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Treatment of Vitiligo by Narrow Band UVB Radiation alone in Comparison to Combination of NB-UVB plus Topical Vitiskin (Case, Therapeutic, Controlled Study)

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Abstract:
Background: *Narrow band ultraviolet B (NB-UVB) phototherapy has been used successfully for the treatment of vitiligo. Recently, Vitiskin a topical antioxidant complex gel used successfully as complementary treatment to NB-UVB.*
Objective: *To assess the clinical efficacy of NB-UVB plus Vitiskin in the treatment of vitiligo in comparison with Narrow band UVB Radiation alone.*
Patients and Methods: *This is a case, controlled, comparative, therapeutic trial that was conducted in the Department of Dermatology , Baghdad Teaching Hospital, Medical City, Baghdad, Iraq from March 2010-March 2011.*
Forty five patients with generalized vitiligo were enrolled in this study. NB-UVB alone was given to 25 patients (Group I) twice weekly, and NB-UVB plus Vitiskin (Group II) twice daily was given to 20 patients The response to treatment was evaluated after 8 sessions and then after each 16 sessions of therapy.
Results: *Forty patients completed the study (13 males and 27 females), their ages ranged from 10-50(22.245± 8.073) years. Improvement in BSA-V with combination of NB-UVB and vitiskin was not statistically significant from that of NB-UVB alone.*
Conclusion: *The combination of NB-UVB and Vitiskin add no benefit to NB-UVB alone.*
Keywords: *NB-UVB, topical vitiskin , phototherapy, treatment, vitiligo.*

I. Introduction

Vitiligo is a specific, common, acquired disorder with a genetic predisposition and well established association with autoimmunity characterized by well-circumscribed milky-white macules devoid of identifiable melanocytes[(1)].

Although many therapeutic options have been used for treatment of vitiligo, it is still one of the difficult dermatological disorders to treat [(2-3)]. Narrow band ultraviolet B (NB-UVB) has been used in vitiligo treatment, either as mono-therapies or as part of combination protocols.[(4-6)] Recently, Vitiskin has been used in vitiligo treatment as a complimentary therapy to NB-UVB[(7)].

So, the aim of the present study was to compare the clinical efficacy of NB-UVB alone and NB-UVB plus topical Vitiskin in treatment of vitiligo.

II. Patients and Methods

This is a case, controlled, comparative therapeutic study was done in the Department of Dermatology and Venereology - Baghdad Teaching Hospital -Baghdad Medical City, Baghdad, Iraq extending from March 2010-March 2011.

Forty five patients with vitiligo were included in the study 16 (35.5%) male and 29 (64.5%) females. Their ages ranged between 10-50 years with a mean age of 23±10 years, while the mean disease duration is 5.06±4 years. The body surface area of vitiligo % (BSA- V %) ranged from 5-20% with a mean of 12.08±2.9. All patients were fully interviewed regarding different medical aspects and examined under good light. Wood's light was used when needed to confirm the diagnosis.

The inclusion criterion was vitiligo affecting 5% to 20% of the body surface area. Exclusion criteria included previous treatment within last 2 month before starting treatment, renal or hepatic disease, history of photosensitivity and any dermatoses affected by UV light.

Formal consent was taken from each patient before trial after a full explanation about the nature of disease, course and its complications in addition to method of treatment, course, duration, side effect of therapy and duration of follow up.

The ethical approval was obtained from Scientific Council of Dermatology and Venereology –Iraqi Board for Medical Specializations.

Patients were divided into 2 groups of treatment in which each patient had the chance to be in any group.

Group I: Those patients treated with NB-UVB twice weekly, (25 patients), 9(36%) males, and 16(64%) females with a mean age of 25.24±11.27 with body surface of vitiligo ranged from 5-15% of a mean 11.96±2.2. The NB-UVB treatment were administered in Amedisun 2800 cabinet containing 44 philips,100-w NB-UVB fluorescent tube, (Shultz + Böhm–Germany).

