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Titel des Beitrags: Bendamustine combined with rituximab in patients with relapsed and/or refractory chronic lymphocytic leukemia: a multicenter phase II trial of the German Chronic Lymphocytic Leukemia Study Group.

Abstract: The objective of this trial was to evaluate safety and efficacy of bendamustine combined with rituximab (BR) in patients with relapsed and/or refractory chronic lymphocytic leukemia (CLL). Seventy-eight patients, including 22 patients with fludarabine-refractory disease (28.2%) and 14 patients (17.9%) with deletion of 17p, received BR chemoimmunotherapy. Bendamustine was administered at a dose of 70 mg/m² on days 1 and 2 combined with rituximab 375 mg/m² on day 0 of the first course and 500 mg/m² on day 1 during subsequent courses for up to six courses. On the basis of intent-to-treat analysis, the overall response rate was 59.0% (95% CI, 47.3% to 70.0%). Complete response, partial response, and nodular partial response were achieved in 9.0%, 47.4%, and 2.6% of patients, respectively. Overall response rate was 45.5% in fludarabine-refractory patients and 60.5% in fludarabine-sensitive patients. Among genetic subgroups, 92.3% of patients with del(11q), 100% with trisomy 12, 7.1% with del(17p), and 58.7% with unmutated IGHV status responded to treatment. After a median follow-up...
time of 24 months, the median event-free survival was 14.7 months. Severe infections occurred in 12.8% of patients. Grade 3 or 4 neutropenia, thrombocytopenia, and anemia were documented in 23.1%, 28.2%, and 16.6% of patients, respectively. Chemoimmunotherapy with BR is effective and safe in patients with relapsed CLL and has notable activity in fludarabine-refractory disease. Major but tolerable toxicities were myelosuppression and infections. These promising results encouraged us to initiate a further phase II trial evaluating the BR regimen in patients with previously untreated CLL.

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