Nicotine replacement therapy in smoking cessation

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Evidence for benefit from nicotine replacement therapy in hospital patients is inconclusive, although the results of a trial reported in this issue of Thorax give cause for optimism and should stimulate further studies.

Most smokers become nicotine dependent and, when they stop smoking, experience withdrawal symptoms and craving. Nicotine replacement therapy (NRT) reduces these unpleasant symptoms and, theoretically, should decrease the risk of relapse. Smoking cessation is properly defined as validated sustained abstinence from cigarettes and/or other tobacco products for at least 6 months, but preferably for 1 year. This editorial includes evidence only from those studies which have applied such a definition and which have specified their settings and populations.

NRT is available as chewing gum, transdermal patches, sublingual tablets, lozenges, inhalation cartridges and nasal spray. In specialised cessation clinics and in primary care, prospective randomised clinical trials have shown that NRT, used as an adjunct to advice and support, results in better cessation rates than does advice and support alone. In the clinics success rates with NRT tend to be higher (11–30%) and more consistent than in primary care, where some studies have found no significant difference from placebo. One study in primary care showed 8% success with nicotine chewing gum compared with 4% with advice plus leaflet, but there was no placebo controlled arm. Two studies of transdermal nicotine in primary care have shown success rates of around 10%, which were superior to those with placebo (around 6%). The benefit for transdermal nicotine in cessation clinics and in primary care is thus clear, whereas nicotine chewing gum, inhaler, nasal spray and lozenges have only proved superior to placebo in cessation clinics. Success rates of 15–28% have been reported with NRT—systemic effects of excessive nicotine can occur (chiefly nausea). In pregnancy and in patients with myocardial infarction NRT, which delivers less nicotine than cigarettes and no carbon monoxide, is less hazardous than continued smoking but, nevertheless, there is still reluctance to use it.

NRT is now available in the UK on NHS prescription. Smoking cessation counsellors have been employed by the NHS to provide advice and support in the community to smokers who self-refer or are referred by other health professionals. NRT is usually offered as part of the package. The sustained validated 6 month or 1 year quit rates achieved through this service are eagerly awaited. These results should not only inform local health groups, primary care trusts, and government of how cost effective the service has proved and how best to shape it in future, but should also make an interesting comparison with the results obtained in the clinical trials.

For hospital inpatients and outpatients the evidence for the efficacy of NRT as an adjunct to advice and support is not convincing. Many reports stemming from cessation services located in hospitals have been wholly or partly based on populations of self-referred smokers or smokers recruited via the media. Such populations differ in motivation and other aspects from patients who, despite presenting to secondary care services, continue to smoke. The quit rate should not therefore be taken as representing the quit rates of populations of patients. The first randomised trial of NRT in hospital patients in the UK enrolled 1550 inpatients or outpatients with smoking related diseases (SRDs); neither nicotine chewing gum nor its placebo significantly improved on the success rate of 9% achieved by brief advice from the hospital physician and follow up in an outpatient clinic at 3, 6 and 12 months. This success rate is little different from the 11% reported from Nottingham by Molyneux et al in this issue of Thorax in a study of hospital inpatients which was not restricted just to those with SRDs. Interventions compared were: (a) usual care, (b) 20 minutes' bedside counselling by a research doctor or nurse trained in smoking cessation counselling plus an advice leaflet, and (c) 20 minutes' bedside counselling by the same personnel plus 6 weeks of NRT. Patients were allowed to choose one of five forms of NRT, 63% electing transdermal nicotine. They were reviewed in outpatients or interviewed by telephone 3 and 12 months after entering the trial. Exhaled air carbon monoxide was used to validate claims of abstinence. In the usual care group 7.6% were classified as successes (continuous abstinence) compared with 4.4% in those receiving counselling plus advice leaflet and 11% in the counselling plus NRT group (p=0.25). Thus, like a previous trial by Campbell et al of transdermal nicotine plus counselling in 234 hospital outpatients and inpatients with SRDs which showed 21% success with active versus 14% with placebo patches (p=0.15), there was a suggestion that NRT was of benefit but smaller than expected sample sizes have limited the power to detect differences caused by treatment rather than chance.

Previous trials of NRT and counselling in hospital patients with SRDs have included a group given NRT placebo, a design feature missing in the Nottingham study. Nicotine chewing gum was no more effective (20% success) than placebo in a study of 219 inpatients, nor was transdermal nicotine (14% success) better than placebo in 584 outpatients with ischaemic heart disease. In a more recent outpatient...
trial conducted among 245 hospital inpatients and outpatients but excluding patients with recent myocardial infarction, advice and support plus the combination of regular transdermal nicotine and as required nicotine inhalator resulted in a success rate of 16% compared with 14% for advice and support alone.\textsuperscript{19} Higher success rates have been achieved in the hospital trials which provided more intensive support during the first weeks after quitting than was provided in the Nottingham trial. For hospital patients the evidence for benefit from NRT as an adjunct to advice and support (minimal or intensive) remains inconclusive, although the trial by Molyneux \textit{et al} gives cause for optimism.

Guidance on the use of NRT and bupropion for smoking cessation was issued by the National Institute of Clinical Excellence (NICE) in March 2002.\textsuperscript{20} It is likely that UK hospitals will appoint smoking cessation counsellors to provide advice and support in conjunction with NRT or bupropion, as recommended by NICE. It is important not only that the success rates of these programmes be properly evaluated, but also that there should be further placebo controlled clinical trials of NRT in hospital patients. Such trials are both justified and desirable.

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\textbf{REFERENCES}