PostScript

LETTERS

Measuring peak flow enhances adherence to monitoring in asthma

Peak expiratory flow (PEF) monitoring is recommended in the management of moderate to severe asthma,¹ and PEF outcome variables are used in many clinical trials. However, adherence with PEF monitoring is poor, and this is often attributed to the burden of measurement and recording. This analysis examined whether adherence with symptom monitoring was impaired by asking patients also to record PEF measurements.

Data were obtained from a randomised double blind study of breathing techniques in adults with poorly controlled asthma. Full details of the clinical trial are reported elsewhere.² Subjects were non-smokers aged 19–80 years, using reliever as-needed ≥ 4 times/week and taking inhaled corticosteroids ≥ 200 $\mu\text{g/day}$. Figure 1 shows the study design, with between-visit intervals of 2 or 6 weeks. Throughout the study, 57 subjects used electronic diary spirometers (AM2, Erich Jaeger GmbH, Hoechberg, Germany) twice daily to answer questions about symptom frequency/intensity and treatment. There were three “PEF periods” during which subjects also measured spirometry twice daily. PEF was displayed after each of three manoeuvres followed by the highest PEF. At study visits, data were uploaded and reviewed by the research assistant but physician feedback was not provided. Subjects with poor adherence were not withdrawn. Weekly adherence was calculated as

[(number of monitoring sessions completed)/(expected number sessions)*100] using a maximum of two sessions/day to exclude data “dumping”.³ Mixed model analysis (SAS 9.1) was used to examine the effect on adherence of PEF monitoring, time until/since closest study visit, age and gender. The ethics committees of Royal Prince Alfred Hospital, Camperdown and The Alfred Hospital, Melbourne approved the study and all patients provided written informed consent.

Figure 1 shows that adherence to monitoring was *higher* during PEF periods than non-PEF periods (79% vs. 65%, $p < 0.0001$). Mixed model analysis showed that weekly adherence with monitoring increased by 13% with PEF monitoring ($p < 0.0001$) and by 5% with each 10 years of increasing age ($p < 0.0001$). There was no effect of gender ($p = 0.80$) or time to next/last visit ($p = 0.59$).

In contrast with the perception that PEF monitoring is burdensome to patients, this analysis showed that, with electronic diaries, asking adults to measure PEF significantly *improved* their adherence with monitoring. While a randomised study would be required to formally evaluate the impact of PEF measurement on adherence with monitoring, this is the first study to assess differences in adherence with monitoring with and without PEF. We used subjects as their own controls as they crossed over between periods.

We have previously reported good adherence with long-term electronic monitoring of symptom and PEF data, when PEF data were closely incorporated into asthma management.⁴ In the present study, good adherence was also achieved with similar electronic devices,

despite the routine nature of the monitoring for assessment of study outcome variables and the absence of physician feedback to subjects.

Adherence represents a balance between burden and benefit, both real and perceived. Although electronic devices can reduce the burden of monitoring in asthma,⁴ patients may perceive little personal benefit from recording how they feel (symptom monitoring). By contrast, PEF monitoring provides patients with objective information, complementary to their subjective experience.¹ Such personal feedback may act as an incentive, improving adherence with monitoring, even if the PEF data are not—as in previous electronic monitoring studies—interpreted by a clinician⁴ or displayed on-screen as a time-trend analysis.⁵

Self-monitoring is a cornerstone of chronic disease management and clinical trial design by providing data about patients' day-to-day status that is not captured by interval assessments. Although patients who agree to participate in clinical trials are likely, by nature, to be more adherent than those in clinical practice, plans for monitoring in either setting should incorporate strategies which enhance adherence and preclude retrospective completion, and hence improve the validity and utility of self-recorded data. The present findings show that the provision of feedback to patients, such as by PEF measurement, may improve rather than hamper adherence with monitoring, provided the burden of monitoring is minimised by use of patient-friendly electronic devices.

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The clinical trial from which these data were obtained was completed in August 2004 and was therefore not required to be registered in a clinical trial registry. The study of adherence was initiated by HKR. EGB and CAS conducted data analysis with input from Wei Xuan and HKR. CAS and HKR co-wrote the manuscript. The clinical trial protocol was developed by Christine R Jenkins and HKR and was carried out by CAS, HKR, Karen Symons, Susan Forrest-Blythe, Caroline Reddel, Frank Thien and Cica Santos, with input from Carol Armour and Sinthia Bosnic-Anticevich.

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Figure 1 Adherence with symptom and peak expiratory flow (PEF) monitoring. Adherence was assessed as the percentage of scheduled twice daily “diary sessions” (symptoms with or without PEF) completed, with a maximum of two sessions/day evaluated. Median values and interquartile range (IQR) for adherence during each period are shown.

