

The Role of a Self-management Program in the Control of Mild to Moderate Asthma: a Randomized Controlled Study

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ABSTRACT

Background: Asthma patient education has been recognized as an important component of asthma control. The aim of the present study was to carry out a cost-effectiveness analysis of patient education in patients with mild to moderate asthma during 6 months of follow up.

Methods: We randomly allocated asthma patients who were covered by health insurance to a control group (group C) or a self-management group (group S). Self-management consisted of measurement of peak expiratory flow (PEF) and monthly individual education and advice by a specialist. Effectiveness was evaluated on the basis of PEF, quality of life, and mean total cost of medical expenses. Furthermore, we asked the patients about symptom improvement and their level of satisfaction with this program.

Results: PEF values in group S gradually increased at 3 months after the self-management program and remained at high levels. The total costs decreased by 30% from baseline in group S, whereas they increased by 15% in group C. The cost of one-day visits showed no difference between the two groups, but the frequency of visits to general practitioners decreased in group S as compared with group C. Furthermore, the number of episodes of asthma attacks decreased in group S but not in group C, and 94% of the group S patients replied that they considered the self-management program to have been useful.

Conclusions: We conclude that an individual self-management program is not only a safe and effective aid in the treatment of mild to moderate asthma but can also reduce medical expenses.

KEY WORDS

asthma, cost-effectiveness, medical expense, PEF, self-management

INTRODUCTION

Asthma occurs in 3% of the adult population and 6% of children in Japan, and there is evidence that the incidence is increasing. The annual cost for asthma patients during the past 10 years is estimated at 302 to 450 billion yen. Because asthma is a chronic respiratory disease and the costs are largely due to the consequences of uncontrolled disease, it is presumed that the costs could be reduced if asthma control is improved.¹ Therefore, health economical evaluations may be strongly warranted.^{2,3} Asthma patient education has been recommended in several clinical guide-

lines.^{4,5} To achieve the ultimate goals of such guidelines, patients need to be able to manage their conditions on their own more safely. It was reported that 12-month asthma education programs improved quality of life, level of pulmonary function, and compliance with inhaled corticosteroid treatment.⁶

However, previous cost-effectiveness assessments after asthma education are rare and of limited applicability to clinical practice. Gallefoss *et al.*⁷ reported that one-year self-management of asthma increased forced expiratory volume in one second (FEV₁) and reduced costs. In the present trial, to determine whether short-term self-management programs are

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Table 1 Baseline characteristics of the asthma patients in this study

	Control group	Self-management group
Age	25 ± 16	26 ± 20
Adult/children	15/7	11/10
Male/female	14/8	11/10
Frequencies of clinic visits (time/M)	0.96 ± 0.77	0.96 ± 0.86
Inhaled corticosteroids	7	8

All data are expressed as means ± SEM.

also effective in improving pulmonary function and asthma symptoms and reducing cost, we conducted a randomized parallel-group study in patients with mild to moderate asthma.

METHODS

PATIENTS

This study was a randomized, parallel-group, prospective trial. The study population was recruited between February and July 2003. We extracted patients with mild to moderate asthma diagnosed according to the criteria of the Asthma Prevention and Management Guidelines, Japan (JGL, 2003)⁸ who had been treated by general practitioners (GP) from the receipts of the Japan Health Insurance Society. They were all invited by mail to participate in a self-management trial. Of 114 asthma patients recruited, 4 who refused to participate afterwards and 67 who discontinued submitting the diary within 4 weeks were excluded from the study. The remaining 43 subjects were thus enrolled in the study. The inclusion criteria were as follows: age 6 to 67 years, asthma severity mild to moderate according to the JGL, 2003.⁸ Patients younger than 6 years were excluded because it was difficult for them to use the peak flow meter correctly.

SELF-MANAGEMENT PROGRAM

None of the randomized patients had previously received any organized asthma education. The 43 subjects were randomized into a self-management group (group S) and a control group (group C). The group S patients were given an AirZone peak expiratory flow (PEF) meter (Matsuyoshi & Co., Ltd, Tokyo, Japan) and were given a booklet with instructions on its correct use. At the beginning of this program, all patients continued the treatment they had been receiving.

