

Health-Related Quality of Life of Patients Receiving Home May Mechanical Ventilation: The Spanish Version of the Severe Respiratory Insufficiency Questionnaire

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OBJECTIVE: Home mechanical ventilation is used with patients with severe, chronic respiratory failure, a condition that has a serious impact on quality of life. The aim of this study was to produce a translation and cultural adaptation of the Severe Respiratory Insufficiency Questionnaire for the Spanish population, the first health-related quality of life questionnaire specifically designed for patients receiving home mechanical ventilation.

METHODS: Four bilingual German-Spanish translators were used to translate and back-translate the questionnaire. Meetings were held with the translators following each step of the translation process to produce a single version that could be used in the next step. At the end of the process, the questionnaire was piloted to assess its comprehensibility. A scoring system using a scale of 1 (lowest) to 10 (highest) was used to rate both translation difficulty and the naturalness of the language produced. The equivalence of the original and translated items was also evaluated.

RESULTS: Three Spanish versions of the questionnaire were produced. Task difficulty was rated as quite low: the mean (SD) ratings were 1.4 (0.6) for translation and 2.2 (1.1) for back translation. The naturalness of the translated items was rated as very high, with scores improving with the successive versions (version 1, 8.4; version 2, 8.7; version 3, 9.1; $P < .001$). Thirty of the questionnaire items (61.2%) were judged to be fully equivalent, 13 (26.5%) to be similar, and 6 (12.2%) to be non-equivalent. The meaning conveyed by 5 of the items was changed or clarified during piloting.

CONCLUSIONS: The translation of the questionnaire using the translation—back-translation procedure has produced a version that is both comparable to the original and accessible to the Spanish population. Its validity is currently being tested in a multicenter study.

Key words: *Quality of life. Home mechanical ventilation. Cross-cultural studies.*

Calidad de vida relacionada con la salud de pacientes en programa de ventilación mecánica domiciliaria. La versión española del cuestionario SRI

OBJETIVO: La ventilación mecánica domiciliaria se aplica a pacientes con insuficiencia respiratoria crónica y grave, lo que tiene un impacto considerable en su calidad de vida. El objetivo de este trabajo ha sido realizar una traducción y adaptación transcultural para la población española del cuestionario Severe Respiratory Insufficiency (SRI), el primer cuestionario de calidad de vida relacionada con la salud específico para estos pacientes.

MÉTODOS: Intervinieron 4 traductores bilingües alemán-español siguiendo el método de la traducción y retrotraducción. Después de cada paso se realizaron reuniones con los traductores para obtener una versión única antes de continuar. Al final del proceso se realizó una prueba piloto para valorar su comprensibilidad. El proceso de traducción se evaluó en dificultad y naturalidad, mediante una escala entre 1 (mínimo) y 10 (máximo), así como en equivalencia de los ítems con la versión original.

RESULTADOS: Se obtuvieron 3 versiones en español. La dificultad de la traducción fue considerablemente baja para la traducción (media \pm desviación estándar) 1,4 \pm 0,6) y la retrotraducción (2,2 \pm 1,1). La naturalidad de los ítems fue muy elevada y mejoró con las sucesivas versiones (versión 1: 8,4; versión 2: 8,7; versión 3: 9,1; $p < 0,001$). Se catalogaron como totalmente equivalentes 30 ítems (61,2%), 13 (26,5%) fueron similares y 6 (12,2%) no fueron equivalentes. Durante la prueba piloto se matizaron 5 ítems.

CONCLUSIONES: La traducción del cuestionario siguiendo el método de la traducción-retrotraducción ha dado una versión española equiparable a la original y asequible para los pacientes. Actualmente se está llevando a cabo la validación del cuestionario mediante un estudio multicéntrico.

Palabras clave: *Calidad de vida. Ventilación mecánica domiciliaria. Estudios transculturales.*

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Introduction

Health-related quality of life (HRQL) questionnaires are multidimensional tools that explore aspects of patients' lives that are not covered by other diagnostic tools. They are an invaluable source of information on how disease affects a patient's life. HRQL questionnaires have gained increasing importance in both research and clinical settings in recent years. Several types of questionnaires exist,¹ from generic ones devised for the general population to specific questionnaires tailored to certain groups of patients.² Respiratory medicine questionnaires tend to deal with high-prevalence disorders such as chronic obstructive pulmonary disease (COPD),³ bronchial asthma,⁴ and bronchiectasis.⁵ Until very recently, however, no specific questionnaires were available for a particularly important group of patients: those with chronic respiratory failure, and particularly those requiring chronic ventilatory support and receiving home mechanical ventilation.

