ORIGINAL ARTICLE

Validation of the Polish version of Severe Respiratory Insufficiency Questionnaire

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KEY WORDS

chronic respiratory failure, quality of life, Severe Respiratory Insufficiency Questionnaire, translation, validation

ABSTRACT

INTRODUCTION Improvement in the quality of life (QoL) is an essential outcome in patients with chronic respiratory failure (CRF). However, its reliable and comparative assessment is difficult in this highly heterogeneous group of patients. Severe Respiratory Insufficiency Questionnaire (SRI) has shown to have high psychometric properties to measure specific health-related QoL in patients with CRF due to different pathologies.

OBJECTIVES The aim of this study was to validate the Polish version of the SRI.

PATIENTS AND METHODS The Polish version of the SRI was created according to the procedure of translation and back-translation of the original version. Patients with CRF treated with long-term oxygen therapy (LTOT) or home mechanical ventilation (HMV) were invited to the study. Polish SRI and 36-Item Short Form Health Survey (SF-36) questionnaires were completed during 2 consecutive visits scheduled at a 2–4 week interval. The results were statistically tested for validity, viability, and reliability. The time and ability of completing, sociodemographic and clinical data were recorded.

RESULTS A total of 113 patients were enrolled. Seventy-five participants (66%) completed the questionnaires without any assistance. A significant concurrent validity was confirmed by a correlation analysis between the SRI and the SF-36 scales. An exploratory factor analysis explained 69% of the variance of the questionnaire. High internal consistency was proved by the Cronbach α coefficient 0.951 for the Summary Scale. Repeatability was very high for all subscales (intraclass correlation coefficient, 0.871–0.915) and for the summary score (0.923, $P < 0.001$).

CONCLUSIONS Our study demonstrated that the Polish version of the SRI is valid, reliable, and reproducible and may be used in research involving CRF.

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INTRODUCTION It has been shown that long-term oxygen therapy (LTOT) and home mechanical ventilation (HMV) not only reduce the rate of exacerbations and hospital admissions in patients with chronic respiratory failure (CRF) but also improve the quality of life (QoL).[1,2] Health-related quality of life (HRQL) covers physical and psychological well-being and social functioning that are influenced by health status.[3]

To date, several tools have been developed to assess HRQL. Some of these instruments, including the 36-Item Short Form Health Survey (SF-36)[4] and the Nottingham Health Profile[5] are intended for the general population, whereas disease-specific tools are intended for patients with specific diseases.[6] In terms of the underlying diseases, patients with CRF treated with HMV represent a highly heterogeneous group, including individuals with chronic obstructive pulmonary disease (COPD), restrictive thoracic disorders, obesity hypoventilation syndrome (OHS), neuromuscular diseases, and less commonly diverse metabolic, traumatic, and vascular diseases. Owing to the heterogeneity of patients requiring

WHAT'S NEW?

The manuscript presents the first Polish validation of the Severe Respiratory Insufficiency Questionnaire (SRI). The study demonstrated that the newly developed Polish version of the SRI has good psychometric properties similar to those of the original version, and can be reliably used not only for scientific purposes but also as a follow-up tool in daily clinical practice.

HMV, there was a need to develop a universal tool that would allow for HRQL assessment and comparison in these patients. To date, 2 such questionnaires have been created. The first questionnaire, developed by Italian authors in 1999, is known as the Maugeri Respiratory Failure-28 Questionnaire (MRF-28).[7] However, the MRF-28 has not gained worldwide recognition and is used only locally in Italy. The second questionnaire was presented by a German group in 2003 and is called the Severe Respiratory Insufficiency Questionnaire (SRI).[8]

The SRI consists of 49 items allocated to 7 domains that affect QoL: respiratory complaints, sleep quality and other symptoms, exercise capacity, social functioning and relationships, as well as psychological issues, and anxiety. The patients rate every item on a 5-point scale from "strongly agree" to "strongly disagree" with respect to the perception from the previous week. The original version of the SRI was validated in 2003 by German authors among 226 patients receiving long-term noninvasive ventilation (NIV). The validation process demonstrated high psychometric properties. The internal consistency reliability was high, with Cronbach α coefficient above 0.7. The construct validity was confirmed via a factor analysis, indicating 1 summary scale that accounted for 59.8% of the variance. The SRI has already been translated and validated in several languages, including Spanish,[9] English,[10] Dutch,[11] French,[12] Norwegian,[13] Finnish,[14] Portuguese,[15] Greek,[16] Hungarian,[17] Chinese,[18] and Japanese,[19] and the process is still ongoing. Almost 20 years after its creation, the SRI has become an international standard assessment tool for HRQL.

