# The Effect of a Peak Flow-Based Action Plan in the Prevention of Exacerbations of Asthma*

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***Study objective:*** **To determine the effect of a symptom-based and a peak flow-based action plan in preventing acute exacerbations in subjects with poorly controlled asthma.**
***Design:*** **A randomized controlled trial in which subjects who had required urgent treatment for their asthma were allocated to receive no action plan, a symptom-based plan, or a peak flow-based action plan.**
***Setting:*** **A university hospital asthma clinic.**
***Population:*** **One hundred fifty subjects were recruited after attending an emergency department or a clinic for urgent treatment of asthma.**
***Interventions:*** **All subjects received evaluation and education for asthma before being randomly allocated to receive no action plan, a symptom-based action plan, or a peak flowmeter and a peak flow-based action plan.**
***Measurements:*** **Subjects were assessed by questionnaire at 3 and 6 months after enrollment with questions relating to their asthma control and their need for urgent treatment or hospital admission for asthma.**
***Results:*** **At 6 months after enrollment, although all three intervention groups experienced improvement in their asthma control, there was a striking reduction in emergency department visits for asthma only in the peak flow-based action plan group ($p=0.006$). No significant difference in emergency visits was apparent between the symptom-based action plan and no action plan groups.**
***Conclusions:*** **We conclude that a peak flow-based action plan is effective, at least in the short term, in protecting patients with asthma against severe exacerbations of their disease.**
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**Key words:** action plan; asthma; emergency treatment; exacerbation; peak flow

It is now widely recommended that patients with asthma be provided with advice concerning the monitoring of their disease and with action plans to assist with adjustment of their therapy.[1-4] Although some studies have demonstrated benefit from monitoring and self-management,[5,6] others have shown that the benefit is limited[7] or insignificant.[8-10] We have been concerned that the subgroup of asthmatics who seek urgent treatment for their disease might suffer from diminished awareness of their disease.[11] This subgroup is known to be at increased risk of dying of asthma[12] and clearly requires special attention. We recruited asthmatic subjects who had required urgent treatment for their disease and provided them with basic information about asthma and its treatment. These subjects were then randomly allocated to receive no action plan, a symptom-based action plan, or a peak expiratory flow-based action plan. They were followed up for 6 months to determine the impact of these interventions. In particular, we wished to measure the impact on their need for urgent treatment of their asthma.

## Materials and Methods

Adult and adolescent patients who had received urgent treatment for their asthma in the preceding 12 months were invited to participate in this study. Subjects were recruited by contacting those who had been treated for an exacerbation of asthma in an emergency department in one of the teaching hospitals in the city of Calgary. Subjects were also recruited from those attending a university asthma clinic when they gave a history of having received urgent treatment for their asthma in the previous 12 months. Urgent treatment was defined as treatment sought to

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provide immediate relief of asthma symptoms that were perceived to be severe and that had failed to respond to the subject's usual reliever medication. The urgent treatment ordinarily included nebulized $\beta_2$-agonist with or without an oral or injected bolus of corticosteroid. The treatment was generally provided in a hospital emergency department but may also have been given at a suitably equipped clinic. Each subject was interviewed using a questionnaire to determine how often they had required urgent asthma treatment in the previous 12 months and to assess the severity of their disease with questions relating to night wakening, $\beta_2$-agonist use, impact on their lifestyle, admissions to hospital, use of oral corticosteroid, and their current dose of inhaled corticosteroid. Additional questions assessed the subject's exposure to asthma triggers and inducers, including tobacco smoke (first and second hand), domestic animals, and their occupational environment. They were also assessed by spirometry before and after a $\beta_2$-agonist. The subjects were then given individual instruction from a nurse clinician concerning the nature of their disease, asthma triggers, medication, and inhalation devices. Their use of inhalers was checked and corrected when necessary. The role of medication to control asthma was emphasized and all subjects were given the general information that medication and dosage may need to be adjusted as asthma severity changed.

