

Bendamustine Retreatment of CLL in the Outpatient Setting

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Background: Several studies have proven that bendamustine is a highly active drug in the therapy of CLL^{1,2}. Nevertheless, only few data exist about the real-life use and efficacy of bendamustine-therapies in the non-trial setting. The project group of internistic oncology (PIO) therefore implemented a registry for patients in the routine use of bendamustine in the therapy of CLL³. Since 2008 a total of 616 patients have been registered, out of which 473 have been thoroughly documented. To evaluate whether a retreatment with bendamustine in relapsed CLL is still active and well tolerable we present comparative data on therapies in patients with (**group A**) or without (**group B**) bendamustine pretreatment. **Methods:** 228 documented patients in relapsed situation were retrospectively appointed to one of two groups:

	Group A	Group B
n	83	145
Gender m/w	53/30	88 /57
Median Age (range)	51-84 (74)	45-93 (72)
Ratio B/B+Rituximab in %	57/43	51/49
ECOG 0/1/2 in %	11/64/25	21/64/15
Binet A/B/C in %	4/54/42	4/45/51
Line 2./3./4./5./6.+ in %	30/30/22/13/5	56/26/10/6/2
Med. B-dose-intensity over 4 weeks	180,0 mg/m ²	185,7 mg/m ²

Results: In Group A the ORR was 80 % and the median PFS lasted 15.6 month. In the patients without prior bendamustine treatment the ORR was 84% and the median PFS lasted 21.2 month. In both groups the median OS has not been reached yet. The grade 3/4 toxicities were mostly hematologic and comparable in both groups. Similar grade 3/4 toxicities were observed for neutropenia (about 25% of the patients), thrombocytopenia (16%) and infections (5%). **Conclusions:** Bendamustine is broadly used in the routine treatment of CLL. Bendamustine-therapies show impressionable high activity and tolerability, even in an advanced-line context with prior exposition to bendamustine. The treatment results are comparable to results of clinical trials and underline the quality and feasibility of bendamustine in the outpatient treatment. Nevertheless, it is to note that this is a registry and that both groups therefore are not composed of randomized patient-populations. (cf. ECOG, patients in lines and ratio of rituximab combinations).

¹ Knauf et al. J Clin Oncol. 2009;27(26):4378-84

² Fischer et al. J Clin Oncol. 2011;29(26):3559-3556

³ Sauer et.al. Onkologie 2010;33(suppl 6):12