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ORIGINAL RESEARCH

Comparative evaluation of microneedling followed by methotrexate 1% gel versus microneedling followed by tacrolimus solution (0.1%) in localised stable vitiligo

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Abstract

Aims: Microneedling followed by methotrexate 1% gel versus microneedling followed by tacrolimus solution (0.1%) in localised stable vitiligo

Materials & Methods: 50 patients with localized stable vitiligo were enrolled after meeting the inclusion and exclusion criteria. They were randomly divided into 2 groups of 25 patients each. In Group A Methotrexate 1% gel was applied and in Group B Tacrolimus ointment (0.1%) was applied and dressing was done and changed after 24 hours. Then the patients were advised to apply the agent twice daily. This procedure was repeated at 3 weekly intervals till 24 weeks. In Group A and Group B microneedling with methotrexate gel and tacrolimus solution respectively was done with subsequent dressings. The procedure was repeated every three weeks for maximum 6 months. Vitiligo Area Severity Index (VASI) was used for evaluation of results. Analysis of results was done by using SPSS software.

Results: While analysing the outcome statistically, it was seen that at 12 weeks and 36 weeks follow-up, significantly better outcome was observed among subjects of group A in comparison to subjects of group B. However; while comparing the incidence of complications in between the two study groups, non-significant results were obtained.

Conclusion: Microneedling followed by methotrexate 1% gel in comparison to microneedling followed by tacrolimus solution (0.1%) in localised stable vitiligo showed significantly better improvement.

Key words: Microneedling, Methotrexate, Tacrolimus, Vitiligo

Introduction

Vitiligo is an acquired pigmentary skin disorder by the absence of pigmentary cells from the epidermis that results in white macules and patches on the body. The condition is usually associated with few autoimmune disorders, with thyroid abnormalities are the commonest one. The etiology of vitiligo is unknown but there are different theories to explain its pathogenesis. Vitiligo presents clinically with signs and symptoms of white spots on the body distributed symmetrically and more obvious in people with dark skin. The lesions are characterized by well-demarcated pearly white or depigmented macules and patches, oval, round, or linear-shaped, and the borders are convex, range from the size of few millimeters to

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centimeters and enlarge centrifugally. There are different clinical variants of vitiligo which are Trichrome, Marginal inflammatory, and Quadrichrome vitiligo. Koebner phenomenon (Development of vitiligo at specific trauma prone sites, like cut, burn, or abrasion) is also a common clinical manifestation. Initial lesions occur most frequently on the hands, forearms, feet, and face, favoring a periocular or perioral distribution.[1- 3]

In management of vitiligo, counselling of the patient is very important.Various treatment options available are: Phototherapy, Steroid therapy, Topical therapies (Tacrolimus ointment, Methotrexate gel etc). Newer modalities: non cultured melanocyte keratinocyte suspension transfer. Tacrolimusis a calcineurin inhibitor derived from the bacterium Streptomyces tsukubaensis. Methotrexate is an antimetabolite and antifolate drug. It decreases the number of T-cells capable of TNF-α production, but the number of T cells producing IL-10 are increased.[4- 6] Hence; the present study was conducted for comparing the efficacy and safety of microneedling followed by methotrexate 1% gel versus microneedling followed by tacrolimus solution (0.1%) in localised stable vitiligo.

Materials & methods

The present study was conducted for comparing the efficacy and safety of microneedling followed by methotrexate 1% gel versus microneedling followed by tacrolimus solution (0.1%) in localised stable vitiligo.50 patients with localized stable vitiligo were enrolled after meeting the inclusion and exclusion criteria. They were randomly divided into 2 groups of 25 patients each. In Group A Methotrexate 1% gel was applied and in Group B Tacrolimus ointment (0.1%) was applied and dressing was done and changed after 24 hours. Then the patients were advised to apply the agent twice daily. This procedure was repeated at 3 weekly intervals till 24 weeks. In Group A and Group B microneedling with methotrexate gel and tacrolimus solution respectively was done with subsequent dressings. The procedure was repeated every three weeks for maximum 6 months. Vitiligo Area Severity Index (VASI) was used for evaluation of results. Analysis of results was done by using SPSS software.

