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Comparative Analysis Of Efficacy Of Weekly Oral Multidrug Therapy In Vitiligo Cases Using Trimethylepsoralen, Corticosteroid And Cyclophosphamide

Pankaj Kumar Gond[1], Dev Prakash Shivhare[2]*, Neetu Purwar[3], P K Singh[4], Ashish Kumar Sharma[5]

[1]Associate Professor, Department of dermatology, M.R.A. Medical College, Ambedkar Nagar, Uttar Pradesh

[2]Associate Professor, Department of dermatology, G.S.V.M. Medical College, Kanpur, Uttar Pradesh

[3]Associate Professor, Department of pathology, G.S.V.M. Medical College, Kanpur, Uttar Pradesh

[4]Ex-Professor and Head, Department of dermatology, S.N Medical College, Agra, Uttar Pradesh

[5]Assistant Professor, Madhav Prasad Tripathi Medical College, Siddharthnagar, Uttar Pradesh

***Corresponding author:**

Dev Prakash Shivhare

Associate Professor, Department of dermatology, G.S.V.M. Medical College, Kanpur, India

drdev.derma@ gmail.com

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Abstract:

Introduction: Vitiligo is social taboo in the Indian Society. There are various modalities used for the treatment of vitiligo but none of the modalities alone can effectively treat vitiligo. The aim of the study was to compare the efficacy of weekly oral multidrug therapy in vitiligo cases using trimethylepsoralen, corticosteroid and cyclophosphamide.

Methods: Total 108 clinically diagnosed vitiligo patients were enrolled and 26 patients missed during the follow up. So, only 82 patients were included in the study were divided into 2 groups depending on the treatment modalities which includes modality I treated with oral methyleprednisolone (64 mg), oral cyclophosphamide (200 mg), and oral trimethylepsoralen (100 mg) one day in a week after breakfast and were advised to expose all the lesions to sunlight daily for at least half an hour, any time of their own convenience and modality II treated with oral trimethylepsoralen (25 mg) daily at morning time after breakfast. After that patients were advised to expose all the lesions of vitiligo to sunlight after 2 hours of intake of trimethylepsoralen for at least half an hour. Evaluation of efficacy was done by measurement of pigment spread in millimetres. Patients were categorized in four grades on the basis of percentage of pigmentation; they gained during 6 months of follow up as excellent response: 75%-100% repigmentation, good response: 50%-75% repigmentation, moderate response: 25%-50% repigmentation, poor response: 0%-25% repigmentation.

Results: Patients treated with modality I and II responded best with focal type of vitiligo, female patients, below 30 years of age, unstable vitiligo, lesions on the face and neck. Statistically significant (p-value<0.05) association was observed with lower age group, unstable vitiligo with modality I response. Patients on modality-I showed excellent response in 20% of cases and 60.01% of cases showed more than 50% of repigmentation compared to modality-II showed excellent response in 10% of cases and 32.24% of cases showed more than 50% of repigmentation after 6 month of therapy.

Conclusion: Weekly oral pulse therapy by using three drugs trimethylepsoralen, cyclophosphamide and corticosteroids seems to be good options for treatment vitiligo. Response of this therapy is better with minimal side effect as compared to conventional therapy of vitiligo.

Key words: Vitiligo, modality, trimethylepsoralen, Response

INTRODUCTION:

