Combination therapy improves survival outcomes for patients with acute myeloid leukemia

August 13 2020

A combination regimen of venetoclax and azacitidine was safe and improved overall survival (OS) over azacitidine alone in certain patients with acute myeloid leukemia (AML), according to the Phase III VIALE-A trial led by The University of Texas MD Anderson Cancer Center.

The results were presented in the virtual 25th European Hematology Association (EHA) Annual Congress and were published today in the New England Journal of Medicine.

The addition of venetoclax, an inhibitor of the BCL-2, to azacitidine resulted in a median OS of 14.7 months compared to 9.6 months in patients receiving azacitidine alone. Additionally, 66.4% of patients receiving the combination therapy achieved complete remission, while azacitidine alone achieved a 28.3% complete remission rate.

The responses to treatment were both rapid and durable: 43% of patients in the combination therapy group exhibited a response to treatment during the first cycle, and the observed median duration of remission was 17.5 months.

Treating a subgroup of AML patients without effective therapeutic optionsAlthough there is not yet a reliable standard treatment regimen for AML, many patients receive chemotherapy and/or a stem cell transplant. However, not all patients are eligible for these therapies.

"A large portion of patients with AML, including those older than 75 or those who have medical comorbidities, cannot tolerate existing treatment strategies, and the patients with AML who are ineligible for intensive chemotherapy often experience poor prognoses," said Courtney D. DiNardo, M.D., lead investigator and associate professor of Leukemia. "We launched the VIALE-A trial to evaluate whether we could safely use a combination therapy to treat this critical patient population."

In this multi-institution trial, 431 patients were randomized in a 2:1 ratio to receive either the combination of venetoclax and azacitidine or azacitidine plus placebo. The primary objective was to evaluate whether the combination improved OS compared to azacitidine, with additional goals to examine the safety of the combination therapy.

Combination treatment shows positive safety resultsThese results demonstrate that the combination of venetoclax and azacitidine has a safety profile similar to that of both drugs separately. The most common adverse events in both the experimental and placebo treatment groups were hematologic and gastrointestinal. In general, rates of adverse events were consistent between the two treatment groups, although a higher frequency of neutropenia (42% vs. 29%) and febrile neutropenia (42% vs.19%) was observed with the combination therapy comparted to azacitidine and placebo.

"The primary adverse events seen with azacitidine and venetoclax are related to increased cytopenias, including neutropenia and neutropenia-related infections," said DiNardo. "Key management guidelines include dosing interruptions between cycles to allow for count recovery in the setting of a leukemia-free marrow, and the use of granulocyte colony-stimulating factor as an adjunct to improve neutrophil count once a patient is in remission."

New research provides options for patients This research is likely to be

practice-changing for the treatment of some groups of patients with AML. Additional research is needed to evaluate how new therapies, including this combination therapy, can improve outcomes for all patients with AML.

"While this combination represents a key advance in AML therapy, improving both remission and survival rates in newly diagnosed patients with AML, many unfortunately will still relapse," said DiNardo. "Our next steps include an evaluation of azacitidine and venetoclax as a backbone to which additional novel therapeutics are being evaluated in particularly high risk populations."

More information: This trial (NCT02993523) was supported by Abbvie and Genentech.

Provided by University of Texas M. D. Anderson Cancer Center

Citation: Combination therapy improves survival outcomes for patients with acute myeloid leukemia (2020, August 13) retrieved 26 April 2024 from https://medicalxpress.com/news/2020-08-combination-therapy-survival-outcomes-patients.html

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