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Extended-Release Intramuscular Naltrexone

A Viewpoint by Falk Kiefer

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Alcohol craving and alcohol intake have been shown to be targets for pharmacological treatment of patients with alcoholism. In particular, naltrexone, a compound with antagonistic activity mainly at the μ-opioid receptor, has been shown to reduce alcohol intake under a variety of conditions. Naltrexone is thought to attenuate the positively reinforcing, pleasurable effects of alcohol and to reduce craving. To date, results of 24 placebo-controlled trials in approximately 3000 patients have been published for oral naltrexone. It can be concluded from these data that oral naltrexone produces a consistent decrease in the rate of relapse to heavy drinking and in drinking frequency. Medication compliance was shown to be an important predictor of outcome, and for some studies a significant treatment effect was demonstrated only when noncompliant subjects were excluded from analysis. Therefore, oral naltrexone, which requires daily administration, is likely to interfere with adherence, especially in nonabstinent patients.

Vivitrol™ [1] is an extended-release formulation of naltrexone for intramuscular administration that requires an application once every 4 weeks. Extended-release intramuscular naltrexone shows pharmacological properties consistent with oral naltrexone. In a clinical trial, the 380mg dosage of extended-release intramuscular naltrexone in combination with psychosocial therapy was shown to reduce the heavy drinking rate by 25% compared with placebo. Three earlier studies on oral naltrexone demonstrated that the effect of naltrexone on relapse to heavy drinking has a tendency to fade in the months following the end of treatment, whereas extended-release intramuscular naltrexone appeared to improve drinking outcome over a period of 18 months. This latter formulation was generally well tolerated; as with oral naltrexone, the most common adverse events were nausea, headache and fatigue.

Efficacy data for extended-release intramuscular naltrexone are in line with earlier results for oral naltrexone, suggesting that naltrexone is useful for handling relapses rather than maintaining absolute abstinence. Thus, treatment outcomes with naltrexone may be contingent upon concurrent alcohol consumption. However, patients continuing to use alcohol are highly noncompliant with any treatment option. Hence, the potential disadvantage of the reduced flexibility of a depot medication is a strong advantage in this specific situation. The once-monthly administration of extended-release intramuscular naltrexone should offer practical advantages in the use of naltrexone, and may facilitate efficacy by improving adherence to the medication. ▲

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1 The use of trade names is for product identification purposes only and does not imply endorsement.