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Abstract

PURPOSE: Minimal residual disease (MRD) is an important prognostic factor in adults with acute lymphoblastic leukemia (ALL) and may be used to guide treatment decisions. The Programa Español de Tratamientos en Hematologia (PETHEMA) ALL-AR-03 trial (Treatment of High Risk Adult Acute Lymphoblastic Leukemia [LAL-AR/2003]) assigned adolescent and adult patients (age 15 to 60 years) with high-risk ALL (HR-ALL) without the Philadelphia (Ph) chromosome to chemotherapy or to allogeneic hematopoietic stem-cell transplantation (allo-HSCT), according to early cytologic response (day 14 flow-MRD level) after consolidation.

PATIENTS AND METHODS: Patients with good early cytologic response (< 1% blasts in bone marrow at day 14 of induction) and a flow-MRD level of 0.005 to 0.011 80% at the end of consolidation were assigned to delayed consolidation and maintenance therapy, and allo-HSCT was scheduled in patients with poor early cytologic response or a flow-MRD level of 0.005 to 0.011 80% at the end of consolidation.

RESULTS: Complete remission was attained in 202 (87%) of 232 patients, and 175 (76%) of 232 who completed early consolidation were assigned by intention-to-treat to receive allo-HSCT (71% of chemotherapy) (105). Five-year disease-free survival (DFS) and overall survival (OS) probabilities were 37% and 55% for the whole series, 33% and 57% for patients assigned to allo-HSCT, and 50% and 65% for those assigned to chemotherapy. Multivariable analysis showed poor MRD clearance (HR = 1.010-3) after induction and HR = 1.055(4) after early consolidation as the only prognostic factors for DFS and OS.

CONCLUSION: Prognosis for Ph-negative HR-ALL in adolescents and adults with good early response to induction and low flow-MRD levels after consolidation is quite favorable when allo-HSCT is avoided. In this study, the pattern of MRD clearance was the only prognostic factor for DFS at 5 years.