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Genetic Mutational Testing in CLL Patients in the Routine Care of Eight EU Member States

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INTRODUCTION

- Testing for poor prognostic factors such as del(17p) chromosomal anomaly, mutated TP53 or NOTCH1, and unmutated IGHV has significant relevance in guiding therapy selection in CLL. [1-3]
  - These biomarkers have a major impact on disease progression and patient outcomes
- International and national guidelines are widely available. However, little is known about real-world testing implementation. [4]

OBJECTIVES

- Primary objective
  - To characterize the routine practices of testing for poor prognosis factors - del(17p), TP53 mutated, IGHV, NOTCH1, and stereotype #2 of IGHV - in patients with CLL in Belgium, France, Germany, Italy, the Netherlands, Spain, Sweden, and the United Kingdom based on published studies
- Secondary objectives:
  - To explore the reasons for performing or not performing the tests in routine clinical practice
  - To collect cost data related to testing for poor prognosis

METHODS

- A literature search was conducted in Medline (PubMed), Embase, and CENTRAL databases on 11th June 2021.
- Search was limited to articles on the study countries in English language published between 2015 and 2020.
- The systematic literature review focused on routine practice, therefore research articles where testing for biomarkers was driven by study protocols were excluded.
- The proportions of tested patients with CLL for the different markers among full study cohorts were calculated and were expressed in fractional form (0 to 1).
- Information on the reasons for not testing and real-world costs was also collected.
- Qualitative and descriptive quantitative synthesis of extracted data was performed.
- The review protocol was registered with the PROSPERO register, in accordance with PRISMA guidelines [5] (CRD42021296570).

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RESULTS

- Our review identified 90 relevant articles with observational studies of CLL patients (***Figure 1***):
  - 68% of the included studies reported data on routine screening for IGHV mutational status, 67% on del17p, 27% on TP53 disruption, 21% on TP53 mutation and 10% on NOTCH1 mutation
  - None of the identified studies reported data on routine testing for IGHV stereotype #2
- A trend for increased testing rates was observed in publications from 2010 onwards with the highest growth in TP53 mutation testing (***Figure 2***).
- Reported routine testing rates in regional and country-level studies tended to be lower than rates for institutional studies (***Figure 3***).
- Reasons for not testing all patients were reported only in 4 studies
  - Limited availability of biological samples and/or testing facilities, lack of testing recommendations in national guidelines and in local CLL clinical protocols were mentioned as reasons.
- No cost data could be identified in the literature, except for a single study in Germany where internal hospital costs of testing were calculated.

FIGURE 1: PRISMA diagram for the review

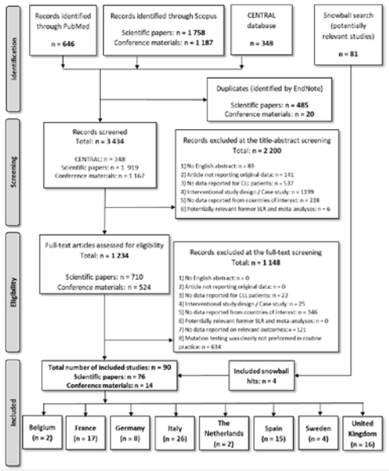
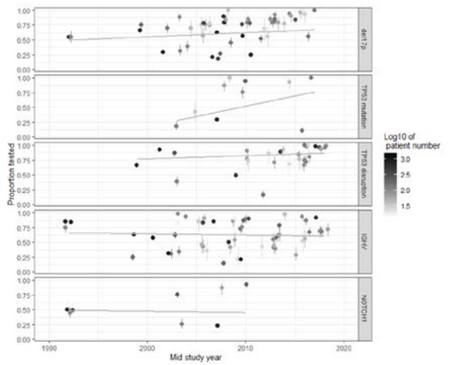
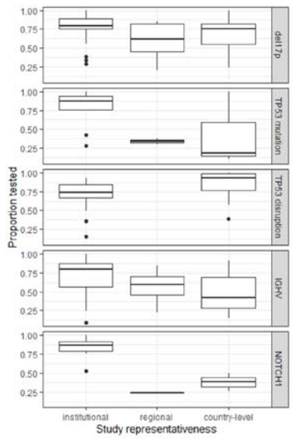


FIGURE 2: Temporal trends in the proportions of tested patients in observational study cohorts



The horizontal axis shows the middle year of the study period. Symbol darkness indicates study size (number of enrolled patients). The vertical lines across symbols show 95% margin of error of proportion estimates.

FIGURE 3: Testing rates in the included studies, stratified by geographical representativeness of the involved study sites



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KEY TAKEAWAY

A large number of studies is available on poor prognosis marker testing in routine clinical care of patients with CLL. However, there is a large heterogeneity, which was illustrated here, with geographical representativeness of the studies.

Testing rates should be increased in order to improve the outcomes of patients with CLL.

CONCLUSIONS

- A positive trend for testing to increase over time was observed in the included studies, with the vast majority of patients tested for del(17p)/ TP53 disruption in the recent years.
- Common reasons for not testing some patients in routine care was poorly reported in literature and require further elucidation.
- Testing rates appeared higher in studies conducted at single institutions than in studies from regional/national studies.

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DISCLOSURES

Marcell Csanádi, János G. Pitter, Tamás Ágh, and Zoltán Vokó are employees of Syreon Research Institute and Emőke Rédai is employee of Syreon Research Romania. Syreon Research Institute received grant from Janssen Global Services, LLC to conduct the study.

Anna Walder was MSc candidate at University of Lucerne and intern at Janssen Pharmaceutical Companies of Johnson & Johnson during conduct of study.

Stefan Boes is an employee of University of Lucerne.

Liva Andersone, Clare Hague, Gonçalo MC Rodrigues are employees of Janssen Pharmaceutical Companies of Johnson & Johnson.

The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the poster apart from those disclosed.

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