To assess the concurrent validity of the newly developed questionnaire, researchers should compare it with another questionnaire that is well validated and widely used in the healthy general population and specific disease groups. It seems that the most adequate questionnaire for this purpose is the SF-36,[20] which is constructed similarly to the SRI. The SF-36 consists of 36 items grouped in 8 health domains, which correspond to the domains included in the SRI; therefore, comparison of certain health domains, such as physical activity or social functioning, is easy. Not surprisingly, the SF-36 was used for SRI validation in most of the translations.[9,10,13,15,17,19]

Later studies found that the SRI is a practical tool useful in managing patients requiring HMV and that it has very good discriminative and responsive features.[21] Moreover, the SRI score was established as an independent predictor of mortality,[22-24] and may be used not only for scientific purposes but also as a follow-up tool in daily clinical practice.

To date, the Polish version has not yet been validated. Therefore, the aim of this study was to validate the Polish version of the SRI. With our study, Polish patients joined the selected group of patients of different nationalities, whose key clinical outcome, namely HRQL, can be easily assessed and followed.

PATIENTS AND METHODS

General characteristics of the Severe Respiratory Insufficiency Questionnaire and 36-Item Short Form Health Survey The SRI is a multidimensional tool with high psychometric properties designed to measure specific HRQL in patients requiring HMV. The survey consists of subscales covering 49 items related to CRF: 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). The following 5-point Likert scale was used to rate the level of responder agreement with each item: 1 = strongly disagree, 2 = mostly disagree, 3 = sometimes agree, 4 = mostly agree, 5 = strongly agree. Each item belongs to a single scale, and the final summary score (SRI-SS), which ranges from 0 to 100, is calculated from the mean of all subscales. The higher the SRI-SS score, the higher the HRQL.[8]

The SF-36 consists of 8 subscales measuring different domains of HRQL, yielding 2 summary measures: physical and mental health. Physical health (SF-36 PH) measures include physical functioning (SF-36 PF), role-physical (SF-36 RP), bodily pain (SF-36 BP), and general health (SF-36 GH). Mental health (SF-36 MH) measures include vitality (SF-36 VT), social functioning (SF--36 SF), role-emotional (SF-36 RE), and psychological well-being (SF-36 PW). The results from all subscales are transformed into a 0–100-point scale, where higher scores indicate better health status.[4]

Translation and cultural adaptation of the Polish version The Polish version of the SRI was created according to the translation and back-translation procedures of the original version.[25,26] Back--translation was evaluated by the author of the original version so that each sentence was scored into 3 categories according to the equivalence to the original one. Eighteen items (37% of all) were scored as category A (fully equivalent to the original version), 25 items (51%) as category B (not fully equivalent, but similar in meaning), and 6 items (18%) as category C (not equivalent and needed to be checked). All questions from category C were proofed by translators and again scored to eventually reach at least category B. Category B was acknowledged to be fully sufficient for the aim of this translation, since the aim was not to translate literally, but

to preserve the identical meaning in the specific language. Thereafter, the Polish version of the SRI was tested in 10 patients receiving HMV in terms of understanding and ease of completion. All questions were correctly understood, and no further improvements were required. The Polish version of the SRI and respective guidance for scoring are available free of charge for non-profit research activities at SRI – Quality of life and ventilation – Deutsche Atemwegsliga e.V. (https://www.atemwegsliga.de/en-sri.html).

Patients and study design This was a prospective multicenter study. The patients were recruited between 2015 and 2018 at 2 medical facilities providing HMV: St. Vincent Medical Center in Warsaw and Kuyavian-Pomeranian Pulmonology Center in Bydgoszcz, and 2 LTOT centers: Department of Internal Medicine, Pulmonary Diseases and Allergy of the Medical University of Warsaw and Department of Lung Diseases and Respiratory Failure at the Kuyavian-Pomeranian Pulmonology Center in Bydgoszcz. The research protocol was approved by the Medical Ethics Committee of the Medical University of Warsaw (KB/95/2010), and informed written consent was obtained from all participants.

The inclusion criteria were as follows: (1) age above 18 years; (2) LTOT or HMV (NIV or invasive ventilation [IV] via tracheostomy) or both for at least 3 months before entering the study; (3) clinically stable condition in the preceding 2 months.

The exclusion criteria were as follows: (1) mental impairment; (2) inability to understand the questionnaire questions; (3) continuous positive airway pressure therapy; (4) any change in the clinical state between the first and second assessment that might have affected the patient's condition, including exacerbation of CRF or acute illness.

The eligible patients were randomly invited to participate in the study. Two consecutive visits at the patients' homes were scheduled at a 2–4-week interval. On the first visit, the patients were asked to complete the Polish SRI and Polish SF-36. On the second visit, they were asked about potential deterioration of symptoms or occurrence of new symptoms and any change in their health status. When the patients had nothing to report, they were asked to complete the Polish SRI. All questionnaires were completed in the presence of medical staff. The time required to complete each questionnaire was also measured. The ability to self-administer or the need for help from caregivers was noted. Moreover, sociodemographic (sex, age, educational level, and employment situation) and clinical data were recorded. The clinical data included medical history (smoking and comorbidities), the main indication for establishing HMV, type of ventilation, use of oxygen therapy, hours of ventilation per day, time of treatment, and presence of symptoms of hypoventilation. The performance status was scored according to the British Thoracic Society guidelines (1, normal activity without restriction; 2, strenuous activity limited; 3, can do light work; 4, limited activity but capable of self-care; 5, limited activity and self-care and confinement to bed / chair; 7, no self-care).[27] The severity of breathlessness was measured using the Medical Research Council (MRC) dyspnea scale.

