Psychometric Validation of the Severe Respiratory Insufficiency Quality of Life Questionnaire for the Chilean Adult Population Under Noninvasive Home Mechanical Ventilation

Marianela Andrade A.
Ministry of Health
Monica Antolini T.
Ministry of Health
Krishnna Canales H.
Ministry of Health
Cesar Maquilon O. (cmaquilon@davila.cl)
Clínica Dávila
Mauricio Fuentes A.
Escuela de Salud Pública, Universidad de Chile
Marinella Mazzei P.
Escuela de Salud Pública, Universidad de Chile

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Abstract

Introduction: Noninvasive home mechanical ventilation (NIHMV) has an impact on the health-related quality of life of patients with chronic global respiratory failure (CGRF) of different causes. There are generic and specific questionnaires for various respiratory diseases, and recently, in 2003, a patient-specific questionnaire was developed for NIHMV, called the Severe Respiratory Insufficiency (SRI) questionnaire, which has been shown to be reproducible and reliable and has been validated in several languages.

Objective: Validate the Chilean version of the SRI questionnaire (IRS-cl) in adults with CGRF who use NIHMV.

Methods: Cross-sectional study with non-probabilistic convenience sampling of stable patients from five regions of Chile. The IRS-cl and SF-36 (gold standard) questionnaires were applied, and demographic and ventilatory data were collected. Reliability was analyzed using Cronbach's alpha and intraclass correlation (test-retest). Construct validity was tested using exploratory factor analysis (principal component extraction and equimax orthogonal rotation) and hypothesis testing (Mann-Whitney test). Convergent criterion validity was tested using Spearman's rho.

Results: The sample comprised 248 patients, 132 of whom were women (53.2%), with a median age of 62±17.5 years. There was a predominance of older adults, and 40% had a low education level. The completion time of the questionnaire was 18.8 ± 9.1 minutes (viable), and 100% of the items were answered. The questionnaire was self-applied by 46.8% of the sample. The IRS-cl showed very good overall reliability (0.95) and by scales (>0.7). It also showed a good correlation with the SF-36, with equivalent scales, a rotated matrix with 8 factors and hypotheses that explain the underlying constructs.

Conclusions: The IRS-cl has good psychometric properties. It is feasible, valid and reliable for application to evaluate CGRF of various causes. It was found to be sensitive to assess the characteristics of the local population.

Introduction

In Chile, national health surveys conducted in 2003, 2010 and 2017 showed that over the last three decades, the prevalence of obesity and smoking has increased significantly [1, 2, 3]. This has led to the development of functional respiratory disorders in adults who may eventually develop COPD and obesity hypoventilation syndrome (OHS) [4, 5], pathologies that are added to the list of diseases that benefit from noninvasive home mechanical ventilation (NIHMV), which also include neuromuscular diseases and kyphoscoliosis. These patients represent a serious public health problem due to frequent hospitalizations and the consumption of health resources.

NIHMV has an impact on the health-related quality of life (HRQL) of these patients, and although there are generic questionnaires that can be applied to them, such as the Sickness Impact Profile (SIP), Medical Outcome Study (MOS), and 36-item Short-form Health Survey (SF-36), or specific questionnaires for the most prevalent respiratory diseases, such as chronic obstructive pulmonary disease (COPD) – St. George's Respiratory Questionnaire (SGRQ), Chronic Respiratory Disease Questionnaire (CRDQ), and London Chest Activity Daily Living (LCADL) [6] – these questionnaires are not sensitive for the specific group of patients on NIHMV.

The Severe Respiratory Insufficiency (SRI) questionnaire [7], developed in Germany in 2003, responds to the need to monitor changes in HRQL in adults with NIHMV. It was developed with a solid methodological design and has good psychometric properties. It has been translated and validated in different languages in European and Asian countries as part of the SRI Project [8].

Chile has had a federal home mechanical ventilation program for children since 2006 and one for adults since 2008. However, the demand is growing, and therefore, it is pertinent to validate the SRI instrument for Chile in order to avoid the lack of equivalence when using an external version (SRI Spain) [9], improve the analysis of results and collaborate in the development of health objectives.

Our working group previously performed the translation and cultural adaptation of the SRI questionnaire to Chilean Spanish, following the translation/back-translation method [10, 11, 12, 13], obtaining an equivalent version to the original, called IRS-cl. (Additional file 1. Semantic validation of the SRI quality of life questionnarie 2021 Articulo Protocolo IRS 1.0.docx)

The present study will evaluate the psychometric properties (validity and reliability) of the IRS-cl as the first experience in Latin America.

