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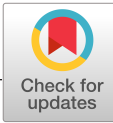
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Validation of the Finnish severe respiratory insufficiency questionnaire

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Abstract

Introduction: Chronic respiratory insufficiency impacts patients' lives and reduces quality of life. The Severe Respiratory Insufficiency (SRI) questionnaire examines health-related quality of life and is designed specifically for patients receiving home mechanical ventilation (HMV) for chronic respiratory failure (CRF).

Objectives: The aim of this study was to validate the Finnish version of the SRI and study its reproducibility in patients with CRF.

Methods: Our 74 patients receiving HMV or long-term oxygen treatment for CRF or both completed the SRI and St George's Respiratory questionnaires (SGRQ) three times (at baseline, and then one week and one month later). Reliability and validity of the questionnaires was analysed with Cronbach's alpha and intraclass correlation coefficient. Patients were prospectively followed up for 5 years, with data collected on their use of hospital services and mortality.

Results: Cronbach's alpha in the SRI ranged from 0.67 to 0.88 and was >0.7 on all subscales except the "attendant symptoms and sleep". On four subscales, Cronbach's alpha was >0.8, and on the summary scale, 0.95. The SRI showed high correlation with SGRQ. Both tests showed good reproducibility. During the 5-year follow-up, 27 (36%) patients died.

Conclusions: The Finnish SRI proved valid, reliable and reproducible. Its psychometric properties were good and similar to those of the original questionnaire and of other validation studies.

KEYWORDS

chronic respiratory failure (CRF), Finland, health-related quality of life (HRQL), severe respiratory insufficiency questionnaire (SRI), validation

1 | INTRODUCTION

Chronic respiratory failure (CRF) can result from various underlying diseases such as chronic obstructive pulmonary

disease (COPD), obesity hypoventilation syndrome (OHS), restrictive thoracic wall disease (RTWD) or neuromuscular disease (NMD).¹ All of these severe, often incurable diseases can affect deeply patients' quality of life (QoL).² Home mechanical ventilation (HMV) is a well-established treatment

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for CRF. It may be delivered either by non-invasive (NIV) or by invasive mechanical ventilation. Long-term oxygen treatment (LTOT) is used for hypoxemic CRF patients, alone or combined with HMV.

To assess the impact of a chronic disease and its treatment on patients' lives, health-related quality-of-life (HRQL) questionnaires are important instruments. Many are generic, like the MOS 36-Item Short-Form Health Survey (SF-36), and allow comparison of HRQL between different diseases. They may not be able to detect changes in QoL in a specific disease, however. CRF patients treated with NIV or LTOT or both show specific problems—ones absent in generic or even respiratory-specific HRQL questionnaires. Assessment of their HRQL therefore requires a more explicit questionnaire.

The severe respiratory insufficiency questionnaire (SRI) and Maugeri respiratory failure questionnaire (MRF) are HRQL questionnaires specifically designed for patients with CRF who are receiving HMV. The SRI is multidimensional HRQL questionnaire with good psychometric properties.³ It has proven valid, reliable and sensitive to changes, and—when compared to other questionnaires (eg, MFR, SGRQ)—it has scored the best.⁴⁻⁶ The MRF is faster to complete, but it lacks a psychological domain and measures mainly patients' activity and level of health. The SRI has been translated and validated in many countries including Spain,^{7,8} the United Kingdom,⁹ Norway,¹⁰ Portugal,¹¹ Japan,¹² and China,¹³ In Germany¹⁴ and in China,¹⁵ the SRI has also been validated in LTOT users.

The aim of this study was to validate the Finnish SRI in patients who are using HMV for CRF, also including patients using LTOT alone or combined with HMV. We followed up the patients for 5 years, to be able also to assess their 5-year mortality.

2 | MATERIALS AND METHODS

2.1 | Patients and study design

Patients with CRF treated with HMV or LTOT or with both, having a follow-up visit in the Peijas or Meilahti Hospitals pulmonary outpatient clinic from June 2012 to 2013, received invitations to participate in this validation study. Patients were excluded if they were undergoing invasive ventilation or had obstructive sleep apnea (OSA) treated with continuous positive airway pressure (CPAP). All patients had to be clinically stable, without any exacerbations in the preceding 3 months, and treated with HMV or LTOT or with both for at least three months before entering the study. Their respiratory failure may be attributed to various diseases. In addition, some patients had OSA treated with NIV due to severe hypoxemia without hypercapnia. Of the 155 patients

fulfilling our inclusion criteria, 74 (48%) entered the study and answered the questionnaires. Each patient signed a written consent form. Both the SRI and the SGRQ were mailed to the patients at three time points: the first (baseline) between March and November 2013, and then 1 week and then 1 month later. The patients also provided basic sociodemographic data.

