IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 21, Issue 8 Ser.8 (August. 2022), PP 14-19
www.iosrjournals.org

Comparative Evaluation Of Local And Systemic Therapies In Vitiligo Using Psoralens And Corticosteroids

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Abstract:
Vitiligo is an acquired depigmentation disorder of autoimmune origin. In the present study, we compared therapeutic efficacy of (Oral PUVASOL i.e. Psoralens + Solar Ultraviolet A) + Topical Fluticasone and (Oral PUVASOL + Topical Fluticasone + oral mini pulse methylprednisolone). 60 clinically diagnosed cases of Vitiligo were enrolled in the study. The patients were divided into two equal groups of 30 patients each. Group A patients were given oral PUVASOL and topical steroids for local application and Group B all the medications were same with additional use of oral methylprednisolone. Mean age of patients in group A was 26.60± 10.862 & Group B was 28.13 ± 12.437. The patients in the group B (Oral PUVASOL + Oral Steroid + Topical Fluticasone) showed early repigmentation at the end of 1 month. 19 patients showed mild response & 4 patients showed moderate pigmentation which was maintained throughout the study period. At the end of 6 months in Group B, 3 patients achieved complete pigmentation, 9 showed excellent response and 10 patients showed good response. Whereas in Group A, 2 patients achieved complete pigmentation, 7 patients showed excellent response and 10 patients showed good response. Mean repigmentation achieved in 29 patients of group A (Oral PUVASOL + Topical Fluticasone) was 39.87%, while 28 patients in group B (Oral PUVASOL + Oral Steroid + Topical Fluticasone), i.e. 55.90% achieved repigmentation. This difference was statistically significant. (p=0.012 <0.05 significant).

Keywords: *Vitiligo, Psoralens, Methylprednisolone, Fluticasone*

Date of Submission: 07-08-2022 Date of Acceptance: 22-08-2022

I. INTRODUCTION

Vitiligo is characterized by depigmentation of epidermis. It is an acquired depigmentation disorder characterized by selective destruction or disappearance of some or all melanocytes in the interfollicular epidermis and manifest clinically as localized and / or generalized depigmentation of the skin and / or mucous membranes[1,3].

Clinical Features: Clinically Vitiligo is characterized by depigmented macules on the skin that can be few or many in number, having sharply defined borders with chalky white color in most cases but can also have trichrome or multichromatic colors. The depigmentation can be localized, moderate in extent or widespread and even complete loss of pigments[2].

Why this study: Vitiligo warrants many and multiple combination therapies for its treatment. This study compared and evaluated therapeutic efficacy of (Oral PUVASOL + Topical Fluticasone) with (Oral PUVASOL + Topical Fluticasone + oral mini pulse methylprednisolone) and its adverse effects.

AIMS AND OBJECTIVE: To study and compare Local and Systemic Therapies in Vitiligo Using Psoralens and Corticosteroid.

II. MATERIALS & METHODS

The study was carried out in patients of Vitiligo attending Dermatology OPD, at a tertiary care hospital at Jaipur between Aug 2020 - 2022. 60 patients clinically diagnosed as a case of Vitiligo were enrolled in the study. Out of these 57 patients completed full follow up. The treatment was explained to each of the patient and prior consent was obtained. At the time of first visit the clinical type, Distribution, activity of lesions, follicular involvement (Leucotrichia) and total body surface area including mucous membranes were assessed and recorded on a proforma.

Methods

The patients were divided into two equal groups of 30 each i.e. A & B.

Group A: Patients were given oral PUVASOL and topical steroids. Oral PUVASOL (Trioxsalen) was given 0.6 mg/kg (max dose 30mg/day) on alternate day followed by sun exposure after 2hrs of drug ingestion and eyes covered with protective sunglasses. Immediately after sun exposure cream Fluticasone 0.05% was applied as a thin film over affected area.

Group B: In this group, all the medications were same i.e. Oral PUVASOL + Topical Steroid with additional use of oral methylprednisolone at the dose of 0.8 mg/kg was taken once a week after breakfast. Rest, all the guidelines were same for the patients as in group A.

Follow up: The patients were followed up monthly for six months. At each visit patients were examined for regimentation of the lesions, appearance of fresh lesions and fresh depigmentation, adverse effects if any were noted.

