

## **A COMPARATIVE STUDY OF CLOBETASOL PROPIONATE (0.05%) CREAM AND TACROLIMUS (0.1%) OINTMENT IN THE MANAGEMENT OF VITILIGO**

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**ABSTRACT: AIMS AND OBJECTIVES:** To study and compare Tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%) in the management of vitiligo. To know the type of vitiligo, age and sex distribution, and to know the percentage of repigmentation and adverse effects encountered with Tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%).

**RESULTS:** In the present study 50 cases of vitiligo divided in to two equal groups treated with either Tacrolimus ointment (0.1%) or clobetasol propionate cream (0.05%) were included. In this study the peak incidence of vitiligo is in the age group of 21-30 years, with slight female preponderance (58%), focal form of vitiligo is common (36%), response to clobetasol propionate cream (0.05%) is 76% whereas with tacrolimus ointment (0.1%) it is 64%. Adverse effects with clobetasol propionate cream (0.05%) is seen in 7 patients (28%) and with tacrolimus in one patient (4%). **CONCLUSION:** In the present study clinical efficacy of Tacrolimus ointment (0.1%) was almost equal to clobetasol propionate cream (0.05%) and Tacrolimus ointment (0.1%) had a fewer side effects than clobetasol propionate cream (0.05%) but the compliance was found to be better with clobetasol propionate cream (0.05%) due to its cost effectiveness.

**KEYWORDS:** Vitiligo, Tacrolimus ointment (0.1%), clobetasol propionate cream (0.05%).

**INTRODUCTION:** Vitiligo is a specific type of pigmentary disorder manifested by depigmentation, occasionally hypo pigmentation of the epidermis. Clinically it is characterized by circumscribed chalky white macules or patches, few or many in number, which tend to enlarge centrifugally over time.<sup>1</sup> All races and ethnic groups are equally affected with female preponderance. vitiligo is neither contagious nor does it contribute to the loss of general health. There is immense social stigma associated with this condition. The resultant effect of psyche of the patient is dramatic, often with a distortive body image, fear and anxiety. Vitiligo cannot be considered as a single disease entity but as the end result of interplay of numerous factors.<sup>2</sup> Vitiligo involves 0.5%-4% of the world's population and causes alteration in the physiology of the epidermis as well as cosmetic and psychological problems.<sup>3</sup>

A variety of therapeutic agents are used for the treatment of vitiligo, but none is clearly a definitive cure. Therapy for vitiligo must emphasize not only the medical and surgical aspects but also take in to account of the psychological aspects. The present study is a comparative study of Tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%) in the management of vitiligo.

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**MATERIALS AND METHODS:** The present prospective study includes 50 cases of clinically diagnosed vitiligo attending the outpatient department of dermatology, Kurnool medical College, Kurnool from December 2011 to December 2012 over a period of 12 months. In this study patient with focal, local, segmental, lip tip, mucosal and acrofacial vitiligo were included. Generalized and universal vitiligo was excluded in this study.

A detailed history including the age, sex, occupation, and socioeconomic status, duration of disease, diabetic status and personal history was taken. Routine investigations like urine examination and blood investigations were done. The patients were divided in to two groups. One group was treated with tacrolimus ointment (0.1%) and other group was treated with clobetasol propionate cream (0.05%) for a period of 3 months. They were devoid of any other topical or systemic therapy for 2 months prior to inclusion. Patients were evaluated every month for a period of 3 months, repigmentation and adverse effects were recorded.

**RESULTS:** In the present study 50 cases of clinically diagnosed vitiligo divided in to two groups. One group was treated with tacrolimus ointment (0.1%) and other group was treated with clobetasol propionate cream (0.05%) for a period of 3 months.

In the present study peak incidence of vitiligo is seen in the age group of 21-30 years, accounting for 40% of cases and sex distribution shows slight predominance of females. Male to female ratio being 1: 1.38.

In the present study focal vitiligo is more common than other clinical forms of vitiligo with 36%, segmental form (24%), mucosal form (18%), lip tip form (14%) and acrofacial vitiligo (8%).

In this study percentage of response with tacrolimus ointment(0.1%) in the first month was 37.5%, second month 50%, third month 12.5% respectively and with clobetasol propionate cream (0.05%) was 47.36% in the first month, 42.10% in the second month, 10.52% in the third month respectively. In total the percentage of patients responding to tacrolimus ointment (0.1%) is 64% and clobetasol propionate cream (0.05%) is 76%.

In the present study tacrolimus ointment(0.1%) showed 1-25% of repigmentation in 9 patients, 26-50% in 4 patients, 51-75% in 2 patients and only one patient showed >75% of repigmentation. 4 patients did not show any repigmentation and 5 patients were lost for follow up. Like-wise, with clobetasol propionate cream (0.05%),8 patients had 1-25% of repigmentation, 6 patients had 26-50%, 3 patients had 51-75% and only 2 patients showed >75% of repigmentation, No response was seen in 4 patients and 2 patients were lost for follow up. The percentage of patients showing repigmentation in a period of 3 months was 64% in patients treated with tacrolimus ointment(0.1%) and 76% in patients treated with clobetasol propionate cream (0.05%). The clinical efficacy was almost equal with both the drugs.