Although patients undergoing mechanical ventilation at home have a variety of diseases, they have in common chronic severe respiratory failure and a considerably impaired quality of life.⁶ It would therefore be highly desirable to have a questionnaire specifically designed to deal with their needs. Many important aspects of these patients' lives are not covered by generic or COPD questionnaires,⁷⁻⁹ and this results in incomplete HRQL scores. The Severe Respiratory Insufficiency questionnaire (SRIQ)¹⁰ is a recently published multidimensional HRQL questionnaire found to have good psychometric properties when used in the population it was specifically designed for: patients receiving home mechanical ventilation. The aim of the present study was to produce a translation and cultural adaptation of this questionnaire for the Spanish population.

Methods

Tool

The SRIQ is a self-administered questionnaire containing 49 items that patients score on a 5-point scale (1: completely false; 2: quite false; 3: partly true/partly false; 4: quite true; 5: completely true) according to how true each statement has been for them in the preceding week. The questionnaire contains 7 HRQL domains, or subscales, and is designed in such a way that each item belongs to just 1 subscale. The 7 subscales are respiratory complaints (8 items), physical functioning (6 items), attendant symptoms and sleep (7 items), social relationships (6 items), anxiety (5 items), psychological well-being (9 items), and social functioning (8 items). The final score for each subscale is calculated by recoding certain items and calculating a percentage. The overall score is obtained by calculating the arithmetic mean of the subscale scores in such a way that this calculation would not be possible if any of the scores were missing. A high overall score indicates a good quality of life while a low overall score indicates a poor quality of life.

Spanish Translation and Cultural Adaptation

The original questionnaire, which was written in German, was translated into Spanish using the translation—back-translation procedure.¹¹ The process was supervised by the team in charge of the Master's Degree in Specialized Translation offered by the Department of German Language and Literature at the University of Sevilla, Spain. The translations and back-translations were carried out by 4 bilingual translators (2 German and 2 Spanish), each with extensive experience in the translation of specialized texts. A parallel, blind design was used. The 2 Spanish translators translated the questionnaire from German into Spanish (version 1) while the 2 German translators translated the resulting Spanish text back into German. Both groups were asked not to translate concepts literally but to use natural-sounding equivalent expressions. Both the questionnaire items and the introductory phrases were translated and back-translated. Meetings were held between the principal investigator and the translators following each step of the process in order to produce a single version for the next step. The back-translation of the questionnaire was sent to the main author of the original SRI study. The author then reported back on the equivalence of the expressions, as described below. A second meeting was held with the Spanish translators and any expressions that were not considered fully equivalent were modified and incorporated into the second version of the questionnaire.

Piloting

Finally, the questionnaire was piloted among a group of 11 nontracheostomized patients receiving home mechanical ventilation in order to evaluate its applicability and comprehensibility. Each of the patients was given the questionnaire and asked to explain the meaning of each item and to suggest an alternative when items were difficult to understand or when the desired meaning was not quite conveyed. This information was then used to produce the third version of the questionnaire (Appendix). During the piloting phase of the project, information was also gathered on the patients' educational backgrounds, their level of physical activity according to British Thoracic Society criteria,¹² why they required mechanical ventilation, the type of respirator they used, and the use they made of it. Finally, in order to gather preliminary information on the viability of the questionnaire, we analyzed the percentage of questionnaires answered by the patients, the time it took for them to be answered, and the number of items that were left answered.

Process Evaluation

The translation—back-translation process was evaluated in terms of difficulty, naturalness, and equivalence. Each translator evaluated the difficulty of finding a suitable expression for each item according to a 10-point scale, where 1 was the lowest and 10 was the highest. A member of the research team (ALJ) evaluated the naturalness of the Spanish translations and the main author of the original questionnaire¹⁰ evaluated the naturalness of the German back-translations on a scale of 1 (lowest) to 10 (highest). The German author also evaluated the equivalence of the back-translated items to the original items and grouped these into 3 categories¹³: category A, items that were fully equivalent; category B, items that were not fully equivalent or that contained questionable wording; and category C, items that were not equivalent or that needed to be checked.

Statistical Analysis

Statistical analysis was performed using version 12.0 of the Statistical Package for Social Sciences (SPSS, Chicago, Illinois, USA). For the descriptive analysis, quantitative variables were expressed as means (SD). Absolute and relative frequencies were calculated for qualitative data and corrected values were used for missing data. The α error was set at .05 for the inferential analysis. Parametric tests were set up to analyze the results of the translation process. The Student *t* test for paired samples was used to analyze the differences between the results obtained for the different versions of the questionnaire. The differences between the different items in each subscale were evaluated using analysis of variance, and post hoc Bonferroni adjustment was used to detect within-group differences where applicable. All other quantitative variables were analyzed using the Student *t* test for nonpaired samples. Item equivalence distribution patterns between different subscales were analyzed using the χ^2 test.

