Short-term effectiveness of an asthma educational program: results of a randomized controlled trial

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Abstract Asthma educational programs have been shown to reduce the use of emergency room, frequency of severe asthma attacks and hospitalization. However, its effectiveness in other morbidity parameters and on quality of life has yet to be fully understood. This prospective randomized control trial evaluated the effectiveness of a patient education program in 77 asthmatics according to "Teach Your Patients About Asthma: A Clinician's Guide" (1992). Forty asthmatic patients were randomly allocated to Group A (usual treatment) and 37 to Group B (usual treatment plus a patient education program). The effectiveness of the educational program was evaluated by comparing morbidity outcomes at baseline and 3 months after initial evaluation. At enrolment, the two groups were not different with regard to age, sex, smoking, asthma severity, atopy, FEV_1, symptom-free days, use of rescue salbutamol and quality of life. Three months later, subjects in Group B showed a significant improvement in the overall quality of life ($p < 0.01$) and in the "Symptoms" domain ($p < 0.01$). None of the other parameters (use of rescue salbutamol, symptom-free days, days absent from work or school, FEV_1) showed any significant change. After stratification for asthma severity, only subjects with moderate-to-severe asthma showed a significant improvement in the overall quality of life ($p < 0.05$) and in the "Symptoms" ($p < 0.01$) and "Activities" ($p < 0.05$) domains. Moreover, in subjects with moderate-to-severe asthma FEV_1 value at the 3rd month of follow-up was higher in Group B than in Group A ($p < 0.05$). In conclusion, the educational program improved the quality of life in asthmatic subjects, mainly in patients with moderate-to-severe asthma.

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Keywords quality of life; asthma educational program; effectiveness; short-term.

INTRODUCTION

Asthma, a very frequent disease in children and adults, continues to be a major cause of morbidity even though pharmacological treatment has greatly improved in recent years (1).

For this reason patient education has been used to support the usual asthma therapy (1) with the aim of improving patients' knowledge about the disease and, most of all, of encouraging a partnership between patients and physicians.

This approach has been shown to reduce the use of emergency room (2), frequency of severe asthma attacks (2) and hospitalization (2) in very high-risk patients, and to improve patients' welfare with consistent financial savings (3). However, its effectiveness in other morbidity parameters has yet to be fully understood.

Received 20 November 2001, accepted in revised form 23 April 2002.
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The effect of an educational program on quality of life (QOL), a parameter whose importance is currently growing (4), has not yet been adequately investigated (5–7).

This prospective randomized controlled trial assessed the effectiveness of an educational program in a group of asthmatic outpatients and its impact on quality of life.

MATERIALS AND METHODS

Subjects

Seventy-seven patients selected from outpatients attending the asthma clinic, Institute of Occupational Medicine, University of Perugia, Italy were enrolled in the study. All were aged 18 years or over and had had a primary diagnosis of persistent asthma (mild, moderate or severe) at least 1 year earlier according to the criteria of the American Thoracic Society. Their asthma was stable in the 3 months before recruitment.

Subjects were randomly allocated to two groups: Group A (control group): usual treatment, and Group B

(educational group): usual treatment plus educational program. Every effort to optimize treatment in both groups was made; therefore, pharmacological treatment for each subject followed the guidelines of the American Heart, Lung and Blood Institute (1). Every patient gave informed consent.

Details of the subjects are shown in Table 1. No differences were found in the two groups, even after stratification for asthma severity (mild *vs*. moderate to severe). At enrolment 12 subjects (15.6%) were unemployed or retired. Only employed patients or students were included in the analysis of days of absence from school or work.

Study design and outcomes

This study is a randomized controlled trial designed to evaluate the effectiveness of a program of patient education in asthmatics.

Upon enrolment, only subjects in Group B took part in an educational program (carried out by the same Group A physician), based on "Teach Your Patients About Asthma: A Clinician Guide" (8). The three 2 h sessions included: (1) basic information about asthma; (2) information about asthma medications (bronchodilators and anti-inflammatory agents), use of inhalers and peak flow meters; (3) identification of asthma-warning signs, avoidance of, and/or reduction of exposure to asthma triggers, development of action and emergency plans [each patient was given written instructions about managing asthmatic attacks, according to the asthma management zone system (1)]. Handouts covering the key points of each lesson for learning reinforcement were distributed.

The investigators made a concerted effort to maintain a partnership with each patient and listening was an active part of the program. Patients were involved in decision-making with regard to therapy and were taught how to deal with symptoms early.

