Background and importance:
Ibrutinib is a potent Bruton tyrosine kinase inhibitor involved in the proliferation and survival of chronic lymphatic leukemia (CLL) B cells. This study was mainly motivated by suspensions for toxicity.

Aim and objectives:
The objective was to analyse the effectiveness and safety of ibrutinib in CLL.

Material and methods: This was a retrospective observational study including all patients with CLL treated with ibrutinib until September 2020 from two hospitals. Data were obtained from Formatoools and clinical records. SPSS Statistics V17.0 was used for statistical analysis. The analysed variables were demographic and clinical data (D/C), treatment, effectiveness and safety.

- **D/C:** number of patients; sex; age; the presence of mutations of chromosome 17 (del17p); progression to Richter (PR).
- **Treatment:** previous lines (PL_ibrutinib); duration of treatment (DT_ibrutinib).
- **Effectiveness:** progression free-survival (PFS) and overall survival (OS) using Kaplan–Meier statistical analysis.
- **Safety:** the most frequent number, type and degree of adverse events (AE) according to the common terminology criteria for adverse events (CTCAE) V.4.03 and necessary treatment modifications (TM) (dose reduction (DR), treatment suspension (TS), both (DR–TS)).

Results:
- **D/C:** 60 patients (58% men; median age 80 years; 55% del17p; 15% PR).
- **Treatment:** PL_ibrutinib (56% one–third, 3% ≥ four); median DT_ibrutinib 13.5 months (1–53).
- **Effectiveness:** at 12–24 months, PFS was 73.9–72.8%; OS was 85.1–76.4%. Mean values obtained were xPFS = 38 months ± 3.3 (95% CI 31.7 to 44.5) and xOS = 40.5 months ± 2.9 (95% CI 34.8 to 46.2).
- **Safety:** the most frequent AE (≥ 15%) were diarrhoea, pneumonia, skin rash and haematomas. The most frequent G3–4 AE (≥ 5%) were neutropenia, pneumonia, skin rash, anaemia and atrial fibrillation. A 53% TM by AE: 23% TS, 19% DR–TS and 11% DR.

Conclusion and relevance:
The effectiveness and safety results obtained were similar to those of pivotal studies (PS). PFS and OS at 12–24 months in our study (79.3–72.8% and 85.1–76.4%) were lower than the results of PS (89.8–82.3% and 90.2–89.6%). With regard to the safety data, PS showed lower dropout rates due to AE (6% vs 23%) and lower dose reductions (8% vs 19%) although the toxicity profile and the most frequent G3–4 AEs were similar to the PS.

REFERENCES AND/OR ACKNOWLEDGEMENTS:

1. doi: 10.1056/NEJMoa1400376
2. doi: 10.1056/NEJMoa1215637

Conflict of interest:
No conflict of interest

BACKGROUND AND SAFETY OF IBRUTINIB IN CHRONIC LYMPHATIC LEUKAEMIA: MULTICENTRE STUDY

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