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Efficacy of Tacrolimus plus Narrow Band Ultraviolet B Phototherapy versus Narrow Band Ultraviolet B Phototherapy alone in the Treatment of Vitiligo

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ABSTRACT

Introduction: Vitiligo Is Considered As One Of The Most Prevalent Depigmentary Condition Affecting 3-4 % Of Indian Population. In Pakistan The Reported Prevalence Is 4.4- 7.5 %. Vitiligo Is Divided Into Generalized Or Non-Segmental Vitiligo Characterized By White Patches, Therapies Include Topical Corticosteroids, Topical Immunomodulators, Calcium Modulators, Phototherapy, Surgery, Laser, Combination Therapies, Depigmentation Of Normally Pigmented Skin And Adjunctive Therapies Like Sunscreen And Camouflage Are Used.

Objective: To Compare The Efficacy Of Tacrolimus Plus Narrow Band Ultraviolet B Phototherapy Versus Narrow Band Ultraviolet B Phototherapy Alone In The Treatment Of Vitiligo.

Methodology: The Current Randomized Controlled Trial Was Carried Out At The Department Of Dermatology, Lady Reading Hospital, Peshawar For A Period Of Six Months From January 2023 To June 2023. Total Sample Size Was 94 Patients I.E 47 In Each Group. All Patients Were Randomly Allocated Into Two Groups By Lottery Method. Patients In Group A Were Subjected To Combined Treatment I.E; Narrow-Band Ultraviolet B Three Times A Week Plus Topical Tacrolimus 0.1% Once Daily Application While Patients In Group B Were Subjected To Narrow-Band Ultraviolet B Three Times A Week Alone For Three Months. Assessments At Baseline And Repigmentation Of Vitiligo Areas On Follow Up After 12 Weeks Was Recorded. Data Were Analyzed In Spss Version 24

Result: A Total Of 94 Patients Were Observed, Which Were Divided In Two Equal Groups. Male To Female Ratio Was 0.59:1. Average Age Was 28.59 Years+ 8.86sd With Range 15-51 Years. Efficacy Wise Distribution Was Significant With P-Value = 0.022. Group Group A Showed 41(87.2%) Efficacy While Non-Effective In 6(12.8%) Patients. Similarly Group B Showed 32(68.1%) Efficacy While Non Effective In 15(31.9%) Patients. The Combination Therapy Have Greater Efficacy Than Monotherapy.

Conclusion: Combination Therapy Is More Effective Than Monotherapy In The Treatment Of Vitiligo. ..

Keywords: Efficacy, Tacrolimus, Narrow Band, vitiligo.

1. INTRODUCTION

Vitiligo is a common acquired, idiopathic pigmentary disorder characterized by progressive circumscribed depigmented macules or patches that corresponds histologically with reduced or absent cutaneous melanocytes, afecting 1% of world's.

population ,1 though the prevalence has been reported as high as 4% in some South Asian, Mexican and American populations 2. It is considered as one of the most prevalent depigmentary condition affecting 3-4 % of Indian population 3. In Pakistan the reported prevalence is 4.4- 7.5 % 4.The exact cause of vitiligo is unknown. It occurs at any age , irrespective of race, ethnic group or skin colour. Both sexes are affected equally though female predominance has been reported 5. Vitiligo is divided into generalized or Non-segmental vitiligo characterized by white patches, often symmetrical, usually increasing in size with time and Localized or Segmental vitiligo characterized by white patches with unilateral distribution that may totally or partially match a dermatome but not necessarily 1There is no universally effective therapy specific for vitiligo. Different treatment options currently

