International Journal of Cutaneous Disorders & Medicine
ISSN: 2689-6168

Research Article *Volume 3 Issue 2*

The Effectiveness of Topical Pimecrolimus in Patients with *Alopecia Areata*

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Received Date: November 13, 2020; **Published Date:** December 07, 2020

Keywords: Immunological; Pimecrolimus; Inhibitors

Abbreviations: AA: Alopecia Areata; NAAF: National Alopecia Areata Foundation; SPSS: Statistical Package for Social Sciences.

Introduction

Alopecia areata (AA) is a nonscaring, autoimmune, hair loss on the scalp and/or body. Although the etiopathogenesis of the disease is not fully known, genetic factors, immunological factors, neurological factors, infections and emotional stress are thought to play a role. Interferon γ, TNF-**α** IL-1, IL-2, IL-5, IL-6, IL-16 have been shown to play a role in the pathogenesis of AA. In AA, the peribulbar mononuclear cell infiltrate is composed predominantly of activated CD4+ and CD8+ T lymphocytes. Pimecrolimus is an ascomycin macrolactam derivative with anti-inflammatory and immunomodulatory activity like tacrolimus. It prohibits calcineurin-mediated dephosphorylation of activated T-cells, which inhibits synthesis of T-helper1 and T-helper 2 cytokines from T lymphocytes**.** It also prevents the formation and release of IL-1, IL-2, IL-3, IL-8, IL-10, TNF α, interferon γ. Corticosteroids, minoxidil, anthralin, immunomodulators (Dinitrochlorobenzen) and photochemotherapy (PUVA) have been used topically and, immunosuppressive agents such as corticosteroids, cyclosporine, JAK inhibitors and biologic agents have been used in the treatment of AA. During recent years the use of pimecrolimus in AA has given controversial results [1-4]. The aim of our study was to evaluate the efficacy and safety of topical pimecrolimus 1% cream in AA.

Materials and Methods

In total, 20 patients with AA affecting 10-25% of scalp, beard and eyebrows for no more than 2 years duration were enrolled in the present research.

Study Plan

The patients enrolled in the present study were questioned about the duration of the disease, the onset age, and the presence of atopy, family history and the presence of other autoimmune diseases, which are considered to influence the prognosis. In the dermatological examination, clinical type (patchy, ophiasic, reticular), nail involvement and the presence of the activity were evaluated. The activity was defined by hair around the lesion coming out easily when pulled and symptom of exclamation point hair. The patients were questioned about their previous treatments and whether responses to these treatments were obtained. Other diseases that are likely to interfere clinically with AA (telogen effluvium, androgenic alopecia, trichotillomania, tinea capitis superficialis) were excluded. In case of suspected tinea infection, examination of native preparations was performed. Out of the factors that are considered to influence the prognosis of the disease, the percentage of disease involvement, the involvement score and disease duration score were calculated in accordance with the scoring system of (American) National Alopecia Areata Foundation. Additionally, during the inclusion period, photos were taken of the patients to allow an objective evaluation of the efficacy of the treatment in follow-ups.

Treatment Protocols and Evaluation of Patients

Topical 1% pimecrolimus cream was applied twice daily for 6 months. The cases were checked once every month and the width of the alopecic focus was measured with the scoring system of (American) National Alopecia Areata Foundation [5]

Scoring the hair regrowth:
Score 1: no hair regrowth or worse
Score 2: vellus-type hair growth
Score 3: non-pigmented terminal hair growth.
Score 4: the presence of pigmented terminal hair
Score 5: mixed-type hair growth (the association of vellus and terminal hair)

In evaluation of the percentage recovery in alopecic plaques, existing percentage hair loss was taken as the base value. For example, when the patient was referred with a percentage hair loss of 75% at the beginning of the treatment and when the size of the alopecic plaque was 50% at the end of the treatment, then percentage recovery = (75–50/75 = 0.33 = 33%) (Olsen et al 2004). While calculating the percentage recovery, the presence of pigmented terminal hair only was taken as the base. Vellus-type hair growth was recorded but not used in the calculation of percentage recovery. After the percentage recovery was calculated, the scoring was performed as follows [5].

Percentage of recovery score:
Score 0 = no change or further loss
Score 1 = <25% regrowth
Score 2 = 25–49% regrowth
Score 3 = 50–74% regrowth
Score 4 = 75–99% regrowth
Score 5 = 100% regrowth

During the examinations, the presence of alopecic areas was also evaluated and recorded. Possible side effects were taken into consideration and recorded. Side effects such as erythema and burning were evaluated for treatment with pimecrolimus 1%.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS Inc, Chicago, IL, USA) 13.0 for Windows was used for the data analysis. Descriptive statistics were expressed as mean ± standard deviation and %. Student t-test was used to compare parametric values and c2 test to evaluate the non-parametric values.

Results

A total of 20 patients with AA were enrolled in the our study. Of these, 11 patients were male and 9 patients were female and the female to male ratio was 1:1.22. The ages of the patients ranged from 6 to 50 years and the mean age was 25.9 ± 7.23 years. The duration of the disease was 11.5 ± 2.48 months. Complete improvement was observed in one (5%) of 20 patients, moderate improvement in 1 (5%) and mild improvement in 3 (15%). Fifteen patients (75%) did not response to the treatment. No adverse effects were observed in the cases.

Discussion

Pimecrolimus cream is an approved product for the treatment of atopic dermatitis, and is used in numerous dermatological diseases today [6,7]. Because of its effects on the immune system, the efficacy of pimecrolimus is being tested for the treatment of AA which is a disease of autoimmune origin. There are only two study in the literature investigating the use and efficacy of pimecrolimus in the treatment of AA [3,4]. Rigopoulos et al. evaluated the efficacy and tolerability of pimecrolimus in patchy AA patients with 10–25% of involvement of the scalp. In that study, pimecrolimus cream 1% was applied to one alopecic plaque of patients and panthenol cream was used as placebo in another plaque. At the end of the 24-week treatment, an acceptable result was obtained only in 2 of 15 patients. They emphasized that pimecrolimus cream 1% was not superior to placebo in the treatment of AA Ucak, et al. suggest that topical pimecrolimus treatment is as effective as topical corticosteroids and is superior to topical corticosteroids in terms of side effects in the treatment of AA. In that study, they reported an acceptable recovery rate (>50% recovery) of 53.7% in patients who were treated with pimecrolimus cream at the end of the 12-week treatment period and found the treatment with pimecrolimus cream 1% to be effective. In our study, no response was obtained in 15 patients who received topical 1% pimecrolimus treatment twice daily for 6 months. Complete improvement was observed in 1 patient, moderate improvement in one patient and mild improvement in 2 patients. This improvement is thought to be spontaneous in 5 patients. Topical 1% pimecrolimus treatment was ineffective in patients with alopecia. For this reason, it is thought that it should not be considered as a treatment option in alopecia areata cases that do not respond to topical treatments.

Funding: none

Conflicts of Interest: The authors have no disclosures.

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