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Original article

Development of a questionnaire to evaluate asthma control in Japanese asthma patients

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Abbreviations:
ACT, asthma control test; ACQ, asthma control questionnaire; AIRJ, asthma insights and reality in Japan; AQLQ, asthma quality of life questionnaire; COPD, chronic obstructive pulmonary disease; ICC, intra-class correlation coefficients; JACS, Japan asthma control survey; PEF, peak expiratory flow; QOL, quality of life; VAS, visual analogue scale

ABSTRACT

Background: The asthma control questionnaires used in Japan are Japanese translations of those developed outside Japan, and have some limitations; a questionnaire designed to optimally evaluate asthma control levels for Japanese may be necessary. The present study was conducted to validate the Japan Asthma Control Survey (JACS) questionnaire in Japanese asthma patients.
Methods: A total of 226 adult patients with mild to severe persistent asthma were enrolled and responded to the JACS questionnaire, asthma control questionnaire (ACQ), and Mini asthma quality of life questionnaire (Mini AQLQ) at Weeks 0 and 4. The reliability, validity, and sensitivity/responsiveness of the JACS questionnaire were evaluated.
Results: The intra-class correlation coefficients (ICCs) were within the range of 0.55–0.75 for all JACS scores, indicating moderate/substantial reproducibility. For internal consistency, Cronbach's alpha coefficients ranged from 0.76 to 0.92 in total and subscale scores, which were greater than the lower limit of internal consistency. As for factor validity, the cumulative contribution ratio of four main factors was 0.66. For criterion-related validity, the correlation coefficients between the JACS total score and ACQ5, ACQ6, and Mini AQLQ scores were −0.78, −0.78, and 0.77, respectively, showing a significant correlation ($p < 0.0001$).
Conclusions: The JACS questionnaire was validated in terms of reliability and validity. It will be necessary to evaluate the therapeutic efficacy measured by the JACS questionnaire and calculate cutoff values for the asthma control status in a higher number of patients.
Clinical Trial registration: UMIN000016589

Introduction

Bronchial asthma is a respiratory disease characterized by clinical symptoms such as recurring cough, wheezing, and breathing difficulty, which may have varying degrees of impact on the patients' lives, and this impact is more pronounced among people with severe or poorly controlled asthma.

In the treatment of asthma, the establishment of management methods through the introduction of inhaled corticosteroids and the refinement of the Asthma Prevention and Management Guideline has dramatically improved long-term control of asthma,[1] enabling patients live their daily lives as healthy people do. However, the findings of Asthma Insights and Reality in Japan (AIRJ) in 2011, a fact-finding survey of asthma patients in Japan, showed that the goals proposed in the guidelines for asthma had not been fully achieved due to poor adherence.[2] Furthermore, pathological phenotypes based on cluster analysis have recently been identified to obtain an objective view of a variety of clinical presentations of asthma,[3] but a treatment choice according to each phenotype has not yet been established and recent population survey conducted by the Ministry of Health, Labour and Welfare in 2015 reported that 1511 people had died of asthma,[4] highlighting that the goal of "no death associated with asthma" had not been achieved. The goal of asthma treatment to accomplish is no death by asthma. At present, although treatment for severe asthma has been conducted by

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antibody-targeted medicines, the use of these medicines will incur the escalation of medical costs.

Poor asthma control, as exemplified by unscheduled hospital visits due to persistent symptoms or exacerbation of asthma, impairs the quality of life (QOL) of asthma patients by adversely affecting daily living, limiting activities, and even increasing psychological burden.

More than one questionnaire has been developed to evaluate QOL and control level for asthma patients, and the representative questionnaires had been the Asthma Control Questionnaire (ACQ)[5,6] and Asthma Control Test (ACT),[7] both of which had been translated into Japanese. These questionnaires have been conveniently used as the most common measures for evaluating asthma control status in daily clinical practice. However, the questionnaires used in Japan are Japanese translations of those developed outside Japan, and have some limitations, including a failure to verify whether the questionnaire is optimum for Japanese, and evaluations of asthma control based exclusively on symptoms. Also, based on these questionnaires alone it is possible that levels of partially uncontrolled asthma had not been detected. Therefore, a questionnaire designed to optimally evaluate asthma control status in Japanese, with their physical functions and psychology taken into account, may be necessary to contribute to the accomplishment of "no death by asthma."

As a part of the development of a new questionnaire "Japan Asthma Control Survey (JACS) questionnaire", an original tool for measuring asthma control levels in Japanese asthma patients, the present study was conducted to validate the JACS questionnaire.

