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# REAL-WORLD EFFECTIVENESS OF IBRUTINIB MONOTHERAPY IN CHRONIC LYMPHOCYTIC LEUKEMIA

I. Bretones Pedrinaci1, B. Sanchez Rodriguez2, D. Gamez Torres2, P. Nieto Guindo2, F. Sierra García 2
1 H.U. Poniente, Pharmacy, Almeria, Spain
2 H.U Torrecárdenas, Pharmacy, Almeria, Spain.

## Background and importance

Ibrutinib, the first-in-class BTK inhibitor, demonstrated superior progression-free survival (PFS) compared to chemotherapy in clinical trials. However, real-world effectiveness data are limited.

## Aim and objetives

To evaluate the real-world effectiveness and safety of ibrutinib monotherapy in CLL patients in a Spanish healthcare setting and compare it with clinical trial efficacy data.

## Material and methods

This retrospective cohort study included CLL patients treated with ibrutinib monotherapy between May 2016 and June 2023. Data were collected from electronic health records and pharmacy dispensing systems. Patients were stratified into subgroups based on treatment line: first-line, second-line, and third-line or later. Kaplan-Meier survival analyses were performed for PFS and overall survival (OS) for each subgroup and the total cohort. Safety data collected included treatment interruptions, adverse events, and specific toxicities (dermatological reactions, gastrointestinal intolerance, atrial fibrillation, infections, neutropenia, and thrombocytopenia). Statistical analysis was conducted using IBM SPSS Statistics v. 26

## Results

A total of 60 patients were included in the study. The median age was 72 years (range: 55-89), and 63.3% were male. The distribution of patients across treatment lines was: 16 (26.7%) first-line, 32 (53.3%) second-line, and 12 (20%) third-line or later. After a median follow-up of 36.6 months (range: 3.6-86.9): Median PFS and OS were not reached. Estimated mean PFS: 72.2 months (95% CI: 63.7-80.7). Estimated mean OS: 72.1 months (95% CI: 63.5-80.7). 85% of patients remained progression-free and alive. 51% of patients experienced adverse events, with 46% requiring treatment interruptions. Most common toxicities: gastrointestinal intolerance (15%) and infections (13%).
Stratified analysis:

- **First-line (n=16):** 87.5% progression-free, 93.7% survived
- **Second-line (n=32):** 86% progression-free and survived
- **Third-line or later (n=12):** 75% progression-free, 67% survived

## Conclusion and relevance

Real-world effectiveness of ibrutinib in CLL appears comparable to clinical trials data, such as RESONATE, when adjusted for follow-up time. However, safety profiles differ, with higher rates of adverse events and treatment interruptions in the real-world setting. These findings highlight the importance of real-world studies in complementing clinical trial data and informing clinical practice.

Junta de Andalucía
TORRECÁRDENAS Hospital Universitario
Hospital Universitario Poniente
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