Randomised comparison of guided self management and traditional treatment of asthma over one year

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Abstract

***Objective*—To compare the efficacy of self management of asthma with traditional treatment.**

***Design*—12 month prospective randomised trial.**

***Setting*—Outpatient clinics in Finland.**

***Subjects*—115 patients with mild to moderately severe asthma.**

***Interventions*—Patient education and adjustment of anti-inflammatory therapy guided by peak flow measurements.**

***Main outcome measures*—Unscheduled admissions to hospital and outpatient visits, days off work, courses of antibiotics and prednisolone, lung function, and quality of life.**

***Results*—The mean number of unscheduled visits to ambulatory care facilities (0·5 *v* 1·0), days off work (2·8 *v* 4·8), and courses of antibiotics (0·4 *v* 0·9) and prednisolone (0·4 *v* 1·0) per patient were lower and the quality of life score (16·6 *v* 8·4 at 12 months) higher in the self management group than in the traditionally treated group. In both groups admissions for asthma were rare.**

***Conclusions*—Self management reduces incidents caused by asthma and improves quality of life.**

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Introduction

Deaths from asthma have been associated with underestimation of its severity, delays in starting treatment in exacerbations, and unsatisfactory routine management and treatment of asthma.[1,2] Potentially preventable factors are common in deaths from asthma, and 73% of admissions to hospital for acute asthma could be avoided with proper prior medical care.[1] At least 40% of people with asthma do not react appropriately when symptoms of asthma worsen and over half of the patients admitted with acute asthma have had alarming symptoms for a week before admission.[4,5] In its study of deaths due to asthma in the early 1980s the British Thoracic Association recommended that patients should measure their own peak flow rates and treat deteriorating symptoms themselves.[1,2]

Although some guidelines on asthma have also recommended self management,[6,7] conflicting results exist about its efficacy.[8-11] Some of these studies have been either uncontrolled or have relied on retrospective data analysis.

We describe here a one year multicentre trial in which the efficacy of guided self management of asthma was compared with that of traditional asthma treatment.

Patients and methods

STUDY DESIGN

The study was performed as a multicentre, prospective, single blind, randomised parallel group trial. Three centres participated, and the patients entered the trial at staggered intervals over 12 months. They were randomised into self management or traditional treatment groups. The block randomisation method was used and, because double blinding was not possible, blocks of variable sizes (14, 10, 16, and 10) were used to eliminate the predictability. Participating centre was a stratification variable, and randomisation lists were prepared separately for each centre by computer. The method of sealed numbered envelopes was used in patient allocation.

During the one month run in period after randomisation the ability of the patients in the self management group to measure peak expiratory flow values was evaluated visually from their peak expiratory flow charts, along with their optimal morning peak expiratory flow values while they were clinically stable. The patients in both groups were then followed for one year and made three follow up visits to the outpatient department every fourth month.

Those patients recruited for self management were given personal education. During these sessions they received basic information about asthma and its causes, lung anatomy and physiology, the effect and purpose of asthma drugs, and the principles of self management by specially trained nurses. Physiotherapeutic counselling, including proper breathing and relaxation techniques, was also given by physiotherapists. During this first visit each patient in the self management group spent about two and a half hours in the outpatient department and each patient in the traditionally treated group about one hour.

Guided asthma self management included daily morning peak expiratory flow measurements. The patients were instructed to blow three times every morning into a peak flow meter (Mini Wright flow meter, Clement Clarke International, London) and to record the best reading in a diary. They also recorded a symptom score (a single score of 0 to 3 was assigned to each 24 hour period) and whether inhaled budesonide or supplemental β_2 agonist was used that day. According to the changes in morning peak expiratory flow values, the following actions were advised.

(1) If the peak expiratory flow value fell below 85% of the patient's predetermined individual optimal value on any morning the patient doubled his or her inhaled corticosteroid dose for two weeks. If the patient did not reach the optimal peak expiratory flow value within two weeks or the situation was deteriorating he or she had to contact the attending nurse or doctor by phone.

(2) If the peak expiratory flow value fell below 70% of the optimal value the patient started an oral course of prednisolone (40 mg/day) for seven days and immediately contacted the attending nurse or doctor by phone.

