

New drug shows promise for myeloma patients

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Studies found lenalidomide lengthened time disease did not worsen, but risk of second cancers was doubled.

(HealthDay) -- Three new studies confirm that the drug lenalidomide can significantly lengthen the time that people with multiple myeloma experience no worsening of their disease, either after having a stem cell transplant or getting chemotherapy.

However, what isn't clear from the studies is whether or not the improved "progression-free" survival time will translate to a longer overall survival.

"These are very promising, early studies," said the author of an accompanying editorial, Dr. Ashraf Badros, a professor in the department of medicine at the University of Maryland School of Medicine, in Baltimore. "I think these studies will generate a lot of discussion."

Potential areas of debate, he said, include whether or not progression-free survival is enough if there isn't an overall [survival benefit](#). He said that progression-free survival may well justify this treatment if quality of life is significantly improved. However, none of the studies looked at quality-of-life measures. Another important factor is cost; this drug is estimated to cost about \$163,381 a year to treat one patient, according to Badros' editorial.

The studies and the editorial are published in the

May 10 issue of the [New England Journal of Medicine](#).

Multiple myeloma is a cancer that affects [plasma cells](#) in the blood. Each year, about 22,000 Americans are diagnosed with multiple myeloma, according to the [American Cancer Society](#). The current five-year survival rate for multiple myeloma is only 40 percent. However, recent advances will likely increase the survival rate for people who are diagnosed going forward, according to the cancer society.

Lenalidomide (Revlimid) alters the [immune system response](#), and has direct toxic effects on tumors, according to background information in one of the studies.

In younger people, the standard treatment is generally a stem [cell transplant](#) to replace the many of the cancerous plasma cells. However, many older patients are ineligible for this treatment.

The first study looked at lenalidomide treatment in people who weren't candidates for stem cell transplants, and it included just over 450 people over age 65 who had recently been diagnosed with [multiple myeloma](#). One group received initial chemotherapy that included lenalidomide that was also followed by maintenance therapy with lenalidomide, while the second group just received the initial chemotherapy including lenalidomide. The final group received standard chemotherapy without lenalidomide.

After an average follow-up period of 30 months, the researchers found that the first group had an average progression-free survival of 31 months compared with just 14 months for the second group and only 13 months for the final group. This study wasn't designed to assess overall survival.

"This approach is approximately doubling the remission duration of old therapies from 15 to 30

months," said study author Dr. Antonio Palumbo, from the department of hematology at the University of Torino in Italy.

Palumbo said that cost always has to be considered in treatments. He said there are some cost savings associated with lenalidomide because it's an oral medication, not one that has to be given intravenously. In addition, if it prevents complications, such as bone fractures, it may help prevent hospitalization costs and disability.

The second study, conducted by researchers from Roswell Park Institute in New York, included 468 people younger than 71 years old who were undergoing stem cell transplants. Beginning 100 days after their transplants, half the group was given daily lenalidomide and the other half received placebo. Once the disease progressed, study participants were told which treatment they were receiving, and if they were on placebo, they were allowed to start taking lenalidomide.

At the time results were unblinded, just 20 percent of those on lenalidomide had disease progression compared with 44 percent of those on placebo.

The third study, reported by French researchers, also looked at lenalidomide maintenance therapy in people who'd had a [stem cell transplant](#). This study included 614 people younger than 65. The group taking lenalidomide had an average progression-free survival of 41 months compared to 23 months with placebo. Four years after the study began, the average overall survival was similar in both groups, according to the study.

The most significant and concerning side effect was an increased risk of a second cancer. In all three studies, the rate of second cancers was more than doubled in people taking lenalidomide. Low white blood cell counts were also more commonly associated with lenalidomide therapy.

Badros said that all cancer treatments have side effects, and that for the most part, [lenalidomide](#) didn't appear to have any unexpected effects, except for the increased rate of second cancers. That finding, he said, warrants further study.

More information: Learn more about multiple myeloma from the [American Cancer Society](#).

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