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### Treatment of High-Risk Philadelphia Chromosome-Negative Acute Lymphoblastic Leukemia in Adolescents and Adults According to Early Cytologic Response and Minimal Residual Disease After Consolidation Assessed by Flow Cytometry: Final Results of the PETHEMA ALL-AR-03 Trial.

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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 for treatment decisions. The Programa Español de Tratamientos en Hematología (PETHEMA) ALL-AR-03 trial (Treatment of High Risk Adult Acute Lymphoblastic Leukemia [LAL-AR/2003]) assigned adolescent and adult patients (age 15 to 80 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 (< 10% blasts in bone marrow at day 14 of induction) and a flow-MRD level less than  $5 \times 10^{-4}$  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 flow-MRD level  $\geq 5 \times 10^{-4}$ .

**RESULTS:** Complete remission was attained in 282 (87%) of 326 patients, and 179 (78%) of 236 patients who completed early consolidation were assigned by intention-to treat to receive allo-HSCT (71) or chemotherapy (108). Five-year disease-free survival (DFS) and overall survival (OS) probabilities were 37% and 35% for the whole series, 32% and 37% for patients assigned to allo-HSCT, and 55% and 59% for those assigned to chemotherapy. Multivariable analysis showed poor MRD clearance ( $\geq 1 \times 10^{-3}$  after induction and  $\geq 5 \times 10^{-4}$  after early consolidation) as the only prognostic factor 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

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