available are directed towards stopping progression of the disease and achieving repigmentation [1,4'6]. Therapies include topical corticosteroids, topical immunomodulators, calcium modulators, phototherapy, surgery, laser, combination therapies, depigmentation of normally pigmented skin and adjunctive therapies like sunscreen and camouflage are used [7]. Among the available therapies, Narrow-Band Ultraviolet B phototherapy is considered as the 'gold standard' for the treatment of diffuse vitiligo due to its simplicity, safety and efficacy.[8,9] Many studies have reported the efficacy and safety of Tacrolimus ointment in vitiligo inducing repigmentation especially when located on head and neck [1,10]. Combination of Narrow-Band Ultraviolet B with Tacrolimus is the most effective with the least side effects. [6,9,11] ·Tacrolimus (FK-506) is an immune mediator inhibiting T cell activation and the production of proinflammatory cytokines , whose levels are higher in vitiligo lesional skin. It also enhances the proliferation of melanocytes[1,7,12]. Narrow-Band Ultraviolet B radiation with an emission spectrum of 310-312 nm causes induction of local immunosuppression and stimulation of the proliferation of melanocytes in the skin and the outer root sheath of hair follicles. There is a stimulatory effect on melanogenesis and on the production of Melanocyte Stimulating Hormone and tanning[9].117 patients with vitiligo lesions were assessed. Among these the vitiligo lesions achieved 74.34% repigmentation with combined Tacrolimus and Narrow-Band Ultraviolet B compared to 45.3% repigmentation on Narrow-Band Ultraviolet B alone [13].Vitiligo is a common problem in the field of dermatology with severe cosmetic and social impact, and to achieve repigmentation various strategies have been tried [6]. As melanogenesis is a complex, multi-stage process & different topical agents act at different stages of the process, thus providing a rationale for combinations of agents i.e, topical with phototherapy to act in synergism for better therapeutic results.[14]The rationale of our study is to validate the efficacy of combined Narrow-Band Ultraviolet B with topical Tacrolimus after comparing it with Narrow-Band Ultraviolet B alone in treating vitiligo patients in our local population. The idea behind doing this study came into our mind after thorough literature search which revealed the importance of phototherapy and Tacrolimus. Since very limited statistical data is available for developing countries like Pakistan, I want to see them in my local population, and if found to be effective, then the results will be shared with other dermatologists and recommendations will be given so that patients are treated efficiently and effectively.

2. MATERIAL AND METHODS:

The current Randomized controlled trial was carried out at the Department of Dermatology, Lady Reading Hospital, Peshawar for a period of six months from January 2023 to June 2023. Total Sample size was 94 patients i.e 47 in each group with 5% level of significance and 90% power of test, efficacy in combination group taken as 74.35% and in Narrow Band Ultraviolet B alone group, the efficacy taken as 45.3%[13] using WHO software for sample size determination.Non probability Consecutive sampling technique was used in our study.

3. INCLUSION CRITERIA:

Age more than 5 years

Any gender.

Chronic localized and generalized vitiligo of duration more than one year.

Involving atleast 10% of the body surface area

Fitzpatrick skin type 2-5

4. EXCLUSION CRITERIA:

Pregnancy and lactation

History of skin malignancy or patients with pre malignant skin lesions.

History of photosensitivity and erythroderma.

Other forms of treatment for vitiligo within the previous 3 months.

Patients with Diabets Mellitis, thyroid disease, herpes simplex, bacterial and fungal infection.

Patients suffering from claustrophobia

Patients receiving PUVA phototherapy.

Hypersensitivity to Tacrolimus

The above factors are confounders and make the study results baised if included.

5. DATA COLLECTION PROCEDURE:

The study was conducted after getting approval from hospitals ethical and research committee. All patients meeting the inclusion criteria were included in the study through OPD. The purpose and benefits of the study were explained to the patients and they were assured that the study is done purely for data publication and research purpose and a written informed consent were obtained. All patients were subjected to detailed history, dermatological and clinical examinations taking note of the number of depigmented macules and approximate percentage of body surface area by using "Rule of nine". Relevant haematological and biochemical investigations were carried out. All patients were randomly allocated into two groups by lottery method. Patients in group A were subjected to combined treatment i.e; Narrow-Band Ultraviolet B three times a week plus topical Tacrolimus 0.1% once daily application while patients in group B were subjected to Narrow-Band Ultraviolet B three times a week alone for three months. The starting treatment of Narrow-Band Ultraviolet B were based on the MED. Assessments at baseline and repigmentation of vitiligo areas on follow up after 12 weeks was recorded. The responses were analyzed by VASI repigmentation score. All the observations, VASI assessments and phototherapy procedures were conducted under supervision of a single expert dermatologist having minimum of five years experience. All of the above information including name , age, gender were recorded in a pre designed proforma. Strictly exclussion criteria were followed to control confounders and bias in the study results.

