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Minimal Clinically Important Differences (MCIDs) of the Thai Version of the Leicester Cough Questionnaire for Subacute and Chronic Cough

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ABSTRACT

Objectives: To investigate the minimal clinically important differences (MCIDs) of the Thai version of the Leicester Cough Questionnaire (LCQ-T) in patients with subacute and chronic cough. **Methods:** Patients with cough for 3 or more weeks were recruited from outpatient clinics. They self-completed the LCQ-T at an initial evaluation and repeated the LCQ-T with a Global Rating of Change scale at follow-up. For the anchor-based method, the MCID was defined as a change in the LCQ scores that corresponded to the smallest improvement in Global Rating of Change score (+2 to +3). For distribution-based methods, the MCIDs were estimated from the standard error of measurement and a half and one-third of the SD of the LCQ score changes from baseline to follow-up. **Results:** A total of 107 patients were included. The causes of cough were postinfectious cough/bronchitis (35.5%), asthma (20.6%), rhinosinusitis (16.8%), bronchiectasis (17.8%), and chronic obstructive pulmonary disease (9.3%). The anchor-based method yielded MCIDs of 1.1, 0.4, 0.4, and 0.4 for the total, physical, psychological, and social domains, respectively. The distribution-based method using standard error qof measurement yielded MCIDs of 0.8, 0.3, 0.3, and 0.3, whereas those using a half SD yielded MCIDs of 2.0, 0.6, 0.8, and 0.8 and those using one-third SD yielded MCIDs of 1.4, 0.4, 0.5, and 0.5 for the total, physical, psychological, and social domains, respectively. **Conclusions:** The MCIDs of the LCQ-T for subacute and chronic cough are 1.1, 0.4, 0.4, and 0.4 for the total, physical, psychological, and social domains, respectively. These estimates should be useful in making meaningful interpretations of the changes in quality of life because of cough.

Keywords: Leicester Cough Questionnaire, MCID, minimal clinically important difference, Thai.

Introduction

Subacute and chronic cough are associated with adverse impacts on physical, psychological, and social elements. The assessment of cough severity and the impact of cough on health-related quality of life (HRQOL) are important for evaluating the response to therapy [1]. One of the subjective and validated tools widely used is the Leicester Cough Questionnaire (LCQ), which is a cough-specific HRQOL questionnaire. It is a self-completed questionnaire comprising 19 items exploring the impact of cough on three domains: physical (8 items), psychological (7 items), and social (4 items). The total score ranges from 3 to 21, with a lower score indicating greater impairment in health status because of cough [2]. The LCQ has been translated into and validated in various languages and used to determine the impact of acute and chronic cough on HRQOL [3–6] as well as the efficacy of cough treatment across various conditions including chronic obstructive pulmonary disease (COPD) [7] and bronchiectasis [4,8].

A *minimal clinically important difference* (*MCID*) is defined as a change in health domain of interest that is the smallest meaningfully perceived by the patients. As proposed by Raj et al. [9], the MCID expressed as mean of the original LCQ total score in patients with chronic cough was 1.3 ± 3.3, whereas the MCIDs expressed as mean for physical, social, and psychosocial domains

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were 0.2 ± 0.8, 0.2 ± 1.1, and 0.8 ± 1.5, respectively. Because the Thai version of the LCQ (LCQ-T) has been recently validated in patients with subacute and chronic cough but its MCIDs have not yet been determined [10], this study aimed to determine the MCIDs of the LCQ-T in patients with subacute and chronic cough.

Methods

Subjects

Patients with cough lasting at least 3 weeks were prospectively recruited from the outpatient pulmonary and allergy clinics at Ramathibodi Hospital from March to December 2015. Eligible patients were those with postinfectious cough (PIC)/bronchitis, asthma, COPD, rhinosinusitis, or bronchiectasis during the stable period and the exacerbation period. Exclusion criteria included being younger than 18 years, or having diseases that might influence the HRQOL, for example, active cancer, chronic liver disease, chronic kidney disease, and congestive heart failure. This study was approved by the Committee of the Ethics in Human Research of Ramathibodi Hospital (authorization no. ID 07-57-02). All patients provided their written informed consent before study participation.

