Primary Therapy of WM with Bortezomib and Rituximab.

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This study aimed to determine the activity and safety of weekly bortezomib and rituximab in patients with untreated Waldenström Macroglobulinemia (WM). Patients with no prior therapy and symptomatic disease were eligible. Patients received bortezomib IV weekly at 1.6 mg/m^2 on days 1, 8, 15, q 28 days x 6 cycles, and rituximab 375 mg/m^2 weekly on cycles 1 and 4. Primary endpoint was the percent of patients with at least a minor response (MR). Twenty-six patients were treated. At least MR was observed in 23/26 patients (88%) (95% CI: 70-98%) with 1 complete response (4%), 1 near complete response (4%), 15 partial remission (58%), and 6 MR (23%). The median duration of response (MR or better) has not been reached; >12 month in 59% (95% CI: 31%, 78%) of patients. The median time to progression (TTP) has not been reached, with an estimated 1-year event free rate of 79% (95% CI, 53, 91%). Common grade 3 and 4 therapy related adverse events included reversible neutropenia in 12%, anemia in 8%, and thrombocytopenia in 8%. No grade 3 or 4 neuropathy occurred. The combination of weekly bortezomib and rituximab exhibited significant activity and minimal neurological toxicity in patients with untreated WM.