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Original Article

Development and Validation of a Quality-of Life Questionnaire for Patients With Chronic Respiratory Disease (CV-PERC): Preliminary Results

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ABSTRACT

Introduction and Objectives: The instruments used to assess quality of life in patients with chronic respiratory difficulties have approached this construct in a limited and partial way. Due to this fact, the present paper aimed at describing the development and validation of the CV-PERC scale contemplating the dimensions of physical, psycho-emotional and social, cognitive, working, sexual functionalities and health perception and wellbeing.
Patients and Methods: It was built stemming from the Saint George Respiratory Questionnaire and the SF-36, generating new items after a theoretical revision and interviews to patients. The selected items were submitted to expert's judgments (Neumonologists and Health Psychologists) to assess validity, wording and appropriateness of language. The initial 60-item instrument was applied to a sample of 101 patients for item selection and analysis. Lastly, the final 50-item scale was administered to a sample of 255 patients from four hospitals in Caracas, Venezuela, to collect data for reliability and validity analyses.
Results: A 7-dimension factorial structure was found which explained 62.47% of the total variance (physical functionality, sexual functionality, working functionality, health perception and wellbeing, psycho-emotional functionality, cognitive functionality and social functionality). Internal consistency of each dimension and of the total scale was over 0.67. Convergent validity and discriminant coefficients were above 0.64.
Conclusions: The results provide evidence that the CV-PERC scale is a valid and reliable measure to assess quality of life in asthma and EPOC patients.

Construcción y validación del instrumento Calidad de Vida en Pacientes con Enfermedades Respiratorias Crónicas (CV-PERC). Resultados preliminares

Palabras clave:
Calidad de vida relacionada con la salud
Asma
Enfermedad pulmonar obstructiva crónica (EPOC)
Fiabilidad
Validez

RESUMEN

Introducción y objetivos: Los instrumentos para medir la calidad de vida en pacientes con dificultades respiratorias crónicas han abordado este constructo multidimensional de forma parcial y limitada. Debido a ello, el presente trabajo ha tenido por objetivo desarrollar y validar la escala Calidad de Vida en Pacientes con Enfermedades Respiratorias Crónicas (CV-PERC), que contempla las funciones física, psicoemocional, social, cognitiva, laboral y sexual, y la percepción de salud y bienestar.

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Pacientes y método: La CV-PERC se ha construido a partir de la revisión del Cuestionario Respiratorio de Saint George y del SF-36, así como de la generación de nuevos ítems tras la revisión teórica y la realización de entrevistas a pacientes. Los ítems seleccionados se sometieron al juicio de expertos (neumólogos y psicólogos de la salud) para evaluar su validez, redacción y adecuación del lenguaje. El instrumento inicial, de 60 ítems, se aplicó a una muestra de 101 pacientes para el análisis y selección de ítems. Finalmente se aplicó la escala definitiva de 50 ítems a una muestra de 255 pacientes de 4 hospitales de Caracas (Venezuela) para los análisis de fiabilidad y validez.

Resultados: Se encontró una estructura factorial de 7 dimensiones que explican el 62,47% de la varianza total (Función Física, Función Sexual, Función Laboral, Percepción de Salud y Bienestar, Función Psicoemocional, Función Cognitiva y Función Social). La consistencia interna de cada dimensión y de la escala total es superior a 0,67. Los coeficientes de validación convergente y discriminante son superiores a 0,64.

Conclusión: Los resultados evidencian que la escala CV-PERC es una medida válida y fiable para evaluar la calidad de vida en pacientes con asma y enfermedad pulmonar obstructiva crónica.

Introduction

Despite the enormous interest in quality of life and the growing number of studies in this area, no consensus has yet been reached on how it should be defined or on which domains should be assessed. The World Health Organization (WHO) recently defined this concept as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."[1] The definition added that it was "a broad-ranging concept incorporating in a complex way the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of the environment." This predominantly multidisciplinary view reflects the fact that health is no longer seen as just the absence of disease but as something that involves physical, mental, and social well-being.[2] The above definition, however, is not the only one, nor is it definitive.