The patients were subcategorized according to the type of the underlying CRF cause: COPD, restrictive chest wall disorders (RCWDs), neuromuscular disorders (NMDs), OHS, and others.

Validation The validation consisted of the verification of the psychometric properties of the questionnaire. We modeled the process using similar protocols that were used in previously validated SRI questionnaires in other languages. Therefore, we evaluated the following psychometric properties:

1. Viability was defined as the ability to complete the questionnaire, assessed by: recording the time spent on completing, the ability to complete the questionnaire without any help, and the rate of missing items in the questionnaire.

2. Reliability was defined as the consistency of the survey results, including internal consistency and reproducibility (test-retest reliability).

2A. Internal consistency was defined as the extent to which the questionnaire items were consistent in the measurement of the same subscale. Internal consistency was determined using Cronbach α coefficient. A scale was deemed reliable when the Cronbach α coefficient was greater than 0.7 and when its items correlated better (Pearson correlation coefficient) with their own scale than did the items of the rest of the scales.

2B. Reproducibility was defined as the extent to which the individuals' responses to the questionnaire items remained relatively consistent across repeated administration of the questionnaire. Reproducibility was assessed by determining the correlation of the results (intraclass correlation coefficient [ICC]) of the 2 questionnaires submitted by the same patient at 2 different time points.

3. Validity was defined as the verification of whether the questionnaire measured what it was intended to measure and consisted of 2 aspects: content validity and construct validity.

3A. Content validity was defined as the verification of whether the questionnaire included the most adequate aspects of a concept in the context of a given problem. Content validity was evaluated during the validation of the original SRI.[8]

3B. Construct validity was defined as the degree to which the results of the questionnaire related to other means of measuring the same content. The construct validity was assessed by exploratory factor analysis using Principal Component Analysis (PCA) with varimax rotation, followed by confirmatory factor analysis (CFA) using PCA with varimax rotation to examine the factor structure of the Polish version of SRI.

TABLE 1 Characteristics of the study population

Underlying disease	COPD	OHS	RCWD	NMD	Other	Total
Demographic data						
Patients	57 (50)	8 (7)	20 (18)	15 (13)	13 (12)	113 (100)
Age, y	65 (60–72)	67 (57–72)	62 (56–69)	58 (30–63)	60 (48–62)	63 (56–70)
Male sex	34 (61)	6 (75)	3 (17)	11 (85)	10 (77)	65 (59)
Treatment						
LTOT	36 (64)	3 (37.5)	0	0	8 (62)	47 (42)
NIV	0	2 (25)	8 (40)	3 (23)	1 (8)	14 (13)
NIV + LTOT	19 (32)	3 (37.5)	11 (55)	0	3 (22)	37 (32)
IV	2 (4)	0	1 (5)	10 (77)	1 (8)	15 (13)
Treatment duration, mo	21 (7.5–37.5)	5 (4–44)	10 (7–24)	15.5 (10.5–24)	30.5 (15–50)	19.5 (7–35)
Education level						
Primary	16 (29)	2 (25)	4 (22)	4 (33)	1 (8)	27 (25)
Secondary	33 (60)	6 (75)	11 (61)	5 (42)	12 (92)	70 (64)
Tertiary	6 (11)	0	3 (17)	3 (25)	0	12 (11)
Employment status						
Employed	1 (2)	0	1 (5)	1 (9)	2 (16)	5 (5)
Pension	34 (62)	4 (50)	10 (56)	4 (33)	2 (16)	54 (49)
Illness allowance	20 (36)	3 (38)	7 (39)	7 (58)	9 (68)	49 (45)
Unemployed	0	1 (12)	0	0	0	1 (0.9)
Performance status and dyspnea level						
MRC	4 (3–4)	2.5 (1–3.75)	3 (2–4)	4 (2.5–4)	4 (2–4)	4 (2–4)
BTS	3 (3–4)	4 (3–4)	4 (3–4)	7 (4.5–7)	4 (3–4.5)	4 (3–4)

Data are presented as median (interquartile range) or number (percentage).

Abbreviations: BTS, performance status according to the British Thoracic Society Guidelines; COPD, chronic obstructive pulmonary disease; IV, invasive ventilation; LTOT, long-term oxygen therapy; MRC, Medical Research Council scale; NIV, noninvasive ventilation; NMD, neuromuscular disease; OHS, obesity hypoventilation syndrome; RCWD, restrictive chest wall disease

A minimum eigenvalue of 1.0 was used as the extraction criterion for factors. The construct validity was also evaluated by assessing correlation of the SRI with corresponding scales of the Polish version of the SF-36, with which it should be positively correlated.

