Allergology International (2004) **53**: 145–151

Original Article

Questionnaire-based analysis of the current level of asthma control and management in Niigata Prefecture, Japan: Changes from 1998 to 2000

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Abstract

Background: It is very important to use anti-inflammatory agents, including inhaled corticosteroids, in the management of asthma because bronchial inflammation is a fundamental component of bronchial asthma. Although management according to this strategy is recommended in several countries, the actual situation of asthmatic patients in Japan is poorly understood. To clarify the actual management of asthma in Japan, the present study was undertaken.

Methods: In 1998, for 8 weeks from September through to October, questionnaires on asthma control and satisfaction in daily life were given to asthmatic patients. In addition, questionnaires regarding patient profiles and medication were given to the patients' physicians. The same questionnaires were repeated in 1999 and 2000. The information obtained from the same patients and their physicians who responded in each of the three years was used for analysis.

Results: We analyzed 840 cases. During this period, over 80% of patients used oral theophylline, although the percentage of patients using inhaled steroids and leukotriene receptor antagonists increased from 67.0 and 29.8% in 1998 to 75.1 and 34.2%, respectively, in 2000. Asthma control (including the presence of attacks and self-evaluation by each patient), asthma-related symptoms and sleep disturbance improved significantly. However, there was no improvement in satisfaction in daily life of asthmatic patients surveyed. Multiple-regression analysis revealed that self-evaluation of asthma control by each patient was significantly related to improvement in satisfaction in daily life.

Conclusion: These results indicate that anti-inflammatory agents, including inhaled corticosteroids and leukotriene receptor antagonists, contributed to improved asthma control, whereas oral theophylline is characteristically used in Niigata Prefecture, Japan. However, not all asthma-related problems, such as satisfaction in daily life, improved and self-evaluation of asthma control by patients may play a key role in improving their satisfaction in daily life.

Key words: bronchial asthma, inhaled steroid, questionnaire, satisfaction in daily life, theophylline.

Introduction

There have been advances in the pathophysiological understanding of bronchial asthma and the fundamental component of this disease has been identified as inflammation of the bronchi caused by the infiltration of a number of different inflammatory cells, including lymphocytes and eosinophils.[1,2] Consequently, airflow is limited, asthmatic symptoms are present, hypersensitivity

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Received 1 September 2003. Accepted for publication 26 December 2003.

in the bronchial tract is exacerbated and chronic airway inflammation results in irreversible airflow limitation (remodeling).[3,4] This understanding of the pathogenesis of asthma has changed the management and treatment of bronchial asthma, with anti-inflammatory therapy, including inhaled corticosteroids (ICS), now widely recommended. More recently, the efficacy of adding bronchodilators, including a long-acting β_2-adrenergic receptor agonist to inhaled steroids, has been reported.[5] These findings have resulted in establishing and modulating guidelines for managing bronchial asthma in some countries.[6,7]

However, because bronchial asthma is a common disease and can sometime be fatal,[8,9] it is important to understand the current state of bronchial asthma in actual clinical situations and changes that have occurred. This information is important in modifying asthma-control guidelines. In fact, the Asthma Insights and Reality in Europe (AIRE) study has revealed that the actual control of asthma in western Europe is very different from the goals of asthma control stated in their guidelines.[10] In Japan, however, there are few data on the state of asthma control and management in practice, although Makino has reported the expanded relevance of asthma guidelines.[11]

To clarify the state of asthma control and management in Niigata Prefecture, Japan, and any changes, a questionnaire-based investigation was undertaken between 1998 and 2000 among over 3000 patients each year who had bronchial asthma, as well as their physicians, in cooperation with a number of medical institutions in Niigata Prefecture. The information obtained from the same patients and their physicians who answered each year was used for analysis in the present study.

