

Varenicline Helps COPD Patients Quit Smoking

BY BRUCE JANCIN

SAN DIEGO — Varenicline is a particularly effective and well tolerated smoking cessation therapy in one of the toughest-to-treat of all groups: long-time smokers with chronic obstructive pulmonary disease.

That was the key finding in a 27-center, randomized, double-blind, placebo-controlled trial involving 499 highly nicotine-dependent subjects with mild to moderate COPD and an average 41-year history of smoking, Dr. Donald P. Tashkin said at the annual meeting of the American College of Chest Physicians.

Participants were randomized to 12 weeks of varenicline (Chantix) at 1 mg twice daily or placebo and were followed out to 52 weeks in the blinded post-

Varenicline is 'probably one of the most effective' treatment strategies to help one of the toughest-to-treat of all groups: long-time smokers with chronic obstructive pulmonary disease.

treatment phase of the trial. All subjects received smoking cessation counseling throughout the study.

The primary study end point was continuous abstinence during weeks 9-12—the last month of therapy—as confirmed by exhaled carbon monoxide measurements. This was achieved by 43% of the varenicline group and 9% of controls, reported Dr. Tashkin, emeritus professor of medicine at the University of California, Los Angeles.

The major secondary end point was continuous abstinence during weeks 9-52. This was accomplished by 19% of the varenicline group, a success rate more than triple the 6% figure among controls.

Serious adverse events occurred in 2.8% of varenicline-treated patients and 4.4% of controls. There was no difference between the two groups in the incidence of depression or other psychiatric disorders; however, patients with serious mental illnesses were not eligible to enroll in the study.

The most common adverse events associated with varenicline were nausea, reported by 27% of treated patients compared with 8% of controls, and abnormal dreams, reported by 11% on varenicline and 3% on placebo.

Study participants averaged 24 cigarettes per day at baseline. Eighty percent had previously made one or more unsuccessful attempts to quit. Their mean 6.1-point score on the 10-point Fagerström Test for Nicotine Dependence was indicative of their high level of nicotine dependence.

Dr. Tashkin noted that more than 12 million Americans carry the diagnosis of COPD, and 80%-90% of them are smokers. Treatment guidelines from the Global Initiative for Chronic Obstructive Lung

Disease identify smoking cessation as the single most effective intervention both in preventing the development of COPD as well as in slowing progression of the disease.

"I would think that varenicline would be first-line therapy for patients with COPD who continue to smoke," Dr. Tashkin said in an interview. "This is a very effective—probably one of the most effective—treatment strategies

to help smokers with COPD quit."

He was the lead investigator in an earlier double-blind, placebo-controlled, randomized trial that established sustained-release bupropion as a safe and effective aid in helping smokers with COPD to quit (*Lancet* 2001;357:1571-5).

"It's really not fair to compare different trials because the patient populations may be a little bit different, but nonetheless the effectiveness of bupro-

pion in the study I was involved in was less impressive than the effectiveness of varenicline in this particular study," the physician observed. ■

A related video is at www.youtube.com/InternalMedicineNews (search for 71671).

Disclosures: Dr. Tashkin is a consultant to Pfizer, which sponsored the varenicline study.

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*Whether these observed differences represent true differences in the effects of Levemir®, NPH insulin, and insulin glargine is not known, since these trials were not blinded and the protocols (eg, diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences in weight has not been established.

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