RESEARCH ARTICLE

Validation of the Greek version of the Severe Respiratory Insufficiency questionnaire

Tsara V[1], Michailidis V[1], Perantoni E[1], Nena E[2], Moysiadis N[1], Windisch W[3], Steiropoulos P[4]

[1]Department of Pneumonology, "G. Papanikolaou" General Hospital, Thessaloniki, Greece
[2]Laboratory of Hygiene and Environmental Protection, Medical School, Democritus University of Thrace, Alexandroupolis, Greece
[3]Department of Pneumonology, Lung Centre Cologne, Kliniken der Stadt Köln gGmbH, University of Witten/Herdecke, Germany
[4]Department of Pneumonology, Medical School, Democritus University of Thrace, Alexandroupolis, Greece

Abstract

Background: The Severe Respiratory Insufficiency (SRI) questionnaire is a multidimensional, well-validated tool for the assessment of health-related quality of life (HRQL) in patients with severe chronic respiratory failure (CRF), due to a variety of underlying disorders. The aim of this study was to validate the SRI questionnaire in the Greek language (Gr-SRI).

Methods: Reliability and validity analyses were performed for the Gr-SRI using data of 136 consecutive patients with CRF, due to chronic obstructive pulmonary disease (COPD) or non-COPD respiratory diseases (kyphoscoliosis, obesity-hypoventilation, and post-tuberculosis sequelae). Sixty-three patients (46.3 %) were under long-term oxygen therapy (LTOT), while 73 (53.7 %) under long-term non-invasive mechanical ventilation at home (HMV), either with or without LTOT.

Results: Cronbach's alpha was high for the Summary Score of the SRI (0.86) showing high internal consistency, comparable to that of the original German version. The results of the principal component analysis on the SRI Summary Score produced a one-factor construct with a variance of 54 %, which confirmed a single Summary Score for the Greek SRI also. The highest and the lowest scores were detected in Respiratory Complaints and Physical Functioning subscales, respectively. The SRI was capable of discriminating COPD patients and non-COPD patients, with COPD patients having lower mean SRI scores, but no difference was observed between COPD patients under HMV or LTOT.

Conclusions: Greek SRI has high psychometric properties qualifying its use for HRQL assessment in patients with CRF. HIPPOKRATIA 2017, 21(4): 186-190.

Keywords: Chronic obstructive pulmonary disease, COPD, chronic respiratory failure, health-related quality of life, home mechanical ventilation, long term oxygen therapy, severe respiratory insufficiency questionnaire

Corresponding author: Paschalis Steiropoulos, MD, PhD, FCCP, Department of Pneumonology, Medical School, Democritus University of Thrace, 68100 Alexandroupolis, Greece, tel: +302551077377, fax: +302551352096, e-mail: pstirop@med.duth.gr

Introduction

In recent years, health-related quality of life (HRQL) questionnaires have gained increasing popularity for the evaluation of costs and benefits of medical treatment[1-3]. It is particularly important to evaluate HRQL in patients with chronic diseases because improved HRQL is one of the primary treatment targets in non-curable patients[1]. HRQL is based on different components of health status, including physical state, psychological well-being, social relations and functional capacities that are influenced by individual experiences, beliefs, expectations, and perceptions[1,4]. Questionnaires are commonly used for HRQL assessment in clinical trials. They are multidimensional tools, exploring various aspects of patient's life that may not be identified by other diagnostic procedures. Disease-specific questionnaires are more sensitive than general questionnaires to assess changes in HRQL and are, therefore, very appropriate for prospective clinical trials[1].

The Severe Respiratory Insufficiency (SRI) questionnaire is a new disease-specific and multidimensional HRQL measurement tool, which presents encouraging psychometric properties[5,6] and it was designed for patients with severe chronic respiratory failure (CRF) resulting from a broad spectrum of diseases leading to severe CRF.

The SRI was first designed to measure specific HRQL in various patients receiving home mechanical ventilation (HMV)[5]. It was also proved to be valid for chronic obstructive pulmonary disease (COPD) patients with severe CRF[6,7] or chronic hypercapnic failure[8]. The original German SRI questionnaire has already been translated in French, Turkish, Swedish, Polish[9-11], while the Spanish, English, Norwegian, Japanese, Chinese, and Portuguese versions have already been validated[12-18].

The aim of the present study was to validate the Greek version of SRI questionnaire in a sample of Greek patients with CRF.