Results

The mean age in Group A was 36.5 years and in Group B 37.8 years respectively. Majority proportion of patients of both the study groups were females. While analysing the outcome statistically, it was seen that at 12 weeksand 36 weeks follow-up, significantly better outcome was observed among subjects of group A in comparison to subjects of group B. However; while comparing the incidence of complications in between the two study groups, non-significant results were obtained.

Table 1: Comparison of outcome at 12 weeks and 36 weeks follow-up

Grades of improvement	12 weeks follow-up		36 weeks follow-up	
	Group A N (%)	Group B N (%)	Group A N (%)	Group B N (%)
No response	2 (10%)	3 (25%)	1 (5%)	3 (15%)
Mild	7 (35%)	6 (30%)	5 (25%)	5 (25%)
Moderate	8 (40%)	10 (40%)	9 (45%)	9 (45%)
Good	3 (15%)	1 (5%)	3 (15%)	3 (15%)
Very good	0	0	2 (10%)	0
Total	20 (100%)	20 (100%)	20 (100%)	20 (100%)
p- value	0.001 (Significant)		0.001 (Significant)	

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Table 2: Adverse events

Adverse events	Group A N (%)	Group B N (%)
Pain	2 (8%)	2 (8%)
Erythema	1 (4%)	4 (16%)
Pruritus	2 (8%)	2 (8%)
Burning	2 (8%)	3 (12%)

Discussion

The pathogenesis is complex and involves the interplay of multiple factors; however, the exact pathogenesis is not well known. Lerner et alin the 1950s firstly proposed the neural theory, and after that, model of reactive oxygen species (ROS), the autoimmune hypothesis and the melanocytorrhagy hypothesis have appeared. Pruritus, elevated lesions, and erythematous margins present in inflammatory vitiligo. There are 2 main types: generalized vitiligo (GV) (widespread macules with a symmetrical distribution), whereas focal vitiligo (FV) (1 or few depigmented not elevated areas at a single site). After coalescing of vitiliginous areas in GV, or becomes extensive in the body with remaining of few normal areas, thus called vitiligo universalis. Non-segmental vitiligo enrolled FV and GV, but segmental vitiligo (SV) restricted to one unilateral region. The lesions of vitiligo are asymptomatic except in inflammatory vitiligo, which is associated with pruritus and characterized by elevated lesions, and erythematous margins.[7- 10]Hence; the present study was conducted for comparing the efficacy and safety of microneedling followed by methotrexate 1% gel versus microneedling followed by tacrolimus solution (0.1%) in localised stable vitiligo.

While analysing the outcome statistically, it was seen that at 12 weeks and 36 weeks follow-up, significantly better outcome was observed among subjects of group A in comparison to subjects of group B. However; while comparing the incidence of complications in between the two study groups, non-significant results were obtained. In a previous study conducted by Bhuvana K et al, authors assessed the effect of 0.1% tacrolimus ointment in localized vitiligo. The improvement in VASI score represents the repigmentation of vitiligo lesions which was statistically significant as observed in other studies. 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. 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. Steroid application causes atrophy of skin, telangiectasia, hypertrichosis and acne, but these are not seen with tacrolimus treatment. 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). They concluded that treatment with topical tacrolimus (0.1%) ointment is a safe and effective therapy for localized vitiligo.[11]

In another study conducted by Alghamdi K, all the patients received MTX for 6 months and assessed at 0, 1, 3, 6 and 9 months. All the six patients received 25 mg dose per week with folic acid 5 mg daily except the day on which they took MTX. Clinical and photographic assessments revealed no change in their vitiligo lesions. No patient withdrew from the course and none of the patient discontinued the therapy. The Methotrexate therapy was well tolerated and no side effect was noted. Follow up laboratory investigations, chest X ray and liver ultrasound were normal. Hence; treatment with methotrexate appears to be a safe option.[12]

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Conclusion

Microneedling followed by methotrexate 1% gel in comparison to microneedling followed by tacrolimus solution (0.1%) in localised stable vitiligo showed significantly better improvement.

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