Real-World Effectiveness of Obeticholic Acid in Patients With Primary Biliary Cholangitis

Randomized studies have shown that UDCA, available since 1990, enables patients to live longer without liver transplantation.1,2 In 2016, OCA was approved by the FDA as a second-line treatment for the many patients who do not respond to UDCA. OCA is a potent farnesoid X receptor agonist and a semi-synthetic derivative of chenodeoxycholic acid. Although OCA has been studied in clinical trials,3 data on its real-world effectiveness are limited.

Dr Robert G. Gish and colleagues conducted a retrospective analysis on OCA in a real-world setting, and presented their findings in a poster at the AASLD 2020 Liver Meeting Digital Experience.4 They examined data from adult patients diagnosed with PBC who received OCA between May 2016 and September 2019, using administrative claims and a laboratory database. The analysis reviewed biochemical responses to treatment. A total of 319 patients were included in the study; 290 (90.9%) were female, and 132 (41.4%) were 65 years of age or older, with varying numbers of patients tailed for each biochemical marker.

The researchers reported a trend toward lower mean values for several relevant markers of liver function. The follow-up duration was a mean of 11.6 months (± standard deviation [SD] 9.8). ALP, which measured 293 IU/L (± SD 193) at baseline, decreased to 239 (± SD 141) in the 177 patients with follow-up data. ALT dropped from 49 IU/L (± SD 37) to 38 IU/L (± SD 33) in the 179 patients with follow-up data. AST fell from 53 IU/L (± SD 35) to 45 IU/L (± SD 33) in the 178 patients with follow-up data. GGT changed from 229 IU/L (± SD 201) to 141 IU/L (± SD 161), and total bilirubin decreased from 1.1 mg/dL (± SD 1.6) to 0.9 mg/dL (± SD 1.1).

Figure 5 shows biochemical response to OCA over follow-up based on Toronto criteria (ALP ≤1.67 × ULN) and Paris I criteria (ALP ≤3 × ULN, AST ≤2 × ULN, total bilirubin ≤1.0 mg/dL).

The study was descriptive, and statistical significance was not considered. In addition, the data were culled from insurance claims, which are subject to possible coding errors. Nevertheless, the researchers concluded that the effectiveness of OCA was seen via decreases in biochemical markers of disease progression (ALP, ALT, AST, GGT, and bilirubin) in this real-world study of PBC patients and that the responses were sustained for up to 3 years.

References
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