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COMPARISON OF SAFETY AND EFFECTIVENESS OF TOPICAL TACROLIMUS VERSUS PIMECROLIMUS IN MANAGEMENT OF STABLE VITILIGO

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Abstract

The purpose of the current study was to examine the safety and effectiveness of topical tacrolimus versus pamicrolimus in the treatment of stable vitiligo.

Methods: 97 patients with vitiligo were taken in this study. Patients were groups into two: pimecrolimus cream (49) and tacrolimus ointment (48). Each vitiligo activity was assigned to 0 day, 2 week, 4, 8, 12, and 24 weeks for the all duration of therapy. Patients were tested using digital images, and treatment efficacy was measured based on the percentage and score of regurgitation of all scored lesions.

Results: At the end of the 24th week, Tacrolimus users showed 25% regimentation with a score of 2.62 regimentation while Pimecrolimus users showed 20% regimentation with a score of 2.02 regimentation. After 24 weeks, Tacrolimus users reported more prominent than Pimecrolimus topical drug users.

Keywords: Pimecrolimus; Tacrolimus; Stable Vitiligo

Introduction

Vitiligo is a disease that begins with the immune system against melanocytes and causes the skin to lose its oily cells, manifested by hypopigmented or achromic spots and spots. Wounds can be localized or enlarged and have a very negative effect on quality of life. The disease may be accompanied by one or more macula (localized vitiligo) grouped in a non-localized way, or may extend to the entire macula (universal vitiligo) [1]. Vitiligo itself is classified into two major forms on medical grounds: segmental vitiligo (SV) and non-segmental vitiligo (NSV), and later several variants (generalized vitiligo, facial vitiligo, universal vitiligo). It is included, NSVs are found through depigmented macula with different sizes from a few centimeters to a few centimeters in diameter and often include both sides of the body that tend towards a harmonious distribution. Temporary erythema may be observed on depigmented skin after UV (UV) irradiation, which can be misleading in the medical context. Boundaries of hyperpigmented lesions may be seen during the course of the disease, especially in people with dark skin after exposure to UV light. Local spots on the white hair or white hair may appear on the scalp and other parts of the hair. Unlike SVs, NSVs can cause hair discoloration as the disease progresses, but hair usually survives and remains colored. [2].

Basic approaches to vitiligo therapy include the use of potent corticosteroids and the administration of phototherapy, including psoralen-UVA (PUVA) or NB-UVB [3]. Topical calcineurin inhibitors are another recently introduced option for treating vitiligo. These compounds provide the benefits of long-term use while avoiding the adverse effects of long-term use of topical steroids [4, 5]. Topical immunomodulators contains 0.1% tacrolimus ointment and 1% pimecrolimus cream [6, 7]. The objective of the current study is to compare pimecrolimus and tacrolimus treatments and to find out the effectiveness and toxicity of in the patient condition with vitiligo.

Criteria of Patient

97 patients with vitiligo diagnosed were included in the study through medical history. The patients visited the dermatologist between August 2020

and August 2021 in tertiary care hospital were included.

The exclusion criteria

Pregnant women, infectious disease, neuropathy or psychiatric disorders, autoimmune disorders (systemic lupus erythematosus, dermatomyositis, polysclerosis, or Graves' disease), immune disorders, heart disease, renal failure, history of neonates or current Medical history. Patients received any topical or systemic immunosuppressive therapy for them wash out period will be 6 months duration. The patients are also excluded who received phototherapy, or any side effects of phototoxic reactions or any photosensitivity history or some related disorders are not included.

Method:

Informed written consent were taken after informing the patients regarding treatment for vitilig and possible side effect in detail. Patients were examined with digital photographs at week 0, 4, 8, 12, 16 and 24. The dermatologists then independently reviewed the image and compared it to the original image. Treatment efficacy was measured based on mean repigmentation percentages and lesions score. The patients were clearly informed about their disease, possible treatment options, possible side effects and the study plan.

