

Extending Higher Dosage of Etanercept Found Safe

Some prescribers may keep patients on a regimen in order to maintain insurance coverage of the drug.

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — Maintaining patients with moderate to severe psoriasis on a higher than recommended dose of etanercept is safe, according to new long-term multicenter phase III data.

Although the recommended dosing in the United States is for 3 months of 50 mg etanercept twice weekly, followed by a reduction to a maintenance dose of 50 mg per week, the current analysis evaluated 50 mg twice weekly through 48 weeks.

The study reflects the off-label use of etanercept (Enbrel) at the higher dose to tackle new lesions that develop in about half of patients and to maintain continuous insurance coverage.

"The most difficult thing is to justify to the insurance company that you need to put a patient back on 100 mg a week," lead author Stephen Tying, M.D., told this newspaper. "They won't pay for the 100 mg beyond the 3 months if you reduce it.

If you just keep them on 100 mg, often they don't notice."

This scenario has left physicians facing the most important question, which is whether the higher extended dosing is safe.

The safety is definitely indistinguishable from placebo, and there were twice as many patients as controls, said Dr. Tying, who presented the data in a poster at the American Academy of Dermatology's Academy 2005 meeting.

The study randomized 307 patients to placebo and 311 patients to etanercept 50 mg twice weekly for 12 weeks.

A total of 599 patients continued in the ongoing open-label phase of the study in which patients continued on treatment or were switched from placebo to etanercept 50 mg twice weekly.

Analysis through week 48 showed there



were no deaths and no cases of opportunistic infections, tuberculosis, demyelinating diseases, hematologic events, or congestive heart failure.

Dr. Tying and colleagues at the University of Texas, Houston, perform chest x-rays and purified protein derivative TB skin tests as standard of care. But not all

sites screened for TB, nor did they perform MRIs.

The safety of the higher dosing was indistinguishable from placebo in patients with psoriasis.

There have not been enough cases of multiple sclerosis in psoriasis patients using biologic therapies to determine if there is a cause-and-effect

DR. TYRING

relationship or if it is just background, Dr. Tying said.

For the time being, he does not treat psoriasis patients with etanercept if they have multiple sclerosis or if they have close family members who have multiple sclerosis.

There was one case of lymphoma in the study. Dr. Tying said it was probably background, and noted that some studies put the risk of lymphoma in psoriasis patients as at least twice that of healthy controls.

In the double-blind period, nine patients discontinued because of an adverse event; 13 additional patients have since discontinued because of an adverse event.

Finally, the data showed that there was no diminished treatment effect from baseline, which has been a problem with some psoriasis treatments.

At week 48, dermatologists accessed about 55% of patients as clear or almost clear, whereas 65% of patients made the same assessment.

The study was funded by Immunex Corp., a subsidiary of Wyeth Research and Amgen Inc., which markets etanercept.

Dr. Tying did not disclose any financial relationship to any of the three companies. ■

Biologic Therapies Tackle Palmoplantar Pustulosis

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — Evidence is mounting that biologic therapies such as alefacept and efalizumab can successfully treat palmoplantar pustular psoriasis.

Preliminary data from a pilot study of 15 patients at two sites showed a 16-week course of alefacept (Amevive), including 8 weeks of alefacept 30 mg once weekly, resulted in substantial improvements in clinical outcomes, Daniel Pearce, M.D., reported in a poster at the American Academy of Dermatology's Academy 2005 meeting.

The mean improvement in palmoplantar psoriasis severity instrument (PPSI) scores was 18% among nine patients at site A and 45% among six patients at site B.

Physician's global assessment (PGA) of palmoplantar psoriasis improved significantly at site A from 2.3 at week 4 to 1.8 at week 28, and improved at site B from 2.4 at week 4 to 2.0 at week 16.

Patients in this study were injected intramuscularly with 15 mg/wk of alefacept for 16 weeks, compared with the recommended 12-week course for adult psoriasis patients.

The dose was increased in the majority of patients to 30 mg/wk at 8 weeks due to a limited response.

All patients were allowed to remain on methotrexate 25 mg/wk or less or acitretin 50 mg/day or less during the trial, sponsored by Biogen Idec Inc., which

markets Amevive and is headquartered in Cambridge, Mass.

There was no plateau in response for PPSI and PGA scores at week 16, suggesting that the longer treatment may possibly offer greater benefit for some patients, reported Dr. Pearce of the Center for Dermatology Research at Wake Forest University, Winston-Salem, N.C.

CD4 T-cell counts were predictably reduced by alefacept. But no patient had CD4 T-cell counts less than 250 cells/mm³, and no alefacept doses were withheld due to low counts at either site. No one withdrew from the study because of adverse events.

In a separate poster that was reported at the same meeting, a 50-year-old patient remained clear of palmoplantar pustular psoriasis 11 months after beginning treatment with efalizumab (Raptiva).

The patient remains on continuous efalizumab therapy and is currently able to walk without pain as well as being able to use her hands again, reported Loretta A. Jones, a nurse practitioner at the Abilene (Texas) Dermatology and Skin Surgery Center.

A response was observed in 1 month of initiating subcutaneous efalizumab 1 mg/kg per week, and the patient was asymptomatic after 5 months.

There were neither any flares nor any adverse events attributed to the drug, according to the poster, which was developed with support from Genentech Inc. of South San Francisco, Calif., which markets Raptiva. ■

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