General objective

Obtain a specific HRQL questionnaire for the Chilean population of adults with chronic global respiratory failure (CGRF) on NIHMV through the psychometric validation of the Severe Respiratory Insufficiency (SRI) questionnaire (2).

Specific objectives

1. Perform the reliability analysis of the IRS-cl
2. Evaluate the construct validity of the IRS-cl questionnaire.

Methods

Study design and sample

This was a cross-sectional study with non-probabilistic convenience sampling of patients older than 20 years with CGRF on NIHMV belonging to the AVNIA Program of the Chilean Ministry of Health (MINSAL, for its acronym in Spanish) from five regions of the country. Patients with cognitive impairment that prevented understanding the instructions, patients experiencing cardiorespiratory exacerbation and users of invasive ventilation or continuous positive airway pressure (CPAP) (SRI not validated for them) were excluded.

A sample size of at least 245 patients was estimated for an adequate factor analysis (5 patients for each item of the instrument) [14, 15, 16, 17]. The study was conducted by the School of Public Health of the University of Chile with the authorization of the original author of the instrument.

The field work was supervised by a central coordinator and was carried out in the patients' homes by a team of interviewers (nurses) trained for the activity, who were impartial and tasked with obtaining good quality records. Two questionnaires were administered on the same day: the Chilean SRI and the SF-36 v2, and their completion time was recorded. Sociodemographic and clinical data were also collected.

The study was approved by the ethics committee of the North Metropolitan Health Service, an informed consent was signed by all participants, and the data obtained were kept confidential by the principal investigator.

Characteristics of the SRI Instrument

The original SRI [7] was the first questionnaire specific for CGRF and was validated through a multicenter study with 226 patients. It has 49 items divided into seven dimensions (subscales): Respiratory Complaints (RC), 8 items; Physical Functioning (PF), 6 items; Attendant Symptoms and Sleep (AS), 7 items; Social Relationships (SR), 6 items; Anxiety (AX), 5 items; Psychosocial Well-Being (WB), 9 items; and Social Functioning (SF), 8 items. It is scored on a five-point Likert scale. The final score, called the summary scale, is obtained by recording the questionnaire with the items scored in the same direction and calculating the mean of the seven dimensions. The score ranges from 0 to 100, and high scores indicate good quality of life.

The IRS-cl was translated and culturally adapted, had the same structure and subscales, and did not require removal of items.

Statistical analysis

Descriptive

A sociodemographic analysis of the sample and description of the items and dimensions were performed by calculating measures of central tendency and dispersion. The statistical software SPSS version 21 was used.

Reliability

Reliability was evaluated using Cronbach's alpha [14, 15], measuring the correlation of each item with the total score of the questionnaire and of each item with the total score of its scale, expecting to obtain coefficients > 0.70 [11, 12]. In addition, the test-retest reliability was evaluated by applying the same IRS-cl at two different times (baseline and 7–10 days later) to a subgroup of the sample comprising 20 patients, calculating the intraclass correlation coefficient (ICC), expecting to obtain ICC > 0.8 with a confidence interval (CI) of 95%.

Construct validity

To evaluate whether the different items of the IRS-cl adequately represented the dimensions of the underlying theoretical construct, two analyses were performed: i) exploratory factor analysis (EFA) and ii) simple hypothesis testing.

I) In the EFA, the following measures of sample adequacy were assessed: Kaiser-Meyer-Olkin (KMO), expecting an adequate value ≥ 0.70; Bartlett's test of sphericity; and principal components extraction, with the Kaiser rule stating that all factors with eigenvalues > 1 should be retained [21, 22]. To facilitate interpretation, varimax orthogonal rotation was applied, and in the face of difficulty in interpretation, a second analysis was performed with equimax orthogonal rotation to simplify the factors and items [21, 22, 23, 24].
II) The hypotheses proposed were based on the fact that HRQL is differently affected according to the underlying disease [7, 9]. The five are as follows: i) Patients with COPD have a lower score on the Respiratory Complaints (RC) dimension than patients without COPD; ii) Patients with respiratory failure of obstructive origin have more respiratory complaints (RC) than those with respiratory failure of restrictive origin; iii) Patients with COPD are more affected by anxiety (AX) than patients without COPD; iv) Patients with neuromuscular disease have lower scores on the Physical Functioning (PF) scale than patients with non-neuromuscular disease; and v) Patients who are connected more hours a day to NIMV have worse quality of life. The Mann-Whitney test (i-iv) and Spearman's correlation (v) were applied.

