ELEVATE-PBC: REAL-WORLD EVIDENCE IN UDCA NON-RESPONDERS PREVIOUSLY TREATED WITH OBETICHOLIC ACID OR FIBRATES

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The ELEVATE-PBC study demonstrates that elafibranor is effective and well tolerated in real-world Italian patients with primary biliary cholangitis who had inadequate response to ursodeoxycholic acid, including those previously treated with obeticholic acid or fibrates.

KEY POINTS

- At 3 months, 84.2% of patients achieved biochemical response (ALP less than 1.67 times upper limit of normal with normal bilirubin) and 41.0% achieved complete biochemical response (normalization of both ALP and bilirubin).
- At 6 months, 82.1% achieved biochemical response and 41% achieved complete biochemical response, with no elevations in serum creatinine or total bilirubin detected.
- The study enrolled 281 patients from the Italian PBC Registry, mostly women (86.8%) with median age 61 years, of whom 27.4% had cirrhosis, 68.7% had prior obeticholic acid exposure, and 28.5% had prior fibrate exposure.
- Treatment effectiveness appeared comparable regardless of prior second-line therapies.
- Elafibranor was discontinued in 15 patients, most frequently due to gastrointestinal intolerance in 7 cases (46.6%).
- The findings are consistent with clinical trial results and support elafibranor as effective and well tolerated in UDCA non-responders.

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