Statistical analysis Statistical calculations were performed using the statistical software R version 3.4.0 (R Core Team (2020), "R: A language and environment for statistical computing." R Foundation for Statistical Computing, Vienna, Austria). Continuous data were presented as means with standard deviations, medians with interquartile ranges (IQRs), and minimum and maximum. Categorical data were presented as the number and percentage of occurrences. To compare the distribution of variables between groups, the Fisher exact test was used for categorical variables, and for continuous variables distribution of variables within subgroups was first tested for normality using the Shapiro–Wilk test. Then, in the case of normal distribution of a variable within groups, the *t* test and 1-way analysis of variance were used to compare the variable distribution between 2 and more than 2 unrelated groups, respectively. Otherwise, the Mann–Whitney test and the Kruskal–Wallis test were applied to compare a variable distribution between 2 and more than 2 unrelated groups, respectively. Statistical significance level was set at *P* below 0.05. Two-sided tests were used. The Spearman rank correlation between viability measures and age was calculated. The Spearman correlation coefficient was used to calculate the correlations between the total and subscale SRI and SF-36 scores.

RESULTS A total of 113 patients (65 [59%] men, median age, 63 years [IQR, 56–70]) completed the questionnaires. Forty-seven patients (42%) were treated with LTOT, 66 (58%) with HMV, 37 (33%) with both NIV and LTOT, and 15 (13%) with IV. The patients with COPD (n = 56) constituted the largest subgroup (50%), followed by those with RCWD (n = 20; 18% of all). Of the 15 patients with NMD, 10 (77%) were on IV. Most patients (n = 90 [82.6%]) lived in households with their families.

The median treatment time for the entire cohort was 19.5 months (IQR, 7–35). Detailed patient characteristics are presented in **TABLE 1**. The SRI results according to the pathology group

TABLE 2 Reliability of the Severe Respiratory Insufficiency Questionnaire scales

SRI subscale	Cronbach α
SRI-RC	0.829
SRI-PF	0.803
SRI-AS	0.808
SRI-SR	0.682
SRI-AX	0.777
SRI-WB	0.883
SRI-SF	0.850
SRI-SS	0.951

SRI, Severe Respiratory Insufficiency Questionnaire; SRI-AS, attendant symptoms and sleep; SRI-AX, anxiety; SRI-PF, physical functioning; SRI-RC, respiratory complaints; SRI-SF, social functioning; SRI-SR, social relationships; SRI-SS, summary scale; SRI-WB, psychological well-being

and treatment method are provided in Supplementary material, *Tables S1* and *S2*).

Viability Except for item 31 ("My partner suffers with my disease"), the items were responded to by 95.6% to 100% of the patients. Seventy-five patients (66%) completed the questionnaires on their own, with no need for any external assistance; 10 (9%) needed help with less than 10 questions; and 5 (5%) needed assistance with 10–19 questions. Twenty-three patients (20%) required assistance while responding to all the questions. Item 31 was not completed by 20.4% of the patients because they were not in a relationship at the time the test was administered.

The median time needed to complete the SRI was 12.0 minutes (IQR, 10.0–19.3). There was a positive correlation between the patients' age and the time needed to complete the SRI ($\rho = 0.23$, $P = 0.02$). However, there was no significant relationship between the time needed to complete the SRI and the educational level, employment status, independence in completing the questionnaire, or ability to read or write. There were no differences in the completion time of the questionnaires between the patients with different underlying diseases.

Most patients with NMD (69%) required help with completion of the entire questionnaire, as compared with 17%, 38%, and 13% of the patients with COPD, OHS, and RCWD, respectively. The patients with RCWD were the most independent in completing the questionnaire (75%); the percentages in the subgroups of patients with COPD, OHS, and NMD were 66%, 63%, and 15%, respectively.

In terms of the treatment modality, the highest percentage of patients who were able to fully complete the questionnaire with no need for external assistance was found in those receiving LTOT (76%), followed by those receiving NIV (67%), both NIV and LTOT (58%), and IV (21%). The percentage of patients who required assistance while completing the entire questionnaire was as follows: 71% of the patients receiving IV; 25%, NIV; 16%, both NIV and LTOT; and 12%, LTOT.

Reliability Except for the SRI-SR, Cronbach α coefficient was higher than 0.7 in all subscales and ranged between 0.777 and 0.883 for 6 subscales. The reliability of the SRI-SS was even higher (0.951) than that of the other subscales (TABLE 2).

