Chronic graft-versus-host disease: long-term results from a randomized trial on graft-versus-host disease prophylaxis with or without anti-T-cell globulin ATG-Fresenius.

Abstract:
Previous randomized graft-versus-host disease (GVHD)-prophylaxis trials have failed to demonstrate reduced incidence and severity of chronic GVHD (cGVHD). Here we reanalyzed and updated a randomized phase 3 trial comparing standard GVHD prophylaxis with or without pretransplantation ATG-Fresenius (ATG-F) in 201 adult patients receiving myeloablative conditioning before transplantation from unrelated donors. The cumulative incidence of extensive cGVHD after 3 years was 12.2% in the ATG-F group versus 45.0% in the control group (P<.0001). The 3-year cumulative incidence of relapse and of nonrelapse mortality was 32.6% and 19.4% in the ATG-F group and 28.2% and 33.5% in the control group (hazard ratio [HR] = 1.21, P = .47, and HR = 0.68, P = .18), respectively. This nonsignificant reduction in nonrelapse mortality without increased relapse risk led to an overall survival rate after 3 years of 55.2% in the ATG-F group and 43.3% in the control group (HR = 0.84, P = .39, nonsignificant). The HR for receiving immunosuppressive therapy (IST) was 0.31 after ATG-F (P<.0001), and the 3-year probability
of survival free of IST was 52.9% and 16.9% in the ATG-F versus control, respectively. The addition of ATG-F to standard cyclosporine, methotrexate GVHD prophylaxis lowers the incidence and severity of cGVHD, and the risk of receiving IST without raising the relapse rate. ATG-F prophylaxis reduces cGVHD morbidity.