

FPIN's Clinical Inquiries

Baclofen for Alcohol Use Disorder

Elin Kondrad, MD; Abria Bonner, MD; Stephanie Sandhu, MD; and Kathryn Seitz, MD

Saint Joseph Hospital Family Medicine Residency, Denver, Colorado

Stephanie Weldon, MLSS, Intermountain Health, Denver, Colorado

Clinical Question

Is baclofen effective in achieving abstinence in patients with alcohol use disorder (AUD)?

Evidence-Based Answer

Baclofen with psychosocial therapy is modestly effective in helping patients with AUD achieve abstinence, increasing abstinent days by approximately 10%. (Strength of Recommendation [SOR]: A, systematic review and meta-analysis of randomized controlled trials and cohort studies.) A total of 40% to 50% of patients can achieve or maintain abstinence at 1 year after treatment initiation. (SOR: B, several small cohort studies.) Baclofen does not show evidence of worsening liver function in patients with cirrhosis.

Evidence Summary

A 2023 Cochrane review evaluated 17 randomized controlled trials (n = 1,818) investigating the use of baclofen in patients with AUD.¹ Studies assessed baclofen compared with placebo, no treatment, and other pharmacologic therapies for achieving alcohol abstinence or reduced consumption in patients with AUD. The mean age of participants was 46.5 years, and 70% were men. Three studies recruited people with severe liver disease. In all but one study, patients

received psychosocial therapy. Treatment duration was at least 4 weeks, with a mean duration of 16 weeks. The daily baclofen dosage ranged from 30 to 300 mg. Most studies started at fixed dosages of 5 mg three times per day and increased to a total daily dosage of 30 to 80 mg. When compared with placebo, baclofen was found to increase the percentage of abstinent days in patients taking low-dose daily regimens of 30 mg or less (mean difference [MD] = 10.6%; 95% CI, 0.8 to 20.4; eight studies; 583 participants) and high-dose regimens of 100 mg or more (MD = 11.1%; 95% CI, 4.4 to 17.8; three studies; 465 participants). There were no differences in abstinent days between patients taking baclofen vs. placebo among studies using medium dosages of 30 to 100 mg daily (MD = 7.1%; 95% CI, -3.1 to 17.4; five studies; 225 participants). Compared with placebo, baclofen was found to decrease the risk of relapse in people no longer drinking alcohol (risk ratio = 0.87; 95% CI, 0.77 to 0.99; 12 studies; 1,057 participants). There were no differences in the risk of relapse at the end of treatment between low, medium, and high dosages compared with placebo. Moderate to substantial heterogeneity was noted between the included studies.

Several observational studies were not included in the Cochrane review but reported patient outcomes over a longer duration and evaluated patient safety in those with alcoholic cirrhosis. In a 2023 multicenter cohort study in France (n = 71), patients diagnosed with AUD and cirrhosis were followed over 12 months while taking baclofen.² The starting dosage was 5 mg three times per day, titrated until patient cravings ceased, with a mean titrated dosage of 75 mg per day. The participants were 79% male with a mean age of 55 years. At 12 months, 41% of patients had achieved abstinence, defined as at least 7 consecutive days without consuming an alcoholic drink. Although all the study subjects had cirrhosis, there were no serious adverse events. Limitations of this study included the small study population and recruitment bias.

A 2017 cohort study in France (n = 100) evaluated alcohol consumption and abstinence in patients treated with baclofen over 12 months.³ Participants had a mean age of 53 years, 75% were male, and 65% had cirrhosis. Baclofen was prescribed at 5 mg three times daily and titrated to a median dosage of 40 mg daily. Participants had access to a multidisciplinary team, including a hepatologist, addiction

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specialist, and psychologist. Daily alcohol consumption decreased from a median of 80 g (range: 50 to 120 g per day) to a median of 0 g (range: 0 to 30.5 g per day; $P = .004$), and 44% of patients were completely abstinent at the end of the study period. No significant adverse effects were noted in participants with or without cirrhosis. The multidisciplinary care provided may not be available to most patients in the United States, which is a possible confounding factor.

A 2016 cohort study in the United Kingdom ($n = 219$) studied the effect of baclofen on abstinence rates at 3 and 12 months in patients with AUD and liver disease.⁴ Participants had a median age of 48 years, 51% were male, and 88% had cirrhosis. Baclofen was started at 10 mg three times per day, and participants titrated to a maximum dosage of 30 mg three times per day. The final mean dose of baclofen used was not reported. Participants reported abstinence rates of 55% at 3 months and 53% at 12 months.

Recommendations From Others

The 2017 American Psychiatric Association practice guideline for the pharmacologic treatment of patients with AUD found insufficient evidence to recommend treatment with baclofen.⁵ However, the European Association for the Study of the Liver and the American Association for the Study of Liver Diseases suggest that baclofen is safe and effective in treating patients with alcohol-related liver disease.^{6,7}

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Address correspondence to Elin Kondrad, MD, at elin.kondrad@imail.org. Reprints are not available from the authors.

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