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Tacrolimus 0.1% ointment for facial seborrheic dermatitis: A randomized, double-blind, placebo-controlled trial

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Background: Seborrheic dermatitis (SD) is a common chronic inflammatory skin disease characterized by persistent erythema, scaling and pruritus of the face, scalp, and chest. The current mainstay of therapy are corticosteroids in conjunction with antifungals. Tacrolimus ointment, a nonsteroidal immunomodulatory agent, may be beneficial in the treatment of SD while avoiding the adverse effects associated with chronic use of corticosteroids.

Objectives: To compare the efficacy and tolerability of topical tacrolimus 0.1% ointment with placebo in the treatment of facial SD.

Methods: Twelve patients with facial seborrheic dermatitis were included in this study, 6 in the topical tacrolimus 0.1% group and 6 in the placebo group. After a 2-week washout period for subjects using conventional therapy, patients were randomized to either treatment ointment or identical-looking inactive placebo ointment and instructed to apply a thin layer of the study product to the face twice daily for 3 weeks. Lesional extent and severity were assessed at baseline, day 1, day 7, day 14, and day 21. The parameters clinical assessment of erythema, scale, and pruritus were evaluated with the use of a 4-point scale (0-3); investigator global assessment and subject global assessment were evaluated with the use of a 5-point scale (0-4).

Results: Ten (83%) of the 12 patients completed the study protocol. Two patients from the placebo group were lost to follow-up at week 3. Tacrolimus reduced all three parameters, erythema, scaling, and itching, more effectively than placebo. Four patients noted transient stinging on application, and 3 noted flushing with alcohol related to tacrolimus use, but no serious adverse events were observed.

Conclusions: This randomized, controlled trial suggests that tacrolimus 0.1% ointment is an effective and well-tolerated alternative to topical corticosteroids in the short-term treatment of facial SD, although a larger study is needed to give statistically significant results.

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P2841

The brain-skin axis

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The effect of psychologic stress on a number of inflammatory skin diseases including psoriasis, atopic dermatitis, and acne has been recognized for many years; however, the underlying mechanisms whereby psychologic factors trigger skin diseases are not understood. We have termed this relationship the "brain-skin axis," which describes the interaction between the psyche, immune system, and inflammation. The physiologic stress response has both central and peripheral nervous system components. The central components are located in the hypothalamus and brainstem; the peripheral components include the peripheral limbs of the hypothalamus-pituitary-adrenal (HPA) axis, the efferent sympathetic adrenomedullary system, and components of the parasympathetic system. Recent studies have shown that psychologic stress compromises cutaneous permeability function and, in examination-induced stress, the alterations in barrier homeostasis were proportional to the extent of the stress. Work in mice has demonstrated that stress—in the form of insomnia—inhibits epidermal lipid synthesis, which leads to abnormalities in permeability barrier homeostasis and stratum corneum integrity. Topical application of a lipid mixture that has no effect on normal mice increased the rate of barrier recovery in the stressed mice. Furthermore, patients with acne may experience worsening of the disease during examinations. Alteration in acne severity appears to correlate highly with increasing stress, which suggests that emotional stress from environmental factors may significantly influence acne. We have investigated the activation of the HPA axis in patients with psoriasis and shown that these patients, particularly those whose disease appears stress-responsive, exhibit an altered HPA response to acute social stress. The implication is that such patients may perhaps be primed to flares of psoriasis. Furthermore, we have shown that individuals with psoriasis who worry excessively take longer to respond to treatment with PUVA photochemotherapy than those in the low-level worry group. More studies to elucidate the brain-skin axis are central to our understanding of the role that stress plays in the neuroimmunology of skin.

