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AML Intergroup Study

Abstract

Purpose

Identifying true therapeutic progress in patients with acute myeloid leukemia (AML) requires a comparison of treatment strategies and results on the basis of uniform patient selection. To foster comparability across five clinical studies, we introduced a common standard arm combined with a general upfront randomization and performed prospective analyses with adjustment for differences in prognostic baseline characteristics.

Patients and Methods

Whereas the studies' own regimens differed in chemotherapies, risk adaption, and guidelines for allogeneic stem-cell transplantation, the standard arm contained uniform cytarabine- and anthracycline-based standard-dose remission induction and high-dose consolidation courses.

Results

Of 2,995 evaluable patients aged 16 to 60 years, 290 patients were randomly assigned to the common standard arm. Seventy percent of the 290 achieved complete remissions (62% with complete recovery, 8% with incomplete recovery; 95% CI, 65% to 76%). Five-year survival probabilities were 44.3% (95% CI, 37.7% to 50.7%) for overall survival, 44.8% (95% CI, 37.0% to 52.2%) for relapse-free survival, and 31.5% (95% CI, 25.7% to 37.4%) for event-free survival. Neither the unadjusted survival probabilities of the Kaplan-Meier method nor their adjustment for prognostic variables in multiple Cox regression models led to statistically significant different results in the three survival end points when the outcomes of each study were compared with the standard arm.

Conclusion

A strictly prospective comparison of different treatment strategies in patients with AML did not show clinically relevant outcome differences when compared through a common standard treatment arm. The results provide a representative basis for further therapeutic approaches.