Patients in the control group received instructions from the physician on medication use, and influence of allergenic and non-allergenic triggers, and were taught how to use their inhaler properly. Explanations to specific questions, if raised by the patients, were also given.

The effectiveness of the educational program was evaluated by comparing morbidity outcomes at baseline and 3 months after the initial evaluation. Parameters included symptom-free days, use of rescue salbutamol, days absent from school or work and drug expenses. These events were compared with those occurring in the month before the study period.

Disease-specific quality of life was also included in the evaluation of the effectiveness by using the Asthma Quality of Life Questionnaire (9) administered at baseline and at the 3rd month of follow-up. The Asthma Quality of Life Questionnaire has 32 questions in four domains: activities, emotions, symptoms, and environmental triggers. Quality of life is expressed as a score ranging from 1 (total impairment) to 7 (no impairment). We used two methods to interpret QOL results clinically. The first one according to the recommendations of Juniper *et al.* (10) stating that a difference in score $\geqslant 0.5$ is clinically relevant for overall QOL and for each of the individual domains. The second method interprets QOL results as expressed by the proportion of patients benefiting from the educational program (11).

Spirometry was carried out and PEF was measured at enrolment and 3 months after the initial evaluation. FEV_1

Table 1. Patients' social, demographic and clinical data

	Group A (n=40)	Group B (n=37)	p
Age (years)*	49.3 ± 16.8	53.1 ± 16.8	NS
Sex, M/F	18/22	18/19	NS
Smoking habits, *n* (%)			NS
Nonsmokers	25 (62.5)	21 (56.8)	
Ex-smokers	9 (22.5)	14 (37.8)	
Current smokers	6 (15.0)	2 (5.4)	
Duration of asthma (years)	14.9 ± 37.5	13.4 ± 10.6	NS
Atopy, *n* (%)	15 (37.5)	12 (32.4)	NS
Asthma Severity, *n* (%)			NS
Mild persistent	8 (20.0)	5 (13.5)	
Moderate persistent	22 (55.0)	28 (75.7)	
Severe persistent	10 (25.0)	4 (10.8)	

NS=not significant.
*Values are mean ± SD.
Group A=usual treatment, Group B=usual treatment+educational program.

and FVC were measured on a dry wedge spirometer according to the recommendations of the American Thoracic Society (12). Values are expressed as percent of predicted values (13).

Statistical analysis

Data were analyzed using the Statistical Analysis System (SAS) package for mainframe (14). Values for continuous variables are expressed as the mean $\pm$ SD. Wilcoxon rank sum test and the Chi-square test or Fisher exact test were used, when appropriate, to compare the two Groups (A and B) at each time point (baseline and 3rd month of follow-up). Differences in continuous variables between baseline and the 3rd month follow-up point were tested in each group using the two-tailed paired *t*-test (when the variables were normally distributed) or the Wilcoxon signed-rank test (when the variables were not normally distributed). Differences in Group A were compared with those in Group B using Student's t-test or the Wilcoxon rank sum test, when appropriate. Since FEV_1 (% predicted) at baseline was slightly higher in Group B than in Group A analysis of covariance (ANCOVA) was used to adjust FEV_1 values at the 3rd month of follow-up, and to compare the adjusted FEV_1 at the 3rd month in the two groups. The same analysis was performed after stratification of the subjects into two groups according to asthma severity (mild asthma, and moderate-to-severe asthma (1). Differences were considered significant at $p < 0.05$.

RESULTS

Table 2 shows lung function and morbidity parameters in both groups at baseline and the 3rd month. Infra-group analysis: no significant improvements in any of the outcomes were found in Group B or Group A. During follow-up subjects in Group B tended to use more rescue salbutamol, while subjects in Group A used less rescue salbutamol, but the differences were not significant. In particular, three of the 37 subjects in Group B reported a marked increase, and two of the 40 subjects in Group A a great decrease in the use of rescue salbutamol. Inter-group analysis: no statistically significant difference emerged in any parameter at the 3rd month.

After stratification for asthma severity only baseline FEV_1 (% predicted) in subjects with moderate-to-severe asthma, was significantly higher in Group B than in Group A (81.2 $\pm$ 16.5 *vs.* 72.5 $\pm$ 16.6, $p < 0.05$). After adjusting for baseline FEV_1, at the 3rd month of follow-up FEV_1 (% predicted) was higher in Group B than in Group A ($p < 0.05$). No differences were found in subjects with mild asthma.

