

## New therapy for vasculitis will help patients avoid infertility and cancer

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Researchers have identified that Rituxan, a drug previously approved for the treatment of non-Hodgkin's B cell lymphoma and rheumatoid arthritis, can treat severe ANCA-associated vasculitis as effectively as cyclophosphamide, the current standard therapy. The news will be presented October 18 at the annual meeting of the American College of Rheumatology in Philadelphia.

"The reason this is a big deal is that this is a disease where people would come in and be told 'listen, we are probably going to be able to get on top of your life-threatening disease by using cyclophosphamide, there is the potential for major side effects down the road from this drug,'" said Robert Spiera, M.D., an associate attending rheumatologist at Hospital for Special Surgery in New York. "This study provides strong evidence that Rituxan works as well as cyclophosphamide, at least in terms of getting patients into remission, and over that acute hump of being very ill. And, we can treat patients without the likelihood of causing infertility or causing secondary cancers, which have been a concern with the use of cyclophosphamide."

Hospital for Special Surgery was one of nine centers involved in the Phase III trial, which was led by Ulrich Specks, M.D., a professor of medicine in the Department of Pulmonary and Critical Care Medicine at the Mayo Clinic, and John Stone, M.D., MPH, director, Clinical Rheumatology, Massachusetts General Hospital.

Vasculitis, an [inflammation](#) of the [blood vessels](#), can damage tissues and

organs and, in severe cases, lead to death. Specifically, the study examined something known as ANCA-associated vasculitis that includes Wegener's granulomatosis and microscopic polyangiitis. "The reason this is such a significant study is that this is an uncommon but devastating group of diseases," said Dr. Spiera. Prior to the use of cyclophosphamide treatment, 70 percent of patients who were diagnosed with severe forms of ANCA-associated vasculitis could be expected to be dead within three years. In the 1970s, doctors discovered that cyclophosphamide was extremely effective at combating the disease and could put people into remission. In the ensuing decades, however, doctors recognized that these drugs came with a price.

"If you followed patients long enough, you found they had a higher risk of leukemias, lymphomas and solid tumors," said Dr. Spiera, who is also an Associate Professor at Weill Cornell Medical College. "People would sometimes develop terrible infections. Women, almost reliably, would become infertile, as did many men. So, although it was a dramatically effective drug at reducing remissions in these patients, it came at a price."

In the current study, nine centers enrolled a total of 197 patients with severe Wegener's granulomatosis or microscopic polyangiitis, two of the more common types of ANCA-associated vasculitis. Patients were given steroids and randomized to receive either the standard treatment with cyclophosphamide or Rituxan given at a dose of 375 mg/m<sup>2</sup> weekly for four weeks. Investigators used the standard tools to assess disease status and remission. The study was rigorously designed and was double-blinded, meaning that neither patient nor doctor knew which drug individuals were getting.

At the time of the data analysis, 84 of the 99 (85%) patients in the Rituxan arm and 81 of the 98 patients (83%) in the cyclophosphamide arm had completed six months of follow-up. Investigators found that the

treatments were equally effective in putting patients into remission and that, in fact, the treatment outcomes looked slightly better in patients receiving Rituxan (64% vs. 55%). This difference, however, was not considered statistically significant (P=0.21).

"These results show that the Rituxan worked at least as well as cyclophosphamide," Dr. Spiera said. "If anything, there was almost a hint of it maybe looking a little better, and even in the short term, it looked safer in some respects. This study shows that there is strong evidence that Rituxan may be an alternative to cyclophosphamide in this disease. It might help manage flares in patients who have gone into remission, and it could be a consideration as first-line therapy, especially in women of child bearing potential who have a good chance of losing their fertility if treated with cyclophosphamide."

Until this study, there was only anecdotal evidence that Rituxan would be beneficial in patients with vasculitis. ANCA-associated vasculitis is one of the few rheumatic diseases that is equally represented in men and women. It can occur in people of all ages. Rituxan, manufactured by Genentech, is currently approved in the U.S. to treat non-Hodgkin's [lymphoma](#) and [rheumatoid arthritis](#).

Source: Hospital for Special Surgery

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