

## Bupropion Therapy Is Effective for Smoking Cessation in Community Primary Care Clinics

Fossati R, Apolone G, Negri E, et al. A double-blind, placebo-controlled, randomized trial of bupropion for smoking cessation in primary care. *Arch Intern Med* 2007;167:1791–7.

### Study Overview

**Objective.** To determine the effectiveness of sustained-release bupropion for smoking cessation in primary care.

**Design.** Randomized, double-blind, placebo-controlled trial.

**Setting and participants.** Participants were recruited from 6 administrative centers in northern Italy and were eligible if they were aged  $\geq 18$  years, smoked  $\geq 10$  cigarettes/day for  $\geq 1$  years, were motivated to quit, and were in good health. Patients were excluded if they had a medical history of seizures and concomitantly used medications that could lower seizure threshold; had a history of eating disorders; or had severe kidney, liver, pulmonary, or neurologic disease.

**Intervention.** Patients were randomized in a 2:1 ratio and received either sustained-release bupropion 150 mg/day for 6 days followed by 150 mg twice daily for 7 weeks or matching placebo.

**Main outcome measures.** The primary endpoints were continuous abstinence from smoking from week 4 to week 7 and from week 4 to week 52. Abstinence was confirmed by measuring carbon monoxide concentration of expired air. Secondary outcomes included the point prevalence of abstinence measured at the study visits, the number of cigarettes smoked in nonabstinent patients, and body weight changes.

**Main results.** 593 participants were enrolled; 400 were allocated to the intervention and 193 to placebo. Baseline characteristics and smoking histories were similar in the 2 groups. 41% (95% confidence interval [CI], 36.1%–46.0%) of patients in the intervention arm had biochemically verified continuous abstinence from week 4 to week 7 compared with 22.3% (95% CI, 16.6%–28.8%) of patients in the placebo arm ( $P < 0.001$ ). Continuous abstinence from week 4 to week 52 was biochemically validated for 25.3% (95% CI, 21.2%–29.8%) of patients in the intervention arm compared with 13.6% (95% CI, 9.1%–19.3%) in the placebo arm ( $P < 0.001$ ). Even after adjusting for age, gender, and strength of nicotine addiction (measured by the Fagerstrom index), bupropion-treated patients had a significantly increased odds of maintaining continuous abstinence at week 7 and at week 52 compared with placebo-treated patients (odds ratios [ORs], 2.37 [95% CI, 1.60–3.53] and 2.11 [95% CI, 1.32–3.39], respectively). At all clinical visits during the study, the point prevalence of abstinence was greater in the intervention group compared with the placebo group ( $P < 0.001$ ). There were no significant differences between the groups with respect to weight change or number of cigarettes used in nonabstinent patients.

**Conclusion.** Sustained-release bupropion was efficacious for promoting smoking abstinence in a primary care setting.

### Commentary

The benefits of smoking cessation are so pronounced and

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widespread that providers should constantly be encouraging their patients who smoke to quit. Unfortunately, smoking cessation is very challenging for most patients. Nicotine replacement therapy appeared moderately effective for smoking cessation when combined with intense psychological support [1]. Early clinical trials with bupropion, an antidepressant, demonstrated impressive short-term cessation rates when compared with placebo [2]; these rates improved when bupropion was combined with nicotine replacement therapy [3]. Because many of these trials were performed at specialty clinics and included behavioral counseling in addition to pharmacologic therapy, it was unclear whether these results would be applicable in clinical practice. Busy primary care practices may not have the support to combine intensive behavioral counseling with bupropion therapy.

This randomized trial by Fossati et al sought to reproduce the findings of earlier trials in a more "real-world" primary care setting. Even in this setting, bupropion almost doubled the rate of short-term cigarette cessation. In general, the trial was well conducted with few limitations, and it helps to generalize the results of earlier findings into primary care practices where most smoking cessation efforts will take place and where intensive psychological support may not be available.

Despite these positive results, in head-to-head comparisons, bupropion has been less effective in promoting smoking cessation than varenicline [4]. In addition, varenicline

appears better tolerated than bupropion. What is not yet known is the overall cost-effectiveness of using 1 agent over the other. Nevertheless, at present, varenicline would likely be the smoking cessation drug of choice.

### Applications for Clinical Practice

In this study performed by general practitioners with limited support for behavioral counseling, bupropion was effective for increasing smoking cessation rates. These findings suggest that bupropion therapy should be applicable to multiple clinical settings regardless of the level of ancillary support.

—Review by Harvey J. Murff, MD, MPH

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