

Therapeutic Abstracts:

Hassan Riad

Efficacy of different concentrations of ciclopirox shampoo for the treatment of seborrheic dermatitis of the scalp: results of a randomized, double-blind, vehicle-controlled trial.

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Int J Dermatol. 2004 Jul; 43 Suppl 1:9-12.

Abstract:

BACKGROUND: Seborrheic dermatitis is a common inflammatory skin disorder affecting 1-3% of the population. It is thought to be linked to dandruff via a common etiology, yeasts of the genus *Malassezia*. Ciclopirox is a broad-spectrum, hydroxypyridone-derived, synthetic antifungal agent with anti-inflammatory properties. **METHODS:** A total of 203 patients were enrolled in this vehicle-controlled, double-blind, randomized study designed to compare vehicle with three different concentrations of ciclopirox shampoo: 0.1%, 0.3% and 1%, with each applied twice a week. The main efficacy parameters were based on 6-point ordinal scales describing the disease's signs and symptoms (scaling, inflammation and itching), global status of disease, and global change in disease. **RESULTS:** A tendency towards improvement of the sum score from baseline was found in all ciclopirox treatment groups. The most pronounced improvement was found in the ciclopirox 1% group, which changed from a baseline sum score of 8.3 to 4.4 at the end of the 4-week study period (P-value vs. vehicle 0.0372). In addition, the therapeutic index showed increasing efficacy with the use of increased concentrations of ciclopirox.

CONCLUSIONS: The study supports the use of 1% ciclopirox shampoo in the treatment of seborrheic dermatitis of the scalp. Furthermore, ciclopirox shampoo at each concentration was found to be safe and well tolerated.

The impact of a two-compound product containing calcipotriol and betamethasone dipropionate (Daivobet/ Dovobet) on the quality of life in patients with psoriasis vulgaris: a randomized controlled trial. van de Kerkhof PC.

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Abstract:

BACKGROUND: Psoriasis is a common disease and may have a significant impact on patients' quality of life (QoL). **OBJECTIVES:** To assess the impact on QoL of a new two-compound product (TCP) (Daivobet/Dovobet; LEO Pharma) which combines the topical vitamin D analogue calcipotriol (50 microg(-1)) and the World Health Organization group III corticosteroid betamethasone dipropionate (0.5 mg g(-1)) in a single ointment vs. calcipotriol monotherapy using a placebo-controlled study design. **METHODS:** The Psoriasis Disability Index and the EuroQoL 5D questionnaire and visual analogue scale (VAS) were used in this study, which enrolled 828 patients with psoriasis vulgaris for treatment lasting up to 4 weeks. These QoL instruments were completed by patients before and after treatment with the TCP of calcipotriol and betamethasone dipropionate used once or twice daily, calcipotriol alone twice daily and vehicle twice daily. **RESULTS:** The TCP used once or twice daily and calcipotriol used twice daily were found to have statistically significant beneficial effects on patients' QoL over the course of treatment, and each was demonstrated to have a statistically significant benefit on QoL over vehicle. The TCP, applied once daily, was superior to calcipotriol twice daily in terms of reductions on the EuroQoL 5D questionnaire and VAS. **CONCLUSIONS:** The results suggest that calcipotriol twice daily and the new TCP applied twice daily have a substantial effect on QoL. Once-daily application of the TCP is superior to calcipotriol twice daily terms of QoL, which reflects the superior efficacy of this combination and the advantage of once-daily application when compared with twice-daily application.

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Intravenous immunoglobulin (IVIg) for therapy-resistant cutaneous lupus erythematosus (LE)

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Abstract:

BACKGROUND: A group of patients exists with predominantly cutaneous lupus erythematosus (LE) who do not respond to standard oral therapies. There has been interest in the role of intravenous immunoglobulin (IVIg) in a number of connective tissue diseases, and its role in some circumstances has been proven. In the case of LE, there are suggestions

that the use of IVIg for cutaneous and more systemic disease may be of value.

OBJECTIVE: To investigate the use of low dose IVIg for therapy-resistant cutaneous disease.

METHODS: Twelve patients with histologically confirmed cutaneous LE were given IVIg, with starting doses of 1 g/kg \times 2, followed by 400 mg/kg monthly until disease resolution or for 6 months. Disease assessment was by scoring erythema, induration, scaling and the extent before and at the end of therapy. Immunological parameters indicating systemic disease activity were measured before and after therapy.

RESULTS: One patient became pregnant, five patients had complete or near complete clearing of their skin disease (>75%), two had partial but helpful improvement (>50%) and three had limited responses (<50%). One patient developed acute cutaneous vasculitis and received no further therapy.

CONCLUSION: Overall, therapy was well tolerated and side effects were limited. A formal study of IVIg for cutaneous disease would be valuable, but evidence indicates that IVIg may be a useful therapy for cutaneous disease in lupus erythematosus.

Tazarotene 0.1% gel for refractory mycosis fungoides lesions: An open-label pilot study

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Abstract:

Background Topical skin-directed therapies are used to induce remissions in early-stage mycosis fungoides (MF). They are rarely curative, and responding patients are subject to frequent relapses, emphasizing the need for alternative therapies.

