Tacrolimus Comes Out on Top for Treating Atopy

BY JOHN R. BELL
Associate Editor

NEW YORK —Tacrolimus ointment is more effective than pimecrolimus cream in treating adults with moderate to severe atopic dermatitis, results from a randomized, blinded, multicenter trial indicate.

A total of 281 study patients were randomly assigned to receive tacrolimus 0.1% ointment or pimecrolimus 1% cream (141 and 140 patients, respectively), Dr. Alan B. Fleischer Jr. reported at the American Academy of Dermatology's Academy 2007 meeting.

The difference became greater with time and achieved significance at week 3.

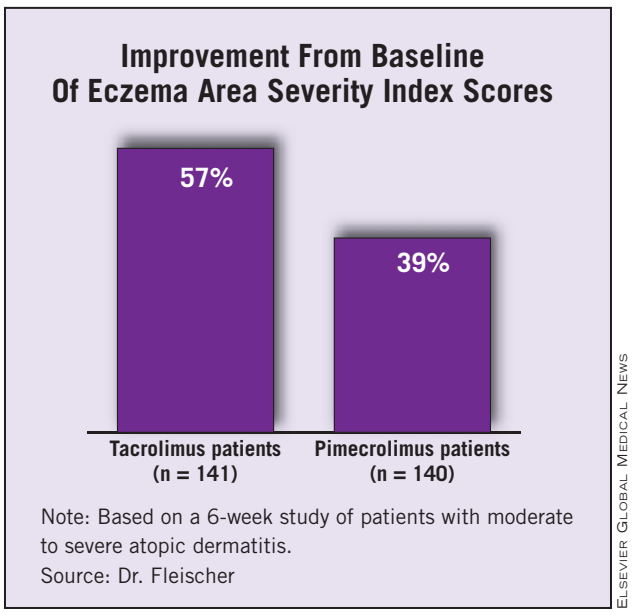
DR. FLEISCHER

Patient characteristics were similar in the two groups. Patients were at least 16 years old, and the mean age of each group was 40 years and 39 years, respectively, noted Dr. Fleischer of Wake Forest University, Winston-Salem, N.C., and colleagues. The study, which was sponsored by Astellas Pharma US Inc., was presented and discussed in a poster session at the meeting. Dr. Fleischer disclosed that he has received funding from Astellas as well as from Novartis.

In both groups, patients applied the medication twice daily for up to 6 weeks, until the disease cleared. The primary end point was change in disease severity between baseline and week 6 using Eczema Area Severity Index (EASI) scoring (J. Dermatol. Treat. 2007;18:151-7). Secondary end points were treatment success as measured by the Investigators' Global Atopic Dermatitis Assessment (IGADA); reduction in affected body surface area (BSA); change in the patient's self-assessment of itching; and the incidence of adverse events.

EASI scores improved by a mean of 57% from baseline in the tacrolimus patients, versus 39% in the pimecrolimus patients. This difference became greater with time and achieved statistical significance at week 3. At 6 months, the tacrolimus group had more favorable results on some secondary outcomes, compared with the pimecrolimus group: 40% vs. 22% rated as "clear" or "almost clear" on IGADA; 49% vs. 34% improvement in BSA, respectively.

The improvement in mean itch rating via the visual analog scale was more favorable for tacrolimus but did not reach significance. Both groups began with a mean score of 6.7. In the tacrolimus group, it fell to 3.2 by week 6, and in the pimecrolimus group, it dropped to 3.8. Adverse events occurring in both groups included application-site burning and application-site pruritus. The pimecrolimus group alone had one report each of skin infection, impetigo, infected dermatitis, and herpes simplex. ■



Note: Based on a 6-week study of patients with moderate to severe atopic dermatitis.
Source: Dr. Fleischer

Elsevier Global Medical News

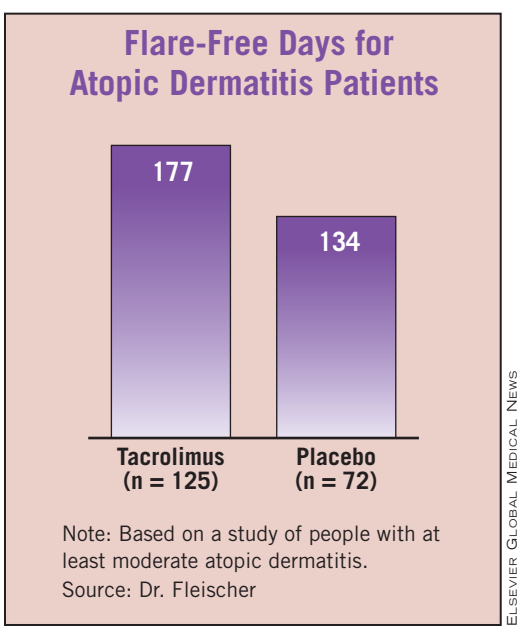
Long-Term Use of Tacrolimus for AD Flares Found to Reduce Relapse Risk

BY JOHN R. BELL
Associate Editor

NEW YORK — Long-term use of tacrolimus ointment was effective in managing atopic dermatitis and preventing disease flares in a group of adults and children, Dr. Alan B. Fleischer said in a poster presented at the American Academy of Dermatology's Academy 2007 meeting.

Dr. Fleischer of Wake Forest University, Winston-Salem, N.C., and his colleagues enrolled 383 patients with at least moderate atopic dermatitis in a study sponsored by Astellas Pharma Inc., manufacturer of tacrolimus (Protopic).

Patients first went through a 16-week, randomized, double-blinded disease-stabilization phase. In the first 4 days, 190 patients received twice-daily doses of tacrolimus ointment (0.1% for adult patients and 0.03% for pediatric patients) and 193 patients received a corticosteroid twice a day. For the remaining portion of the stabilization phase, they received twice-daily open-label tacrolimus ointment until clear or almost clear of disease for at least 2 weeks, up to 16 weeks.



Note: Based on a study of people with at least moderate atopic dermatitis.
Source: Dr. Fleischer

Elsevier Global Medical News

For the maintenance phase of the trial, patients with clear or nearly clear skin were randomly assigned to either tacrolimus ointment (125 patients) or a placebo vehicle (72 patients) in a double-blind fashion. Both were applied three times a week for up to 40 weeks. Patients who relapsed were given up to 8 weeks of open-label tacrolimus twice a day until clear or almost clear of their atopic dermatitis, at which point they returned to the study regimen. Patients whose disease did not achieve this response dropped out of the study.

Use of corticosteroids was permitted only in the initial portion of the stabilization phase.

At the end of 40 weeks, patients receiving tacrolimus ointment had 177 flare-free treatment days (the primary end point) versus 134 for those in the placebo group—a difference that reached statistical significance. Moreover, the time to first relapse was 169 days for patients who received tacrolimus and 43 days in the placebo group, and tacrolimus was associated with fewer total relapse days (45.5 days) than the placebo vehicle (64.5 days). Among patients in the tacrolimus group, 6% experienced disease relapse, compared with 17% in the vehicle group.

Adverse events primarily involved itching and burning and occurred predominantly in the stabilization phase of the study. The only significant difference in adverse events was seen at day 4 of the stabilization phase, with 18% (33 patients) in the tacrolimus group reporting any adverse event versus 9% (17 patients) in the corticosteroid group, Dr. Fleischer said.

Although tacrolimus was effective in this study population, efficacy might vary in other groups, given the widely divergent presentation possible with atopic dermatitis. ■

Web Use May Be Reason for Eczema Patient's Steroid Fear

BY DAMIAN McNAMARA
Miami Bureau

TORONTO — A common fear of corticosteroid use and heavy reliance on the Internet for research are among the findings of a large online survey about eczema awareness, treatment, and quality of life, Isaiah J. Day said at the annual conference of the Canadian Dermatology Association.

The survey of 1,071 English- and French-speaking Canadians included 767 people with eczema and another 304 close relatives of someone affected by the condition. Assessment of self-education about eczema and opinions about corticosteroids and topical immunomodulators were among the goals of the Eczema Awareness, Support, and Education (EASE) database Web survey.

Respondents were asked if they were concerned about using topical steroids. A total of 77% indicated yes, with thinning of the skin cited as the No. 1 reason. "There is steroid phobia—it is pervasive—and this may influence compliance," said Mr. Day, a third-year medical student at the University of Alberta, Edmonton.

"Patients may not be aware that steroids come in different potencies," he said.

A total of 632 respondents (59%) reported use of topical corticosteroids by themselves or a relative. Only 44% were aware of topical immunomodulators as a treatment option. Of these, 251 participants (24% of 1,071) reported use of Protopic (tacrolimus) and 150 (14%) reported use of Elidel (pimecrolimus). Three percent did not specify treatment.

The survey was conducted between August 2005 and January 2006. The research was sponsored by Astellas Pharma Inc., which manufactures Protopic. Mr. Day had no disclosure, but his supervisor, Dr. Marlene Dytoc, received funding from Astellas in the past.

"Some fascinating data came when we asked about where they go for information," he said. The leading source was the Internet, cited by 66%, followed by a family physician (55%), dermatologist (50%), and brochures (39%).

"The Internet—hate it or love it. Patients will increasingly turn to the Internet for information," Mr. Day said. Physicians can help patients with eczema by previewing Web sites and recommending those with credible and accurate information.

Another 36% of respondents said that they get information on eczema from articles in newspapers and/or magazines. "This emphasizes the importance of physicians being aware of what is printed in the lay press. It will affect patients accepting or rejecting certain therapies," he said.

The quality of eczema information that respondents received from their doctor was another survey item. A total of 21% felt it was excellent or very good, but 46% felt it was fair or poor, which "suggests there is still room for improvement in delivery of information to patients," Mr. Day noted. ■