All patients received a diary in which to register their asthma symptoms (both daytime and nighttime), medication use, and twice daily PEF measurements (morning and evening), and submitted the diary once a week. The PEF values were compared with the baseline values at 4, 8, 12, 18 and 24 weeks after the start of the self-management program. Those belonging to group S also received a booklet in which the pathophysiology of asthma, the role of

asthma medication and side effects, allergic and non-allergic triggers, and symptoms indicating an impending exacerbation were described. The personal best peak flow value was defined as the highest morning prebronchodilator PEF measurement as recorded in the 4-week diary. The patients were provided with a 3-zone (green: 80–100% of personal best value (PBV), yellow: 60–80% PBV, and red: <60% PBV) self-management plan, based on symptoms and morning prebronchodilator PEF.⁸ In the case of the green zone, we advised patients to continue maintenance treatment or reduce their medication if the PEF values remained in the green zone for more than 3 months. If the PEF values went down to the yellow zone, we asked patients to increase the dosage of the controller medicine or to take reliever medicine. If patients whose PEF values were in the red zone had continued asthma symptoms in spite of bronchodilator therapy, we advised them to consult a GP or other physician promptly. All subjects were encouraged to ask questions about personal matters related to their disease. Furthermore, we assessed the frequency of asthma exacerbations during the trial. Exacerbations were defined as episodes which required admission to the hospital, emergency room visits and/or intravenous administration of bronchodilators and we compared the frequency before and after 24 weeks of the trial.

COSTS

Medical expenses consist of direct costs borne by the health care system, community, and family, and indirect costs, which are defined as productivity loss and time costs borne by the individual, family, and society or by the employer. In this study, we examined direct costs based on the actual expenses related to GP consultations including the costs of emergency clinic visits and pharmaceuticals. Any expenses related to other diseases were excluded, but pharmaceutical costs associated with asthma exacerbations were included.

QUESTIONNAIRE

We asked the patients about symptom improvement and their level of satisfaction with this program. The questionnaire items were as follows: 1) Was this pro-

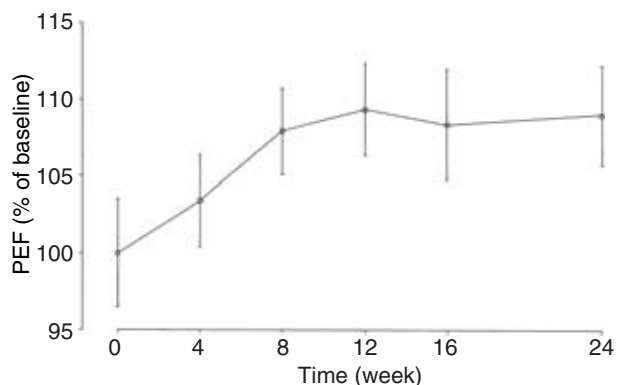


Fig. 1 Changes in peak expiratory flow (PEF) from baseline values in the self-management group (group S). Data are expressed as means \pm SEM.

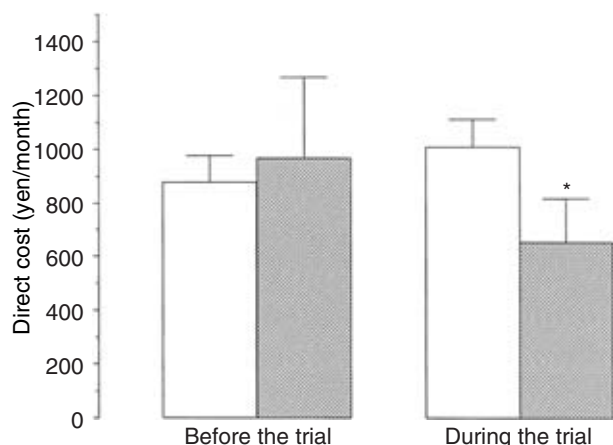


Fig. 2 Direct costs of asthma per month in the control group (group C, open columns) and self-management group (group S, shaded columns). Data are expressed as means \pm SEM.

gram useful for you? 2) Could you understand your asthma condition? 3) Did your knowledge of asthma increase? 4) Did you like this program ?

STATISTICAL ANALYSIS

All values were expressed as means \pm SEM. Analyses within and between groups were performed by *t*-test and *P*-values less than 0.05 were considered to indicate statistically significant differences.

