

Quality of Life Assessment after Patient Education in a Randomized Controlled Study on Asthma and Chronic Obstructive Pulmonary Disease

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The effect of patient education in patients with asthma and Chronic Obstructive Pulmonary Disease (COPD) on health-related quality of life (HRQoL) is not previously investigated using the St. George's Respiratory Questionnaire (SGRQ). We randomly allocated at our out-patient clinic 78 asthmatics and 62 patients with COPD to either a control or an intervention group. Intervention consisted of two 2-h group sessions and one to two individual sessions each by a nurse and a physiotherapist. A self-management plan was developed. Baseline quality of life assessment showed comparable scores independent of treatment groups among asthmatics and patients with COPD, but statistically significantly better scores ($p < 0.05$) for the educated asthma group after 12 mo compared with the control group. This aligned with the 12-mo SGRQ assessment, which revealed better symptoms, activity, impact, and total scores by 11 ($p < 0.02$), 15 ($p < 0.01$), 19 ($p < 0.001$), and 16 ($p < 0.001$) units, respectively. Patient education among asthmatics increased the FEV₁ by a mean value of 6.1% (SD, 12) compared with the control group ($p < 0.05$). Education among patients with COPD did not indicate a significant increase in HRQoL as measured by the SGRQ or increased FEV₁. We conclude that patient education increased HRQoL and FEV₁ among asthmatics, but not among patients with COPD. Gallefoss F, Bakke PS, Kjærsgaard P. Quality of life assessment after patient education in a randomized controlled study on asthma and chronic obstructive pulmonary disease.

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In recent years we have seen an increased prevalence of asthma in the western world with consequent rising burdens on the health budgets (1, 2). One action to cope with this problem has been to educate the patients about their disease to promote self-management. The focus has mainly been put on asthma, and little attention has been given to chronic obstructive pulmonary disease (COPD).

Asthma management studies (3) have been shown to reduce the number of hospital admissions (4-8), days off work because of asthma exacerbations (4-6, 9, 10), and improve symptom scores (11, 12) and inhalation techniques (13). Limited knowledge is available on the effect of patient education on health-related quality of life (HRQoL). Boulet and colleagues (9) found after patient education in a randomized study in 84 patients with moderate asthma better quality of life as measured by the Asthma Quality of Life Questionnaire (14). In a randomized, controlled study of 115 patients with mild-to-moderate asthma, the subjects attending the education program had better scores using selected components (Part 3) of the St. George's Respiratory Questionnaire (SGRQ)

during a 12-mo follow-up (5). No asthma education program has been evaluated by means of the full version of SGRQ. In a randomized, controlled study on patients with COPD in general practice with a 6-mo follow-up, no difference was found between the intervention group receiving education and the control group, using the full SGRQ version (15).

The present study on patients with mild-to-moderate asthma and COPD was undertaken to examine the influence of an education program on HRQoL after a 12-mo follow-up. We also examined the effects of the education on the level of lung function.

METHODS

Study Design

Between May 1, 1994 and December 1, 1995 a total of 140 consecutive patients were included in the study. Before randomization they had received ordinary consultation care at our out-patient chest clinic at Central Hospital of Vest-Agder, Kristiansand, Norway. Eligible subjects were patients with bronchial asthma and COPD between 18 and 70 yr of age, not suffering from any serious disease such as unstable coronary heart disease, heart failure, serious hypertension, diabetes mellitus, kidney or liver failure.

Subjects with asthma were to have a FEV₁ equal to or higher than 80% of predicted value (16) in stable phase. Furthermore we required either a positive reversibility test (16), a documented 20% spontaneous variability (PEF and FEV₁), or a positive metacholine test (PD₂₀) (17). A positive reversibility test required at least a 20% increase (FEV₁ or PEF) after inhalation of 400 µg salbutamol. Subjects with COPD were to have a FEV₁ equal to or higher than 40% and lower than 80% of predicted. Among patients with COPD, 32% were re-

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versible to ipratropium bromide 80 µg and/or salbutamol (18, 19). These measures were obtained from the participants' charts.

Of the eligible patients, the inclusion rate was 92% (78 of 85) and 91% (62 of 68) for the asthma and COPD groups, respectively.

The patients signed a written consent and were then randomly assigned. The control group were followed by their General Practitioner (GP) and the intervention group received an education program and were then also transferred to a 1-yr follow-up by their GP.