Five years later, in 2018, we collected information from patient records concerning treatment modality, diagnosis of CRF, use of hospital services and mortality data during the 5-year period. The patients made up six diagnosis groups: COPD, OHS, RTWD, NMD, OSA and miscellaneous.

The study took place at the Peijas and Meilahti Hospitals, both associated with Helsinki University Hospital (HUU), Finland. The medical ethics committee of Helsinki University approved the study (study number 370/13/03/01/2012). The author of the SRI questionnaire, Wolfram Windisch, gave his permission to use this questionnaire.

2.2 | The SRI and SGRQ questionnaires

The SRI is a HRQL questionnaire containing 49 items assessing the patient's physical, social and psychological health. Its seven subscales are respiratory complaints (RC), physical functioning (PF), attendant symptoms and sleep (AS), social relationships (SR), anxiety (AX), psychological well-being (WB) and social functioning (SF). The summary scale (SS) is the average of the subscale scores. Each item is scored on a 5-point Likert scale. All subscales and the SRI-SS range from 0 to 100, a higher score indicating a better QoL.³

The SGRQ is a frequently used respiratory-specific HRQL questionnaire validated for various respiratory diseases (eg, COPD, asthma¹⁶⁻¹⁸). The SGRQ has not been validated in patients receiving HMV or LTOT or both for CRF. It comprises three subscales: symptoms, activity and impacts, and a total score calculated from these subscales. In the SGRQ, the scale is also 0-100, but 100 represents the poorest and 0 the best QoL. Due to this difference, the SGRQ results were modified so that these two scales are comparable to each other and in the analysis 100 represents the best QoL.

2.3 | Translation of the Finnish SRI

The SRI questionnaire was first translated from German into Finnish by a professional translator utilizing medical glossaries and parallel texts. The source text and the translation were then forwarded to a German-speaking medical professional (Bachelor of Medicine) who revised the translation particularly in regard to its medical terminology. The final terminological and translation decisions depended on the collaboration of both parties. Lastly, an independent third-party

translator reviewed the equivalence between the original and the translation in order to guarantee the validity of the process and the Finnish version of the SRI questionnaire.

2.4 | Statistical analysis

Statistical analysis was by SPSS, version 24 (*IBM SPSS Statistics*). We considered P values < 0.05 statistically significant. Diagnostic groups' comparison was by t -test and ANOVA. Reliability calculation involved analysis of internal consistency with Cronbach's alpha in the subscales and the SRI-SS. Cronbach's alpha 0.7-0.79 was considered as acceptable, 0.8-0.89 as good and >0.9 as excellent. Validity came from a comparison of the Finnish SRI to the Finnish SGRQ. Spearman's correlation coefficient served for calculating correlations between the SRI and SGRQ. Analysis of reproducibility of the SRI utilized the Intraclass Correlation Coefficient. The number of patients varies slightly in the analyses, because if a patient left even one question unanswered, the SPSS excluded this patients' questionnaire. Test scores were calculated as averages, and because of the relatively small patient cohort, also as percentiles. We analysed the difference in HRQL between patients who died and survived and its association with 5-year mortality with the independent samples t -test.

3 | RESULTS

3.1 | Patient characteristics

Among their characteristics, 74 patients' mean average smoking amount was 27 pack years (Table 1). Between January

2013 and March 2018, each patient had on average 3.8 (SD 2.7, maximum 13) follow-up visits in the pulmonology outpatient clinic, and 2.5 (SD 3.4, maximum 22) episodes of care in the pulmonology ward. In total, these patients had 285 visits to the outpatient clinic and 183 episodes of care in the ward.

3.2 | Differences between diseases in HRQL

The SRI-SS for all patients was 59.3 ± 16.8 (Figure 1 and Table S1). In the Finnish SRI, HRQL was best in the OSA group (71.8 ± 14.5), second best in the NMD group (64.4 ± 11.7), and poorest in the COPD (55.3 ± 14.6) and miscellaneous (55.4 ± 29.2) groups.

The highest SRI scores were on the SR subscale for all but the OHS, NMD and miscellaneous groups. The lowest scores were for PF, except for the OSA group, which had the lowest score for the AX (Figure 1).

