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Abstract title:
Prospective multicenter phase II study of myeloablative conditioning consisted of intravenous busulfan and fludarabine +/- total body irradiation for older patients (55 years and older): Interim analysis of the JSCT FB09 study.

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Abstract Text:
Aim: Multicenter phase II study has been conducted to investigate whether myeloablative dose of intravenous busulfan (ivBu) can be used for elderly recipients.
Method: This study started in September 2009, and 32 centers participated (Trial identifier: UMIN000002426). Patients aged from 55 to 70 with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) who were planned for allo-SCT (bone marrow (BM), peripheral blood (PB), and cord blood (CB)) were enrolled. Pretransplant conditioining consisted of 30 mg/m2 of fludarabine (Flu) for 6 days (total 180 mg/m2) and 3.2 mg/kg of ivBu for 4 days (divided by 4 daily, total 12.8 mg/kg) with or without total body irradiation depending on type of donor cells. Calcineurine inhibitors + methotrexate for BM or PB recipients, and tacrolimus + mycophenolate mofetil were used for CB recipients.
Result: Thirty-eight patients were enrolled, and the study was closed in August 2010. Median age was 60 (55-68), 22 male and 16 female, 31 AML and 7 MDS were included. Donors were 8 matched and 2 1-Ag/allele-mismatched related BM/PB, 8 matched and 4 1-Ag/allele-mismatched unrelated BM, and 16 CB (≤2-Ag-mismatched). There was 1 whose total dose of ivBu was reduced (11.2 mg/kg) due to neurotoxicity (grade III). Thirty-five achieved neutrophil recovery (median day 17 (range, 11-45)). There was 1 who died early before engraftment (CB recipient, day 27) due to cerebral hemorrhage, and were 2 who failed to engraft (both CB recipients). There were 2 VOD/SOS observed. Up to 12 months post-transplant, there were 7 relapse, and 7 non-relapse mortality. Overall and event-free survivals were estimated to be 62 % and 59 % at 1 year post-transplant.
Conclusions: Myeloablative conditioning using Flu/ivBu12.8 mg/kg +/- TBI was well tolerated with acceptable low toxicities and was sufficient to allow donor cell-engraftment post allo-SCT for elderly patients with AML or MDS. (298 words)
Conflict of Interest Statement: No conflict of interest to disclose.