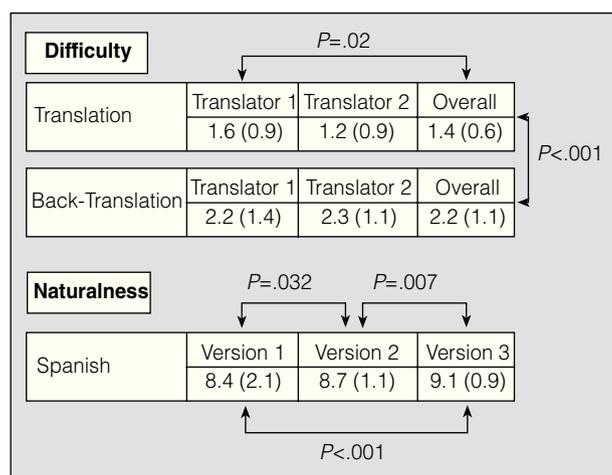


Figure 1. Questionnaire translation difficulty and naturalness.

Results

Translation and Back-Translation

Task difficulty was rated as quite low for both translation and back-translation, with mean scores of 1.4 (0.6) and 2.2 (1.1), respectively. There were significant differences between the difficulty rating given by the Spanish translators and the overall difficulty ratings given by the translators and back-translators: the German translators were generally more

demanding than the Spanish translators (Figure 1). The Spanish translators gave all items except items 19 and 28 a difficulty rating of less than 3, while the German translators gave 11 items (3, 16, 19, 25, 28, 29, 30, 33, 34, 35, and 39) a difficulty rating of 3 or more. Three of the 11 items (30, 34, and 39) were given a difficulty rating of 5 or more. When translation difficulty was analyzed by subscale (Table 1), it was seen that the

TABLE 1
Questionnaire Subscales With Difficulty, Naturalness, and Equivalence Values*

Subscales	No. of Items	Difficulty		Naturalness				Equivalence
		Translation†	Back-Translation	Version 1	Version 2	Version 3	Back-Translation‡	
Respiratory complaints	8	2.1 (0.6)	2.4 (0.6)	8.5 (1.1)	9.1 (0.6)	9.3 (0.7)	7.5 (3)	A: 3 (37.5%) B: 4 (50%) C: 1 (12.5%)
Physical functioning	6	1.2 (0.4)	2.5 (1.09)	9 (0.8)	8.8 (0.9)	9.1 (0.7)	9.6 (0.8)	A: 5 (83.3%) B: 1 (16.7%) C: 0 (0%)
Attendant symptoms and sleep	7	1.1 (0.2)	1.4 (0.1)	8.5 (1.2)	9.1 (0.3)	9.1 (1.1)	10 (0)	A: 6 (85.7%) B: 0 (0%) C: 1 (14.3%)
Social relationships	6	1. (0.2)	1.6 (0.6)	8.1 (0.7)	8.1 (1.7)	8.8 (1.1)	10 (0)	A: 4 (66.7%) B: 1 (16.7%) C: 1 (16.7%)
Anxiety	5	2.4 (1.1)	2.8 (1.4)	8.2 (1.6)	8.6 (0.5)	9 (1)	9.6 (0.8)	A: 3 (60%) B: 2 (40%) C: 0 (0%)
Psychological well-being	9	1.2 (0.5)	2.6 (1.7)	8.6 (0.5)	8.7 (1.2)	8.8 (0.3)	9.3 (1.3)	A: 5 (55.6%) B: 4 (44.4%) C: 0 (0%)
Social functioning	8	1.1 (0.2)	2.3 (1.2)	7.3 (1.6)	8.2 (1.4)	9 (0.9)	10 (0)	A: 4 (50%) B: 1 (12.5%) C: 3 (37.5%)
Total	49	1.4 (0.6)	2.2 (1.1)	8.3 (1.2)	8.7 (1)	9 (0.8)	9.3 (1.5)	A: 30 (61.2%) B: 13 (26.5%) C: 6 (12.2%)

*Data are shown as means (SD) in columns 3 through 8 and as number of patients (percentage) in the last column. A indicates items that were fully equivalent; B, items that were not fully equivalent or that contained questionable wording; C, items that were not equivalent or that needed to be checked.
 †*P* < .001 according to analysis of variance (ANOVA).
 ‡*P* = .014 according to ANOVA.

