

Smoking cessation: time for action

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Introductory article

Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV₁: the Lung Health Study

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Objective. To determine whether a program incorporating smoking intervention and use of an inhaled bronchodilator can slow the rate of decline in forced expiratory volume in 1 second (FEV₁) in smokers aged 35 to 60 years who have mild obstructive pulmonary disease. **Design.** Randomized clinical trial. Participants randomized with equal probability to one of the following groups: (1) smoking intervention plus bronchodilator, (2) smoking intervention plus placebo, or (3) no intervention. **Setting.** Ten clinical centers in the United States and Canada. **Participants.** A total of 5887 male and female smokers, aged 35 to 60 years, with spirometric signs of early chronic obstructive pulmonary disease. **Interventions.** Smoking intervention: intensive 12-session smoking cessation program combining behavior modification and use of nicotine gum, with continuing 5-year maintenance program to minimize relapse. Bronchodilator: ipratropium bromide prescribed three times daily (two puffs per time) from a metered-dose inhaler. **Main outcome measures.** Rate of change and cumulative change in FEV₁ over a 5-year period. **Results.** Participants in the two smoking intervention groups showed significantly smaller declines in FEV₁ than did those in the control group. Most of this difference occurred during the first year following entry into the study and was attributable to smoking cessation, with those who achieved sustained smoking cessation experiencing the largest benefit. The small noncumulative benefit associated with use of the active bronchodilator vanished after the bronchodilator was discontinued at the end of the study. **Conclusions.** An aggressive smoking intervention program significantly reduces the age-related decline in FEV₁ in middle-aged smokers with mild airways obstruction. Use of an inhaled anticholinergic bronchodilator results in a relatively small improvement in FEV₁ that appears to be reversed after the drug is discontinued. Use of the bronchodilator did not influence the long-term decline of FEV₁. (JAMA 1994;272:1497-505)

Writing in 1977, Fletcher and Peto suggested that "severe or fatal obstructive lung disease could be prevented by screening smokers' lung function in early middle age if those with reduced function could be induced to stop smoking".¹ The reasoning behind their view was straightforward. Observed declines in lung function with age were reduced in men who stopped smoking compared with those who continued to smoke, and reverted to the normal rate seen in non-smokers.² Similar arguments about preventing coronary heart disease have also been advanced based on the reduction in observed risk of myocardial infarction in men who give up smoking. But sceptics could counter that those who elect to give up smoking are a self-selected group who may differ in ways relevant to risk of disease, so

that observational studies may not provide a reliable guide to the value of smoking interventions. Only randomized trials can answer the question definitively. In the case of the Multiple Risk Factor Intervention Trial (MRFIT) no significant reduction in deaths from heart disease was seen in high risk men in the intervention condition by comparison with controls, although it was seen in those who stopped smoking compared with those who did not.³ Similar findings emerged in that study regarding rate of decline in lung function.⁴ Perhaps the main reason the MRFIT did not find an effect on death rates or on lung function was that the smoking intervention was not very successful in achieving cessation.⁵ The Lung Health Study summarised in the introductory article, by contrast, has rightly been hailed

as a triumph.⁶ There was a significant benefit in reducing the rate of decline of lung function in an intention-to-treat comparison of the smoking intervention group with non-intervention controls, and the benefit was even greater when those who succeeded in stopping smoking were contrasted with those who did not.⁷ The results amply confirm the suggestion made by Fletcher and Peto, and leave no doubt about the value of smoking cessation in preventing lung disease. Interesting questions remain, however, about the type of smoking intervention likely to be of most value, and about the best means of delivering it.

The Lung Health Study was conducted in 10 centres across the USA and Canada, and funded by the National Heart, Lung, and Blood Institute. Over 70 000 individuals were screened in order to find 6000 otherwise healthy eligible individuals aged 35–60 with mild impairment of lung function and judged to be at high risk for COPD who were entered into the trial.⁸ In the smoking arm of the trial 3923 participants were randomised to an intensive smoking intervention and 1964 to be usual care non-intervention controls. The initial cessation programme was offered to spouses as well as participants and involved 12 group meetings in the first 10 weeks.⁹ There were subsequent visits to the clinic to check smoking status at four month intervals and formal group support continued to be available for relapsers throughout the study. Nicotine replacement therapy in the form of nicotine chewing gum was used “aggressively” (to adopt the trialists’ words), and was available free. Smoking status was carefully verified by measurement of expired carbon monoxide at each visit and by salivary cotinine levels at annual checks. All this represented a smoking intervention that was genuinely state-of-the-art for its time, and one which made few concessions to cost containment. It was rewarded by some of the highest cessation rates ever achieved in rigorously evaluated interventions – a one year intention to treat cessation rate of 35% in the intervention group compared with 9% in controls, and sustained cessation over five years of follow up of 22% versus 5%. The latter figures were close to the design estimates of 24% versus 7% in controls, and gave the study ample power to detect smoking cessation effects on decline in forced expiratory volume in one second.

