Escitalopram for the prevention of peginterferon-?2a-associated depression in hepatitis C virus-infected patients without previous psychiatric disease: a randomized trial.

Abstract:
Depression is a major complication during treatment of chronic hepatitis C virus (HCV) infection with interferon-? (IFN-?). It is unclear whether antidepressants can prevent IFN-induced depression in patients without psychiatric risk factors. To examine whether preemptive antidepressant treatment with escitalopram can decrease the incidence or severity of depression associated with pegylated IFN-? in HCV-infected patients without a history of psychiatric disorders. Randomized, multicenter, double-blind, prospective, placebo-controlled, parallel-group trial. (ClinicalTrials.gov registration number: NCT00136318) 10 university and 11 academic hospitals in Germany. 181 HCV-infected patients with no history of psychiatric disorders enrolled between August 2004 and December 2008. Escitalopram, 10 mg/d (n = 90), or placebo (n = 91) administered 2 weeks before and for 24 to 48 weeks during antiviral therapy. The primary end point was the incidence of depression, defined as a Montgomery-Asberg Depression Rating Scale (MADRS) score of 13 or higher. Secondary end points were
time to depression, incidence of major depression according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, quality of life, sustained virologic response, tolerability, and safety. 32% (95% CI, 21% to 43%) of the patients in the escitalopram group developed a MADRS score of 13 or higher compared with 59% (CI, 48% to 69%) in the placebo group (absolute difference, 27 percentage points [CI, 12 to 42 percentage points]; P < 0.001). Major depression was diagnosed in 8% of the patients in the escitalopram group and 19% in the placebo group (absolute risk difference, 11 percentage points [CI, 5 to 15 percentage points]; P = 0.031). Tolerability and safety parameters did not differ between the groups. In the escitalopram group, 56% (CI, 46% to 66%) of patients achieved a sustained virologic response compared with 46% (CI, 37% to 57%) in the placebo group (P = 0.21). Results might not be generalizable to patients with previous psychiatric disease. Some patients withdrew or developed temporary elevated MADRS scores after randomization but before the study medication was started. Prophylactic antidepressant treatment with escitalopram was effective in reducing the incidence and severity of IFN-associated depression in HCV-infected patients without previous psychiatric disease. Roche Pharma and Lundbeck.