Criterion validity

The IRS-cl was compared with the generic questionnaire SF-36 v2 (gold standard in HRQL and validated in Chile) as an external criterion to evaluate convergent validity [25, 26]. The SF-36 has 36 items distributed across eight scales: Physical Functioning, Physical Role Functioning, Bodily Pain, General Health Perceptions, Vitality, Social Role Functioning, Emotional Role Functioning and Mental Health. It was used in the original and European validations of the SRI, correlating its results according to the equivalent subscales, using Spearman's rho correlation coefficient [10, 16]. High correlation was expected between the homonymous and conceptually related dimensions, and low correlation was expected for the unrelated dimensions (e.g., Bodily Pain versus Attendant Symptoms and Sleep).

Results

The IRS-cl and SF-36 questionnaires were administered to 268 patients, all with CGRF in stable phase. Twenty patients were excluded for not completing the IRS-cl, 19 for not answering item #31, " My marriage/relationship is suffering because of my illness", corresponding to patients without a partner. Finally, the valid sample with 100% of the items answered comprised 248 patients, of whom 132 were women (53.2%), with median age of 62 ± 17.5 years, age range of 20 and 88 years, thus predominantly older adults. A total of 40% of the sample had a low educational level (incomplete primary education, 36%; no schooling, 4.0%), most of whom were women.

A total of 51% of the sample was in a relationship (48% married, 3% cohabitating). Regarding occupation, 22.2% were retired due to old age and 24.2% due to disability, followed by 30.6% who were homemakers.

The sample was grouped into eight diagnostic groups found in the MINSAL databases: 1) COPD 2) COPD and obstructive sleep apnea-hypopnea syndrome (COPD-OSA); 3) Tuberculosis (TB) sequelae; 4) Non-cystic fibrosis bronchiectasis (non-CF BE); 5)

Neuromuscular diseases; 6) Kyphoscoliosis (KYPH); 7) Obesity hypoventilation syndrome (OHS) and 8) Miscellaneous disorders (Table 2).

A total of 68.5% (n = 170) of the patients used continuous oxygen therapy, 34.7% of them 24 hours a day. Regarding smoking, 61.3% reported stopping smoking (for at least 6 months), and 2.4% reported active smoking.

Table 1
Distribution by diagnosis, age, sex and times on home ventilation

Diagnostic groups	Age in years (median ± SD)	Sex male/female	Months on NIHMV (mean ± SD)	Use of NIHMV (hr/day)
COPD	71 ± 8.2	33/33	29.7 ± 25.6	7.4 ± 2.3
COPD-OSA	67 ± 10.7	18/16	41.4 ± 25.0	7.5 ± 1.7
TB sequelae	67 ± 8.7	3/5	44.5 ± 27.1	8.3 ± 1.4
Non-CF bronchiectasis	46 ± 15.1	11/7	31.0 ± 22.1	8.4 ± 2.0
Neuromuscular	24 ± 15.2	17/11	55.1 ± 42.6	8.1 ± 3.2
Kyphoscoliosis	54 ± 20.8	15/12	39.0 ± 27.1	8.4 ± 3.9
OHS	61 ± 11.6	18/42	37.2 ± 25.9	7.0 ± 1.4
Miscellaneous	59 ± 21.6	1/6	30.0 ± 16.1	7.8 ± 1.1

The completion time of the IRS-cl was 18.8 ± 9.1 minutes, which was considered viable. It was self-administered in 46.8% (n = 116) of the patients, and 53.2% required interviewer assistance, reporting difficulty in reading and writing due to low educational level, severe dyspnea, essential hand tremor and visual difficulty. In these cases, the interviewer used an enlarged printed Likert scale as an aid for the patients to indicate their response.

Analysis of the instrument items

The distribution of the raw responses showed that the IRS-cl items were heterogeneous and had discriminatory capacity (34). The item-scale correlations between the 49 items and their theoretical dimensions were significant and direct (positive), with rho values > 0.40, being higher than the correlations with other scales (Table 2).