Treatment Plan

The patients were scheduled on the basis of a computer-generated randomization into two groups: 49 patients were treated with pimecrolimus cream twice in day, 48 patients applied tacrolimus ointment twice in day both the treatment were given for 24 weeks. Males and female were both included in study and had actively participated in study. Efficacy assessments were done by dermatologists at 0, 4, 8, 12, 16 and 24, the patients were examined with digital photographs. Treatment efficacy was measured based on mean repigmentation percentages and scores for all lesions. The Repigmentation score was measured were as follows [9]: No repimentation rate- 0 Score, Repigmentation between 1- 25%- 1 Score, Repigmentation between 25- 50%- 1 Score, Repigmentation between 51- 75%- 3 Score, Repigmentation above 75%- 4 Score side effects such as itching, burning, and erythema were recorded at 4, 12, and 24 weeks of treatment, from mild to severe using a 4-point scale (0 to 3) i.e mild to severe scale.

Statistical analysis

Statistical analysis method were used to analysis data and change in values are written in mean ± SD.

Results

The effectiveness of both drugs was interpreted in terms of percentage of repigmentation and the corresponding score given for that. 4 weeks of study, percentage of repigmentation was negligible. At the end of 8 weeks, Tacrolimus patients showed 1.84 % and Pimecrolimus patients showed 1.32% repigmentation. At the end of 12th and 16th week, Tacrolimus patients showed better treatment comparing in Pimecrolimus patients. At the end of 24th week, Tacrolimus patients showed 26% repigmentation with repigmentation score 2.32 as compared, Pimecrolimus patients showed 21% repigmentation with repigmentation score 2.01.

Table 1: Demographic data of vitiligo patients

	Tacrolimus	**Pimecrolimus**
Men	32	30
Women	16	19
Age*	22±7.5	19±6.4
Duration*	5±3.5	7±5.2

Table 2: Tacrolimus and Pimecrolimus Treatment in Patients Lesions

		Tacrolimus	Pimecrolimus
Baseline	Percentage of involvement	45±20.7	30±10.6
4th week	Repigmentation Score	0.12±0.2	0.08±0.5
	% Repigmentation	0.32±0.5	0.28±0.4
8th week	Repigmentation Score	2.12±0.71	1.79±0.4
	% Repigmentation	0.92±0.4	0.79±0.2
12th week	Repigmentation Score	10.65±0.9	8.85±0.9
	% Repigmentation	1.41±0.2	1.26±0.2
16th week	Repigmentation Score	20.24±0.2	15.4±0.2
	% Repigmentation	1.85±0.4	1.85±0.4
24th week	Repigmentation Score	29.12±5.1	23.26±6.7
	% Repigmentation	2.32±0.5	2.01±0.7

Table 3: Side effects of Tacrolimus and Pimecrolimus in Patients

		Tacrolimus	Pimecrolimus
4th week	Erythema	0.8±0.5	0.74±0.42
	Burning	0.4±0.4	0.44±0.81
	Pruritus	0.32±0.5	0.30±0.3
12th week	Erythema	0.65±0.71	0.5±0.15
	Burning	0.29±0.4	0.24±0.22
	Pruritus	0.25±0.9	0.21±0.41
24th week	Erythema	0.31±0.2	0.24±0.12
	Burning	0.24±0.2	0.19±0.3
	Pruritus	0.19±0.4	0.14±0.7

Discussion

Numerous alternative therapies, including topical corticosteroids, topical calcipotriol, some other topical calcineurin inhibitors and any phototherapy related to UVB, NB-UVB OR PUVA are been recently used in combination or individually for the treatment of the vitiligo. Despite this type of treatment alternative, the response to treatment varies significantly [9, 10]. It has been seen that acrylic lesions are not much effective to treatment, but the lesions present on neck or facial seen better effect to some patients who have both types in them and received the treatment [11, 12]. In recent study, we compared and compared the effectiveness and side effects of two topical drugs, tacrolimus and pamicrolimus. The calcineurin inhibitors shows two basics mechanisms of action for treatment is melanocyte induction and immunosuppression. First, TCI inhibits the cytotoxic CD8 + T cells, which are the autoimmunity of vitiligo, by inhibiting calcineurin-mediated phosphorylation of activated T cell atoms. It has been seen that in vivo studies vitiligo lesions shows effective with TCI treatment and reduced TNF factor and also seen increased in IL-10. Second, TCI stimulates vitiligo regulation by stimulating melanocyte proliferation and migration and melanin synthesis [13, 14]. This process involves increased activity of MMP-2 and MMP-9, increased expression of endothelin B receptors in melanoblasts, and enhanced release of stem cell factor from keratinocytes after TCI treatment. In addition, a low level of oxidative stress and an increase in antioxidant capacity have been observed in serum samples of patients treated with topical tacrolimus. We confirmed a positive therapeutic response to TCI monotherapy for