The interview, spirometry, and education session lasted an average of 45 min (30 to 60 min). Subjects who had peak flowmeters were not excluded from the study but subjects with written asthma management plans were ineligible. Eligible subjects provided informed consent before enrollment. After enrollment, which followed the education and assessment, the subject was allocated to one of the three limbs of the study. Their allocation to no action plan, a peak flow-based action plan, or symptom-based action plan was determined by opening the next of the 150 sequentially numbered sealed envelopes. Randomization was achieved by using three lists of random numbers, one for each of the treatment limbs. These lists were then combined in a database and indexed in ascending order. The study number allocated to each random number and recorded on the sealed envelope was thus the random number's rank in the indexed list. This process provided approximately equal numbers in each limb and an unpredictable sequence of allocations.

Subjects allocated to no action plan were reminded that asthma is a variable disease and that their dose of corticosteroid might need to be adjusted from time to time using the principles addressed during the education session. Subjects allocated to an action plan received a printed plan completed according to their current or recommended therapy. These subjects were also given a prescription for prednisone to enable them to utilize the third level of treatment recommended in their action plans. Each plan included baseline therapy with inhaled corticosteroid, a step-up level of therapy in which the dose of inhaled corticosteroid was doubled, a third level in which oral prednisone was added, and a fourth level in which treatment in an emergency department was recommended. The action plans had been modified from those of Charlton et al[9] and Beasley et al.[1]

The instructions for the symptom-based plan listed common symptoms of asthma, including waking at night or a persistent cough and symptoms of a common cold as indications for doubling their inhaled corticosteroid. The third step required the introduction of prednisone if their relief following the use of a bronchodilator lasted $\leq$2 h or if they became short of breath doing their normal daily activities. The fourth step required them to seek urgent treatment if their bronchodilator provided relief for $\leq$30 min or if their breathing made it difficult for them to speak.

Those subjects allocated to the peak flow-based plan were given a peak flowmeter (Mini-Wright; Ferraris Medical, Inc; Holland, NY) and brief instructions in its use and in recording the data. Their action plan included peak flow measurements that were estimated from their measured and predicted peak expiratory flows. Peak flow readings at or below which each step should be initiated were written into each subject's action plan. Doubling of their inhaled corticosteroid was recommended when the peak expiratory flow was $<$70% of their estimated best reading or when the diurnal variation was $\geq$20%. Initiation of the third step (prednisone) was advised at $\leq$50%, and the fourth step (urgent treatment in an emergency department) at $\leq$30% of their estimated best peak expiratory flow.

A letter was sent to each subject's family physician to inform them that their patient had been enrolled in the study. In those instances in which the subject's prescribed medication (usually inhaled corticosteroid) was thought to be inadequate, a suggestion was made for an adjustment of therapy. A copy of the action plan was included in the letter for those subjects allocated to one of the action plan limbs of the study. Subjects were sent a questionnaire by mail 3 months after enrollment and were interviewed by telephone using a questionnaire by a research assistant, with no knowledge as to the subject's allocation in the study, approximately 6 months after enrollment. Repeated attempts to contact subjects were made and discontinued only when the interview was refused or it was established that the subject had moved leaving no forwarding address or telephone number. The questions included in the questionnaire were identical to those in the entry questionnaire with the exception that the inquiry concerning the need for urgent treatment for asthma related to the period since entry.

Comparisons were made among the three intervention groups to assess their comparability on entry and the degree of asthma control achieved at 6 months with attendance for urgent treatment of asthma as the primary outcome variable. Data were analyzed by $\chi^2$ analysis of contingency tables and by analysis of variance (or Kruskal-Wallis, depending on the similarity of the variances of the groups)[13] with $p<0.05$ considered significant.

The study received approval from the Conjoint Ethics Board of the Medical Faculty, University of Calgary.