Education Intervention

The intervention group received a specially made 19-page booklet with essential information about asthma/COPD, medication, compliance, self-care, and self-management plan. Instructions in the recording of peak expiratory flow (PEF) and symptoms in a diary were given to both asthmatics and patients with COPD.

The asthmatics and patients with COPD were educated in separate groups. The COPD group received more information about tobacco weaning, but besides this the educational interventions were comparable. The education consisted of two 2-h group sessions of five to eight persons on two separate days. The subjects then had one to two individual sessions by a nurse and one to two individual sessions by a physiotherapist.

During the first group session given by a medical doctor, the importance of self-care was emphasized. Patients were given a basic introduction to asthma/COPD, concentrating on the airway smooth muscle cramp and inflammatory components of obstruction, which is the target for medical treatment. Prevention of attacks and factors causing exacerbations were emphasized as well as the dangers of smoking.

The second group session was held by a pharmacist and included pharmacology of the asthma drugs, how they affect the components of obstruction, and the rationale for their use.

The third group session was held by a specially trained nurse who reviewed the essentials from the first day and concentrated then on self-care. The recording of PEF and symptoms in a diary was emphasized, and then the model of a stepwise treatment plan at exacerbations was presented in general.

The fourth group session was held by a physiotherapist. The themes were respiration, respiration during exacerbations, pursed-lip breathing, rest positions, relaxation exercise, consciousness about breathing, and activity proposals.

During individual sessions effort was made to establish a partnership with the patient by using open-ended questions, acknowledging concerns and fears about the obstructive lung disease, and normalizing it. The essentials of the educational group sessions were briefly repeated, but now with a much more individual approach. A checklist was used to cover the important issues and was ticked off when the educator felt satisfied with the level of understanding.

The succession of individual sessions (one to two times for 40 min) by a specially trained nurse was as follows. The goals of asthma/COPD treatment were stated and again the components of obstruction were emphasized together with the site of action of individual antiasthmatic medication. The patient's symptoms were noted trying to attain consciousness about early symptoms at exacerbations. The individual factors causing attacks/exacerbations were discussed. Tobacco weaning was emphasized. Fears of adverse effects of medication was obtained. Inhalation technique was checked and PEF and symptoms were discussed. At the final teaching the patients received an individual treatment plan on the basis of the acquired personal information. The personal understanding of the treatment plan was discussed and tested.

The individual physiotherapist teachings (one to two times for 40 min) concentrated on a practical approach of the themes discussed in the group sessions.

Group sessions were confirmed the day before by phone. Patients who could not attend planned group sessions could participate at the next course. Persons not attending all group sessions or who failed to meet at individual sessions, were withdrawn.

Outcome Variables

At randomization, no validated lung-specific health-related quality of life (HRQoL) instrument was available in Norwegian. We used four

simple HRQoL questions translated from the Omnibus interviews (20). Wording of the questions and the preprinted alternatives for answering were as follows. (1) The last year my chest trouble has become: Worse, unchanged, or better. (2) The last 2 wk I have had asthma/COPD symptoms during the day: All the time, two to four times a day, every day, two to three times a week, or more seldom. (3) The last 2 wk I have had asthma/COPD symptoms during the night: Waken three times or more, waken one to two times, or do not wake up. (4) My asthma/COPD have the last 2 wk restricted me from doing what I want: To a great extent, medium extent, or little or no extent.

We asked the same four questions after a 1-yr follow-up. At the 1-yr follow-up we added the St. George's Respiratory Questionnaire (SGRQ) (21), which at that time had been translated to Norwegian and validated by translation back to English. The SGRQ is a disease-specific instrument and has 76 items that are weighted to produce three component scores: "Symptoms," measuring distress caused by respiratory symptoms; "Activity," measuring the effect of disturbances to mobility and physical activity; "Impact," quantifying the psychosocial impact of the disease. A number of items in the Symptoms component relate to the frequency of symptoms during the previous year. Both the Activity and Impact components relate to the patient's current state. A "Total" score is also calculated from all component items, thus providing a global estimation of the patients respiratory health. Each of these scores ranges from 0 to 100, a score of 100 indicating maximum disability (22). A difference of four units indicates a slight clinical effect, a difference of eight or 12 units indicates moderate or very good clinical effects, respectively (23).

Spirometry was performed prior to randomization and at 12-mo follow-up by standard methods (24) using a Jaeger MasterLab Body Box (Würzburg, Germany). The patients were told to abstain from bronchodilators for 6 h before testing. The technical staff did not know whether the patients belonged to the control or to the intervention group. The questionnaires were filled in before spirometry at the 1-yr follow-up. Smoking was measured using standard questions on status, daily number of cigarettes, and duration in years (25).