(3) Except in these circumstances they were told to keep their asthma treatment stable at all times.

All patients in the self management group used budesonide in an inspiratory flow driven multidose powder inhaler (Pulmicort Turbuhaler, Astra) (200 μg/dose) as their inhaled corticosteroid from the start of the run in period. As rescue medication salbutamol or terbutaline were used.

The patients in the traditional treatment group were advised how to use their inhalers correctly and given general information on their disease during their routine visits to the outpatient department. The patients did not have peak flow meters and they were not instructed to make any changes in their medication by themselves. During their scheduled outpatient visits every fourth month, their clinical state and the treatment were evaluated in the usual way by a doctor.

PATIENTS

Adult (18 or older) patients with mild to moderately severe asthma were enrolled for the study after they were evaluated by a chest physician. The morning-evening peak expiratory flow value had to vary by more than 15% in two days within one week during the past six months. The optimal peak expiratory flow value had to be at least 250 l/min as defined by daily morning peak expiratory flow value recordings. The anti-inflammatory treatment had to be either budesonide 400-1600 μg/day or beclomethasone dipropionate 500-2000 μg/day during the past six months. At least four weeks had to have elapsed since the last course of oral corticosteroids.

Informed written consent was obtained from all patients and the study was approved by the Finnish Medical Board and the local ethics committees.

OUTCOME MEASURES

In both groups during the study year the following incidents caused by asthma were recorded: admissions to hospital, unscheduled visits to ambulatory care facilities (outpatient clinics or primary care), days off work, courses of oral antibiotics, and courses of oral prednisolone. Quality of life was evaluated at the start of the trial and thereafter during scheduled outpatient visits every fourth month using selected components (part 3) of the St George's respiratory questionnaire focusing on the symptoms of asthma and the sickness impact caused by asthma.[14] The assessments performed at the scheduled clinic visits at the start of the trial and at 4, 8, and 12 months of follow up included spirometry (with a dynamic wedge bellows spirometer, Vitalograph Alfa, Vitalograph Ltd, Buckingham, United Kingdom) and checks of the patients' diaries in the self management group. The patients were instructed to take the last dose of their regular medication in the evening before each appointment and not to use supplemental medication in the six hours before the appointment. Possible adverse events were also registered in both groups during their scheduled visits.

STATISTICAL ANALYSIS

A total of 122 patients were initially included in the study. Analysis of the results is based on 115 patients who had at least four months of follow up.

Mann-Whitney U tests were used to compare the number of asthma incidents in the two groups. The percentage of patients reporting at least one incident were compared using χ_2 test. Fisher's exact test was used to compare the need for admission. Because the proportion of women was higher in the self management group, additional Mantel-Haenzel tests were performed to determine whether the effects of treatment were equal for both sexes.

To study the relative effect of self management, the one year relative risks of asthma incidents and 95% confidence intervals were estimated using the incidence density ratio method.

A cumulative incidence free survival curve was drawn describing the percentage of patients in both groups who, up to a specific point in the follow up, had survived without any incidents caused by asthma.

The log rank test (Mantel-Cox test) was used to test whether the survival curves obtained for the groups were equal.

Quality of life was assessed adding the scores for 25 items. The scores for each item ranged from -2 to +2, with positive scores indicating improvement and negative scores deterioration in quality of life compared with one year ago. The analysis of covariance with repeated measures was used to compare the total scores in the two groups at the second, third, and fourth visits. The total score measured at the first visit was included as a covariate to adjust for differences at the baseline. Owing to a large standard deviation the variables were log transformed before the analysis.

All tests were two tailed and P values below 0·05 were considered to indicate statistical significance.

The sample size calculations were based on the primary variable, the number of "incidents caused by asthma." We assumed that these incidents occur according to Poisson processes with constant intensities in both groups. If the average number of asthma incidents per year is 1 with traditional treatment there is an 80% probability of detecting a significant ($P < 0·05$) difference with 60 patients per group if in the self management group the corresponding figure per year is 0·47.

