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Original Article

Comparison of efficacy and safety of topical betamethasone valerate 0.1% with narrowband-UVB in atopic dermatitis

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Abstract

Objective To compare the efficacy and safety of topical betamethasone valerate 0.1% with narrowband ultraviolet B (NB-UVB) therapy in atopic dermatitis.

Method Sixty patients with AD fulfilling the inclusion criteria were entered in the study. Patients were divided into 2 groups. Group A were given betamethasone valerate 0.1% twice a day for 4 weeks. Group B were given NB-UVB thrice a week for 8 weeks. Starting dose was 75% of minimal erythema dose (MED) for the skin type III and IV. Dose was increased by 20% on each visit as tolerated by the patients. During treatment patients were assessed at 2nd and 4th week for betamethasone valerate and 2nd, 4th, 6th and 8th week for NB-UVB.

Results 84% patients in group A (betamethasone) showed >50% reduction in Scoring of Atopic Dermatitis (SCORAD) whereas 94% patients in group B (NB-UVB) showed >50% reduction in SCORAD (p=0.554). Side effects were seen in 34% patients in group A and 20% in group B.

Conclusion Both betamethasone valerate 0.1% and NB-UVB are almost equal in terms of efficacy but NB-UVB is more safe than betamethasone valerate 0.1%.

Key words
Atopic dermatitis, betamethasone Valerate 0.1%, efficacy, NB-UVB, safety.

Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disorder which is characterized by itchy papules, vesicles, excoriations and lichenification.[1] Genetic, environmental, skin barrier defects and immunological factors are involved in its pathogenesis.[2,3] Atopic dermatitis tends to be a chronic disease with relapsing course so that long-term treatment is usually required to control the flare ups.[4] Treatment of atopic dermatitis can be divided into topical and systemic therapy. Topical agents include steroids, ichthammol, tar and calcineurin inhibitors. Systemic therapies include corticosteroids, azathioprine, cyclosporine, sodium cromoglycate, mycophenolate mofetil, ketoconazole, methotrexate and phototherapies.[5]

Numerous types of phototherapies have undergone trials for the treatment of severe atopic dermatitis and proven to be effective. Reynolds *et al*.[6] reported that more than 90% of study cases were improved considerably when UVB was administered. Jekler *et al*.[7] reported that more than 60% of study cases improved considerably when UVB was administered for 8

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weeks. NB-UVB has a wavelength ranging between 311±2nm. The exact mechanism of action of NB-UVB is unknown. NB-UVB phototherapy lowers peripheral natural killer cell activity, lymphocyte proliferation and immune regulatory cytokine production by both Th1 (IL-2, IFN-γ) and Th2 (IL-10) cell population.[8] Topical steroids have been the mainstay of atopic dermatitis treatment for the past few decades. They act by reducing number and activity of lymphocytes, inflammatory cytokines (IL-12 and INF-γ), cyclooxygenase mediators and platelet activating factors.

There is no local data on the safety and efficacy of steroids and narrowband UVB in patients with atopic dermatitis to the best of our knowledge. The present study will help to compare betamethasone with narrowband UVB in atopic dermatitis.

Methods

This quasi-experimental study was conducted at Dermatology Department Unit II, King Edward Medical University, Mayo Hospital, Lahore. 60 diagnosed cases of AD of either sex, 5-60 years of age, Scoring of Atopic Dermatitis (SCORAD) score between 15-60, skin types III and IV were enrolled. Patients on topical therapy during last 1 week and on systemic disease modifying therapy during last 4 weeks, patients having any premalignant or malignant skin disorder or any systemic disease, known case of photosensitivity or on photosensitizing therapy were excluded.

After getting informed consent and explaining the risks and benefits of treatment to the patient or the parent/guardian, the demographic data was obtained. Detailed history about duration of disease, remission and relapses, family history and use of any topical and systemic medication was taken. General physical, cutaneous and relevant systemic examination was carried out. Baseline investigations were done.

Patients were randomized into 2 groups. Group A was given betamethasone valerate 0.1% twice a day for 4 weeks, as when topical steroids are used beyond 4 weeks continuously side effects are known to occur. Group B was given NB-UVB thrice a week for 8 weeks as the effects of NB-UVB may be visible after 3-4 weeks of starting the therapy. Starting initial dose was 75% of minimal erythema dose (MED) for the skin type III and IV. Dose was increased by 20% on each visit as tolerated by the patients. Emollients were applied in both groups. During treatment patients were followed at 2nd and 4th for betamethasone and 2nd, 4th, 6th and 8th weeks for NB-UVB.

