

# Higher-dose pneumococcal vaccines improve immune response in ANCA-associated vasculitis patients receiving rituximab

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New research presented this week at ACR Convergence 2022, the American College of Rheumatology's annual meeting, showed that a higher dose of pneumococcal vaccine safely and effectively improved antibody response in patients receiving rituximab for ANCA-associated

vasculitis.

Anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis is a group of disorders characterized by inflammation and destruction of blood vessels, often accompanied by the production of antibodies that target neutrophil antigens. The standard induction therapy is glucocorticoids plus [rituximab](#). Yet rituximab increases infection risk, especially pneumococcal infection, while weakening response to the pneumococcal vaccine. Researchers undertook this randomized phase 2 trial to develop [pneumococcal vaccine](#) strategies that would increase [immune response](#) in ANCA-associated vasculitis patients and autoimmune patients in general.

Study participants included 95 adults from the French Vasculitis Study Group, a multidisciplinary network of centers throughout France involved in the management of systemic vasculitis. Patients with newly diagnosed or relapsing ANCA-associated vasculitis with active disease and planned rituximab induction therapy were randomized in a 1:1:1 ratio to one of three parallel arms:

- A standard regimen consisting of an initial dose of pneumococcal conjugate vaccine (PCV13) followed by a dose of pneumococcal polysaccharide vaccine (PPV23) five months later (arm 1);
- A double dose of PCV13 at both day zero and day seven followed by a dose of PPV23 at month five (arm 2);
- Or four doses of PCV13 at day zero followed by a dose of PPV23 at month five (arm 3).

Age is a known factor in poor immune response, so all study arms were balanced for age.

The primary endpoint was the immune response at six months against 12 serotypes of *Streptococcus pneumoniae* common to the PCV13 and

PPV23 vaccines: 0-3, 4-6, 7-9 or 10-12 serotypes. Secondary endpoints were local and systemic reactions seven days after each vaccination as well as any adverse events possibly related to immunization.

Overall, patients in arm 2 were more likely to be in higher response categories (56.3%, 28.1%, 15.6% and 0%, respectively) compared to the standard regimen after adjustment for age. The second high-dose regimen—arm 3—tended to improve vaccine response only (60.6%, 33.3%, 6.1% and 0%, respectively).

Local and systemic reactions were higher seven days after each dose of high-dose vaccine as were adverse events related to vaccination at six months, though none were severe. Six patients experienced vasculitis flares about 90 days after vaccination: one patient in arm 1, two patients in arm 2 and three patients in arm 3.

"Our study highly suggests that patients receiving rituximab to treat an inflammatory disease could receive a higher dose of vaccine, especially two doses of PCV13 seven days apart, then PPV23 five months later, to induce a better vaccine response," says Benjamin Terrier, MD, a professor of medicine at Cochin Hospital, Paris Cité University and the study's lead author. He adds that the results weren't surprising.

"Since these patients received a high dose of glucocorticoids and rituximab, it was expected that a higher dose of vaccine was required to induce a sufficient response, but it was very important to confirm and demonstrate that."

Dr. Terrier says that since rituximab targets B cells, he and his colleagues chose to increase the dose of T-cell dependent PCV13 rather than T-cell independent PPV23. But he thinks the data suggest using higher doses of any vaccine "could improve antibody response in patients treated with immunosuppressive agents, especially for the current COVID-19

pandemic."

Although the study was open-label and not double-blind, "the primary outcome—the level of antibodies—was a strong endpoint that does not seem to be impacted by the lack of a double-blind [design]," Dr. Terrier says. "Our study shows that using a higher dose of [vaccine](#) is safe and effective for improving the protection of [patients](#) treated with rituximab against pneumococcal pneumonia."

**More information:** [Conference abstract](#)

Conference: [www.rheumatology.org/Annual-Meeting](http://www.rheumatology.org/Annual-Meeting)

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