The difference was statistically significant between NMD and COPD patients on the RC subscale ($P = .002$), and on the PF subscale between COPD and OSA ($P = .003$), OHS and OSA ($P = .040$), and NMD and OSA ($P = .041$). SGRQ scores were similarly distributed among all patient groups (Tables S2 and S3).

3.3 | Reliability and validity of SRI, and reproducibility of SRI and SGRQ

Cronbach's alpha ranged on the SRI subscales between 0.67 and 0.89 and was >0.7 on all subscales except the AS (Table 2). The SRI-SS was 0.95. These results demonstrated high internal consistency.

TABLE 1 Patients' characteristics

N(%)	COPD	RCWD	NMD	OHS	OSA	Misc ^a	Total
Patients	28 (38)	7 (9)	12 (16)	15 (20)	7 (9)	5 (7)	74 (100%)
Men	21 (75)	2 (33)	5 (42)	8 (53)	4 (57)	0	40 (54)
Age (mean \pm SD)	71 \pm 6.3	64 \pm 14.4	59 \pm 14.0	64 \pm 8.1	64 \pm 7.0	67 \pm 18.2	66 \pm 10.7
5-y mortality	18 (64)	1 (14)	3 (25)	2 (13)	0	3 (60)	27 (36)
Smoking ^b : Current/ Ex-smoker/ never-smoker	5/21/2	0/2/4	0/7/4	1/9/5	1/4/1	0/2/3	7(10)/45(63)/19(27)
NIV	7 (25)	6 (86)	9 (82)	10 (67)	6 (86)	1 (20)	39 (53)
LTOT	8 (29)	0	0	0	0	3 (60)	11 (15)
LTOT and NIV	12 (43)	1 (14)	1 (9)	4 (27)	1 (14)	1 (20)	20 (27)
Treatment cessation ^c	1 (4)	0	1 (9)	1 (7)	0	0	3 (4)

Abbreviations: COPD, chronic obstructive pulmonary disease; LTOT, long-term oxygen treatment; Misc, miscellaneous; NIV, non-invasive ventilation; NMD, neuromuscular disease; OHS, obesity hypoventilation syndrome; OSA, obstructive sleep apnea; RCWD, restrictive thoracic wall disease.

^aThree had pulmonary hypertension, one obliterative bronchiolitis and severe asthma, and one status post-pulmonary embolism.

^bSmoking information missing for three patients.

^cDuring the 5-year follow-up.

