Study: Mycophenolate is superior to azathioprine as treatment for lupus nephritis

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Mary Anne Dooley, M.D., MPH, is first author of the study, which is published in the *New England Journal of Medicine.* Credit: UNC Rheumatology/Thurston Arthritis Research Center

A new large, international study finds that the immunosuppressant drug mycophenolate mofetil is superior to azathioprine, an older immunosuppressant, as a maintenance therapy for lupus nephritis.

"This is a huge step forward for people who suffer from lupus nephritis," said Mary Anne Dooley, MD, MPH, associate professor in the University of North Carolina at Chapel Hill School of Medicine and first

author of the study, which is published in the Nov. 17, 2011 issue of the New England Journal of Medicine.

Lupus nephritis is an inflammation of the kidney caused by systemic lupus erythematosus (SLE), a disease of the immune system. Lupus nephritis may cause weight gain, high blood pressure, dark urine, or swelling around the eyes, legs, ankles, or fingers. In some patients the inflammation may be severe enough to cause kidney failure. However, some people with SLE have no symptoms of kidney disease.

The new study adds one more badly needed drug to the arsenal that physicians can use to treat lupus, Dooley said. In addition, it should help persuade health insurance companies to pay for the drug when it is used as maintenance therapy for lupus nephritis. Some insurers have refused to cover it because the drug is not FDA-approved for that indication, she said.

Both mycophenolate mofetil and azathioprine have been FDA-approved since the mid-1990s for use in kidney transplant patients, to help prevent organ rejection. Neither is FDA-approved as a maintenance therapy for lupus nephritis, but their immunosuppressant qualities make them useful for that purpose and physicians have been prescribing them off-label for that indication for many years.

The study included 227 patients who had previously responded well to an earlier round of treatment, called induction therapy. The patients were enrolled at 71 centers in 19 countries in Asia, Australia, Europe, North America, Latin America and South Africa. Researchers followed the patients for three years (36 months), with 116 receiving mycophenolate mofetil twice a day while 111 received azathioprine twice a day.

The results showed that mycophenolate mofetil was superior in virtually every aspect to azathioprine. There was a 16.4 percent treatment failure

rate in the mycophenolate group, compared to 32.4 percent in the azathioprine group. Patients responded well to mycophenolate for a longer period of time than patients on azathioprine, and negative side effects were more common with azathioprine.

This study also found that African-American patients in particular responded better to mycophenylate mofetil than to cyclophosphamide (Cytoxan) as an induction therapy and better than azathioprine as a maintenance treatment, Dooley said.

Provided by University of North Carolina School of Medicine