Vitiligo is precise, general, often genetic, acquired disorder characterized by well-circumscribed milky white cutaneous macules devoid of identifiable melanocytes [1-3]. It can affect emotional and psychological well being of a person, particularly when vitiligo develops on visible areas of the body and genitals [4]. The cause of vitiligo is exactly not known [5]. So, causative treatment is not yet available [6]. Current modalities are directed towards stopping progression and to achieve repigmentation in order to repair the morphology and functional deficiencies of the depigmented areas [7, 8]. Photochemotherapy (PUVA) is the combined use of drug psoralen and ultraviolet (UVA: 315-400 nm) radiation [9]. When sun exposure used as the source of UVA, this therapy is called as PUVASOL therapy [10]. Phototherapy is the therapeutic use of ultraviolet radiation without exogenous photosensitizers and comprises of broadband and narrowband UVB irradiation [9]. Out of these PUVA, PUVASOL, narrow and broadband UVB have all been used successfully for the treatment of vitiligo [11]. On the presumption of role for autoimmunity in the etiology of vitiligo, systemic corticosteroids arrest the progression of vitiligo and lead to repigmentation by suppressing immunity [12]. Role of concurrent use of corticosteroids and cyclophosphamide in different doses have been established in various immunological disorders including vitiligo [13, 14]. However PUVA / PUVASOL are the mainstay of treatment for vitiligo, but to control the activity of the disease, PUVA/PUVASOL alone is not expected to achieve this effect. So, immunosupressants such as corticosteroids, cyclophosphamide or levamisol are needed for more effective controlling of the disease activity [15, 16]. That's why in this study, weekly oral pulse therapy of corticosteroid, cyclophosphamide and trimethylepsoralen had been tried in vitiligo cases.

MATERIAL AND METHODS:

As per the sample size formula [(sample size= Z^2PQ/M^2 where, Z = 1.96 at 95 % confidence interval, P is the prevalence of vitiligo, Q= 1-P, and M is margin of error (5%)] 108 clinically diagnosed vitiligo patients were selected from the outpatient department of dermatology, venereology and leprosy, G. S. V. M. Medical College, Kanpur (U.P.) and were subjected to detailed clinical examination, investigations, and treatments. Out of 108 patients 26 patients missed during the follow up. Only 82 patients were included in the study for detail analysis. Informed written consent was taken from each patient prior to the study. Ethical approval was taken from institutional ethical Committee. Pregnancy or women, who were likely to become pregnant, nursing mother, liver diseases and history of jaundice, significant renal dysfunction, patients under immunosuppressive therapy, chemotherapy, HIV, malignancy, diabetes mellitus, HSV and poor general condition were excluded from the study.

Workup before therapy: After selecting the patient, a detailed clinical record was prepared including age, sex, address, occupation, family history, duration of the disease, size and extent of lesions, history of previous treatments. Then cases were examined in detail for local and systemic examination. After that all patients were subjected to necessary investigations which includes- Hb, TLC, DLC, ESR**,** blood sugar**,** SGPT / SGOT**,** serum creatinine**,** urine analysis**,** and biopsy whenever needed.

Methods: All the patients of vitiligo attending to the out patients department (OPD) was selected for the study, on the basis of inclusion and exclusion criteria. Total 108 patients were selected and they were randomly divided into two groups for the two different modalities to be evaluated. Group I patients were treated with modality-I and group II patients were treated with modality-II. Two modalities which were compared and evaluated are as follows:

(A) Group I (Modality I): Weekly oral pulse using methyl prednisolone, cyclophosphamide, trimethylepsoralen: In this modality patients were given oral methyleprednisolone (64 mg), oral cyclophosphamide (200 mg), and oral trimethylepsoralen (100 mg) one day in a week after breakfast and were advised to expose all the lesions to sunlight daily for at least half an hour, any time of their own convenience. During sun exposure patients were advised to wear sun-glasses to protect eyes and to cover unaffected areas with clothing.

(B) Group II (Modality II): Daily oral trimethylepsoralen: In this modality patients were given oral trimethylepsoralen (25 mg) daily at morning time after breakfast. After that patients were advised to expose all the lesions of vitiligo to sunlight after 2 hours of intake of trimethylepsoralen for at least half an hour. During sun exposure patients were advised to wear sun-glasses to protect eyes and to cover unaffected areas with clothing.

Follow up and evaluation: Patients were followed at every four weeks of interval for at least six months. During each follow up routine investigations such as Hb, TLC, DLC, blood sugar, serum creatinine, SGOT, SGPT and urine routine and microscopic examination were done. Evaluation of efficacy was done by comparison from previous photographs and measurement of pigment spread in millimetres. Patients were categorized in four grades on the basis of percentage of pigmentation; they gained during 6 months of follow up-

1. Excellent response: 75% -100% repigmentation
2. Good response: 50%-75% repigmentation
3. Moderate response: 25%-50% repigmentation
4. Poor response: 0%-25% repigmentation

Statistical Analysis: all the clinical recorded data was compiled in Microsoft Office Excel 2013. Categorical variables were presented as percentage. Statistical analysis was performed in SPPS version 23. Significant conclusion was drawn after applying the Chi-square Test.