Final assessment: Initial area of depigmentation, Total surface area of regimentation after treatment, Percentage of regimentation

Improvement	Noted as
Nil	No response
Mild	< 25% repigmentation
Moderate	26- 50% repigmentation
Good	51- 75% repigmentation
Excellent	> 75% repigmentation
Complete	Total resolution of the lesions

The statistical data analysis was done with the help of SPSS 17 software.

III. OBSERVATIONS & RESULTS

Out of total 60 patients included in the study, 30 were males (50%) and 30 were Females (50%). F:M = 1:1

Mean age of patients in group A was 26.60± 10.862 & Group B was 28.13 ± 12.437. P value is 0.613 (>0.05). There was no statistically significant difference between two groups and both the groups were comparable. Group A had 13 males (43.30%) and 17 Females (5.709%) Whereas group B had 17 males (56.70%) & 13 females (43.30%).

Occupation wise 63% of the patients were students/unemployed followed by skilled worker 16.67%, semi-skilled worker (8.33%), Farmer/clerical/shop owner (6.67%) and unskilled worker (5.0%)

Sr. No.	Site of disease	Group A-No. of Patients (N=60)	Group B-No. of Patients (N=60)
1	Generalized	15(50.00%)	15(50.00%)
2	Focal Segmental Vitiligo	4(13.33%)	5(16.33%)
3	Focal Non- Segmental Vitiligo	4(13.33%)	3(10.00%)
4	Uni-, Bi-, or Plurisegmental	5(16.66%)	3(10.00%)
5	Acrofacial	2(6.66%)	3(10.00%)
6	Mucosal Non-Segmental Vitiligo	0	1(3.33%)
	Total	30	30

Table 1: Type of Vitiligo (Group A & B)

In both the group most, common type of Vitiligo was generalized Vitiligo affecting 50% in group A & B respectively. In group A 13.33% and group B 16.33% were diagnosed as focal segmental Vitiligo. Focal Non –Segmental Vitiligo was seen in 13.33% and 10.00% respectively. Uni-, Bi- or Plurisegmental Vitiligo was seen in 16.66% and 10.00% respectively. While Acrofacial Vitiligo was seen in 6.66% and 10% respectively. Mucosal Non- Segmental Vitiligo was seen only in 3.33% of Group B patient.

