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# Analysis of longitudinal changes in the psychological status of patients with asthma

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**Summary**
Significant relationships between the psychological status and poor asthma outcomes are often reported. However, most of these studies are cross-sectional and none have evaluated how the psychological status progresses over time during the management of asthma patients. Therefore, we examined the longitudinal changes in the psychological status of asthma patients, and compared them with changes in other clinical measurements.
Eighty-seven outpatients with stable asthma after 6 months of treatment were enrolled in this study. The psychological status was evaluated using the Hospital Anxiety and Depression Scale (HADS), the health status using the Asthma Quality of Life Questionnaire (AQLQ) and the St. George's Respiratory Questionnaire (SGRQ). The patient's pulmonary function, peak expiratory flow values and airway hyperresponsiveness were measured at entry and every year thereafter over a 5-year period.
Using mixed effects models to estimate the slopes, the HADS anxiety and depression scores did not change significantly over time ($p = 0.71$ and 0.72, respectively). The changes in the HADS scores correlated noticeably with changes in the AQLQ and SGRQ scores, but not with changes in the physiological measurements. The baseline HADS anxiety and depression scores were significantly correlated to the subsequent annual changes in each measurement.
The psychological status remained clinically stable over the 5-year study period in patients with stable asthma. Changes in the psychological status were significantly correlated to

*Abbreviations:* AHR, airway hyperresponsiveness; AQLQ, Asthma Quality of Life Questionnaire; COPD, chronic obstructive pulmonary disease; $FEV_1$, forced expiratory volume in 1 s; HADS, Hospital Anxiety and Depression Scale; $PD_{20}$–$FEV_1$, provocation dose that causes a 20% fall in $FEV_1$; PEF, peak expiratory flow; SGRQ, St. George's Respiratory Questionnaire

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changes in the health status. The baseline HADS scores were a useful indicator in detecting patients who would show subsequent deterioration in their psychological status.


## Introduction

Psychological disturbances such as anxiety or depression are important features of asthma, because many patients with chronic disorders are generally at risk for mental disorders. These mental disorders are associated with poor asthma outcomes such as worse asthma control and impaired health status,[1] frequent utilization of emergency and hospital admissions,[2] more asthma symptoms,[3] higher dosing of corticosteroids,[4] medication non-adherence,[5] a worsening of chronic inflammation,[5] or even death.[6] Therefore, like physiological indices such as airflow limitation or airway hyperresponsiveness (AHR), the psychological components should also be monitored closely. However, most of the research on these psychological components is limited to cross-sectional studies.

Long-term pharmacological treatment consisting of inhaled corticosteroids is recommended in the management of asthma. Although many studies covering the clinical course of asthma have focused mainly on changes in physiological outcomes such as airflow limitation, changes in outcomes from the patient's viewpoint have rarely been reported. To capture the overall management of chronic asthma, patient reported outcomes as well as conventional physiological outcomes should be followed simultaneously. However, to our knowledge, the longitudinal course of the psychological status of asthmatic patients has not been investigated.

When analyzing longitudinal data on the psychological status, analyzing dropouts becomes a problem. The exclusion of dropout data can cause some bias in calculating slopes for the changes, since the psychological status may affect patient withdrawal from the study. Therefore, data analyses that include both completers and dropouts are important, and we have attempted to do so in our longitudinal studies of patients with asthma[7,8] and chronic obstructive pulmonary disease (COPD).[9–11]

We previously recruited outpatients with stable asthma and followed the longitudinal changes in their physiological outcomes and patient reported outcomes over a 5-year period, and partially reported the changes elsewhere regarding the health status as compared to changes in airflow limitation, AHR and peak expiratory flow (PEF) variability.[8] In the present observational study, we reviewed the data and attempted to analyze longitudinal changes in the psychological status of patients with asthma, and compared them with changes in other outcomes.

## Methods

### Subjects

We recruited 87 consecutive outpatients with stable asthma, as previously reported.[8] The entry criteria included: (1) meeting the definition of asthma by the American Thoracic Society (ATS)[12]; (2) confirmation of an over 20% improvement in force expiratory volume in 1 s ($FEV_1$) or PEF values after the inhalation of $\beta_2$-agonists (salbutamol 200 μg); (3) regular attendance and treatment for asthma over 6 months; (4) a best ratio of $FEV_1$ to forced vital capacity of more than 0.7 when a subject had a smoking history to exclude COPD; (5) no other co-morbidities likely to affect changes in any clinical parameters; (6) no exacerbations over the preceding 4 weeks; and (7) no changes in treatment within 4 weeks. All clinical measurements were evaluated on the same day. Eligible patients meeting the entry criteria were asked to have their clinical outcomes and smoking status evaluated at entry, and every year thereafter over a 5-year period. The present study was performed as part of our standard outpatient treatment and care.

All patients had their PEF monitored regularly, and had undergone stepwise treatment with inhaled beclomethasone dipropionate or fluticasone propionate for their asthma according to the guidelines proposed by the Global Initiative for Asthma,[13] because long-acting $\beta_2$-agonists had not been available in Japan during the study. Furthermore, the changes in the therapeutic regimen have been reported elsewhere.[8] When an exacerbation of asthma requiring a change in treatment occurred within 4 weeks of a reassessment, the evaluation was postponed for at least 4 weeks until the patient had stabilized.

### Outcome measurements

The psychological status was evaluated using the Japanese version of the Hospital Anxiety and Depression Scale (HADS),[11,14] which consists of 14 items, seven for anxiety and seven for depression. Each item is scored from 0 to 3, where a score of 3 represents a state corresponding to the worst anxiety or depression. The sum of these items produces two subscales ranging from 0 to 21. Values on the HADS of 7 or less were regarded as normal, 8–10 as indicating a possible abnormality, and values of 11 or more as being abnormal.[14] An increase in the score indicates a worsening of the psychological status.

The health status was assessed by the Japanese versions of the Asthma Quality of Life Questionnaire (AQLQ)[8,15] and the St. George's Respiratory Questionnaire (SGRQ).[8,16] The AQLQ consists of 32 items composed of four domains: symptoms, activity limitations, emotional function, and exposure to environmental stimuli. The patients were asked to recall their experiences during the previous 2 weeks and to respond to each item using a 7-point interval scale ranging from 1 (maximal impairment) to 7 (no impairment). The overall score of the AQLQ was calculated as the mean of the sum of all items. A decrease in the score indicates a worsening of the health status. The SGRQ consists of 50 items composed of three components: symptoms, activity