

SHORT REPORT

Three year continuous abstinence in a smoking cessation study using the nicotine transdermal patch

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Abstract

A total of 305 subjects from Sydney were randomly allocated to receive either an active (24 hour transdermal nicotine patch over a 10 week course) or placebo nicotine patch. All subjects participated in a multicomponent cognitive-behavioural smoking cessation programme over five weeks in two-hour group sessions. The continuous abstinence rates at three years (validated by expired carbon monoxide) were 13.8% for the active group and 5.2% for placebo group ($p = 0.011$). The active nicotine patch with behavioural therapy achieved more than double the abstinence rates early in treatment compared with placebo and this difference was maintained throughout the three year follow up.

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The nicotine transdermal patch has been shown to more than double 12 month continuous abstinence rates compared with placebo.¹⁻³ Only one study has reported two year abstinence from smoking when the nicotine patch was used as an adjunct.⁴ The aim of this paper

is to present continuous abstinence rates from the end of treatment to three years.

Methods

A total of 305 subjects from Sydney, Australia were randomly assigned to receive either an active nicotine patch or a placebo patch. Subjects in the active treatment group were given a 24 hour transdermal nicotine delivery system over a 10 week course: 21 mg of nicotine/day in patches for six weeks, and 14 and 7 mg for two weeks each thereafter.

All subjects attended a multicomponent cognitive-behavioural smoking cessation programme consisting of five consecutive weeks of two-hour group sessions conducted at a hospital outpatient clinic. Components of the programme and subject characteristics have been described previously.⁵

The outcome measure for this paper was continuous abstinence determined by calculating the percentage of patients who had validated abstinence at every measurement point from the end of treatment through three years. Validation of self-reports of abstinence was based on expired carbon monoxide levels ≤ 10 ppm, or collateral confirmation obtained for three participants at the two and three year assessment points (for example, moved interstate). Other participants were classified as continuing smokers.

Distributions of the active and placebo groups were compared using the logrank test. For each case the time until restarting smoking was taken to be the last measurement point where abstinence was maintained. For those cases who did not restart smoking during the study, times to event were censored at the end of the three year study period.

Results

There was a significantly different continuous abstinence rate between the active and placebo patch groups ($p = 0.0001$) (fig 1). For both groups, the greatest relapse to smoking occurred in the first three months after the intervention, particularly in the first few weeks. However, the placebo group showed the greatest decline of abstainers in the early weeks and continued to show a lower level of abstainers

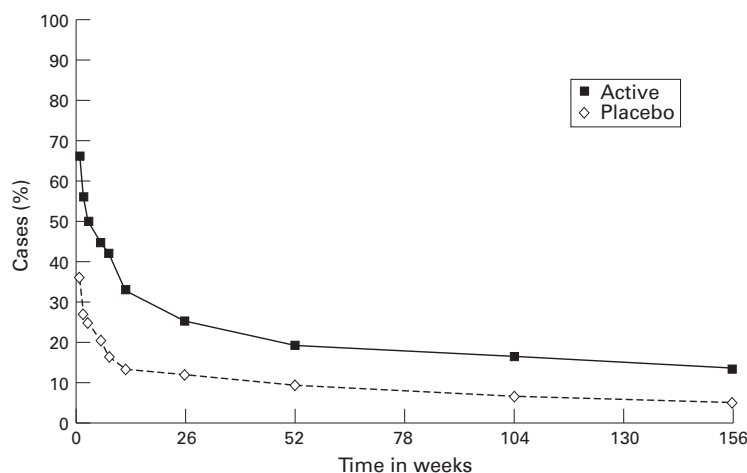


Figure 1 Percentage of subjects remaining abstinent at each measurement point.

throughout the study. For both groups, the decline of abstainers after three months was less to six months, and relatively small to three years. The resulting continuous abstinence rates at three years for the active and placebo groups was 13.8 and 5.2%, respectively, a difference of 8.6% (95% confidence intervals 1.4% to 15.8%; $p = 0.011$).

Dropouts from the study were frequent in the first eight weeks, resulting in 16–50% of cases assigned to continuing smoking by default for non-attendance, although telephone follow up invariably revealed relapse to smoking had occurred. However, at later follow up, only two cases, one each at three and 12 months, were allocated to be continuing smokers solely on the basis of missed attendance.

Discussion

This study presents estimates of continuous abstinence as a result of nicotine versus placebo patch treatment in conjunction with behavioural therapy, and is the first to show continuous abstinence as an outcome measure at three years. These data are the first to support the common assumption that smokers who abstain from smoking for a year will continue abstinence indefinitely.

The active nicotine patch with behavioural therapy achieved more than double the abstinence rates early in treatment compared with placebo and this difference was maintained throughout the three year follow up. The sharpest decline in abstinence occurred in the first three months following intervention, where both patches, but particularly placebo,

appeared unable to alleviate withdrawal symptoms and prevent relapse to smoking. Abstinence remained relatively stable in both groups after the six month follow up point, with small declines to three years. This suggests that once individuals have abstained for six to 12 months, they are likely to remain continuously abstinent thereafter. The active patch tends to influence how many smokers become abstinent during the earlier stages. Indeed, the sustained difference in abstinence rates between placebo and active patch treatment for such a long period is important because we found in a previous study of nicotine gum delivered in general practice that, when gum was discontinued, any significant treatment effect disappeared.⁶

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