

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).Between 1996 and 2002,123 patients were enrolled,and 85 of them were randomized 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 comparable in regard with age and FAB classification.Of 41 patients of the chemotherapy group,12 patients were excluded because of the complications and disease conditions. 19 of 44 patients in the PBSCT group were also excluded from the analysis for some reasons. At a median follow up of 50 months. 6 year relapse-free survival (RFS) was 47% in the chemotherapy group and 55% in the PBSCT group. On the other hand,duration required for cessation of the treatment was 359 days in the chemotherapy group and 180 days in the PBSCT group.

In our prospective randomized phase II study comparing the maintenance chemotherapy with HDC with autologous PBSCT as postremission therapy of AML,RFS appeared to be relatively higher in the HDC group than in the maintenance group; the difference was not significant.However,the treatment duration was significantly shorter in the HDC group than in the maintenance group.In order to access the efficacy of HDC with autologous PBSCT as postremission therapy of AML,we have started a prospective randomized phase III study of high-dose Ara-C versus HDC with autologous PBSCT for good and standard risk AML in first CR.