

and published a policy document which clearly states that every trainee must be individually assessed.¹⁶ It has gone further and clarified that there are four parts to this assessment: 'Tests of factual knowledge and problem solving, submission of practical work, evaluation of clinical and consulting skills and the trainer's overall assessment'.¹⁶ These four are likely to be welcomed and accepted throughout the general practice educational world, and the second and third points represent real advances.

The only serious remaining issue is how far the assessment should be a national and/or a regional process. The paper by Campbell, Howie and Murray in this issue of the *Journal* highlights the assessment issue and reports on one of the leading regional systems in the United Kingdom.¹⁷ In July 1993 the council of the RCGP finally clarified the issue. Fortified by an important letter from CRAGPIE, it decided that vocational training must be a nationally consistent process with certificates of equal value from all regions. The RCGP decided to adopt the 1979 recommendation of the Royal Commission on the NHS and to agree that all future principals in the NHS should hold the MRCGP. In doing so it gave firm and tangible support to the work of all its examiners over the years, especially the current panel and its convener, and also to the 1300 or so doctors who have been passing this examination each year,¹⁸ who will now be increasingly at an advantage in NHS and professional appointments.

Although the RCGP has no authority by itself to introduce this reform, its policies carry great weight and in the past most of its recommendations have eventually been adopted by the NHS. It is now likely to be only a matter of time before this comes into effect generally. In 1990, Devon Family Health Services Authority reported that 83% of all principals in east Devon qualified after 1975 held the MRCGP¹⁹ and currently 75% of new principals of all ages throughout Devon do so. All new NHS principals in Northern Ireland now hold the MRCGP.

Thus 1993 is a landmark year: it marks the point when the general practice educational bodies reached consensus on the principles of assessment of vocational training, based on objective examination external to the trainer and the practice. Much remains to be done as far as details and means of implementation are concerned, but the principle of individual endpoint assessment of all vocational trainees has arrived at last.

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Bronchodilators: wrong for the lung in the long run?

THE possible adverse effect of bronchodilators on the prognosis of asthma and chronic bronchitis is a topical subject. However, long-term studies on this subject are scarce. Some have appeared in the last few years and their results do not seem to justify the fear among patients and doctors about the use of bronchodilators. Several publications have pointed to the possible adverse effects of these drugs¹⁻⁹ but none has proven that bronchodilators are dangerous in the long run. This editorial discusses the sense and nonsense of the possible deleterious effects of bronchodilators in the treatment of asthma and chronic bronchitis in general practice.

There have been both epidemiological studies and clinical trials published on the subject. In several epidemiological studies an association was found between beta₂-adrenergic drugs and asthma mortality: the first association was observed between

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fenoterol and asthma mortality in New Zealand in the period 1977-87.¹⁻³ This finding was extended to other beta₂-adrenergic drugs in a recent study from Canada.⁴ However, these epidemiological studies cannot provide evidence for a causal relationship, that is, that the bronchodilators themselves were the cause of increase in asthma mortality. It is probable that overdependence on the beta₂-adrenergic drugs delays the use of necessary anti-inflammatory agents and might therefore be a cause of asthma mortality.

The only way to prove the deleterious effects of the bronchodilator itself is to perform clinical trials in which the treatment regimen is randomized. In such a clinical trial the outcome parameter can never be asthma-related death. Apart from obvious ethical reasons, the incidence of fatal asthma is so low that thousands of asthmatic patients would have to participate in a trial

over a long period. Therefore, clinical trials among patients with asthma and chronic bronchitis focus on parameters that relate to the severity of the disease: decline in lung function, bronchial hyper-responsiveness and bronchial symptoms. Randomized clinical trials on bronchodilators, with and without additional anti-inflammatory treatment, using these parameters have been published. First, the effects of bronchodilator monotherapy will be discussed.

In two independent studies inhaled terbutaline over two to four weeks increased bronchial hyper-responsiveness in some patients with asthma (less than 1.5 doubling dose of histamine).^{5,6} The use of salbutamol for 12 months caused a small (0.7 doubling dose) but statistically significant increase in bronchial hyper-responsiveness in 15 patients who had not used any beta₂-adrenergic drugs during the previous year.⁷ These studies indicate that bronchodilator monotherapy may increase bronchial hyper-responsiveness. However, the effect is small (between 0.5 and 1.5 doubling dose of histamine, which is similar to the repeatability of the challenge test¹⁰) and of doubtful clinical significance. It is unlikely that patients notice this increase in bronchial hyper-responsiveness.