Group II: Those patients treated with NB-UVB twice weekly plus topical Vitiskin twice daily, (20 patients). 7(35%) males and 13(65%) females mean age 19.25±4.87 years. BSV % mean is 12.2±4.06. Vitiskin is a hydrogel that developed by ISIS-pharma Laboratories-France, that contain an SOD complex (superoxide dismutase, reductase catalase) from the Saccharomyces cerevisiae yeast-dismutine BT.

Follow up and termination of therapy:

Treatment was terminated if any of the following occurs:

-Complete or almost complete resolution of vitiligo.

-Absence of improvement after 32 sessions or very slow progression or deterioration.[8]

-Intolerance of therapy due to local or systemic side effects.

Assessment of response to treatment:

All patients were assessed before the commencement of treatment and subsequently after 8 sessions and then after every 16 sessions and photographs were taken on each occasion by Cyber-shot Sony digital Camera (12.1 Mega Pixels) in a good illumination.

-The surface area of the lesion was calculated using graphic paper for small lesions or use rule of nine

-The percentage of reduction in surface area was calculated.

The responses of therapy were evaluated according to the flowing scale: (Table-1)[8].

Table-1: Grading of repigmentation.

Grades	% of response
Grade 0	No response or deterioration.
Grade I	Re-pigmentation of 0-25%.
Grade II	Re-pigmentation of >25% - 50%.
Grade III	Re-pigmentation of >50- 75%.
Grade IV	Re-pigmentation more than 75% to complete pigmentation.

III. Results

Forty five patients with vitiligo were included in this study. Five patients did not complete the treatment. The remaining 40 patients (16 males and 29 females), their ages ranged from 10-50 years with a mean ±SD of 22.2± 8 years completed about 100 sessions. These patients were divided into 2 groups.

The therapeutic results in the 1st month (8 sessions), 3rd month (24 sessions) follow up till reach the 1 year (100 sessions) were recorded as follows:-

Group I: (Treatment by NB-UVB). The results of 20 treated patients were shown in table 2, the mean percent of BSA-V before treatment was 11.96±2.26, after 8 sessions (1 month) became 11.3 ±2.2, p-value (0.278), This reduction is statistically not significant reaching to9.15 ±1.87, by 24 sessions (3 months) p-value (0.001) which is statistically highly significant. The mean BSA-V% reached to 4.15 ±1.92 after 100 sessions (1 year) p-value (0.0001) which is very highly significant. According to the grading system of responses after 100 sessions the following grades were observed: grade I 0 patient, grade II 2(10%) patients, grade III 13 (65%) patients and grade IV 5(25%) patients (Tables-3,6).

Group II: (Treatment with exposure to the NB-UVB plus topical vitiskin).

The result of 20 patients was as following: the mean percent of BSA-V before treatment was 12.2 ± 4.06, after 8 sessions(1 month) this became 11.4 ± 3.676 P-value (0.516) and the reaching to 9.3±3.096 by 24 sessions (3 months) P-value (0.0147) which is statistically significant. After 100 sessions (1year) it became 3.95 ± 1.431.In comparison to BSA-V before therapy, P-value was (0.0081) which is highly significant, (Table -3). This group showed repigmentation after 100 sessions to be grade I 0 patients, grade II 2(10%) patients, grade III 15(75%) patients and grade IV 3(15%) patients(Tables-4,6).

NB-UVB alone and in combination with the topical vitiskin produced a significant improvement in BSA-V %(Tables-3,4). Improvement with NB-UVB alone and in combination of NB-UVB with vitiskin tended to be same (Table-5), P-value (0.656).

In the NB-UVB group, 4 (20%) patients had peripheral repigmentation

7 (35%) patients had perifollicular repigmentation 9(55%) patients had mixed repigmentation. In NB-UVB plus vitiskin, 3 (15%) patients had peripheral repigmentation, 6 (30%) patients had perifollicular repigmentations, and 11 (55%) patients had mixed repigmentation.

Adverse Effects:

All patients were developed side effect (erythema, burning, itching) at some stages during their treatment. These side effects were generally tolerable, that no patients terminate the treatment course because of side effects. No systemic side effects were reported.