Methods

Questionnaire generation process

Item selection

Items to be included in the questionnaire were mainly extracted based on expert opinions. Redundancy was avoided by combining multiple items into one, and the number of items was reduced from 25 to 16 by several expert meetings. The first questionnaire was produced for pilot testing.

Pilot studies 1 and 2

To evaluate the reliability and validity of the prototype questionnaires, pilot studies 1 and 2 were performed. A total of 30 outpatients with asthma were enrolled for each pilot study between February and July 2015. Inclusion/exclusion criteria and patient background for each pilot study are shown in Supplementary Table 1, 2. All patients completed three questionnaires in Japanese (JACS, ACQ, and Mini Asthma Quality of Life Questionnaire [Mini AQLQ]), and the reliability and validity of the JACS questionnaire were evaluated based on factor analysis, internal consistency reliability, and correlation between JACS and ACQ, and Mini AQLQ.

In pilot study 1, a prototype questionnaire with 16 items was evaluated. Based on factor analysis of the data, the questionnaire was revised to 15 questionnaire items, and these were classified into four subscales (symptom: 4 items, emotion: 4 items, treatment: 2 items, activity: 5 items). This revised version with 15 items was used in pilot study 2. The total score and four subscales were found to be reliable, with Cronbach's alpha coefficients of 0.92 for the total score, and 0.85, 0.81, 0.95, and 0.90 for each subscale. In addition, validity was established based on correlation between the JACS and ACQ ($r = -0.61$, $p = 0.0003$) as well as JACS and Mini AQLQ ($r = 0.80$, $p < 0.0001$, Supplementary Fig. 1, 2). In this pilot study, reliability and validity of the preliminary JACS questionnaire were suggested. In the present validation study, the 15-item questionnaire based on the visual analogue scale (VAS) (Table 1), which was used in pilot study 2, was used as the JACS questionnaire. Original JACS questionnaire is shown in Supplementary Methods.

Validation study

Study design

This study was a multi-center, prospective, observational study. Figure 1 shows the study design and patient enrollment.

Patients and methods

Adult patients with mild to severe persistent bronchial asthma who visited the study centers on an outpatient basis between October 2015 and February 2016 were included in the study if they were in Step 2 or higher of asthma treatment as defined in the Asthma Prevention and Management Guideline 2015.[8] The following patients were excluded from the study: patients with evident chronic obstructive pulmonary disease (COPD); patients with respiratory infection; patients with diseases that may affect their responses to the questionnaire; and patients who were judged unsuitable for enrollment in the study by the investigator. Patients enrolled in the study responded to the JACS questionnaire, ACQ, and Mini AQLQ at Weeks 0 and 4. We used ACQ and Mini AQLQ in Japanese. The asthma control status was assessed by respiratory specialists in accordance with the Japanese asthma prevention and management guidelines (JGL 2015).[8]

Ethics

Prior to participation in the pilot studies and this validation study, all patients were fully informed of this study and gave

Table 1
JACS questionnaire.

No.	Subscale	Questionnaire
1	Symptom	Did you experience breathlessness or a hard time breathing because of asthma?
2	Symptom	Did you experience wheezing or crowing when you breathe?
3	Activity	Did you suffer from coughing?
4	Symptom	Did you have symptoms (such as wheezing, crowing, short breath, chest discomfort or chest pain) during bedtime or at the time of awakening because of asthma?
5	Emotion	Did you become anxious because of night sleep disturbances caused by asthma?
6	Activity	Did you stay indoors because of weather or to avoid polluted air, pollen dust, or yellow sand dust?
7	Emotion	Do you feel intense physical activities (such as quick action, exercise, or running) are difficult because of asthma?
8	Activity	Did you have activity limitations at work or at home because of asthma?
9	Activity	Was your daily life disturbed by persisting symptoms despite the current asthma treatment?
10	Activity	Did dust, cigarette smoke, cold air, exhaust fumes, or drinking evoke asthma symptoms?
11	Emotion	Have you been frustrated or disappointed at things going wrong because of asthma?
12	Emotion	Do you feel your asthma is not socially understood at places such as work-site or school?
13	Treatment	Do you think you take medicine regularly as instructed every day?
14	Treatment	Do you think you inhale medicine in a correct way as instructed every day?
15	Symptom	How many times a day did you inhale the drug to dilate your bronchial tubes when you felt difficulty in breathing?

These questionnaires were translated by authors and specialists of this area in English from Japanese original version.

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