Servicio Canario de la Salud

EFFICACY OF OBETICHOLIC ACID IN PATIENTS WITH PRIMARY BILIARY CIRRHOSIS AND INADEQUATE RESPONSE TO URSODEOXYCHOLIC ACID

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BACKGROUND

Obeticholic acid (OCA) is a synthetically modified bile acid and potent agonist of the farnesoid X nuclear receptor that is used to treat of a rare disease, the **primary biliary cholangitis (PBC)**. OCA is recently use in combination with ursodeoxycholic acid (UDCA) in adults who have not responded well enough to UDCA, or alone for adults who cannot tolerate UDCA.

PURPOSE

To evaluate the **clinical results** obtained from patients with PBC who were in treatment with OCA in our hospital.

MATERIALS AND METHODS

In this study, all patients diagnosed with PBC who were treated with OCA in our hospital were located.

Primary endpoint: percent change in alkaline phosphatase (ALP) from baseline.

Secondary endpoints: dose of OCA, change from baseline in markers of cholestasis and hepatocellular injury, analysis of possible interactions with concomitant treatments, side effects and their management.

The Electronic Clinical History (SELENE®) and the Pharmacy Service Managing Software (FARMATOOLS®) were used for the location and collection of clinical data.

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RESULTS

A total of 4 patients were evaluated.
They were all women with a mean age of 46 years (39-57), an average of 10 years (6-14) since the diagnosis, stage 3 fibrosis and a dose of 5 mg/day of OCA in combination with UDCA.
The mean baseline values of ALP were 273 IU/L (182-401) and all patients had normal values of total bilirubin. Half of patients achieved a 50% reduction in baseline levels of ALP after 60 days of treatment. The baseline levels of alanine aminotransferase decreased a 32% (23-43) in 3 patients after 7 weeks of treatment. The baseline triglyceride levels increased by an average of 38% (4-171) and baseline HDL levels decreased 30% (26-32).

Interaction detected: with the ion exchange resins, whose intake was spaced as much as possible from the OCA administration.
Main side effects: pruritus, facial rash and diarrhea. All the patients presented intense pruritus that could be controlled with the use of antihistamines.

CONCLUSIONS

OCA has shown an **excellent early response until now,** improving levels of ALP.
The most frequent adverse reaction is pruritus, which seems to be tolerated acceptably with pharmacological agents.
The combination of AUDC and OCA therefore represents a treatment option with added therapeutic value in the context of which is addressed and is currently the only medication authorized for those patients with PBC who do not obtain an adequate response to UDCA or who do not tolerate it.

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