Results

The number of patients fulfilling the required criteria (data from at least visits 1 and 2) to be included for the final comparisons was 56 in the self management group and 59 in the traditionally treated group (table 1). The groups were comparable in terms of demography and clinical characteristics; only the number of women was slightly greater in the self management group ($P=0·02$), so the mean weight was less than in the traditionally treated group ($P=0·02$) (table 1). The difference in sex ratio did not cause any bias in results: the differences in outcome measures were similar for both sexes. At entry the mean daily dose of budesonide was 990 μg (SD 405 μg) in 42 patients in the self management group and 969 μg (SD 397 μg) in 52 patients in the traditionally treated group. At entry 14 patients in the self management group and seven in the traditionally treated group used beclomethasone dipropionate (mean daily doses

Table 1—*Baseline characteristics of patients included in analyses. Unless otherwise stated values are means (SD)*

	Self management (n=56)	Traditional treatment (n=59)
Sex (M/F)	15/41	28/31
Age (years)	40·6 (14·2)	42·8 (15·2)
Weight (kg)	68·5 (12·2)	74·8 (14·9)
Height (cm)	165·7 (8·4)	167·9 (8·4)
Employed (%)	71	61
Smoking (%):		
Non-smokers	64	63
Smokers	18	15
Ex-smokers	18	22
Duration of asthma (years)	8·2 (8·4)	6·8 (7·6)
Atopy (yes/no)	27/28	32/26
Forced vital capacity (FVC):		
Litres	3·63 (0·88)	3·82 (1·12)
% Of predicted	88·5 (15·2)	88·0 (15·7)
Forced expiratory volume in 1 second (FEV_1):		
Litres	2·84 (0·74)	2·96 (0·89)
% Of predicted	82·4 (15·8)	81·7 (16·6)
FEV_1/FVC (%)	78·3 (10·1)	77·9 (9·7)

971 μg (SD 399 μg) and 1171 μg (SD 373 μg), respectively).

During the study year the mean daily dose of budesonide was 979 μg (SD 375 μg) (Turbuhaler) in the 56 patients in the self management group and 962 μg (SD 392 μg) in 53 patients in the traditionally treated group. In the latter group budesonide Turbuhaler was used by 43 patients and budesonide pressurised metered dose inhaler with a spacer by 10 patients. In six of the traditionally treated group the mean daily dose of beclomethasone dipropionate during the study year was 1167 μg (SD 408 μg); all these patients used beclomethasone pressurised metered dose inhaler with a spacer.

Nine patients in the self management group and 11 in the traditionally treated group were treated with slow release theophylline in low doses. Two patients in both groups also received inhaled nedocromil sodium. Three patients in the self management group and two in the traditionally treated group were treated by inhaled anticholinergics. No patient used long acting inhaled β_2 agonists or regular oral corticosteroids for their asthma. Short acting inhaled β_2 agonists were used as rescue medication by all patients.

Admissions for asthma were rare in both groups: two patients in the self management group and three in the traditionally treated group were admitted once during the study year because of deterioration of asthma. Other incidents caused by asthma were fewer in the self management group. To get a global outcome measure the incidents were combined to "any incident caused by asthma." Any one incident was sufficient to be counted, but when two or more incidents occurred simultaneously only one incident was recorded. Table 2 summarises the incidents per patient seen in both groups.

At least one unscheduled visit for ambulatory care happened in 17 patients (30%) in the self management group and 28 (48%) in the traditionally treated group (P=0·06). Days off work were recorded at least once in 13 patients (23%) in the self management group and 25 (42%) in the traditionally treated group (P=0·03). At least one course of antibiotics was taken by 14 patients (25%) in the self management group and 29 (49%) in the traditionally treated group (P=0·008). At least one course of prednisolone was taken by 13 patients (23%) in the self management group and 27 (46%) in the traditionally treated group (P=0·01).

If the one year risk of traditionally treated patients is defined as 1 then for the patients in the self management group the relative risk for unscheduled outpatient visits was 0·53 (95% confidence interval 0·29 to 0·96), for days off work 0·47 (0·24 to 0·92), for courses of antibiotics 0·44 (0·23 to 0·83), for courses of prednisolone 0·18 (0·07 to 0·44), and for any incidents caused by asthma 0·32 (0·19 to 0·55).

The incidence free survival curves of the two treatment groups were significantly different from each other and in favour of the self management group (fig 1; P<0·0001) and this difference was evident already during the first months of the study.

