

Unprecedented benefit seen in test of three-drug treatment for multiple myeloma

December 6 2014

In the treatment of multiple myeloma, the addition of carfilzomib to a currently accepted two-drug combination produced significantly better results than using the two drugs alone, according to a worldwide research team led by investigators from Mayo Clinic.

Their findings will be reported online Dec. 6 in the *New England Journal of Medicine*, and presented on Dec. 7 at the annual meeting of the American Society of Hematology (ASH), held in San Francisco.

Interim analysis of the ASPIRE clinical trial, which enrolled 792 patients with relapsed [multiple myeloma](#) from 20 countries, found an "unprecedented" prolongation of the time patients were free of disease progression, says the study's lead investigator, Keith Stewart, M.B., Ch.B, a Mayo Clinic oncologist in Arizona. "Patients taking three drugs—carfilzomib, lenalidomide and dexamethasone—stayed free of disease progression for 26 months on average," he says. "No one has reported anything like this before for relapsed multiple myeloma."

Researchers found that adding carfilzomib to standard treatment (lenalidomide and dexamethasone) resulted in 8.7 months of longer remission, almost 50 percent longer than the standard two-drug combination (26.3 months versus 17.6 months).

The number of patients who responded to treatment was also significantly improved by adding carfilzomib to standard treatment—87.4 percent versus 66.9 percent— and more than three

times more patients had no detectable disease after the three-drug treatment (31.8 percent versus 9.3 percent). Although results were preliminary, there was also a trend toward improved overall survival, Dr. Stewart says. "Importantly, patients on the three-drug cocktail also reported a better quality of life despite a higher intensity of treatment," he says.

These findings highlight increasing success in treating myeloma, the second most common blood cancer, says Dr. Stewart.

"Survival of multiple myeloma has almost doubled over the last decade, and the very positive outcomes from use of the three-drug combination will likely further improve outcomes," he says. "This is a nice story to tell."

Lenalidomide, a potent derivative of thalidomide, affects immune system function. Dexamethasone is a steroid drug. Carfilzomib is a proteasome inhibitor approved for use in 2012 by the U.S. Food and Drug Administration (FDA) for patients with advanced, end-stage multiple myeloma. The drug specifically targets regulation of the proteins that fuel growth of multiple myeloma.

The ASPIRE study tested use of the drug in less advanced patients. "There was concern that carfilzomib may increase side effects, especially when used with two other drugs," says Dr. Stewart.

But this was not a big issue, he says. "In fact, it appears that the frequency of most side effects, including serious toxicities, were equal in both arms of the study. When we asked patients how they were feeling, almost from day one, through the entire study, they said they felt better on the three drugs. Carfilzomib performed much better than people had expected."

Mayo Clinic is a leader in carfilzomib clinical research. Given their expertise in basic and clinical research and treatment for multiple myeloma, Mayo Clinic investigators were asked to conduct the phase I study of the agent by its developers. "We were among the first centers in the world to use this drug and the first to have a patient who responded to it, back in 2006," says Dr. Stewart. The Mayo Clinic researchers also participated in the phase II studies and were asked to lead the definitive ASPIRE clinical trial.

"We hope the results of this trial will lead to approval of this treatment combination in patients with relapsed multiple myeloma worldwide," says Dr. Stewart.

Provided by Mayo Clinic

Citation: Unprecedented benefit seen in test of three-drug treatment for multiple myeloma (2014, December 6) retrieved 11 May 2024 from <https://medicalxpress.com/news/2014-12-unprecedented-benefit-three-drug-treatment-multiple.html>

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