Randomized Phase II Study of Maintenance Chemotherapy versus High-Dose Chemotherapy with Autologous Peripheral Blood Stem Cell Transplantation as Postremission Therapy for AML in 1st CR (AML 1996 Study)

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To evaluate the efficacy of high-dose chemotherapy (HDC) supported by autologous peripheral blood stem cell transplantation (auto-PBSCT) as a post remission therapy for acute myelogeneous leukemia(AML), we conducted a randomized phase II study(AML 1996 Study) of conventional maintenance chemotherapy versus HDC with auto-PBSCT for treatment of patients with AML in first complete remission (CR).

Eligibility criteria includes, newly diagnosed leukemia, Age 15-64, FAB classification: M0-M7, performance status(ECOG): 0-2, with adequate organ function and $PaO_2 \geqq 60$mmHg or $SpO_2 \geqq 93\%$ and written informed consent were obtained. No statistical difference were seen in number of FAB subtypes and chromosomal abnormalities. Maintenance therapy consists of 6 coureses of chemotherapy including anthracyclines and Ara-C and HDC including BUS, VP-16 and Ara-C combined with G-CSF priming.

From Dec. 1996 to Dec. 2002, 85 patients were enrolled and 54 pts randomized, 41 in maintenance arm, 44 in HDC arm. 12 pts of maintenance arm were dropped out because of mainly complications and 19 pts of HDC arm dropped out mainly of poor PBSC mobilization. In median follow up was 56 mos, 6 yr relapse free survival of all pts were 47% and 55% in each arm, except dropped out pts were 52% and 60%, except M3 pts were 43% and 42%. No statistical difference were seen between both arms. Duration needed for therapy was 359 days and 180 days in each arm, apparently shorter in HDC group.

In our prospective randomized phase II study of conventional maintenance chemotherapy versus high-dose chemotherapy(HDC) with auto-PBSCT as post remission therapy for AML in first CR(AML 1996 Study), relapse free survival(RFS) appeared to be relatively higher in the auto-PBSCT group than in the maintenance group, but the difference was not significant. The shorter duration for concluding therapy in HDC may be beneficial for pts. In order to assess the efficacy of HDC with auto-PBSCT as post remission therapy for AML, we have started a prospective randomized phase III study of high-dose Ara-C versus HDC with auto-PBSCT for AML in first CR.(AML 2003) for low and intermediate risk group.