Resuming Infliximab Seems Safe, Effective in AS

BY BARBARA J. RUTLEDGE
Contributing Writer

WASHINGTON — Patients with active rheumatoid arthritis preferred the adalimumab autoinjection pen device to the prefilled syringe in an Abbott-sponsored study, Dr. Martin Okun reported in a poster presentation at the annual meeting of the American Academy of Dermatology. Adalimumab, a fully human IgG monoclonal anti-tumor necrosis factor antibody, is approved for the treatment of adults with rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. It can be administered via subcutaneous injection with a prefilled syringe or by an autoinjection pen, which was developed to facilitate self-injection by patients with physically limiting autoimmune diseases, noted Dr. Okun of Abbott Laboratory’s department of medical affairs.

The investigators evaluated existing data from an earlier open-label phase II study that was done in pursuit of the original Food and Drug Administration approval of 52 patients with active RA who self-administered 40 mg adalimumab subcutaneously with the syringe at visit 1, followed by the same dose via the pen at visits 2 and 3 (week 4). The patients chose the site—either thigh or abdomen—and maintained the same site for all three injections. The patients had a mean age of 54 years and a mean RA duration of 8 years. Two thirds were women, and the majority (88.5%) were white. They had been injecting adalimumab via syringe for a mean of 15 months.

On the 10-point visual analog scale, with 0 being “no pain” and 10 being “as bad as it could be,” the patients rated their pain immediately following injection as a mean of 3.7 with the syringe at visit 1, compared with 2.3 and 2.0, respectively, for the pen at visits 2 and 3. Overall, 40 patients (77%) deemed the pen to be less painful than the syringe, while 4 patients (8%) found the syringe less painful and 8 (15%) had no preference. Significant reductions in injection-site pain were observed at 15-30 minutes post injection with the pen, Dr. Okun reported. Overall impressions of the injection experience with the pen were rated “favorable” or “extremely favorable” by 86.5% at visit 2 and 85.5% at visit 3, compared with just 32.6% for the syringe at visit 1. Overall preference was 88.5% for the pen compared with 5.8% for the syringe and 5.8% with no preference.

Response rates for preferring the pen included ease of use, convenience, time to inject (about 30 seconds versus 2 minutes for the syringe), safety, and “less pain.” More than 94% of the patients said they would likely use the pen if it was available at the same cost as the syringe, and the same proportion said they would recommend the pen to a friend.

Poster session moderator Dr. Craig Leonard, a dermatologist at St. Louis University, cautioned that patients must first learn the pen. “It’s not sufficient to just prescribe the pen. You have to show patients how to use it. Otherwise they make mistakes.”

Infliximab readministration after relapse lowered BASDAI scores, CRP levels, and ESRs.

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One patient showed antibodies to infliximab at 6 weeks after withdrawal, despite an initial favorable response during the previous 3-year study, and no clinical relapse until 2 years after withdrawal. This patient withdrew from the study after eight infusions because of repeated local infections. Among the patients who completed the study after infliximab readministration, mean BASDAI scores increased from 2.5 at the time of infliximab withdrawal to 6.0 at the time of clinical relapse. Mean BASDAI scores decreased following infliximab readministration, to mean values of 2.7 at week 24 to 2.6 at week 48. Median C-reactive protein levels increased from 1.0 at infliximab withdrawal to 11.2 at clinical relapse, dropping again after infliximab readministration to 1.6 at week 24 and 1.8 at week 48. Erythrocyte sedimentation rate showed a similar pattern, rising from median values of 32.6 mm/hr at week 0 to 24 at clinical relapse, and decreasing to 6 and 11 at weeks 24 and 48, respectively.

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Inflammatory Hand Pain May Respond to Methylprednisolone

BY DIANA MAHONEY
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I ntramuscular methylprednisolone can significantly improve symptoms and function in patients with inflammatory hand pain, a proof of concept study has shown.

To test the hypothesis that predominant hand pain with diurnal variation and morning stiffness lasting for at least 30 minutes has an inflammatory etiology and should respond to corticosteroids, Dr. Zunaid Karim of Chapel Allerton Hospital in Leeds, England, and colleagues evaluated the efficacy of intramuscular methylprednisolone treatment in 102 patients who presented to the Leeds Early Arthritis Clinic with more than 3 months of symptoms and who had failed to respond to nonsteroidal anti-inflammatory drugs (Ann. Rheum. Dis. 2007 Jan 22 [Epub doi:10.1136/ard.2006.061861]).

Patients with clinical synovitis in five or more joints, as well as those with gout, connective tissue disease, or rheumatoid arthritis were excluded, as were those with sensitivity to corticosteroids or hydrocortisone.

The presence of two of the following three conditions was considered indicative of clinical synovitis: joint swelling, joint tenderness, and reduced range of movement. Ultrasound was performed on the second to fifth metacarpal, phalangeal, and proximal interphalangeal joints, and synovitis was defined as the presence of abnormally hypochoic intra-articular tissue that was nondisplaceable and poorly compressible.

At baseline, 21% of the patients were rheumatoid factor positive, 25% had elevated ESRs, and 28 reported a benefit, the authors wrote. Both ultrasound-detected synovitis and rheumatoid factor were associated significantly with methylprednisolone response, while clinical synovitis and elevated C-reactive protein were not, the investigators reported.

Of the initial 102 patients, 11 did not complete the 4-week assessment and were excluded from the study. The remaining 91 patients, mean age 51 years, were predominantly female (81%) and had a mean symptom duration of 7 months.

Response at 4 weeks was observed in 66 of the 91 patients (73%), with associated significant reductions in morning stiffness, Health Assessment Questionnaire results, painful and tender joint counts, and patient visual analog scores, the authors wrote. Both ultrasound-detected synovitis and rheumatoid factor were associated significantly with methylprednisolone response, while clinical synovitis and elevated C-reactive protein were not, the investigators reported.

Of the 66 responders, 24 remained well to the end of the study. The remaining 42 patients relapsed within 24 weeks and received a repeat methylprednisolone injection and hydroxychloroquine. Of these patients, 28 remained on the drugs. They added 24 of the 28 reported a benefit, the authors noted. The findings may be limited by the lack of sensitivity of the clinical synovitis assessment. Additionally, 25% of the patients had clinical synovitis and 55% had ultrasound-detected synovitis.

Participating patients received an intramuscular injection of 120 mg of methylprednisolone at baseline and were assessed for response (defined as 50% improvement in pain and stiffness symptoms) at 4 weeks, then every 12 weeks for 48 weeks. Patients who responded initially but subsequently relapsed received an additional methylprednisolone injection and were started on 200 mg daily of hydroxychloroquine, with response assessment after 24 weeks.

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