Ankylosing Spondylitis Score Shows Promise

BY MITCHEL L. ZOLER

COPENHAGEN — A new way to assess disease activity in ankylosing spondylitis patients showed good correlation with the Bath score and good responsiveness as patients improved with treatment in an analysis of 60 patients.

The Ankylosing Spondylitis Disease Activity Score (ASDAS) "seems like a promising new tool for assessing disease activity and treatment response," Dr. Susanne J. Pedersen said at the annual European Congress of Rheumatology. But it needs further validation in larger numbers of patients, and further adjustment to more reliably assess patients with low or high levels of treatment response, said Dr. Pedersen, a rheumatologist at Herlev (Denmark) University Hospital. The ASDAS is based on five clinical elements: back pain, duration of morning stiffness, patient's global assessment, peripheral pain and swelling, and serum level of C-reactive protein (Ann. Rheum. Dis. 2009;68:18-24).

To test correlations of the ASDAS with other assessment methods and to track its change with treatment, Dr. Pedersen and her associates used data from 60 AS patients collected as part of a Danish longitudinal study of AS, known as BIOSPA. The patients met the European Spondyloarthropathy Study Group criteria for spondyloarthritis, had sacroiliitis on MRI or x-ray, and had a BASDAI (Bath AS Disease Activity Index) greater than 30 despite treatment with an NSAID. Their average age was 40 years, 80% were men, and their average disease duration was 12 years. Their average ASDAS at baseline was 3.86, and their average BASDAI was 55.

About two-thirds (68%, or 41) of the patients received infliximab (Remicade), 13 (22%) got etanercept (Enbrel), and 6 (10%) got adalimumab (Humira). Patients were assessed at baseline, and after 22 and 46 weeks of treatment. A total of 53 of the 60 (88%) patients finished 22 weeks of treatment, and 47 (78%) completed 46 weeks of treatment.

Measurement of their ASDAS, BASDAI, and other measures of disease activity at baseline and after 22 weeks of treatment showed good correlation between the ASDAS and BASDAI scores. Among patients with a BASDAI greater than 40 at baseline, a change in the BASDAI of 20 (a common minimum criterion for improvement on treatment) correlated with a change in the ASDAS of 1.38. A change in the BASDAI of 50% (another common criterion for improvement) correlated with an ASDAS improvement of 1.95, Dr. Pedersen said.

Dr. Pedersen and several of her coauthors on the study disclosed financial relationships with Abbott, the company that markets adalimumab. Two of her coauthors had similar relationships with Wyeth, the company that markets etanercept, and one coauthor had similar relationships with Centocor Inc., the company that markets infliximab. ■

Registry Shows 63% Response Rate to TNF Inhibitor in AS

BY MITCHEL L. ZOLER

COPENHAGEN — Treatment with a tumor necrosis factor inhibitor produced a 63% clinical response rate in 842 ankylosing spondylitis patients who were treated for a median of more than a year in Denmark.

The Danish experience also showed that women and patients with higher disease activity at baseline were the least able to remain on treatment with a tumor necrosis factor (TNF) inhibitor, Dr. Bente Glintborg said at the annual European Congress of Rheumatology.

The registry data also documented an 8% rate of patients who stopped TNF inhibitor treatment because of adverse effects, said Dr. Glintborg, a researcher at Gentofte (Denmark) Hospital.

Dr. Glintborg and her associates used data collected by DANBIO, a registry begun in 2000 of patients treated with a biologic drug in Denmark. Through November 2008, the registry included 909 patients with ankylosing spondylitis who began first treatment with a TNF inhibitor.

Follow-up data were available for 842 of these patients. Their average age was 41 years (range, 32-50 years), their median disease duration when starting the TNF inhibitor was 5 years (range, 1-13 years), and 28% were women. Roughly half received infliximab (Remicade), about a quarter got adalimumab (Humira), and about 15% received etanercept (Enbrel), with the remaining patients receiving another drug. Patients were followed for a median of 437 days (range, 161-996 days).

TNF inhibitor treatment improved disease activity. BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) scores dropped from an average of 59 at baseline to 21 after a year of treatment among the 644 patients who were assessed with the BASDAI at baseline.

The Bath AS functional index and metrology index, as well as a visual analog scale global assessment, all showed similar declines with treatment. Serum levels of C-reactive protein fell from an average of 14 mg/L at baseline to 5 mg/L after 1 year.

Clinical response (defined as a drop in the BASDAI from baseline of at least 50% or 20 mm) was achieved by 63% of the patients who had undergone BASDAI assessments.

Patients stayed on their starting TNF inhibitor regimen for a median of 4.3 years. The most common reasons for stopping treatment were lack of efficacy in 115 patients (14%) and adverse events in 69 patients (8%).

Treatment duration was shortest among women and patients with higher disease activity at the start of treatment, as measured by the BASDAI. These were the only significant predictors of treatment discontinuation in a multivariate model. Women had a 64% higher rate of stopping TNF inhibitor treatment than did men. Factors included in the model that were not significant determinants were age, C-reactive protein level at baseline, treatment with methotrexate, disease duration, and other baseline measures of disease activity.

Dr. Glintborg and her associates had no financial relationships to disclose. ■