Table -3: Comparison of response to treatment after 1 month, 3months, and 1year interval of group treated with NB-UVB alone.

	Session	**No.**	**Mean % of BSA-V**	**SD**	**P**
Pair I	Before	25	11.96	2.26	0.278
	1 Month	20	11.3	2.2	
Pair 2	Before	25	11.96	2.26	0.0001
	3 Months	20	9.15	1.87	
Pair 3	Before	25	11.96	2.26	0.0001
	1 Year	20	4.15	1.926	

Table-4: Comparison of response to treatment after 1 month, 3 months, 1 year interval of group treated with NB-UVB+ vitskin.

	Month	**No.**	**Mean% of BSA-V**	**SD**	**P**
Pair I	Before	20	12.2	4.06	0.001
	1Month	20	11.4	3.676	
Pair 2	Before	20	12.2	4.06	0.0001
	3Months	20	9.3	3.09	
Pair 3	Before	20	12.2	4.06	0.0001
	1Year	20	3.95	1.43	

Table-5: Comparison between NB-UVB group and NBUVB+ Vitiskin group according to repigmentation area after 1 year therapy.

		N	Mean	Std. Deviation	Minimum	Maximum
Pigmentation after 1 year	NBUVB	20	4.15	1.92	2	9
	NB+Vitiskin	20	3.95	1.43	1	6

P=0.656

Table-6: A comparison between NB-UVB group and NB-UVB+ vitiskin group according to the grade of response.

Group	**NB-UVB** No.	%	**NB-UVB+vitiskin** No.	%
Grade I	0	0	0	0
Grade II	2	10%	2	10%
Grade III	13	65%	15	75%
Grade IV	5	25%	3	15%
Total	20	100%	20	100%

Photo-1(A): Thirteen years old female before treatment with NB-UVB.

Photo-1(B): Thirteen years old female after treatment with NB-UVB.

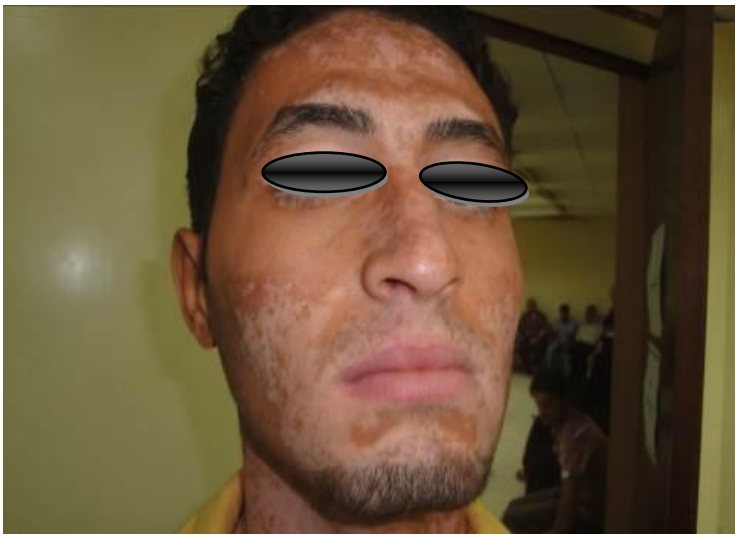

Photo-2(A): Twenty five years old male patient treated with NB-UVB plus Vitiskin (before treatment).

