Preinduction Azacitidine and Venetoclax Followed by Conventional Chemotherapy Conferred a 2-Year Survival Advantage in Acute Myelogenous Leukemia: Phase 2 Study Results

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Introduction

Acute myelogenous leukemia (AML) is a heterogeneous disease treated with standard chemotherapy (eg, 7+3 regimen). There is a high risk of mortality in the induction phase. Some new drugs targeting FLT3 and Bcl-2 are used in combination with chemotherapy. However, the mortality rate is still high in the induction setting.

Aim

new treatment methods for elderly patients with AML to improve the bone marrow microenvironment and consequently decrease the mortality rate in the induction phase.

Objectives

Improving the bone marrow environment in newly diagnosed AML patients through eliminating cancer cells by pre-induction approach

Methods

The study included 20 patients aged 60 to 72 (median: 66) diagnosed with AML. Patients with AML M3 were not included. Preinduction consisted of azacitidine 75 mg/m² for 5 consecutive days per month for 2 months concurrently with venetoclax at a fixed dose of 200 mg daily for the same period. Bone marrow aspiration was performed at the end of every month, and the sample was compared with those from a cohort of 30 age-matched controls

Results

Bone marrow showed blast clearance of 20% to 50% (median: 36%) at the end of the first month. After the end of the following month, blast clearance ranged from 30% to 65% (median: 50%). White blood cell counts normalized in 16 patients (75%), while platelet counts normalized in 18 patients (90%). Mortality was documented in two patients (10%) compared with 60% in the control group. The 15 patients whose bone marrow showed complete response were started on 5+2 induction for 2 cycles, followed by 4 cycles of consolidation. Progression-free survival after 1 year was 60%. Overall survival after 2 years was also 60%. After 2 years of follow-up, progression-free survival is 54% (95% CI, 48.2–58.7), and the overall survival rate remains 60% (95% CI, 56.7–63.8).

Summary

Chemotherapy plus hypomethylating agents and immunomodulators can confer a synergistic effects in AML patients

Discussion

Preinduction with azacytidine and venetoclax for 2 months was shown to decrease the mortality rate and improve progression-free and overall survival in elderly patients diagnosed with AML (excluding M3), by decreasing the percentage of blasts at induction.

References

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