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Conference Abstract A3

Changing Role of Allogeneic Hematopoietic Stem Cell Transplantation in the Treatment of Patients with Chronic Myeloid Leukemia

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Introduction

Chronic myeloid leukemia is a disease in which allogeneic hematopoietic stem cell transplantation remains a key therapeutic modality for patients who are resistant to tyrosine kinase inhibitors, particularly those harboring the T315I mutation and those progressing to the accelerated phase or blast crisis.

Aim

To analyze the indications for allogeneic hematopoietic stem cell transplantation in patients with chronic myeloid leukemia based on the 2025 European Leukemia Net and 2022 European Society for Blood and Marrow Transplantation recommendations as well as on our own clinical data.

Methods

According to the ELN 2025 and EBMT 2022 guidelines, key changes concern the timing of referral for allogeneic hematopoietic stem cell transplantation and the choice of therapy for different phases of chronic myeloid leukemia.

Indications for allogeneic transplantation in the first chronic phase include resistance to second-generation tyrosine kinase inhibitors, mutations conferring resistance to multiple lines of tyrosine kinase inhibitors, or the emergence of additional chromosomal abnormalities. Allogeneic transplantation may be deferred if a response is achieved with the next line of tyrosine kinase inhibitor therapy.

In the accelerated phase an individualized approach (allogeneic transplantation versus tyrosine kinase inhibitor therapy) is required, taking into account mutational status, patient age, and donor availability. In blast crisis, allogeneic transplantation is the standard of care, increasing median overall survival to 60 months compared with 21.4 months without transplantation.

Results

New data have been obtained regarding the efficacy of allogeneic transplantation.

In the first chronic phase, the best outcomes are achieved with early allogeneic transplantation in patients with tyrosine kinase inhibitor resistance.

In the accelerated phase, no significant difference in overall survival was observed between allogeneic transplantation and tyrosine kinase inhibitor therapy (5.3 versus 5.6 years), although early mortality was higher after transplantation.

In blast crisis, allogeneic transplantation increased overall survival to 60 months compared with 21.4 months with conservative therapy. According to the 2024 European registry, three-year overall survival was 23.8 months.

An innovation in the therapy of chronic myeloid leukemia is asciminib, an allosteric BCR-ABL1 inhibitor effective in patients with the T315I mutation. According to our center's data, asciminib is effective after allogeneic transplantation.

For post-transplantation relapse prophylaxis, one-year overall survival was 89% and progression-free survival was 89%. Asciminib demonstrated a favorable toxicity profile after allogeneic transplantation, with minimal vascular complications. In patients with chronic myeloid leukemia carrying the T315I mutation, asciminib is an alternative to ponatinib.

According to updated guidelines, for patients with chronic myeloid leukemia (CML) in chronic phase (CP), first-line targeted therapy (asciminib/ponatinib) is prioritized. Data from our center indicate the necessity of prophylaxis against post-transplant relapse. Prophylactic treatment with dasatinib or asciminib improves 5-year overall survival (OS) (71% vs. 41%) and major molecular response (MMR) rates (55% vs. 33%).

The decision to discontinue tyrosine kinase inhibitor (TKI) therapy is made after two years of sustained molecular remission. Practical recommendations have been established. Referral to transplant centers is indicated for patients who fail to respond to second- to fourth-line TKI therapy, harbor mutations (e.g., ASXL1, 3q26.2), exhibit disease progression, or have intolerance to TKI treatment. A therapeutic algorithm has been developed to guide treatment selection between allogeneic hematopoietic stem cell transplantation (allo-HSCT) and TKIs. In CP, allo-HSCT is recommended in cases of resistance; in accelerated phase/blast crisis, allo-HSCT combined with TKI prophylaxis is advised. Regular monitoring, including assessment of molecular response and mutation status, is essential.

Conclusion

Allogeneic hematopoietic stem cell transplantation retains its role in high-risk chronic myeloid leukemia but requires a personalized approach. New tyrosine kinase inhibitors such as asciminib and ponatinib are changing the treatment paradigm for chronic myeloid leukemia, particularly for T315I-positive disease and in the post-transplantation period, but further studies are needed. Timely referral of patients to transplantation centers improves outcomes.