Quality of life has many definitions in health care. Hörnquist,[3] for example, defined it as "perceived global satisfaction and satisfaction within a number of key domains with special emphasis on well-being." The definition of Patrick and Ericsson,[4] on the other hand, described it as "the value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy." Wilson and Cleary,[5] in turn, consider that quality of life is perceived well-being.

Health-related quality of life (HRQOL) is an even broader construct that has been defined as the subjective perception of how a disease and its treatment affect different aspects of a patient's everyday life.[6] Physical, psychological/emotional, and social functions generally receive the most attention in HRQOL studies,[7,8] with other important aspects such as perceived health and well-being and cognitive, occupational, and sexual functions being neglected. Researchers do not always agree on which domains should be assessed, perhaps because of the need to adapt indicators to different contexts and target populations.[9] Given such differences of opinion, Nissenson et al[7] have also indicated that frameworks vary in accordance with the needs of a research project.

There are a number of quality-of-life measurement tools available for use in health care, in particular with regard to chronic respiratory disease. The scope of these tools, however, is limited by the fact that they deal almost exclusively with physical function, as is the case with the St George's respiratory questionnaire.[10] While other tools measure several aspects of quality of life, they do not consider the construct as a whole. The Chronic Respiratory Questionnaire (CRQ),[11] for example, only measures physical and emotional aspects while the Airways Questionnaire 20 (AQ20) measures symptoms, emotional function, and environmental stimuli.[11,12] The aim of the present study was to develop and validate a scale (named CV-PERC after its Spanish acronym) to measure quality of life in patients with chronic respiratory diseases for use in Venezuela. Because the scale was designed to provide
a measure of quality of life based on a broad-ranging, multidimensional definition of the concept, we sought to provide preliminary data regarding its reliability and construct validity.

Figure 1 shows the different domains which we believe should be considered when evaluating quality of life. As can be seen, we sought to provide an integrated vision of quality of life considering it as the result of the interplay between various factors such as disease type and course, patient personality, the degree of change that inevitably affects different aspects of a patient's life, social support received, and the perception of this support. We believe that such an approach is fitting in the case of chronic respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD), as these produce many and varied changes in the everyday lives of patients, affecting many aspects, among them the relationships with family and friends and the ability to work and enjoy outdoor leisure pursuits.

Patients and Methods

We conducted a preliminary analysis of items, instructions, and time required to administer the questionnaire during an interview in a sample of 101 patients attending the lung function laboratory at Hospital Militar Dr Carlos Arvelo in Caracas, Venezuela; 43 (42.57%) of the patients had COPD and 58 (57.43%) had asthma. There were 41 women (40.59%) and 60 men (59.41%), with a mean age of 62 years.

To determine the validity and reliability of the CV-PERC, we interviewed 255 patients from 4 public hospitals in the metropolitan area of Caracas. Of these patients, 104 (40.80%) had asthma and 151 (59.20%) had COPD; there were 145 women (56.90%) and 119 men (43.10%), and the mean age was 60 years.

Although there are several questionnaires specifically designed to evaluate quality of life in patients with respiratory diseases (such as the CRQ[11] and the AQ20[11,12]), we based the CV-PERC on the 2 most commonly used questionnaires in Venezuela: the SGRQ,[10] which is specifically designed to measure HRQOL in patients with COPD and asthma, and the Short Form-36 Health Survey (SF-36),[13] which provides a general measure of HRQOL. In the first stage of the development process, 3 pulmonologists and 3 psychologists reviewed each of the items in the SGRQ. This questionnaire measures 3 domains: symptoms, activity, and impact. Based on the feedback from these 6 experts, we included revised items from the SGRQ in the CV-PERC, together with reformulated items from the SF-36 and new items created after analyzing information gathered through interviews with

patients with asthma and COPD and a review of the literature. Five health psychologists analyzed the resulting version to evaluate the content and the appropriateness of language and expression for the scale items and instructions.