Table 2
Summary of item-scale correlations of the Chilean SRI using Spearman´s correlation coefficient

Chilean SRI Dimensions	Number of items	Correlation range of the items with their theoretical scale	Correlation range of the items with other scales
Respiratory Complaints (RC)	8	0.59–0.84*	0.20–0.57
Physical Functioning (PF)	6	0.50–0.79*	0.02–0.68
Attendant Symptoms and Sleep (AS)	7	0.45–0.69*	0.04–0.58
Social Relationships (SR)	6	0.52–0.74*	0.09–0.63
Anxiety (Ax)	5	0.61–0.75*	0.11–0.55
Psychosocial Well-Being (WB)	9	0.49–0.74*	0.16–0.56
Social Functioning (SF)	8	0.46–0.74*	0.19–0.64
*p-value < 0.01. Range expressed as minimum - maximum			

Reliability

The IRS-cl presented very good overall reliability (0.95), higher than the original SRI (0.89). Its seven theoretical dimensions showed good internal consistency of between 0.71 and 0.84. The lowest alpha was obtained for Attendant Symptoms and Sleep, and the highest for Respiratory Complaints. The alphas by dimension were similar between the IRS-cl and the original SRI, indicating that both measure their constructs in a similar way. The ICC was very good (> 0.8) in the seven dimensions, indicating excellent agreement and temporal stability of the instrument at both times (Table 3). At this stage, it was not indicated to change or exclude any item from the theoretical dimensions.

Table 3
Analysis of internal consistency according to subscale by the intraclass correlation coefficient (ICC) and Cronbach's alpha.

SRI Dimensions	Number of items	ICC (95% CI) SRI Chile	Cronbach's α SRI Chile	Cronbach's α SRI Germany	Cronbach's α SRI Spain
Respiratory Complaints (RC)	8	0.84 (0.63–0.94)	0.84	0.83	0.81
Physical Functioning (PF)	6	0.94 (0.85–0.98)	0.73	0.80	0.82
Attendant Symptoms and Sleep (AS)	7	0.91 (0.78–0.96)	0.71	0.76	0.73
Social Relationships (SR)	6	0.92 (0.80–0.97)	0.72	0.73	0.63
Anxiety (AX)	5	0.95 (0.87–0.98)	0.78	0.79	0.73
Psychosocial Well-Being (WB)	9	0.93 (0.83–0.97)	0.82	0.89	0.85
Social Functioning (SF)	8	0.91 (0.77–0.96)	0.80	0.84	0.82
SRI Global (Summary Scale)	49	0.97 (0.92–0.99)	0.95	0.89	0.93

Construct validity assessment by exploratory factor analysis

The table of extracted commonalities (common variance) according to the Kaiser criterion favored a solution of 12 factors explaining 64.5% of the variance. However, this analysis suggested, according to the percentage of variance criterion, a model with only 2 factors but this is not convenient because of their low significance in the weightings (36.31%), and so the use of the eigenvalue > 1.0 criterion was prioritized.

To clarify the structure of the factors in the matrix and optimize the differentiation of the items, orthogonal rotations were applied. First, varimax was used, but it did not achieve a completely satisfactory model when extracting 6 to 10 factors. It then decided to use equimax to simplify the factors, finding a solution of 8 factors explaining 55.58% of the total variance, which satisfactorily simplified the model. The factors showed good correlation and number of items; conceptually, they demonstrated that all the constructs of the original instrument are present and that they are relevant for patients with CGRF (Fig. 2). Although the factors found do not conform identically to the dimensions of the theoretical instrument, their organization in the Chilean sample is consistent.

Modifying the structure of the Chilean SRI subscales based on the EFA was rejected, since when performing the reliability analysis of the new factors, the Cronbach's alpha values decreased with respect to the original 7-scale structure.

Construct validity assessment by hypothesis testing

Four out of the five hypotheses were consistent with the results. The worst scores (expressed as medians) on the RC dimension were observed for COPD = 53 vs. Neuromuscular disease = 75 ($p < 0.001$), vs. Kyphoscoliosis = 69 ($p < 0.003$) and vs. OHS = 69 ($p < 0.002$). In addition, on the RC dimension, the group of patients with obstructive disease (n = 129) scored worse than the group with restrictive disease, 53 vs. 69 ($p < 0.001$). Additionally, in the group of patients with obstructive disease, there was not significant difference in scores on the RC among the diagnostic subgroups, as expected: COPD = 53 vs. TB = 44 ($p = 0.65$) and vs. BE = 58 ($p = 0.50$).

