Hospital Universitario Virgen Macarena

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L01- ANTINEOPLASTIC AGENTS

REAL-WORLD SAFETY OF IBRUTINIB IN CLINICAL PRACTICE IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKAEMIA

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Background and importance

Ibrutinib was well-tolerated in clinical trials. However, there is limited data on the safety of Ibrutinib-treated patients with chronic lymphocytic leukaemia (CLL) in routine clinical practice.

Aim and objectives

To describe the safety of ibrutinib in CLL patients in a real-world setting.

Material and methods

Retrospective study in a third-level hospital. All CLL patients treated with ibrutinib (July 2016-June 2022) were included. Safety variables: adverse events observed and their severity according to Common Terminology Criteria for Adverse Events v.5.0. Information was taken from medical records and the Outpatient Dispensing software. SPSS® was used for data analysis.

Collected variables
age
sex
mutations
Binet stage at baseline
B symptoms at baseline
baseline ECOG
comorbidities
line of therapy
starting dose
discontinuation of treatment reason

Presence of high-risk cytogenetics
17p deletion
TP53 mutation
11q deletion
immunoglobulin heavy chain mutational status (IGHV)

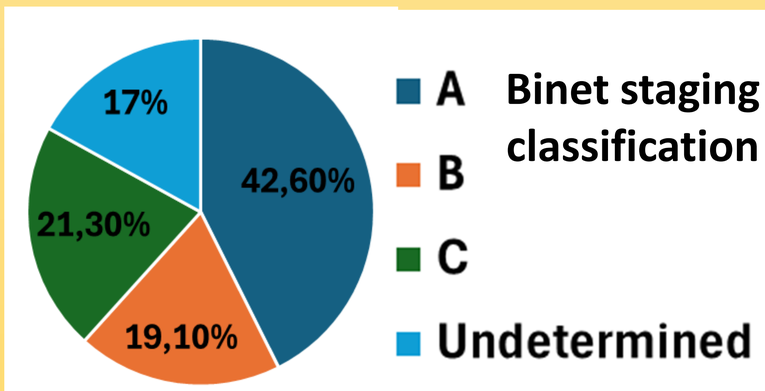
Results

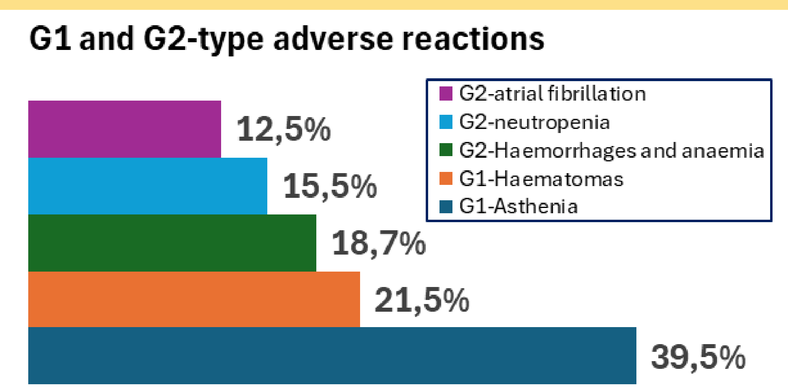
47 patients were included, 68% male, mean(±SD) age of 69.2±11 years. 91.5% were >50 years old. 19.2% patients had TP53 alteration, 59.5% unmutated IGHV, 8.5% 11q deletion, and 8.5% 17p deletion.

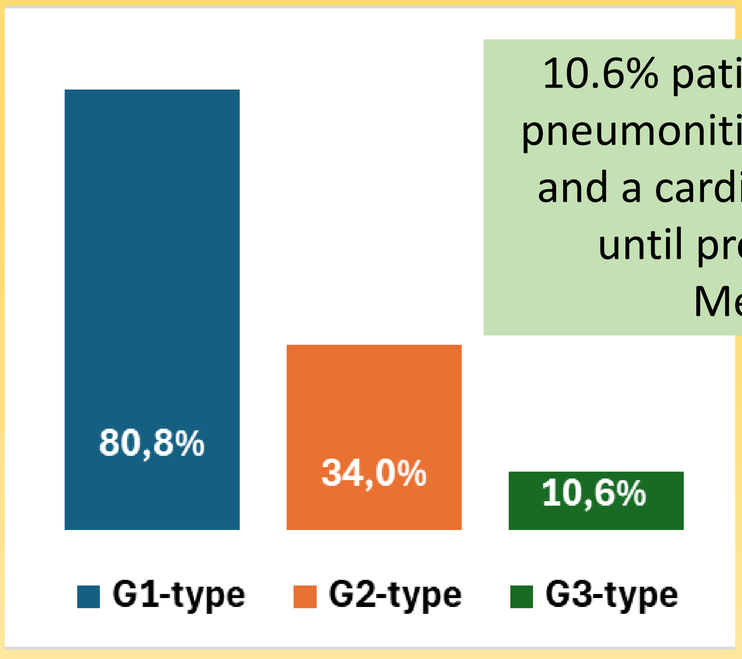
42.6% of patients had B symptoms at baseline. 51% of patients presented ECOG 1 at initiation and 40.4% presented ECOG 0.

61.7% of patients had 2 or more comorbidities: hypertension (63.8% patients), diabetes mellitus (19.15%), dyslipidaemia (19.2%) and atrial fibrillation (12.8%). 66% of patients started as a first-line treatment.

All received doses of 420mg and 4 had dose reductions due to toxicity and 1 due to intolerance. In terms of safety, 14.9% patients had to discontinue due to the occurrence of adverse reactions.







10.6% patients had G3 reactions, these being pneumonitis, neutropenia, uveitis, rectorrhagia and a cardiovascular event. Median follow-up until progression was 55.8±3.8 months. Median PFS was not reached.

Conclusion and relevance

Overall, results are consistent with those reported in clinical trials and other real-world studies. In addition, no increased risk of serious adverse events was observed. Further follow-up is needed to confirm long-term safety.