The Efficacy and Safety of Varenicline, a Selective Alpha4beta2 Nicotinic Receptor Partial Agonist, for Smoking Cessation in Patients Hospitalized with Acute Coronary Syndrome: A Randomized Controlled Trial

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Background: Less than a third of smokers hospitalized with an acute coronary syndrome (ACS) remain abstinent following discharge. We assessed whether varenicline, begun in-hospital, is efficacious for smoking cessation following ACS.

Methods: We conducted a multi-center, double-blind, randomized, placebo-controlled trial in which smokers hospitalized with an ACS were randomized to varenicline (1.0 mg twice daily) or matched placebo for 12 weeks. All patients received low-intensity counseling. The primary endpoint was point prevalence smoking abstinence assessed at 24 weeks by 7-day recall and biochemical validation using expired carbon monoxide.

Results: A total of 302 patients were randomized in the US and Canada. Demographic, smoking, and clinical characteristics were well balanced between the two study arms. Patients were primarily male (75.2%) with a mean age of 55.0 ± 9.3 years. On average, patients had smoked 35.9 ± 11.6 years and were smoking a mean of 21.4 ± 10.6 cigarettes/day at the time of ACS. Scores on the Fagerström Test of Nicotine Dependence ranged from 0 to 10, with 80.4% of patients having scores ≥ 4 indicating moderate or severe dependence on nicotine. Patients presented with ST-segment elevation myocardial infarction (56.0%), non-ST segment elevation myocardial infarction (37.8%), and unstable angina (6.3%). At 24 weeks, patients randomized to varenicline had significantly higher rates of smoking abstinence and reduction than patients randomized to placebo. For the primary endpoint of point prevalence smoking cessation, 47.3% of varenicline patients were abstinent versus 32.5% of placebo patients (number needed to treat = 6.8). Continuous abstinence rates were 35.8% and 25.8%, respectively (number needed to treat = 10.0). Reduction ≥50% in number of cigarettes smoked/day were 67.4% and 55.6%, respectively (number needed to treat = 8.5). Adverse event rates within 30 days of study drug discontinuation were similar between groups (serious adverse events: varenicline 11.3%, placebo 11.3%; major adverse cardiovascular events: varenicline 4.0%, placebo 4.6%).
Conclusions: Varenicline, initiated in-hospital following ACS, is efficacious for smoking cessation.

Disclosure: