Intermittent Therapy for Flare Prevention and Long-term Disease Control in Stabilized Atopic Dermatitis: A Randomized Comparison of 3-Times-Weekly Applications of Tacrolimus Ointment Versus Vehicle


PURPOSE OF THE STUDY. To examine the usefulness of regular intermittent therapy instead of treating flares for the approach of atopic dermatitis (AD).

STUDY POPULATION. A total of 383 patients were randomly assigned to the stabilization phase, and 288 patients were controlled on tacrolimus ointment. There were 68 children (aged 2–16 years) and 57 adults (>16 years) in the tacrolimus arm and 37 children and 35 adults in the vehicle arm. Eighty-five percent had moderate AD, and 15% had severe AD.

METHODS. Adult and pediatric patients with moderate-to-severe AD who were clear of disease after up to 16 weeks of treatment with tacrolimus ointment were randomly assigned in a double-blind fashion to 3-times-weekly treatment with either tacrolimus ointment (0.03% or 0.1%) or vehicle for 40 weeks. The primary end point was the number of flare-free treatment days. Relapses were treated with open-labeled tacrolimus.

RESULTS. There were 288 patients who entered the randomization phase. The largest reasons for not finishing the stabilization phase were voluntary patient withdrawal for 95 patients and loss to follow-up for 55 patients. Only 16 (4.2%) patients were withdrawn for lack of efficacy. A total of 125 patients were randomly assigned to tacrolimus, and 72 patients were assigned to vehicle. The mean number of flare-free treatment days was 177 for the tacrolimus group and 134 for the vehicle group (P = .003). Median time to first relapse was 169 days for the tacrolimus group and 43 for the vehicle group (P = .037).

CONCLUSIONS. Maintenance therapy with tacrolimus ointment was associated with significantly more flare-free days compared with vehicle and a significantly longer time until first disease relapse.

REVIEWER COMMENTS. This article examined the possibility of proactive treatment of AD instead of reacting to flares.

Sustained Efficacy and Safety of Pimecrolimus Cream 1% When Used Long-term (up to 26 Weeks) to Treat Children With Atopic Dermatitis


PURPOSE OF THE STUDY. To evaluate the efficacy and safety of pimecrolimus cream 1% (Elidel [Novartis, East Hanover, NJ]) used for 26 weeks in children with atopic dermatitis (AD).

STUDY POPULATION. This was a prospective study of 403 children aged 2 to 17 years with AD (mean age at enrollment: 6.7 years) recruited from multiple academic centers in the United States.

METHODS. Pooled data were assessed from 20-week, open-label (OL) extensions of 2 previously reported 6-week, double-blind (DB) phase studies in which patients were randomly assigned 2:1 to pimecrolimus or vehicle. During the OL phase, all patients were treated with pimecrolimus. During the DB phase, no other AD treatments except emollients were allowed. The efficacy parameters included the Investigator’s Global Assessment (IGA), Eczema Area and Severity Index, and severity of pruritus scores. Safety assessment consisted primarily of monitoring adverse events. Patients were evaluated on days 8, 15, 22, 29, 43, 71, 99, 141, and 183.

RESULTS. Overall, 60.3% of the patients had moderately severe AD (IGA: 3) at study entry. Twice as many in the control group discontinued during the DB phase compared with the treated group (25% vs 11.4%). The main reason for the higher discontinuation rate in the control group was unsatisfactory therapeutic effect (15.4% vs 2.6%). Eighty-four percent completed the OL phase with similar rates of completion between the groups. At day 43, 34.8% of the pimecrolimus-treated patients versus 18.4% in the vehicle groups (P < .001) had clear or almost clear (IGA: 0 or 1) disease. Pimecrolimus was significantly more effective (P < .0001) in treating the...
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