Materials and methods

Patients

Consecutive patients with chronic respiratory failure either under long-term oxygen treatment (LTOT) or non-invasive HMV for at least six months, who were followed regularly as outpatients, were included. All participants were in a stable condition without any exacerbation or hospitalization during the preceding three months. Patients were divided into two groups: COPD and non-COPD patients [i.e., restrictive thoracic deformities, obesity hypoventilation syndrome, and post-tuberculosis (post-TB) sequelae]. All subjects underwent pulmonary function testing with a dry spirometer (Ganshorn LF8, Medizin Electronic, Niederlauer, Germany) and arterial blood sample analysis while breathing room air at rest.

The study protocol was approved by the Institutional Review Board for Human Studies of "G. Papanikolaou" General Hospital and was performed according to the ethical standards of the Declaration of Helsinki. Written informed consent was obtained from all participating subjects.

Methods

The SRI questionnaire covers 49 items divided into the following seven subscales: Respiratory Complaints (SRI-RC), Physical Functioning (SRI-PF), Attendant Symptoms and Sleep (SRI-AS), Social Relationships (SRI-SR), Anxiety (SRI-AX), Psychological Well-Being (SRI-WB), and Social Functioning (SRI-SF). These seven subscales can be summarised into one Summary Scale (SRI-SS). All items are rated in a five-point Likert-scale from "strongly agree" to "strongly disagree" in relation to the statements of the items, and are related to the patient's condition of the preceding week. For data evaluation, the values as obtained from the questionnaire are scaled from 0 to 100, with higher scores responding to better HRQL.

The original German SRI was translated into Greek by using the forward and back translation method. The translations and back-translations were carried out by four bilingual translators (two native German and two native Greek, respectively), each with extensive experience in the translation of scientific texts. All of them were asked not to translate concepts literally, but to use natural sounding equivalent expressions. The final Greek version of the SRI questionnaire was approved by the principal author of the original German SRI. After distribution, enrolled patients completed the translated questionnaire on their own in the presence of a trained nurse.

Statistical analysis

The calculations were performed with the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA), version 17. Data for continuous variables are presented as mean ± standard deviation (SD) values. Student's t-test was used for comparisons between groups in anthropometric, pulmonary function testing, and SRI mean scores. The Pearson correlation coefficients were calculated for the respiratory function variables and SRI scores. A p-value <0.05 was considered statistically significant.

Reliability of each subscale was calculated as internal consistency of response among the items assigned to each scale by Cronbach's alpha. Nunnaly[19] has indicated 0.7 to be an acceptable reliability coefficient, but lower thresholds are sometimes used in the literature. The validity of the construction was assessed by exploratory factor analysis (EFA) using Principal Component Analysis (PCA) with orthogonal rotation (varimax rotation) to examine the factor structure of the Greek version of SRI. It was used a minimum eigenvalue of 1.0 as the extraction criterion for factors, which explains an important amount of variability in the data. Communalities were fairly high, ranging from 0.387 to 0.659. A cut-off of 0.40 was used for factor loadings. Confirmation Factor Analysis (CFA) relies on several statistical tests to determine the adequate fitness of the model to the data. The Comparative Fit Index (CFI) is equal to the discrepancy function adjusted for the sample size, and ranges from 0 to 1; a larger value indicating a better model fit. An acceptable model fit is indicated by a CFI value of 0.90 or higher. In the model, the Root Mean Square Error of Approximation (RMSEA) is related to residual with its values ranging from 0 to 1; a smaller RMSEA value indicates a better model fit. An acceptable model fit is indicated by an RMSEA value of 0.06 or less. PCLOSE is a "p-value" for testing the null hypothesis of close fit (RMSEA <0.05). CMIN/df is the minimum value of the discrepancy function divided by degrees of freedom.

Results

Overall, 136 patients (94 males; 69.1 %), with a mean age of 68.3 ± 10.1 years completed the study. The mean body mass index (BMI) of the entire group was 33.7 ± 8.5 kg/m², while mean forced expiratory volume in the first second (FEV_1) and mean forced vital capacity (FVC) were 45.5 ± 20 % and 55.2 ± 19 % of the predicted values, respectively. In comparison to those receiving HMV -with or without concurrent use of LTOT- (n =73), patients receiving only LTOT (n =63) were significantly older (70.7 ± 9.7 vs 66.2 ± 10.2 years, p =0.012), with significantly lower BMI (mean ± SD respectively, 31.4 ± 7.9 vs 35.8 ± 8.6 kg/m², p =0.003).