The spirometric values at the clinic visits remained completely stable in both groups during the study period. There were no differences in the occurrence of adverse events between the groups (24 minor adverse events in the self management group and 27 in the traditionally treated group).

The changes in quality of life during the study period are presented in table 3. After adjusting for baseline score there was a significant difference in favour of self management between the groups (P=0·009) throughout the trial. At 12 months, when quality of life was compared to the baseline of the study, the quality of life score was 8 points (95% confidence interval 2 to 15) higher in the self management group than in the traditional treatment group.

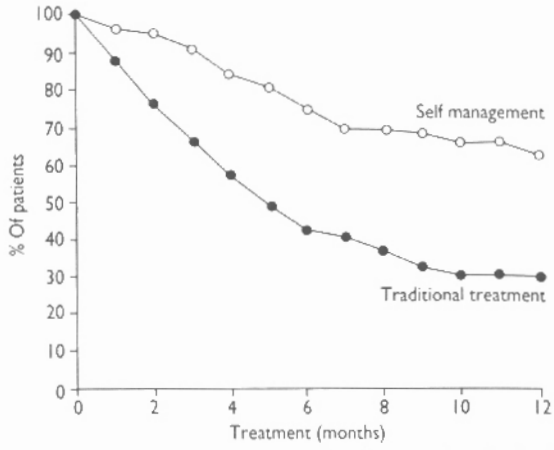

Fig 1—*Cumulative percentage of patients not having had any incident caused by asthma in self management and traditional treatment groups*

Table 2—*Incidents per patient caused by asthma in self management and traditional treatment groups during one year. Values are mean numbers per patient (SD)*

	Self management (n=56)	Traditional treatment (n=59)	P value (95% confidence interval for difference)
Unscheduled outpatient visits	0·5 (0-4)	1·0 (0-4)	0·04
Days off work	2·8 (0-62)	4·8 (0-27)	0·02
Courses of antibiotics	0·4 (0-4)	0·9 (0-4)	0·009
Courses of prednisolone	0·4 (0-4)	1·0 (0-5)	0·006
Total (any incident caused by asthma)	0·6 (0-4)	2·1 (0-8)	<0·0001 (0·9 to 2·1)

Table 3—*Quality of life scores in self management and traditional treatment groups during one year. Values are mean (SD) scores**

	Self management (n=56)	Traditional treatment (n=59)
Baseline	12·4 (15·2)	9·2 (18·2)
4 Months	18·7 (15·7)	10·9 (16·6)
8 Months	14·6 (16·7)	9·1 (17·5)
12 Months	16·6 (15·9)	8·4 (18·4)

*Total score (range −50 to +50) made up of 25 items, each ranging from −2 to +2.
Taking the baseline as a covariate, the grouping factor (self management v traditional treatment) was statistically significant (P=0·009, analysis of covariance of repeated measures) during the study year.

EXPLORATORY ANALYSES

Exploratory analyses were done to estimate adherence to the self management instructions and to assess the possible associations between the symptoms, the peak expiratory flow values, and patients' adherence to the instructions. In 32 patients (57%) in the self management group the peak expiratory flow values fell more than 15% at least once during the study year, yielding a total of 141 occasions. The mean number of occasions per patient was 4·4. The patients' adherence to the self management instructions among these patients varied; three patients did not double the budesonide dose on any occasion, 11 doubled the dose occasionally, and 18 patients doubled the dose on all occasions.

The 141 occasions when the peak expiratory flow values fell more than 15% were examined as if the data were an independent sample. This approach was chosen to look for possible connections and to generate hypotheses. The patients doubled the budesonide dose on 87 of the 141 occasions when the peak expiratory

flow values fell more than 15%, adherence to the self management instructions thus being 62%. The duration of the doubled dose of budesonide was at least eight days on 71 (82%) occasions, and on 74 (85%) occasions the patients started the increased dose within three days, most (55/74) during the very first day, when the peak expiratory flow values fell. On 13 occasions the peak expiratory flow values fell more than 30% and the oral course of prednisolone was started on 10 occasions, adherence being 77%. Patients' adherence to the self management instructions was strongly related to the severity of symptoms of asthma; at a symptom score of 0 it was 29%, at 1 it was 61%, at 2 it was 79%, and at 3 it was 100%.

