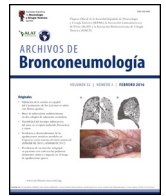




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## Original Article

### Translation to Spanish and Validation of the Specific Saint George's Questionnaire for Idiopathic Pulmonary Fibrosis<sup>☆</sup>

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#### ABSTRACT

**Introduction:** Interstitial lung disease (ILD) is associated with low exercise tolerance, dyspnea, and decreased health-related quality of life (HRQL). Idiopathic pulmonary fibrosis (IPF) is one of the most prevalent in the group. A specific version of the Saint George's questionnaire (SGRQ-I) has been developed to quantify the HRQL of IPF patients. However, this tool is not currently validated in the Spanish language. The objective was to translate into Spanish and validate the specific Saint George's Respiratory Questionnaire for idiopathic pulmonary fibrosis (SGRQ-I).

**Methods:** The repeatability, internal consistency and construct validity of the SGRQ-I in Spanish were analyzed after a backtranslation process.

**Results:** In total, 23 outpatients with IPF completed the translated SGRQ-I twice, 7 days apart. Repeatability was studied, revealing good concordance in test-retest with an ICC (interclass correlation coefficient) of 0.96 ( $P<.001$ ). Internal consistency was good for different questionnaire items (Cronbach's alpha of 0.9 including and 0.81 excluding the total value) ( $P<.001$ ).

The total score of the questionnaire showed good correlation with forced vital capacity FVC% ( $r=-0.44$ ;  $P=.033$ ), diffusing capacity of the lungs for carbon monoxide ( $DL_{CO}$ ) ( $r=-0.55$ ;  $P=.011$ ), partial pressure of oxygen in arterial blood PaO<sub>2</sub> ( $r=-0.44$ ;  $P=.036$ ), Medical Research Council Dyspnea scale ( $r=-0.65$ ;  $P<.001$ ), and number of steps taken in 24 h ( $r=-0.47$ ;  $P=.024$ ).

**Conclusions:** The Spanish version of SGRQ-I developed by our group shows good internal consistency, reproducibility and validity, so it can be used for the evaluation of quality of life (QOL) in IPF patients.

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### Traducción al español y validación del cuestionario Saint George específico para fibrosis pulmonar idiopática

#### RESUMEN

**Introducción:** Las enfermedades pulmonares intersticiales (EPI) se asocian a una baja tolerancia al ejercicio, disnea y disminución de la calidad de vida relacionada con la salud (CVRS). La fibrosis pulmonar idiopática (FPI) es una de las más prevalentes del grupo. Para cuantificar su CVRS, se ha desarrollado una versión específica del cuestionario Saint George (SGRQ-I). Sin embargo, esta herramienta no está actualmente validada en el idioma español. El objetivo fue traducir al idioma español y validar el SGRQ-I en pacientes con FPI.

##### Palabras clave:

Fibrosis pulmonar idiopática

Calidad de vida

Cuestionario Saint George

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**Métodos:** Se estudiaron la repetibilidad, la consistencia interna y la validez de constructo del SGRQ-I en español obtenido luego del proceso de traducción reversa.

**Resultados:** Veintitrés pacientes con FPI completaron 2 veces el cuestionario traducido con 7 días de diferencia cada uno. Encontramos una buena concordancia en el test-retest, con un coeficiente de correlación intraclass (CCI) de 0,96 ( $p < 0,001$ ). En el estudio de la consistencia interna hallamos un coeficiente alfa de Cronbach de 0,9 al incluir al valor total, y de 0,81 al excluirlo ( $p < 0,001$ ), lo cual evidencia una buena interrelación de los diferentes ítems del cuestionario.

El valor total del cuestionario mostro buena correlación con FVC% ( $r = -0,44$ ;  $p = 0,033$ ), DL<sub>CO</sub>% ( $r = -0,55$ ;  $p = 0,011$ ), PaO<sub>2</sub> ( $r = -0,44$ ;  $p = 0,036$ ), disnea escala modificada de Medical Research Council ( $r = -0,65$ ;  $p < 0,001$ ), y pasos dados en 24 h ( $r = -0,47$ ;  $p = 0,024$ ).

**Conclusión:** La versión en español del SGRQ-I desarrollada por nuestro grupo tiene buena consistencia interna, es reproducible y es válida para evaluar calidad de vida en pacientes con FPI.

