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Original article

Validation of the Japanese Severe Respiratory Insufficiency Questionnaire in hypercapnic patients with noninvasive ventilation

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Abbreviations: BMI, Body mass index; CHRF, Chronic hypercapnic respiratory failure; COPD, Chronic obstructive pulmonary disease; FEV_1, Forced expiratory volume in one second; FVC, Forced vital capacity; HRQL, Health-related quality of life; NIV, Noninvasive ventilation; PaO_2, Arterial oxygen pressure; $PaCO_2$, Arterial carbon dioxide pressure; SF-36, Medical Outcomes Study 36-item short form; SRI, Severe Respiratory Insufficiency.

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ABSTRACT

Background: The Severe Respiratory Insufficiency (SRI) Questionnaire was originally developed in German to assess health-related quality of life (HRQL) and was validated as a multidimensional instrument with high psychometric properties in chronic hypercapnic respiratory failure (CHRF) patients receiving noninvasive ventilation (NIV). We aimed to investigate the intercultural adaptation of the Japanese SRI Questionnaire and whether it is a reliable and valid HRQL questionnaire to administer to those patients.

Methods: The SRI Questionnaire was adapted to Japanese using a translation and back-translation procedure, followed by equivalency assessment. It was validated in 56 stable outpatients receiving NIV for CHRF, primarily due to chronic obstructive pulmonary disease (COPD) and/or pulmonary tuberculosis sequelae.

Results: Examination of the frequency distribution of the Japanese SRI Questionnaire showed that the subscales and summary were approximately normally distributed and well balanced. There were no significant differences in SRI scores between patients with COPD and pulmonary tuberculosis sequelae. Cronbach's α values representing internal consistency of seven SRI subscales ranged from 0.56 to 0.80; attendant symptoms and sleep had the lowest values. Cronbach's α value was 0.92 for the SRI summary. The SRI summary score was significantly related to all eight subscales of the Medical Outcomes Study 36-item short form, with correlation coefficients of 0.41–0.66.

Conclusions: The Japanese SRI Questionnaire was produced using a standardized procedure and an equivalency study. It has high psychometric properties with internal consistency and concurrent validity. The Japanese SRI Questionnaire can be used to assess HRQL in patients on NIV for CHRF.

1. Introduction

Long-term noninvasive ventilation (NIV) is frequently used in patients with chronic hypercapnic respiratory failure (CHRF) [1–3]. These patients experience physical, psychological, and social limitations in daily life due to severe progression of various underlying diseases, including chronic obstructive pulmonary disease (COPD), restrictive thoracic diseases, obesity hypoventilation syndrome, and neuromuscular diseases [4]. Survival rates are reduced and health-related quality of life (HRQL) may be impaired. However, it has been clearly established that HRQL can be substantially improved following the commencement of long-term NIV [5–7]. Thus, HRQL assessment is essential in healthcare practice and research [8].

For HRQL assessment, generic HRQL questionnaires like the Medical Outcomes Study 36-item short form (SF-36) [9] are not specific to any particular disease; thus, it might not be capable of sufficiently detecting changes in HRQL following specific treatment interventions [8]. Consequently, disease-specific HRQL questionnaires are preferred in clinical trials, especially when considering the responsiveness to medical intervention [8]. Although the St. George's Respiratory Questionnaire (SGRQ) [10] and the Chronic Respiratory Disease Questionnaire (CRQ) [11] are often used as disease-specific measures in respiratory medicine, they were originally designed for patients with chronic airway obstruction with mild-to-moderate disease. Patients with chronic respiratory failure were not included in the validation of the SGRQ and CRQ. Thus, even in patients with chronic airway obstruction, these tools may be inadequate for clinical assessment if chronic respiratory failure is also present.

To address this issue, two questionnaires were developed and validated for HRQL assessment in patients with chronic respiratory failure: the Maugeri Respiratory Failure (MRF) Questionnaire [12] and the Severe Respiratory Insufficiency (SRI) Questionnaire [4,13]. The SRI Questionnaire was originally developed in German. It was specifically validated as a multidimensional instrument with high psychometric properties for patients receiving long-term NIV. It has been translated to several languages [14] and has been shown to score best [15]. However, there remained a lack of such a tool to assess the HRQL of Japanese patients receiving NIV. To meet this need, we translated and transculturally adapted the SRI Questionnaire for the Japanese population. The purpose of the present study was to validate the Japanese version of the SRI Questionnaire. In this study, we enrolled patients with COPD and/or pulmonary tuberculosis sequelae because these conditions are the most common diseases requiring NIV in Japan.

2. Materials and methods

2.1. Subjects

This study had 56 stable outpatients on NIV for CHRF, primarily due to COPD and/or pulmonary tuberculosis sequelae, as previously described in detail [16]. None of the patients had a tracheotomy or uncontrolled comorbidities, including malignancy, cardiovascular, or cerebrovascular diseases. Their body