TABLE 2
Pilot Group

Characteristics	No. (%)
Educational level	
Incomplete primary education	4 (36.3)
Complete primary education	4 (36.3)
Vocational training	1 (9)
High school education	1 (9)
Tertiary level education, 2-year degree	1 (9)
Level of physical activity	
Unrestricted normal activity	4 (36.3)
Restrictions on strenuous activity, able to perform undemanding tasks	4 (36.3)
Very restricted everyday activity but capable of self-care	1 (9)
Very restricted everyday activity and incapable of self-care	1 (9)
Confined to bed/armchair, incapable of self-care	1 (9)
Reason for mechanical ventilation	
Spinal curvature	7 (63.6)
Neuromuscular disease	1 (9)
Obesity-hypoventilation syndrome	1 (9)
Chronic obstructive pulmonary disease	2 (18)
Type of respirator	
Volume	3 (27.2)
Pressure	8 (72.7)

anxiety and respiratory complaints subscales were considered most difficult ($P<.001$). Although no significant differences were found, the German translators found the attendant symptoms and sleep and social relationships subscales easiest to translate.

The language used to translate the items into Spanish was rated as very natural and the ratings improved with successive versions of the questionnaire (Figure 1). All the items in the first 2 versions were given a naturalness rating of 5 or more and all the items in the third version were given a rating of 7 or more. The language used in the back-translated versions was also rated as very natural (9.4 [1.6]), although 2 of the items (items 19 and 25) were given a rating of under 5. No significant differences were found when naturalness was analyzed by subscale in any of the Spanish versions of the questionnaire (Table 1). In the back-translated version, however, the respiratory complaints subscale scored worse than the others in terms of naturalness ($P=.014$) (Table 1).

In the equivalence study, the majority of items ($n=30$, 61.2%) were placed in category A (fully equivalent). Thirteen (26.5%) items were placed in category B and 6 (12.2%) in category C. Only slight changes, such as the correct expression of certain function words or the suppression of others, were required to correct the items in category B. Category C contained items that had been back-translated quite literally. No significant differences were found in terms of item equivalence distribution patterns between subscales. All the items in categories B and C were corrected in a meeting held with the translators.

Piloting

Eleven patients (9 men and 2 women) with a mean (SD) age of 66 (4) years were selected for the piloting of the questionnaire. The 11 patients differed in terms of cultural background, previous physical activity, the reasons why they needed mechanical ventilation, and the type of respirator they used (Table 2). Mean (SD) respirator use was 7.6 (1.6) hours a day for 6 (2.7) years. All the patients had adapted well to using mechanical ventilation and no serious adverse effects were reported. The meaning conveyed by 5 of the questionnaire items was changed or clarified during the piloting phase (Table 3).

According to the preliminary viability data collected, the mean (SD) time required to complete the questionnaire was 7.1 (7.7) minutes. Seven patients (63.3%) completed the questionnaire themselves. The other 4 completed the questionnaire through an interviewer as their eyesight was not good enough to read it. All of the items were answered by all of the patients.

Discussion

This study presents the results of the cultural adaptation of the SRIQ from German to Spanish using a translation—back-translation procedure, one that has been successfully used in a large number of other cultural adaptation projects. Although most projects to date have involved an English source text, we found that the translation—back-translation procedure worked equally well with a German source text.

The SRIQ is of particular interest in that it is the first questionnaire that has been specifically designed for

TABLE 3
Main Items Whose Meaning Was Corrected or Clarified During Piloting

Item	Spanish	Comment
9	I fall asleep easily	The German verb <i>einschlafen</i> refers only to the action of falling asleep, not to the actual sleeping process
15	I am tied to home because of my disease	Although this expression is relatively common in German, it is less so in Spanish
16	I find it difficult to do chores in the home	Some patients do not do chores in the home for sociocultural reasons
31	My spouse/partner suffers because of my disease	Not all patients have a spouse or a partner
48	My disease restricts my leisure time possibilities	The expression is more common in German than in Spanish

patients with severe respiratory failure and in particular for patients receiving home mechanical ventilation. Such questionnaires are important as they can be used to gather quantifiable information on patients' opinions of how their lives are affected by their disease, to optimize cost effectiveness and resource utilization, and to compare results from different countries, which facilitates the organization of international multicenter studies.¹⁴

One of the initial problems we encountered was the similarity between the names of the different subscales dealing with social aspects. The questionnaire contains 3 such subscales: social relationships, psychological well-being, and social functioning. The social relationships subscale (items 7, 10, 21, 27, 43, and 46) deals with how patients relate to people they are close to; the psychological well-being subscale (items 4, 20, 30, 34, 36, 38, 40, 44, and 49) deals with different feelings that patients experience in everyday situations (like irritability, sadness, and joy); and finally, the social functioning subscale (items 3, 15, 23, 31, 35, 37, 47, and 48) deals with patients' ability to participate in social events.