6. DATA ANALYSIS:

Data were analyzed in SPSS version 24. Mean ± SD were calculated for numerical variables like age, duration of Vitiligo, VASI score at presentation, and at 12^{th} week follow up. Frequencies and percentages were calculated for categorical variables like gender, Fitzpatrick skin type and efficacy. Chi square test was applied to compare the efficacy in two groups while keeping p-value ≤ 0.05, was considered statistically significant. Efficacy in both groups was stratified among age, gender, Fitzpatrick skin type, duration of symptoms and baseline VASI score to see the effect modification. Results ere presented in form of tables, graphs and charts.

7. RESULTS

A total of 94 patients were observed, which were divided in two equal groups A & B. Patients in Group A were managed with combined treatment i.e; Narrow-Band Ultraviolet B three times a week plus topical Tacrolimus 0.1% once daily application while patients in group B were subjected to Narrow-Band Ultraviolet B alone three times a week alone for three months. Sex wise distribution shows that out of 47 patients 16(34%) were male and 31(66%) were female while group B contains 19(40.4%) male and 28(59.6%) were female. Male to female ratio was 0.59:1. Sex distribution among the groups was insignificant with p-value=0.522. (Table 1)Average age was 28.59 years+ 8.86SD with range of 15-51 years. Group A contained 14(29.8%) patients in less than or equal to 25 years, 27(57.4%) patients 26-40 years and 6(12.8%) patients between the ages of more than 40 years. While group B contained 17(36.2%) patients in less than or equal to 25 years, 26(55.3%) in 26-40 years and 4(8.5%) patients with age more than 40 years. The age distribution among the group was also insignificant with p-value 0.701. (Table 2) Efficacy wise distribution was significant with p-value = 0.022. Group Group A showed 41(87.2%) efficacy while non-effective in 6(12.8%) patients. Similarly Group B showed 32(68.1%) efficacy while non effective in 15(31.9%) patients. The combination therapy have greater efficacy than monotherapy. (Table 3).Age wise distribution of drug-efficacy in both the group shows that efficacy was greater in youngere age group and decreases with the increase of age. The patients having less than or equal to 25 years of age have shows efficacy in 13(92.9%) patients while 1(7.1%) patients being non-effectinve. Patients with 31-45 years of age have shown efficacy in 23(85.2%) of patients and 4(14.8%) have shown no efficacy. Similarly 5(83.3%) patients have shown efficacy and 1(16.7%) patients have no efficacy, with age more than 45 years of age in group A. The same pattern was followed in group B , although age wise efficacy was insignificant in both the groups over age with p-value=0.1466, 0.1466 and 0.6667respectivly. (Table 4).When efficacy was stratified among the gender in both the groups it showed insginificanc with p-vlue=0.07493 and 0. 4029. There were 15(93.8%) male patients showing drug efficacy while non-effective in 1(6.2%) male patients in group A. Similarly in female patients, 26(83.7%) gave efficacy while 5(16.1%) showed no efficacy. The same pattern was seen in group B which shows that female have more efficacy than male . (Table 5).When stratification was made over baseline VASI score, duration of vitiligo and Fitzpatrick in both the groups, it shows no significance in both the groups over efficacy except duration of vitiligo more than 6 years and Fitzpatrick skin type III. (Table 6)

TABLE NO: 1. SEX WISE COMPARISON OF BOTH THE GROUPS

		Groups		Total	P-value
		A	B		
Gender	Male	16 34.0%	19 40.4%	35 37.2%	**0.522**
	Female	31 66.0%	28 59.6%	59 62.8%	
Total		**47** **100.0%**	**47** **100.0%**	**94** **100.0%**	

