A randomized controlled study in patients with newly diagnosed severe aplastic anemia receiving antithymocyte globulin (ATG), cyclosporine, with or without G-CSF : a study of the SAA Working Party of the European Group for Blood and Marrow Transplantation

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We evaluated the role of granulocyte colony-stimulating factor (G-CSF) in patients with severe aplastic anemia (SAA) treated with antithymocyte globulin (ATG) and cyclosporine (CSA). Between January 2002 and July 2008, 192 patients with newly diagnosed SAA not eligible for transplantation were entered into this multicenter, randomized study to receive ATG/CSA with or without G-CSF. Overall survival (OS) at 6 years was 76% ś 4%, and event-free survival (EFS) was 42% ś 4%. No difference in OS/EFS was seen between patients randomly assigned to receive or not to receive G-CSF, neither for the entire cohort nor in subgroups stratified by age and disease severity. Patients treated with G-CSF had fewer infectious episodes (24%) and hospitalization days (82%) compared with patients without G-CSF (36%; P = .006; 87%; P = .0003). In a post hoc analysis of patients receiving G-CSF, the lack of a neutrophil response by day 30 was associated with significantly lower response rate (56% vs 81%; P = .048) and survival (65% vs 87%; P = .031). G-CSF added to standard ATG and CSA reduces the rate of early infectious episodes and days of hospitalization in very SAA patients and might allow early identification of nonresponders but has no effect on OS, EFS, remission, relapse rates, and mortality. This study was registered at www.clinicaltrials.gov as NCT01163942.

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