When translating the different expressions into Spanish, the team took particular care to choose phrases that were natural sounding and easy to understand throughout Spain. To do this, they avoided using excessively local words or expressions. All the items were considered relatively easy to translate. There were slight differences between the difficulty ratings given by the Spanish translators and the overall difficulty rating for the 2 languages (Figure 1). This was probably related to the different nature of each language. The most difficult concepts to translate were those dealing with dyspnea and anxiety. This is probably because they can be expressed in different ways, both in German and Spanish, depending on the regions where they are used. The back-translators had greater difficulty with items that contained colloquial expressions (items 30, 34, and 39).

The naturalness of the Spanish expressions was rated as very high and scores increased with successive versions of the questionnaire. This reflects how the comprehensibility of the questionnaire also improved during the process. Item number 15 was considered to be the least natural item and was corrected during the adaptation process. The least natural items in the back-translated version also belonged to the respiratory complaints subscale, which probably reflects the diversity of expressions that exist to express the concept of dyspnea in both Spanish and German.

Equivalence problems were mainly due to an excessively literal and therefore unnatural-sounding translation. These expressions were easily corrected, however, in a meeting held with the translators.

The questionnaire was accessible to and easily understood by the patients that participated in the piloting stage of the project (Table 3). Several patients found it difficult to choose from among 5 options and preferred dichotomous "Yes/No"-type questions. The patients completed the questionnaire in a matter of minutes and understood the questionnaire items,

instructions, and introductory phrases well. This indicates that the questionnaire is feasible. Further feasibility studies, however, are necessary as our data are very preliminary and correspond to only a very small sample.

As a final stage in the cultural adaptation process, the questionnaire's psychometric properties are currently being assessed in a multicenter study. This stage is necessary in order to check that the new version is equivalent to the previous version as this would mean that the results of applying it would also be comparable to those of the original version.

In summary, the SRIQ is a valid measurement instrument that has been specifically designed for assessing HRQL in patients receiving home mechanical ventilation. The translation of the questionnaire using a translation—back-translation procedure has produced a version that is both comparable to the original and accessible to Spanish patients. Its validity is currently being tested in a multicenter study.

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Note

A copy of the SRIQ, together with recoding and interpretation instructions, is available free of charge from the main author of this study.

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APPENDIX

Items in the Spanish Version of the Severe Respiratory Insufficiency Questionnaire*

<ol style="list-style-type: none"> 1. I find it difficult to climb stairs. 2. I get short of breath when I eat. 3. I can go out in the evenings. 4. I often feel down. 5. I also get short of breath even when I'm not making any physical effort. 6. I often get headache. 7. I have a lot of friends and acquaintances. 8. I am worried that my disease will get worse. 9. I fall asleep easily. 10. I get on well with other people. 11. I sometimes feel dizzy. 12. I wake up at night because of shortness of breath. 13. I feel afraid that I will get short of breath during the night. 14. I often have neck ache. 15. I am tied to home because of my disease. 16. I find it difficult to do chores at home. 17. I often wake up at night. 18. I can sleep through the night. 19. I get short of breath when I breathe. 20. I feel optimistic about the future. 21. I feel lonely. 22. I can't get enough air when I speak. 23. Receiving visitors tires me out. 24. I cough a lot. 25. My airways often feel full of phlegm. 	<ol style="list-style-type: none"> 26. I avoid situations in which I might feel embarrassed by my shortness of breath. 27. I feel comfortable with my friends. 28. I am afraid that I will not be able to get enough air. 29. I get short of breath when I make physical effort. 30. The limitations of my disease frustrate me. 31. My spouse/partner suffers because of my disease. 32. I can do the shopping. 33. I can do all the activities I like to do in my free time. 34. I often feel irritated. 35. I have less contact with friends and acquaintances because of my disease. 36. I am happy with my life. 37. I can take part in social events. 38. I often feel sad. 39. My breathing problems bother me in public. 40. I often feel anxious. 41. I can dress myself. 42. I feel tired during the day. 43. I feel isolated. 44. I cope well with my disease. 45. My breathing problems restrict my everyday activities. 46. My disease affects my family life. 47. I have lost touch with other people because of my disease. 48. My disease restricts my leisure time possibilities. 49. I am generally happy with my life.
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*This English version is an unvalidated translation of the questionnaire, provided only for purposes of understanding the present study.