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Assessing the efficacy of spirometry for smoking cessation

In a recent issue of *Thorax* Bednarek *et al*¹ presented interesting results from a large-scale prospective cohort study on the effect of combining spirometric tests with simple smoking cessation advice in 3077 middle-aged smokers with previously undetected airflow obstruction compared with smokers without airflow obstruction. Carbon monoxide-validated smoking cessation rates after 12 months of follow-up were 16% in subjects with airflow obstruction and 12% in smokers without airflow obstruction. These results are promising; however, we think that the authors' conclusion that spirometric screening of chronic obstructive pulmonary disease (COPD) is effective in smoking cessation is too far-reaching because of the limitations of the study design.

The conclusion by Bednarek *et al*¹ that spirometry is efficacious in smoking cessation is limited by the fact that their study was not a randomised controlled trial but a prospective cohort study comparing smokers with previously undetected airflow obstruction with those without airflow obstruction. This might have introduced bias. It is possible, for example, that the smokers with airflow obstruction in this study might have been more susceptible to the "health warnings" given by the doctor who evaluated the spirometric test results with them. This higher susceptibility to health warnings is indicated by the fact that the follow-up response rate was significantly higher among subjects with airflow obstruction (87%) than in those without airflow obstruction (62%), and that the follow-up response rate was associated with disease severity (90% in moderate to severe airflow obstruction compared with 81% in mild obstruction). Another problem is that neither prospective nor retrospective data appear to have been collected on whether smokers used pharmacological aids for smoking cessation on their own initiative during the 12 months of follow-up. The use of pharmacological aids for smoking cessation (such as nicotine replacement therapy, bupropion or nortriptyline) is more effective than behavioural treatment (advice) alone.^{2,3} It cannot be ruled out that this use was differential, meaning that smokers with airflow obstruction were more likely to use this form of treatment in addition to advice from the physician.

The results of the study by Bednarek *et al*¹ are promising and in line with results from other studies.^{4,5} However, evidence from well designed randomised controlled trials is needed on the efficacy of spirometry for

smoking cessation. Smokers with airflow obstruction probably respond differently to smoking cessation treatment than those without airflow obstruction. It has been shown in previous studies that the former group is more likely to be older, to be more addicted to nicotine and tobacco and to have a longer smoking history (and therefore more pack years)—all of which are predictors of treatment outcome.⁶ We therefore suggest that the use of spirometry for smoking cessation should be tested in a homogeneous group of smokers with previously undetected airflow obstruction who are randomised to undergo either counselling including confrontation with spirometry or counselling without confrontation. We are currently conducting such a trial (ISRCTN 64481813).

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Authors' reply

We thank Dr Kotz and colleagues for their interest in our investigations and look forward to the results of their study.¹ Our study did not confirm the opinion that spirometric tests showing normal lung function would encourage smokers to continue to smoke. We are aware that our investigations were not randomised and pointed this out in the discussion. This weakness was also stressed in the accompanying editorial by Mannino.²

With regard to possible bias introduced by the use of pharmacological treatment by smokers in our study during 1 year of follow-up, we would like to repeat that (1) in the study protocol smokers were asked to use their own motivation only to stop smoking and not to take pharmacological treatment, and (2) during the follow-up visit all subjects confirmed compliance with the protocol. Although

we cannot exclude the possibility that deviation from the protocol may have occurred in some cases, it seems unlikely. Pharmacological treatment of nicotine dependence is not reimbursed and is relatively expensive in Poland. Bupropion is on prescription and only nicotine replacement therapy is available over the counter.

The suggestion that approaching younger smokers would be more rewarding is worth exploring. In our experience, airway obstruction is much less frequent (10%) in smokers aged 35–40 years than in older age groups. Since younger smokers are also less inclined to stop smoking, perhaps smoking cessation clinics would be more cost effective for this group than spirometric testing.

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Spirometric screening for COPD: wishful thinking, not evidence

The effect of spirometric screening on smoking cessation rates in the before and after study reported by Bednarek and colleagues¹ is interpreted by the authors and, with reservations, in the accompanying editorial by Mannino² as evidence to support the introduction of spirometric screening to detect early chronic obstructive pulmonary disease (COPD). This goes against the evidence of the study itself, and opposes the results of the comparative study of spirometric screening published by the same workers in 2004.³ Bednarek *et al* show an effect of spirometric screening in smokers with moderate or severe COPD (using 1995 European Respiratory Society criteria), but no effect in mild COPD despite the large numbers in their study. They repeat the findings of their earlier study, which is not mentioned in this paper by the authors themselves, nor is it mentioned by Mannino in his editorial. What is going on? Is there any significance in the fact that this work comes out of a programme entitled National Program of Early Detection and Prevention of COPD?⁴ What seems to be clear from this work is that there is no evidence that early detection leads to prevention in COPD.

In the first study Gorecka *et al*³ also claimed that their findings supported spirometric screening in mild disease. In fact they showed no effect overall, found evidence of an effect in a subgroup analysis of subjects with moderate or severe obstructive lung disease, and went on to make claims for the role of screening: "All smokers irrespective of their lung function tried to modify the habit as the result of screening for COPD combined with smoking cessation advice. The diagnosis of AL (airway limitation) motivated smokers to quit smoking." Yet the results state unequivocally that there was no difference between smokers who had airflow limitation diagnosed and those who had normal lung function (NLF): "The