Protocol

All patients were asked to complete the LCQ-T and the Borg Cough Scale (BCS) at an initial evaluation. They were then treated for individual diseases according to their primary physicians. The patients with improved cough symptoms were asked to repeat the LCQ-T and BCS together with the Global Rating of Change (GRC) scale of cough impact on physical, psychological, social, and overall HRQOL at follow-up. The duration from the first visit to the follow-up visit for assessing response to treatment for each specific disease was based on previous reports [11–19], which was subsequently categorized into three groups: group A: less than 4 weeks (e.g., PIC/bronchitis and infected bronchiectasis); group B: 4 to 16 weeks (e.g., asthma, COPD, and rhinosinusitis); and group C: more than 16 weeks (e.g., bronchiectasis). Patients' demographic data, duration of cough, causes of chronic cough, and medication use were recorded. Spirometric data were also obtained in patients with obstructive lung diseases.

Leicester Cough Questionnaire

The LCQ is a well-validated, self-completed, cough-specific health status questionnaire that has been shown to be both repeatable and responsive in patients with chronic cough. It comprises 19 items from three domains: physical, psychological, and social. Each item is graded from 1 (all the time) to 7 (none of the time) on a Likert scale. Domain scores are calculated by averaging scores from items in each domain (range 1–7). The total score is the sum of the domain scores (range 3–21), with a lower score indicating a greater impairment in health status because of cough. We used the LCQ-T, which has been validated and published [10].

Borg Cough Scale

The BCS was used to measure cough intensity on a scale from 0 (no cough at all) to 10 (maximum cough). It was developed on a 10-cm vertical line fixed at both ends. The patients were instructed to grade the scale on the basis of their subjective feelings of cough symptom severity. Because the BCS is a well-validated rating scale frequently used in clinical studies on cough and psychometric properties testing of the cough-specific HRQOL questionnaire, its score should be suitably linked to the LCQ-T domain score [6,20–22].

GRC Questionnaire

The GRC questionnaire is widely used as a subjective measure and is commonly used as an anchor for independent assessment of changes to determine the MCIDs of HRQOL questionnaires, including the LCQ, in the anchor-based method [23,24]. After having the GRC explained to them, the patients were asked to rate the global change impact of cough on their physical, psychological, social, and overall HRQOL over a period of time after treatment. The score for each GRC was classified as unchanged (−1/0/+1), small change (−3, −2, +2, +3), moderate change (−5, −4, +4, +5), and large change (−7, −6, +6, +7). GRC scores of +2 and +3 were considered to represent minimal but clinically important changes (MCIDs).

Statistical Analysis

SPSS version 20 (SPSS Inc., Chicago, IL) was used for data analysis. The data were presented as mean ± SD or N (%) depending on the type of data. Comparisons of continuous variables among the three lengths of follow-up period were analyzed using analysis of variance, and the least square method was used for post hoc analysis. Comparisons of categorical variables were analyzed by chi-square. Comparisons of scores between baseline and follow-up periods were performed by a paired t test. Pearson correlation coefficients or Spearman rank correlation coefficients were estimated to determine the relationship between the baseline and follow-up score changes in the LCQ-T and GRC scores. The MCID (smallest difference in LCQ-T scores that patients perceive as important) was determined using two methods. The first was an anchor-based method in which changes in the actual LCQ-T score between the first visit and the follow-up visit were averaged within the resulting change categories of the GRC. The MCIDs of the LCQ-T scores were the improvements in LCQ-T scores for a GRC category from +2 to +3 [9,23,24]. The second was a distribution-based method in which the MCID values were calculated from the standard error of measurement (SEM) [25,26], a half of the SD [27,28], and a third of the SD [28–31] of the LCQ scores. The SEMs were calculated using the following equation: $SEM = \delta_x (1 - r_{xx})^{1/2}$, where r_x is a measure of reliability (Cronbach α coefficient) and δ_x is the SD of the LCQ-T scores at baseline. The SD and r_x values that were used as measures of variability and reliability for the total LCQ-T score and each domain score were obtained from our previous published study [10]. In addition to the SEM, a half of the SD and a third of the SD were derived from the LCQ-T scores at baseline, at follow-up, and from the baseline to follow-up score change, with the average of these values also being computed.

Results

Of the 107 patients with subacute and chronic cough, 70 (65%) were female and 37 (35%) were male. Patients' demographic data, diagnosis, and baseline spirometric data are presented in Table 1. The patients' median duration of cough was 2.25 months, with a range from 0.25 to 320 months. On the basis of the duration from the first visit to the follow-up visit for assessing the response to treatment in individual groups, 43 patients (40%) were in group A (follow-up period of <4 weeks), 50 patients (47%) were in group B (follow-up period of 4–16 weeks), and 14 (13%) patients were in group C (follow-up period of >16 weeks). Infectious organisms in patients suffering from cough in group A and group C were viral and bacterial in origin. No active tuberculosis was identified in either group. No infectious diseases were found in group B. All patients with identifiable infections were clinically mild in severity that markedly improved with antibiotics.