On the AX dimension, COPD = 40 was more affected than Neuromuscular disease = 68 ($p < 0.001$) and Kyphoscoliosis = 55 ($p < 0.03$). Conversely, there was no difference in the AX subscale score in the group of patients with obstructive disease: COPD = 40 vs TB = 35 ($p = 0.99$) vs BE = 45 ($p = 0.80$).

Regarding the PF dimension, the score of patients with Neuromuscular vs. Non neuromuscular disease showed no significant difference ($p = 0.60$), contrary to expectations. This may be explained by the severe deterioration in lung function of the sample (higher of $PaCO_2$ levels) at the time of start of NIHMV compared to European patients.

The correlation between hours of ventilation/day and quality of life was negative and significant only for the PF dimension (rho = -152 and $p = 0.05$), and according to diagnostic group, it was only significant for COPD (rho = -0.198 $p = 0.024$).

Criterion or convergent validity

According to Table 4, the IRS-cl showed positive and significant ($p < 0.01$) correlations with the SF-36 v2 in its related dimensions, which were considered good. The strongest correlations were observed for PF, WB and SF.

Table 4
Convergent validity between the dimensions of the Chilean SRI questionnaire and general quality of life measured by the SF-36 v2 (n = 248).

Chilean SRI Questionnaire	SF-36 v2 Questionnaire							
	Physical Functioning	Physical Role Functioning	Bodily Pain	General Health Perception	Vitality	Social Role Functioning	Emotional Role Functioning	Mental Health
Respiratory Complaints	0.39	**0.50**	0.29	**0.57**	0.44	0.46	0.44	0.42
Physical Functioning	0.77	0.67	0.30	**0.55**	**0.56**	**0.55**	**0.57**	**0.53**
Attendant Symptoms and Sleep	0.35	0.44	0.35	0.46	0.44	0.38	0.43	0.49
Social Relationships	0.40	0.47	0.22	0.40	**0.55**	0.48	0.49	**0.57**
Anxiety	0.33	**0.50**	0.27	**0.56**	0.45	0.42	0.43	0.43
Psychosocial Well-Being	0.45	**0.55**	0.31	0.64	0.70	**0.57**	**0.59**	0.77
Social Functioning	**0.53**	0.61	0.33	0.61	0.62	**0.59**	**0.59**	**0.58**
Total SRI Summary Scale	0.57	0.67	0.37	0.69	0.68	0.62	0.64	0.67

Spearman's rho correlation coefficient.

The correlation is significant at the 0.01 level (one-tailed) for all dimensions.

Correlations > 0.50 are bolded, and the highest correlations (> 0.60) are bolded and underlined.

General results of the Chilean version of the SRI

The studied sample showed that patients with CGRF on NIHMV perceived their HRQL as fair, with a summary scale score of 57%, with greater deterioration in HRQL observed in women (51%).

The IRS-cl dimensions with the worst score were Anxiety with 45% and Physical Functioning with 50% and those with the best score were Social Relationships with 65% and Respiratory Complaints with 63%. In the seven dimensions, women presented a worse perception of HRQL than men (Fig. 3).

Table 5. Results of the Chilean SRI according to diagnostic group and instrument dimension

	Obstructive				Restrictive			Miscellaneous	All DG
SRI Dimensions	COPD	COPD-OSA	TB sequelae	Non-CF BE	Neuro musc.	Kyphoscoliosis	OHS		
Respiratory Complaints	0.50	0.59	0.44	0.58	0.75	0.69	0.69	0.72	**0.63**
Physical Functioning	0.38	0.58	0.38	0.56	0.46	0.63	0.54	0.42	**0.50**
Attendant Symptoms and Sleep	0.46	0.50	0.50	0.63	0.66	0.64	0.61	0.57	**0.57**
Social Relationships	0.58	0.58	0.77	0.67	0.83	0.67	0.63	0.67	**0.65**
Anxiety	0.40	0.48	0.35	0.45	0.68	0.55	0.40	0.70	**0.45**
Psychosocial Well-Being	0.53	0.59	0.57	0.55	0.64	0.58	0.55	0.61	**0.56**
Social Functioning	0.38	0.55	0.49	0.53	0.74	0.63	0.53	0.69	**0.53**
Total SRI Summary Scale	**0.48**	**0.56**	**0.48**	**0.57**	**0.66**	**0.64**	**0.57**	**0.63**	**0.57**

Results expressed as the median. Legend: COPD: chronic obstructive pulmonary disease; OSA: obstructive sleep apnea; TB: pulmonary tuberculosis; Non-CF BE: Non-Cystic Fibrosis Bronchiectasis; Neuromusc.: neuromuscular disease; OHS: hypoventilation obesity syndrome. DG: diagnostic groups.