RESULTS

SUBJECTS

Among the asthma patients enrolled, 27% of children and 56% of adults continued to measure the PEF for 6 months. Thus, the number of patients analyzed at the end of the study was 21 in group S and 22 in group C. The patients' characteristics are shown in Table 1. There were no significant differences in the distribu-

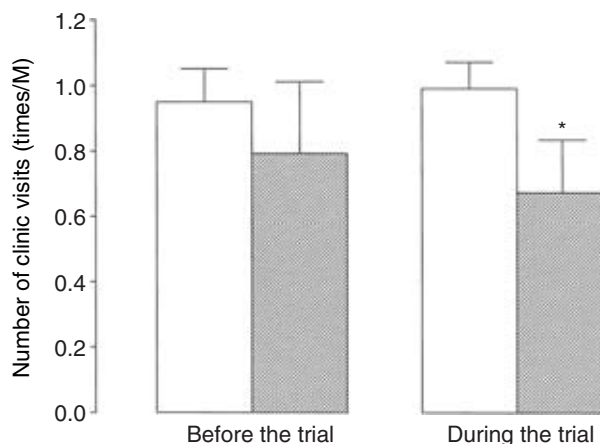


Fig. 3 Number of visits to general practitioners in the control group (group C, open columns) and self-management group (group S, shaded columns). Data are expressed as means \pm SEM. **P* < 0.01, significantly different from data before the trial.

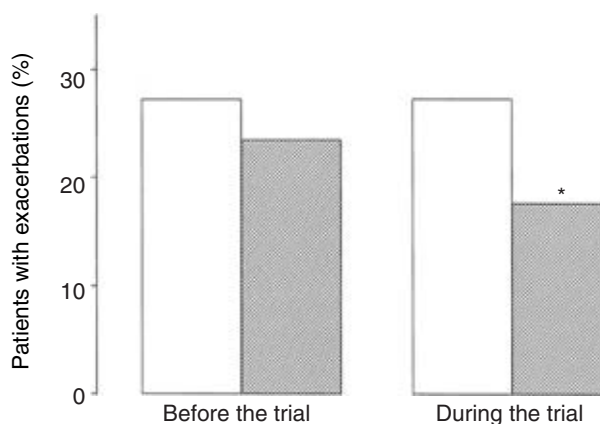


Fig. 4 Percentage of patients who experienced asthma exacerbations in the control group (group C, open columns) and self-management group (group S, shaded columns). **P* < 0.05, significantly different from data before the trial.

tion of age, gender or treatment of inhaled corticosteroids between the two groups.

PULMONARY FUNCTION

As shown in Figure 1, the PEF values in group S increased from 353 \pm 44 l/min at baseline to 384 \pm 38 l/min, which corresponded to a 9.3% increase at 3 months after the start of the self-management program, and the values remained at high levels until 6 months.

COSTS

Direct costs per month were not significantly differ-

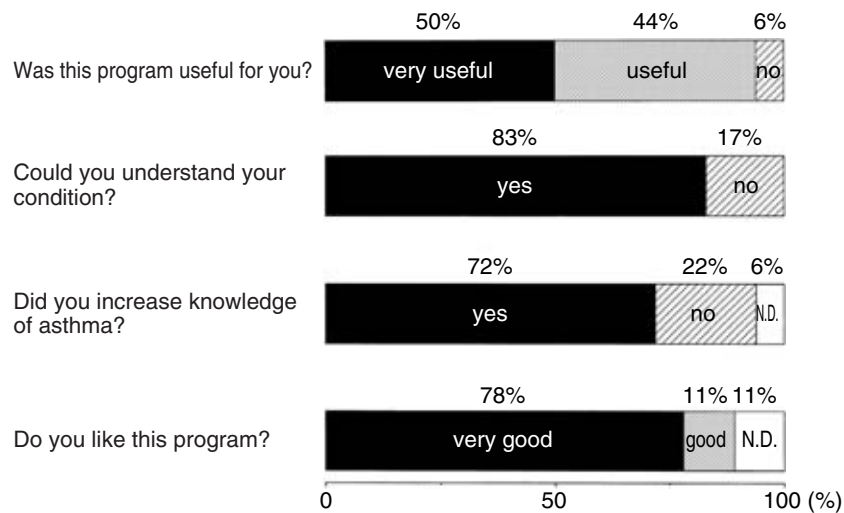


Fig. 5 Questionnaire administered to group S patients about their self-management program. N.D.: not described.