Efficacy of each modality was assessed by reduction in the SCORAD score. It was graded as excellent 91-100% reduction, good 76-90% reduction, satisfactory 51-75% reduction, fair 26-50% reduction and poor <25% reduction in SCORAD score. The modality was considered efficacious when efficacy was more than 50%. Any adverse effects like bruising, skin atrophy, striae, steroid acne, telangiectasia and hypertrichosis for steroids and erythema and burning for NB-UVB were observed to assess safety of the drug.

Data were analyzed through SPSS (version 21). Data master sheet was generated for variables under study. The quantitative data like SCORAD score were presented as mean and standard deviation. Qualitative outcomes variables like sex and adverse effects were presented as frequency, percentage and proportions. Side effects in both treatment groups were compared by using chi-square test and *p* value equal to and less than 0.05 was considered significant. Repeated measurement ANOVA test has been used for SCORAD.

Results

All patients successfully completed the study. Overall male to female ratio was 1.3:1 and age ranged from 5 to 40 years in group A and from 5 to 53 years in group B. The mean baseline SCORAD Score was 35 (minimum 20 to maximum 50) in group A and 39 (minimum 23 to maximum 60) in group B **(Table 1)**.

The mean SCORAD at the end of 4 weeks was 15 and 25, respectively in group A and B **(Table 1)**. There was significant reduction (p=0.000) from baseline to 4 weeks in both groups. But in group A mean SCORAD reduction was greater than group B at the end of 4 weeks (p=0.000). On further extension of NB-UVB till 8 weeks mean SCORAD reduction was 12. At the end of treatment there was no statistically significant difference in the mean SCORAD reduction between the two groups (p=0.194).

Efficacy was seen in 84% patients in group A with excellent result in 30% of patients **(Table 2)**. In group B, efficacy was seen in 94% patients with 23.3% showing excellent response **(Table 2)**. But the difference is statistically insignificant (p=0.554) by chi-square test.

Side effects like acne (6.7%), folliculitis (23.3%) and atrophy (3.3%) were seen in 34% patients in group A while erythema (3.3%), itching (6.7%) and pigmentation (10%) were seen in 20% in group B **(Table 3)**. The most common side effect was folliculitis seen only in group A. Side effects of both groups were not comparable as they were.

Discussion

The present study was conducted to improve the treatment of AD in type III and IV skin by assessing the role of betamethasone valerate and NB-UVB in terms of efficacy and safety. AD is the most widespread eczema seen in children in Pakistan.[9] It affects 15-30% of children and 2-10% of adults in developed countries and this percentage is further rising.

Table 1 SCORAD score group A (betamethasone valerate 0.1%) and group B (NB-UVB phototherapy).

	Group A (n=30)			*Group B (n=30)*		
	Mean	*Minimum*	*Maximum*	*Mean*	*Minimum*	*Maximum*
Baseline	35.20	20.0	50.0	39.80	23.0	60.0
Week 2	26.37	13.0	41.0	33.70	20	55
Week 4	15.07	10.0	34.0	25.93	16.5	49
Week 6	-	-	-	19.47	10.0	44
Week 8	-	-	-	11.98	8.0	40

Table 2 Efficacy in group A (betamethasone valerate 0.1%) and group B (NB-UVB phototherapy).

Grades of efficacy	*N*	*Group A, n(%)*	*Group B, n (%)*
Excellent (91-100% reduction in SCORAD score)	16	9 (30)	7(23.3)
Good (76-90% reduction in SCORAD score)	11	4 (13.3)	7(23.3)
Satisfactory (51-75% reduction in SCORAD score)	26	12 (40)	14(47)
Fair (26-50% reduction in SCORAD score)	5	4 (13.3)	1(3.3)
Poor (1-25% reduction in SCORAD score)	2	1 (3.3)	1(3.3)

p-value = 0.554

Table 3 Side effects in group A (betamethasone valerate 0.1%) and group B (NB-UVB phototherapy).