Discussion

The present protocol has as strengths the application of the questionnaires by professionals in person at the patients' homes. There were no missing items (100% response), unlike when questionnaires are sent by correspondence to patients (28).

The Chilean sample (n = 248) was larger than the original German sample (n = 226) (7) and other European samples (SRI Spanish, n = 115; British n = 152; Portuguese, n = 93) (9,27,28), strengthening the factor analysis. A portion of the respondents in the present sample was socially vulnerable, as expressed by their low education level, predominance of older age and greater percentage of work disability, parameters that indicate further deterioration in health status compared to the Spanish group (9,29).

The main difference between the IRS-cl and the Spanish SRI lies in the Likert scale, which uses "totally disagree/totally agree" instead of "totally false/totally true", in addition to including two local adaptations: an enlarged visual Likert scale for patients requiring assistance and read by the interviewer (approved in the semantic validation), and increased font size of the text (from size 10 to 14). The Chilean sample presented a lower percentage of self-administered tests relative to the total patients surveyed (46.8%; 116 of 248) compared to the Spanish sample (54%; 62 of 115) and the German sample (97%; 219 of 226), that is, the Chilean patients required more assistance from the interviewer.

The IRS-cl showed good psychometric properties through good levels of internal consistency in its seven dimensions and very good temporal stability in the retest (Table 3).

The construct validity assessed by EFA presented very different results from the German SRI. In the latter, 59.8% of the total variance was explained a single factor, thus analysis was not continued, and orthogonal rotation was not performed, ultimately selecting a single-factor model with a single summary scale and seven theoretical dimensions developed by the expert panel (2). The Spanish study, like the Chilean study, did not find in its sample a single-factor model, but rather extracted factors through orthogonal rotations that explained the model.

The Chilean study group rejected modifying the final structure of the questionnaire; that is, the seven original theoretical scales were not changed to eight according to the equimax rotation to avoid decreasing the internal consistency (alpha).

Analyzing the hypotheses, one of the most relevant findings in the Chilean sample is that patients with COPD did not present the worst scores on the Respiratory Complaints or Anxiety dimensions (as postulated by the original SRI) but rather the patients

with TB sequelae (Table 5). This is explained by the level of severity of these patients, who in prior survival analyses had the worst survival since admission to the NIHMV AVNIA program.

Another finding was that the COPD group did not show a significant difference in Anxiety versus the OHS group (p = 0.53), differing from the German or Spanish samples. This difference may lie in underlying psychopathological disorders (depression and anxiety) associated with extreme obesity rather than having a relationship with deterioration in lung capacity.

Additionally, there was no significant difference in Physical Functioning between patients with neuromuscular and non-neuromuscular disease. This is likely related to the pulmonary and functional capacity characteristics of the Chilean patients, who showed greater deterioration than European groups, given the delayed access to ventilatory treatment, which affected the Physical Functioning scores, which were similar between patients with neuromuscular and non-neuromuscular diseases.

Last, in the total sample, there was no significant correlation between hours/day of ventilation and the total SRI score (summary scale). Differences were only found when breaking down the HRQL by dimension, and only Physical Functioning had a significant and inverse correlation and was affected by use > 9 hours/day, with no significant correlation observed in the other six dimensions. This result suggests that patients in the Chilean sample are very similarly affected in the Psychosocial (AX, SF, SR and WB) and Symptoms (RC, AS) dimensions with respect to the number of hours connected to the ventilator.

The analysis of psychometric properties did not eliminate items or modify the theoretical dimensions.

Conclusion

Evaluating HRQL is essential to monitor public and private health programs that provide NIHMV benefits at the national level.

The Chilean version of the Severe Respiratory Failure (SRI) questionnaire has good psychometric properties. It is a viable, valid and reliable instrument to be applied in adults (>20 years old) with CGRF of various causes and was found to be sensitive to assess the underlying characteristics of the local population.

The present study conforms to international validation standards and, similar to the original instrument, is not designed to measure HRQL in subjects under invasive mechanical ventilation (tracheostomized).

The research group hopes to contribute to the study and treatment of patients with respiratory failure at the national level and collaborate in questionnaire validation in other Latin American countries with NIHMV programs.

