PRIMARY BILIARY CIRRHOSIS

Fenofibrate plus UDCA promising for incomplete responders to UDCA

The findings of a pilot study offer hope to patients with primary biliary cirrhosis (PBC) who have an incomplete response to ursodeoxycholic acid (UDCA)—the only FDA-approved treatment for the chronic cholestatic liver disease. "Approximately 40% of patients with PBC do not respond completely to UDCA and may progress toward biliary cirrhosis and liver failure," explains Cynthia Levy, corresponding author of the study.

Several small clinical trials indicate that fibric acid derivatives improve liver biochemistries, serum IgM levels and also histology in patients with PBC. Levy and colleagues therefore investigated the safety and efficacy of fenofibrate in PBC patients with an incomplete response to UDCA.

To address some of the limitations of the previous studies (for example, use of suboptimal doses of UDCA, short duration or retrospective nature), the researchers undertook a prospective, open-label study in which 20 patients took fenofibrate 160 mg per day in addition to their usual dose of UDCA for 48 weeks.

Compared with the effect of UDCA alone, "…fenofibrate led to further improvement of serum alkaline phosphatase levels and this was especially true for those with early stage disease," says Levy. "Importantly, fenofibrate was safe and well tolerated; heartburn was the most common side effect in our population."

"The natural extension of this work is to conduct a randomized controlled trial of fenofibrate versus placebo in PBC patients with an incomplete response to UDCA," concludes Levy.

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