

Quality of Life in RA Improved With Abatacept

BY NANCY WALSH
New York Bureau

MONT TREMBLANT, QUE. — Patients with rheumatoid arthritis treated with abatacept for 2 years reported improvements in fatigue, pain severity, and sleep, three key concerns for these patients, Dr. Anthony S. Russell reported at the annual meeting of the Canadian Rheumatology Association.

Several years ago at a meeting of the international network known as OMER-ACT, which formerly stood for Outcome Measures in Rheumatoid Arthritis Clinical Trials but now simply refers to Outcome Measures in Rheumatology, patients with rheumatoid arthritis (RA) were asked about their treatment priorities.

"Patients wanted to know if treatment will make them feel better, if it will get rid of pain and fatigue, and help them sleep," said Dr. Russell of the University of Alberta, Edmonton.

Accordingly, these concerns were addressed during the open-label phase of two randomized trials of abatacept, a costimulatory modulator that inhibits full T-cell activation and reduces the proliferation of subsequent downstream inflammatory mediators such as interleukin-6 and C-reactive protein (J. Rheumatol. 2006;33:2162-6).

The two trials were the 12-month AIM (Abatacept in Inadequate Responders to Methotrexate) study and the 6-month ATTAIN (Abatacept Trial in Treatment of Anti-Tumor Necrosis Factor Inadequate Responders) study, both of which were sponsored by Bristol-Myers Squibb Co., makers of Orencia (abatacept). Patients who completed the double-blind phase of these trials and achieved at least an ACR 20 response were eligible to enroll in the 2-year open-label extension phase.

The treatment regimen in the blinded phase of the trials involved administration of a fixed dose of abatacept (approximately 10 mg/kg) on days 1, 15, 29, and every 4 weeks thereafter. Every 4-week administration was continued throughout the open-label phase.

To assess fatigue severity, patients were asked, "How much fatigue have you had because of your RA over the past week?" and rated this on a 100-mm visual analog scale (VAS).

Pain severity also was measured on a 100-mm VAS, and sleep quality was assessed using the Medical Outcomes Study Sleep Scale and a sleep problems index.

A total of 378 patients entered the long-term phase of AIM, as did 218 in ATTAIN.

Mean age of patients in AIM was 51 years, 77% were women, and the mean duration of RA was 8 years.

In ATTAIN, patients' mean age was 53 years, 77% were women, and the mean duration of RA was 12 years.

In both trials, the mean number of tender joints was 31 and the mean number of swollen joints was 22. The mean C-reactive protein level was 3.2 mg/dL in AIM and 4.6 mg/dL in ATTAIN.

At baseline in AIM, 44% of patients reported VAS scores higher than 70 for both fatigue and pain, and 9% had this degree

of severity for sleep problems. After 2 years of abatacept treatment, these percentages were reduced to 10%, 4%, and 2%, respectively, Dr. Russell reported in a poster session.

Also after 2 years of treatment VAS scores below 30 were reported by 53%, 64%, and 49% for fatigue, pain, and sleep problems, respectively.

"Pain and fatigue improved markedly," he said.

Similar results were seen in ATTAIN,

despite the fact that patients in that trial were somewhat sicker.

All had failed at least one tumor necrosis factor inhibitor, and many had failed two, Dr. Russell said.

At baseline in ATTAIN, VAS scores of 70 and higher were reported by 68% of study participants for fatigue, by 58% of participants for pain, and by 13% for sleep problems.

After 2 years, these percentages had decreased to 24%, 9%, and 4%, respectively,

while scores below 30 were reported by 33%, 51%, and 39%.

"By providing around-the-clock improvements in quality of life—pain and fatigue during the daytime and sleep quality during the night—abatacept has the potential to provide meaningful patient-centered benefits in moderate to severe RA," Dr. Russell wrote.

"We can say to patients, yes, we listened to your concerns," he said during the poster presentation.

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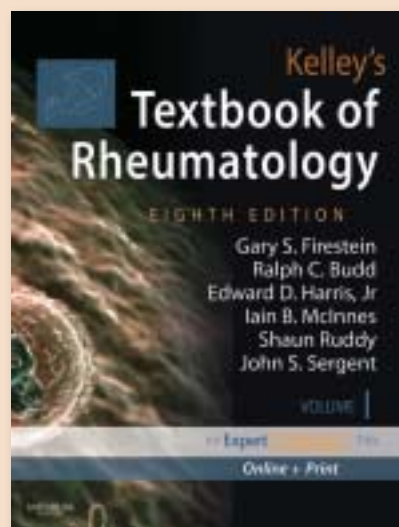
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