## Results

One hundred fifty-one subjects, of whom all had required urgent treatment for their asthma within the previous 12 months, were enrolled in the study. One subject was withdrawn when her physician revised her diagnosis following a normal methacholine challenge. In total, the remaining 150 subjects had required urgent treatment for asthma on 482 occasions and had been admitted to a hospital for treatment of asthma 71 times in the year preceding their entry into the study. Fifty-two of the subjects were allocated to receive no action plan, 50 subjects received a symptom-based plan, and 48 received a peak flow-based action plan. There was no significant difference among the subjects in the three limbs of the study in terms of their age, gender, or years since their diagnosis of asthma (Table 1). They did not differ in terms of their need for urgent treatment or for admissions to a hospital for asthma in the 12 months prior to their entry to the study. They were also similar regarding the severity of their asthma as judged by their nighttime symptoms, use of $\beta_2$-agonist, self-assessed lifestyle restriction, and their

**Table 1—*Demographics of the 139 Subjects Who Completed the Study**

| | No Plan (n=48) | PF Plan (n=46) | Symptom Plan (n=45) |
|---|---|---|---|
| Age, yr (SD) | 36.4 (12.76) | 39.1 (14.41) | 36.8 (16.50) |
| Duration of asthma, yr (SD) | 16.8 (12.06) | 12.8 (10.08) | 13.7 (12.14) |
| Gender, F:M | 29:19 | 29:17 | 25:20 |

*There was no significant difference among the three groups for any of these characteristics. PF=peak flow.

spirometry results. The three groups had similar exposures to tobacco smoke and to animals in their home environment. They did not differ significantly with regard to their daily doses of inhaled corticosteroid and their number of courses of oral corticosteroid in the year before entry to the study (Table 2).

On follow-up, 11 of the 150 subjects could not be contacted or refused to be interviewed 6 months after enrollment. No significant differences were found among these 11 subjects and the group as a whole in terms of their age, medication use, prior number of visits for urgent treatment of asthma, or their allocation in the study. Five of these 11 subjects completed the 3-month postal questionnaire. Only one of them, a subject allocated to receive no action plan, had attended for emergency treatment in the 3 months since entry to the study. The other subject without an action plan, the two with a peak flow-based action plan, and one with a symptom-based plan had not required urgent treatment, and none of the five had been admitted to the hospital for asthma. The most striking difference among the three groups of the 139 subjects who completed the study was the low rate of visits for urgent treatment by the peak flow-based action plan group ($p=0.002$) (Table 3). In this group, five subjects had each visited an emergency department for treatment of their asthma once in the 6 months following entry to the study. No significant difference was apparent for visits for urgent asthma treatment between the symptom-based action plan group (45 visits) and the group with no action plan (55 visits) ($p=0.7$). There was a trend toward fewer hospital admissions in the two groups who received action plans, but the difference did not reach significance. None of the other indexes associated with asthma control, including waking with asthma, $\beta_2$-agonist utilization, or self-rating of asthma severity differed among the three groups at 3 months or at 6 months after entry.

Although the purpose of the study was to determine differences in outcome among the three intervention groups after enrollment, it is worth noting that all of those enrolled displayed some benefit that might be attributed to the education provided. The participants as a whole woke less at night (average, 2.8; SD, 6.48 fewer nights per week disturbed by asthma; $p<0.0001$) and used less $\beta_2$-agonist (average, 2.0; SD, 4.45 fewer doses per day; $p<0.0001$) at 6 months after entry than they had before enrollment. No significant difference in the subjects as a whole on entry and at 6 months or among each of the three groups was apparent with regard to their daily dose of inhaled corticosteroid or the number of courses of prednisone taken.

**Table 2—*Indexes of Asthma Severity on Entry for the 139 Subjects Who Completed the Study**

| | No Plan (n=48) | PF Plan (n=46) | Symptom Plan (n=45) |
|---|---|---|---|
| $FEV_1$, % predicted (SD) | 78 (21.3) | 82 (20.5) | 79 (18) |
| No. of subjects with $FEV_1$ <60% predicted | 10 | 9 | 8 |
| Total urgent visits in 1 yr | 168 | 152 | 117 |
| Average urgent visits per person in 1 yr (SD) | 3.5 (3.40) | 3.3 (7.56) | 2.6 (4.53) |
| Total admissions in 1 yr | 23 | 16 | 22 |
| Night waking, nights/wk (SD) | 4.9 (5.70) | 4.9 (7.11) | 3.6 (6.07) |
| $\beta_2$-Agonist, doses/day (SD) | 4.8 (4.02) | 5.6 (4.54) | 4.3 (4.23) |
| Average daily inhaled steroid, μg (SD) | 1066 (894.0) | 908 (555.7) | 870 (495.5) |
| No. using inhaled steroid | 40 | 33 | 35 |
| No. using prednisone in 1 yr | 32 | 36 | 31 |
| No. with home trigger exposure | 31 | 33 | 31 |

*Urgent visits refer to visits for urgent treatment of asthma. Admissions and night wakings listed relate to asthma. Home trigger exposure refers to subjects who smoked, shared a home with a smoker, or kept a dog, cat, or other furred or feathered pet. There was no significant difference among the three groups for any of these characteristics on entry to the study. PF=peak flow.

