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Addition of amifostine to the CHOP regimen in elderly patients with aggressive non-Hodgkin lymphoma: a phase II trial showing reduction in toxicity without altering long-term survival.

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Abstract

We report the 8-year follow-up of 34 patients aged ≥69 years old with NHL included in a phase IIb openlabel randomized parallel groups study to evaluate the effectiveness of amifostine in preventing the toxicity of cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP regime) . Patients were randomized to receive classical CHOP (cyclophosphamide 750 mg/m(2), doxorubicin 50 mg/m(2), vincristine 1.4 mg/m(2) [maximum 2 mg] on day 1 and prednisone 100 mg/day for 5 days) or CHOP plus amifostine (6 cycles of amifostine 910 mg/m(2) on day 1). Efficacy (time to progression, TTP; disease-free survival, DFS; overall survival, OS) and toxicity endpoints were evaluated. Thirty-four patients were randomized to A-CHOP (n=18) or CHOP (n=16). Patients with A-CHOP vs CHOP had significantly lower toxicity; neutropenia grade 4 ocurred in 13/92 (13%) vs 23/85 (27%, P=0.007) cycles, febrile neutropenia in 3/92 A-CHOP (3%) vs 8/85 (10%, P=.056) CHOP cycles, hospitalization for toxicity in 4/92 (4%) A-CHOP vs 11/85 (13%, P=.05) CHOP cycles. Median hospitalization stay for toxicity was 5 days with A-CHOP vs 8 days with CHOP (P=.05). There were no significant differences at 8 years in TTP (A-CHOP, 48.9% vs CHOP, 36.3%; P=.65), DFS (A-CHOP, 72.9% vs CHOP 55.6%; P=.50) and OS (A-CHOP, 44.3% vs CHOP, 54.4%). There was no long-term toxicity of clinical interest. The only prognostic factor identified to 8 years was the International Prognostic Index (IPI low/low intermediate risk vs high intermediate/high risk; HR=2.98; CI 95%:1.01-8.77; P=.048). These results show that amifostine can be added to the standard CHOP treatment schedule with less acute toxicity and without influencing the outcome.