Objective: We sought to evaluate the efficacy and tolerability of topical tazarotene 0.1% gel as adjuvant therapy in the treatment of refractory MF lesions.

Methods: A total of 20 adult patients with early patch or plaque MF limited to less than 20% body surface area (BSA) involvement whose lesions were either stable or refractory to therapy for at least 8 weeks enrolled in an open-label pilot study. Tazarotene 0.1% gel was applied to MF lesions once daily for 24 weeks. Continued concomitant use of other medications such as low- to mid-potency topical corticosteroids was permitted for the alleviation of skin irritation. Global improvement, overall disease

severity, percent BSA involvement, and pruritus were evaluated every 4 weeks. Up to 6 index lesions were followed up for area, plaque elevation, scaling, and erythema scores. Skin biopsy specimens were to be taken at baseline, week 8, and week 24. Evaluable specimens were stained with hematoxylin and eosin, CD8 antibody, and CD45RO antibody.

Results In all, 20 patients enrolled, 19 received treatment, and 16 completed at least 4 weeks of topical treatment. By intent-to-treat analysis, 11 of 19 patients (58%) achieved at least a moderate (>50%) global improvement in BSA, and 35% of 99 index lesions cleared completely. Significant reductions (mean differences) were also found in the median lesional area score (-37, $P = .0013$), mean plaque elevation score (-.67, $P = .016$), mean scaling (-0.70, $P = .033$), and mean erythema score (-1.03, $P = .002$). Analysis of overall disease also disclosed statistical differences in percent of change for BSA involvement of 22% ($P = .013$) and of mean overall disease severity score of 34% ($P = .011$). Of 19 patients, 16 (84%) experienced mild or moderate local skin irritation manifested by peeling, erythema, burning, and tenderness that was managed successfully with topical steroids or reducing the frequency of treatment. Histopathology and immunohistochemistry results showed reductions in lymphocytic infiltrates and percentage of CD45RO⁺ lymphocytes, and increases in the percentage of CD8⁺ lymphocytes during the course of therapy.

Conclusion In this small pilot study, tazarotene 0.1% gel was a well-tolerated and effective adjuvant topical for the treatment of refractory MF lesions by clinical and histologic assessments.

Mirtazapine for reducing nocturnal itch in patients with chronic pruritus: A pilot study

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Abstract:

Nocturnal pruritus is a significant problem for patients with inflammatory skin diseases and many systemic diseases. The oral therapies currently available have a limited effect. We present an open, uncontrolled pilot study of 3 patients with inflammatory skin diseases and severe nocturnal pruritus who underwent treatment with mirtazapine (Remeron), a noradrenergic and specific serotonergic antidepressant. Mirtazapine is a safe medication without serious side effects and may be an effective alternative for the treatment of nocturnal pruritus.

Treatment of recalcitrant scleromyxedema with thalidomide in 3 patients

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Abstract:

Scleromyxedema is a generalized, papular, and sclerodermoid form of lichen myxedematosus associated with monoclonal gammopathy and systemic changes. Despite anecdotal reports of success with various agents, no satisfactory treatments are currently available. We report 3 adult patients with recalcitrant scleromyxedema associated with paraproteinemia who were treated with thalidomide. All 3 patients had marked improvement of the skin lesions and joint mobility after the first 2 months of therapy, with further amelioration after 4 months, and reduction in paraprotein levels.

Cutaneous T-cell lymphoma treatment using bexarotene and PUVA: A case series

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Abstract:

Background Mycosis fungoides, the most common form of cutaneous T-cell lymphoma, often presents as chronic eczematous or psoriasiform patches and plaques that can be resistant to a variety of single-agent treatment modalities, necessitating combination therapy.

Objective To evaluate the efficacy of combination therapy with bexarotene and psoralen plus ultraviolet A (PUVA) in treating patients with cutaneous T-cell lymphoma (CTCL) that recurred following monotherapy with multiple agents, including electron-

beam irradiation, interferon, PUVA, and topical steroids. This was done by retrospective chart review.

Methods Retrospective chart review analysis of eight patients with CTCL ranging from stage Ia to Iib who failed multiple single-agent treatment regimens treated with low-dose oral bexarotene and PUVA combination therapy.

Results We noted an initial response in all eight patients and complete remission in five of the patients treated, with pruritus being the most common adverse event.

Conclusion In view of its good safety profile, combination therapy with bexarotene and PUVA may be considered for patients with treatment resistant CTCL refractory to monotherapy.

Etanercept therapy for patients with psoriatic arthritis and concurrent hepatitis C virus infection: Report of 3 cases

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Psoriasis and psoriatic arthritis are exacerbated by interferon alfa and other treatments for hepatitis C virus infection. Immunosuppressants and hepatotoxic drugs are relatively contraindicated in hepatitis C. Data in the literature suggest that etanercept is a safe option in the treatment of patients with rheumatoid arthritis and concurrent hepatitis C. We present three cases in which we have successfully used etanercept to treat psoriatic arthritis/psoriasis in patients with hepatitis C without worsening their hepatitis or interfering with their hepatitis treatment. With close monitoring of viral load and hepatic enzymes, etanercept may be a safe option for treating psoriatic arthritis/psoriasis in patients who also have hepatitis C.

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