The revised version was then administered to a convenience sample of 101 patients to assess feasibility (instructions and administration time during an interview) and intelligibility, and to conduct an item discrimination analysis (using 0.60 as the level of adequate discrimination). On completion of this stage, the scale was reduced to 50 items.

The last step in the process was to administer the 50-item questionnaire to a sample of 255 patients to test reliability (internal consistency) and construct validity. To test the convergent and discriminant validity of the CV-PERC, we administered the Venezuelan versions of Diener's Satisfaction With Life Scale[14] and Rosenberg's Self-Esteem Scale.[14] All of the questionnaires were administered during face-to-face interviews.

Results

Content Validation

The pulmonologists who studied the SGRQ concluded that all the items from the symptoms and activity domains and 4 of those from the impact domain measured physical function, and that only 27 of the 48 items in the questionnaire were expressed appropriately. The level of agreement for the assessment of these items was over 65%. They suggested replacing the expressions *falta de aire* (literally, lack of air) with *dificultad para respirar* (difficulty breathing) and *ataques de silbidos* (wheezing attacks) with *pitos en el pecho* (whistling in the chest) and eliminating repetitive and irrelevant items such as those that referred to activities that are not common in Venezuela (eg, bowling and digging in the garden). The 3 health psychologists agreed with the pulmonologists that the questionnaire covered physical function in depth but paid little or no attention to other aspects of quality of life, making it unsuitable for providing a global measure of the construct.

On completion of the preliminary development stages (analysis/revision of the SGRQ, reformulation of items from the SF-36, and analysis of information from patient interviews and review of the literature), the CV-PERC contained 60 items covering the following domains: physical function (17 items from the SGRQ); psychological/emotional function (4 items from the SGRQ and 3 from the mental health scale of the SF-36); social function (2 items from the social functioning scale of the SF-36 and 2 from the SGRQ, 1 of which was divided into 3 items as it expressed 3 separate ideas), work function (4 items from the role-physical scale of the SF-36 and the only related item from the SGRQ), cognitive function (5 new items), sexual function (5 new items), and perceived health and well-being (5 new items).

Finally, 5 psychologists specialized in matters of health reviewed and approved the definitive version of the CV-PERC, coming to agreement 80% of the time or more on their assessment of whether the items corresponded to the proposed domains and of whether they were appropriately written in the correct register for use with patients with a chronic respiratory disease (asthma or COPD).

Construct Validity

To test the underlying empirical structure of the CV-PERC, we conducted exploratory factor analysis. Prior to this, we analyzed the adequacy of the correlation matrices by calculating the Kaiser-Meyer-Olkin measure of sampling adequacy (which was satisfactory at 0.862) and the Bartlett test of sphericity, which was statistically significant χ^2=11 484.572, α<.001). These results indicated the presence of significant correlations and confirmed that factor analysis was pertinent. Principal components analysis (PCA) with varimax rotation was used, with eigenvalues of over 1.5 for the extraction of factors and factor loadings of over 0.35 for the selection of items.

Seven factors emerged, which, combined, accounted for 62.43% of the total variance. Factor 1, which accounted for 25.34% of the variance and was labeled physical function, contained items that measured perceived physical state or health state, frequency and intensity of disease-related symptoms, impact of symptoms on activities of daily living (walking, bathing, dressing, etc), and adverse effects attributable to treatment. Factor 2, which accounted for 9.98% of the total variance, was labeled sexual function and

