

Alternative treatment for preventing relapse of certain type of vasculitis appears less effective

November 8 2010

In a comparison of treatments for maintaining remission of a certain type of vasculitis (inflammation of blood vessels), the immunosuppressant mycophenolate mofetil, regarded as an alternative to the drug often used to prevent relapse, azathioprine, was less effective, according to a study that will appear in the December 1 print edition of *JAMA*. The study is being released early online to coincide with its presentation at the American College of Rheumatology annual scientific meeting.

"Relapses of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) occur in 50 percent of patients within 5 years of diagnosis, and treatment toxicity is common. Safe and effective therapies to maintain remission of AAV are a priority," the authors write. "In AAV, small observational studies and randomized controlled trials reported successful remission induction and remission maintenance with mycophenolate mofetil. Whether mycophenolate mofetil is more effective than azathioprine [an immunosuppressive] for preventing relapses in AAV is uncertain."

Thomas F. Hiemstra, M.D., M.R.C.P., of the University of Cambridge and Lupus and Vasculitis Unit, Addenbrookes Hospital, Cambridge, England, and colleagues examined whether mycophenolate mofetil reduces the risk of relapse compared with azathioprine in patients with AAV in remission, and compared the risk of serious adverse events

between treatment groups. The randomized trial was conducted at 42 centers in 11 European countries between April 2002 and January 2009. Eligible patients had newly diagnosed AAV and were ages 18 to 75 years at diagnosis. Patients were randomly assigned to receive azathioprine or mycophenolate mofetil after induction of remission with the agents cyclophosphamide and prednisolone.

A total of 156 patients were assigned to azathioprine (n = 80) or mycophenolate mofetil (n = 76) and were followed up for a median (midpoint) of 39 months. The researchers found that relapses were more common in the mycophenolate mofetil group (42/76 patients; 18 with major and 24 with minor relapses) compared with the azathioprine group (30/80 patients; 10 with major and 20 with minor relapses).

Severe adverse events did not differ significantly between groups, with 22 severe adverse events in 13 patients (16 percent) in the azathioprine group and 8 severe adverse events in 8 patients (7.5 percent) in the mycophenolate mofetil group. There were 8 severe infections in 8 patients in the azathioprine group and 3 severe infections in 3 patients in the mycophenolate mofetil group.

The secondary outcomes of Vasculitis Damage Index, estimated glomerular filtration rate (a measure of kidney function), and proteinuria (the presence of excessive protein in the urine) did not differ significantly between groups.

"Although mycophenolate mofetil is frequently regarded as a potent alternative to [azathioprine](#), we found no evidence to support its use as the initial [remission](#) maintenance therapy for patients with AAV," the authors write.

More information: *JAMA*. 2010;304[21]
[doi:10.1001/jama.2010.1658](https://doi.org/10.1001/jama.2010.1658)

Provided by JAMA and Archives Journals

Citation: Alternative treatment for preventing relapse of certain type of vasculitis appears less effective (2010, November 8) retrieved 12 March 2023 from

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