METHODS

This questionnaire-based investigation was conducted over three consecutive years, namely 1998, 1999 and 2000. To avoid the influence of seasonal changes, questionnaires in each of the three years were conducted over the 2 months of September and October. Through the questionnaire, patients with adult bronchial asthma who visited the participating institutions were asked their age, duration and onset age of asthma. At the same time, their physicians answered a questionnaire giving details of treatment and the severity of asthma, in accordance with the adult Bronchial Asthma Severity Assessment Committee's standards of the Japanese Society of Allergology. As shown in Table 1, the severity of asthma is classified according to combination of frequency and degree of attacks (as above) during a consecutive 4 week period, when the asthma condition is worst, of the 1 year prior to the completion of the questionnaire. The following cases are judged as severe: more than one attack resulting in unconsciousness, a requirement of 10 mg/day or more systemic steroids (calculated as predonisolone) or the requirement of 5 mg/day or more systemic steroids (calculated as predonisolone) with 600 μg/day or more inhaled steroids (calculated as beclomethasone dipropionate). Cases that require the administration of systemic steroids or 400 μg/day or more inhaled steroids (calculated as beclomethasone dipropionate) are classified as moderate. The investigation involved 156 institutions around Niigata Prefecture, Japan. Information on 3347, 3224 and 3069 cases was collected in 1998, 1999 and 2000, respectively. The information obtained from the same patients and their physicians who answered in all three years was analyzed and there were 840 cases investigated. Subjects were asked about the following issues (Table 2).

For asthma control, patients were asked about the presence of asthma attacks and to self-evaluate asthma control for the 2 weeks prior to completing the questionnaire, choosing one of five options (very good, fairly good, mediocre, slightly bad and bad). This was to evaluate the patients' asthma control. The patients were also

Table 1 Adult bronchial asthma Severity Assessment Committee's standards of the Japanese Society of Allergology

Frequency	Degree of symptoms			
	A	B	C	D (D1/D2)
5–7 /week	Severe	Severe	Moderate	Moderate
3–4 /week	Severe	Moderate	Moderate	Mild
1–2 /week	Severe	Moderate	Mild	Mild

A, impossible to move due to dyspnea; B, impossible to lie down due to dyspnea; C, possible to lie down even with dyspnea; D1, stridor alone; D2, chest tightness alone.

Table 2 Contents of the questionnaires used for asthmatic patients in the study (Original questionnaires were in Japanese)

Question 1
When were you diagnosed as bronchial asthma? Y: M; D:

Question 2
Do you use a peak-flow meter? (Yes, No)

Question 3
Choose in followings
1. How did your asthma attacks appear during the past 12 months? (frequent attacks, seasonal attacks, few attacks)
2. How many times did you have an asthma attack during the past 2 weeks? (5–7/week, 3–4/week, 1–2/week, absent)
3. What degree was your asthma attack(s) during the past 2 weeks? (impossible to move, impossible to lie down, possible to lie down, stridor, dyspnea on exertion)
4. Have you ever been hospitalized due to asthma? (Yes, No)
5. Have you ever been taken by ambulance or visited an emergency room due to at attack? (Yes, No)
6. Have you ever had a respirator due to an asthma attack? (Yes, No)
7. Have you ever been unconscious due to an asthma attack? (Yes, No)
8. Have you ever had an attack induced by anti-inflammatory drugs, including painkillers, antipyretics or cold medicine? (Yes, No)

Question 4
How was your asthma condition during the past 2 weeks? (very good, fairly good, mediocre, slightly bad, bad)

Question 5
List your symptoms during the past 2 weeks in following categories:
1. In the morning (cough, sputa, chest tightness, stridor, dyspnea, absent)
2. At night (cough, sputa, chest tightness, stridor, dyspnea, absent)
3. Sleep disturbance (impossible to fall asleep sometimes due to dyspnea, impossible to have a good sleep due to dyspnea, waking up in the night due to chest oppression, absent)

Question 6
Are you satisfied in daily life? (very satisfied, fairly satisfied, mediocre, slightly unsatisfied, unsatisfied)

asked about their asthma condition during the 1 year period prior to completing the questionnaire, choosing one of three answers (few attacks, seasonal attacks and frequent attacks). The questionnaires also asked about asthma-related symptoms, including coughing and sputum in the morning and at night, and about sleep disturbance in the 2 week period prior to completing the questionnaire.