ent between the two groups at the start of the study (group S; 9650 yen *vs.* group C; 8770 yen). Mean costs from March 2003 to June 2003 decreased by 30% in group S, whereas they increased by 15% in group C (Fig. 2). Although there was no statistically significant difference between the changes in the two groups ($p = 0.058$), the self-management group showed a tendency toward a decrease in total costs. The costs per visit were not significantly different between the two groups, but the frequency of visits to general practitioners showed a significantly larger decrease in group S than in group C (0.79 to 0.67 *vs.* 0.95 to 0.99/month, respectively, $p = 0.012$) (Fig. 3). During the self-management period, significant reductions in the frequency of emergency room visits and admissions due to exacerbation of asthma were noted in group S (Fig. 4).

QUESTIONNAIRE

Figure 5 shows the results of the questionnaire on this self-management program in group S. 94% of patients found the program "very useful" or "useful", whereas 6% found it "non-useful". Furthermore, large numbers of patients responded that they could understand their asthma condition (83%), obtained increased knowledge of the disease (72%), and liked the self-management program (78%).

DISCUSSION

The present study demonstrated that the self-management program in mild to moderate asthma patients improved PEF and symptoms and at the same time decreased costs. These results are in accord with those of a previous study by Gallefoss *et al.*⁷ showing that patient education in mild to moderate asthma patients in a 12-month follow-up study im-

proved quality of life and saved costs. On the other hand, self-management programs are not of additional benefit in all phenotypes of asthma.⁹ For example, self-management programs may not provide substantial improvements in the clinical outcomes in patients with very severe asthma or well-controlled asthma, and patients already on relatively high doses of inhaled corticosteroids.

The PEF is widely used as an objective index of airway narrowing, but most of the patients in this study did not know about the PEF before participating in this program. In our study, PEF measurement compliance was 56% in the adults compared with 27.3% in the children. This difference is probably due to the difficulty for children to measure the PEF consistently, and it seems important to have the understanding and cooperation of their parents. Cote *et al.*¹⁰ reported that compliance with PEF measurements was relatively good during the first month (63%) but fell to 50% at 6 months. These findings are consistent with those of our study. During the self-management program, the PEF values in group S increased at 3 months and remained at high levels thereafter. The reason for this is not clear, but one possibility is that the likelihood of forgetting to take medicine decreased because the patients were asked to keep diaries everyday. In addition, it seems very important for patients to understand the signs which suggest the worsening of their asthma condition. The patients in group S were satisfied with this self-management program. It was surprising that there were several patients who had never been taught about asthma control and treatment by their GP. In this program, it would be effective to have monthly consultations with each patient tailored to their individual problems, thereby providing an opportunity for

patients to express their fears and concerns.

The mean costs from March to June 2003 decreased by 30% in group S, whereas they increased by 15% in group C. On the other hand, the costs per visit were not significantly different between the two groups. Therefore, the decrease in total costs in group S appears to result from a lower frequency of visits to GPs.

The total costs of asthma are rising as the number of asthma patients increases. Anti-inflammatory therapy with inhaled corticosteroids has markedly relieved asthma symptoms and provided better control of asthma worldwide. In consequence, the costs of asthma has decreased in Western countries. A recent report on cost-effectiveness and cost-benefit analyses revealed that for high-cost patients, PEF-based asthma education with a self-management program was the most cost-effective alternative in reducing costs associated with emergency visits and hospitalizations due to asthma exacerbations.¹¹

The Global Initiative for Asthma 2002 (GINA) guidelines,¹² the first section of which covers patient education, states that the key point of patient education is self-management. However, under the Japanese health insurance system, it is difficult to introduce such programs because there is not enough time to devote to patient education, and because there is no medical treatment fee system for such programs.

In this study, we investigated the direct costs of asthma and, in contrast, other reports showed that the indirect costs of asthma were significantly higher in the control group than in the intervention group.¹³ It is important to analyze both direct and indirect costs, but indirect costs have not been sufficiently evaluated in Japan. Better control of asthma results in reduced absence from work due to asthma attacks and mortality due to asthma, and consequently fewer severe asthma patients and thus decreases indirect medical expenses.

In conclusion, the self-management program for patients with mild to moderate asthma was shown in a 6-month follow-up to be a safe and effective means of improving asthma symptoms and reducing the frequency of asthma exacerbations, which may result in decreased costs. Further long-term studies will be needed to determine the long-term role of self-

management programs.

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