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EFFECT OF 0.1% TACROLIMUS OINTMENT IN LOCALIZED VITILIGO: AN OPEN UNCONTROLLED TRIAL

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Sir,

Vitiligo is characterized by well-circumscribed milky white cutaneous macules devoid of melanocytes.^[1] Abnormalities in humoral and cell-mediated immunity have been documented in vitiligo patients.^[1] Definitive studies of effectiveness of topical tacrolimus, particularly on localized vitiligo, are lacking. Hence, the present study was carried out to study the therapeutic response of topical tacrolimus in localized vitiligo and the possible adverse effects.

A prospective study was conducted by the Pharmacology department from October 2005 to September 2006. Sixty-three patients diagnosed as localized vitiligo by the dermatologist at R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Kolar, were included in the study. Informed consent was taken from all the patients. Ethical clearance was obtained from the institutional ethical committee.

The patients included were of either sex in the age group of 2–60 years, with less than 10% involvement of the total body surface area. Patients receiving Psoralen Ultra-Violet A (PUVA) phototherapy, cancer chemotherapy, immunosuppressants and corticosteroids, pregnant women, lactating mothers, patients with diabetes mellitus, thyroid disorders, herpes simplex virus infection, chicken pox, varicella zoster infection, erythroderma, bacterial and fungal skin infections were excluded from the study.

Patients' age, sex, duration of illness, site and percentage of depigmented area of skin were recorded. Baseline and follow-up vitiligo area scoring index (VASI)^[2] was calculated. Tacrolimus ointment (Crolim, Ranbaxy Gurgaon, India) 0.1% was applied twice daily for 3 months. Response to therapy (repigmentation) was assessed at 15 days and then every month up to 3 months using VASI. Wilcoxon paired signed rank test was used to analyze VASI before and after treatment.

Fifty-five patients completed the 3-month study duration. There were 30 female and 25 male patients. The clinical response in relation to sex was similar

($P = 0.5$). Mean age in males was 30 ± 12 years and that in females was 30 ± 16.6 years. The youngest patient was 3 years old and the eldest was 57 years old. There was improvement in the clinical response at the end of 3 months but it was statistically insignificant ($P = 0.2$) when compared between the first two decades and later decades.

Thirty-two patients had 11 months, 19 had 12–23 months and 4 had 36–48 months history of vitiligo. The response to treatment did not change based on the duration of illness ($P = 0.9$). Thirty-seven patients had 1% of body surface area involved, followed by 11 patients with 2% involvement. Also, 3 and 4% of body surface area was involved in four and three patients, respectively. In 32 patients, single region was affected, with 20 patients having lesions on the face especially involving the lips, eyelids, and ears. The clinical response was better over the face as compared to other sites but statistically not significant ($P = 0.9$).

Of the 55 patients, 36 showed response to treatment and 19 of them did not show any response after 3 months of treatment. The P value was 0.317 at the end of 15 days compared with the baseline. It was 0.004, 0.001, and 0.001 at the end of 1, 2, and 3 months, respectively. This shows that the response to treatment was statistically significant after 1 month of treatment and highly significant when the treatment was continued up to 2–3 months. The photographs show the improvement of lesions seen as repigmentation of depigmented areas [Figures 1a and b]. One patient

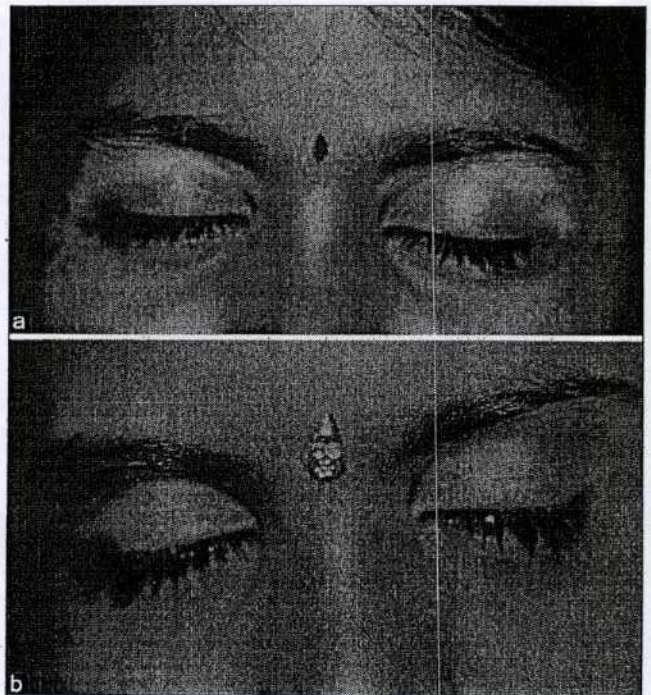



Figure 1: (a) Eyelids before treatment; (b) eyelids 3 months after treatment

had itching initially following the application of tacrolimus ointment and it disappeared with continuation of treatment.

The improvement in VASI score represents the repigmentation of vitiligo lesions which was statistically significant as observed in other studies.^[3,4] Good response observed in patients having lesions involving the face (eyelids, around the ear, and the post auricular region) may be due to greater density of hair follicles in these areas and thus the greater melanocyte reservoir.^[5] Most common therapy in vitiligo involving <10% of the body surface area is with topical steroids. Clinical response and the repigmentation with topical steroids are almost similar to that of topical tacrolimus.^[6] Steroid application causes atrophy of skin, telangiectasia, hypertrichosis and acne,^[6] but these are not seen with tacrolimus treatment.^[3,4,6] Therefore, tacrolimus seems to have a better safety profile than topical steroids and an alternative option in vitiligo involving <10% body surface area (especially face). To conclude, treatment with topical tacrolimus (0.1%) ointment is a safe and effective therapy for localized vitiligo. Further large controlled studies are required to substantiate these findings.

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