RA Progression Halted in Year 2 With Infliximab

BY MITCHEL L. ZOLER

PHILADELPHIA — Treating early rheumatoid arthritis patients with infliximab as part of a multidrug regimen led to less radiographic progression over 2 years than did a regimen without a tumor necrosis factor inhibitor in a randomized, controlled trial with 258 patients.

"The radiological results appear to represent a distinct therapeutic action for methotrexate and an anti-TNF," Dr. Ronald F. van Vollenhoven said at the annual meeting of the American College of Rheumatology. Although radiographic progression in patients receiving infliximab was the same as in patients who were not on infliximab during the first year of treatment, further progression stopped during year 2 in patients on infliximab but continued in the control group, reported Dr. van Vollenhoven, a rheumatologist at the Karolinska University Hospital in Stockholm.

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The benefit of reduced radiographic progression with infliximab treatment came on top of a prior report from the same study that the addition of infliximab led to a significantly better rate of "good" responses after 1 year of treatment, based on EULAR (European League Against Rheumatism) criteria (Lancet 2009;374: 459-66). The earlier report did not include radiographic findings.

"After initial failure of methotrexate in early rheumatoid arthritis, the addition of an anti-TNF is clinically and radiologically superior" to the addition of conventional disease-modifying antirheumatic drugs, Dr. van Vollenhoven said.

The Swedish Pharmacotherapy Trial (Swefot) was done at 15 rheumatology units in Sweden. The study was funded in part by Schering Plough, the company that markets infliximab (Remicade) outside of the United States. In the United States, infliximab is marketed by Centocor Ortho Biotech Products. Dr. van Vollenhoven disclosed receiving research grants and consulting fees or other remuneration from Schering Plough and other drug companies.

The study enrolled adults with RA who had had symptoms for less than a year (early RA) and who initially received methotrexate monotherapy at a starting dosage of 10 mg/week that could rise as high as 20 mg/week. After 3-4 months, patients who tolerated the drug but failed to achieve low disease activity (defined as a Disease Activity Score 28 less than 3.3) were randomized either to oral sulfasalazine (1,000 mg b.i.d.) plus oral hydroxychloroquine (400 mg/day), or to an infliximab infusion. The infliximab regimen used a dosage of 3 mg/kg administered at weeks 0, 2, and 6 and then every 8 weeks. Infliximab treatment was done on an open-label basis. Randomization assigned 130 patients to the sulfasalazine plus hydroxychloroquine group and 128 patients to infliximab treatment. Patients underwent radiographic assessment of their hands and feet at baseline and after 12 and 24 months using the Sharp/Van der Heijde (SVdH) scoring method.

In an intent-to-treat analysis, patients in both treatment arms showed statistically significant radiographic progression, compared with baseline, during the first year of treatment. During the second year of treatment, patients on infliximab had no additional progression, whereas patients in the control arm continued to have significant progression.

The difference in total 24-month progression between the two treatment arms was statistically significant for total SVdH score and erosion score, and for the extent of joint-space narrowing. In addition, the difference in total SVdH score between months 12 and 24 for the two treatment arms was statistically significant.

Patients in the infliximab arm also had less radiographic progression during their second year of treatment, compared with control patients, when analyzed on a per protocol basis. ■