Statistics

For the four simple HRQoL questions, differences between proportions were tested applying a Mantel-Haenszel chi-square test assuming linear correlation. The SGRQ was scored according to the developer's guidelines, and the recommended method for handling missed items were used (21). The SGRQ scores were checked for normality and the scores in the intervention and control groups were compared using analysis of variance (ANOVA) (21). The assumptions for using ANOVA were checked using normality plots for the residuals.

The spirometric differences between treatment groups being normally distributed checked by normality plots, were calculated using Student's *t* test. The relative difference, expressed as percent change, was calculated as follows: $[(FEV_1 \text{ in liters as the 1-yr follow-up} - FEV_1 \text{ in liters at randomization}) / FEV_1 \text{ in liters at randomization}] \times 100$.

Multiple linear regression analysis was applied when testing determinants for the SGRQ scores. Outliers were included in the analyses. All tests were performed two-sided with a significance level of 5%.

The analyses were performed on Compaq computers applying SAS for Windows version 6.12 (SAS Institute) or SPSS for Windows version 7.5 (SPSS Inc.).

Permission to establish a person register was given from the National Data Supervision Center. The methodologic procedures were in accordance with the ethical standards of the Helsinki Declaration as approved by the regional ethical committee.

RESULTS

The study population consisted of 140 patients, of whom 39 were randomized to each asthma treatment group and 31 to each COPD treatment group (Table 1). The patients in the intervention and control groups were found to be equal with regard to baseline parameters. There were 23 (29%) men in the asthma group and 31 (50%) in the COPD group. The asthmatic patients had a mean baseline FEV₁ of 94% of expected value, whereas the patients with COPD had a mean baseline of 57% of expected. Altogether 22 (28%) and 24 (39%) of the

TABLE 1
BASELINE CHARACTERISTICS OF PATIENTS INCLUDED IN THE STUDY

	Asthma		COPD	
	Control Group (n = 39)	Intervention Group (n = 39)	Control Group (n = 37)	Intervention Group (n = 37)
Sex, men (%)	8 (21)	15 (39)	16 (52)	15 (48)
Age, yr, mean (SD)	44 (12)	41 (12)	58 (10)	57 (9)
Smoking habits				
Current smokers (%)	13 (33)	9 (23)	12 (39)	12 (39)
Pack-years, median*	11	6	17	17
Ex-smokers (%)	11 (28)	14 (36)	19 (61)	15 (48)
Never-smokers (%)	15 (39)	16 (41)		4 (13)
Duration of symptoms, median (yr) [†]	6	7	13	15
FEV ₁				
Mean (SD), L	3.0 (0.8)	3.2 (0.7)	1.7 (0.5)	1.8 (0.5)
% predicted, mean (SD)	95 (17)	93 (13)	56 (11)	59 (9)
FVC				
Mean (SD), L	3.8 (0.9)	4.2 (0.9)	3.3 (0.9)	3.3 (1.0)
% of predicted (SD)	105 (15)	104 (12)	89 (12)	88 (14)
(FEV ₁ /FVC) × 100, mean (SD)	78 (9)	75 (8)	52 (10)	55 (9)

* Median values are employed for non-normally distributed data.

[†] Based on the question: How long have you had asthma/COPD symptoms?

asthmatics and the patients with COPD, respectively, were current smokers at randomization and 47 (60%) and 58 (94%) had a smoking history, respectively. The mean age (SD) in the asthma group was 45 (12) yr and in the COPD group it was 60 (9) yr.

In the intervention group nine patients failed to complete the educational program. The reasons for not finishing the program were social problems (n = 1), priority because of hectic work (n = 2), alcoholism (n = 1), unannounced emigration (n = 1), failure to meet at educational group sessions for unknown reasons (n = 3), and serious myocardial infarction (n = 1). Another three patients were withdrawn from the study during the follow-up because of lymphoma (n = 1) and lack of cooperation (n = 2). This left us with 58 patients (83%) for a 1-yr follow-up. The withdrawn intervention group patients did not to our knowledge have any serious deterioration in their obstructive lung disease, and none were hospitalized.

In the control group, patients were withdrawn because of lack of cooperation (n = 2), diagnosis of rectal cancer (n = 1), and emigration (n = 1). Two of the withdrawn control group patients were hospitalized for exacerbations of their COPD. This left us with 66 patients (94%) for the 1-yr follow-up.

