Ibrutinib and venetoclax combo effective as front-line therapy for select chronic lymphocytic leukemia patients

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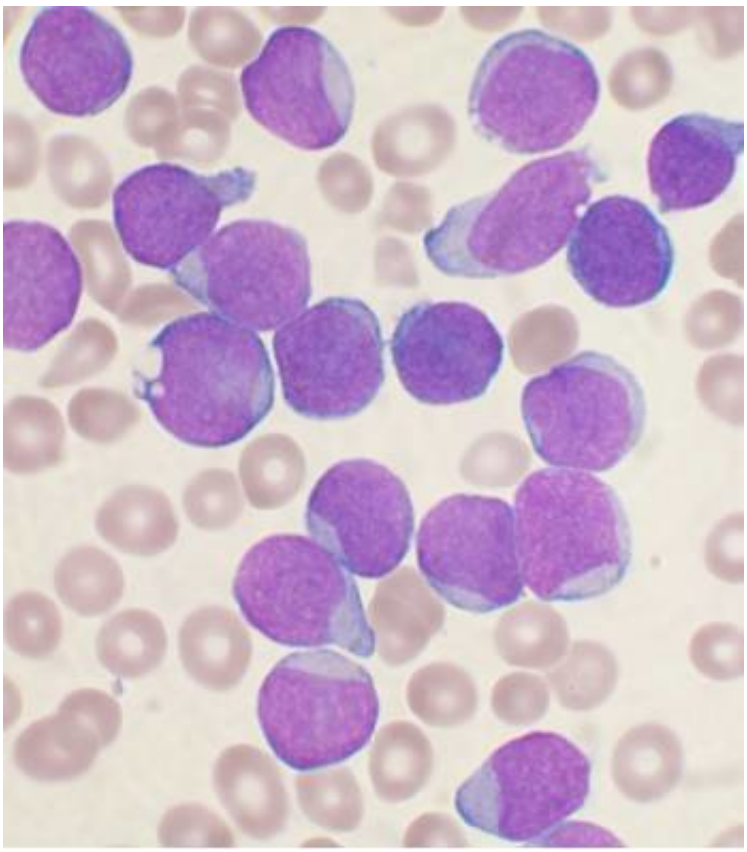

A Wright's stained bone marrow aspirate smear of patient with precursor B-cell acute lymphoblastic leukemia. Credit: VashiDonsk/Wikimedia/CC BY-SA 3.0

Ibrutinib and venetoclax, two FDA-approved drugs for treating chronic

lymphocytic leukemia (CLL), have been shown to be effective when given together for high-risk and older patients with the disease, according to a study at The University of Texas MD Anderson Cancer Center.

Study findings were published in the May 29 online issue of the *New England Journal of Medicine*. Lead researchers included Nitin Jain, M.D., associate professor of Leukemia, William Wierda, M.D., Ph.D., professor of Leukemia; and Varsha Gandhi, Ph.D., department chair ad interim of Experimental Therapeutics.

Researchers followed 80 previously untreated patients in a Phase II study. Median age was 65 years with 30 percent over age 70. Ninety-two percent had high-risk genetic anomalies. Eighty-eight percent of patients had complete remission with normal or incomplete blood count recovery after 12 cycles of treatment. Sixty-one percent of patients had complete remission with undetectable minimal residual disease.

"These efficacy results are substantially better than what has been reported with ibrutinib or venetoclax monotherapy for CLL patients," said Jain "With monotherapy, the majority of responses have been partial, and remissions with undetectable minimal residual disease in bone marrow has been rare."

Jain added that more robust therapies are needed for patients with CLL given that the majority of patients are older than 65 and existing therapies are not always effective.

"This group of patients often has unacceptable side effects and has a lower rate of complete remission and undetectable minimal residual disease," said Jain. "Our data showed that non-chemotherapy, combination therapy with ibrutinib and venetoclax demonstrated no new toxic effects compared to what has been previously reported for the

individual agents."

The study reported that 60 percent of patients developed low white blood cell counts, which was similar to what has been reported in other venetoclax combination trials. No new safety concerns were observed with the combination therapy.

While the current median follow-up of the trial is 14.8 months, Jain said that "a longer follow-up is needed to adequately assess the long-term safety of this combination."

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