

reflect a causal relation between this putative risk factor and terminal transverse defect. It would be necessary to test this finding in a study with the measurement of cigarette related markers, such as maternal serum or urine cotinine concentrations. The low relative risk (about 1.5) for such a common exposure as smoking has important public health implications for congenital limb deficiency in the population (the attributable risk is about 14%). This risk is obviously more important than the association of congenital limb deficiency with chorionic villus sampling.^{27,28} The confirmed teratogenic effect of maternal smoking may be a further strong indication for public health interventions aimed at preventing smoking during pregnancy.

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Randomised trial of nicotine patches in general practice: results at one year

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In the largest randomised, placebo controlled trial of nicotine patches in general practice we showed that the patch was effective in helping heavy smokers (≥ 15 cigarettes a day) to stop smoking in the short term.¹ Among 1686 patients, rates of confirmed cessation three months after starting to use the patch were 19.4% with nicotine patches and 11.8% with placebo patches. These rates are similar to those reported by the only other randomised trial of a nicotine patch in British general practice.²

Trials of interventions to promote smoking cessation have shown that the effect of the intervention diminishes over time. Typically, about half of those abstinent at three months relapse by the end of a year.³ We report here the smoking cessation rates in our trial one year after the patients began to use the patch.

Subjects, methods, and results

Selection of subjects and methods has previously been reported.¹ Briefly, 1686 patients, recruited from 19 general practices in Oxfordshire, were randomised into four equal groups: to receive a nicotine patch or a placebo patch in combination with a special booklet of support material or a standard Health Education Authority leaflet. Nicotinell TTS patches, in reducing

sizes, were used over 12 weeks. Patients were reviewed by a trial nurse at one, four, eight, and 12 weeks.

At four or eight weeks, reported abstinence since the previous visit was confirmed by an exhaled carbon monoxide reading of ≤ 10 ppm. At 12 weeks, reported abstinence since the previous visit was confirmed by a salivary cotinine concentration ≤ 113.5 nmol/l (20 ng/ml).⁴ For 36 patients who failed to provide a saliva sample, an exhaled carbon monoxide reading at 12 weeks of ≤ 10 ppm counted as confirmation of non-smoking.

The 263 patients with confirmed cessation at 12 weeks were reviewed by the trial nurse at 24 and 52 weeks to ascertain their smoking status. Reported smoking cessation was confirmed by salivary cotinine concentration (165 of 180 confirmed at 24 weeks; 143 of 156 confirmed at 52 weeks) or exhaled carbon monoxide. Patients who failed to attend for review were assumed to be smokers.

Two outcome measures are reported: (i) continuous cessation from 12 weeks (confirmed at 12, 24, and 52 weeks) (ii) continuous cessation from one week (confirmed at 4, 8, 12, 24, and 52 weeks). The χ^2 test was used to compare proportions. Confidence intervals were calculated with the 1991 version of the BMJ's confidence interval analysis (CIA) program.

The significant advantage of the nicotine patch over the placebo patch, seen at the end of the treatment period, was still evident (though smaller) at one year (table). Of the 163 patients given nicotine patches who were abstinent at 12 weeks, 91 (56%) maintained abstinence to 52 weeks; 76/91 (84%) were abstinent continuously from the first week.

Sustained cessation rates did not differ between patients who received the special support booklet and those who received the standard leaflet: continuous

	Nicotine patch (n=842)	Placebo patch (n=844)	Rate ratio* (95% confidence interval)	P value for difference
At 12 weeks	163 (19.4)	100 (11.8)	1.63 (1.30, 2.06)	<0.0001
Continuous from 12-52 weeks	91 (10.8)	65 (7.7)	1.40 (1.04, 1.90)	<0.05
Continuous from 1-52 weeks	76 (9.0)	53 (6.3)	1.44 (1.03, 2.01)	<0.05

*Cessation rate in nicotine group divided by cessation rate in placebo group.

cessation from 12-52 weeks was confirmed in 78/842 (9.3%) and 78/844 (9.2%), and from 1-52 weeks in 63/842 (7.5%) and 66/844 (7.8%) respectively.