To evaluate the problems of asthma control and management taking into consideration normal activity levels, the questionnaires asked about satisfaction in patients' daily life, which was used as a strong indicator of the level of activity. Subjects answered choosing one of five answers (very satisfied, fairly satisfied, mediocre, slightly unsatisfied and unsatisfied). A Chi-squared test was performed to detect significant differences. The SPSS program was used to perform multiple-regression analysis.[12] The answers for each context and medical treatment of one patient in the year 2000 were divided into three categories and compared with those in 1998: improvement = 1; exacerbation = –1; and no change = 0. Using these variables, the multiple-regression program analyzed satisfaction in daily life. $P < 0.05$ in each analysis was considered significant.

Table 3 Baseline characteristics of the patients

No. males/females	408/432
Mean (±SD) age (years)	57.5 ± 14.9
Distribution (*n*)	
< 29 years	40
30–39 years	76
40–49 years	122
50–59 years	169
60–69 years	235
> 70 years	198
Mean (±SD) asthma duration (years)	12.5 ± 12.8
Asthma severity (mild/moderate/severe; *n*)	322/361/79

Results

Patient background

Patient backgrounds are given in Table 3. The mean (± SD) age and duration of bronchial asthma were 57.5 ± 14.9 and 12.5 ± 12.8 years, respectively. There

were 408 male subjects and 432 female subjects. The physicians in charge graded the degree of severity of asthma and 42.3% of cases were classified as mild, 47.3% were considered moderate and 10.4% were regarded as severe.

Changes in drug medication

The drugs used were examined based on the questionnaire results from the patients' physicians and changes in drug medication are summarized in Table 4. Almost all drugs were used as controllers, except for inhaled short-acting β_2-adrenergic receptor agonists (SABAs), and the time-frame of drug medication was usually 4 weeks. It was found that ICS, SABAs, oral corticosteroids (OCS), leukotriene receptor antagonists (LTRA), and oral sustained-release theophylline (OSRT) were used in 67.0, 44.4, 21.5, 29.8 and 86.0% of cases in 1998, respectively. The rate of use of ICS and LTRA increased significantly in 1999 and 2000 compared with 1998, indicating that an anti-inflammatory strategy for asthma treatment is becoming widely accepted in actual clinical management. However, the use rate of SABAs in 2000 was significantly lower than that in 1998 and the rate of use of OCS in 1999 and 2000 was also significantly lower than in 1998. This indicates that the necessity for these medications has decreased owing to improved asthma control, the former being used as a reliever and the latter usually being a final controller. During this period (1998–2000), the rate of OSRT use was more than 80% and there was no significant change in this rate over the study period.

Changes in asthma control

To investigate the control of asthma attacks, the presence of asthma attacks and self-evaluation of asthma control by patients over the 2 weeks prior to completion of the questionnaire were classified, as described in Methods. The results are shown in Table 5. The percentage of subjects who experienced attacks in 1998 was 42.2% and this decreased significantly to 30.1% in 2000 ($P < 0.01$ for 1999 *vs* 1998; $P < 0.001$ for 2000 *vs* 1998). In 1998, the responses for each of the five levels (very good, fairly good, mediocre, bad and very bad) were 18.3, 34.5, 30.7, 14.3 and 2.3%, respectively. Significant differences were found in 1999 and 2000 ($P < 0.05$ for 1999 *vs* 1998; $P < 0.01$ for 2000 *vs* 1998; $P < 0.05$ for 1999 *vs* 2000). These results indicate that short-term asthma control has improved.

It is important to eliminate asthma-related symptoms, such as coughing and dyspnea, and to enable satisfactory sleep at night, as well as preventing asthmatic attacks. Based on the questionnaire results, sleep disturbances and the presence of a variety of asthma-related symptoms in the morning, at night and during sleep were

Table 4 Changes in drug medication in asthmatic patients

Date (year)	Rate of use of each drug (%)				
	ICS	SABAs	OCS	LTRA	OSRT
1998	67.0	44.4	21.5	29.8	86.0
1999	73.8***	43.8	18.5*	34.5***	84.9
2000	75.1***	35.0***†	18.9*	34.2**	82.1

*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$ compared with 1998; † $P < 0.001$ compared with 1999.

