

# Utilization of Baclofen in Maintenance of Alcohol Abstinence in Patients with Alcoholic Hepatitis in a Real-life Clinical Setting

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## Introduction

Continued alcohol consumption in alcoholic hepatitis increases mortality despite other medical interventions. Thus, complete abstinence from alcohol is the most effective treatment for alcoholic hepatitis/cirrhosis. Prior studies of drugs used to reduce alcohol intake excluded patients with liver disease. Recently, baclofen, a GABA B-receptor agonist, has been shown to be effective in reducing alcohol intake in a randomized, double-blind controlled study that enrolled patients with alcoholic liver disease and treated for 90 days. Most baclofen-treated patients achieved complete abstinence from alcohol. Also, baclofen has a very low liver metabolism, making it a safe drug to use in patients with liver disease.

## Methods

Data were collected retrospectively for 1 year and parameters such as AST, ALT, total bilirubin, and drinking habits before and after treatment with baclofen. Patients enrolled were ages 21-75, with alcoholic hepatitis and alcohol dependence, with or without concurrent hepatitis infection, and desire to quit alcohol. Baclofen was started at 5mg, three times a day for three days then 10mg three times a day indefinitely. Paired t-test was used for analysis of laboratory data. Patients with hepatorenal syndrome, renal dysfunction, seizures, and psychiatric disorders were excluded.

## Results

Pre & Post Baclofen	N	Mean	Std Dev	p-value
T. Bili – pre	8	19.825	11.236	0.0057
T. Bili – post	8	3.050	3.499	
AST – pre	8	174.13	134.57	0.0438
AST – post	8	50.25	30.50	
ALT – pre	8	47.13	32.50	0.0830
ALT – post	8	23.00	6.23	

Drinking Pre-Baclofen	Drinking Post-Baclofen
1pt whiskey +6pack beer/day	Complete abstinence
1pint vodka/day	Complete abstinence
5 drinks + 1pint scotch/ day	Complete abstinence
6pack + 300ml whiskey/ day	Complete abstinence
4 drinks of vodka/day	Complete abstinence
1/2 pint /day	Complete abstinence
Whiskey/beer? /day	Complete abstinence
50 drinks/ day	3 drinks/ day

Those with the most severe illness were more willing to comply with medication, thus, showing the most improvement. About 70% reduction in total bilirubin was observed at 5 months and 90% reduction after 8 months of baclofen use. Reduction in total bilirubin and AST were statistically significant based on paired t-test. On average, baclofen was used 5 months, with 2 patients treated for over 8 months. No side effects were reported.

## Discussion

Our own clinical observation validates the previous double blind randomized trial. We had statistically significant improvement in markers of liver injury such as total bilirubin and AST. Moreover, our patients used baclofen for more than 90 days, unlike the previous study, with no side effects, validating the safety of baclofen. Alcohol abstinence is very important as it aids in reversing liver fibrosis and therefore improving liver tests and avoiding liver failure. This study demonstrates the safety and efficacy of longer duration treatment.

We demonstrate here the effectiveness of baclofen in real-life setting via retrospective review. Although the number of subjects was quite small, our study may stimulate interest in the use of this drug for this indication and lead to larger-scale prospective studies with longer duration of baclofen administration to attempt to optimize its use.

## Reference

Addolorato G, Leggio L, et al. Effectiveness and safety of baclofen for maintenance of alcohol abstinence in alcohol dependent patients with liver cirrhosis: randomized, double-blind controlled study. Lancet. 2007 Dec 8; 370(9603):1922.



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