Validity PCA with varimax rotation, using an eigenvalue above 1 for extraction, identified 11 components for the questionnaire with eigenvalues above 1 and explained 68.97% of the variation (FIGURE 1). The items related to each of the 11 components indicated in exploratory factor analysis by PCA corresponded to the items included in each of the 7 domains of the Polish version of the questionnaire (Supplementary material, *Table S3*). CFA for the 7 subscales of the Polish version of the SRI showed 1 component for 3 (SRI-PF, SRI-AX, SRI-SF) and 2 components for 4 of the subscales. A tendency toward further division into 2 scales was revealed for the following subscales: SRI-RC, SRI-AS, SRI-SR, and SRI--WB (Supplementary material, *Table S4*).

In addition, significant concurrent validity was confirmed in the correlation analysis between the SRI and SF-36 subscales. The strongest correlations were observed between the SRI-SS and SF-36 MH ($\rho = 0.784$, $P < 0.001$), SRI-PF and SF--36 PF ($\rho = 0.741$, $P < 0.001$), SRI-WB and SF-36 PW ($\rho = 0.792$, $P < 0.001$), and SRI-SF and SF-36 SF ($\rho = 0.722$, $P < 0.001$). The subscales referring to the same aspects of QoL most closely correlated with each other (TABLE 3).

Reproducibility The repeatability of the SRI was very high for all subscales (ICC = 0.871–0.915) as well as for the SRI-SS (ICC = 0.923). Detailed data regarding reproducibility are presented in TABLE 4.

DISCUSSION

Our study proved that the Polish version of the SRI is valid, reliable, reproducible, and easily used among patients with CRF treated with HMV and LTOT. Significant concurrent validity was confirmed in the correlation analysis between the SRI and SF-36 subscales. The subscales of both questionnaires relating to the same aspects of QoL correlated with each other the most. The PCA with varimax rotation, using an eigenvalue above 1 for extraction, identified 11 components with eigenvalues above 1, explaining 68.97% of the variation; this is similar to the original German SRI and other SRI validations. CFA for the subscales of the Polish version showed 1 component only for 3 of them (SRI-PF, SRI-AX, SRI-SF) and 2 components for 4 of the subscales (SRI-RC, SRI-AS, SRI-SR, SRI--WB), which indicates a tendency for further division. However, such results were also presented for validations of other language versions.[16,17]

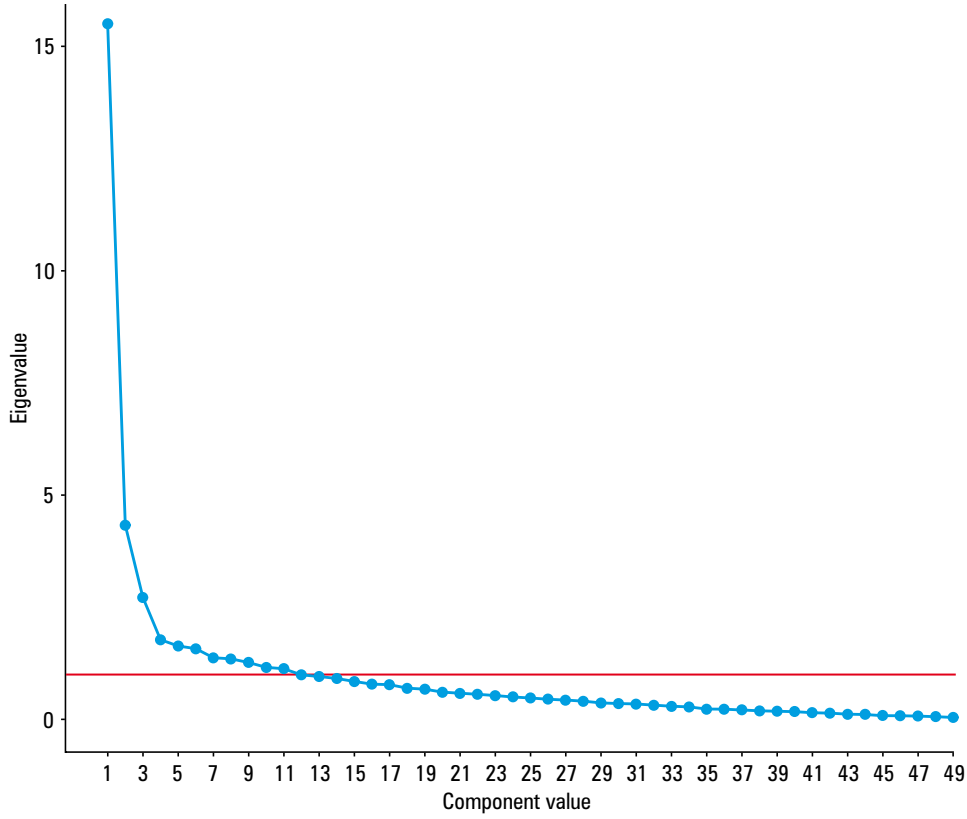

FIGURE 1 Validity assessment of the Polish version of the Severe Respiratory Insufficiency Questionnaire. Scree plot for the exploratory factor analysis. Principal component analysis method with varimax rotation, using an eigenvalue above 1 for the extraction identified 11 components with eigenvalues above 1