OBSERVATION AND RESULTS:

The study was started with 108 patients, out of which 26 patients were lost to follow up. So, 82 patients were analyzed, out of which 45 patients continued the weekly pulse therapy of multiple drugs (modality I) and 37 patients continued the daily therapy of trimethylepsoralen (modality II). Factors influencing the response of therapy are age of the patients, sex of the patients, types of vitiligo (focal, generalised, acrofacial, segmental), progression of vitiligo (stable or unstable), and sites of vitiligo (face, neck, trunk, proximal extremities, lips, hands and feet). Most of the patients had their onset of age below twenty years of age. Four patients had hypothyroidism and took treatment for this, 2 patients had alopecia areata as association and 13 patients were found to anemic and were treated for this. During analysis following observations were made-

Table no.-1: Socio-demographic characteristics of the vitiligo patients

Variables		No. of patients (n=82)	Percentage (%)
Sex	Male	34	41.46%
	Female	48	58.54%
Age (in years)	21 – 25	26	31.71%
	26 – 30	25	30.49%
	31 – 35	14	17.07%
	36 – 40	9	10.97%
	41 – 45	8	9.76 %
Type of Vitiligo	Focal	22	26.82%
	Generalized	38	46.34%
	Acrofacial	18	21.95%
	Segmental	4	4.87%
Progression	Stable	21	25.61%
	Unstable	61	74.39%
Site of Vitiligo	Face	19	23.17%
	Neck	18	21.95%
	Lips	7	8.53%
	Trunk	26	31.7%
	Proximal Upper Limb	30	36.58%
	Proximal Lower Limb	39	47.56%
	Hand	17	20.73%
	Feet	19	23.17%

Table no.-2: Modality I and Modality II Response to the various factors of the patients

(a) Response to modality I Vs type of vitiligo					
Response	**Focal [n=12(%)]**	**Generalized [n=22(%)]**	**Acroorificial (n=9(%))**	**Segmental [n = 2(%)]**	**P-Value**
Excellent (75 – 100%)	4 (33.3%)	5 (22.7%)	0 (00.0%)	0 (0%)	P=0.12
Good (50 – 75%)	6 (50.0%)	10 (45.5%)	2 (22.3%)	0 (0%)	
Moderate (25 – 50%)	1 (08.3%)	4 (18.2%)	2 (22.2%)	1 (50.00%)	
Poor (0 – 25%)	1 (08.4%)	3 (13.6%)	5 (55.5%)	1 (50.00%)	
(b) Response to modality II Vs type of vitiligo					
Response	**Focal [n=10(%)]**	**Generalized [n=16(%)]**	**Acroorificial (n=9(%))**	**Segmental [n = 2(%)]**	**P-Value**
Excellent (75 – 100%)	2 (20.00%)	2 (12.50%)	0 (0.00%)	0 (0%)	P=0.56
Good (50 – 75%)	3 (30.00%)	4 (25.00%)	1 (11.2%)	0 (0%)	
Moderate (25 – 50%)	3 (30.00%)	5 (31.25%)	3 (33.3%)	0 (0%)	
Poor (0 – 25%)	2 (20.00%)	5 (31.25%)	5 (55.5%)	2 (100%)	
(c) Response to modality I Vs sex of patients					

Response	Male		Female		P-Value
	Number	Percentage (%)	Number	Percentage (%)	
Excellent (75 – 100%)	3	15.78%	6	23.07%	P= 0.89
Good (50 – 75%)	8	42.12%	10	38.46%	
Moderate (25 – 50%)	3	15.78%	5	19.24%	
Poor (0 – 25%)	5	26.32%	5	19.24%	