TABLE NO: 2.AGE WISE DISTRIBUTION IN BOTH THE GROUPS

		Groups		Total	p-value
		A	B		
Age (in years)	<= 25.00	14 29.8%	17 36.2%	31 33.0%	
	26.00 - 40.00	27 57.4%	26 55.3%	53 56.4%	**0.701**
	41.00+	6 12.8%	4 8.5%	10 10.6%	
Total		**47** **100.0%**	**47** **100.0%**	**94** **100.0%**	

TABLE NO: 3.EFFICACY WISE DISTRIBUTION OF PATIENTS IN BOTH THE GROUPS

		Groups		**Total**	**p-value**
		A	**B**		
Efficacy	Yes	41 87.2%	32 68.1%	73 77.7%	**0.022**
	No	6 12.8%	15 31.9%	21 22.3%	
Total		**47** **100.0%**	**47** **100.0%**	**94** **100.0%**	

TABLE NO: 4. AGE WSIE STRATIFICATION OF EFFICACY IN BOTH THE GROUPS

			Groups				p-value
			A		B		
			Efficacy		Efficacy		
			Yes	No	Yes	No	
Age (in years)	<= 25.00	Count	13	1	11	6	0.1466
		%	92.9%	7.1%	64.7%	35.3%	
	26.00 - 40.00	Count	23	4	19	7	0. 1466
		%	85.2%	14.8%	73.1%	26.9%	
	41.00+	Count	5	1	2	2	0.6667
		%	83.3%	16.7%	50.0%	50.0%	

TABLE NO: 5. GENDER WSIE DISTRIBUTION OF EFFICACY

			Groups				p-value
			A		B		
			Efficacy		Efficacy		
			Yes	No	Yes	No	
Gender	Male	Count	15	1	12	7	0.07493
		%	93.8%	6.2%	63.2%	36.8%	
	Female	Count	26	5	20	8	0.4029
		%	83.9%	16.1%	71.4%	28.6%	

TABLE NO: 6. STRATIFICATION WSIE DISTRIBUTION OF EFFICACY

		Groups								**p-values**
		A				**B**				
		Efficacy				**Efficacy**				
		Yes		**No**		**Yes**		**No**		
		Count	**%**	**Count**	**%**	**Count**	**%**	**Count**	**%**	
Baseline VASI Score	<= 10.00	30	31.9%	3	3.2%	26	27.7%	10	10.6%	0.271
	11.00+	11	11.7%	3	3.2%	6	6.4%	5	5.3%	0.3976
Duration of vitiligo (in years)	<= 5.00	4	4.3%	0	.0%	4	4.3%	0	.0%	0.152
	6.00+	37	39.4%	6	6.4%	28	29.8%	15	16.0%	0.043
Fitzpatrick skin type	II	10	10.6%	4	4.3%	9	9.6%	3	3.2%	0.310
	III	9	9.6%	0	.0%	5	5.3%	6	6.4%	0.0238
	IV	9	9.6%	1	1.1%	8	8.5%	2	2.1%	0.5000
	V	13	13.8%	1	1.1%	10	10.6%	4	4.3%	0.3259

8. DISCUSSION

Vitiligo is one of the most common depigmentation disorder of the skin. Despite significant advances made in the past few years the treatment of vitiligo remains a challenge. The British Association of Dermatologists clinical guidelines for the management of vitiligo recommend narrow-band ultraviolet light B (NB-UVB) (311 to 312 nm), Tacrolimus, and topical steroids to treat the condition[15]. Previously published studies in our region regarding treatment of vitiligo focused on therapies like topical corticosteroids, Tacrolimus, calcipotriol and NB-UVB etc. It is the first time that study in Khyber Pakhtunkhwa

is conducted to see the additive effect of topical Tacrolimus to NB-UVB phototherapy.

The systematic review updates concluded that light combination interventions were superior to monotherapies[16]. However, larger studies are needed to provide stronger evidence for the many combination interventions that have shown promise in treating vitiligo[16]. The result of my study is in accordance to that and shows that combination phototherapy shows better results than phototherapy alone.

NB-UVB has been used in combination with different topical agents to increase its efficacy and thus shorten the total duration of treatment. Treatment options that have been used with NB-UVB in vitiligo till date include topical Tacrolimus[17]. Similar findings were observed in my study in which combination therapy showed earlier maximum repigmentation (at 20-24 weeks) compared to NB-UVB alone showing maximum repigmentation later (30-36 weeks), i.e. combination therapy led to shorter sessions of phototherapy .

