tients in both the tacrolimus and vehicle groups responded to tacrolimus treatment of relapse. With regard to safety, patients treated during the stabilization phase with tacrolimus versus topical steroid were more likely to have cutaneous site reactions (18% vs 9%; \( P = .015 \)) during the first 4 days of treatment; this was not seen during the rest of the treatment course.

CONCLUSIONS. Tacrolimus maintenance therapy increased the number of symptom-free days and the time to relapse, compared with vehicle alone.

REVIEWERS COMMENTS. AD is a disease characterized by intermittent flares and symptom-free periods. Maintenance, intermittent, topical corticosteroid dosing regimens have been successful in preventing relapse. The use of maintenance steroid-sparing therapies is desirable. This study indicates that maintenance therapy may prevent relapse occurrence and decrease the severity of disease and provides an interesting treatment option for patients with AD with frequent relapses. Also, in light of recent Food and Drug Administration warnings concerning topical calcineurin inhibitors, it is valuable to know that dosing could be reduced to 3 times weekly for maintenance. Overall, this well-designed study provides convincing support for maintenance therapy of AD with topical nonsteroidal calcineurin inhibitors. Similar results were seen in 3 other studies using 2 or 3 times per week dosing schedules for topical steroids and topical calcineurin inhibitors. These studies indicate that maintenance therapy is superior to as-needed use of topical medications for patients with moderate-to-severe AD.

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Three Times Weekly Tacrolimus Ointment Reduces Relapse in Stabilized Atopic Dermatitis: A New Paradigm for Use

PURPOSE OF THE STUDY. To evaluate the safety and efficacy of intermittent topical tacrolimus as maintenance therapy in patients with moderate-to-severe atopic dermatitis.

STUDY POPULATION. Subjects 2 to 15 years of age with moderate-to-severe atopic dermatitis.

METHODS. Subjects underwent stabilization with either 0.05% aclometasone ointment or 0.03% tacrolimus in a double-blind fashion for 4 days, followed by twice-daily, open-label, 0.03% tacrolimus treatment for all subjects. Subjects who became “clear” or “almost clear” entered phase II (maintenance phase) and underwent double-blind, random assignment to either 0.03% tacrolimus or vehicle applied once daily, 3 times per week, for up to 40 weeks. Emollients were permitted, but corticosteroid use was prohibited; open-label tacrolimus use was permitted to treat relapses.

RESULTS. A total of 206 patients were randomly assigned, and 50 subjects completed the study. There were no significant differences between groups at baseline. Aclometasone-treated patients showed more improvement in the acute phase than did tacrolimus-treated patients, and there were no differences in application-site adverse events between groups. During maintenance, tacrolimus-treated patients had a significantly greater number of disease-free treatment days, compared with vehicle-treated patients (mean: 174 vs 107 days; \( P = .0008 \)), and a longer time to first relapse (median: 116 vs 31 days; \( P < .04 \)).

CONCLUSIONS. Long-term intermittent application of 0.03% tacrolimus to clinically normal-appearing but previously affected skin was significantly more effective than vehicle at maintaining disease stabilization in patients with moderate-to-severe atopic dermatitis. The safety profile of intermittently applied tacrolimus was similar to that of vehicle.

REVIEWERS COMMENTS. Atopic dermatitis is a chronic relapsing disease. Prevention of relapse is aimed at skin hydration and avoidance of triggers. Adverse effects of topical steroids limit their long-term use and, although there are concerns that calcineurin inhibitors may carry an increased risk of malignancy, long-term data on the safety of topical calcineurin inhibitors contradict this notion. This study shows promise that intermittent application of 0.03% tacrolimus offers a novel, steroid-sparing approach to maintaining stabilization of atopic dermatitis that seems both safe and efficacious.

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MAS063DP Is Effective Monotherapy for Mild to Moderate Atopic Dermatitis in Infants and Children: A Multicenter, Randomized, Vehicle-Controlled Study

PURPOSE OF THE STUDY. To examine the safety and efficacy of MAS063DP (Atopiclair [Graceway Pharmaceuticals, Bristol, TN]), a topical nonsteroidal antiinflammatory agent, in the management of mild-to-moderate atopic dermatitis in infants and children.
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Satyen Gada and Susan Laubach
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