multidimensional HRQL tool with high psychometric properties, specific for patients receiving HMV [8]. SRI questionnaire was originally developed in German language following a complete methodology, and it was validated in a muticenter study including noninvasively ventilated patients from four centers in Germany [8]. In a previous study, our group translated and transculturally adapted the SRI questionnaire for the Spanish population [9]. The transcultural adaptation used the translation−back-translation procedure and produced a version that was both comparable to the original and accessible to the Spanish population. The aim of the present study was to validate the Spanish version of the SRI questionnaire.

2. Methods

The study was designed as a prospective multicenter study in which five hospitals participated. Participating hospitals recruited patients receiving HMV for different conditions during a routine visit at their outpatient clinics. All patients were informed of the objective of the study and gave written consent before inclusion in the study. The study was approved by the institutional review board. Adult patients receiving HMV via nasal or facial mask who were clinically stable and well adapted for at least 3 months met the inclusion criteria. Exclusion criteria included the patient's refusal to participate, a recent exacerbation (<3 months), or receiving HMV through a tracheostomy. Patients enrolled were scheduled for two consecutive visits. On the first visit, sociodemographic and clinical data were recorded, and both the Spanish SRI and the Spanish SF-36 questionnaires were administered. On the second visit 2 weeks later, clinical data were recorded, and the Spanish SRI was administered.

The sociodemographic data recorded were gender, age, highest academic degree or level of study (doesn't read or write, Spanish basic compulsory studies, i.e., primary + secondary school were completed or uncompleted, high school completed, university completed, or other), and employment situation (unemployed, employed, housewife, pensioner, disabled, student, or other). Clinical data recorded were previous medical history (tobacco smoking, comorbidities such as arterial hypertension, diabetes, or hyperlipidemia, and any other previous diseases), performance status according to the British Thoracic Society guidelines [10] (normal activity without restriction; strenuous activity limited; can do light work; limited activity, but capable of self care; limited activity, limited self care; confined to bed/chair, no self care; and no record), the main indication to establish HMV, dyspnea measured by the Medical Research Council scale [11], presence of morning headaches or daytime sleepiness, spirometry, arterial blood gas analysis, type of mask, type of ventilator (pressure or volume), use of oxygen therapy, hours of ventilation per day, and months receiving HMV.

2.1. Instrument

The SRI is a self-administered questionnaire with 49 items that the patient qualifies according to his degree of agreement on an ordinal scale with five degrees (1 = totally false; 2 = rather false; 3 = in part false, in part true; 4 = rather true; 5 = totally true). Questions refer to his or her health status during the previous week. Items record information on seven specific aspects or dimensions of HRQL related to chronic respiratory failure: respiratory complaints (RC: eight items), physical functioning (PF: six items), attendant symptoms and sleep (AS: seven items), social relationships (SR: six items), anxiety (AX: five items), psychosocial well-being (WB: nine items), and social functioning (SF: eight items). Each item belongs to one single scale. After item recoding, punctuation of each scale is obtained by a simple mathematical formula. The final punctuation or summary scale (SS) is obtained by the arithmetic mean of the values of each scale. High SS values (range 0−100) indicate a better HRQL.

The questionnaires were completed in the presence of the investigator, who only intervened if the patient had any doubt about being able to complete the questionnaire. Patients were told to be sincere and autonomous, and were encouraged to self-administer the questionnaire. When this was not possible, the investigator administered the questionnaire and noted the reason for doing so.

2.2. Psychometric properties

Psychometric properties studied were viability, validity, and reliability. Viability was studied by recording the time spent to complete the questionnaire, the response rate for each item, and the number of questionnaires that were self-administered.

Validity was determined using three methods. Structural validity was assessed by factor analysis as described below. Criterion validity was determined by comparing the Spanish SRI questionnaire with the SF-36 and establishing correlation coefficients between the different scales of both questionnaires. In this case, a high correlation between scales studying similar aspects of HRQL in both questionnaires was expected. To address construct validity, a number of simple plausible ad hoc hypotheses were formulated to see if the questionnaire fulfilled them. The hypotheses formulated were the following: (1) COPD patients have more respiratory complaints and are more frequently affected by anxiety and depression than patients without COPD [12]; (2) neuromuscular patients have a worse punctuation in the PF scale; and (3) patients receiving more hours of HMV per day have a worse HRQL.

Reliability was analyzed from two perspectives: reproducibility and homogeneity, or internal consistency. Reproducibility was assessed by administering the questionnaire on two consecutive visits to verify that the questionnaire punctuation was concordant. Thus, reproducibility was studied by calculating the intraclass correlation coefficients (ICCs) for each scale [13]. Internal consistency was calculated by means of the Cronbach alpha coefficient [14], which was considered acceptable when alpha exceeded 0.7 (Nunally criterion [15]), and by studying the correlation of each item with its own scale correcting for overlap, and with the rest of the items in the other scales. Thus, items should be more closely related to their own scales than to those on the other scales (item-discriminant validity).