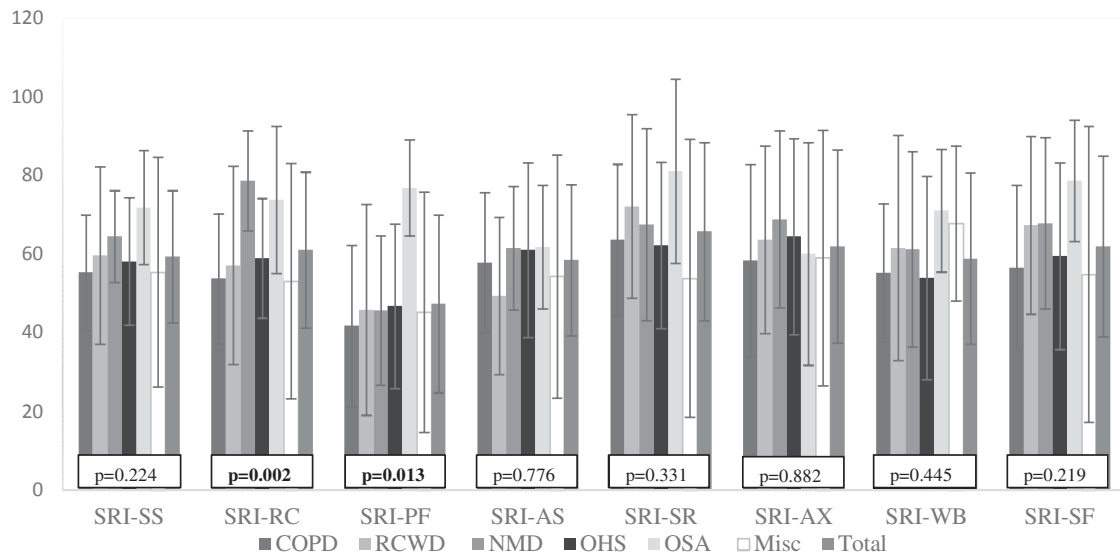


FIGURE 1 Average scores and standard deviations for SRI (0 week). The statistically significant differences bolded. P is < 0.05 when there exists a statistically significant difference between the scores of two or more diagnosis groups. COPD, chronic obstructive pulmonary disease; Misc, miscellaneous; NMD, neuromuscular disease; OHS, obesity hypoventilation syndrome; OSA, obstructive sleep apnea; RCWD, restrictive thoracic wall disease; SRI, severe respiratory insufficiency questionnaire; SRI-SS, summary scale; SRI-RC, respiratory complaints; SRI-PF, physical functioning; SRI-AS, attendant symptoms and sleep; SRI-SR, social relationships; SRI-AX, anxiety; SRI-WB, psychological well-being; SRI-SF, social functioning

TABLE 2 Reliability of the subscales of the Finnish severe respiratory insufficiency questionnaire

	Number of items	Cronbach's α
Respiratory complaints (RC)	8	0.80
Physical functioning (PF)	6	0.72
Attendant symptoms and sleep (AS)	7	0.67
Social relationships (SR)	6	0.76
Anxiety (AX)	5	0.81
Psychological well-being (WB)	9	0.89
Social functioning (SF)	8	0.84
Summary scale (SS)	49	0.95

The correlation matrix between SRI and SGRQ is presented in Table 3. Correlations between the two questionnaires and their subscales were high, with the highest correlation between SRI-RC and SGRQ total (0.84, $P < .001$); RC also had a very high correlation with all the SGRQ subscales. The correlation was good between the SRI-SS and the SGRQ impacts (0.80, $P < .001$), even better than correlation of the SRI-SS and SGRQ total (0.75, $P < .001$). The SRI AX had a good correlation with SGRQ impacts (0.74, $P < .001$) and with total score (0.73, $P < .001$). Those subscales targeting the same aspects of life were generally well comparable; the lowest correlation was between SR and SGRQ activity (0.19, $P = .132$), which measures very different aspects.

The reproducibility of SRI and SGRQ results between the three different assessments was also high (Table 4).

Comparison of the HRQL between those patients who died during the follow-up and those who survived showed statistically significant differences in the SRI-SS, RC, SR and SF; a lower score in these subscales was associated with increased mortality (Figure 2). Moreover, patients who died had undergone more treatment episodes in the pulmonary ward ($P = .007$), but fewer visits in the pulmonary outpatient clinic ($P = .032$).

4 | DISCUSSION

The HRQL of patients with CRF is severely diminished. Thus far, we have lacked any specific HRQL questionnaire for CRF patients receiving HMV or LTOT or both in Finland. Our study showed that the Finnish SRI had high psychometric properties and good reliability and validity. Reproducibility of both the SRI and the SGRG was good among three different assessments occurring during 1 month.

Reliability was analysed with internal consistency using Cronbach's alpha. Cronbach's alpha was over 0.7 in all subscales, except in the AS, and the SRI-SS was 0.95. In the original German SRI, the Cronbach's alpha was 0.73-0.79 on three subscales, 0.80 to 0.89 on four subscales, and SRI-SS was 0.89.³ Our results were similar to this original SRI and to other SRI validations. In the Spanish SRI, the SRI-SS was 0.93⁸; in the English one, 0.93⁹; in the Norwegian, 0.94¹⁰; in

TABLE 3 Correlation matrix between the SRI and SGRQ (Spearman's correlation)

	SGRQ symptoms	SGRQ activity	SGRQ impacts	SGRQ total
SRI-RC	0.67	0.61	0.80	0.84
SRI-PF	0.29	0.55	0.63	0.64
SRI-AS	0.34	0.28	0.51	0.42
SRI-SR	0.42	0.19*	0.46	0.40
SRI-AX	0.59	0.58	0.74	0.73
SRI-WB	0.44	0.31	0.51	0.48
SRI-SF	0.42	0.43	0.63	0.58
SRI-SS	0.62	0.53	0.80	0.76

Note: The highest correlations in bold.

Abbreviations: SGRQ, St George's respiratory questionnaire; 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.

*In all the result, $P < .05$, except the one marked *, where $P = .132$.

