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.


Abstract

We report the 8-year follow-up of 34 patients aged ≥69 years old with NHL included in a phase llb open-label 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 occurred 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.