

# Study: Varenicline Safe for Depressed Smokers

BY KATE JOHNSON

MONTREAL — Despite postmarketing concerns about the psychiatric side effects of varenicline for smoking cessation, the medication appears to be safe in patients who are depressed or at risk for depression, Jennifer B. McClure, Ph.D., reported at the annual meeting of the Society of Behavioral Medicine.

In a subanalysis of the Chronicle Of

fers Management to Patients With Advanced Signs and Symptoms of Heart Failure (COMPASS-HF) trial, 661 smokers with a baseline history of depression, or a risk of depression, were monitored for mood changes and compared with 516 nondepressed smokers during their 12-week course of varenicline (Chantix) combined with behavioral smoking-cessation counseling (J. Gen. Intern. Med. 2009;24:563-9).

“We think that physicians should continue to closely monitor patients who are using varenicline, particularly if they have a psychiatric history,” she said. Although people with a history of depression were more likely than nondepressed people to report side effects with the medication, “we didn’t find an overall difference in their qualitative symptom experience, or treatment outcomes,” said Dr. McClure, who is affiliated with Group Health Cen-

ter for Health Studies, Seattle.

The study, funded by the National Cancer Institute, was a collaborative effort between Group Health; Free & Clear Inc., Seattle; and SRI International, an independent, nonprofit, research and development organization in Menlo Park, Calif. Medication was provided by Pfizer Inc., maker of varenicline.

Varenicline was approved by the Food and Drug Administration about 3 years ago. It works by blocking nicotinic receptors and thus the rewarding effects of nicotine, while stimulating some dopamine release to provide relief from craving and withdrawal, Dr. McClure said.

Shortly after its release to market, the FDA raised concerns that varenicline might be associated with increased neuropsychiatric symptoms, including depressed mood, agitation, suicidal ideation, and behavior—particularly in people with a psychiatric history, she said.

“Unfortunately, due to the nature of the reports to the FDA, we are not able to determine if varenicline itself was the cause of the symptoms reported—it’s possible they were due to nicotine withdrawal, substance use, the psychiatric conditions themselves, or some other factors. Unfortunately, subjects with a psychiatric history were excluded from the original efficacy trials.”

Research shows that between one- and two-thirds of smokers have a history of depression, and that smokers with a history of depression report more symptoms of nicotine withdrawal, have more negative affect after they quit, and have higher relapse rates, compared with nondepressed smokers, she added.

“But because varenicline does stimulate some release of dopamine, it’s possible that it might ameliorate some of this negative effect and other side effects, and so prevent relapse.”

At baseline, the subjects in the study were screened for symptoms of depression. “We didn’t do an in-depth clinical interview; we just looked for the hallmark symptoms by asking: ‘Have you ever, for a 2-week period or more, felt down, depressed, or hopeless, or had little interest or pleasure in doing things?’” she said.

Depressed and nondepressed subjects had similar nonsmoking rates at 21 days (49% vs. 47%, respectively), and 3 months (45% vs. 43%, respectively). However, depressed patients were more likely to endorse depression, anxiety, tension, agitation, difficulty concentrating and sleeping, and confusion. Depressed patients also were more likely to report other known side effects of the medication. However, despite this, negative affect actually declined in both groups, Dr. McClure said. One case of suicidal ideation was reported in a subject with undisclosed, untreated bipolar disorder.

Additional research is necessary to tease out the safety and effectiveness of varenicline among psychologically vulnerable populations, she concluded.

Dr. McClure said she had no conflicts to disclose in connection with this study. ■



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