ICS, inhaled corticosteroid; SABA, inhaled short-acting β_2-adrenergic receptor agonist; OCS, oral corticosteroid; LTRA, leukotriene receptor antagonist; OSRT, oral sustained-release theophylline.

Table 5 Changes in the existence of asthma attacks and self-evaluation of asthma control by each patient over the 2 weeks prior to answering the questionnaire

Date (year)	PA (%)	SA (very good/fairly good/mediocre/slightly bad/bad; %)
1998	41.2	18.3/34.5/30.7/14.3/2.3
1999	34.4**	22.4/33.7/28.5/13.4/2.0*
2000	30.1***	21.0/38.2/26.4/11.8/2.6**†

*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$ compared with 1998; † $P < 0.05$ compared with 1999.

PA, presence of asthma attacks over the 2 weeks prior to answering the questionnaire; SA, self-assessment of asthma over the 2 weeks prior to answering the questionnaire.

Table 6 Changes in asthma-related symptoms and sleep disturbances over the 2 weeks prior to answering the questionnaire

Date (year)	Asthma-related symptoms (%)		Sleep disturbance (%)
	Morning	Night	
1998	54.0	31.4	20.9
1999	49.6	26.0**	17.2
2000	44.3**†	24.2**	16.1*

*$P < 0.05$, **$P < 0.01$ compared with 1998; † $P < 0.05$ compared with 1999.

Table 7 Changes in asthma attacks over the 1 year prior to answering the questionnaire

Date (year)	Asthma attacks over the 1 year period		
	Frequent (%)	Seasonal (%)	Few (%)
1998	24.9	31.4	20.9
1999	18.9*	32.7	48.4
2000	13.5*†	30.7	55.9*†

*$P < 0.001$, compared with 1998; † $P < 0.001$ compared with 1999.

Table 8 Changes in satisfaction in daily life

Date (year)	SDL (very satisfied/fairly satisfied/mediocre/slightly unsatisfied/unsatisfied; %)
1998	18.6/59.7/12.0/9.0/0.6
1999	16.8/60.1/13.5/8.7/0.8
2000	16.7/61.1/14.3/7.1/0.8

No significant changes were found. SDL, satsifaction in daily life.

examined (Table 6). Of the respondents, 54.6% answered that they had symptoms in the morning and 31.4% said they experienced symptoms at night in 1998 over the 2 weeks prior to answering the questionnaire. A total of 20.9% of patients experienced sleep disturbances, such as 'waking up in the night due to chest oppression'. This percentage decreased each year and there was a significant reduction in asthma-related symptoms and sleep disturbances in 2000. These results mainly indicate improvement in the prevention of asthmatic symptoms.

To clarify long-term asthma control, asthma attacks over the 1 year prior to answering the questionnaire were classified, as described in the Methods. The percentage of patients responding that they had 'frequent attacks' and 'few attacks' in 1998 was 24.9 and 41.9%, respectively. The former decreased and the latter increased significantly each year, reaching 13.5 and 55.9%, respectively, in 2000 (Table 7), which indicates that the long-term prevention of asthma attacks is also improving.

Changes in satisfaction in daily life and predicting satisfaction in daily life by multiple-regression analysis using study variables

Another target of asthma treatment is to allow patients to gain normal activity levels, so satisfaction in daily life was used as one of the most important factors in this study. In 1998, 18.6 and 59.7% of respondents responded that they were 'very satisfied' and 'fairly satisfied' with daily life, respectively. Responses of 'mediocre', 'slightly unsatisfied' and 'unsatisfied' were obtained from 12.0, 9.0 and 0.6% of patients, respectively. There was no significant percentage change in response at any level of satisfaction in daily life during the study period (Table 8). To identify factors related in improving satisfaction in daily life, we performed multiple-regression analysis using SPSS and the results are shown in Table 9. Significant factors were changes in the self-evaluation of asthma control ($P < 0.001$) between 1998 and 2000, indicating that a change in this factor plays a key role in improving satisfaction in daily life.

