

General AML

## EBMT 2018 | Thiotepa-busulfan-fludarabine *versus* busulfan-cyclophosphamide as MAC conditioning regimen for allo-SCT in AML patients



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Francesco Saraceni from the Ravenna Hospital, Ravenna, IT, presented at the 44<sup>th</sup> Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT), results from a retrospective study by the Acute Leukemia Working Party of the EBMT, which compared the use thiotepa, busulfan, fludarabine (TBF) to busulfan plus cyclophosphamide (BuCy) conditioning regimen in adult acute myeloid leukemia (AML) patients in complete remission (CR1) who underwent allogeneic stem cell transplantation (allo-SCT).

In this retrospective study, 2,523 adult AML patients in CR who underwent first allo-SCT from either from a matched sibling donor (MSD) or unrelated donor (URD) between 2007–2015 were analyzed. Patients received either TBF (n = 153) or BuCy (n = 2,370). In order to reduce bias in this retrospective study, a 1:3 paired-matched analysis was performed and 146 patients treated with TBF was compared to 438 patients receiving BuCy.

### Key findings:

- 5-year non-relapse mortality rate for patients in the TBF and BuCy arm were 22% and 13% respectively,  $P = 0.36$
- 5-year relapse incidence (RI) rate for patients in the TBF and BuCy arm were 22% and 33% respectively,  $P = 0.4$
- 5-year leukemia-free survival for patients in the TBF and BuCy arm were 53% and 50% respectively,  $P = 0.56$
- 5-year overall survival for patients in the TBF and BuCy arm were 54% and 59% respectively,  $P = 0.88$
- 5-year graft-vs-host disease-free, relapse-free survival (GRFS) in the TBF and BuCy arm were 48% and 40% respectively,  $P = 0.48$
- TBF associated significantly with lower RI (HR = 0.6,  $P = 0.02$ ) compared to BuCy

In subgroup analysis of patients in CR1, it was observed that compared to the BuCy arm, patients in the TBF arm had a lower risk of RI (5-year RI rate, 18% vs 38%,  $P = 0.003$ ) and a trend to a better LFS (5-year LFS rate, 57% vs 50%,  $P = 0.07$ ) with no impact on OS.

TBF provides a strong anti-leukemic activity and is a valid alternative to BuCy as myeloablative conditioning for MSD and UD-SCT in young patients with AML in remission, the speaker concluded. He further added that data from this study “may serve as the scientific background for a well-designed randomized two-arm study comparing TBF to BuCy as MAC pre SCT in AML patients” below the age of 50 years in CR.

### References

1. Saraceni F. et al. Thiotepa-busulfan-fludarabine compared to busulfan-cyclophosphamide conditioning regimen for allogeneic stem cell transplantation in acute myeloid leukemia: A study from the ALWP of the EBMT. Oral abstract #OS8-7. 2018 European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting, Lisbon, PT.

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