We also analysed the time between peak expiratory flow and symptoms on 141 occasions when peak expiratory flow decreased below 85% of the optimal value (fig 2). A slight increase in symptoms preceded the decrease in peak expiratory flow values, which then occurred quite abruptly. After the doubling of the inhaled steroid the peak expiratory flow values slowly started to return towards the previous level and some improvement in symptoms also happened.

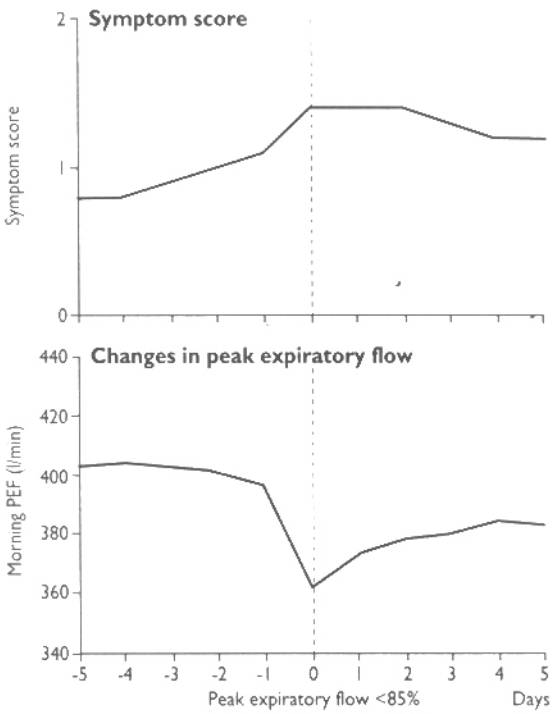

Fig 2—*Relation between occurrence of asthma symptoms and peak expiratory flow (PEF) values on 141 occasions five days before and five days after the values dropped more than 15% below optimal levels*

WITHDRAWALS

Sixty patients were initially recruited to the self management group and 62 to the control group. One patient in the self management group did not fulfil the enrolment criteria (no treatment with inhaled steroids before the trial) and was excluded. During the run in period three patients withdrew from the self management group: one because his asthma was severe and he did not want to participate, another because the asthma was too mild, and a third for unknown reasons. Between visits 1 and 2 three patients withdrew from the traditionally treated group: one patient did not comply with treatment, one moved to another city, and one could not attend the clinic visits. Between visits 2 and 3 there were two withdrawals due to non-compliance from the self management group and one from the traditionally treated group. In addition one patient in the traditionally treated group withdrew because of acute thyroiditis that was treated with corticosteroids. Between visits 3 and 4 one patient was withdrawn from the self management group because of non-compliance.

Discussion

Our study shows that guided self management reduced by half or more the number of incidents caused by asthma when compared with traditional treatment. The difference became evident early during the follow up and increased during the study year. Patients with severe asthma were not included because most patients with severe asthma already have a peak flow meter and do practise some kind of self management. As a consequence hospital admissions were few in both study groups.

Antibiotics were used significantly more often in the traditional treatment group than in the self management group, suggesting that during exacerbations a false diagnosis of bacterial infection is easily made, leading to unnecessary use of antibiotics. Compared with viral infections, the role of bacterial infections is minimal in exacerbations of asthma.[15,16] The early introduction of anti-inflammatory treatment during exacerbations in our self management group probably reduced useless antibiotic treatment.

The usefulness of daily measurements of peak expiratory flow in asthma self management has been questioned.[12,17] Contrary to the findings presented here, the Grampian study of integrated care gave negative results for their routine.[12] However, the elements of these patients' self management practices were poorly described and it is unclear whether they used their peak expiratory flow meters daily or only sporadically.

Different limits for peak expiratory flow values guiding the intervention have been used in previous studies. In two studies 70% of the potential normal peak expiratory flow value was the threshold for doubling the dose of inhaled steroid and 50% for starting oral steroids,[7,11] while in the New Zealand "credit card" study the corresponding limits were 80% and 60%.[11] The International Consensus Report[6] and Canadian guidelines[16] use 50% as the cut off peak expiratory flow value for advising the patient to go to the emergency department. The peak expiratory flow thresholds we used, 85% of the patient's optimal value for doubling the dose of the inhaled steroid and 70% for starting oral steroids, were higher than previously used.