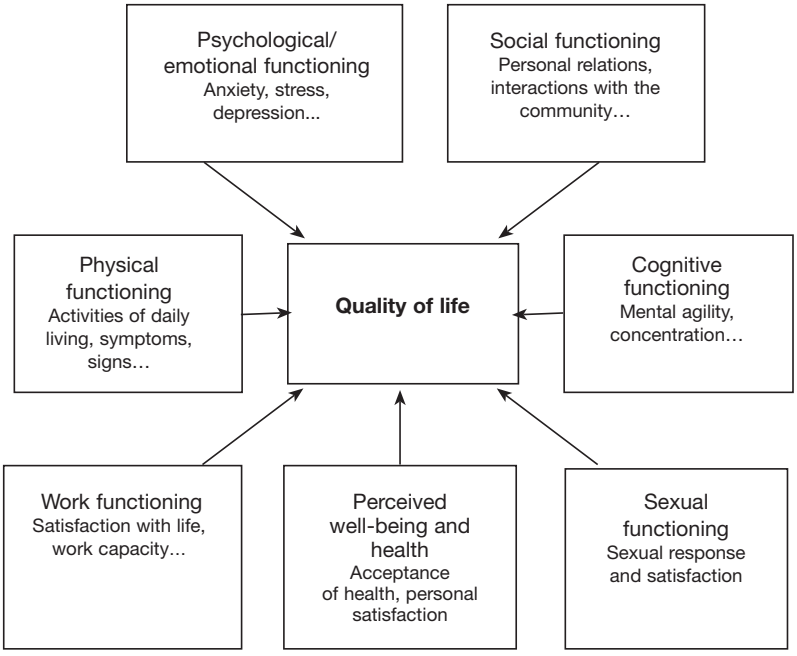

Figure 1. Domains that should be assessed when measuring quality of life.

Table 1
Factor Loadings of Items in Each Domain of the CV-PERC Scale[a]

	Factors						
Items	1	2	3	4	5	6	7
Physical function							
In the last month, I have had...							
1. cough	0.4 74						0.2 49
2. phlegm	0.5 06						0.2 33
3. whistling in my chest (noise)	0.4 83						
4. pain in my chest or back	0.5 39						0.2 35
5. feelings of tiredness	0.6 79						
6. difficulty breathing when seated	0.6 72						
7. difficulty breathing when talking	0.7 26					0.2 43	
8. difficulty breathing when doing everyday tasks such as bathing or dressing	0.7 67						
9. difficulty breathing when walking on a flat surface inside the house	0.8 17						
10. difficulty breathing when walking on a flat surface outside the house	0.8 06						
11. difficulty breathing when walking up 5 stairs or fewer	0.8 49						
12. difficulty breathing when doing activities that require moderate effort such as walking for half an hour or walking uphill	0.7 38						
13. difficulty breathing when doing activities that require intense efforts such as running or lifting heavy objects.	0.6 10						
14. in the last month…I've taken longer than before to do everyday tasks such as bathing or dressing	0.6 47						
15. I've needed help to do everyday tasks such as bathing or dressing myself	0.4 77						
16. I've had to stop to rest when walking	0.7 18						
17. my sleep has been interrupted by coughing	0.5 97						
Sexual function							
In the last month, my respiratory problems...							
46. have reduced my sexual desire		0.8 33					
47. have made me avoid sexual relations		0.9 44					
48. have decreased my satisfaction during sexual intercourse		0.9 27					
49. have obliged me to reduce the frequency of my sexual intercourse		0.9 42					0.2 44
50. have obliged me to be sexually inactive		0.9 42					
Work function							
In the last month, my respiratory problems...							
41. have made me reduce the time I spend at my job			0.9 15				
42. have obliged me to reduce the number of tasks I do at work			0.9 34				
43. have caused continuous work delays			0.9 23				
44. have made me feel dissatisfied with my current work performance			0.8 23				
45. have prevented me from continuing to work			0.9 22				
Perceived health and well-being							
In the last month...							
25. I've accepted my current state of health				0.5 16			
26. I've experienced a feeling of well-being despite my respiratory problems				0.8 58			
27. I've felt inner peace				0.9 23			
28. I've felt that I live in harmony with everything around me				0.9 14			
29. my life has been meaningfu				0.4 87			
Psychological/emotional function							
In the last month...							
18. I've felt embarrassed coughing in public					0.7 33		0.2 35
19. my difficulty breathing has embarrassed me in public					0.7 84		
20. I've felt afraid when short of breath	0.2 24				0.6 17		
21. I've been in a bad mood		0.21 1	–0.2 00		0.3 60		
22. I've felt embarrassed using my medication in public					0.7 30		
23. I've felt very agitated			–0.2 41		0.5 48		
24. I've felt dispirited and sad			–0.2 03		0.5 09		
Cognitive function							
In the last month...							
30. I've been less able to memorize things						0.8 33	
31. I've been less able to concentrate on what I am doing						0.8 52	
32. it's been hard for me to understand what others are saying to me	0.2 44					0.8 18	
33. I've been constantly thinking about my state of health	0.2 50					0.3 50	
34. it's been hard to take decisions						0.7 00	
Social function							
In the last month...							
35. I've felt satisfied with the medical care I have received					0.2 37		0.3 59
36. I've felt supported by my religion or my religious beliefs							0.3 54
In the last month, my respiratory problems...							
37. have bothered my family and friends		0.2 40					0.3 50
38. have bothered my partner						0.2 50	0.5 81
39. have made it hard to participate in social activities with my family, friends, neighbors, and other people							0.4 60
40. have made people around me reject me			0.2 49				0.5 07