The patients in the intervention and control groups were found to be equal with regard to the baseline four-question HRQoL parameters (Table 2). After a 1-yr follow-up, statistically significant differences were found in the scores for all four questions, with better scores in the asthma intervention group than in the control group: 81% of the educated asthmatics then answered that their chest trouble had improved during the last year compared with 43% in the uneducated group. Likewise, 19% of the educated asthmatics reported daily or weekly symptoms compared with 64% in the uneducated group. The corresponding values for nighttime symptoms were 6 and 41%, and for impact in daily life they were 13 and 38%, respectively. The educated patients with COPD showed no clear tendency towards better HRQoL scores when compared with the control group after 1 yr.

Regarding the total SGRQ scores at the 1-yr follow-up, a statistically significant difference of 16.3 units (p < 0.001) was seen between the asthma intervention group and the control group (Table 3). For the subscores the corresponding differences varied between 18.6 (Impact) and 11.4 (Symptoms). In

the COPD group no significant differences for either of the scores were seen, the differences being one sixth to one half of those in the asthma group (Table 3).

During the 12-mo follow-up the mean FEV₁ (SD) increased by 112 (386) ml in the asthma intervention group, whereas it fell by 83 (383) ml in the asthma control group (p value for the difference < 0.05) (Figure 1). In the patients with COPD no statistically significant differences were noted between the intervention group and the control group (Figure 1).

During the 1-yr follow-up one asthmatic in the control and intervention groups reported stopping smoking. The corresponding figures for the patients with COPD in the control and intervention groups were three and two subjects, respectively.

Multiple linear regression analysis with SGRQ total scores as dependent variable was performed in a model with sex, age, smoking status at baseline, treatment group, and FEV₁ in percent predicted at the 1-yr follow-up as independent variables (r² for the model = 0.44). The asthma intervention group showed a SGRQ total score 11.3 units lower than the control group (95% CI = -18.6 to -3.9, SE = 3.7, p = 0.003). In the same model current smoking gave a higher SGRQ total score by 14.7 units (95% CI = 6.1 to 23.3, SE = 4.3, p = 0.001). Corresponding analysis were performed on the subscores of SGRQ (Figure 2). After adjusting for sex, age, smoking status, and FEV₁ in percent predicted at the 1-yr follow-up, lower subscores were seen in the intervention group than in the control group, and current smoking was associated with statistically significant higher subscores (all p values < 0.01).

DISCUSSION

To our knowledge this is the first randomized, controlled study to examine the impact of an education program on quality of life in asthmatics and patients with COPD using the full version of the SGRQ. In the asthmatics the intervention group had less symptoms, higher activity, and less impact on their daily life, as measured by the SGRQ, compared with the control group. We also found that educated asthmatic patients increased their FEV₁, whereas the asthmatics in the control group had a decreased FEV₁ after 12 mo. In the patients with COPD, no statistically significant differences between the con-

TABLE 2
FOUR LUNG-SPECIFIC QUALITY OF LIFE QUESTIONS AT RANDOMIZATION
AND AFTER A ONE-YEAR FOLLOW-UP*

	Asthma					COPD				
	Baseline		End		p Values	Baseline		End		p Values
	Control Group (n = 39)	Intervention Group (n = 39)	Control Group (n = 39)	Intervention Group (n = 32)		Control Group (n = 37)	Intervention Group (n = 37)	Control Group (n = 27)	Intervention Group (n = 26)	
A1										
Worse, %	54	49	11	0	0.005 [†]	57	48	22	12	0.21
Unchanged, %	23	28	46	19		17	32	37	27	
Better, %	23	23	43	81		27	19	41	62	
A2										
All the time/2–4 times a day, %	15	13	25	3	0.001 [†]	37	45	27	15	0.25
Every day/2–3 times a week, %	49	41	39	16		37	34	31	38	
More seldom, %	36	46	36	81		27	21	42	46	
A3										
Waken > 3 time/wakens 1–2 times, %	38	33	41	6	0.001 [†]	40	53	37	42	0.92
Does not wake up, %	62	67	59	94		60	47	63	58	
A4										
To a great extent/medium extent, %	36	23	38	13	0.031 [†]	47	50	44	42	0.30
Little/no extent, %	64	77	62	88		53	50	56	58	

* The answers are presented partially dichotomized to simplify the table. All categories were taken into account when calculating p values using Mantel-Haenszel chi-square test. Wording of questions and alternatives for answering were:

1. The last year my chest trouble has become: Worse, unchanged, or better.
2. The last two weeks I have had asthma/COPD symptoms during the day: All the time two to four times a day, every day two to three times a week or more, seldom.
3. The last two weeks I have had asthma/COPD symptoms during the night: Wakens three times or more, wakens one to two times, or do not wake up.
4. My asthma/COPD have the last two weeks restricted me from doing what I want: To a great extent, medium extent, or little or no extent.