COPD was the most prevalent cause of CRF (47.8 %). Regarding the remaining 71 non-COPD patients, CRF was attributed to kyphoscoliosis, obesity-hypoventilation, and post-TB sequelae (26.5 %, 16.2 %, and 9.5 % of the total sample, respectively). Demographic characteristics and pulmonary function test results in COPD and non-COPD patients are shown in Table 1. Forty-six COPD patients received LTOT and 19 received LTOT plus HMV. A significant difference was only observed between them in BMI (p =0.09) (Table 2).

Table 1: Demographic and pulmonary function testing characteristics of the 136 chronic obstructive pulmonary disease (COPD) and non-COPD patients.

	COPD	non-COPD
Number	65 (47.8 %)	71 (52.2 %)
Age (years)	70.9 ± 9.8	65.8 ± 9.8
BMI (kg/m^2)	31.2 ± 7.9	36.1 ± 8.6
FEV$_1$ (% predicted)	37.1 ± 16	54.2 ± 19
FVC (% predicted)	52.6 ± 18.8	57.9 ± 19.5
PaO$_2$ (mmHg)	55.6 ± 4.2	62.5 ± 4.6
PaCO$_2$ (mmHg)	42.3 ± 3.4	43.2 ± 3.6

Values are given as means ± standard deviation or number of patients (percentage in brackets), COPD: chronic obstructive pulmonary disease, BMI: body mass index, FEV_1: forced expiratory volume in the first second, FVC: forced vital capacity, PaO_2: oxygen partial pressure, $PaCO_2$: carbon dioxide partial pressure.

In the preliminary analysis for the validity construction a moderately high factorability-Bartlett's test was revealed ($p < 0.001$) while the overall value of the Kaiser-Meyer-Olkin test was 0.823. Cronbach's alpha was high for the SRI-SS with a value of 0.86, showing high internal consistency. Three of the sub-components exhibited Cronbach's alpha greater than 0.7, whereas the other four had lower scores, ranging between 0.461 and 0.622 (Table 3). The results of EFA analysis with PCA implementation showed that one of the subscales (SRI-AX) could be presented by one factor, two factors were extracted for five of the subscales (SRI-SF, SRI-RC, SRI-SR, SRI-PF, and SRI-AS) and finally, a three-factor solution came out for the remaining subscale (SRI-PW). For these new factors, the reproduced correlation matrix showed significant differences from the original correlation matrix proving that the extracted components were significantly different in variance compared to the original subscales. PCA on the SRI-SS produced a one-factor construct with a variance of 54 %, which validated the preexisting one-factor SRI-SS. Further investigation using CFA shows that five subscales (SRI-RC, SRI-PF, SRI-SF, SRI-AS, SRI-SR) could be represented by a two-factor model, one (SRI-AX) by one-factor and one (SRI-WB) using a three-factor model. Because of the observed correlation between their factors, SRI-RC, SRI-PF, SRI-WB, and SRI-SF multifactor models were rejected. SRI-AS showed a good fit both for two-factor and one-factor models, but SRI-SR showed the best fit with a two-factor model, due to negative correlation value for question 27, on the one-factor model for SR scale (Table 4).

Scores of the seven subscales and the SRI-SS for all patients are shown in Table 3. The lowest and the highest score were detected in the subscale SRI-PF and SRI-RC, respectively. A significant correlation was found between FEV_1 and the following subscales: SRI-RC ($r = 0.366$, $p < 0.001$), SRI-PF ($r = 0.180$, $p = 0.05$), SRI-AX ($r = 0.246$, $p = 0.007$), and SRI-SF ($r = 0.281$, $p = 0.002$). In patients under HMV, SRI-SS score was higher than that of the LTOT group. Higher scores were observed in SRI-RC (71.2 ± 24.0 vs 69.3 ± 19.8, respectively) and lower scores in SRI-PF (49.9 ± 24.9 vs 50.4 ± 20.0, respectively). No statistically significant differences in total score as well as in subscale scores were observed between these two groups of patients.

Table 2: Demographic and pulmonary function testing characteristics in chronic obstructive pulmonary disease patients under long term oxygen therapy (LTOT) and home mechanical ventilation (HMV).