vitiligo. TCI monotherapy showed a good response rate to treatment, with 55.0% of patients achieving a mild response (> 25% reperfusion) after a 3-month treatment interval. In pediatrics patients the single drugs treatment shows effective with calcineurin inhibitor. 66.4% of children responded mildly and 31.7% responded significantly (75% regimen). One study shows that rehabilitation therapy with TCI prevents recurrence of vitiligo after successful regimentation. Active treatment with TCI is recommended to treat atopic dermatitis to prevent new attacks [15]. In other parts of the body, the face and neck responded best, with at least 73.1% of patients responding mildly compared to other parts of the body. Some hypotheses help explain these results. Hair follicles, which act as a reservoir of melanocytes, are formed early in the foetation and separate after birth as the skin develops, so children's hair follicles are denser than adults and are also found on the face and neck. In addition, daily exposure to sunlight on the head and neck may be associated with better results. The effectiveness of pimecrolimus in the treatment of vitiligo is still controversial. The effective measurement in of Choi's treatment was compared to 52 patients with vitiligo who received immunomodulatory treatment (51 tacrolimus and 1 picrolimus) and 27 patients with vitiligo who received topical steroid treatment. They reported that the local immunomodulatory group initiated statistically short regulation, but the results of both treatments were similar, and local immunomodulators were as effective and reliable as topical steroids. There are other studies reporting similar results [16]. Mometazone cream and Pimechlorimus cream were used for 3 months in 40 children with vitiligo. The average rate of regimen was found to be higher in patients who used momitazone cream (65%) than in patients who used pimchlorimus cream (42%), but the difference was statistically significant. It wasn't. However, this study concludes that Momitason Cream is more effective for body wounds and Pemicrolimus is more effective for facial wounds, but not for other wounds field. In contrast to this study, Ho et al. [17] showed that pmicrolimus was as effective as clobetasol propionate in facial and non-facial lesions, patients enrolled inthis study was around 100, and compared with three drugs treatments which are clobestasol, tacrolimus and placebo. In addition, patients were divided into two groups, one with facial scars and one without facial scars, and were followed for 6 months. The use of tacrolimus and clobetasol propionate was found to be equally beneficial in the face and non-face groups, with significant statistical improvements in both groups compared to the placebo group [18]. The current study shows the effective measurement of both drugs were interpreted in terms of percentage of repigmentation and the corresponding score given for that. At the end of 4 weeks, percentage of repigmentation was negligible. At the end of 8 weeks, Tacrolimus users showed 1.84 % and Pimecrolimus users showed 1.32% repigmentation. At the end of 12th and 16th week, Tacrolimus users showed better efficacy comparing Pimecrolimus users. On 24th week assessment, Tacrolimus users showed 26% repigmentation with score of repigmentation 2.32 whereas Pimecrolimus users showed 21% repigmentation with score of repigmentation 2.01. The common side effects like erythema, burning sensation and pruritis was noted in the study population. On 4th week assessment, Tacrolimus users showed more side effects comparing Pimecrolimus users. On 12th and 24th week assessment, both topical users got negligible side effects.

Conclusion

After 24 weeks, Tacrolimus 0.1% users showed more efficacy comparing Pimecrolimus 1% topical drug users. The side effect of pimecrolimus and tacrolimus after 24 weeks were seen negligible.

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