Abbreviations

NIHMV: Noninvasive home mechanical ventilation; CGRF: chronic global respiratory failure; SRI: Severe Respiratory Insufficiency questionnaire.

Declarations

Acknowledgments

Not applicable

Authors' Contributions

The lead author was MAA, who contributed substantially with study conception and design, data collection and analysis. MFA, and MMP, contributed to the development of the Gantt chart and to the selection and application of the statistical tests. MAT, CMO, and KCH collaborated with the published information, study design, data analysis and writing of the final manuscript version. All authors approved the final version of the manuscript, especially regarding the veracity and integrity of each of the phases of this study.

Other contributions: We thank all the nurses and physiotherapists of the national Adult Home Ventilation Assistance Program (AVNIA) of the MINSAL for their excellent collaboration in the application and compliance with the work protocol.

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Availability of date and materials

The datasets generated and /or analyzed during the current study are not publicly available due to the ethical standards established by the law of duties and rights of patients Nº 20584 promulgated in 2012 by the Chilean State but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The study was approved by the research ethics committee of the North Metropolitan Health Service Santiago, Chile (Nº 004/2016). Participation was voluntary and informed written consent was obtained from all participants or their legal representatives. All procedures performed involving human participants were in accordance with the ethical standards established by the law of duties and rights of patients Nº 20584 promulgated in 2012 by the Chilean State and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interest