	LTOT	LTOT+HMV	p
Number	46 (70.8 %)	19 (29.2 %)	
Age (years)	71.6 ± 9.3	69.1 ± 11.4	0.200
BMI (kg/m^2)	29.9 ± 7.4	34.6 ± 8.4	0.009
FEV$_1$ (% predicted)	38.0 ± 16.0	34.2 ± 17.7	0.105
FVC (% predicted)	54.5 ± 17.2	46.9 ± 22.9	0.079

Values are given as means ± standard deviation or number of patients (percentage in brackets), LTOT: long-term oxygen therapy, HMV: home mechanical ventilation, BMI: body mass index, FEV_1: forced expiratory volume in the first second, FVC: forced vital capacity.

In COPD patients, SRI-SS score was lower than that of non-COPD patients, without significant difference. The highest and the lowest scores for both groups were identified for the subscales SRI-RC (65.1 ± 23.0 vs 75.3 ± 21.0, $p = 0.009$) and SRI-PF (47.7 ± 23.0 vs 51.7 ± 21.5, $p = 0.305$) respectively. Significant differences were also observed in SRI-AX and SRI-SF score ($p = 0.05$) (Table 5). Especially for COPD patients, lower values were observed in all SRI scales with a significant difference in SRI-AX between the patients who received LTOT compared to patients under HMV but without a difference in SRI-SS score (59.8 ± 3.7 and 52.7 ± 22.2, respectively).

Discussion

The SRI questionnaire is a valuable tool for assessing reliably HRQL of patients with CRF in Greece. Indeed, internal consistency in the SRI-SS for the Greek SRI was high (Cronbach's alpha value at 0.86) and was comparable to that of the original German version. On the other hand, there was a different range of Cronbach's alpha value from the original SRI version, with values <0.7 in some scales. Three of the Greek SRI scales (SRI-RC, SRI-AX, SRI-SF) had a good consistency (Cronbach's alpha values higher than 0.7) as well, whereas SRI-PF, SRI-AS, SRI-SR, and SRI-WB scales produced lower values. Nevertheless, this does not compromise the integrity of the Greek SRI since the results are validated by the whole statistical analysis and similar results have been produced by other studies. Indeed, lower values than the German version have been reported in the Japanese version in SRI-AS[16], the Spanish in SRI-SR[12], the Norwegian and Portuguese in SRI-AS and SRI-SR scales[15,18]. Results of the PCA on the SRI-SS produced a one-factor construct, which validates the preexisting one-factor SRI-

Table 3: Greek Severe Respiratory Insufficiency questionnaire values in all, chronic obstructive pulmonary disease (COPD) and non-COPD patients.

Scale	All	COPD	non-COPD	p (COPD vs non-COPD)
Number	136	63	73	
RC	70.5 ± 22.0	65.1 ± 23.0	75.3 ± 21.0	0.009
PF	50.2 ± 22.6	47.7 ± 23.0	51.7 ± 21.5	0.305
AS	60.4 ± 17.3	59.6 ± 17.0	61.9 ± 17.8	0.388
SR	66.7 ± 21.4	65.0 ± 22.0	68.5 ± 20.5	0.358
AX	64.7 ± 25.4	60.4 ± 27.2	70.0 ± 22.7	0.05
PW	58.3 ± 17.5	57.8 ± 18.0	58.5 ± 16.6	0.983
SF	56.4 ± 22.7	52.4 ± 22.3	60.5 ± 22.0	0.05
SS	60.8 ± 15.8	57.9 ± 16.5	63.8 ± 14.3	0.05

Values are given as means ± standard deviation or number of patients, COPD: chronic obstructive pulmonary disease, AS: Attendant Symptoms/ Sleep, AX: anxiety, PF: Physical Functioning, PW: Physiological Well Being, RC: Respiratory Complaints, SF: Social Function, SR: Social Relations, SS: Summary Scale.

Table 4: Mean scores and reliability of each scale of the Greek Severe Respiratory Insufficiency questionnaire in all participants

Scale	Number (n)	Patients (n)	Mean scores	Standard deviation	Cronbach's alpha
RC	8 items	136	70.49	22.05	0.818
PF	6 items	136	50.24	22.67	0.622
AS	7 items	136	60.42	17.36	0.461
SR	6 items	136	66.72	21.42	0.581
AX	5 items	136	64.78	25.47	0.740
PW	9 items	136	58.31	17.54	0.590
SF	8 items	136	56.39	22.70	0.737
SS	7 scales	136	60.83	15.83	0.856

AS: Attendant Symptoms/Sleep, AX: anxiety, PF: Physical Functioning, PW: Physiological Well Being, RC: Respiratory Complaints, SF: Social Function, SR: Social Relations, SS: Summary Scale.