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## Introduction

Interstitial lung diseases (ILD) are associated with low exercise tolerance, increased dyspnea, and reduced health-related quality of life.<sup>1,2</sup> The same tools used in other respiratory diseases to quantify these factors are also used in ILD, including the 6-minute walk test (6MWT) to evaluate exercise tolerance (and other aspects), and the Saint George's Respiratory Questionnaire (SGRQ) to measure quality of life.<sup>3-5</sup> The SGRQ is a self-administered questionnaire with 3 domains that explore different disease aspects, including a special section for evaluating accompanying symptoms.<sup>6</sup> Recent studies have demonstrated that this questionnaire is less than optimal for evaluating the quality of life of patients with idiopathic pulmonary fibrosis (IPF), and it has been found to be deficient particularly in the symptoms domain.<sup>7</sup> This may be because this domain of the questionnaire addresses cough, sputum, wheezing, and respiratory failure, symptoms that are prevalent in other diseases, such as chronic obstructive pulmonary disease (COPD), bronchial asthma, bronchiectasis, etc.,<sup>6,8,9</sup> but uncommon in IPF patients.

The SGRQ-I is a modified version of this specific HRQoL questionnaire that has recently been validated in patients with IPF. This model showed good internal consistency and correlation with prognostic variables and disease severity.<sup>10</sup> However, no validated tool is currently available in Spanish to specifically assess quality of life in IPF patients.

Since clinical trials carried out to date have not yet identified drugs that can reduce mortality in this disease, improving quality of life is a major objective in the treatment of these patients.<sup>11,12</sup> The importance, then, of having a valid, reliable and reproducible tool to evaluate quality of life in IPF cannot be overstated. The aim of this study was to translate and validate a Spanish version of the SGRQ-I.

## Methods

### Translation of the Questionnaire

SGRQ is a self-administered questionnaire consisting of 50 items, divided into 3 domains: symptom (S) with 8 items, activity (A) with 16 items, and impact (I) with 26 items. These 3 domains, which consist of multiple-choice and true-false questions, are then pooled to obtain a final result with a total score (T). The result is a numeric value (0-100) for each domain that is expressed as a continuous variable, in which the patients with higher scores have a worse quality of life.<sup>6</sup> An adapted version of the SGRQ, the SGRQ-I, was developed and validated to create a specific tool for IPF patients. To this end, some questions (2 on symptoms, 6 on activities, and 8 on impact) that may have been unsuitable for evaluating IPF patients were deleted, and some response categories were

combined, leaving 34 items (6 for symptoms, 10 for activities, and 18 for impact).<sup>10</sup>

Authorization to translate the questionnaire was obtained from the copyright holders. Two translations of the questionnaire from English to Spanish were made by 2 separate healthcare professionals (trained in the use of this type of tools) from our hospital team. A single, consolidated version of both questionnaires was then produced. To ensure that the translation was generic and applicable to the overall Spanish-speaking population, and to avoid the use of local expressions, it was reviewed by the Department of Linguistics of the Ibero-American Society of Scientific Information (SIIC), who offered their advice. This version was then backtranslated into English by 2 qualified translators. Finally, both versions in English (the original version and the backtranslation) were compared and found to contain no significant differences (Fig. 1).

### Patients and Measurements

Patients with a diagnosis of IPF confirmed by the multidisciplinary group of ILD specialists using ATS/ERS/ALAT 2011 criteria<sup>4</sup> were enrolled consecutively between January 2016 and January 2017. Patients were asked to complete the Spanish version of the SGRQ-I during the first visit, and to complete it again 1 week later, without receiving any intervention in the intervening period. Demographic data were recorded. Lung function tests were performed and forced vital capacity (FVC) and diffusing capacity for carbon monoxide (DL<sub>CO</sub>) were recorded. Habitual dyspnea was determined using the modified Medical Research Council (mMRC) scale. Exercise tolerance was evaluated using the 6MWT, and minimum saturation and meters walked were recorded. These tests were performed according to the recommendations of the relevant scientific societies.<sup>13,14</sup> Arterial blood was drawn to determine PaO<sub>2</sub>. Physical activity levels were recorded over 6 days (4 week days and 2 weekend days) using the SenseWear Armband (Body-Media Inc., Pittsburgh, PA, USA), a multisensor device that has been widely used in patients with COPD and IPF.<sup>15-17</sup> Patients were instructed to use the accelerometer 24 h a day except during personal hygiene activities. The study was approved by the ethics committee of the Hospital de Rehabilitación Respiratoria María Ferrer de Buenos Aires, Argentina. All patients gave informed consent in writing.

### Questionnaire Validation

The repeatability of the questionnaire was evaluated using the test-retest technique with an interval of 1 week between measurements. Before the second measurement, patients were asked if they had experienced any worsening or appearance of any new symptom in the previous week. Patients who answered in the affirmative were excluded.

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