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731.AUTOLOGOUS TRANSPLANTATION: CLINICAL AND EPIDEMIOLOGICAL

The Efficacy of Modified Melphalan and Busulfan-Based Conditioning Regimen for Autologous-HSCT in Low-Risk and Intermediate-Risk AML Patients

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Abstract: Background: Treatment options for patients with low-risk and intermediate-risk acute myeloid leukemia (AML) patients (non-M3) who achieved complete response (CR) after one course of induction chemotherapy include consolidation chemotherapy, autologous hematopoietic stem cell transplantation (auto-HSCT) and allogeneic hematopoietic stem cell transplantation (allo-HSCT). Compared with chemotherapy, auto-HSCT could significantly reduce relapse rate, as was associated with significantly lower transplant-related mortality compared with allo-HSCT, but relapse rate was relatively high. The selection of conditioning regimen was crucial to reduce relapse rate after transplantation. In this study, we made refinements in the conditioning regimen with two alkylating agents, namely MCBA (the combination of melphalan, cladribine, busulfan, and cytarabine). We aim to investigate the efficacy of MCBA conditioning regimen for auto-HSCT in low-risk and intermediate-risk AML patients who achieved CR after one course of induction chemotherapy. **Methods:** This prospective multi-center clinical trial was conducted in 5 tertiary hospitals in China, and enrolled low-risk and intermediate-risk AML patients (non-M3) who achieved CR after one course of induction chemotherapy, followed by 1-3 courses of high-dose cytarabine consolidation chemotherapy, and underwent auto-HSCT from May 2021 to June 2023 (ChiCTR Registration ID: ChiCTR2200056167). The MCBA conditioning regimen consists of melphalan 70mg/m ^{2}/d, day -6~-5, cladribine 5mg/m ^{2}/d, day -4~-2, busulfan 3.2mg/kg/d, day -8~-7, cytarabine 2g/m ^{2}/d, day -4~-2. **Results and Discussion:** This study included a total 21 AML patients, 14 males, 7 females, with median age 41 years (ranged 20-56 years). There were 8 of low-risk and 13 of intermediate-risk. The median infused mononuclear cell and CD34+ cell counts were 12.22×10^8/kg (ranged $1.79\text{-}34.68\times10^8$/kg) and 2.28×10^6/kg (ranged $1.05\text{-}17.15\times10^6$/kg) respectively. Neutrophil and platelet engraftment were achieved in all patients, with a median time of 13 days (ranged 11-27 days) and 32 days (ranged 12-150 days) respectively. On the day of reconstitution, all patients exhibited good responses, including hematologic CR and minimal residual disease (MRD) negativity rates of 100%. 11 (52.4%) patients received maintenance therapy after auto-HSCT, with a median time of 3.5 months (ranged 1-9 months). Azacytidine, venetoclax or geritinib were the main maintenance therapies. With a median follow-up of 306 days(ranged 43-798 days), the estimated 1-year overall survival (OS) and 1-year disease-free survival (DFS) were 80.4±13.4% and 70.9±12.8%, respectively. 4 patients relapsed within 1year, and the median time from HSCT to relapse was 240 (101-314) days. The probability of relapsed rate was 29.1±12.8%. Mucositis was the main reported regimen-related toxicity, mostly were mild and well tolerated. Severe mucositis included grade II liver damage (4.8%), grade II oral mucositis (4.8%) and grade III-IV diarrhea (9.5%), respectively. **Conclusion:** The preliminary data demonstrated the efficiency of MCBA conditioning regimen for auto-HSCT in low-risk and intermediate-risk AML patients who achieved CR after one course of induction chemotherapy. The regimen-related toxicity was well tolerated.

Disclosures No relevant conflicts of interest to declare.

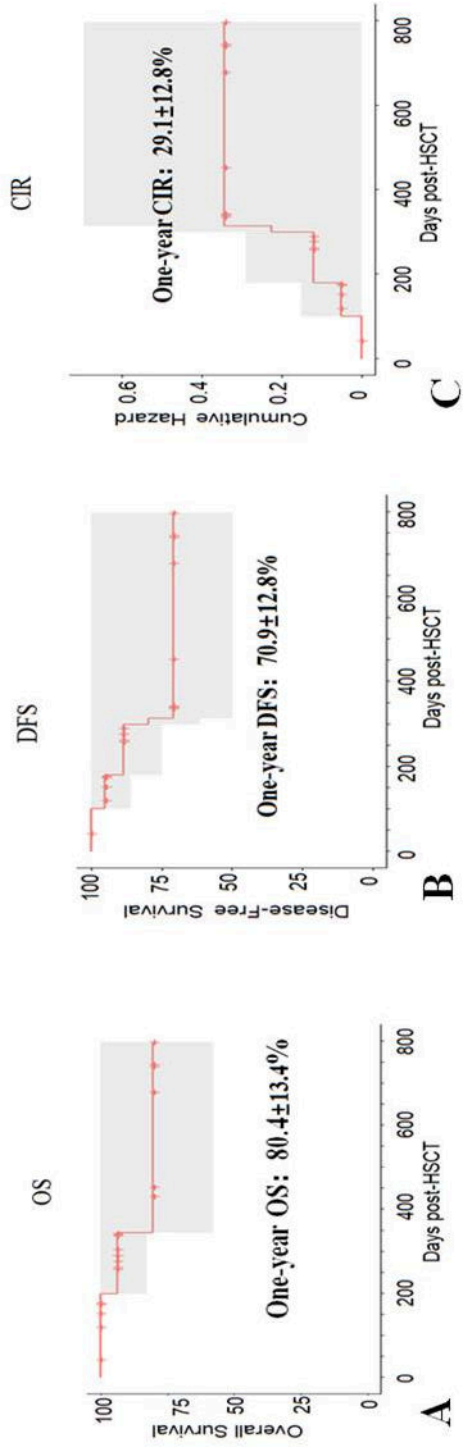

Figure 1

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