(d) Response to modality II Vs sex of patients

Response	Male		Female		P-Value
	Number	Percentage (%)	Number	Percentage (%)	
Excellent (75 – 100%)	1	06.66%	3	13.63%	P=0.00
Good (50 – 75%)	3	20.00%	5	22.73%	
Moderate (25 – 50%)	4	26.67%	7	31.82%	
Poor (0 – 25%)	7	46.67%	7	31.82%	

(e) Response to modality I Vs age of the patients in year

Response	21 – 25 [n=14(%)]	26 – 30 [n=14(%)]	31 – 35 [n=9(%)]	36 – 40 [n=4(%)]	41 – 45 [n=04(%)]	P-Value
Excellent (75 – 100%)	4 (28.6%)	4 (28.6%)	1 (11.1%)	0 (00.0%)	0 (00.0%)	P= 0.023
Good (50 – 75%)	7 (50.0%)	9 (64.3%)	1 (11.1%)	1 (25.0%)	0 (00.0%)	
Moderate (25 – 50%)	1 (07.2%)	0 (00.0%)	4 (44.4%)	1 (25.0%)	2 (50.0%)	
Poor (0 – 25%)	2 (14.2%)	1 (07.2%)	3 (33.4%)	2 (50.0%)	2 (50.0%)	

(f) Response to modality II Vs age of the patients in year

Response	21 – 25 [n=12(%)]	26 – 30 [n=11(%)]	31 – 35 [n=7(%)]	36 – 40 [n=4(%)]	41 – 45 [n=3(%)]	P-Value
Excellent (75 – 100%)	2 (16.6%)	1 (09.1%)	1 (14.2%)	0 (00.0%)	0 (00.0%)	P= 0.93
Good (50 – 75%)	3 (25.0%)	3 (27.3%)	2 (28.6%)	0 (00.0%)	0 (00.0%)	
Moderate (25 – 50%)	4 (33.4%)	3 (27.3%)	2 (28.6%)	1 (25.0%)	1 (33.4%)	
Poor (0 – 25%)	3 (25.0%)	4 (36.3%)	2 (28.6%)	3 (75.0%)	2 (66.6%)	

(g) Response to modality I Vs progression of disease

Response	Stable (n = 12)		Unstable (n = 33)		P-Value
	No.	Percentage (%)	No.	Percentage (%)	
Excellent (75 – 100%)	0	0%	9	27.27%	P=0.00
Good (50 – 75%)	1	8.33%	17	51.51%	
Moderate (25 – 50%)	3	25.00%	5	15.16%	
Poor (0 – 25%)	8	66.67%	2	6.06%	

(h) Response to modality II Vs progression of disease

Response	Stable (n = 9)		Unstable (n = 33)		P-Value
	No.	Percentage (%)	No.	Percentage (%)	
Excellent (75 – 100%)	0	0%	4	14.28%	P =0.19
Good (50 – 75%)	1	11.12%	7	25.00%	
Moderate (25 – 50%)	2	22.22%	9	32.15%	
Poor (0 – 25%)	6	66.66%	8	28.57%	

(i) Response to modality I Vs sites of vitiligo involved

Response	Face [n=11(%)]	Neck [n=9(%)]	Lips [n=4(%)]	Trunk [n=13(%)]	Prox-UL [n=16(%)]	Prox-LL [n=18(%)]	Hands [n=12(%)]	Feet [n=11(%)]	P-value
Excellent (75–100%)	3 (27.27%)	2 (22.22%)	0 (0.00%)	3 (23.07%)	3 (18.75%)	3 (16.67%)	0 (0.0%)	0 (0.0%)	P=0.65
Good (50–75%)	5 (45.46%)	4 (44.44%)	0 (0.00%)	5 (38.40%)	6 (37.50%)	6 (33.33%)	1 (14.28%)	3 (27.27%)	
Moderate (25–50%)	2 (18.18%)	1 (11.12%)	1 (25.00%)	2 (15.38%)	2 (12.50%)	5 (27.77%)	2 (28.58%)	3 (27.27%)	
Poor (0–25%)	1 (9.09%)	2 (22.22%)	3 (75.00%)	3 (23.07%)	5 (31.25%)	4 (22.23%)	4 (57.14%)	5 (45.46%)	