[†] Intervention Group.

trol and the intervention groups were noted regarding health-related quality of life (HRQoL) and lung function.

A limitation of our design is that the participants were not examined with the SGRQ before entering the survey. Hence, we can only observe differences in quality of life scores between the control and intervention groups at the 12-mo follow-up and not changes in quality of life scores within the two groups during the follow-up period. On the other hand the four lung-specific quality of life questions were asked at baseline and at follow-up (Table 2). At baseline the patients in the intervention and control groups from a clinical point of view were equal regarding the four quality of life questions. At follow-up a clear improvement was observed in the intervention group relative to the control group among asthmatics, but not for the patients with COPD, a result that aligns with the SGRQ scores. Consequently, it is likely that the differences in the scores of the SGRQ at follow-up mostly reflect an effect of the intervention program.

The four lung-specific Quality of Life questions at the 1-yr follow-up in the asthma group revealed important differences between the groups. For example none of the educated asthmatics answered that they deteriorated during the follow-up year, and four out of five actually felt that their condition had improved. Furthermore, four out of five and nine out of ten of the educated asthmatics experienced no daytime or nighttime symptoms. These answers were in contrast to the uneducated asthma group and revealed a positive effect of patient education on HRQoL in asthmatics of notable and significant clinical importance.

The SGRQ scores after a 1-yr follow-up confirms these measurements. In the asthmatics the mean score differences between the control and intervention groups varied between 11 and 19 units for the Symptoms, Activity, and Impact part of the SGRQ (Table 3). This is three to five times higher than what has been regarded as a clinically significant change (23). The largest difference was observed for the impact part of

TABLE 3
ST. GEORGE'S RESPIRATORY QUESTIONNAIRE SCORES AT 12 mo
FOLLOW-UP IN THE INTERVENTION AND CONTROL GROUPS OF
THE ASTHMATICS AND PATIENTS WITH COPD*

	Asthma			COPD		
	Control Group (n = 39)	Intervention Group (n = 32)	p Values [†]	Control Group (n = 27)	Intervention Group (n = 26)	p Values [†]
Symptoms	42.5 (20)	31.1 (20)	0.018	51.3 (22)	44.9 (21)	0.28
Activity	44.3 (20)	29.7 (22)	0.007	50.9 (21)	53.2 (19)	0.68
Impact	32.4 (21)	13.8 (14)	0.0001	37.4 (24)	30.9 (18)	0.27
Total	36.5 (18)	20.2 (15)	0.0002	43.1 (21)	40.0 (16)	0.54

* Values are means with SD shown in parentheses.

[†] p Values calculated using ANOVA, model SGRQ-SCORE = GROUP, where group is either Control or Intervention.

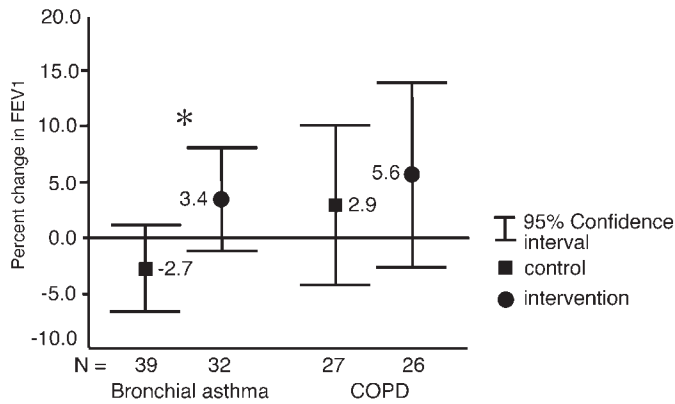


Figure 1. Changes in FEV₁ during a 12-mo follow-up in the intervention and control groups of the asthmatics and the patients with COPD (percentage change with 95% confidence intervals). *p < 0.05. Probability values are calculated using two-sample t-test.

SGRQ. This is in agreement with results of previous studies in asthmatics receiving nedocromil sodium (26) and patients with COPD receiving salmeterol (27). Lahdensuo and colleagues (5) showed in a randomized, controlled education study of patients with mild-to-moderate asthma applying the symptom part of the SGRQ, a baseline difference of 3 units and at 12 mo, 8 units.

