

# EFFICACY OF OBETICHOLIC ACID IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS: A MULTICENTRE STUDY IN REAL-LIFE

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## Background and importance

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the revocation of the marketing authorization for obeticholic acid (OA). Efficacy in primary biliary cholangitis (PBC) could not be confirmed with available evidence.

## Aim and objectives

To assess the efficacy of OA treatment in patients diagnosed with PBC in our region.

## Material and methods

- Multicentric, retrospective and descriptive study (June 2017 to September 2024)
- Demographic and clinical variables collected: age, sex, previous treatment with ursodeoxycholic acid (UDCA), treatment duration and analytical data of liver markers [alkaline phosphatase (ALP), total bilirubin (TB), gamma-glutamyl transferase (GGT), aspartate aminotransferase (AST) and alanine aminotransferase (ALT)] at the beginning of treatment with OA and at 12 months.
- Primary endpoint: composite variable defined as the percentage of patients who achieve ALP < 1.67 times upper limit of normal (ULN), normal total bilirubin level, and a decrease in ALP  $\geq 15\%$  at 12 months.
- Secondary variables: percentage of patients who had plasma levels ULN of GGT, AST and ALT after 12 months.

## Results

- 62 patients were included (83.9% women and 16.1% men)
  - Median age 61 (35-88) years
  - All patients were treated with UDCA previously.
  - Median treatment time with OA: 36 months.

Liver markers	Basal values	At 12 months
ALP (UI/L)	233 (108-813)	180 (56-815)
TB (mg/dL)	0.5 (0.2-1.5)	0.49 (0.3-1.5)
GGT (UI/L)	173 (19-981)	61 (12-790)
AST (UI/L)	40 (17-103)	30 (12-97)
ALT (UI/L)	38 (11-118)	26 (9-137)

- At 12 months: ALP < 1.67 times ULN was achieved by 58.1% of patients, 66.1% of cases showed a normal total bilirubin level and a reduction in ALP  $\geq 15\%$  was reached by 54.8% of the population.
- After 12 months, 20.9% of patients presented plasma levels ULN of GGT, AST and ALT.

## Conclusion and relevance

- OA improved the analytical parameters of patients in our region after 12 months.
- However, a longer follow-up period is needed in our study to detect the impact on robust variables such as death or liver transplantation.

