Bezafibrate Add-on Therapy in High-Risk Primary Biliary Cholangitis is Associated with Prolonged Predicted Survival even in Patients with Incomplete Biochemical Improvements

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INTRODUCTION

Among the 50 patients of the BZF group, a total of 14 (30%) out of 46 patients with available biochemical data at 24 mo. still exhibited a Paris-2 incomplete response to BZF add-on therapy (47%), response.

In a univariate analysis, clinical significant puritus (I itch score ≥ 3), portal hypertension (PH), high values of liver stiffness as assessed by vibration-controlled transient elastography (Fibroscan), and high serum levels of total bilirubin, ALP, or AST were baseline factors associated with Paris-2 incomplete biochemical response to BZF add-on therapy (Table 1). In a multivariable analysis, PH and high levels of ALP (optimal high risk threshold > 2.53 kU/L) were independent predictors of incomplete biochemical response to BZF add-on therapy (Table 2).

The relative changes from baseline to EOS in ALP levels of BZF complete responders (BCR), BZF incomplete responders (BIR), and placebo patients (PP) are shown in Figure 1. The EOS ALP levels in BCR, BIR, and PP are shown in Figure 2.

The median (interquartile) relative changes from baseline to EOS in 15-year Globe and UK-PBC predicted mortality or need for LT of BCR, BIR, and PP are shown in Figure 3.

CONCLUSIONS

A third of PBC patients with an incomplete UDCA Paris-2 response at baseline still exhibits an incomplete biochemical response after 24 months of BZF add-on therapy.

At baseline, these patients more frequently show features of portal hypertension or ALP levels > 2.53 kU/L.

At 24 months, their ALP levels and predicted mortality or need for LT are significantly lower than those of UDCA plus placebo-treated patients, suggesting that BZF add-on therapy should not be discontinued in this situation.

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REFERENCES


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