Although the COPD group (n = 53) was smaller than the asthma group (n = 71), and thereby leaving us with less ability to detect a statistical difference, the study showed smaller and clinically less significant differences in SGRQ scores between the COPD intervention and control groups compared with those in the asthma group. This may have several reasons.

First, the questionnaire may theoretically be less sensitive to changes in quality of life in the patients with COPD than in the asthmatics. However, the SGRQ has been shown to respond to changes in health over time in patients with COPD (21). On the other hand SGRQ does not reflect the management and control (mastery) aspect of quality of life as revealed by the Chronic Respiratory Questionnaire (28).

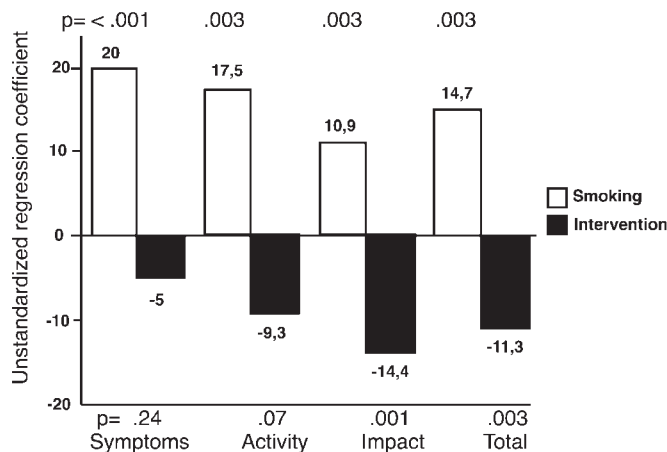


Figure 2. Effects on SGRQ total score and subscores of being current smoker versus ex- or never-smoker at baseline and having received education versus not, after adjusting for age, sex, and FEV₁ in percent of predicted at the 1-yr follow-up in a linear regression model (Asthma).

Second, the self-management plan may suit the asthmatic patients better than the patients with COPD. Asthmatic patients have higher variability in lung function than do patients with COPD. The asthmatics may be motivated to stick to the self-management plan by experiencing that it works. Changes in PEF values and symptoms lead to changes in medication according to the plan and a subsequent improvement in these measures. If the patients with COPD observe limited changes in PEF and symptoms when following a treatment plan, they may be less inclined to stick to the plan at the next exacerbation.

Third, the education given to the patients with COPD may have suited their needs less than the education given to the asthmatics. We might be wrong trying to emphasize education instead of rehabilitation in a group with mild-to-moderate COPD. There is a need to assess which part of an education program that works (29) and at what level of FEV₁ or to what personality traits the rehabilitation aspect is more important than education. The cognitive impairment on standard neuropsychologic tests seen in patients with COPD (30, 31) and its implications for patient education and rehabilitation should be more completely investigated.

Fourth, we measured quality of life at 12 mo of follow-up. The effect on quality of life in the COPD group may have been present earlier than this and then disappeared. On the other hand, an effect at 6 mo was not present in a controlled intervention study examining the effect of an education program on quality of life in patients with COPD (15).

The fact that the asthmatics were younger than the patients with COPD might theoretically influence the SGRQ scores. However, SGRQ has also been tested to show that age as such does not influence the scores (21).

The asthmatics receiving education showed a mean increase in FEV₁ of 112 ml (3.4%), whereas the asthmatics in the control group showed a mean drop of 83 ml (-2.7%). This finding agrees with results of previous studies (4, 12). However, not all studies have found an effect on spirometry after patient education (10, 32).

In the asthma group the contribution of the intervention to improve the total SGRQ score at 12 mo of follow-up was two-thirds the size of the adverse contribution of smoking (Figure 2). The negative effect of smoking on HRQoL, as measured by the other SGRQ scores, was also highly significant. Smoking seems to decrease HRQoL as measured by the SGRQ.

At first sight the asthma intervention group could seem slightly healthier than the control group as judged by lower age and fewer current smokers. As long as age does not influence the SGRQ scores (21) and the proportion of never-smokers is equal in the two groups, we do not believe that this influences our findings. This is supported by the substantial improvement in the intervention group and the fact that both age and smoking status were adjusted for in the multiple linear regression analysis (Figure 2).

In conclusion, asthmatics improved their health-related quality of life and lung function after patient education as compared with asthmatics not being educated. Patients with COPD receiving intervention did not improve these measures either clinically or statistically compared with those in the COPD control group.

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