In the present study side effects were encountered in 7 patients with clobetasol propionate cream (0.05%) and in one patient with tacrolimus ointment (0.1%).Thus tacrolimus has a wider safety profile than clobetasol propionate.

In the present study tacrolimus Ointment (0.1%) Proved to be costlier for patients in contrast to clobetasol propionate cream (0.05%) which was cheaper. For this reason the compliance was better with clobetasol propionate cream (0.05%) than tacrolimus ointment (0.1%).

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**DISCUSSION:** Vitiligo has been mentioned in the literature of various ancient civilizations. Earliest reports on patchy skin diseases were found in Ebers papyrus dating back to as far as 1500B.C. The social effects of skin diseases may cause more hardship than physical limitations. The psycho social aspects of vitiligo were evaluated in various studies by porter et al.<sup>4</sup>

In the present study 50 clinically diagnosed cases of vitiligo attending the outpatient department of dermatology, government general hospital, Kurnool were studied for comparing the efficacy of tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%) in the treatment of vitiligo. The patients are divided in to two groups of 25 each to study the effect of tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%). Clinical response was observed once in a month during the study period of 3 months.

The observations showed that the peak incidence of vitiligo was in the age group of 21-30 years (40%) with a slight female preponderance in the ratio of 1:1.38. In the study conducted by R. V. Korame et al, patients below the age of 30 years constituted 85% of study group.<sup>5</sup> In another study by N. R. Mehta et al males and females were similarly affected, the age of specific incidence was found to be maximal in age group of 6-15 years, with 33% of cases falling in this age group.<sup>6</sup>

The most common clinical form of vitiligo was focal vitiligo (36%) and the least common was acrofacial vitiligo (8%). The other clinical forms of vitiligo with descending order were segmental (24%), mucosal(18%), and lip tip (14%). Generalized and universal vitiligo were excluded from this study because of the risk of systemic absorption of the medication and the financial inputs associated with the treatment. In this study percentage of response with tacrolimus ointment (0.1%) in the first month was 37.5%, second month 50%, third month 12.5% respectively and with clobetasol propionate cream (0.05%) was 47.36% in the first month,42.10% in the second month, 10.52% in the third month respectively. The clinical response in a period of 3 months was almost equal for both tacrolimus ointment (64%) and clobetasol propionate cream (76%).

In the present study tacrolimus ointment (0.1%) showed 1-25% of repigmentation in 9 patients, 26-50% in 4 patients, 51-75% in 2 patients and only one patient showed >75% of repigmentation. 4 patients did not show any repigmentation and 5 patients were lost for follow up. Like-wise, with clobetasol propionate cream (0.05%), 8 patients had 1-25% of repigmentation, 6 patients had 26-50%,3 patients had 51-75% and only 2 patients showed >75% of repigmentation, No response was seen in 4 patients and 2 patients were lost for follow up. Tus it may be concluded that the repigmentation grades were almost the same for both the drugs.

In a randomized trial by Lepe V, Moncada et al 18(90%) of 20 patients experienced some pigmentation. The percentage of repigmentation was (49.3%) for clobetasol propionate cream (0.05%) and 41.3% for tacrolimus ointment (0.1%). Lesions in 3 patients using clobetasol propionate cream (0.05%) presented with atrophy, and 2 lesions incurred telangiectasia; tacrolimus ointment (0.1%) caused burning sensation in 2 lesions.<sup>7</sup> In another study sanjay singrodia et al the safety and efficacy of topical tacrolimus (0.1%) showed moderate response in 5%, poor response in 30%. Neither topical tacrolimus nor topical clobetasol showed excellent response. It was concluded from their study that neither of the drugs alone was effective for the

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treatment of segmental vitiligo and topical tacrolimus (0.1%) caused lesser side effects than clobetasol propionate.

In the present study the clinical efficacy was almost similar with tacrolimus ointment (0.1%) clobetasol propionate cream (0.05%). Side effects like atrophy was observed in 7 patients treated with clobetasol propionate cream (0.05%) and burning sensation was observed in one patient treated with tacrolimus ointment (0.1%). Thus tacrolimus is a safer drug with fewer side effects than clobetasol propionate and can be used safely for prolonged periods even in the sensitive areas of skin.

Tacrolimus ointment (0.1%) is costlier than clobetasol propionate cream (0.05%). Since tacrolimus is costly the drop outs with tacrolimus was 20% (5 cases) and drop outs with clobetasol propionate cream was only 8% (2 cases).

**CONCLUSION:** In the present study clinical efficacy of Tacrolimus ointment (0.1%) was almost equal to clobetasol propionate cream (0.05%) and Tacrolimus ointment (0.1%) had a fewer side effects than clobetasol propionate cream (0.05%) but the compliance was found to be better with clobetasol propionate cream (0.05%) due to its cost effectiveness.

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**Fig. 1: Clinical photograph showing before and after treatment with clobetasol propionate cream (0.05%)**



**Fig. 2: Clinical photograph showing before and after treatment with tacrolimus ointment (0.1%)**

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