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Development and psychometric properties of the Pulmonary-specific Quality-of-Life Scale in lung transplant patients

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BACKGROUND: The Pulmonary-specific Quality-of-Life Scale (PQLS) was developed to measure quality of life (QoL) among patients awaiting lung transplant. The objective of this study was to determine the psychometric properties of the PQLS, identify empirically derived sub-scales, and examine ability to detect changes in pulmonary-specific QoL scores after lung transplantation.

METHODS: Data were derived from the INSPIRE trial, a dual-site randomized controlled trial of coping skills training in 389 lung transplant candidates (obstructive [48.3%], restrictive [24.2%], cystic fibrosis [13.6%], and other [13.9%]). Cronbach alpha was calculated to assess the internal reliability of the PQLS ($n = 388$). Test-retest reliability was assessed with correlation coefficients between baseline and 12-week post-baseline scores for the usual care control condition ($n = 140$). Convergent validity was assessed with correlation coefficients between the PQLS and established measures of QoL and emotional distress, 6-minute walk test distance, forced expiratory volume in 1 second, and use of supplemental oxygen at rest ($n = 388$). Change from baseline to 6 months post-transplantation was assessed with repeated measures analysis of variance ($n = 133$).

RESULTS: The PQLS was internally reliable and stable across 12 weeks. The PQLS correlated strongly with QoL measures (e.g., Shortness of Breath Questionnaire, $r = 0.78$, $p < 0.0001$), moderately with mood and anxiety (e.g., Beck Depression Inventory-II, $r = 0.59$, $p < 0.0001$), and modestly with lung disease severity (e.g., 6-minute walk test, $r = -0.41$, $p < 0.0001$). PQLS scores improved by nearly 2 SDs after transplant.

CONCLUSIONS: These results demonstrated the reliability, validity, and sensitivity to change of the PQLS for measuring pulmonary QoL among patients with advanced lung disease and the responsiveness of the PQLS to changes in QoL after lung transplantation.

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For many patients with end-stage lung disease, lung transplantation is the only treatment option that offers hope for improved longevity. However, lung transplant candidates typically face a prolonged and arduous evaluation process,

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and after transplantation, lung transplant recipients experience high rates of diabetes, renal dysfunction, hypertension, malignancy, and negative side effects from immunosuppressant medication.[1] In recognition of the high costs (financial and human) associated with lung transplantation and the high frequency of significant post-transplant complications, quality of life (QoL) has become an increasingly important clinical end-point to evaluate treatment effectiveness.[2]

In longitudinal studies, health-related QoL tends to improve significantly in the first 6 months after lung transplantation and may continue to improve through the first year. For example, among 112 lung transplant recipients followed from 2 to 12 months post-transplant, QoL as measured by the Short Form General Health Survey (SF-36) improved between post-transplant months 2 and 6 and stabilized from 6 to 12 months.[3] Among 61 patients followed from before transplant to 12 months post-transplant, QoL as measured by the SF-36, the Quality of Life Profile for Chronic Diseases, and the Saint George's Respiratory Questionnaire revealed considerable improvement from before transplant to 6 months post-transplant and stable scores for most domains from 6 to 12 months.[4] Post-transplant QoL results are mixed after the first year, with some studies showing stable scores and some studies showing declines in QoL associated with comorbidities or bronchiolitis obliterans syndrome.[5]

Various instruments have been used to assess generic QoL, but few are specific to patients with advanced lung disease. The widely used SF-36[6] and the Nottingham Health Profile[7] have been used to assess QoL in lung transplant candidates.[8,9] However, generic QoL instruments such as these may not be sensitive to the unique effects of lung disease on QoL, such as the physical and emotional toll associated with dyspnea and the use of supplemental oxygen. The St. George's Respiratory Questionnaire[10,11] is a widely used respiratory distress questionnaire that yields a total QoL score and 3 sub-scale scores.[12] However, this instrument was designed to measure the impact of breathlessness from mild chronic obstructive pulmonary disease and asthma and may not adequately measure the impact of more severe lung disease (e.g., the use of high-volume supplemental oxygen) or other lung diseases such as cystic fibrosis (CF) or idiopathic pulmonary fibrosis. The University of California, San Diego Shortness of Breath Questionnaire (SOBQ)[13] was designed to measure the effects of dyspnea on QoL in patients with moderate-to-severe chronic lung disease. However, the SOBQ is a unidimensional measure that does not assess multiple dimensions of QoL.

The Pulmonary-specific Quality-of-Life Scale (PQLS)[14] was specifically developed to measure multidimensional pulmonary QoL among patients with advanced lung disease who are awaiting lung transplantation. However, psychometric evidence for the PQLS is lacking. The aim of the present study was to evaluate the psychometric properties of the PQLS. First, we conducted a factor analysis of the PQLS to identify sub-scales. Next, we examined internal consistency and test-retest reliability. We then explored convergent validity with regard to generic and disease-specific measures of QoL, measures of emotional distress, and measures of lung disease severity. Finally, we considered the sensitivity of the PQLS to change after lung transplantation.

Methods

Patients

Data were derived from the INSPIRE study, a randomized, controlled trial of patients awaiting lung transplant. A detailed description of the methods and results is published elsewhere.[15] The INSPIRE study was approved by the institutional review boards of Duke University Medical Center and Washington University. Briefly, all patients listed for lung transplantation at Duke University Medical Center and Washington University between September 2000 and August 2004 were eligible to participate and were contacted. The study enrolled 389 lung transplant candidates, who were randomly assigned to 12 weeks of either a coping skills training program or usual medical care. Participants completed assessments at baseline and at 12 weeks. Participants who went on to receive a lung transplant also completed assessments at 6 months post-transplant. Figure 1 presents a detailed description of participant recruitment for the study and retention for the 6-month post-transplant follow-up assessment.

Demographics and medical information

Patients were asked to self-report their age, gender, ethnicity, years of completed education, medical diagnosis, and supplemental oxygen use at rest in liters per minute.

Procedures

PQLS

The 25-item PQLS[14] was designed to assess health-related QoL across 7 domains during the past month in patients with pulmonary disease using a 5-point Likert-type scale. The PQLS yields a Total Score, calculated by reverse scoring 10 items and then summing all 25 items. The PQLS was also designed to produce 7 sub-scales: physical functioning, psychological/emotional status, functional status/activities of daily living, social activities, intimacy/relationships/sexuality, occupational functioning, and view of self. However, these 7 sub-scales were conceptually derived and consequently of questionable validity. One of the goals of the present study is to derive data-driven sub-scales. In the event of missing data, we scored the PQLS by inserting the mean score for the data-derived sub-scale.

The PQLS was created with considerable input from patients, consistent with patient reported outcome standards for "patient centeredness."[16,17] Patients who were listed for lung transplantation were contacted through their medical providers and asked to participate in a questionnaire development study. Consenting patients were interviewed in focus groups and on a one-to-one basis. They were asked broad questions (e.g., "how has your pulmonary disease affected your life?") and specific questions about the effects of pulmonary disease on QoL domains identified through literature review. Responses from patients were used to compile the questions for the PQLS. In addition, items from the Duke Activity Status Index[18] were adapted to tap activities of daily living and physical functioning. The resulting instrument was