High-dose daunorubicin in older patients with acute myeloid leukemia.

BACKGROUND: A complete remission is essential for prolonging survival in patients with acute myeloid leukemia (AML). Daunorubicin is a cornerstone of the induction regimen, but the optimal dose is unknown. In older patients, it is usual to give daunorubicin at a dose of 45 to 50 mg per square meter of body-surface area. METHODS: Patients in whom AML or high-risk refractory anemia had been newly diagnosed and who were 60 to 83 years of age (median, 67) were randomly assigned to receive cytarabine, at a dose of 200 mg per square meter by continuous infusion for 7 days, plus daunorubicin for 3 days, either at the conventional dose of 45 mg per square meter (411 patients) or at an escalated dose of 90 mg per square meter (402 patients); this treatment was followed by a second cycle of cytarabine at a dose of 1000 mg per square meter for 6 days. The primary end point was event-free survival. RESULTS: The complete remission rates were 64% in the group that received the escalated dose of daunorubicin and 54% in the group that received the
conventional dose (P=0.002); the rates of remission after the first cycle of induction treatment were
52% and 35%, respectively (P<0.001). There was no significant difference between the two groups in
the incidence of hematologic toxic effects, 30-day mortality (11% and 12% in the two groups,
respectively), or the incidence of moderate, severe, or life-threatening adverse events (P=0.08).
Survival end points in the two groups did not differ significantly overall, but patients in the
escalated-treatment group who were 60 to 65 years of age, as compared with the patients in the
same age group who received the conventional dose, had higher rates of complete remission (73%
vs. 51%), event-free survival (29% vs. 14%), and overall survival (38% vs. 23%). CONCLUSIONS: In
patients with AML who are older than 60 years of age, escalation of the dose of daunorubicin to twice
the conventional dose, with the entire dose administered in the first induction cycle, effects a more
rapid response and a higher response rate than does the conventional dose, without additional toxic
effects. (Current Controlled Trials number, ISRCTN77039377; and NetherlandsNational Trial Register
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