TABLE 3 Correlation analysis (Spearman rank correlation coefficient) between the Severe Respiratory Insufficiency Questionnaire and the Short-form Health Survey subscales

SRI subscale	SF-36 PF	SF-36 RP	SF-36 BP	SF-36 GH	SF-36 VT	SF-36 SF	SF-36 RE	SF-36 PW	SF-36 PH	SF-36 MH
SRI-C	0.319	0.473	0.486	0.391	0.622	0.515	0.470	0.531	0.421	0.586
SRI-PF	0.741	0.624	0.235	0.448	0.507	0.622	0.451	0.488	0.599	0.530
SRI-AS	0.186[a]	0.311	0.576	0.211[a]	0.543	0.355	0.296	0.504	0.333	0.493
SRI-SR	0.298	0.405	0.244	0.293	0.526	0.461	0.464	0.615	0.154[a]	0.606
SRI-AX	0.304	0.442	0.360	0.419	0.537	0.501	0.492	0.561	0.313	0.587
SRI-WB	0.372	0.523	0.396	0.463	0.687	0.576	0.553	0.792	0.293	0.777
SRI-SF	0.647	0.620	0.365	0.465	0.651	0.722	0.533	0.676	0.531	0.705
SRI-SS	0.531	0.625	0.486	0.495	0.743	0.690	0.596	0.759	0.491	0.784

Data are presented as the Spearman rank correlation coefficient (ρ).

a *P* value >0.05

Abbreviations: SF-36, Short-form Health Survey; SF-36 BP, bodily pain; SF-36 GH, general health; SF-36 MH, mental health; SF-36 PF, physical functioning; SF-36 PH, physical health; SF-36 PW, psychological well-being; SF-36 RE, role-emotional; SF-36 RP, role-physical; SF-36 SF, social functioning; SF-36 VT, vitality; others, see **TABLE 2**

Reliability was confirmed by a high Cronbach α coefficient that exceeded 0.7 in all subscales, except for the SRI-SR (0.682). These results are comparable to those of other SRI language versions.[8,14,17] Moreover, the Cronbach α coefficient for the SRI-SS reached 0.951 and was even higher than that in the original German (0.89)[8] and English SRI versions (0.93).[10] This result suggests that the reliability of the Polish SRI is fully comparable to that of the original version and other language versions. A sufficient reproducibility of the Polish SRI was confirmed by a strong correlation between the results of the 2 questionnaires completed by the same patient at different time points for all subscales and the summary score.

Furthermore, we showed that the Polish version of the SRI is simple and convenient to use. Most study participants managed to complete the questionnaire with no external assistance, and it took them approximately 12 minutes to answer all the questions. However, this time was

TABLE 4 Correlations between the results of the 2 Severe Respiratory Insufficiency Questionnaires completed at different time points. Reproducibility calculated with intraclass correlation coefficient

SRI subscale	ICC for test-retest
SRI-RC	0.891; P <0.001
SRI-PF	0.915; P <0.001
SRI-AS	0.910; P <0.001
SRI-SR	0.899; P <0.001
SRI-AX	0.871; P <0.001
SRI-WB	0.913; P <0.001
SRI-SF	0.908; P <0.001
SRI summary score	0.923; P <0.001

Abbreviations: ICC, intraclass correlation coefficient; others, see **TABLE 2**

longer than the time reported for the Hungarian (8–10 minutes) and Spanish versions (10–11 minutes),[17,28] which might be attributed to language differences. Not surprisingly, the time needed to complete the questionnaire positively correlated with age in our study. However, there was no difference in the completion time between the patients with various underlying diseases and the educational level. This differed from the findings of the Hungarian validation study where the diagnosis and educational level but not age influenced the speed of completing the SRI. In our study, 20% of the patients omitted the answer to the question about the impact of the disease on their relationship with their partner (item 31). This number was comparable to that in other validation studies, including the Spanish[9] and Portugese[15] ones with 30% and 10% of omissions, respectively. The lack of 1 or 2 answers did not influence the assessment quality. According to the authors of the original version, the value of every domain may be calculated if there are more than 50% of the answers in the domain.

Originally, the SRI was created with the intention to assess HRQL in patients with CRF treated with noninvasive respiratory support and was validated in this specific group, including patients with various underlying diseases, such as COPD, NMD, RCWD, and OHS.[1,29] NIV is a therapeutic modality intended for patients with hypoventilation as a mechanism underlying respiratory failure. However, there is an even higher number of patients without hypoventilation who experience hypoxemic CRF and whose HRQL is comparably affected by decreased exercise capacity and other respiratory symptoms, which eventually result in social exclusion and emotional concerns. Based on the clinical rationale for the use of the SRI not only in patients receiving NIV but also in those receiving LTOT, a German group validated the SRI specifically in patients with COPD receiving LTOT in 2016.[30] They found high reliability and validity of the questionnaire and interestingly showed that the HRQL in patients receiving LTOT was poorer than in those receiving NIV.[30] In 2018, Chinese authors demonstrated good validity and reliability of the SRI in the same group of patients.[31] Finnish and Greek authors enrolled a mixed group of patients receiving LTOT and NIV to validate their SRI.[14,16] We also decided to conduct validation in a heterogeneous group of patients with CRF. The patients receiving LTOT constituted almost half of the cohort (42%), while the patients receiving NIV accounted for 43% of the cohort. Considering the substantial size of both groups of patients in our study, we concluded that the Polish version of the SRI is valid and reliable for both NIV- and LTOT-treated patients.