Of clinical importance might be the effect of bronchodilator monotherapy on decline in lung function. A comparison of regular bronchodilator treatment and treatment on demand found that the decline in lung function was 72 ml per year during regular use and 20 ml per year during treatment on demand ($P < 0.05$).⁹ The difference in decline was observed over a two-year period and needs to be confirmed in longer studies before definite conclusions can be drawn.

It is important to know what effect bronchodilators have on bronchial hyper-responsiveness and lung function when used in combination with anti-inflammatory drugs, for example, inhaled corticosteroids. It has been recommended that if asthmatic patients need to inhale a bronchodilator more than once daily, it is advisable to add anti-inflammatory medication.¹¹ Lately more quantitative data have become available that may support this recommendation.¹² Two studies show that the combination of bronchodilator and inhaled steroid improves bronchial hyper-responsiveness and lung function compared with bronchodilator alone.^{13,14} Another study investigated whether a rapid decline in lung function among patients with asthma or chronic obstructive airways disease could be reversed or slowed by additional anti-inflammatory treatment.¹⁵ The initial annual decline in forced expiratory volume of 160 ml per year was decelerated to 100 ml per year with the use of an inhaled steroid. These studies provide evidence that the combination of bronchodilator and inhaled steroid clearly improves bronchial hyper-responsiveness and lung function, whereas a bronchodilator alone has no effect.

If the combination of bronchodilator and steroid is superior to the use of bronchodilators alone, the question remains whether the bronchodilator should be used continuously or on demand. Sears and colleagues showed that 6% of 64 asthmatic subjects had increased bronchial hyper-responsiveness during six months of intermittent use of fenoterol, compared with 34% who were regularly using fenoterol.⁸ These results suggest that the bronchodilator should be taken in low doses or on demand when used in combination with a steroid. However, the results need to be confirmed by further studies.

Recently, the long-acting beta₂-adrenergic drugs, salmeterol and formoterol, have become available. They have been found to be effective drugs which cause no tolerance for their bronchodilating effect during long-term treatment.^{16,17} However, one study suggested that salmeterol causes tolerance for its protective effect against provocative stimuli.¹⁸ As no tolerance was observed in its bronchodilator effect, patients will probably not notice this increase in susceptibility to acute bronchoconstriction. Concern has been expressed that patients may be misled by the

apparent state of well being produced by long-acting bronchodilators, as they are more effective in suppressing symptoms, for example morning breathlessness, and may therefore suppress the subjective need for anti-inflammatory treatment.¹⁹ This concern increased when data from a two-year intervention study with short-acting bronchodilators were reanalysed:⁹ there was some correlation between symptoms experienced and decline in lung function in symptomatically treated patients, but there was no correlation in continuously treated patients.²⁰ An explanation for this finding may be that because of the rapid bronchodilator response in the day-to-day control of symptoms, continuous bronchodilation masks the ongoing decline in lung function and any deterioration of the disease.²¹ If suppressing symptoms is more effective with long-acting bronchodilators, they may suppress the subjective need for anti-inflammatory medication to an even greater extent. This has already been observed during long-term use of formoterol.²²

Overall, there is no convincing evidence that the use of bronchodilators is wrong for the lung in the long run. The association between the prescription of beta₂-adrenergic drugs and asthma mortality probably indicates that patients rely on the strong symptom-suppressing effects of these drugs, which might delay the use of necessary anti-inflammatory drugs. High doses of a beta₂-adrenergic drug may increase bronchial hyper-responsiveness in some patients with asthma, but this increase is small and of doubtful clinical relevance. There are indications that the decline in lung function increases during continuous use of a bronchodilator, when compared with treatment on demand. There is abundant evidence that the combination of bronchodilator and inhaled steroid improves bronchial hyper-responsiveness and lung function, when compared with the use of a bronchodilator alone.

On the basis of these observations it is recommended that over-reliance on bronchodilators should be avoided. The use of anti-inflammatory treatment, such as inhaled steroids or cromoglycate, should be given serious consideration when a bronchodilator needs to be used daily. Patients should be instructed to inform their general practitioner when they need the bronchodilator more than once daily. The bronchodilator should preferably be taken in the lowest possible doses or on demand when used in combination with the anti-inflammatory drug. Long-acting beta₂-adrenergic drugs should always be used in combination with an anti-inflammatory drug.

In conclusion, when bronchodilators are used adequately (that is, in combination with anti-inflammatory drugs) the general fear among patients and doctors about the chronic use of these drugs does not seem to be justified.

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