XIX CONGRESSO NAZIONALE SIES2026
Firenze | 4-6 marzo 2026
Palazzo degli Affari

XIX Congress of the Italian Society of Experimental Hematology ABSTRACT N. P077

Chronic lymphocytic leukemia and Chronic Lymphoproliferative Disorders

CLINICAL PROFILES AND TREATMENT APPROACHES IN ITALIAN PATIENTS WITH CLL IN CLINCAL PRACTICE: FINDINGS FROM A EUROPEAN CROSS-SECTIONAL SURVEY

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Introduction: Chronic lymphocytic leukemia (CLL) is a mature B-cell malignancy with a heterogeneous clinical course. Patients experience periods of remission and relapses requiring multiple lines of therapy. This work addresses a gap in real-world evidence by characterizing Italian consulting CLL population, focusing on evolving treatment patterns over time.

Methods: This study presents a descriptive analysis of real-world data from Italian patients included in a global cross-sectional survey with retrospective data collection from physicians (Adelphi CLL II Disease Specific Programme), conducted between Sept-2022 and Feb-2023. Each hematologist provided data for 8 consecutively consulting adult patients with CLL/SLL (small lymphocytic lymphoma) undergoing systemic therapy in a pre-specified 3:5 ratio of those on first-line (1L) treatment vs. previously treated (2L+). Patients were grouped by whether their 1L treatment began before or after Jan-2020, when 2nd generation covalent Bruton's tyrosine kinase inhibitors (cBTKi) had been introduced.

Results: A total of 528 Italian patients with CLL/SLL were included. At data collection, median age was 71 years and 61% were male. Initial symptoms included lymphocytosis (57%), fatigue (39%), and painless swelling (36%). At diagnosis, comorbidities were hypertension (35%), dyslipidemia (18%), and diabetes (14%). Genetic marker testing showed TP53 mutations in 25% of the 90% tested, IGHV unmutated in 56% of the 87% tested, and del(17p) detected in 19% of the 75% tested.

Among 440 patients with a documented 1L treatment start date, 193 initiated 1L before 2020, while 247 started in 2020 or later. For 88 patients, year of 1L initiation was not available.

Among patients who initiated 1L prior to 2020 (n=193), the therapeutic approach predominantly consisted of chemoimmunotherapy (CIT), with fludarabine + cyclophosphamide + rituximab (FCR, 40%) and bendamustine + rituximab (BR, 35%). Ibrutinib monotherapy was utilized in only 9% of patients. In 2L (n=182), ibrutinib monotherapy was most used (52%), followed by venetoclax (Ven) + R (15%) and Ven monotherapy (8%). In 3rd line (n=34), > 90% of patients received targeted therapies.

Of patients starting 1L treatment in 2020 or later (n=247), 39% received ibrutinib monotherapy, 15% BR, 12% FCR, 13% a Ven-based regimen, 6% acalabrutinib, and <1% zanubrutinib as 1L. At analysis, 90 of these patients had received a 2L: targeted agents predominated (ibrutinib 30%, Ven+R 23%, Ven 18%, acalabrutinib 6%), with only 20% receiving CIT in 2L. Of the 114 patients who had been treated with cBTKi in 1L, 28 subsequently received a Ven-based regimen and 84 had not yet required further therapy; only 2 patients received CIT after cBTKi.

Conclusions: Since 2020, CLL treatment has shifted toward targeted therapies, particularly the use of cBTKi in 1L. As novel treatments (e.g. non cBTKi) become available, determining the therapy after progression on cBTKi will be increasingly important.