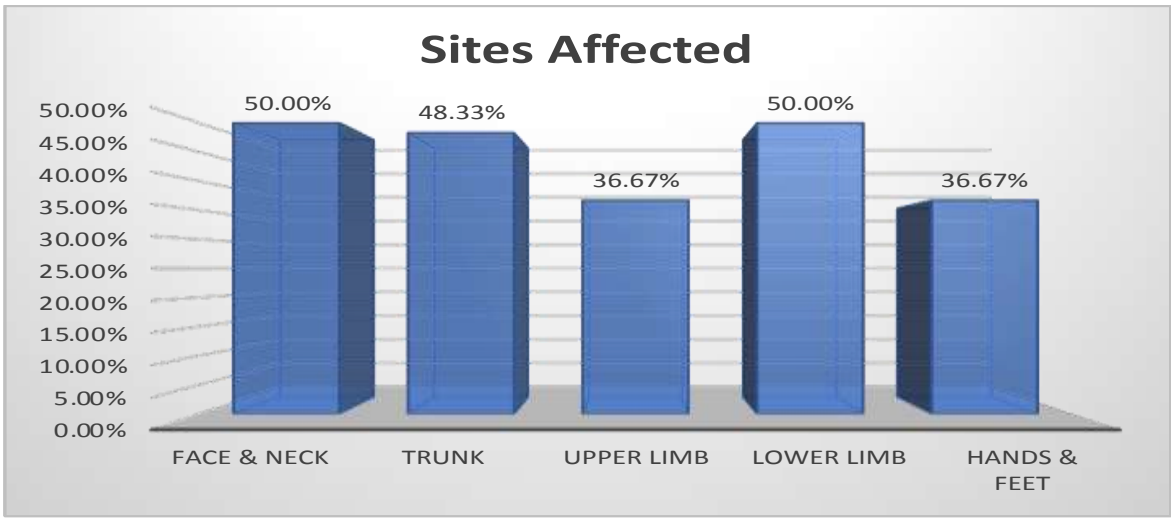

Figure 1 – Sites affected in Vitiligo

Duration wise, 45% of patients were having disease duration of >5 years, 10% with 3 -5 years, 26.67% with 1 year – 3 years, 10% with 3month – 1year, 8.33% of patients were having duration <3 months.
Out of 60 patients involved in the study, 18 patients had onset between 11 – 20 years, 12 patients had onset between 21 -30 years & 0-10 years in each group, followed by 10 patients in 31-40 40 years, and 3 patients had age of onset between 41-50 years.
Out of 60, only 2 (3.33%) patients were found to have thyroid disease (Hypothyroidism).
Family history was present in 14 patients (23.33%), in remaining 96% of patients there was no family history of Vitiligo.
Leucotrichia, Kobnerization, premature graying and Halo Nevus were observed to be present in 28 (46.7%), 16 (26.7%), 10 (16.70%) and 4(6.70%) of Vitiligo patients respectively.

Table 2: Final response (Percentage Pigmentation) in two groups

S. NO.	Percentage Pigmentation	Final Result	
		Group A	Group B
1	Good	10 (34.49%)	8(28.57%)
2	Excellent	7 (24.14%)	9(32.14%)
3	Moderate	6 (20.69%)	5(17.86%)
4	Mild	3 (10.34%)	2(7.14%)
5	Complete	2 (6.89%)	3(10.72%)
6	Nil	1 (3.45%)	1(3.57%)
	Total	29	28

1 patient in group A and 2 patients in group B were unable to come for follow up.

Table 2 shows final follow up 2/29 (6.89 %) patients in - Group A showed complete repigmentation at final follow up, while in group B, 3/28 (10.72%) patients showed complete repigmentation (Figure 6). Excellent repigmentation was seen in about 24.14% (7/29) patients in group A (Figure 4), while in group B 32.14% patients showed excellent repigmentation. All the 29 and 28 patients in group A & B respectively showed some degree of repigmentation during the course of the therapy.

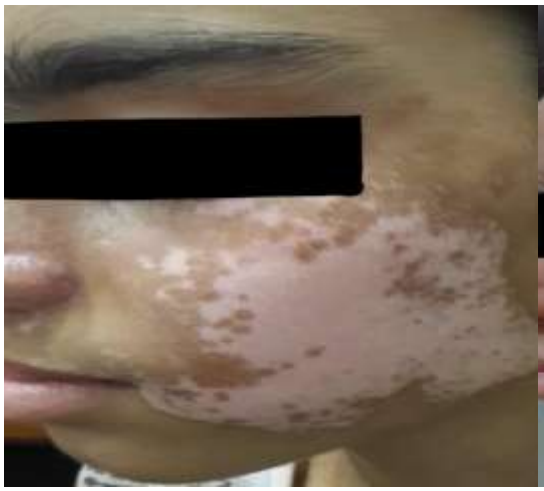

Figure 3 - Group A (after 1 Month treatment)

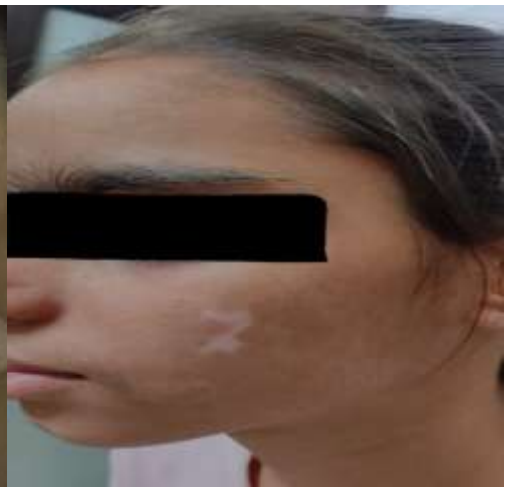

Figure 4 - Group A (after 6 months treatment)

