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PENTOSTATIN, CYCLOPHOSPHAMIDE AND RITUXIMAB: AN EFFECTIVE REGIMEN FOR PATIENTS WITH WALDENSTRÖM'S MACROGLOBULINEMIA.

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Pentostatin has demonstrated significant activity as a single agent in patients with low-grade B- and T-cell lymphomas, and is less myelosuppressive than other purine analogs. We have conducted a phase II trial with the combination of pentostatin, cyclophosphamide and rituximab in patients with Waldenström's Macroglobulinemia (WM), followed by a maintenance therapy with rituximab (375mg/m²) every 3 months) for those patients achieving complete or partial remission after 4 to 6 cycles. 17 patients with WM have been enrolled to date, 11 of whom are evaluable for tumor response after at least 3 cycles. 9 patients were untreated, 8 had previously been treated with 1 to 3 regimens. All patients received pentostatin 4 mg/m², cyclophosphamide 600 mg/m², and rituximab 375mg/m² on day 1, and cycles were repeated every 3 weeks. An objective tumor response after PC was confirmed in 9 out of 11 evaluable patients (82%), with 2 CR (18%) and 7 PR. Toxicity was mild, with only infections WHO grade 2-3 and nausea/vomiting grade 2. Hematotoxicity grade 3 occurred after 9 of 49 cycles (18.3%), grade 4 after 2 cycles (4%). 9 patients were subsequently treated with rituximab every 3 mo. None of them has relapsed to date with stable IgM serum levels. In 3 patients with PR after completion of chemotherapy, remission has further improved, with normalisation of the IgM level in 1 patient and achievement of a complete remission in another. Our data indicate that PC is safe and highly active in patients with WM. Maintenance therapy of WM with rituximab as single infusion every 3 months can be administered safely and may convert patients with PR to CR.