Concomitant Golimumab Lessened Clinical RA

VITALS

Major Finding: RA patients who received methotrexate plus golimumab showed significantly better RAMRIS scores on MRI than did those who received MTX alone, as early as week 12 and continuing through week 24.

Data Source: A substudy of the GO-BEFORE study, involving 318 patients with active RA whose response to treatment was monitored via MRI.

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BY MARY ANN MOON

FROM ARTHRITIS & RHEUMATISM

Adding golimumab to methotrexate therapy lessened synovitis, osteitis, and bone erosion to a greater degree than did placebo plus methotrexate, a study has shown.

These improvements were evident as early as the 12th week of treatment on serial magnetic resonance imaging exams, which proved to be much more sensitive than conventional radiography at demonstrating the changes, said Dr. Mikkel Ostergaard, professor of rheumatology at Copenhagen University Hospital at Glostrup, Denmark, and his associates.

They reported the results of a substudy of the 1-year GO-BEFORE (Golimumab Before Employing Methotrexate as the First-Line Option in the Treatment of Rheumatoid Arthritis of Early Onset) study, a large randomized controlled trial comparing various combinations of oral methotrexate (MTX), golimumab injections, and placebo in rheumatoid arthritis (RA) patients. GO-BEFORE's findings demonstrated that after 28 weeks, "golimumab in combination with MTX reduced signs and symptoms and radiographic progression of RA in MTX-naive patients, with a safety profile similar to other anti-[tumor necrosis factor] agents," the investigators said.

Their substudy involved 318 of these subjects who underwent serial MRI evaluations of the wrist and metacarpophalangeal joints at 12 and 24 weeks. Synovitis and osteitis (bone marrow edema), which signal heavy infiltration by inflammatory cells including osteoclasts, are precursors of new bone erosions. These changes are visible on MRI well before conventional radiography can detect them.

The MRIs were assessed by two readers and an adjudicator using the Rheumatoid Arthritis MRI Scoring (RAMRIS) system, "which has demonstrated very good reliability and a high level of sensitivity to change." Study subjects who received MTX plus golimumab showed significantly better RAMRIS scores than did those who received MTX alone, as early as week 12 and continuing through week 24, Dr. Ostergaard and his colleagues said (Arthritis Rheum. 2011 Aug. 31 [doi 10.1002/art.30592]).

For example, at week 12, synovitis scores decreased by 1.92 points for the wrist and metacarpophalangeal joints and by 0.85 points for the wrist alone with combined therapy, compared with 0.14 points and 0.02 points with MTX alone. Bone edema–osteitis score decreased by 1.82 points with combined therapy but only by 0.56 points with MTX alone, and bone erosion scores decreased by 0.40 points vs. 0.24 points.

"Similar trends were observed in the sensitivity analyses conducted for the mean change in RAMRIS scores from baseline to week 24," they added.

In a series of MRIs that were representative of the substudy population as a whole, "images show bone edema that was extensive at baseline, markedly decreased at week 12, and nearly resolved at week 24," they noted.

The researchers emphasized that the substudy confirmed the conclusion of the entire GO-BEFORE clinical trial, but that MRI demonstrated the statistically significant difference between study groups in less than half the time (12 weeks rather than 28 weeks) and using fewer than half the subjects (318 patients rather than 637 patients). This documents that MRI is a more sensitive tool for detecting structural damage than conventional radiography, they said. ■