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TO COMPARE THE EFFICACYAND SAFETY OF TOPICAL TACROLIMUS 0.1%+ PLATELET RICH PLASMA (PRP) V/S TOPICAL TACROLIMUS 0.1% IN STABLE VITILIGO PATIENTS

Dermatology

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ABSTRACT

Background: An armory of treatments is available for vitiligo yet there is no single efficacious treatment modality, with ideal efficacy and cure rates up to present time. It generally requires a multidisciplinary approach. Recently topical calcineurin inhibitors(TCI),JAK-STAT- inhibitors, Platelet rich plasma (PRP) are some novel therapies tried in vitiligo.Objective: To compare Efficacy and Safety of Topical Tacrolimus0.1% +Platelet rich plasma V/S Topical Tacrolimus 0.1% in stable vitiligo.Methods: 50 patients were randomly divided into two groups; Group A (25 patients) received of Topical Tacrolimus0.1% +PRP intralesional , and Group B (25 patients) received Topical Tacrolimus 0.1% treated at 2-week intervals up to 12 weeks .Results: In Group A: Good response in 11 patients (44%), average response in 8 (32%) patients and poor response 6(24%) patient. In Group B: good response in 8(32%) patients, average response in 10(40%) patients and poor response in 7(28%) patients. The good response observed was slightly higher in group A than B. Conclusions: Both intralesional PRP and tacrolimus are simple, safe, effective, and cost-benefit modalities for the treatment of stable vitiligo with minimum recurrence and scarring.

KEYWORDS

INTRODUCTION

Vitiligo is a pigmentary disorder characterized by depigmentation of the skin, that results from a progressive loss of functional melanocytes. Vitiligo is most common acquired idiopathic hypomelanotic disorders specified by circumscribed depigmented macule. The pathogenesis is complex and thought to be caused by interplay between genetic and environmental factors that initiates an autoimmune attack on melanocytes in the skin that lead to skin infiltration by CD8+ T cells, increased serum interleukin (IL)-2R receptor and increased lesional tissue levels of IL-2, which produce increased levels of IFN-gamma and TNF-alpha. It has a profound psychological impact and greatly affects the quality of life[1].

TCIs (topical calcineurin inhibitors) inhibit the activation, proliferation, and cytokine production of CD8+ T cells. The suppression of TNF-alpha after topical application in repigmentary vitiliginous skin is also documented2. Vascular endothelial growth factor, platelet-derived growth factor, transforming growth factor, and insulin-like growth factor are released from concentrated platelets that have been triggered by aggregation inducers. The growth factors of PRP suppress cytokine release, limit inflammation, and limit apoptosis of melanocytes3.

MATERIALS AND METHODS

STUDY DESIGN

This hospital-based, prospective study was conducted in the Department of Dermatology, venereology and leprosy at Jawahar Lal Nehru hospital, Ajmer, over a period of 3 month among 50 patients attending outpatient department. Informed consent was obtained from all patients to be a part of the study.

INCLUSION CRITERIA

1.Patients diagnosed with vitiligo clinically.
2.Patients Age group 18 years and above.
3. Patients with stable vitiligo, who had not reported any new lesions since last 6 months.
4. Informed consent accepted Patients willing to involve in the study.

EXCLUSION CRITERIA

1.Patients with Koebner phenomenon.
2.Keloidal tendency and History of Keloid
3.Collagen or elastin disorders
4.patients with bleeding tendency.
5. Active bacterial, viral, fungal infection.
Study Subject-

Clinically diagnose 50 patients of vitiligo recruited for the study. All baseline investigations were done for all the patients to rule out any infection, liver disease, kidney disease, haematological abnormalities and any immunosuppressive disorder. Written informed consent was obtained from all the patients.

PROCEDURE

Using an insulin syringe, 5-10 units of PRP will be injected intradermally into every depigmented patch, every 2 weeks for 12 weeks. Patients will be counselled to apply Tacrolimus (0.1%) ointment in the night, Multivitamin supplement will also be started. Each patient will be explained to expose the part to sunlight daily morning for 10 minutes. The patients will be called back every 2 weeks for the subsequent injections till a total of 6 injections.

