Baclofen Cuts Alcohol Use in Cirrhosis Patients

BY JOHN R. BELL
Associate Editor

Alcohol-dependent persons with cirrhosis of the liver who were treated with baclofen, a γ–aminobutyric acid-B receptor agonist, were more than six times as likely to cease their alcohol use as were patients who took a placebo, according to a study.

The trial is the first "in which effectiveness and safety of an anticraving drug has been investigated in individuals with advanced liver disease," wrote Dr. Giovanni Addolorato of the Catholic University of Rome, and colleagues. They reported results for 84 alcohol-dependent patients with a diagnosis of cirrhosis who were randomly assigned in equal number to a 12-week regimen of either baclofen or placebo.

The baclofen dosage was 5 mg three times daily for the first 3 days and 10 mg three times daily thereafter. Mean patient age was 49 years in both groups. Patients were seen weekly for the first month, then every 2 weeks until the end of the study (Lancet 2007;370:1915-22).

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In addition, those given baclofen showed improvements in measures of liver function, including ALT, bilirubin, international normalized ratio, γ-glutamyltransferase, and albumin. The drug was also associated with a greater number of nondrinking days than was placebo (63 days vs. 31 days), as well as a lower rate of relapse to heavy drinking at 60 days (19% vs. 45%).

Treatment with baclofen also reduced alcohol cravings, as measured with the obsessive-compulsive drinking scale.

Baclofen was not associated with any hepatotoxicity. There were no incidents of encephalopathy or hyperammonemia and no serious events leading to discontinuation of the drug. Tolerability was reported as fair, with headache, tiredness, vertigo, and sleepiness reported in small numbers of patients in both groups.

These results "suggest that baclofen, because of its anticraving action and safety, could have an important role for treatment of alcohol-dependent patients with advanced liver disease," the researchers wrote. They cautioned that further studies are needed to establish optimal treatment duration and longer-term tolerance.

In a commentary accompanying the report, Dr. James C. Garbutt of the University of North Carolina at Chapel Hill, and Barbara Flannery, Ph.D., of RTI International, Baltimore, called the findings "surprisingly robust" and of potentially great clinical importance, given the routine exclusion of alcoholic patients with cirrhosis from trials of anticraving drugs because of the concern about hepatotoxicity (Lancet 2007;370:1884-5).

They also noted that the higher dropout rate in the placebo group (31%) versus the baclofen group (14%) is of interest, because it may have skewed the results in favor of baclofen, given that these were assumed to be because of relapse, and thus affected the primary end point.

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Substance Abuse Survey Findings Out

The Substance Abuse and Mental Health Services Administration has released the findings of the 2006 National Survey of Substance Abuse Treatment Services, an annual census of treatment facilities that provides data on the location and nature of alcohol and drug abuse treatment services in the United States. Almost 13,800 facilities participated in the 2006 survey. Copies of the report can be ordered, free of charge, by calling 877-726-4727 and requesting inventory number SMA06-4296. ■