2.3. Statistical computations

Statistical computations were performed with the Statistical Package for Social Sciences (SPSS, Chicago, IL, USA) version 12.0. For descriptive purposes, the mean ± standard deviation was used for quantitative variables, and the absolute and relative frequencies of each category were used for qualitative ones. Parametric tests were used for comparative analysis. To compare quantitative variables, the Student's *t*-test was used for independent or paired data, depending on the case. Variance similitude was previously studied with the Levene test. To study quantitative differences with more than two categories, ANOVA test was used and completed with a post hoc study using the Bonferroni correction to detect intergroup differences. Qualitative variables were studied using the chi-square test and Fisher's exact test when the expected frequency was <5. Pearson coefficients were used to study correlations between quantitative variables. Factor analysis was performed using the principal component method with a varimax rotation, using an eigenvalue >1 for extraction. The alpha error was set at 0.05.

3. Results

The sample was composed of 115 patients with a mean age of 62 ± 13 years; of them, 53 (52.4%) were males. Most of the patients (82; 71.3%) had completed or not completed Spanish basic compulsory studies (primary + secondary school). The most frequent employment situation was disabled/unable to work (45; 39.1%), followed by pensioner (34; 29.6%) and housewife (26; 22.6%). Only five patients were current smokers, and 69 (60%) had never smoked. The most common diagnostic groups were thoracic cage abnormalities, obesity-hypoventilation syndromes, neuromuscular disorders, tuberculosis sequelae, and COPD. The clinical characteristics of the sample are summarized in Table 1. Patients received HMV for a mean of 8.7 ± 3.2 hours per day, and they had used HMV for a mean of 55 ± 49 months. Pressure support ventilators were used in 88 (76.5%) cases, and the most commonly used interface was a nasal mask in 103 (89.6%) patients. Sixty-two (53.9%) patients required supplemental oxygen during ventilator use (mean flow: 1.6 ± 0.6 L/min), and 13 (11.3%) were on long-term oxygen therapy (mean flow: 1.5 ± 0.5 L/min). All patients were well adapted with no or minor adverse effects. Neuromuscular patients required HMV for more hours of the day than the other diagnostic categories (10.8 ± 5 hours vs. 8.2 ± 2.5 hours; $P = 0.046$).

3.1. Viability

There were small but significant differences in the time needed to complete the SRI questionnaire on the two visits (SRI first visit 10.9 ± 5.4 minutes vs. SRI second visit 10.0 ± 4.3 minutes; $P < 0.001$). Nonetheless, the time spent administering the SRI was the same as that for the SF-36 (SRI on the first visit 10.9 ± 5.4 minutes vs. SF-36 10.9 ± 5.4 minutes; $P = 0.215$). Sixty-two (54%) questionnaires were self-administered. The reasons given for not self-administering the questionnaire were unable to read or write fluently (17 patients), did not bring his/her reading glasses (10 patients), could not understand how to complete the questionnaire (nine patients), too physically disabled to write (eight patients), the patient preferred not to self-administer (three patients), and not specified (five patients). With the exception of item 31 (''My partner suffers with my disease''), items were responded by 96−100% of patients. Thirty percent of patients did not complete item 31,

Table 1
Clinical characteristics of the patient sample

Parameter	Thoracic cage	OHS	Neuromuscular	Tuberculosis sequelae	COPD	Total
n (%)	33 (28.6)	37 (32.1)	18 (15.6)	12 (10.4)	15 (13.3)	115 (100)
HMV (hr/d)	8 ± 1.8	7.6 ± 1.8	10.8 ± 5	9.1 ± 2.6	9.8 ± 4.4	8.6 ± 3.2
HMV (mo)	68 ± 55	55 ± 49	57 ± 45	43 ± 42	34 ± 34	55 ± 49
FVC (%)	36 ± 13	66 ± 16	44 ± 15	46 ± 16	65 ± 10	48 ± 17
FEV_1 (%)	33 ± 12	58 ± 18	44 ± 16	36 ± 11	34 ± 16	43 ± 18
FEV_1/FVC	72 ± 11	74 ± 12	74 ± 20	59 ± 7	53 ± 12	68 ± 14
pH	7.39 ± 0.04	7.41 ± 0.04	7.42 ± 0.08	7.40 ± 0.02	7.36 ± 0.02	7.40 ± 0.05
pCO_2	47 ± 8	45 ± 7	43 ± 6	47 ± 6	52 ± 11	47 ± 8
pO_2	70 ± 21	65 ± 9	76 ± 9	65 ± 8	64 ± 12	68 ± 14

Abbreviations: OHS, obesity-hypoventilation syndrome; COPD, chronic obstructive pulmonary disease; HMV, home mechanical ventilation; FVC, forced vital capacity; FEV_1, forced expiratory volume in one second.

because they did not have a partner at the time the test was administered.

