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

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BACKGROUND AND IMPORTANCE

Ibrutinib is a potent Burton tyrosine kinase inhibitor involved in the proliferation and survival of chronic lymphatic leukaemia (CLL) B-cells. **This study was mainly motivated by suspensions for toxicity.**

AIM AND OBJECTIVES

The objective is to analyse the **effectiveness and safety of ibrutinib in CLL.**

MATERIALS AND METHODS

Retrospective observational study including all patients with CLL treated with ibrutinib until September-2020 from **two hospitals**. Data were obtained from Farmatools® and clinical records. SPSS Statistics® v17.0 was used for statistical analysis. The analyzed variables were:

DEMOGRAPHIC AND CLINICAL DATA (D/C)	TREATMENT	EFFECTIVENESS	SAFETY
Number of patients	Previous lines ($PL_{IBRUTINIB}$)	Progression-free-survival (**PFS**) and overall-survival (**OS**) using Kaplan-Meyer statistical analysis.	The most frequent number, type and degree of adverse events (**AE**) according to the Common Terminology Criteria for Adverse Events (CTCAE) v4.03
Sex and age			
Presence of mutations in chromosome TP53 (**mut-TP53**) and deletion of chromosome 17 (**del17p**)	Duration of treatment ($DT_{IBRUTINIB}$)		Necessary treatment modifications (**TM**) (dose reduction (**DR**); treatment suspension (**TS**); both (**DR-TS**)).
Progression to Richter (**PR**)			

RESULTS

- **Effectiveness**: at 12-24 months, the PFS was 79.3%-72.8%; the OS was 85.1%-76.4%. Mean values obtained were $\bar{x}$PFS=38 months ± 3.3 [95% CI 31.7-44.5] and $\bar{x}$OS=40.5 months ± 2.9 [95% CI 34.8-46.2].
- **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.

D/C	TREATMENT
60 patients	$PL_{IBRUTINIB}$
58% Male; median 80 years old (55-98)	56% one-third; 3% ≥four
Mut-TP53 (8.3%); **Del17p** (15%)	Median $DT_{IBRUTINIB}$ 13.5 months (1-53)
PR (8.3%)	

CONCLUSION AND RELEVANCE

The effectiveness and safety results obtained were similar to those of the pivotal studies (PS). The **PFS** and **OS** at 12-24 months of our study (79.3%-72.8% and 85.1%-76.4%) **were lower than the results of the PS** (89.8%-82.3% and 90.2%-89.6%). With regard to the safety data, **the PS show 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 AE's were similar** to the PS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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