Adding drug to standard care may prolong lymphoma survival

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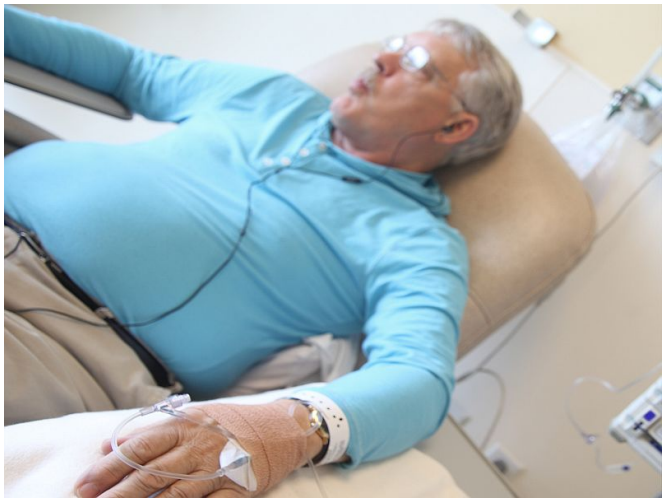

(HealthDay)—Long-term treatment with the drug rituximab (Rituxan) may extend the lives of some patients with a rare form of blood cancer, a new clinical trial finds.

The disease, known as mantle-cell lymphoma, is generally incurable. But various treatments can prolong people's lives. Some patients, for instance, are able to undergo chemotherapy to wipe out the cancer cells, followed by a stem cell transplant—to restore normal blood cells.

But while that approach can be effective for a while, most patients see the cancer come back.

So the new trial, funded by Rituxan maker Roche, looked at whether an additional step could help: Having patients take Rituxan for three years following their stem cell transplant.

Overall, researchers found, the tactic did improve patients' outlook. After four years, 83 percent of rituximab patients were still alive and progression-free—versus 64 percent of patients who had standard treatment alone.

Experts said the findings should have an immediate impact on patients' treatment.

"This should be considered a new standard of care," said Dr. Anas Younes, chief of the lymphoma service at Memorial Sloan Kettering Cancer Center, in New York City.

However, there are concerns with the long-term use of rituximab, according to Younes, who wasn't involved in the study.

The drug suppresses the immune system, so infections are always a risk, he noted.

"But," Younes added, "the benefits seem to outweigh the risks."

Dr. Steven Le Gouill, of Nantes Medical University, in France, led the study.

He agreed that "rituximab maintenance"—using it long-term, after a stem cell transplant—should become a new standard.

"The gain in terms of overall survival should encourage hematologists to prescribe rituximab maintenance for transplanted patients," Le Gouill said.

Mantle-cell lymphoma is one of about 70 subtypes of non-Hodgkin lymphoma, according to the Leukemia & Lymphoma Society. In the United States, about 4,200 people are diagnosed with the disease each year—most commonly, older men.

Doctors have long used rituximab to treat certain cancers, including mantle-cell lymphoma. The drug is a lab-engineered antibody that latches onto a protein on white blood cells (lymphocytes) called B cells; those are the cells that are affected in mantle-

cell lymphoma.

As it stands, rituximab is used along with high-dose chemotherapy drugs to wipe out the cancerous B cells. Some patients then undergo an "autologous" stem cell transplant. That means they have some of their own blood-forming stem cells removed before their drug regimen; afterward, the stem cells are infused back into the body, to restore new, healthy blood cells.

Some patients—including those who are older and frail—cannot have a transplant.

But other research has shown that rituximab maintenance, given after standard drug therapy to drive out the cancer, can extend those patients' lives, Younes said.

The new findings show the same is true for patients who do have a transplant.

The trial involved 299 patients who were younger than 66 when they were diagnosed with mantle-cell lymphoma. All underwent standard drug therapy, with rituximab and chemotherapy. Most—86 percent—responded well enough to undergo a stem cell transplant.

Half of the patients were then randomly assigned to three years of rituximab maintenance therapy, receiving IV infusions of the drug every two months. The rest were followed up with standard care.

After four years, 89 percent of rituximab patients were still alive, compared with 80 percent in the comparison group, the investigators found.

The rituximab patients were also more likely to remain free of a cancer relapse, or serious side effects —including severe infections and allergic reactions: That was true of 79 percent of rituximab patients, versus 61 percent of patients on standard care.

According to Le Gouill, "Rituximab maintenance after stem cell transplant is one new weapon in the arsenal to fight against mantle-cell lymphoma."

He noted that other treatments have been recently approved—oral drugs that target abnormalities on the cancer cells—while still others are in development.

Like other antibody drugs, rituximab is costly—running thousands of dollars per month after hospital charges, according to a published report. Reimbursement "could be an issue in some countries," Le Gouill noted.

But, he added, the cost has to be weighed against the fact that the drug lengthens patients' lives and has "low toxicity."

Younes said that the "important message" from the findings is that patients' survival time is continuing to improve.

The study findings were published Sept. 28 in the *New England Journal of Medicine*.

More information: Steven Le Gouill, M.D., Ph.D., hematology service, Nantes Medical University, Nantes, France; Anas Younes, M.D., chief, lymphoma service, Memorial Sloan Kettering Cancer Center, New York City; Sept. 28, 2017, *New England Journal of Medicine*

The Lymphoma Research Foundation has more on mantle-cell lymphoma.