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## **Bezafibrate: A novel and effective alternative for relieving pruritus in patients with primary biliary cirrhosis**

**Category:** Human Cholestatic and Autoimmune Liver Diseases

**Descriptor:** IO1. PBC/PSC and Other Cholestatic Disease

A. Reig, P. Sese, A. Pares, Liver Unit, Hospital Clinic, University of Barcelona, IDIBAPS, CIBERehd, Barcelona, SPAIN

**Background and Aims:** Pruritus is a common and distressing symptom in patients with primary biliary cirrhosis (PBC), and when uncontrollable it is an indication for liver transplantation. Different therapeutic approaches for pruritus have been proposed including resins, rifampicin, naltrexone, sertraline and albumin dialysis. Recent observations have indicated that fibrates may improve cholestatic itching, although no specific studies have been carried out. Therefore, we have assessed the effects of fibrates on pruritus in patients PBC who had a suboptimal response to ursodeoxycholic acid (UDCA). Patients and

**Methods:** 46 PBC patients (43 females, age  $54.3 \pm 1.5$  years) with suboptimal biochemical response to UDCA were treated with bezafibrate (400 mg/d). Apart from clinical and biochemical changes, pruritus severity was assessed by a specific questionnaires (PBC-40 and pruritus score) and with a visual analogue scale (VAS) (form 0 to 10), at baseline and after a mean of  $29 \pm 4$  months. Moreover, bezafibrate therapy was discontinued in 13 patients to evaluate the course of this symptom after bezafibrate withdrawal.

**Results:** Twenty seven patients (58.7%) experienced pruritus at baseline (mean VAS:  $4.4 \pm 0.5$ ). No significant differences regarding to prior duration of UDCA therapy, age, gender and severity of biochemical cholestasis were observed between patients with and without pruritus at the beginning of bezafibrate therapy, except for ALT which were significantly higher in patients with pruritus. Triglyceride and cholesterol levels as well as transient elastography ( $8.9 \pm 0.8$  vs  $9.3 \pm 2.7$  kPa, p: n.s) were also similar in patients with and without pruritus. Bezafibrate therapy resulted in a significant mitigation of pruritus (VAS from  $4.4 \pm 0.5$  to  $0.8 \pm 0.2$ ,  $<0.001$ ). Itch disappeared completely or partly in 17 and 7 patients, respectively. No changes in pruritus were only reported by three patients (11%). Bezafibrate discontinuation in 13 patients who have no pruritus (6 patients) or minimum pruritus (7 patients) under therapy, resulted in an increase or recurrence of pruritus (within 19 to 120 days) in all cases

(mean VAS from  $0.8 \pm 0.3$  to  $5.7 \pm 0.6$ ,  $p < 0.001$ ). In these patients, itching decreased or disappeared again after resuming bezafibrate therapy.

**Conclusion:** Bezafibrate therapy is associated with a clear relief of pruritus in patients with primary biliary cirrhosis, thus supporting that this agent must be taken into account as an effective alternative for relieving this distressing and often difficult to treat symptom of chronic cholestatic diseases.

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