Bendamustine in combination with rituximab for previously untreated patients with chronic lymphocytic leukemia: a multicenter phase II trial of the German Chronic Lymphocytic Leukemia Study Group.

We investigated the safety and efficacy of bendamustine and rituximab (BR) in previously untreated patients with chronic lymphocytic leukemia (CLL). In all, 117 patients, age 34 to 78 years, 46.2% of patients at Binet stage C, and 25.6% of patients age 70 years or older received BR chemoimmunotherapy for first-line treatment of CLL. Bendamustine was administered at a dose of 90 mg/m² on days 1 and 2 combined with 375 mg/m² rituximab on day 0 of the first course and 500 mg/m² on day 1 during subsequent courses for up to six courses. Overall response rate was 88.0% (95% CI, 80.7% to 100.0%) with a complete response rate of 23.1% and a partial response rate of 64.9%. Ninety percent of patients with del(11q), 94.7% with trisomy 12, 37.5% with del(17p), and 89.4% with unmutated IGHV status responded to treatment. After a median observation time of 27.0 months, median event-free survival was 33.9 months, and 90.5% of patients were alive. Grade 3 or 4 severe infections occurred in 7.7% of patients. Grade 3 or 4 adverse events for neutropenia, thrombocytopenia, and anemia were documented in
19.7%, 22.2%, and 19.7% of patients, respectively. Chemoimmunotherapy with BR is effective and safe in patients with previously untreated CLL.