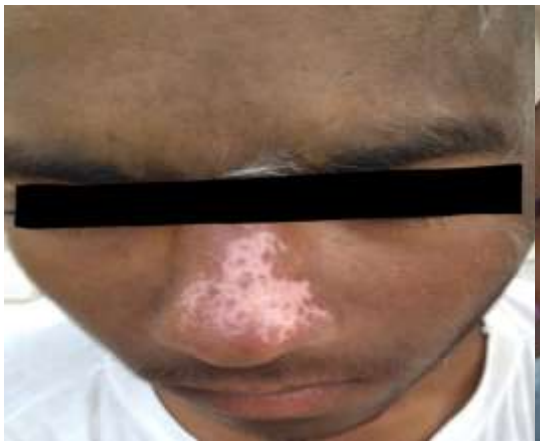

Figure 5 - Group B (after 1 month treatment)

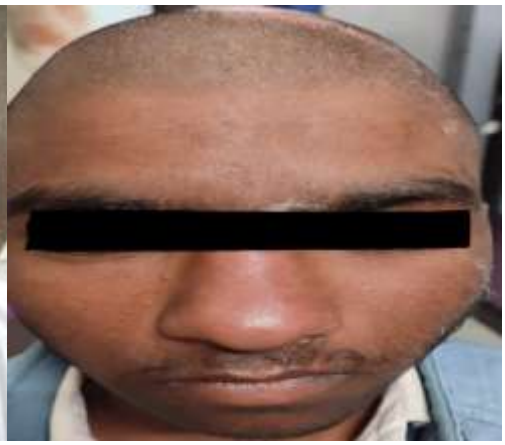

Figure 6 - Group B (after 6 months treatment)

IV. DISCUSSION

Repigmentation in Vitiligo has always been a difficult goal for the Dermatologist. The ultimate aim is to achieve complete and cosmetically acceptable repigmentation. Since Vedic time to modern era the treatment of Vitiligo has undergone many changes.

In the study 60 clinically diagnosed cases of Vitiligo presenting at a tertiary care hospital in Jaipur from August 2020 to 2022 were enrolled for the study. These patients were divided into two equal groups (Group A - 30 patients and Group B 30 patients) and were treated with combination of oral Psoralens and Local steroids while patients in group B systemic steroid were added on to Oral Psoralens and local steroids. The patients were followed up once a month for next 6 months and the observations were recorded, analyzed & compared.

Age and Sex of patients: Out of these 60 patients, 50.0% were males and 50.0% were females, in our study male female ration was 1:1.

Age of Onset: In our study, the mean age of onset in females was 18.77 years while 21.67 years in males.

Associated disease: In present study two patients were having thyroid disease associated with Vitiligo.

Family history: In our study, 23.33% patients had family history of Vitiligo. Various other studies [2, 3,4,11] also reported family history in their studies.

Precipitating factors: No specific precipitating factors could be identified in our study except trauma in 7 cases and skin infection in one case.

Site of onset of lesions: Lower limbs were most commonly affected area in 19 patients (31.67%), followed by face and trunk in 17 patients (28.33%), upper limbs in 6 patients (10.00%) and genital area in 1 patient (1.67%).

Site of Distribution of lesions: All 60 patients had multiple lesions on various sites i.e. Face & Neck, Trunk, Upper limb, Lower limb and Hands & Feet. Face and lower limb were the most common sites affected in 30 patients each (50.0%) followed by the trunk in 29 patients (48.33%), upper limbs in 22 patients (36.67%).

Clinical types of Vitiligo: Generalized Vitiligo was most common (50.0%) in both the groups. In group A 13.33% and group B 16.33% were diagnosed as focal segmental Vitiligo. Focal Non –Segmental Vitiligo was

seen in 13.33% and 10.00% respectively. Uni-, Bi- or Plurisegmental Vitiligo was seen in 16.66% and 10.00% respectively. While Acrofacial Vitiligo was seen in 6.66% and 10% respectively. Mucosal Non- Segmental Vitiligo was seen only in 3.33% of Group B patient. Almost similar findings have also been reported in various other studies.[1,8,9,10]

Oral PUVASOL therapy with topical Fluticasone propionate in Vitiligo: In our study we compared two groups, one with oral PUVASOL and topical Fluticasone propionate and in other group oral PUVASOL, topical Fluticasone propionate and oral mini pulse therapy using methylprednisolone. Various Studies reported poor response to Psoralens therapy alone [7] When systemic PUVASOL was added with topical corticosteroid application, the response was better, sustained and at times complete with low relapse rates.