Results of QOL at baseline and at the 3rd month of follow-up are shown in Fig. 1. Three months after the initial evaluation, subjects in Group B had a significant improvement in the overall QOL (from 5.7 $\pm$ 0.8 to 6 $\pm$ 0.7, $p < 0.01$) and in the "Symptoms" domain (from 5.8 $\pm$ 1.1 to 6.2 $\pm$ 0.8, $p < 0.005$). There was no statistically significant change in QOL in subjects in Group A. An improvement $\geqslant$ 0.5 in the QOL score in the overall and "Symptoms" domains was found in 12 and in 16 subjects in group B, and in seven and nine subjects in Group A, respectively. The analysis to assess the number of patients that needed to be treated (NNT) to obtain a single patient benefit (11) showed that, except for the "Emotions" domain with an NNT equal to 17, NNT was similar in the other domains, ranging from 3.1 in the "Symptoms" domain, and 3.4 in the "Environment" domain, to 4.3 in the "Activities" and overall domains.

At the 3rd month of follow-up Group B compared to Group A had an higher score in the overall (6 $\pm$ 0.7 *vs.* 5.6 $\pm$ 0.9, $p < 0.05$) and in the "Environment" (6.6 $\pm$ 0.7 *vs.* 6 $\pm$ 1.2, $p < 0.005$) and "Symptoms (6.2 $\pm$ 0.8 *vs.* 5.7 $\pm$ 1.1, $p < 0.005$) domains.

At the 3rd month of follow-up subjects in Group B with moderate-to-severe asthma had a significant

Table 2. Lung function and morbidity parameters in the two groups at baseline and at the 3rd month of follow-up

	Group A		Group B	
	Baseline	3rd month	Baseline	3rd month
FEV_1 (% predicted)	77.5 $\pm$ 18.5	76.2 $\pm$ 20.7	83 $\pm$ 16.5	85.4 $\pm$ 15.1 *
PEF (l/min)	382 $\pm$ 112	397 $\pm$ 130	389 $\pm$ 118	411 $\pm$ 109
In the last month				
Days absent from work/school, (*n*)	0.1 $\pm$ 0.6	0	0.2 $\pm$ 0.9	0
Symptom-free days, (*n*)	21.4 $\pm$ 11.0	22.8 $\pm$ 10.9	22.2 $\pm$ 10.9	23.0 $\pm$ 9.5
Rescue salbutamol (*n* of puffs)	22.9 $\pm$ 34.9	16.4 $\pm$ 34.1	14.8 $\pm$ 37.8	25.8 $\pm$ 51.1
Medication expenses (US)	57.5 $\pm$ 46.1	60.6 $\pm$ 48.8	62.6 $\pm$ 43.1	56.6 $\pm$ 43.8

*$P < 0.05$ as compared with the 3rd month value in the control group, by analysis of covariance, after adjusting for FEV_1 baseline values.

Group A=usual treatment; group B=ususal treatment+educational program.

