Pilot trial of 1% pimecrolimus cream in the treatment of seborrheic dermatitis in African American adults with associated hypopigmentation

Whitney A. High, MD,[a] and Amit G. Pandya, MD[b]
Denver, Colorado, and Dallas, Texas

Background: African Americans with seborrheic dermatitis may manifest associated hypopigmenation. Corticosteroids and antifungals are often used for treatment, yet chronic use of corticosteroids may be associated with skin atrophy, increased intraocular pressure, or further hypopigmenation. Pimecrolimus has been used successfully in a few patients with seborrheic dermatitis.

Objectives: This open-label, pilot trial assessed the efficacy and tolerability of pimecrolimus in the treatment of seborrheic dermatitis in African Americans with hypopigmentation.

Methods: Five African American adults with seborrheic dermatitis used a thin layer of pimecrolimus on the involved areas twice per day for 16 weeks. Clinical measures of improvement included erythema, scaling, and pruritus. Hypopigmentation was measured objectively using a mexameter.

Results: All participants noted a marked decrease in the severity of their condition. An improvement in hypopigmentation was also noted. For all indicators, the magnitude of improvement was most marked during the initial 2 weeks of treatment.

Limitations: This was an open-label pilot trial limited to just 6 participants, only 5 of whom completed the study.

Conclusions: Topical pimecrolimus cream may be an excellent alternative therapeutic modality for treating seborrheic dermatitis in African Americans, particularly in those with associated hypopigmentation. (J Am Acad Dermatol 2006;54:1083-8.)

Seborrheic dermatitis is a common skin disease, affecting 3% to 5% of the general population.[1] No racial predilection has been reported. Certain ailments, such as HIV infection or chronic neurologic conditions, may yield extensive or severe involvement.[2,3] Common manifestations include erythema, scaling, and variable pruritus. Sites of predilection include areas rich in sebaceous follicles—the face, scalp, ears, neck, and upper aspect of the trunk. The origin of seborrheic dermatitis has remained a matter of debate. Many investigators favor a pathogenic role for the liphophilic yeast *Pityrosporum/Malassezia*.[4-6] Others have argued the reports of yeast overgrowth represent a mere consequence of a larger immunodysregulatory process.[7-9]

Treatment often involves topical corticosteroids or antifungal products, often with concomitant use of shampoos containing ketoconazole, selenium sulfide, or zinc pyrithione.[10-14] Clinical trials have also demonstrated varying success with topical lithium succinate, metronidazole, ciclopirox olamine, vitamin D_3 derivatives, and, most recently, topical immunomodulators such as tacrolimus and pimecrolimus.[15-24]

Possessing potent anti-inflammatory properties, topical immunomodulators may be used in delicate

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Reprint requests: Whitney A. High, MD, University Dermatopathology Associates, University of Colorado Health Sciences Center, PO Box 6510, Mail Stop F703, Denver, CO 80045-0510.

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Table I. Inclusion and exclusion criteria for pimecrolimus 1% cream in treatment of seborrheic dermatitis of African Americans with hypopigmenation

Inclusion criteria	Exclusion criteria
African American affiliation (self-reported)	Known sensitivity to the investigational agent or the chemical family of investigational agent
Definitive clinical diagnosis of seborrheic dermatitis	Pregnant women or women actively seeking pregnancy
Capability to grant informed written consent	Clinical evidence of a superinfection of the skin
Amenable to follow-up as scheduled in protocol	Topical corticosteroids or topical antimycotic agents in last 2 wks (see washout period)
Total baseline severity score for the primary efficacy measurement of 3 as a prerequisite for entrance	Previous therapy with oral antimycotic drugs in last 4 wks
	Systemic corticosteroids or other immunosuppressive agents in the last 4 wks
	Immunocompromised state (including previously documented HIV)

areas of the body, such as the face, without many of the attendant risks of topical steroids; namely dermal atrophy, increased intraocular pressure, or hypopigmentation.[25] African Americans may derive added benefit from such a therapeutic alternative, as seborrheic dermatitis in this population may lead to noticeable hypopigmentation and cosmetic disability.[26] Certain cultural practices, such as less frequent hair washing, may limit treatment options, heighten the risk of recurrence, or both.[27] For these reasons, pimecrolimus 1% cream, which may be used for extended periods without the risks inherent to corticosteroid use, may be of particular benefit for these patients.

Using a 16-week, open-label, uncontrolled pilot study, we sought to assess the efficacy of pimecrolimus 1% cream in the treatment of seborrheic dermatitis involving the face of African American adults. In particular, we used a mexameter, a device for objectively measuring skin pigmentation, to study the benefit of treatment on skin hypopigmentation associated with seborrheic dermatitis within this ethnic group.

METHODS

This pilot study was approved by the our institutional review board. Six African American adults with seborrheic dermatitis resulting in hypopigmentation, as diagnosed by clinical criteria, participated in this investigation. The inclusion and exclusion criteria are demonstrated in the Table I. After obtaining informed consent, patients underwent a baseline evaluation. Departmental funds were used to purchase the medicine. Medication was provided to patients free of charge.

A 2-week washout period was required for entrance, during which all other treatments were discontinued. Patients were instructed to apply the cream to affected areas twice daily. No other medications for seborrheic dermatitis were allowed during the trial, except for over-the-counter dandruff shampoos started more than 1 month in advance and not used on the face.

At the initial evaluation, patients were examined at 4 sites (anterior hairline, browline, nasolabial folds, and ears). Sites were graded numerically for scaling and erythema using an ordinal scale from 0 to 3 (0 = none, 1 = mild, 2 = moderate, and 3 = severe). Patients also provided a numeric assessment of the pruritus they were experiencing in these areas (0 = none, 1 = mild, 2 = moderate, and 3 = severe). The sum of these scores served as the primary efficacy end point. A secondary efficacy end point was improvement in hypopigmentation in a preselected target area: the area of maximal hypopigmentation on the first visit. Pigmentary improvement was measured using a mexameter with comparison made to uninvolved, sun-exposed, skin adjacent to the target area. The mexameter is a reflectance device that accurately and objectively measures skin pigmentation.[28] In brief, the device measures the reflectance of skin and, thereby, indirectly pigmentation, using a scale from absolute reflectance (pure white, 0) to absolute absorption (pure black, 1000).

Patients were examined at 2, 4, 8, 12, and 16 weeks, with composite scores and hypopigmentation measurements determined at each visit. A patient occasionally missed a scheduled follow-up and this was noted. Patients were asked to report any adverse effects from the trial medication.

RESULTS

Demographics

Six African American adults (2 women and 4 men) enrolled. The age range was 29 to 72 years. One participant promptly disenrolled, as he found it too difficult to travel to the medical center. As we did not have any information regarding a change in his