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Figures

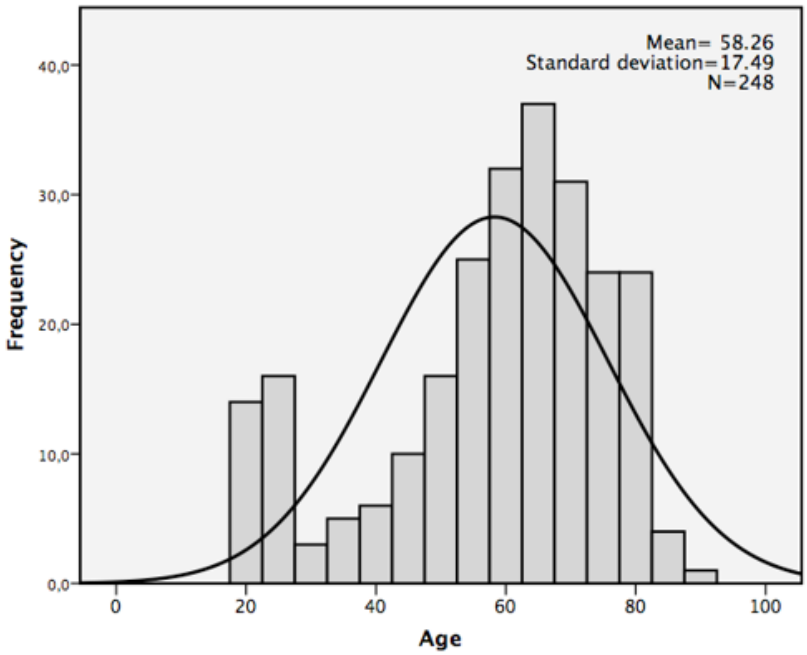

Figure 1

Distribution graph of the sample by age and descriptive statistics

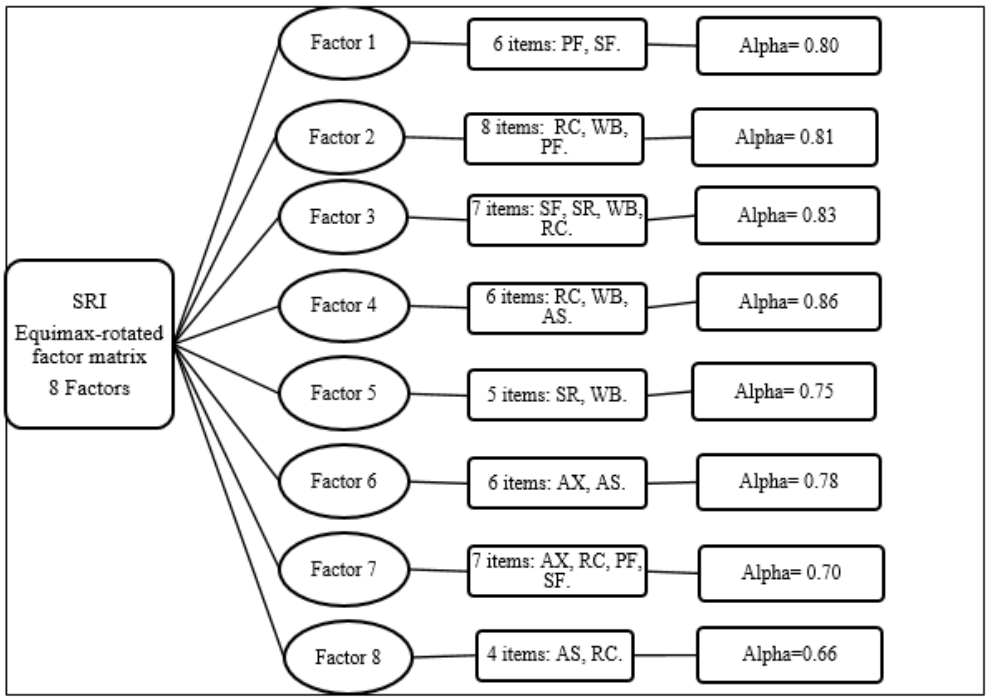

Figure 2

Schematization of the factors extracted from the IRS-cl with equimax orthogonal rotation The SR dimensions are presented: Respiratory Symptoms; FF: Physical function; SS: Accompanying symptoms and sleep; SR: Social relations; AX: Anxiety, BP: Psychosocial Well-being; FS: Social function.

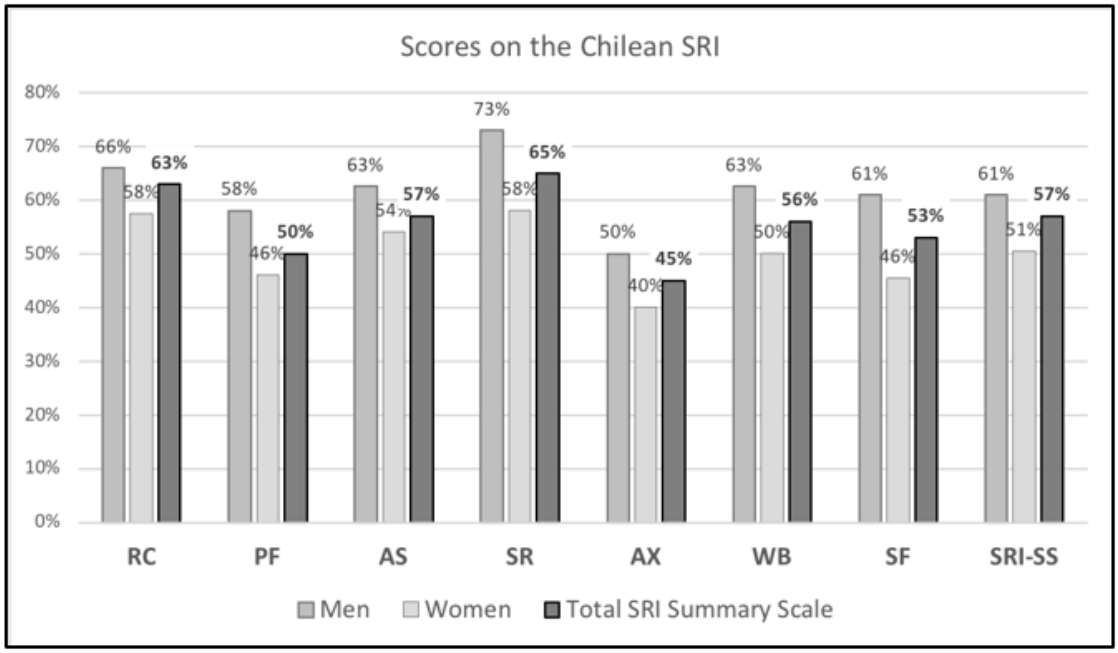

Figure 3

Scores on the Chilean SRI by dimension and sex (n = 248). The scores are expressed as percentage. Legend: RC: Respiratory Complaints; PF: Physical Functioning; AS: Attendant Symptoms and Sleep; SR: Social Relationships; AX: Anxiety; WB: Psychosocial Well-being; SF: Social Functioning

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- BMCSemanticValidationoftheSevereRespiratoryInsufficiency.docx
- HOMEMECHANICALVENTILATIONTECHNICALSTANDARDversions20082012and2013ANDINFORMEDCONSENTCHILE.docx