TABLE 4 Reproducibility calculated with intraclass correlation coefficient (ICC) from SRI and SGRQ 0 week, 1 week and 1 month

	ICC	95% Confidence interval
SRI-RC (N = 48)	0.95	0.92-0.97
SRI-PF (N = 48)	0.96	0.94-0.98
SRI-AS (N = 48)	0.93	0.88-0.96
SRI-SR (N = 48)	0.95	0.92-0.97
SRI-AX (N = 48)	0.93	0.89-0.96
SRI-WB (N = 48)	0.94	0.91-0.97
SRI-SF (N = 48)	0.95	0.92-0.97
SRI-SS (N = 48)	0.97	0.96-0.98
SGRQ symptoms (N = 45)	0.90	0.84-0.94
SGRQ activity (N = 38)	0.96	0.92-0.98
SGRQ impact (N = 43)	0.96	0.93-0.98
SGRC total (N = 35)	0.97	0.95-0.98

Abbreviations: SGRQ, St George's respiratory questionnaire; 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.

the Portuguese, 0.84¹¹; in the Japanese, 0.92¹²; in the Chinese, 0.94-0.95^{13,15}; and in the German version comparing LTOT and NIV, 0.90.¹⁴ In our study, the AS subscale scored the lowest (0.67), similar to the Chinese,¹³ Norwegian¹⁰ and German¹⁴ versions. If question 9 were excluded from the Finnish version, the Cronbach's alpha in AS would rise to 0.73, indicating that the question might be measuring a slightly different aspect than the other questions on that subscale measured. Question 9 asks about the person's ability to fall asleep, while the other questions on the subscale inquire about daily symptoms or sleep quality. The reliability of the Finnish version was good, and similar to or even stronger than the original German SRI.

We compared the SRI with the SGRQ. To our knowledge, all other SRI validations have compared the SRI to SF-36. SGRQ is a widely used HRQL questionnaire validated for many respiratory diseases, but not validated in patients receiving HMV. The best correlation was between SRI RC (respiratory complaints) and SGRQ total. The RC had a good correlation with all the SGRQ subscales, as well. The SRI summary scale and the SGRQ impacts subscale correlated well also, even better than did the SRI-SS and the total SGRQ. This indicates that the SGRQ concentrates more on the respiratory symptoms, whereas the SRI measures more broadly the physical and mental health factors. Overall, the subscales that targeted comparable aspects of life showed good correlations with each other.

SRI-SS scores were similar to the other validations, where the results ranged from 52.93 (SD 15.11) to 59.4 (SD 20.2)^{9-13,15} even though the patient-group distributions differed from those of the other SRI validations. In many validations, COPD patients have been the only or the largest group, which largely explains the similar results. The SGRQ and SRI scores were comparable to each other. The SGRQ finding of our COPD group is also in line with findings of other studies with GOLD stage-IV patients.^{19,20}

In our study, 5-year mortality was 36% and was even higher (over 60%) in the COPD and miscellaneous groups. In other studies on COPD patients' mortality, mortality during 3-7 years ranged from 19.5% to 33%.²¹⁻²⁴ In studies which included patients with CRF due to different pathologies, the mortality was 19%-58% during 4-11 years.^{25,26} Compared to these studies' findings, the mortality rate in our COPD patients was higher, and in the RCWD, NMD and OHS groups, lower. This imbalance is probably due to our small patient cohorts, and shows also how severely ill our COPD patients treated with HMV were.

The HRQL questionnaires can also be useful for assessing their discriminative property (to distinguish patients with