When drops in peak expiratory flow values greater than 15% were analysed we observed that a slight increase in symptoms preceded the drop, which then occurred quite abruptly. The 85% intervention limit seemed to work well in this study. Also, after the start of the doubled dose of inhaled steroid peak expiratory flow started to rise.

A previous self management study has shown symptoms to be as good an indicator of deterioration as peak flow measurements.[11] We used peak expiratory flow measurements, however, because we considered it difficult to assign definitive intervention levels by relying only on symptoms. As many as 60% of patients are bad at judging their dyspnoea,[19] and poor perception of pulmonary function cannot be altered through training in peak expiratory flow measurements.[20] On the other hand, we found that patients' adherence to the self management instructions was strongly related to the severity of symptoms.

In self management the positive impact of patient education has been better documented than the use of peak expiratory flow measurements, although here too there are controversies.[8,21-23] Clear and definitive instructions in self management and good general patient education must be considered fundamental for a successful self management programme.

The adherence of patients to the self management instructions has not been thoroughly studied. The adherence of our patients, 62% to the instructions on doubling the inhaled steroid and 77% to those on

Key messages

- Previous studies of patients managing their own asthma treatment have given conflicting results over whether such self management improves the control of symptoms
- This trial of 115 patients with mild to moderately severe disease randomised half to a traditional care and half to a self management programme consisting of education about asthma and daily peak flow readings
- Intervention thresholds of <85% of the optimal peak flow for doubling the dose of inhaled steroid for two weeks and of <70% of the optimal peak flow for starting a course of oral steroids worked well
- The self management group had fewer incidents (consultations, days off work, courses of prednisolone or antibiotics) than the traditionally treated group and better quality of life scores
- Adherence of patients to the self management instructions was better than expected

starting the oral steroids during exacerbations, was reasonably good. The great majority started the doubled dose of inhaled steroid quickly enough and in most cases maintained higher doses of inhaled steroid for eight days or longer.

No objective measurement for general treatment compliance was available in our study so it is impossible to say to what extent possible differences in treatment compliance explain our results. Studies of adherence with medication in adults with chronic asthma have found adherence levels of 30-40%,[24 25] and self management has been shown to improve this.[6]

We conclude that supervised self management using patient education and adjustment of anti-inflammatory treatment on the basis of peak expiratory measurements reduces incidents caused by asthma and improves quality of life. There were, however, four elements in our study: early treatment of airway inflammation (which we previously have shown to result in good control of asthma[26 27]), peak expiratory flow measurements per se (changed lifestyle), patient education about asthma, and possibly improved general compliance with treatment. We have not determined which of these is most important to the success of guided self management of asthma.

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ANY QUESTIONS

Senior surgeons may be seen on television wearing their masks beneath their nose. This is contrary to what I was taught as a student because of the risk of staphylococcal infection. What should current practice be?

The role of the face mask worn by the operating team in preventing wound infection is doubtful,[1] but if a mask is considered necessary it should be of a filter type, close fitting and covering the nose as well as the mouth. Studies carried out many years ago showed that few organisms were dispersed from the respiratory tract during quiet breathing or talking and that *Staphylococcus aureus* was mainly dispersed on skin scales. The skin scales, contaminated from nasal secretions, are mainly shed from the face, hair, and clothing and are unlikely to be influenced by the wearing of a mask. In addition, carriers of perineal staphylococcus tend to be heavier dispersers than nasal carriers.

Some general surgeons do not wear masks when operating and have no evidence of an increased infection rate.[2] A prospective randomised study of 3000 operations in Sweden showed a wound infection rate of 4·7% (95% confidence interval 3·9% to 5·8%) when masks were not worn by the surgical team and 3·5% (2·6% to 4·5%) when they were.[3] Although there is no evidence that wearing a mask reduces the infection rate in general surgery, no evidence is available for other types of surgery—for example, implant surgery. Many surgeons will, however, continue to wear masks to protect them from blood splashes.—GRAHAM A J AYLIFFE *is emeritus professor of medical microbiology in Birmingham*

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