What are the clinical implications of the study for smoking cessation? Those who work in the National Health Service in the UK or the health care systems of other countries will ruefully recognise that, however much they might wish it, smoking cessation interventions of this intensity and sophistication are simply not an option in the real world of routine patient care, whether it be in general practice or hospital chest clinics. Few resources are devoted to helping smokers to give up, and certainly nothing which would entail such a heavy investment of resources on individual smokers. In addition subjects recruited to the Lung Health Study do not represent a group that could be readily targeted for help to stop smoking without yet further investment of resources.

Different recruitment procedures were used in the collaborating centres, but very few participants came from hospital clinics or other medical settings.^{10,11} Most responded either to publicity in the local media or to direct mail shots. This was, thus, essentially a general

population sample of people who were generally healthy, not especially aware of their high risk status for chronic obstructive pulmonary disease, and highly motivated to participate. This was shown by the three separate screening visits required before randomisation and by about 95% attending each annual follow up.

The Lung Health Study therefore tells us that smoking cessation works in preventing lung disease, and shows the success rates that can be achieved with an optimised smoking intervention. It has already given rise to several interesting and important papers on the process of the smoking intervention^{12,13} and will no doubt yield more. However, it does not provide a guide to how best to help smokers in routine clinical practice.

What can physicians achieve in routine practice?

For practical smoking cessation interventions of proven efficacy and maximal cost efficacy, arguably what is required is a brief package which can be delivered to all smokers – or all motivated smokers – encountered in routine clinical contacts.¹⁴ The study reported by Stapleton *et al* of a randomised trial of nicotine skin patches in primary care gives a viable model.¹⁵ Across 30 participating general practices a total of 1200 smokers of 15 or more cigarettes per day, judged to be well motivated to try to give up smoking, were randomised to receive either active nicotine skin patches or placebo. Brief support was provided either by the general practitioner or practice nurse, or in combination, as suited the individual practice. No special training in smoking cessation counselling was provided for the participating practices who were left to formulate their own approach to patients. The outcome was rigorously defined as sustained cessation throughout a year of follow up and was carefully validated biochemically. Among those assigned to the active patch condition, 9.6% abstained from smoking throughout the year compared with 4.8% on placebo, a doubling of the success rate.

These results confirm the value of nicotine replacement in enhancing cessation rates, an issue which could not be addressed directly in the Lung Health Study because of the absence of placebo controls. The doubling of successful cessation is in line with the results of other trials of nicotine skin patches in primary care^{16,17} and with the conclusions of several recent meta-analyses that have examined the efficacy of nicotine replacement.^{18–20} The effect was found at all levels of nicotine dependence in the study, so this treatment is likely to benefit lighter smokers as well as heavier and should not be reserved for only the most dependent minority. Indeed, it now seems clear that nicotine replacement is a cost effective adjunct to all forms of smoking intervention, from the very brief to the most intensive, and should be a basic component of any smoking cessation intervention.

The intervention was brief and did not require special training for the therapists. The relatively low success rate achieved with a single episode of intervention is more than offset by the potentially wide reach. Since some 70% of smokers attend their general practitioner at least once in any given year, an intervention of this kind could be delivered to most smokers and has the potential to make a real impact on national rates of smoking prevalence.

LEARNING POINTS

- * 70% of regular smokers consult their family physician at least once in any given year.
- * The addition of nicotine replacement to brief advice doubles success rates.
- * Nicotine replacement therapy is an effective adjunct, irrespective of the usual level of tobacco consumption.
- * High cessation rates are seen only in highly motivated populations, and rarely exceed 20%.
- * Sustained success is almost invariably associated with complete cessation by day 7. Immediate complete cessation should be the priority target of all intervention policies.

Of particular interest was the way in which the success or failure of the attempt to give up smoking appeared to be determined very early in treatment. All but one of the 96 subjects who achieved long term abstinence stopped smoking completely in the first week; those who were close to cessation at one week but not succeeding completely, or who succeeded in stopping only after one week, had a prognosis that was uniformly bleak. Similar findings have been reported recently from other studies,^{21,22} and this would now appear to be an established feature of treatment for smoking cessation. This implies that efforts should be tightly focused on helping smokers to make an initial clean break with cigarettes, with little investment of effort in encouraging prolongation of their attempt on the part of stragglers.

Hospital patients with smoking-related disease

Both the Lung Health Study and the patch study by Stapleton *et al* concern smokers in the general population. Smokers attending hospital with smoking-related diseases often seem a particularly resistant group for whom it is hard to come up with successful interventions.^{23,24} The insidious onset of lung disease, lacking the jolt of a first heart attack, may take away its ability to provide a sharp motivational shock; alternatively, those who choose to ignore the signs of increasing breathlessness and carry on smoking may be a group selected for being hard-core addicted smokers. Either way, we have to acknowledge that at present we do not have very successful interventions for those in the later stages of lung disease. This remains a research priority and may well demand more intensive treatment. Nevertheless, the Lung Health Study and the study by Stapleton *et al* show that treatment works in preventing lung disease, and that effective treatment is available. Delivering smoking cessation treatment to smokers in the general population before they reach the stage of frank smoking-related disease will help to lower the incidence of disabling conditions that need more elaborate interventions. The challenge is now to make such smoking cessation intervention a part of routine health care.

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