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Conference Abstract A26

Efficacy of the Combination of Azacitidine, Venetoclax, and Midostaurin in A Patient With Refractory-Relapsed FLT3-ITD-Positive Acute Myeloid Leukemia: A Clinical Case

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Relevance

Acute myeloid leukemia (AML) with FLT3-ITD or FLT3-TKD mutation is characterized by high proliferative activity and a poor prognosis, including a high risk of relapse and resistance to standard chemotherapy (CT) regimens. The introduction of FLT3 inhibitors in combination regimens has shown improved remission rates and survival, especially when combined with hypomethylating agents (HMAs) and the BCL-2 inhibitor venetoclax (VEN). However, data on the efficacy of triple combinations in refractory cases remain limited.

Objective

To present a clinical case of successful remission achievement in a patient with FLT3 mutation and refractory disease treated with a combination of azacitidine (AZA), VEN, and midostaurin.

Materials and Methods

Patient T., 47 years old, was diagnosed with AML with an FLT3-ITD mutation. Initial therapy with 7+3 induction regimen (cytarabine + daunorubicin) resulted in partial remission. Reinduction with idarubicin and cytarabine (7+3 Ida) combined with midostaurin followed. Control bone marrow examination showed persistent blastemia, indicating refractory disease.

A decision was made to switch to a less intensive regimen: azacitidine 75 mg/m^2 subcutaneously on days 1–7; venetoclax with dose titration up to 400 mg/day (dose adjusted to 100 mg in combination with azoles); and midostaurin 50 mg twice daily starting from day 8 of the cycle.

Results

After the first cycle of AZA+VEN+midostaurin, the patient reported general improvement and reduced cytopenia severity. Bone marrow examination after the second cycle showed morphological remission. The treatment was continued in the same manner.

Adverse events included grade 3 neutropenia (managed with colony-stimulating factors) and transient transaminase elevation (grade 1–2). As of the latest follow-up (8 months after starting the combination), the patient remains in remission and is preparing for haploidentical hematopoietic stem cell transplantation from a sister donor.

Conclusion

In this case, failure of repeated induction, even with the inclusion of a FLT3 inhibitor in the 7+3 Ida regimen, confirmed the high chemoresistance of AML with FLT3 mutation. The use of azacitidine, venetoclax, and midostaurin allowed achievement of deep remission with complete MRD eradication and transition to potentially curative treatment— allogeneic transplantation.

These results are consistent with NCCN (v2.2025) guidelines and recent studies confirming that triple therapy including a FLT3 inhibitor and BCL-2 inhibitor on the background of HMAs may provide high MRD-negative remission rates in patients with an unfavorable molecular profile and early relapse. Thus, the combination of azacitidine, venetoclax, and midostaurin may be considered an effective bridging therapy option in this patient category, provided that toxicity and MRD status are closely monitored, with the potential for confirmation in multicenter trials.