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RIC Allo-SCT with Flu/Bu in Comparison to Flu/Mel for AML Results in Similar Overall Survival: A Report from the ALWP of the EBMT

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Abstract



AN and MM are co-senior authors.

Background. Fludarabine plus busulfan (FB) and fludarabine plus melphalan (FM) are two widely used reduced-intensity conditioning (RIC) regimens for allogeneic hematopoietic stem cell transplantation (allo-SCT).

Patients and Methods. In the current survey, we compared transplantation outcomes in a cohort of 394 acute myeloid leukemia (AML) patients given grafts from HLA-identical siblings after FB (n=218; with a total busulfan dose ranging between 7.1 and 8.9 mg/kg p.o., or between 6.0 and 6.9 mg/kg i.v.) or FM (n=176; with a total melphalan dose ranging between 130 and 150 mg/m²). Patients given manipulated grafts and those given T cell depleting agents (ATG or alemtuzumab) were not included. At time of transplantation, 266 patients (68%) were in first complete remission (CR1), 69 (18%) in later CR, while 59 patients (15%) had advanced diseases. Three-hundreds and fifty-two patients (89%) received peripheral blood stem cells while the remaining 42 patients received bone marrows as stem cell source.

Results. Three FB patients but no FM patients failed to engraft. Median time for reaching 500 neutrophils was 17 (1-50) days in FB patients versus 14 (9-43) days in FM patients (P<0.001) probably due to the more frequent use of methotrexate in FB patients. Proportion of patients with grade I, II, III and IV acute GVHD in FB versus FM patients were 11 versus 14%, 14 versus 16%, 5 versus 7% and 4 versus 3%, respectively (P=0.7). At 2-years, cumulative

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incidence of chronic GVHD was 54±4% in FB patients, versus 48±4% in FM patients (P=0.15). After adjusting for variables with different distribution between FB and FM, incidence of chronic GVHD remained similar in FM and in FB patients (HR 0.8, 95% CI 0.6-1.1; P=0.13). Two-year relapse incidence (RI), non-relapse mortality (NRM), leukemia-free survival (LFS) and overall survival (OS) in FB vs FM patients were 31±3% versus 20±3% (P=0.007), 18±3% versus 20±3% (P=0.4), 51±4% versus 60±4% (P=0.08), and 54±4% versus 62±4% (P=0.2), respectively. Among FB patients given i.v. busulfan (n=81), 2-year RI, NRM, LFS and OS were 26±5%, 25±6%, 49±7% and 54±7%, respectively. Restricting the analyses to patients transplanted in CR1, 2-year RI, NRM, LFS and OS in FB vs FM patients were 28±4% versus 14±3% (P=0.005), 17±3% versus 22±4% (P=0.2), 55±5% versus 64±5% (P=0.2), and 59±4% versus 66±5% (P=0.5), respectively. Among FB patients given i.v. busulfan (n=59), 2-year RI, NRM, LFS and OS were 22±6% (P=0.4 in comparison to FM patients), 23±7% (P=0.5), 55±8% (P=0.2) and 60±7% (P=0.4), respectively. After adjusting for variables with different distribution between FB and FM and associated with p<0.05 in univariate analyses and taking data from all included patients, RI was significantly lower in FM than in FB patients (HR 0.5, 95% CI 0.3-0.8; P=0.01), while there was a suggestion for higher NRM in FM than in FB patients (HR 1.6, 95% CI 0.9-2.7; P=0.1). This translated to similar LFS (HR 0.8, 95% CI 0.6-1.2; P=0.2) and OS (HR 0.9, 95% CI 0.6-1.3; P=0.6) in FM and in FB patients.

Conclusions. These results suggest that although FM provided a better AML control than FB as RIC regimen for allo-SCT, the two regimens provided similar OS. Despite the current survey included a relatively large cohort of patients transplanted only as treatment for AML, multicenter randomized studies are needed to confirm these results.

Disclosures Nagler: *Pierre-Fabre Medicament*: Honoraria. **Mohty:** *Pierre-Fabre Medicament*: Honoraria.

- ✱ Asterisk with author names denotes non-ASH members.

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