Comment

The relapse rate after use of nicotine patches in general practice is similar to that in other settings. In this trial and in the two other published randomised trials in general practice, about half the patients abstinent at the end of three months' treatment remained abstinent at one year.^{2,5}

With strict validation criteria, our sustained cessation rate was 10.8%, a clinically useful result in a group of heavy (average 24 cigarettes/day) and long standing (average 25 years) smokers.

A striking result was the high sustained cessation rate in the placebo group. It is not possible to isolate the factors contributing to this effect, but in addition to the placebo patch the scheduled follow up by a nurse is likely to have been important. Four factors seem to contribute to success in smoking cessation in primary care: selection of motivated patients, initial advice

from doctors, follow up support by nurses, and nicotine replacement. The efficacy of nicotine patches obtained over the counter and used without support remains uncertain.

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A MEMORABLE PATIENT

A living death

Just three days after the funeral of 3 year old Johnathan Ball following terrorism in Warrington I certified dead another victim of Irish terrorism in a hospice in north Derbyshire. Ray was 65 years old and had been "disturbed" for 20 years, finally dying of lung cancer accompanied by an invasive Pancoast plexalgia giving much discomfort in his shoulder and right arm. This certificated diagnosis gave no indication of the living hell he had been through.

Ray had been admitted to the hospice on two occasions, increasingly unable to cope on his own at home. A nursing and medical assessment was undertaken and grudgingly accepted. Some changes were made to his regimen to improve comfort and the following day a colleague saw him on the ward round. Eager to review his progress he opened with, "How are things today, Ray?" This was followed by a long pause, much grinding of teeth, and shaking (part of his existing problem), and then a mighty yell which resounded around the hospice—"Bugger off."

Slow progress was made for this loner who had been labelled schizophrenic just one year after a tragedy 20 years before. His ability to relate to any of the staff was minimal and his only real activity was his regular shuffle to the smoke room and frequent massaging of the arm while assuring us in more friendly moments that the pain was not very severe.

His extrapyramidal movements, perhaps associated with long term phenothiazine treatment, increased at times of attention to him. He did become more communicative and managed to spend some time at home on his birthday and then a further two or three weeks before finally coming back to us for inpatient management in his final days.

Our social worker visited him for a home assessment before this admission and after initial hostility with exaggerated body language and sweeping arm movements he started to talk about his past. It was painful and went back to his unofficial adoption as a small child and being reclaimed by his alcoholic father, who physically abused

him. He left home and joined the army and was serving in Northern Ireland when he met his wife. They had a happy marriage and two children, whom Ray adored. He left the army and set up home in Ireland with his family, working in a factory. Overtime was available and his wife would spend some of her time with the children at their grandparents. Money was tight and they needed all the extra cash he could earn so on the day that his name was called over the tannoy at the manager's office he knew something was drastically wrong and his heart was pounding and his stomach churning as he walked to the office.

Police who were with the manager told him that there had been a serious accident during which his wife and children had walked into a terrorist bomb site at a supermarket and triggered the explosion. His children were dead, his wife critically ill on a life support machine. He left work at once and went to see his children and kissed them saying that he had to leave them because mummy needed him now. He went to his wife, who had lost both legs and had serious internal injuries and was in intensive care on a life support machine. Doctors explained to him the seriousness of his wife's condition and that the likely outcome was death, which indeed it was.

The following year he was diagnosed as a paranoid schizophrenic—a label which he kept to his own death at our hospice 20 years later. Both children had been killed and he had had to give permission for his wife's ventilator to be turned off. How much hidden and unresolved grief lay behind this convenient diagnosis? How little the terrorist world has changed in 20 years. Are children still to be the sacrificial lambs in another 20 years? Shall we still have cases like Ray—a social outcast with alcoholism and unresolved grief—in another 20 years? The way the world seems at present we shall have more like him.—R E ATKINSON is medical director of a hospice in Chesterfield