3.2. Validity

3.2.1. Structural validity

Factor analysis explained 60% of the variation of the questionnaire, but it resulted in 13 scales. The PF, WB, and SF maintained their scales considerably well. The RC scale was divided into two scales, the first of which included items for respiratory symptoms in daily life, and the second referred to dyspnea in passive situations. The SR was also divided into two scales, with each measuring positive and negative aspects of personal relationships. Anxiety was divided into two different scales, the first for anxiety as a consequence of dyspnea and the second expressing the patient's inability to overcome his or her disease. The most divided scale was AS, which included four different symptoms that were assessed separately in four scales: cough and expectoration, sleep symptoms, headache, and sickness.

3.2.2. Criterion validity

The correlation matrix for both questionnaires is presented in Table 2. The best correlations were achieved between both PF scales ($r = 0.750$; $P < 0.001$), and between the SF-36 mental health and SRI WB ($r = 0.739$; $P < 0.001$).

3.2.3. Construct validity

All the hypotheses established were fulfilled. Patients with COPD had a worse punctuation than non-COPD patients on the RC (43 ± 20 vs. 64 ± 21; $P < 0.001$), SR (67 ± 20 vs. 78 ± 16; $P = 0.023$), and AX scales (45 ± 19 vs. 57 ± 25; $P = 0.05$). Neuromuscular patients had a worse punctuation on PF scale than the rest of the patients (26 ± 29 vs. 46 ± 25; $P = 0.006$). Finally, patients receiving HMV for more than 9 hours a day had a worse HRQL in the RC (52 ± 20 vs. 65 ± 22; $P = 0.003$), PF (32 ± 23 vs. 48 ± 26; $P = 0.003$), AX (49 ± 21 vs. 59 ± 26; $P = 0.049$), SF (42 ± 21 vs. 59 ± 26; $P = 0.008$), and SS scales (50 ± 13 vs. 60 ± 19; $P = 0.022$).

3.3. Reliability

ICCs, Cronbach alpha coefficient, and correlation of each item with its own scale correcting for overlap and with the rest of the scales are listed in Table 3. The Cronbach alpha coefficient was above 0.7 for all scales except SR. Correlations of an item to its own scale, correcting for overlap (item correlation coefficient with its own scale [ICS]), were good compared with the correlations with the rest of the scales in the questionnaire (item correlation coefficient with the rest of the questionnaire [ICQ]) in most cases, reaching higher correlations in ICS than in ICQ.

4. Discussion

The SRI is a newer disease-specific HRQL questionnaire with high psychometric properties designed for patients receiving HMV for various conditions. The transcultural adaptation of the questionnaire using a translation–back-translation procedure produced a Spanish version that was both comparable to the original and accessible to Spanish patients [9]. The validation of this Spanish version of the questionnaire indicates that its psychometric properties are similar to those of the original version, and sufficient to be used in the Spanish population. The sample population included patients with the most common diagnoses for starting HMV. The HRQL is strongly influenced by the underlying disease, and although there were differences in some scales among different diagnostic groups, the final punctuation of the questionnaire was not different for each diagnostic group with the exception of the number of hours HMV was required. This suggests that our patients were similarly impaired in HRQL.

Table 2
Correlation matrix between the Spanish SRI and SF-36

	SF-36									
SRI	PF	RP	BP	GH	VT	SF	RE	MH	PHC	MHC
RC	**0.365**	**0.431**	0.161	**0.471**	**0.543**	**0.485**	0.163	**0.242**	**0.477**	**0.281**
PF	**0.750**	**0.519**	0.089	**0.504**	**0.601**	**0.508**	**0.214**	**0.322**	**0.657**	**0.275**
AS	**0.378**	**0.399**	**0.476**	**0.501**	**0.530**	**0.393**	**0.241**	**0.340**	**0.558**	**0.279**
SR	**0.294**	**0.346**	−0.093	**0.335**	**0.404**	**0.485**	**0.280**	**0.538**	**0.165**	**0.527**
AX	0.152	**0.401**	0.098	**0.479**	**0.365**	**0.433**	**0.224**	**0.374**	**0.285**	**0.367**
WB	**0.296**	**0.505**	0.185	**0.587**	**0.574**	**0.603**	**0.365**	**0.739**	**0.346**	**0.638**
SF	**0.652**	**0.547**	0.210	**0.537**	**0.621**	**0.645**	**0.232**	**0.514**	**0.602**	**0.463**
SS	**0.700**	**0.619**	**0.263**	**0.659**	**0.764**	**0.686**	**0.262**	**0.604**	**0.673**	**0.535**

Notes: The SRI scales were respiratory complaints (RC), physical functioning (PF), attendant symptoms and sleep (AS), social relationships (SR), anxiety (AX), psychosocial well-being (WB), social functioning (SF), and summary scale (SS). The SF-36 scales were physical functioning (PF), role physical (RP), body pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), mental health (MH), physical health component (PHC), and mental health component (MHC).