Group	*Pigmentation*	*Erythema*	*Itching*	*Acne*	*Folliculitis*	*Atrophy*
Group A (n=30)	0	0	0	2(6.6%)	7(23.33%)	1(3.3%)
Group B (n=30)	3 (10%)	1 (3.3%)	2 (6.6%)	0	0	0

In our study male to female ratio was 1.3:1 while international sex distribution of AD which is 1:1.[1,10] As epidemiologic studies of AD have not been conducted in Pakistan there may be difference in sex distribution of AD in this part of the world. This male predominance is supported by Indian studies in our region.[11] Another reason may be social setup in which lesser number of females with AD present to hospitals.

Group A patients were relatively younger as compared to group B elderly patients had opted for NB-UVB as we used a closed chamber (Philips TL-01®). Other reason for this variation seems to be that group B patients were referred to visit the hospital thrice a week.

We found the mean age to be 11 (5-40) years in group A. This differed from the studies of Johanna *et al.*[12] and Aschoff *et al.*[13] in which the mean age was 29 and 34 years, respectively. They included patients of more than 18 years of age while our lower limit was 5 years of age. Mean age in group B was 22 years. This was similar to studies by Jekler and Larko[7] and Salvaag *et al.*[14]

The results of our study indicated that both topical betamethasone and NB-UVB are highly effective in the treatment of moderate to severe atopic dermatitis. There was no significant difference in both therapies but NB-UVB was better due to lesser side effects.

The mean percentage reduction in SCORAD score in our study was 57% in group A at the end of 4 weeks of treatment with betamethasone valerate in contrast to study done by Nakagawa[15] which was 73.4% at the end of 3 weeks of treatment. It can be due to the difference in scoring system. We used SCORAD score but he used mEASI (modified eczema area and severity area). Overall 84% of our patients showed greater than 50% reduction in group A patients.

The side effects observed in this group were acne, folliculitis and skin atrophy, but Nakagawa[15] did not observe any side effects in his patients. It can be due to difference of environment in Lahore and Tokyo as we have a hot and humid weather in Pakistan many months around the year while it is much cooler in Tokyo throughout.

The mean percentage reduction of SCORAD score after 8 weeks of treatment with NB-UVB in our study was 70% whereas in Der-Petrossian *et al.*[16] study it was 64.1% at the end of 6 weeks. In the study by Der-Petrossian *et al.*[16] 10 of the 12 patients showed improvement with NB-UVB, at the end of 6 weeks. The overall evaluation scores were reduced, however, mean percentage reduction in our study was better than Der-Petrossian *et al.*[16] study which could be due to more number of sessions i.e. 24 sessions in our study as compared to 18 sessions in their study. Another reason seems to be the dose. Mean cumulative dose in our study was 21 J/cm^2 compared to 14 J/cm^2 in the Der-Petrossian *et al.*[16] study. Skin type in both the studies was also different which is type I, II and III in the Austrians. Overall 94% of our patients showed greater than 50% reduction in group B patients.

In another study by Grundmann-Kollmann *et al.*[17] 5 patients showed improvement when NB-UVB was given five times a week for 3 weeks. The total score and subjective symptoms were reduced. A complete remission (100%) was seen in their patients after 22 sessions. This may be due to increased number of sessions per week. As the number of patients in his study was small (n=5), enrollment of greater number of patients may have produced different results.

Regarding side effects of NB-UVB, the major side effect observed was pigmentation. It was seen in 10% of our patients after 18 sessions. In the study by Grundmann-Kollmann *et al.*[17] 60% of patients had developed erythema while in our study erythema was seen in 3.3% of patients. This may be due to difference in skin type. The patients in their study were of skin type II and III while in our study the patients belonged to skin type III and IV.

Comparing the mean SCORAD reduction of group A and group B, after 4 weeks the difference was significant (p=000). Steroids when applied for short-term had better results than NB-UVB. But when we extended NB-UVB till 8 weeks in group B the difference became insignificant. Regarding the safety, 34% patients in group A had side effects. One of the patients also had atrophy of skin whereas even after 8 weeks of treatment of NB-UVB only 20% patients showed side effects. These results showed that both types of treatment were effective in AD, but NB-UVB was safer than betamethasone.

Both betamethasone valerate 0.1% and NB-UVB are almost equal in terms of efficacy but NB-UVB is safer than betamethasone valerate 0.1%.

Conclusion

Both betamethasone valerate 0.1% and NB-UVB are almost equal in terms of efficacy but NB-UVB is safer than betamethasone valerate 0.1%.

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