Several factors appeared to affect the degree of treatment response, including site of disease, darker skin color, and age. Patients who had casual, daily sun exposure to the application site during treatment experienced the greatest benefit from Tacrolimus ointment 0.1%. Patients with darker skin tones, especially those with disease involvement of the head and neck, had the best response. A pvious rstudy showed that treatment with NB-UVB phototherapy can produce approximately 42.9 % repigmentation in vitiligo patches after six months of therapy [18] compared to combination of topical Tacrolimus with NB-UVB which achieved repigmentation of approximately 71% in another study [13]. More studies showed synergistic activity in combination therapy with Tacrolimus and NB-UVB .In addition Tacrolimus can prevent UVB induced erythema by suppressing early phase events of inflammatory process . This is consistent with findings in our study with no obvious side effects seen with topical Tacrolimus.

The younger patients in this series also appeared to respond particularly well. In previous randomized, doubleblind, vehicle-controlled clinical studies of topical Tacrolimus for treating atopic dermatitis[19] showed similar results. Same findings were obtained in our study with better results in younger age groups especially < 25 years. Also important in the treatment of chronic skin disorders and those that require long-term therapy is that no skin atrophy or other significant adverse events have been reported with the use of Tacrolimus ointment 0.1%[20] even in the longterm.[18] Similar findings were in our study with no side effects with Tacrolimus 0.1%. In addition, only minimal systemic absorption has been observed with topical Tacrolimus use and no increase in infection or other indicators of systemic immunosuppression have been seen with use in both children and adults with atopic dermatitis for up to 4 years.[20]

One randomized controlled study compared 0.1% Tacrolimus and 0.05% clobetasol cream in 20 children with vitiligo. The level of repigmentation was 49.3% with clobetasol and 41.3% with Tacrolimus suggesting that topical Tacrolimus may serve as valuable alternative to corticosteroids use in children and on fascial areas that may be easily subjected to corticosteroids side effects.[21] In another doouble-blind study, intra-patient comparison of 1% pimecrolimus cream with placebo cream in 20 patients with vitiligo predominantly situated on the extremities and not on the face and found no significant change in mean target lesion.[22]

According to patients evaluation the level of repigmentation of 50 % was considered cosmetically satisfactory. The only adverse effect observed in 2 patients was mild burning that regressed spontaneously. Among the established therapies phototherapy (NB-UVB) and photochemotherapy (PUVA) have limited use for reasons such as adverse reactions, difficult access to the sources of light and time spent during treatment. Recent study evaluated the effectiveness and tolerability of NB-UVB, pimecrolimus and topical tracolimus and the improvement was better using pimecrolimus and tracolimus for facial lesions and NB-UVB for the cervical 2 area.

Regarding topical corticosteroids a double-blind randomized study compared Tacrolimus 0,1% to ointment of clobetasol 0,05%, with repigmentation of 49,3% related to clobetasol and of 41,3% related to Tacrolimus. Despite the best answer, the side effects associated with corticosteroids, mainly in the acrofacial lesions, are relevant[23]. Analogues of Vitamin D3 presented better results when combined with phototherapy.[24]

9. CONCLUSION

From this study we conclude that: Treatment of vitiligo with combined Tacrolimus ointment 0.1% and Narrow Band-UVB produced better results in the majority of patients in this series. Patients experiencing the greatest treatment response appear to have benefited from concomitant natural sunlight exposure. Further clinical studies are warranted to determine which vitiligo patients are most likely to benefit from topical Tacrolimus therapy, and whether the best response is attained with topical Tacrolimus monotherapy or with combination therapy using additional treatment modalities.

Furthermore no specific international studies comparing the ages of vitiligo patient and their response to treatment is present. The better results seen in younger age group obtained from my study gives opportunity and recommendations that treatment should be started at early age for better outcome.

Studies investigating the safety and efficacy of topical Tacrolimus in combination with natural sunlight, UV light, excimer laser, and PUVA also are warranted..

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