[a] This English version is an unvalidated translation of the CV-PERC, provided only for purposes of understanding the present study.

measured perceived sexual response, frequency, and satisfaction. Factor 3, accounting for 7.42% of the variance, was labeled work function and measured perceived ability or inability to perform usual work-related tasks and level of satisfaction with current performance. Factor 4, which accounted for 6.33% of the variance and was labeled perceived health and well-being, contained items related to perceived satisfaction with and acceptance of health and physical state. Factor 5, accounting for 5.11% of the variance and labeled psychological/emotional function, dealt with perceived psychological and emotional function. It included indicators of emotional state, stress, anxiety, distress, fear, and depression, among others. Factor 6, accounting for 4.49% of the variance and labeled social function, measured perceived impact of disease and treatment on personal relations and community interactions. It also dealt with social roles, interruption or reduction of typical social activities, need for family and community support, and satisfaction with the doctor-patient relationship. Finally, factor 7, which accounted for 3.75% of the total variance and was labeled cognitive function, measured perceived ability to think, concentrate, reason, take decisions, and plan. It also dealt with characteristics that are an inherent part of the thought and self-perception processes.

Table 1 shows the specific items grouped by domain together with their respective factor loadings, showing that they clearly define the domains to which they belong, thus supporting the construct validity of the CV-PERC scale. In our analysis of convergent and discriminant validity, we found that the scale was positively and moderately correlated with the Satisfaction With Life Scale[14] (r=0.65) and the Self-Esteem Scale[15] (r=0.64).

Reliability

To assess the reliability of the CV-PERC, we calculated the Cronbach α for each of the dimensions and for the scale as a whole. Internal consistency values were high, with Cronbach α ranging from 0.68 to 0.98 and the majority of domains having an α level over 0.80 (Table 2).

Definitive Questionnaire

The definitive version of the CV-PERC contains 50 items rated on a Likert-type scale of 4 points ranging from "No, not at all/No, absolutely not" to "Yes, definitely/Definitely." The 50 items are distributed in 7 domains: physical function (17 items), psychological/emotional function (7 items), cognitive function (5 items), social function (6 items), work function (5 items), sexual function (5 items), and perceived health and well-being (5 items). The score for each domain is calculated by totalling the points of each item in the group and the total overall score (0-150) is calculated by totalling the points for all the items. In the case of items 25-29 and 35-36, the scores were calculated inversely, ie, if the answer was "No absolutely not," the score, allocated was 3 instead of 0; if the answer was "A little," the score was 2 instead of 3; and finally, if the answer was "Definitely," the score was 0 instead of 3. The minimum score is 0 (highest quality of life) and the maximum, 150 (lowest quality of life). The test can be self-administered or administered during an interview; it takes approximately 20 minutes in either case.

