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

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Previous lines (PLIBRUTINIB)</th>
<th>Progression-free-survival (PFS) and overall-survival (OS) using Kaplan-Meyer statistical analysis.</th>
<th>The most frequent number, type and degree of adverse events (AE) according to the Common Terminology Criteria for Adverse Events (CTCAE) v4.03</th>
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<tbody>
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<td>Sex and age</td>
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<td>Necessary treatment modifications (TM) (dose reduction (DR); treatment suspension (TS); both (DR-TS)).</td>
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<td>Presence of mutations in chromosome TP53 (mut-TP53) and deletion of chromosome 17 (del17p)</td>
<td>Duration of treatment (DTIBRUTINIB)</td>
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<td>Progression to Richter (PR)</td>
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RESULTS

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

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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