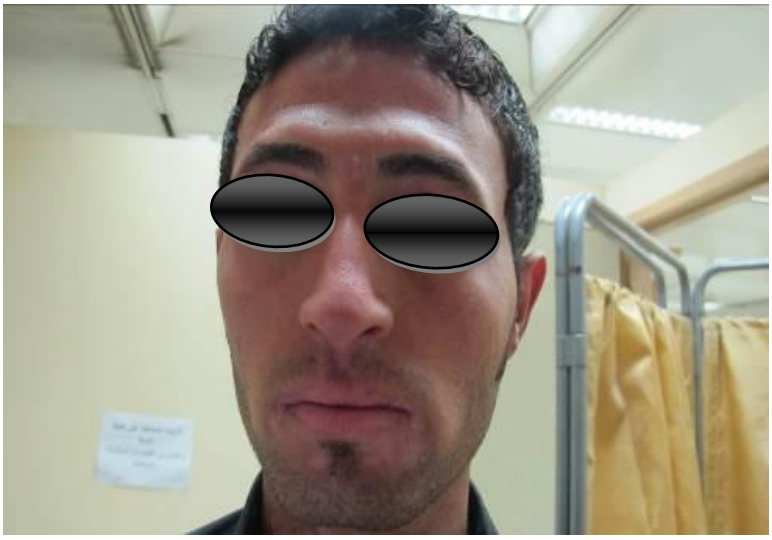

Photo-2(B): Twenty five years old male patient treated with NB-UVB plus Vitiskin (after treatment).

IV. Discussion

Vitiligo is a major health problem all over the world where immune etiology was incriminated. It is had a bad disfiguring role in a behavior of the patient. There is individual variation regarding response to treatment; rapid responder and slow responder [(1)].

Different mode of treatment have been used to treat the vitiligo like :phototherapy, photochemotherapy, immunemodulators, steroid[(1)], topical lactic acid 15% [(9)], Topical tincture iodin 5%[(10)], infrared radiation[(11)],direct electrical current[(12)], Topical sour-orange solution 20%[(13)], cosmetics ,surgical procedures, and many others. Each has its advantages and limitations [(1)].

NB-UVB has been advocated as more accepted than PUVA as its not need for psoralen induction and is effective as PUVA [(8)].

Recently, Vitiskin has been used in vitiligo treatment as a complimentary therapy to NB-UVB. Vitiskin is a hydrogel have developed by ISIS-pharma laboratories that contain an SOD Complex (superoxide dismutase, reductase ctalase) from the *Saccharomyces cerevisiae* yeast – Dismutine BT. This complex has a detoxifying action with antiradical properties. That can stimulate the general metabolism of the cells. This formula has been enriched with vitamin B12, with calcium pantothenate (precursor of melanin) and zinc and copper acetate. Several trials have demonstrated the efficacy of the Vitiskin gel in treatment of vitiligo. Regarding the present work, combination of NB-UVB with Vitiskin in comparison to NB-UVB alone has shown that NB-UVB with Vitiskin as effective as NB-UVB alone, and this result suggest that Vitiskin play no role in repigmentation of vitiliginous skin as has been reported.[(7)] Accordingly there is no benefit to add Vitiskin with NB-UVB therapy.

The results of previous studies of NB-UVB therapy for vitiligo showed that approximately 50% of patients who continued with treatment for 6-12 months had 75% repigmentation or better as shown in table-7. These results

suggest fewer efficacies than this. This is may be due to differences in patients' characters, difference in device used and variations in calibration [(8)].

Table- 7: Previous studies of treatment of vitiligo with NB-UVB.[(8,14-18)]

Source	Design	No. of Subjects	Results & Conclusions
Westerh of and Nieuweboer-krobotoval 1997	NB-UVB treatment for 12 months	51	After 100 sessions, 63% (32 patients) had repigmentation over 75% of the affected BSA-V
Kanwar and Dogra, 2005	Open	20 children	After one year of treatment 75% (15 children) had repigmentation over 75% of the affected BSA-V
Natta R, Somsak T., Wisuttida T. 2003	Retrospective	60	After 63-175 sessions, 33% (20 patients) had repigmentation over 75% of the affected BSA-V
Parsad D. 2006	Retrospective	69	41.9% of NB-UVB treated patients showed marked to complete repigmentation
Sami Sasi Younis	Randomized study	56	16 (64%) of 25 patients treated with NB-UVB showed great than 50% reduction in BSA-V
El Mofty, 2006	Left – righr comparison: NB-UVB vs oral PUVA	15	At 60 sessions,57% (9 patients) had repigmentation over 75% of the affected BSA-V

V. Conclusions

Narrow Band UVB radiation therapy for vitiligo is an effective mode but it is need a long course of treatment. The combination of Narrow Band UVB and Vitiskin add no significant result superior than NB-UVB alone.

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