Discussion

We have presented preliminary data on the CV-PERC, a new questionnaire designed to evaluate how patients with asthma and COPD perceive their quality of life from a broad-ranging, multidimensional perspective that spans 7 domains: physical function, sexual function, work function, psychological/emotional function, cognitive function, social function, and perceived health and well-being.

As is known, the SGRQ[10] is the gold standard for evaluating quality of life in patients with respiratory diseases such as asthma,[16] stable bronchiectasis,[17] COPD,[18-21] and even cystic fibrosis.[22] Nonetheless, it almost exclusively addresses aspects related to physical function, and neglects the multidimensional nature of quality of life. Although other instruments such as the CRQ[11] and the AQ20[11] include a few additional aspects, they do not provide a broad, comprehensive assessment of HRQOL.

The CV-PERC scale was designed to overcome this limitation. The domains it includes could serve as a model for questionnaires seeking to provide a more in-depth analysis of HRQOL in patients with other diseases. We have presented construct validity results as this is the first chronic respiratory disease questionnaire that contemplates all the key areas of HRQOL that might be affected by the intensity of symptoms. The 7-factor structure provides initial proof of the validity of the theoretical framework used during development of the instrument. It analyzes aspects such as cognitive function, work, sexual function, and perceived health and well-being[7] in addition to more typically included functions such as physical health, psychological/emotional state, and social function.[7,8] These domains provide information on physical and functional limitations experienced by patients with chronic respiratory diseases in different aspects of their life as the result of disease and related treatment.[23] We have also demonstrated that the questionnaire was positively and moderately correlated with the Satisfaction With Life Scale[14] and the Self-Esteem Scale.[15] These results were expected and demonstrate the convergent validity of the scale in accordance with the criteria of Anastasi and Urbina.[24]

The reliability results were also satisfactory, with Cronbach α values for each of the domains suggesting a high level of internal consistency and supporting the factor structure identified.

A possible limitation of this study is that it only provides data on construct validity, but we consider that this should be the first data presented for any new measurement tool. Further research is therefore required to support the empirical or criterion-referenced validity of the CV-PERC. Specifically, levels of agreement with objective disease severity measures such as lung function parameters or dyspnea levels must be explored. The sensitivity of the scale also needs to be analyzed, in terms of the instrument's predictive validity, and in particular, its ability to assess whether the objectives set by quality-of-life improvement interventions have been reached. Finally, because smokers have a worse HRQOL than nonsmokers,[26] future studies could also examine the applicability of the CV-PERC in smokers and determine the usefulness of the scale in smoking cessation programs in terms of identifying aspects of patients' lives that are adversely affected by smoking.

In summary, the CV-PERC scale appears to have adequate construct validity and appears to be suitable for measuring quality of life in patients with asthma and COPD. Unlike other instruments, it evaluates the impact that symptoms and their intensity have on various aspects of a patient's life, not just on physical or emotional

Table 2
Internal Consistency of Domains in the CV-PERC Scale

Domains	No. of Items	Cronbach α
Physical function	17	0,935
Sexual function	5	0.975
Work function	5	0.970
Perceived health and well-being	5	0.843
Psychological/emotional function	7	0.834
Cognitive function	5	0.819
Social function	6	0.674
Total	50	0.918

states; this makes it potentially very useful for helping health-care personnel to choose the best treatment based on patient needs and to monitor progress. The CV-PERC could also be used in the interpretation of the clinical significance of results because, as Sanjuás Benito[25] has stated, HRQOL is often part of the assessment of the outcome of treatment of patients with chronic respiratory diseases. Although the scale contains a greater number of items than is customary, it can be administered in just 20 minutes, making it ideal for obtaining, in a relatively short space of time, specific information on different aspects of a patient's life that can be used to help clinical practitioners take steps that will improve quality of life and researchers to investigate it.

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