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BEZAFIBRATE FOR PRIMARY BILIARY CHOLANGITIS: EFFICACY, SAFETY, AND EFFICIENCY OF AN OFF-LABEL USE PROTOCOL IN REAL WORLD PRACTICE

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BACKGROUND AND IMPORTANCE

Primary biliary cholangitis (PBC) is an autoimmune disease affecting bile ducts. Ursodeoxycholic acid (UDCA) is first-line therapy, but around 40% of patients do not respond. Obeticholic acid (OCA), approved as second-line therapy, is under review. **Fibrates**, used off-label, have shown potential as an alternative.

AIM AND OBJECTIVE

This study evaluates the **effectiveness** and **safety** of bezafibrate as a second-line treatment for PBC. Additionally, it assesses the **economic impact** of protocolizing fibrate use.

MATERIALS AND METHODS

Observational
Retrospective
Tertiary hospital

Pharmacists and hepatologists

Patients with PBC who did not respond to UDCA and receiving treatment with bezafibrate as a second-line therapy

VARIABLES
Alkaline phosphatase (ALP)
Alanine aminotransferase (ALT)
Total bilirubin (BiT)
Liver stiffness → FibroScan
Steatosis → FibroScan
Adverse effects
Treatment discontinuations

Follow-up → **12 months** (until June 2024)

- **Wilcoxon paired tests** → compare values before and after treatment
- **95% confidence intervals** → percentages

EFFECTIVENESS

Comparing before and after treatment

- **Biochemical variables**
- **Changes in FibroScan values**

SAFETY

- **Adverse effects**
- **Treatment discontinuations**

ECONOMIC IMPACT

Patients meeting POISE study inclusion criteria
(therefore being candidates to treament with OCA)

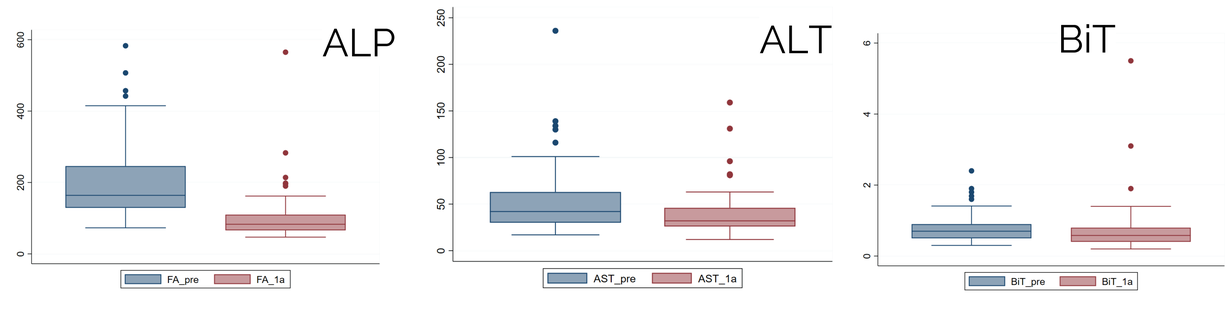
Cost-minimization analysis

OCA 5/10 mg VS **Bezafibrate 400 mg**

RESULTS

57 patients

- **ALP ↓ 81 IU/L** ($p < 0,05$)
- **ALT ↓ 14 IU/L** ($p < 0,05$)
- **BiT ↓ 0.12 mg/dL** ($p < 0,05$)
- **Normal ALP → 63%** (48,3-76,6)



No significant changes were observed in FibroScan results.

57 patients

- **Adverse effects → 11 %** (4-21)
- **Discontinuations → 7%** (2-19)

23 patients

OCA 5/10 mg	Bezafibrate 400 mg
27.507,93€ patient / year	67,12€ patient / year

Diference in anual cost → **€27,507** patient / year

Total savings → **€631,138** During the first year of follow-up

CONCLUSION AND RELEVANCE

Bezafibrate is an **effective and safe second-line therapy** for PBC, achieving significant biochemical improvements and maintaining disease control. The cost-minimization analysis highlights substantial **economic savings** when bezafibrate is protocolized, supporting its integration into clinical practice.

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