CLL/NHL – Patient registry OncoReg (Rituximab original vs. biosimilar)

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Introduction

Rituximab is a biotechnologically produced chimeric anti-CD20 monoclonal antibody that is used as a drug in cancer immunotherapy, primarily for the treatment of malignant lymphomas. Since May 2017, the first biosimilar Truxima has been available for the treatment of chronic lymphocytic leukemia (CLL) and non-Hodgkin's lymphoma (NHL).

Methods

Data on the therapy of CLL (ICD-10 C91.1) and NHL (ICD10 C82-C88) were analysed within the national scientific progress registry ONCOReg of the Project team of Internal Oncology (PIO). The registry contains the progress documentation of a total of 35,713 patients with 100,604 therapies from 373 practices, among them 1,944 haematological diseases from 76 practices nationwide.

Results

This analysis examines patients who started therapy in June 2017 and who had been treated with a therapy containing rituximab. Out of 286 registered patients, 174 are documented and evaluable. 93 (53.4%) patients received a biosimilar, of which 82 (88.2%) received Truxima. 1 patient received a biosimilar and MabThera.

76 (43.7%) patients had chronic lymphocytic leukemia, 98 (56.3%) had non-Hodgkin's lymphoma. The median age at the start of therapy was 72 (26-92) years, the general condition 1 (0-2) according to ECOG, 64.9% men; 35.1% women.

Therapy: 123 (70.7%) patients received a first-line therapy, 125 (71.8%) patients received a combination therapy of bendamustine/rituximab. A median of 6 cycles was administered. The median dose of rituximab is 2,250 mg/m². 42 (24.1%) patients continue to receive rituximab as maintenance therapy.

Concomitant medication per patient: 26.4% G-CSF; 14.9% blood substitute; 21.3% antibiotic; 13.8% analgesic

The dose was reduced for 39 (22.4%) patients, the therapy was postponed for 79 (45.4%). 30 (17.2%) patients had to be hospitalised.

Response: 28.2% CR; 59.2% PR; 5.7% NC; 2.3% PD; 4.6% not assessable

Heme side effects grade 3/4 per patient: 25.9% neutropenia; 23.6% leukopenia; 8.1% thrombopenia; 7.5% anemia

Non-heme side effects grade 1-4 per patient (<20%): 32.8% nausea; 29.9% infection; 28.7% fatigue; 22.4% pain

Conclusion

More than 50% of patients receive a biosimilar in clinical routine. Objective response rates and side effects are comparable to the original.

Further data will be presented.