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Therapeutic drug monitoring does not improve remission for patients starting infliximab

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New research presented at ACR Convergence, the American College Rheumatology's annual meeting, showed that patients with rheumatic

diseases whose infliximab treatment was individually assessed and adjusted with a new strategy called therapeutic drug monitoring did not achieve remission at higher rates compared to those who received standard care. (ABSTRACT #2029)

Tumor necrosis factor inhibitors (TNFi) are drugs approved for treatment of rheumatoid arthritis, psoriatic arthritis and other inflammatory conditions. They are part of a class of drugs called biologic disease-modifying anti-rheumatic drugs, or biologics. TNFi drugs may help patients lower their disease activity, relieve debilitating symptoms, and manage their condition long term.

Some patients experience a lack or loss of response to TNFi, possibly due to low serum drug levels and or the formation of anti-drug antibodies. Therapeutic drug monitoring is one proposed strategy to prevent loss of response and to optimize TNFi effectiveness. It is an individualized strategy that includes regular assessments of a patient's serum drug levels. This personalized monitoring can be time-consuming and costly, and it is unclear whether it actually improves clinical outcomes. To learn more, researchers in Norway launched the first open-label, multi-center, randomized, controlled trial to assess its effectiveness in achieving remission in patients with several inflammatory diseases.

"Based on observational data showing associations between serum drug levels and effectiveness, we believed that individual treatment, with optimizing drug levels and early identification of anti-drug antibodies, would optimize the efficacy, safety and cost effectiveness of TNFi therapy," says the study's principal author, Silje Watterdal Syversen, MD, Ph.D., a rheumatologist at Diakonhjemmet Hospital in Oslo, Norway.

Adults with rheumatoid arthritis, psoriatic arthritis, spondyloarthritis,

ulcerative colitis, Crohn's disease and psoriasis who were starting infliximab therapy were recruited for the study. Patients were randomly assigned to receive infliximab either with or without therapeutic drug monitoring. They were examined at each infusion visit. The study's primary endpoint was remission at week 30. The study included 411 patients from 21 medical centers between January 2017 and December 2018: 80 with rheumatoid arthritis, 42 with psoriatic arthritis, 117 with spondyloarthritis, 80 with ulcerative colitis, 57 with Crohn's, and 22 with psoriasis. The researchers included 198 patients in the therapeutic drug monitoring arm and 200 patients were included in the control group. Researchers also recorded any adverse events the patients experienced, such as infections or infusion reactions.

According to their results, therapeutic drug monitoring was not superior to standard treatment for achieving disease remission at 30 weeks in people with a range of rheumatic diseases. In the study's therapeutic drug monitoring arm, 100 or 53% of patients achieved remission, while 106 or 54% of the patients in the standard treatment group also achieved remission. The study also found that 10% of patients who had therapeutic drug monitoring and 15% of patients receiving standard treatment developed significant levels of anti-drug antibodies. Adverse events were similar for both treatment groups as well, but infusion reactions were less frequent in patients who received therapeutic drug monitoring.

"Our study does not support therapeutic drug monitoring be applied as a general treatment strategy during induction of infliximab. Despite a lack of clinical trial data and diverging guidelines, proactive therapeutic drug monitoring has already been adopted in clinical practice across different specialities. This study highlights the need for thorough evaluation of monitoring tools and treatment strategies before their implementation in clinical care," says Dr. Syversen. "We feel that our results put to rest a long-standing debate on the merits of using therapeutic drug monitoring

in all patients starting TNFi."

Future research should explore if more targeted applications of therapeutic drug monitoring, such as assessment of serum drug levels in treatment failures, could be a useful clinical tool, she adds.

More information: acrabstracts.org/abstract/ther … ial-of-400-patients/

Provided by American College of Rheumatology