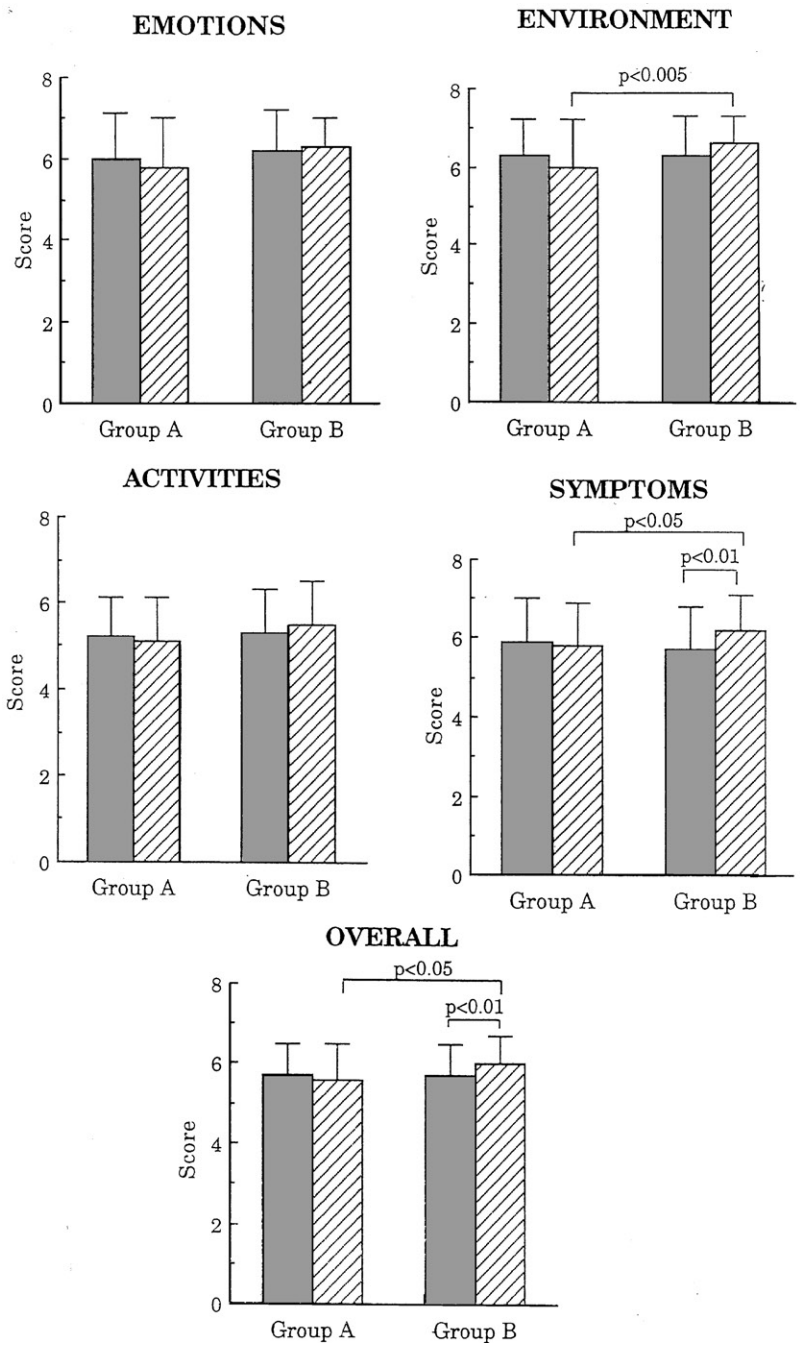

Fig. 1. Overall quality of life and separate domains in the two groups at baseline and at the 3rd month of follow-up. ■, Baseline value; ▨, 3rd month of follow-up.

improvement in the overall QOL score (from 5.6 ± 0.8 to 6 ± 0.7; $p < 0.05$) and in the "Symptoms" (from 5.7 ± 1.1 to 6.2 ± 0.8; $p < 0.01$) and "Activities" (from 5.1 ± 0.9 to 5.4 ± 0.9; $p < 0.05$) domains. In Group A subjects with moderate-to-severe asthma QOL scores at the 3rd month of follow-up remained unchanged. Nine, 14, and 10 subjects in Group B, and 5, 8 and 6 subjects in Group A showed a $\geqslant 0.5$ improvement in the overall, "Symptoms" and "Activities" domains, respectively. Inter-group analysis at the 3rd month of follow-up showed that subjects in Group B with moderate-to-severe asthma had a higher overall QOL score (6 ± 0.7 *vs.* 5.5 ± 1; $p < 0.05$), and "Environment" (6.7 ± 0.5 *vs.* 5.9 ± 1.3; $p < 0.005$) and "Symptoms" domain scores (6.2 ± 0.8 *vs.* 5.6 ± 1.2; $p < 0.01$) than subjects in Group A.

No changes in QOL were found in subjects with mild asthma at baseline and at the 3rd month of follow-up in either group.

DISCUSSION

This study showed that the educational program was effective in improving QOL, mainly in patients with moderate-to-severe asthma. We observed improvements in the overall QOL score and "Symptoms" domain in all patients, whereas an improvement in the "Environment" domain was found only in subjects with moderate-to-severe asthma. In spite of recent awareness of the relevance of health-related QOL in clinical assessments (4), to the best of our knowledge, the outcome of QOL after an educational program has been investigated in few studies (5–7). The results of these studies concur with ours. In fact, Turner *et al.* (5), Kauppinen *et al.* (7), and Kelso *et al.* in an uncontrolled study (6) observed a significant and rapid increase in the QOL score in subjects who participated in an educational program.

Interestingly, when we stratified by severity of asthma, the improvement in QOL was observed in patients with moderate-to-severe asthma, but not in those with mild asthma. Consequently, the educational program was in fact effective only in a subgroup, confirming results of other studies conducted in children (15,16). Subjects with mild asthma may have higher baseline QOL values than those with moderate-to-severe asthma. A significant increase in QOL values is therefore difficult to obtain since these subjects have less room for improvement. On the other hand, because of multiple testing, interpretation of these results should acknowledge the risk of having significant differences just by chance.