FOLLOW- UP

The patients will be followed up monthly for a period of 3 months after cessation of injections to check for recurrence of lesions. Any local side effects such as erythema,swelling,secondary infection, pigmentation, and any visible scar were noted during this period.

ASSESSMENT

Clinical photographs will be taken before the procedure and subsequently after every 2 weeks. Evaluation of pigmentation would be done by VASI score. The repigmentation response will be expressed as reduction in VASI score.

VASI SCORE 100% - complete depigmentation
90%- speckles of pigmentation
75%- depigmented area exceeds pigmented area 50%- pigmented area equals depigmented area
25%- pigmented area exceeds depigmented area
10%- speckles of depigmented area
The response to therapy was graded as follows-
VASI Score 10-25 = Good
VASI 50-75 = Average VASI
VASI 90-100 =Poor

RESULTS

In Group A, 11 patients (44%) had good response, 8 patients (32%) had average response and poor response was found in 6 patients (24%) and in Group B, 8 patients (32%) had good response, 10 patients (40%) had average response and poor response was found in 7 patients (28%) (table no. 2). The side effect profile of our patients was minimal and well tolerated. In Group A, most frequent complications was burning

sensation found in 2 patients (8%) In Group B, most frequent complication was erythema found in 3 patients (12%)

TableNo.1: Demographic and clinic characteristics of patients.

Age (years)	Group A	Group B
18-30	17 (68%)	19(76%)
31-40	6 (24%)	4(16%)
41-50	1(4%)	2(8%)
>50	1(4%)	0(0%)
Mean age (years)	28.76 + 9.32	27.8 + 7.15
Age range (years)	18-60	20-45
Gender		
Male	10(40%)	11(44%)
Female	15(60%)	14(56%)
Mean VASI at 0 week	92.4±9	92.2±8.047.
Mean VASI at 12 weeks	50.6 ±33.7	54.6±31.587

Table No. 2- Response of vitiligo Lesions In both groups at end of study

RESPONSE	Group A No. of patients	Group B No. of patients
Good	11 (44%)	8 (32%)
Average	8 (32%)	10 (40%)
Poor	6 (24%)	7 (28%)
Total patients	25 (100%)	25(100%)

DISCUSSION

Vitiligo is a pigmentary disorder characterized by depigmentation of the skin, mucous membrane, hair that results from a progressive loss of functional melanocytes.Among the various topical therapies used for vitiligo, topical calcineurin inhibitors (TCIs), such as tacrolimus, are widely used.

PRP encourage the release of inflammatory mediators and modulators. Indeed, platelets may release numerous anti-inflammatory cytokines, such as IL-1

receptor antagonist (IL-1ra), soluble tumor necrosis factor (TNF) receptor (sTNF-R) I, IL-4, IL-10, IL-13 and interferon γ[4].

Rashmi Mahajan et al[5] Ibrahim et al[6]Prajul Mehta et al[7] also studied PRP in treatment in vitiligo Out of 50 cases with regular follow up upto 12 weeks, In Group A Good response was noted in 11(44%), Average response in 8(32%) and Poor response in 6(24%) patients, In Group B above three responses 8(32%),10(40%) 7 (28% were noted respectively.

Fig. A – Showing vitiligo lesion improvement after 3 months of PRP + Tacrolimus.

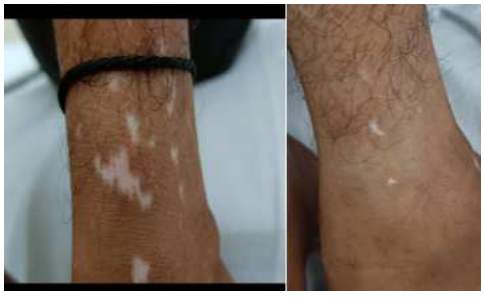

Fig B – showing vitiligo improvement after 3 months of PRP+Tacrolimus

Limitations of our study were larger sample sizes, longer follow up periods and more studies with control groups are needed to further establish intralesional PRP and topical Tacrolimus efficacy and safety in stable vitiligo.

DECLARATION OF PATIENT CONSENT-

Written consent was taken from the patients or parents of patients about procedure and for images and other clinical information reported in the article.

FINANCIAL SUPPORT AND SPONSORSHIP

Nil.

CONFLICTS OF INTEREST

There are no conflicts of interest

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