**Table 3—*Follow-up Data 6 Months After Entry to Study*

| | No Plan (n=48) | PF Plan (n=46) | Symptom Plan (n=45) |
|---|---|---|---|
| Total 6 mo visits for urgent treatment of asthma* | 55 | 5 | 45 |
| No. of subjects attending for urgent treatment of asthma in 6 mo† | 19 | 5 | 14 |
| Total 6-mo admissions for asthma | 12 | 2 | 6 |
| No. admitted in 6 mo | 6 | 2 | 2 |

*Kruskal-Wallis one-way analysis of variance, $p=0.002$. PF=peak flow.

†$\chi^2$ (2)=10, $p=0.006$.

## Discussion

The implementation of action plans based on symptom or peak flow monitoring has been widely advocated for the management of asthma. Such an intervention, if effective, would seem to be clearly justified in those asthmatics who have severe exacerbations that require urgent treatment. The need for urgent asthma treatment might identify a subset of asthmatics who may be at increased risk of dying of their disease.[11,12] It has been postulated that this group of asthmatic subjects might lack awareness of the severity of their disease[14,15] and might thus be best treated by peak flow monitoring and a peak flow-based action plan. The present study provides some evidence to support this opinion. It does, however, support the findings of other studies of peak flow-based action plans that such an intervention has no measurable impact on conventional measures of asthma control such as nocturnal symptoms, $\beta_2$-agonist usage, and quality of life.[8,10,16] Overall, the subjects showed an improvement in their nocturnal symptoms and had decreased their $\beta_2$-agonist use. The extent to which these improvements occurred was not related to their allocation in the study and might have resulted from the education that they had all received but could not be attributed to the use of either action plan.

The participants in this study were not told to avoid urgent treatment for their asthma and a visit to an emergency department was recommended as the fourth step in the action plans. Subjects were not informed that the primary outcome measure of the study was their need for continued urgent treatment of their disease. Subjects who had a peak flowmeter prior to entry were not excluded from the study and 10 subjects in the symptom-based action plan group and 20 in the no action plan group had peak flowmeters before enrollment. These study design features appear to strengthen the findings which suggest the effectiveness of a peak flowmeter linked with an action plan in reducing the incidence of exacerbations of asthma which require urgent treatment.

We do not believe that our findings are necessarily in conflict with those of Chan-Yeung et al[17] who showed that a 30% drop in peak flow was less sensitive than a symptom score in indicating an asthma exacerbation. In that study, a broader than usual definition of an acute exacerbation of asthma was used and only 8 of their 41 exacerbations appear to have required urgent treatment and to thus conform with the definition used in our study. Their subjects may thus have had a greater awareness of symptoms than might have been the case with our subjects.

We believe that the results of our study have wide applicability to the management of asthma in the emergency department. Our subjects demonstrated at least a short-term benefit from an intervention administered by a nurse educator on one occasion for a period of approximately 45 min at an estimated cost in our center of $35. This intervention and the additional cost of the peak flowmeter (approximately $25) appear to have been more than compensated for by the reduction of visits to the emergency department, with the cost per visit recently estimated to be between $120[18] and $209[19] Canadian. Even if the impact of such an intervention is of only 6 months' duration, it would seem to be feasible to repeat the process and if necessary provide a new peak flowmeter for those who showed an initial response but had reverted to crisis management of their asthma.

In conclusion, this study has shown that the provision of a peak flow-based action plan is associated with a reduction in visits for urgent treatment of asthma. No difference in this respect was found between subjects given a symptom-based action plan and those with no formal action plan.

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