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P2842

The impact of first-line biologic choice on pharmacy budget

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Introduction: Patients with moderate to severe chronic plaque psoriasis who failed traditional therapy or could not tolerate traditional therapy may be treated with biologics. Maximizing success rates while minimizing cost is often a goal of therapy. We explored a strategy to reduce cost by selecting a preferred first-line self-injectable biologic. Methods: We modeled the effect on cost of choosing either etanercept or efalizumab as first-line biologic for psoriasis. Using clinical trials for dosing and efficacy, and average wholesale price for cost, we modeled 100 patients beginning treatment with either etanercept or efalizumab. The costs of treatment of adverse events, monitoring, and physician visits were not included in the analysis, since these costs primarily affect the medical budget instead of the pharmacy budget. We assumed those patients who did not achieve PASI50 would switch to the second biologic after 6 months. We compared annual and per-patient costs for each scenario. We assumed all etanercept patients reduced their doses after 12 weeks of therapy consistent with the dosing recommendations in the package insert.

Results: Etanercept costs $1.29 million to treat 100 patients for 24 weeks (drug cost only). On the basis of clinical trial efficacy, 77% would achieve PASI50 and continue on etanercept for another 28 weeks, for an additional cost of $0.77 million. The 23% who failed would switch to efalizumab for the next 28 weeks at cost of $0.22 million, for a total annual cost of $2.29 million. With efalizumab as the first-line biologic, treating 100 patients for the first 24 weeks costs $0.95 million; 67% of patients would achieve PASI50 and continue for the next 28 weeks, with an additional cost of $0.64 million. The remaining 33% would switch to etanercept for the following 28 weeks, costing an additional $0.47 million and resulting in a total annual cost of $2.07 million. Therefore, using efalizumab first could reduce costs by $0.22 million ($2,222 per treated patient). Conclusion: Health plan decision makers may choose to include multiple biologics on formulary. Our model suggests that positioning efalizumab as first-line biologic therapy for psoriasis results in cost savings to a health plan.

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The impact of psoriasis on quality of life: Use of DLQI and PDI questionnaires

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Background: Psoriasis is a chronic disease that affects about 0.1% to 3% of the world's population and most people underestimate the social and psychologic impact of the disease. Several studies described many ways in which psoriasis affects patient's quality of life (QoL), and questionnaires (eg, DLQI and PDI used in this study) have been created to quantify the disability caused. Both are self-administered, and PDI is specifically for psoriasis and DLQI for all dermatologic diseases.

Objective: The aim of this study is to evaluate the impact of psoriasis on QoL of patients examined in the Dermatology Clinic at Federal University of Rio de Janeiro, through the correlation between the PDI and DLQI scores and those from PASI, and also to compare the results between these two questionnaires.

Methods: We administered the DLQI and PDI to 54 patients who were examined in the Dermatology Clinic at Federal University of Rio de Janeiro. We also rated the severity and extension of the disease by means of the PASI, which is used to evaluate the quantity of the skin surface affected, the extent of erythema, infiltration, and scales. Results were examined in light of those originated by DLQI and PDI. The score in our study was the same reported by DLQI and PDI originators (DLQI varies between 0 to 30, and PDI, 0 to 45).

Results: The mean score of DLQI was 7.6 $\pm$ 7.4; PDI was 11.3 $\pm$ 8.6; and PASI was 12 $\pm$ 12.5.We used the Spearman coefficient (r_s) for statistical analysis that measures the correlation between two numeric variables with no parametric distribution. This coefficient varies from -1 to +1 and, when closer to 1, the more perfect is the correlation There is a significative association between DLQI and PDI (r_s = 0.820; P = .0001; n = 54); a significative association between DLQI and PASI (r_s = 0.475; P = .0003; n = 54); and also a significative association between PDI and PASI (r_s = .371; P = .005; n = 54).

Conclusions: Our study highlights the impact of psoriasis on QoL and demonstrates that, as the PASI score increased, the DLQI and PDI scores increased. It shows that the greatest impact on QoL happens in more severe cases. We also found that these two questionnaires are correlated, although DLQI is general and PDI is specific for psoriasis.

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