Significant correlations are shown in bold type; in light gray, outstanding results for each scale, excluding summary scales; in dark gray, summary scales of each questionnaire.

Table 3
Reliability of the Spanish SRI questionnaire

Scale	ICC (95% CI)	Cronbach alpha	ICQ (min−max)	ICS (min−max)
RC	0.901 (0.854−0.933)*	0.813	0.13−0.59	0.58−0.79
PF	0.960 (0.942−0.973)*	0.820	0.22−0.74	0.60−0.84
AS	0.910 (0.868−0.939)*	0.736	−0.01 to 0.58	0.46−0.72
SR	0.888 (0.834−0.924)*	0.629	−0.004 to 0.61	0.47−0.73
AX	0.837 (0.814−0.913)*	0.731	0.11−0.51	0.27−0.82
WB	0.907 (0.862−0.937)*	0.846	0.23−0.58	0.61−0.75
SF	0.924 (0.879−0.952)*	0.829	0.11−0.72	0.48−0.81
SS	0.952 (0.918−0.972)*	**0.932**	—	—

Abbreviations: ICC, intraclass correlation coefficient; 95% CI, 95% confidence interval; ICS, item correlation coefficient with its own scale; ICQ, item correlation coefficient with the rest of the questionnaire.
*$P < 0.001$.

The present study did not include tracheotomized patients to make it comparable to the original study [8]. Because HRQL is thought to be different in patients with noninvasive compared to invasive ventilation [5], patients who were tracheotomized were not included. However, it would be of interest to study HRQL in tracheotomized patients compared with nontracheotomized patients and to see if the SRI can discriminate between these two groups.

The questionnaire was practicable with items that were understandable and easy, and could be completed in about 10 minutes. The time to complete the questionnaire was shortened in the second visit, probably due to a training effect.

Factor analysis found 13 scales compared with the seven initial ones. There are at least three explanations for this finding. Firstly, the social items in the original questionnaire were divided into three different scales. SR refers to the relationship the patient has with people who are close to him or her; the WB scale is related to feelings the patient has during daily life situations; finally, the SF scale assesses the patient's capacity to participate in social activities. As a result, these social items were distributed differently among the social scales, and some negative social scales' items were ascribed to one of the AX scales. Secondly, the AS scale assessed information on many different symptoms and was found to be segregated into four different scales in our analysis. Similarly, dyspnea was further divided into two scales: one for the presence of respiratory symptoms in daily living and one for dyspnea in passive situations. These differences in item distribution are common after transcultural adaptation of HRQL questionnaires, or after administering the same questionnaire to different populations. For instance, Garratt et al. [16] and Ayuso-Mateos et al. [17] found five rather than eight scales in the SF-36 questionnaire. Similarly, Failde and Ramos [18] found the same eight scales, but with a different item distribution between scales. Finally, and more importantly, the methodology for the construction of the original questionnaire was done by a panel of experts, instead of factor analysis, to assure face validity [8]. It is possible that this different methodology may be responsible for the differences encountered in the item−scale distribution.

When analyzing the correlation matrix with the SF-36, the division of the social aspects of HRQL of the SRI into three different scales influenced the results. For example, the SRI SF correlated with three SF-36 scales (PF, vitality, and SF), the SRI WB was related to the SF-36 SF and mental health scales, and the best correlation for the SRI SR scale was mental health. The SRI AX scale was best correlated with the SF-36 general health scale indicating a relationship between these two general scales, because both scales may indicate general aspects of HRQL that affect patients' lives in many ways. As expected, the SRI PF scale correlated with the SF-36 PF and vitality scales. Scales directed toward symptoms correlated most with the SF-36 vitality and general health scales.

Although the questionnaire was reproducible when no intervention was performed, the sensitivity after clinical intervention was not measured in this study and should be evaluated in a prospective study [19]. Another quality-of-life issue is evaluating change in HRQL after the institution of HMV for the first time. Studies performed in COPD patients have had contradictory results in this regard, with some showing differences [6] and others not [20]. This may be because previously used instruments were not specifically developed for patients with severe respiratory insufficiency receiving HMV. Because disease-specific instruments have been postulated to be most appropriate for clinical trials with specific therapeutic interventions [21], the SRI may be more sensitive to changes in HRQL after the establishment of HMV. Therefore, it is important to assess the effect of initiating HMV on the HRQL using the SRI questionnaire.

In conclusion, the Spanish version of the SRI questionnaire has high psychometric properties which are similar to the original version. These psychometric properties make it applicable to the Spanish population receiving HMV.

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