Comparison of Oral PUVASOL with Topical Fluticasone propionate and Oral PUVASOL, topical Fluticasone propionate with oral mini pulse therapy using methylprednisolone: In our study, the mean repigmentation achieved in group A (Oral PUVASOL + Topical Fluticasone) was 60.03% in 29 patients, while in group B (Oral PUVASOL + Oral Steroid + Topical Fluticasone), it was 65.34% in 28 patients after 6 months of treatment. In the study most of the patients (93%) responded at least to some extent to the treatment and achieved mild to complete repigmentation in both groups. Similar findings have been reported by various other studies.[6, 14]

Out of 29 patients in group A (Oral PUVASOL + Topical Fluticasone), 6.89% patients had complete repigmentation and 58.61% patients showed more than 50% repigmentation and remaining 3.45% Showed no response. In 28 patients of group B (Oral PUVASOL + Oral Steroid + Topical Fluticasone) complete repigmentation was seen in 10.34% patients and about 60.71% showed more than more than 50% repigmentation and remaining 3.57% showed no response.

In our study, the mean repigmentation achieved in group A (Oral PUVASOL + Topical Fluticasone) was 39.87% in 29 patients, while in group B (Oral PUVASOL + Oral Steroid + Topical Fluticasone), it was 55.90% in 28 patients at the end of 3 months treatment, statistically the difference was significant between two groups ($P=0.012 < 0.05$ significant) i.e. better response in group B at the end of 6 months.

In our study the perifollicular and perimarginal repigmentation was noted as early as in 4 weeks of therapy in both the groups. The findings were similar to other studies.[12, 13, 14]

In relation to sex, there was no intra group difference between males and females in group A. In- group B females responded better with complete repigmentation in 23.07% (3/13) as compared to 1/15 (6.66%) male patients showing complete repigmentation.

In relation to type of Vitiligo, complete repigmentation was seen in generalized & Focal Segmental Vitiligo 1 (6.70%) patient in each group A, whereas in group B 2 (28.57%) patients of focal segmental Vitiligo showed complete repigmentation.

Side effects in two groups: There was no serious side effected reported from both the groups. Only 3 out of 29 patients of Group A complained of mild burning (6.89%) and pain (3.45%). Whereas 2 out 28 patients from group B complained of mild burning (3.57%).

V. CONCLUSION

The patient in the group B (Oral PUVASOL + Oral Steroid + Topical Fluticasone) showed early repigmentation at the end of 1 month. 19 patients showed mild response & 4 patients showed moderate pigmentation. At the end of 2 months most of the patients showed moderate to good response with excellent pigmentation in 1 patient & 1 patient of group B showed complete pigmentation as compare to group A at the end of 1 month, 1 patient showed good pigmentation and at the end of 2 months, 2 patients showed excellent response. The better response in group B patients was maintained at the end of 6 months.

Mean repigmentation achieved in 29 patients of group A (Oral PUVASOL + Topical Fluticasone) was 39.87%, while 28 patients in group B (Oral PUVASOL + Oral Steroid + Topical Fluticasone), it was 55.90%. This comparison was statistically significant. ($p=0.012 <0.05$ significant).

However, at the end of six month though the mean regimentation was clinically better in group B in comparison to group A, the difference was statistically not significant i.e. mean repigmentation achieved in group A (Oral PUVASOL + Topical Fluticasone) was 60.03% in 29 patients, while in group B (Oral PUVASOL + Oral Steroid + Topical Fluticasone), it was 65.34% in 28 patients.

Routinely used Psoralens have shown reasonable effects but at the same time it produces side effects like pain abdomen, photosensitivity etc. in some patients, such side effects are not observed with the use of Trioxsalen.

Use of systemic steroid in pulse manner increases the efficacy without any significant systemic side effects.

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DR. HARDIK SHAH. "Comparative Evaluation Of Local And Systemic Therapies In Vitiligo Using Psoralens And Corticosteroids." *IOSR JOURNAL OF DENTAL AND MEDICAL SCIENCES (IOSR-JDMS)*, 21(08), 2022, PP. 14-19.