Table 9 Satisfaction in daily life as predicted by multiple-regression analysis using study variables

Variable	β	*P*
		0.053
Changes in peak-flow meter use	−0.046	0.300
Changes in frequency of asthma attacks (2 weeks)	0.076	0.158
Changes in asthma attacks (1 year)	−0.034	0.497
Changes in self-evaluation of asthma control by each patient (2 weeks)	0.352	<0.001
Changes in asthma-related symptoms in the morning (2 weeks)	0.024	0.638
Changes in asthma-related symptoms at night (2 weeks)	−0.015	0.764
Changes in sleep disturbance (2 weeks)	0.049	0.303
Changes in use of oral sustained-release theophylline	−0.018	0.681
Changes in use of inhaled β-adrenergic receptor agonists	−0.035	0.429
Changes in use of oral corticosteroids	0.007	0.877
Changes in use of inhaled corticosteroids	0.032	0.468
Changes in use of leukotriene receptor antagonist	0.039	0.374

Significant factors were changes in self-assessment for the condition of asthma control by each patient ($P < 0.001$) from 1998 to 2000. 2 weeks, over the 2 weeks prior to answering the questionnaire; 1 year, over the 1 year prior to answering the questionnaire.

Discussion

In this questionnaire-based investigation, information was obtained on 840 patients. The majority of patients were regular visitors to institutions. This presented two problems. One was the exclusion of patients with temporary symptoms who were treated only when asthmatic symptoms appeared, which is different from previous reports, including the AIRE report.[10] Another problem was the severity of asthma. The majority of patients required regular visits to institutions, which means that our study focuses on patients with more severe asthma compared with all asthmatic patients managed by the attending institutions. Another problem in the study design was that the questionnaires used were not validated. However, there are few validated questionnaires on asthma conditions and management. Instead of validation, the same patients were asked to respond over the duration of the study (3 years).

The greater than 80% use rate of OSRT as a medication was a notable aspect of the present study and the rate of use of OSRT remained constant throughout the study period. This indicates that OSRT was administered not only to patients with moderate or severe asthma, but also to patients with mild asthma. This reflects that OSRT was characteristically used in the actual clinical setting in Japan, although OSRT has been reported to be less effective than ICS.[13] In addition, the use of anti-inflammatory therapy with ICS and LTRA (pranlukast), which has only become available in Japan during this period, has increased gradually. Taken together, note that our investigation reflects the state of bronchial asthma under the combined management of anti-inflammatory therapy and OSRT.

In the present study, overall asthma control was considered to improve, although information on asthma control that is less objective was investigated compared with more subjective information. The effect of OSRT in addition to ICS on asthma control, which corresponds with that reported in previous studies,[14,15] may explain the improved asthma control observed to occur over the 3 year period of the present study.

Although there was a considerable improvement in asthma control, satisfaction in daily life did not change. This was very surprising if the answers for satisfaction in daily life were directly related to bronchial asthma itself, because we expected that satisfaction in daily life would be included in the quality of life of patients with asthma and because ICS and LTRA have been reported to improve both asthma control and quality of life.[16,17] Our results indicate that satisfaction in daily life is not dependent on quality of life, but on the important problems remaining in asthmatic patients despite improvement in their asthma control. Regression analysis revealed that improvement in the self-evaluation of asthma control plays a key role in this, because it has been reported that emotional factors are closely related to asthma control and management.[18] Self-evaluation is usually considered an indicator not only of asthma control, but also of quality of self-feelings. In this context, we are now analyzing the somatosensory amplification scale in asthma, because it is related to self-feeling[19] and related to self-evaluation. This approach may contribute to improving the apparent problem of no improvement in satisfaction in daily life.

In summary, more than 80% of patients used OSRT, whereas the percentage of patiens using ICS and LTRA

increased significantly. Short- and long-term asthma control improved significantly and asthma-related symptoms, including wheezing, coughing and sleep disturbances, decreased significantly. However, there was no improvement in satisfaction in daily life. Multiple-regression analysis revealed that self-assessment of asthma is significantly related to improvement in satisfaction in daily life. These results indicate that anti-inflammatory agents, including ICS and LTRA, greatly contribute to practical asthma control, whereas treatment with OSRT was widely used in Niigata Prefecture, Japan. However, the problem of satisfaction in daily life remains, and self-evaluation of asthma control may play a key role in improving satisfaction in daily life.

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