

Older AML patients show promising response in drug study

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Older patients with acute myloid leukemia (AML) who were once told that nothing could be done for them are finding new hope – and life – through a clinical trial at The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute.

Preliminary findings of the phase II study suggest that older, previously untreated AML patients can achieve complete remission at a higher than expected rate when treated with the drug decitabine using a novel dosing schedule.

"This study could provide a new treatment paradigm for elderly patients with AML," says co-author Dr. John Byrd, associate director of translational research at Ohio State's Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute.

The study will be a poster presentation at the 50th Annual Meeting of the American Society of Hematology in San Francisco on Monday (12/8).

About 13,300 new cases of AML are expected this year in the United States. It is a rapidly progressive disease that results in the accumulation of immature, functionless cells in the marrow and blood, leaving the body unable to fight infections or produce enough normal red blood cells, white blood cells and platelets. The disease primarily affects people age 60 and older and is the second most common form of leukemia in adults.



Most elderly AML patients diagnosed today are offered only supportive care because their bodies are believed to be too weak to withstand the effects of chemotherapy treatment, says principal investigator Dr. William Blum, a hematologist and oncologist and researcher at Ohio State.

"The treatment of AML is difficult in anybody, but particularly for older patients who don't tolerate the 'thunderbolt' of intensive chemotherapy well," says Blum. "Some of the patients we are treating successfully had previously been told by other physicians to 'go home and die.' They were judged not to be candidates for any treatment at all because they likely would not survive the traditional, harsh chemotherapy approach."

"The development of a less toxic therapy may enable this 'silent majority' of patients who never receive treatment today to actually benefit from prolonged remissions with improved quality and length of life, without paying the price exacted by today's intensive therapy regimens," says Blum.

This ongoing study involves 33 patients age 60 to 83. A total of 58 percent of patients responded, including 42 percent who achieved complete remission. In some cases, Blum says, patients who achieved remission were then able to receive bone marrow transplants designed to further improve their chances for cure, as part of another clinical trial of transplantation specifically designed for older AML patients.

On the decitabine trial, patients received the intravenous drug for one hour a day for 10 consecutive days each month until the leukemia was gone. Subsequent cycles of the drug were given for three to five days, customized for each patient based on clinical response or toxicity.

"Results have been extremely promising, with high remission rates," says senior investigator Dr. Guido Marcucci, a researcher and medical



oncologist at Ohio State's Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute. "This research reveals the potential for a paradigm shift in the treatment of AML away from highly toxic drugs to a much less toxic alternative."

Source: Ohio State University Medical Center

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