Table 5: Confirmatory factor analysis in the Greek Severe Respiratory Insufficiency questionnaire scales in all patients

	RC	PF	AS		SR		AX	WB	SF
Correlation	0.45	1.08	N/A	-0.10	N/A	0.08	NA	-0.44	0.31
CFI (>0.8)	0.954	0.649	0.864	1	0.603	1	0.954	0.907	0.953
P for RMSEA (<0.08)	0.08	0.199	0.067	0.00	0.202	0.00	0.093	0.087	0.067
P CLOSE (>0.05)	0.113	0.00	0.266	0.731	0.00	0.693	0.146	0.047	0.244
CMIN/DF (<5)	1.858	6.371	1.602	0.994	6.506	0.949	2.174	2.02	1.602
FACTORS	2- Factor	2- Factor	1- Factor	2- Factor	1- Factor	2- Factor	1- Factor	3- Factor	2- Factor

CFI: Comparative Fit Index, RMSEA: Root Mean Square Error of Approximation, PCLOSE: a "p value" for testing the null hypothesis of close fit, CMIN/DF: the minimum value of the discrepancy function divided by degrees of freedom, AS: Attendant Symptoms/Sleep, AX: anxiety, PF: Physical Functioning, PW: Physiological Well Being, RC: Respiratory Complaints, SF: Social Function, SR: Social Relations.

SS. In addition, CFA showed that the one-factor model could be accepted for the six of the seven subscales except for SRI-SR, which showed a clear two-factor model fit. Since the one-factor model has been verified in various other studies, it can be assumed that this problem can be solved by increasing the number of cases. This will presumably also increase Cronbach's alpha in the four subgroups of the questionnaire.

Our results indicate that patients with severe CRF due to obstructive or restrictive lung diseases have poor HRQL, as expressed by the low SRI-SS. Interestingly, COPD patients report lower scores than non-COPD patients in many SRI subscales. This is in accordance with the observation by Windisch et al[5] during the development and validation of the original SRI in German. Budweiser et al[8] have also found that the SRI-SS among patients with chronic hypercapnic respiratory failure of different etiologies under HMV was low while the HRQL was more impaired in COPD patients. Anxiety and respiratory complaints were more evident in COPD patients than in non-COPD patients. Self-reported respiratory symptoms are common in COPD patients, with reported dyspnea being associated with poor HRQL in Greek COPD patients with CRF under LTOT, as assessed by the generic SF-36 questionnaire[20]. Moreover, COPD patients with HRF under LTOT reveal a statistically significant difference in SRI-AX (p =0.027) and lower values in SRI-PF, SRI-AS, SRI-SR, and SRI-SF than COPD patient under HMV. These observations are in accordance with those reported recently in a population of COPD patients under LTOT or HMV plus LTOT[21]. The authors pointed out the potential benefit of HMV in COPD patients as showed by SRI values. In general, the SRI-SS was lower in Greek COPD patients in comparison to COPD patients in other countries although there were some differences in the subscales scores.

The present study has some limitations; for example, the comparison of the SRI results to another generic questionnaire, which could possibly improve the validity strength, was not performed. On the other hand, all included patients presented common pathogenesis of CRF in whom HMV is generally acceptable as therapy. The validity criterion could be strengthened by comparing with other chronic disorders with respiratory distress. Another drawback might be the lack of a special cultural adaptation of the final Greek translation of the questionnaire. However, this was not considered necessary, since concepts were not translated literally, but the translators used natural sounding equivalent expressions.

In conclusion, the Greek version of SRI can be considered equivalent to the original questionnaire and easily reproducible in patients with severe CRF. Therefore, this questionnaire qualifies for use in scientific trials on HRQL assessment in Greek-speaking people and probably can be used to evaluate the potential effects of more recent drugs[22] or other therapeutic modalities (e.g., CPAP) on HRQL of patients with CRF. In this context, the present study adds to the current understanding that SRI is a well- established HRQL assessment tool for a broad spectrum of patients with CRF, despite existing cultural and social differences in Europe.

Conflicts of interest

The authors state that there is no conflict of interest.

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