(j) Response to modality II Vs sites of vitiligo involved

Response	Face [n=8(%)]	Neck [n=9(%)]	Lips [n=3(%)]	Trunk [n=13(%)]	Prox-UL [n=14(%)]	Prox-LL [n=21(%)]	Hands [n=10(%)]	Feet [n=8(%)]	P-value
Excellent (75–100%)	1 (12.50%)	1 (11.11%)	0 (0.00%)	2 (15.38%)	1 (7.14%)	2 (9.52%)	0 (0.00%)	0 (0.0%)	P=0.41

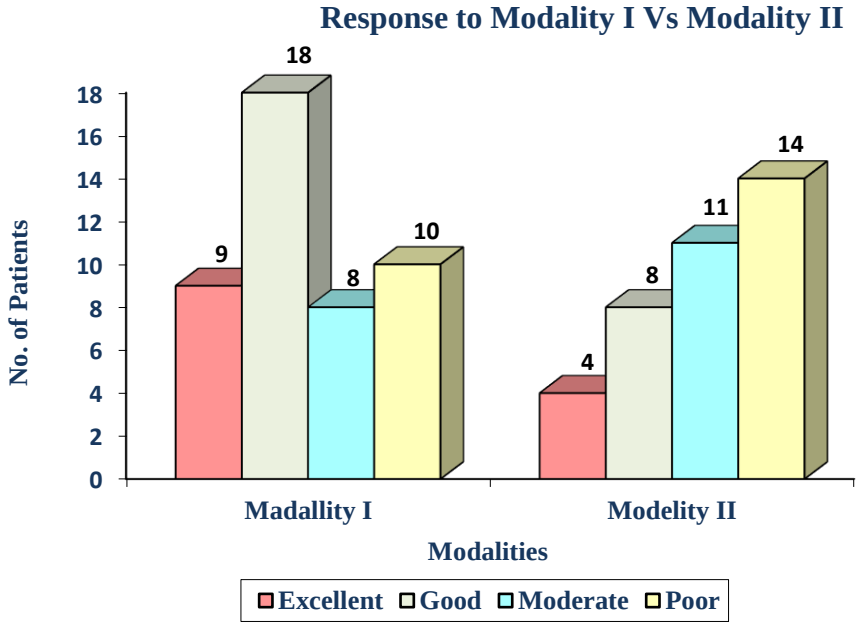
Good (50–75%)	2 (25.00%)	3 (33.33%)	0 (0.00%)	3 (23.08%)	3 (21.42%)	5 (23.84%)	1 (10.00%)	1 (12.50%)	
Moderate (25–50%)	3 (37.50%)	2 (22.22%)	0 (0.00%)	3 (23.08%)	5 (35.72%)	6 (28.54%)	2 (20.00%)	1 (12.50%)	
Poor (0–25%)	2 (25.00%)	3 (33.33%)	3 (100.0%)	5 (38.46%	5 (35.72%)	8 (38.10%)	7 (70.00%)	6 (75.00%)	

Table no.-3: Response to modality I Vs modality II

Response	Modality I (n= 45)		Modality II (n= 37)		P-value
	Number	Percentage (%)	Number	Percentage (%)	
Excellent (75 – 100%)	9	20 .00%	4	10.82%	P= 0.10
Good (50 – 75%)	18	40.01%	8	21.62%	
Moderate (25 – 50%)	8	17.77%	11	29.73%	
Poor (0 – 25%)	10	22.22%	14	37.83%	

Table no.-4: Adverse effect to modality I Vs modality II

Response	Modality I (n = 45)		Modality II (n = 37)		P-value
	Number	Percentage (%)	Number	Percentage (%)	
Puritus and Burning	3	6.06%	4	10.81%	P=0.08
Erythema and Blistering	1	2.22%	2	5.40%	
Xerosis	3	6.06%	11	29.70%	
Tanning	2	4.44%	7	18.91%	
Acne	5	11.11%	0	0.00%	
Gastric Discomfort	5	11.11%	8	21.62%	
Hepatic Derangements	1	2.22%	1	2.70%	
Renal Derangements	1	2.22%	1	2.70%	
Weight Gain	2	4.44%	0	0.00%	



