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Correlation between the IgG plasma concentrations and the incidence of infections in patients with chronic lymphocytic leukemia (CLL) under treatment with Privigen®

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Introduction: Privigen® is a 10% polyvalent iv. IgG preparation (IVIG) using L-proline as stabilizer. In order to investigate the efficacy and safety of Privigen® in patients with secondary immunodeficiency due to CLL, we conducted an observational study in 32 centers in Germany and Austria. The objective of the analysis presented here was to examine the correlation between IgG plasma concentrations under Privigen® treatment and the incidence of infections requiring antimicrobial treatment.

Methods: Average post-baseline IgG trough levels were calculated using the available measurements between the 2nd and the last Privigen® infusion, excluding values from treatment pauses >2 months and from the first treatment cycle (dosing interval) after IVIG re-start. Infections requiring specific antimicrobial treatment (antibiotic, antifungal, antiviral) were evaluated starting with the 2nd Privigen® infusion. In case of treatment pauses >2 months, infections during the first treatment cycle after a re-start were neglected. Furthermore, infections were neglected if they started >6 weeks after the preceding infusion. Infections lasting >1 month were counted in more than one cycle, as appropriate. For the analysis, the patient population (n = 160) was subdivided into a high-IgG-level group (average trough IgG >5 g/L; mean 6.6 g/L; n = 91) and a low-IgG-level group (average trough IgG ≤5 g/L; mean 4.3 g/L; n = 20); 49 patients had no evaluable IgG trough levels.

Results: 160 CLL patients (88 m, 72 f; mean 70 years, 78 kg) were included in the study. 46% had Binet stage A, 37% B and 14% C (3% missing). The patients underwent a total of 1,480 treatment cycles with Privigen®, with a median observation period of 10.2 months. Average doses per treatment cycle were higher in the high-IgG-level group than those in the low-IgG-level group (15.2 g vs. 10.4 g; p = 0.013); the median duration of the treatment cycles was 28 d in both groups. Infections requiring specific antimicrobial treatment were recorded in 3.9% vs. 8.0% of the treatment cycles (high-IgG-level group vs. low-IgG-level group, p = 0.028), corresponding to 51 vs. 104 of such infections per 100 patient years. Adverse events possibly related to Privigen® were reported for 1.2% of all infusions; no increase with dose was observed.