The finding of a statistically significant increase in QOL score is an important result, but does the statistical difference mean a clinical difference as well? The recent paper by Juniper *et al.*, the investigators who developed the questionnaire we used (10), pointed out that a difference in score $\geqslant 0.5$ is clinically important. In our study, an inter-group clinical difference was found in subjects with moderate-to-severe asthma in the overall, "Symptoms" and "Environment" domains. Moreover, subjects with moderate-to-severe asthma also showed a clinically significant improvement from baseline to the 3rd month of follow-up in the "Symptoms" domain, but not in the other domains. These results suggest that, at least in moderate-to-severe asthmatics, the educational program could determine a noticeable clinical effect in the QOL.

Although other results were statistically significant, the lack of an improvement $\geqslant 0.5$ might be explained by the fact that the baseline QOL was quite high in this population making great changes unlikely in such a short period of time.

Guyatt *et al.* recently suggested another way to interpret QOL results (11). The index used is the number of patients needed to treat (NNT) for a single patient benefit. In our study, similar NNT were found in the "Symptoms", "Activities", "Environment" and "Overall" domains, with values ranging from 3.1 to 4.3, while the NNT in the "Emotions" domain was higher. Therefore, for example, for every 20 patients completing the educational program six showed an improvement in the "Symptoms" domain, four in the "Activities" and overall domains, and only one in the "Emotions" domain. This confirms that the effect of the educational program on QOL may be incomplete and not fully uniform in each domain.

We are actually unable to determine which aspect of the educational program was primarily responsible for the improvements we found. Knowing more about asthma, trigger factors, medication use and management of exacerbations is an important part of the program but, in our opinion the partnership between patient and doctor might be the determining factor. As was pointed out in a recent paper (17), in the so-called co-management model, "the physician assumes the role of consultant and teacher, eliciting and addressing patients' fears and concerns about the disease and the use of medication". Therefore, the physician not only provides information, but also helps to develop the patient's skills in controlling the disease, shares responsibilities with him and together they come to a mutual agreement on therapy. Thus, we would expect such an approach to increase the likelihood of better disease management.

The education program was not effective in any of the other morbidity parameters (symptom-free days, use of rescue salbutamol, days absent from school or work). Even if most of the previous studies were able to show improvement in some morbidity outcomes (18–20), results similar to ours have been reported (21–23). Differences in patient selection could partly explain these discrepancies. In fact, unlike our subjects the patients included in some studies (18–20) were very high-risk subjects (hospitalized because of asthma (19) or affected by severe (20) or refractory to treatment (18) asthma). Moreover, baseline values of some of the morbidity outcomes in our subjects were indicative of a group of patients whose asthma was well controlled (many symptom free days and few days of absence from work or school). However, 3 months after the educational program, the lack of differences between Groups A and B was quite surprising but, as Cote *et al.* commented, (22) controls did receive some sort of education during the study along with more than the usual attention (i.e. longer visits, more answers to questions, and administration of the QOL questionnaire), thereby reducing the likelihood of major differences.

Even if the difference was not statistically significant, more use of rescue salbutamol was observed in Group B because of the marked increase in β2-agonist use reported by three of the 37 subjects in the group. Since no other signs of asthma exacerbation were present in these patients we can, like others (15), presume that the educational program taught them a more appropriate use of rescue salbutamol.

The only objective parameter of morbidity, which was statistically higher in the educational group than in the control group, was FEV_1, even after adjustment for baseline FEV_1. This finding was observed only in subjects with moderate or severe asthma, thus confirming the effectiveness of the educational program only in these asthmatic patients. Although similar observations have been reported elsewhere (4,7,20), other studies failed to find such an improvement (21,24). Rather than overemphasize this finding, as the follow-up period was short and the number of subjects not high, it is reasonable to suggest that an improvement in objective variables, such as FEV_1 needs to be confirmed in other studies and in longer follow-ups.

In conclusion, the educational program improved the quality of life, mainly in patients with moderate-to-severe asthma. More patients need to be followed-up for a longer period of time to confirm these findings.

Acknowledgements

The authors would like to thank Dr G. A. Boyd for her help in reviewing this paper and Stefania Rometta for her secretarial assistance. We would also like to acknowledge the financial support of the National Research Council, Italy.

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