

RANDOMIZED PHASE II STUDY OF MAINTENANCE CHEMOTHERAPY VERSUS HIGH-DOSE CHEMOTHERAPY WITH AUTOLOGOUS PERIPHERAL BLOOD STEM CELL TRANSPLANTATION AS POSTREMISSION THERAPY OF AML

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To evaluate the efficacy of high-dose chemotherapy (HDC) supported by autologous peripheral blood stem cell transplantation (PBSCT) as a postremission therapy of acute myelogenous leukemia (AML), we conducted a randomized phase II study of conventional maintenance chemotherapy versus HDC with autologous PBSCT for treatment of patients with AML in first complete remission (CR). During 1996 and 2002, 123 patients with AML in first CR were enrolled to receive either 6 courses of maintenance chemotherapy or HDC consisting of busulfan, etoposide, and Ara-C with G-CSF-priming plus autologous PBSCT. Both groups of patients were compatible in regard with age and FAB classification. Of 42 patients of the chemotherapy group, 7 patients were excluded because of the complications and disease conditions. Fourteen of 44 patients in the PBSCT group were also excluded from the analysis for some reasons. At a median follow up of 30 (4-56) months, continuous CR was obtained in 18 patients (51%), while relapse and non-relapse mortality were observed in 15 (43%) and 2 (6%) patients, respectively in a group of chemotherapy . In a group of PBSCT, continuous CR, relapse and non-relapse mortality were observed in 16 (53%), 10 (33%), and 4 (13%) patients, respectively. Three-year relapse-free survival was 38% in the chemotherapy group and 60% in the PBSCT group (N.S.). Although a relapse rate is lower in a PBSCT group than in a chemotherapy group, a role of HDC with autologous PBSCT as a postremission therapy has not evaluated at this time. The final analysis will be performed in April at a median follow up of 42 (15-71) months.