Notably, our study included some invasively ventilated participants. This group of patients is very specific and may vary significantly from patients receiving NIV. Most of them are affected by NMD, with significant impairment of physical functioning, communication, and eating problems. This raises a question whether the SRI is applicable in such patients with severe disabilities. To the best of our knowledge, only 3 validation studies have included patients ventilated via tracheostomy: Hungarian,[17] Norwegian,[13] and English.[10] Huttmann et al[32] investigated QoL using the SRI in 32 patients with NMD and COPD almost fully dependent on IV and highly dependent on nursing care (Barthel index of <40). They found that the overall HRQL assessed on the basis of the SRI scores was nearly identical in patients treated with invasive and noninvasive HMV. As our intention was to validate the questionnaire that could be used in a wide and heterogeneous group of patients with CRF, the patients treated with tracheostomy and those with NMD were also included in our study. Not surprisingly, most of them (3/4) needed help in completing the entire questionnaire. However, these patients were still able to answer the questions. Interestingly, the patients receiving IV had a comparable SRI-SS to the patients receiving LTOT but had insignificantly lower SRI-SS than those receiving NIV and both NIV and LTOT. Moreover, our results are very similar to those obtained by Huttmann et al[33] in patients treated with long-term invasive HMV following intensive care unit treatment and unsuccessful weaning. Nevertheless, owing to the small number of tracheostomized patients in our cohort, we cannot draw a firm conclusion regarding whether the Polish version of the SRI can reliably assess the HRQL in these particular groups; thus, this issue requires further investigation.

Contrary to other studies that validated the SRI in national languages, we did not report a wide range of clinical and laboratory data of the patients, including blood gas analysis or pulmonary functional tests. This can be considered a limitation of our study. However, we believe that such an approach can be justified on at least several grounds. First, the results of arterial blood gas analyses taken during treatment provide information on the efficacy of the treatment rather

than on the severity of the illness and are not helpful in the analysis of the studied cohort. Second, the questionnaires were completed in the patients' houses during nurse visits, and performing such tests would be difficult. Third, the criteria for LTOT are universal across Poland, are based on arterial blood gas analyses, and are strictly followed by all providers. Fourth, in Poland, the initiation of HMV must be performed in hospital settings, which guarantees a thoughtful qualification process.

In conclusion, our study demonstrated that the Polish version of the SRI is valid, reliable, and reproducible. Its psychometric properties are in line with those of the original German SRI, making the Polish version qualified for use in assessing HRQL in patients with CRF requiring long-term NIV or LTOT. We believe that the use of the national version of the SRI in Poland should be encouraged, as this approach may contribute to a more reliable assessment of the HRQL in patients with CRF.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/paim.

ARTICLE INFORMATION

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REFERENCES

1 Windisch W. Quality of life in home mechanical ventilation study group. Impact of home mechanical ventilation on health-related quality of life. Eur Respir J. 2008; 32: 1328-1336.

2 Simonds AK. Home mechanical ventilation: an overview. Ann Am Thorac Soc. 2016; 13: 2035-2044.

3 Ferrucci L, Baldasseroni S, Bandinelli S, et al. Disease severity and health-related quality of life across different chronic conditions. J Am Geriatr Soc. 2000; 48: 1490-1495.

4 McHorney CA, Ware JE, Jr, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Med Care. 1993; 31: 247-263.

5 Wiklund I. The Nottingham Health Profile - a measure of health-related quality of life. Scand J Prim Health Care Suppl. 1990; 1: 15-18.

6 Farnik M, Brożek G, Czajkowska-Malinowska M, et al. Validation of the Polish-language version of the COPD Assessment Test. Pol Arch Intern Med. 2019; 129: 605-611.

7 Carone M, Bertolotti G, Anchisi F, et al. Analysis of factors that characterize health impairment in patients with chronic respiratory failure. Quality of Life in Chronic Respiratory Failure Group. Eur Respir J. 1999; 13: 1293-1300.

8 Windisch W, Freidel K, Schucher B, et al. The Severe Respiratory Insufficiency (SRI) Questionnaire: a specific measure of health-related quality of life in patients receiving home mechanical ventilation. J Clin Epidemiol. 2003; 56: 752-759.