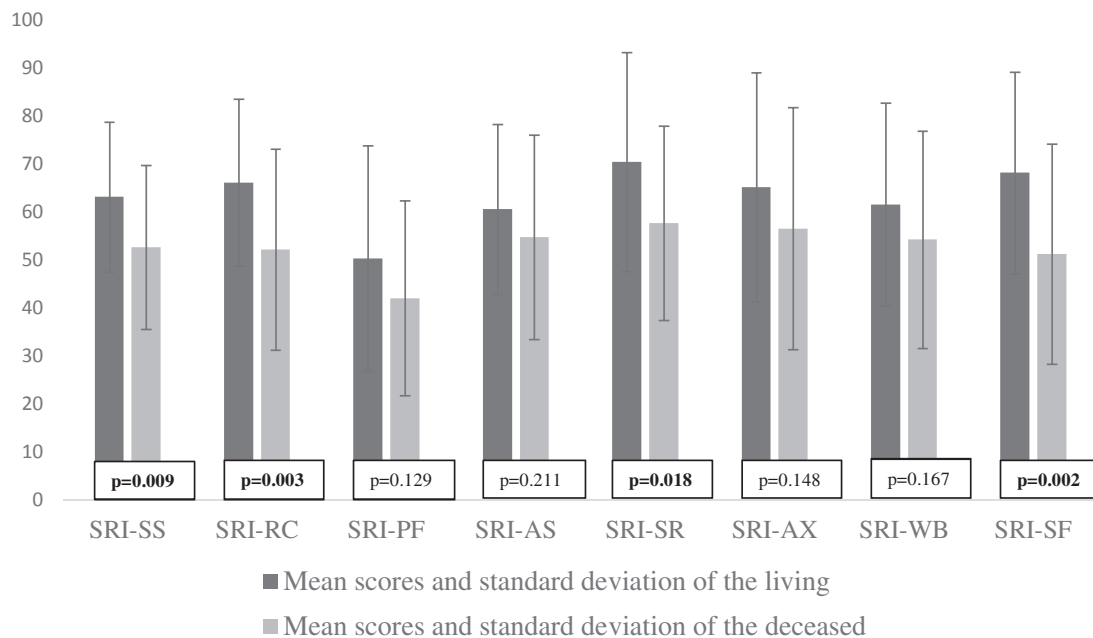


FIGURE 2 Mortality vs HRQL (SRI 0 week) analysed with independent samples *t*-test. The statistically significant differences bolded. HRQL, health-related quality of life; SRI-SS, summary scale; SRI-RC, respiratory complaints; SRI-PF, physical functioning; SRI-AS, attendant symptoms and sleep; SRI-SR, social relationships; SRI-AX, anxiety; SRI-WB, psychological well-being; SRI-SF, social functioning

better from those with worse HRQL), their responsive property (measures how the HRQL changes with treatment intervention or over time) and their predictive property (to predict future outcomes, eg, mortality).²⁷ In recent studies, results for SRI, MRF and SGRQ were strong predictors of mortality in COPD patients, independently of pulmonary function, BMI or hypercapnia.^{21-22,25,27} In our study, results for the SRI-SS and subscales RC, SR and SF were associated with patients' prognosis during the following 5 years: patients who at baseline had lower scores on these subscales and on SRI-SS showed lower HRQL and were more likely to die during the following 5 years. Comparing the patients who survived to those who died, those who died had more treatment episodes in the pulmonary ward, but fewer visits in the outpatient clinic. It is logical that those who died, with lower HRQL, were in the poorest condition and needed more treatment in the pulmonary ward. Another reason for the lower number of outpatient clinic visits is that in HUH the weakest patients often have their follow-up visits in pulmonary wards. However, as the study was neither aimed to nor designed to analyse CRF patients' prognosis, the findings as regards mortality are at best only indicative.

There are some limitations to our study. Our number of patients was relatively small (74 patients in total), which represents only a portion of our CRF patients treated with HMV or LTOT or both at that time. In other validation studies, the number of patients has ranged from 56 to 152.

Only 48% of the patients invited to participate were willing to enter the study, even though their participation

required neither major physical effort nor extra hospital visits. However, answering the long questionnaires was quite laborious. We also assume that this patient group's weak overall condition limited the number of participants. The most common pathologies for CRF were included, and the results were in line with those of the other validations. For validation of the SRI, the patient number can thus be considered to have been sufficient.

A strength of this study was that the reproducibility of both the SRI and SGRQ was also analysed, and found to be good. To our knowledge, reproducibility of SRI has undergone study earlier only in the Spanish validation,⁸ and showed comparable results. Reproducibility of SGRQ has been affirmed to be good.²⁸

In conclusion, we showed that the Finnish version of the SRI was valid, reliable and reproducible. Its psychometric properties are in line with those of the original German questionnaire and other validation studies. The Finnish SRI qualifies for use in assessing the HRQL in CRF patients treated with HMV or LTOT or both.

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CONFLICT OF INTEREST

The authors report no conflicts of interest in connection with this article.

AUTHOR CONTRIBUTIONS

All authors read and approved the final manuscript. P. Kotanen takes responsibility of the whole work.

Study design: Kainu, Kreivi

Data collection: Kainu

Translation of the questionnaires: Lehtomäki

Data analysis: Kotanen, Bergman

Written report: Kotanen, Brander, Kreivi

ETHICS

The medical ethics committee of Helsinki University approved the study (study number 370/13/03/01/2012).

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the Supporting Information section.