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Real-world efficacy and safety of bendamustine with or without rituximab in treatment-naïve older patients with chronic lymphocytic leukemia: retrospective analysis by age group from a German registry

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Purpose: Bendamustine, a unique alkylating agent with a multifaceted mechanism of action, is effective front-line therapy for chronic lymphocytic leukemia (CLL). The cytotoxic activity of bendamustine against CLL-derived cell lines is synergized by rituximab, an anti-CD20 monoclonal antibody. This retrospective analysis assessed real-world efficacy and safety of bendamustine alone and combined with rituximab (BR) in 3 age groups of older treatment-naïve CLL patients from a large registry.

Methods: Records were obtained for all CLL patients in a registry from 57 German oncology practices. Patients received ≥3 cycles of first-line bendamustine monotherapy or BR. Age/treatment groups were: ≤60 years receiving BR ± prednisone [≤*60BR*]; >60 to <70 years receiving bendamustine monotherapy [*60-70B*] or BR ± prednisone [*60-70BR*]; ≥70 years receiving bendamustine monotherapy [≥*70B*] or BR ± prednisone [≥*70BR*].

Primary efficacy measure was ORR (complete response [CR] plus partial response [PR]); secondary efficacy measures included CR, PR, progression-free survival (PFS), and overall survival (OS). Adverse events (AEs) were assessed.

Results: A total 217 patients (≥61% male in each group) were included (Table). At diagnosis, all patients had an ECOG score of 0-2; 87% were Binet stage A or B; of patients with RAI score, 88% were stage 0-II. Mean treatment cycles (28 days/cycle) per group ranged from 5.1 to 5.9. Mean dose per cycle ranged from 133.6 to 165.9 mg/m^2 for bendamustine and 391.1 to 412.1 mg/m^2 for rituximab (Table). Median follow-up was 3 years (range 1-5).

Observed ORRs were >83% in all groups (Table); 1 patient each in the *60-70B* and *60-70BR* groups had progressive disease, and 1 in the ≥*70BR* group was not assessable. By Kaplan-Meier analysis, median PFS (Figure) and OS were reached in the *60-70B* (PFS: 14.8 months, OS: 41.0 months) and ≥*70B* (PFS: 32.5 months, OS: 40.1 months) groups only.

There were 26 deaths. The most common grade 3/4 hematologic AEs were febrile neutropenia (n=28) in the ≥*70BR* group, leukopenia (n=15) in the ≤*60BR* group, and leukopenia (n=25) in the ≥*70BR* group. Depression was the most common grade 3/4 nonhematologic AE, affecting all patients in the ≤*60BR* and *60-70B* groups, 48/50 patients in the *60-70BR* group, 35/36 in the ≥*70B,* and 94/95 in the ≥*70BR*. Other common grade 3/4 nonhematologic AEs included fatigue (2 patients in ≥*70BR* and 1 patient each in *60-70B* and ≥*70B*) and infections/infestations (2 patients in ≤*60BR* and 3 in ≥*70BR)*. Thirty patients were hospitalized (Table). Six hospitalizations were for hematologic, 19 for nonhematologic, 1 for hematologic/nonhematologic, and 8 for other AEs. Dose reductions were most frequent in the ≥*70B* group (67%) and least in the *60-70BR* group (12.0%). Dose delays occurred for 1 patient each in the ≤*60BR, 60-70B,* and ≥*70BR* groups and 4 patients in the ≥*70B* group.

Conclusions: This real-world chart review indicates that bendamustine with/without rituximab provides high response rates and an acceptable safety profile with low rates of dose delay in all patient age groups (≤60, 60-70, and ≥70) with previously untreated CLL. These findings are consistent with reports of large clinical trials.

Support: Teva Pharmaceutical Industries Ltd.

Table

	<60BR n=24	*60-70B* n=12	*60-70BR* n=50	*>70B* n=36	*>70BR* n=95
Mean (SD) age					
At diagnosis	50.3 (6.4)	62.6 (4.9)	63.2 (4.3)	74.5 (5.6)	72.5 (5.5)
Start of therapy	53.1 (6.2)	65.9 (2.1)	65.7 (2.5)	76.9 (4.8)	75.5 (4.5)
Mean dose (mg/m^2) per cycle					
Bendamustine	154.0 (41.5)	153.7 (32.5)	165.9 (27.0)	133.6 (39.0)	147.7 (37.6)
Rituximab	412.1 (107.6)	NA	392.1 (100.4)	NA	402.5 (71.4)
Response					
ORR %	100	83	88	97	90
CR	58	33	44	19	37
PR	42	50	44	78	53
Hospitalizations, patients (%)	3 (13)	2 (17)	6 (12)	5 (14)	14 (15)
Dose reductions, patients (%)	9 (38)	2 (17)	9 (18)	24 (67)	30 (32)
Dose delays, patients (%)	1 (4)	1 (8)	0	4 (11)	1 (1)

Figure: Kaplan-Meier estimates for PFS