9 López-Campos JL, Failde I, León Jiménez A, et al. Health-related quality of life of patients receiving home mechanical ventilation: the Spanish version of the severe respiratory insufficiency questionnaire [in Spanish]. Arch Bronconeumol. 2006; 42: 588-593.

10 Ghosh D, Rzehak P, Elliott MW, Windisch W. Validation of the English Severe Respiratory Insufficiency Questionnaire. Eur Respir J. 2012; 40: 408-415.

11 Duiverman ML, Wempe JB, Bladder G, et al. Health-related quality of life in COPD patients with chronic respiratory failure. Eur Respir J. 2008; 32: 379-386.

12 Cuvelier A, Lamia B, Molano LC, et al. The French translation and cultural adaptation of the SRI questionnaire. A questionnaire to assess health-related quality of life in patients with chronic respiratory failure and domiciliary ventilation [in French]. Rev Mal Respir. 2012; 29: 705-713.

13 Markussen H, Lehmann S, Nilsen RM, Natvig GK. The Norwegian version of the Severe Respiratory Insufficiency Questionnaire. Int J Nurs Pract. 2015; 21: 229-238.

14 Kotanen P, Kainu A, Brander P, et al. Validation of the Finnish severe respiratory insufficiency questionnaire. Clin Respir J. 2020; 14: 659-666.

15 Ribeiro C, Ferreira D, Conde S, et al. Validation of the Portuguese Severe Respiratory Insufficiency Questionnaire for home mechanically ventilated patients. Rev Port Pneumol (2006). 2017; 23: 139-145.

16 Tsara V, Michailidis V, Perantoni E, et al. Validation of the Greek version of the Severe Respiratory Insufficiency questionnaire. Hippokratia. 2017; 21: 186-190.

17 Valko L, Baglyas S, Kunos L, et al. Validation of the Hungarian version of the SRI Questionnaire. BMC Pulm Med. 2020; 20: 130.

18 Chen R, Guan L, Wu W, et al. The Chinese version of the Severe Respiratory Insufficiency questionnaire for patients with chronic hypercapnic chronic obstructive pulmonary disease receiving non-invasive positive pressure ventilation. BMJ Open. 2017; 7: e017712.

19 Oga T, Taniguchi H, Kita H, et al. Validation of the Japanese Severe Respiratory Insufficiency Questionnaire in hypercapnic patients with noninvasive ventilation. Respir Investig. 2017; 55: 166-172.

20 Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care. 1992; 30: 473-483.

21 Oga T, Windisch W, Handa T, et al. Health-related quality of life measurement in patients with chronic respiratory failure. Respir Investig. 2018; 56: 214-221.

22 Markussen H, Lehmann S, Nilsen RM, Natvig GK. Health-related quality of life as predictor for mortality in patients treated with long-term mechanical ventilation. BMC Pulm Med. 2019; 19: 13.

23 Oga T, Taniguchi H, Kita H, et al. Comparison of different disease-specific health-related quality of life measurements in patients with long-term noninvasive ventilation. Can Respir J. 2017; 2017: 8295079.

24 Budweiser S, Hitzl AP, Jörres RA, et al. Health-related quality of life and long-term prognosis in chronic hypercapnic respiratory failure: a prospective survival analysis. Respir Res. 2007; 8: 92.

25 Brislin RW. The wording and translation of research instruments. In: Field Methods in Cross-Cultural Research. Lonner WJ, Berry WJ, eds. Newbury Park, CA; 1986: 137-164.

26 Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol. 1993; 46: 1417-1432.

27 British Thoracic Society Standards of Care Committee. Non-invasive ventilation in acute respiratory failure. Thorax. 2002; 57: 192-211.

28 Lopez-Campos JL, Failde I, Masa JF, et al. Transculturally adapted Spanish SRI questionnaire for home mechanically ventilated patients was viable, valid, and reliable. J Clin Epidemiol. 2008; 61: 1061-1066.

29 Windisch W, Freidel K, Schucher B, et al. Evaluation of health-related quality of life using the MOS 36-Item Short-Form Health Status Survey in patients receiving noninvasive positive pressure ventilation. Intensive Care Med. 2003; 29: 615-621.

30 Walterspacher S, July J, Kohlhäufl M, et al. The Severe Respiratory Insufficiency Questionnaire for subjects with COPD with long-term oxygen therapy. Respir Care. 2016; 61: 1186-1191.

31 Guan L, Xu J, Wu W, et al. Chinese version of the severe respiratory insufficiency questionnaire for patients with COPD receiving long-term oxygen therapy. Int J Chron Obstruct Pulmon Dis. 2018; 13: 1537-1543.

32 Huttmann SE, Windisch W, Storre JH. Invasive home mechanical ventilation: living conditions and health-related quality of life. Respiration. 2015; 89: 312-321.

33 Huttmann SE, Magnet FS, Karagiannidis C, et al. Quality of life and life satisfaction are severely impaired in patients with long-term invasive ventilation following ICU treatment and unsuccessful weaning. Ann Intensive Care. 2018; 8: 38.