Out of 82 patients, male: female ratio was 1:1.41. A predominance of female patents was seen i.e. 58.54% of total cases. The male patients consist of 41.46% of total cases. Majority of patients (62.2%) were between 21 - 30 years of age group. Majority of patients (46.34%) were of generalised vitiligo followed by focal (26.82%), acro-orofacial (21.95%) and segmental (4.87%). Majority of patients (74.39%) were of unstable vitiligo. Among the 82 patients majority of patients had proximal upper & lower limb involvement. Least No. of cases was seen with lips involvement (shown in table no.-1).

Patients with focal type of vitiligo responded the best while patients with acrofacial type of vitiligo responded worst to therapy I. There is no statistical significant (p-value=0.12) association between modality I response and types of vitiligo while patients with focal type of vitiligo responded the best and patients with acrofacial type of vitiligo responded worst to therapy II. There is also no statistical significant (p-value=0.56) association between modality II response and types of vitiligo (shown in table no.-2).

Excellent response was seen in 15.78% of males and 23.07% of females with therapy I. More than 50% of repigmentation was seen in 57.9% of male cases and 61.53% of female cases, so response was seen slightly better in females. No statistical significant difference (p-value=0.89) was observed. Excellent response was seen in about 6.66% of males and 13.63% of females with therapy II. More than 50% of repigmentation was seen in 26.66% of male cases and 36.36% of females. Statistical significant difference (p-value=0.00) was observed. So, females responded better to this therapy (shown in table no.-2).

Patients of age below 30 years responded very well to therapy I which is statistically significant (p-value=0.12). 57.2% of patients below this age group showed excellent response. As, age group was increased response to therapy I was decreased, while patients of age below 30 years responded very well to therapy II also which is statistically insignificant (p-value=0.93). There is no significant relationship between the modality II response and age of individuals (shown in table no.-2).

Patients with unstable vitiligo responded well to therapy I which is statistically significant (p-value=0.00) as compared to patients with stable vitiligo while patients with unstable vitiligo responded well to therapy II also which is statistically insignificant (p-value=0.19) as compared to patients with stable vitiligo (shown in table no.-2).

Patients with lesions on the face and neck responded well with therapy I. More than 50% of repigmentation on face and neck was seen with modality-I. Response on face and neck was followed by that on trunk, proximal upper extremity (Prox-UL), proximal lower extremity (Prox-LL), lips, hands and feet with therapy I. There is no statistical significant (p-value=0.65) association between modality I response and sites of vitiligo involved. Patients with lesions on the face and neck responded good with modality-II. More than 50% of repigmentation was seem with modality-II. Response on face and neck was followed by that on trunk, proximal upper extremity, proximal lower extremity, lips, hands and feet. There is also no statistical significant (p-value=0.41) association between modality I response and sites of vitiligo involved (shown in table no.-2).

Patients on modality-I showed better response compare to modality-II. 20% of cases on modality-I developed excellent response, while about only 10.82% of cases on modality-II showed excellent response. 60.01% of cases on modality-I showed more than 50% of repigmentation after the therapy, while about 32.24% of cases on modality-II showed more than 50% repigmentation after six month of therapy. Poor response was seen more with patients on modality-II with 37.83% cases while in modality-I it was 22.22% cases. Statistically no significant difference (p-value=0.10) regarding response between modality-I and modality-II was observed (shown in table no.-3).

Most common side effect were seen with modality-I was acne and gastric discomfort in11.11% cases, followed by xerosis, puritus and burning, tanning and weight gain in 6.06%, 6.06%, 4.44%, and 4.44% cases respectively. Weight gain, acne formations were observed with modality-I not with modality-II. Hepatic and renal derangements were seen with both modalities in less than 3% cases. Most common side effects were seen with modality-II was xerosis (29.72%) followed by gastric discomfort, tanning, pruritus, erythema and blistering in 21.62%, 18.91%, 10.81% and 5.40% respectively. No statistical significant difference (p-value=0.08) was observed between adverse effects to modality I Vs modality II (shown in table no.-4).

