Extended-release naltrexone, treatment for alcohol dependence, improves quality-of-life measures

1 December 2008

Most studies examining the impact of alcohol-dependence (AD) treatment on quality-of-life (QOL) have looked at psychosocial treatments. This study looked at the impact of pharmacotherapy on QOL, specifically, the effects of extended-release naltrexone (XR-NTX), a once-a-month injectable formulation for the treatment of AD. Results showed significant improvements in the QOL areas of mental health, social functioning, general health, and physical functioning.

Results will be published in the February 2009 issue of *Alcoholism: Clinical & Experimental Research* and are currently available at Early View.

"Alcohol dependence is a chronic and disabling disorder," said Helen M. Pettinati, professor of psychology in the department of psychiatry, and director of the division of treatment research at the University of Pennsylvania School of Medicine. "Heavy drinking is associated with broad impairments in health-related QOL, with the largest impact typically found for mental health and social functioning."

XR-NTX (Vivitrol™) is a once-a-month injectable formulation for AD treatment; its 380 mg dose has been FDA-approved since 2006. Daily oral NTX doses are also available, typically at 50 mg or 100 mg a day.

"If naltrexone is taken orally for 30 days, this translates to a total monthly dose of 1,500 mg or 3,000 mg," explained Pettinati, who is also corresponding author for the study. "When compared to the once-a-month 380 mg injectable dose approved by the FDA and the only dose available clinically, we can see what appears to be a hefty difference in the amount of naltrexone given over a month's period to a single individual when dosed daily versus injection. However, this 'lower' injectable dose does not appear to compromise efficacy, likely due to different and more efficient pharmacokinetic properties in the injectable formulation."

"The important issue is that if you can change people's drinking patterns, then you can also change people's QOL," observed Allen Zweben, professor and associate dean for academic affairs and research in the school of social work at Columbia University. "Pharmacotherapy has never really looked at QOL vis-à-vis drinking behavior, but it would seem that the FDA is interested in learning how people's changes in drinking can have an impact on their QOL. There's an implication that QOL changes naturally, but in this study Dr. Pettinati actually looked at and measured QOL as a factor."

The researchers randomly assigned 624 AD patients (423 males, 201 females) to one of three groups during 24 weeks of treatment – XR-NTX at 380 mg (n=205), XR-NTX at 190 mg (n=210), or placebo (n=209) – in conjunction with a standardized psychosocial intervention. QOL was assessed using the Medical Outcomes Study 36-item short-form health survey, administered at baseline and then at four-week intervals during treatment.

"There were three main findings from this study," said Pettinati. "First, the AD sample showed impairments in QOL at pre-treatment compared with population norms, especially in mental-health and social functioning. Second, the XR-NTX 380 mg group showed meaningful and significant improvements compared to the placebo group in the QOL domains of mental health, social functioning, general health, and physical functioning. Third, reductions in drinking from pre-treatment levels were correlated with improvements

in QOL."

"These finding reinforce the notion that treatment of alcoholism, whether it's by medication or psychotherapy, does work," said Zweben. "Medication thus becomes another option available to people. These findings also have implications for the issue of compliance, in that high compliance rates might have something to do with the fact that people improve their drinking as well as their QOL."

It is one thing to believe that treatment reduces drinking and that time abstinent from alcohol can lead to increased QOL improvements, said Pettinati. "It is another to show this connection with new pharmacotherapies as they become available to our AD patients."

"In terms of treatment options," said Zweben, "this study shows that pharmacotherapy may be very cost-effective. You don't necessarily have to have a separate intervention to deal with QOL issues – whether more intensive psychotherapy, or family therapy – you may be able to use one intervention to reduce drinking, and improve QOL. This study also has implications for using medication as an option. A lot of people don't believe medication has any basis in alcohol treatment, that 'alcohol is a chemical already so why are you prescribing more chemicals?' It is almost a bias against medications. These results help to reduce some of the stigma attached to using medication in terms of alcohol treatment."

Zweben noted, however, that these findings need to be replicated in future studies, that the patients examined were seeking treatment –differentiating them from the more general population of AD individuals – and that 35 to 37 percent of the patients did not receive all six injections.

Source: Alcoholism: Clinical & Experimental Research