

## Combined use of nicotine patch and gum in smoking cessation: a placebo-controlled clinical trial.

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**BACKGROUND.** Smoking is considered as an addiction to nicotine for most subjects consuming 10 cigarettes or more per day. Hence, nicotine replacement therapy by way of gum, patch, or spray has been advocated. The rationale of this study is to evaluate the possible beneficial effects of adding nicotine gum to the routine of subjects using the nicotine patch. The effect of the nicotine patch against the placebo, both groups receiving placebo nicotine gum, has also been assessed. **METHODS.** Healthy subjects (374) were randomized at their work-setting in a 1-year double-blind placebo-controlled trial: 149 subjects to active nicotine patch + active gum (group 1), 150 to active nicotine patch + placebo gum (group 2), and 75 to placebo patch + gum (group 3). Treatment duration was 12 weeks with a 16-hr transdermal patch of 15 mg, followed by a 6 + 6-weeks weaning period on respectively 10 and 5 mg patches. Gum use was not restricted during the first 6 months, with recommendations to use at least four pieces a day. A strict definition of smoking abstinence was used in this study, which did not allow smoking any cigarette after Week 1. Nonsmoking status at each visit, as reported by the subjects, was verified by CO below 10 ppm in expired air. **RESULTS.** Abstinence rates in group 1 against group 2 were 34.2 and 22.7% ( $P = 0.027$ ) at 12 weeks, 27.5 and 15.3% ( $P = 0.010$ ) at 24 weeks, and 18.1 and 12.7% ( $P = 0.191$ ) at 52 weeks. In group 3, abstinence rates were 17.3, 14.7, and 13.3% respectively at 12, 24, and 52 weeks. Using logistic regression with adjustment for six baseline covariates, odds ratios for abstinence (with 95% CI) were computed. For group 1/group 2, OR at 12, 24, and 52 weeks were 1.72 (1.03-2.94) ( $P = 0.039$ ), 2.04 (1.14-3.57) ( $P = 0.018$ ), and 1.47 (0.76-2.76) ( $P = 0.125$ ). No significant differences in OR were observed when comparing groups 2 and 3. Time to relapse is significantly longer in group 1 as compared to that of group 2 ( $P = 0.041$ ), whereas no significant differences between groups 2 and 3 were observed. No significant differences between the three groups in systemic and local adverse drug events were observed. **CONCLUSION.** Adding active gum use to active patch use in subjects smoking 10 cigarettes or more a day increased abstinence rates, which are statistically significant up to 24 weeks.

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