DISCUSSION:

The present study was done on 82 patients of vitiligo of age group 20-45 years, selected from out patients department of, dermatology, venereology and leprosy, G. S. V. M. Medical College, Kanpur (U.P.), India. In present study, 22 (26.82%) patients had focal vitiligo, 38 (46.34%) patients had generalised vitiligo, 18 (21.95%) patients had acrofacial vitiligo and 4 (4.87%) patients had segmental vitiligo. 25.61% patients had stable vitiligo and 74.39% patients had unstable vitiligo. In a study by Dongra S et al., [17] vitiligo vulgaris was the most common (83.5%) followed by focal (5.5%), segmental (4.4%), acrofacial (3.8%), mucosal (2.2%), and universal (0.5%). They also found that the commonest location of vitiligo was on head and neck (24.2%) followed by the proximal limbs (23%), trunk (22%), digital limbs (17.6%), oral/genital mucosae (7.1%), and flexures (6%). In our study, repigmentation of most cases were perifollicular and in some cases pigmentation started from periphery of the lesions. In earlier study by Le Poole IC et al., [18] reported that there is complete absence of melanocytes in the fully depigmented vitiliginous skin, only hair follicles can act as a reservoir. However, recent studies by Tobin et al., [19] and Bartosik et al., [20] provide a more definitive evidence that the melanocytes are still present in the depigmented epidermis of stable vitiligo of as long as 25 years. In study done by Prasad D et al., [21] mostly repigmentation was periffolicular and more stable when treatment was with

PUVA. Modality-I showed better response in compare to modality II, in relation to type of vitiligo. In both therapy females responded better as compare to males. Patients of age group 21-30 years showed the best response to therapy. In this age group more than 50% of repigmentation was seen in 53.33% cases in modality-I and 24.3% cases in modality-II. So, Modality-I showed the better response in compare to modality-II with respect to age group 21-30 years. No excellent response was seen in cases of stable vitiligo by both the therapies. However both the therapies are effective in unstable vitiligo but the modality-I showed better response as compare to modality-II. Modality-I, responses were better in comparison to modality-II in relation to response to site of vitiligo. However side effects were observed with both modalities but more adverse effect were seen more with modality-II. Patients who were treated with modality-I developed excellent response (75%-100% repigmentation) in 20.0% of cases, in compare to modality-II in which only 10.81% cases developed excellent response. In modality-I good response (50%-75% repigmentation) was seen in 40.0% of cases and poor response (0%-25% repigmentation) was seen in about 22.22% of cases, while in modality-II poor response was seen in 37.83% of cases. As studied by Vussuki et al., [22] total or almost total repigmentation was seen in 18% of cases by PUVA therapy. In a study done by Chuan MT et al., [23] on PUVA therapy, 48% patients showed an excellent response and 29% patients showed poor response. Similarly Kwok YK et al., [24] on PUVA therapy, about 8.24% of cases showed complete or almost complete repigmentation. In a study on oral mini pulse therapy, Pasricha JS, Khaitan BK., [25] found that out of 45 patients 3 patients developed almost complete (>90%) repigmentation and 35% cases developed less than 10% repigmentation after oral mini pulse therapy. They concluded that oral mini pulse therapy seems to be an effective treatment modality for vitiligo.

CONCLUSION:

Vitiligo is common problem encountered in dermatology practice. Various medical and surgical modalities are available for this. None of them are satisfying fully in terms of results, complications, and compliance. Weekly oral pulse therapy by using three drugs trimethylepsoralen, cyclophosphamide and corticosteroids seems to be good options for treatment vitiligo. Response of this therapy is better in compare to conventional therapy of vitiligo. Side effects are minimal. Drugs are taken one day in a week so compliance is better and it is easy to take to those persons who not have much time to take drugs daily, due to their busy schedule.

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