

## Narrowband UV-B phototherapy in childhood atopic dermatitis: efficacy and safety\*

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**Abstract:** BACKGROUND: Narrow-band UVB is the most innovative steroid sparing treatment in atopic dermatitis. There are studies showing efficacy of Narrow-band UVB in childhood atopic dermatitis, but there is lack of clinical trials in the literature determining the length of remission. Therefore, we sought to highlight its efficacy, safety and its post-treatment efficacy in childhood atopic dermatitis.

OBJECTIVE: To assess the clinical efficacy, safety of Narrow-band UVB in the treatment of paediatric atopic dermatitis and length of remission during 2 years of post-treatment follow-up.

METHODS: Thirty children (4-14 years) having moderate to severe AD (SCORAD index > 25) were enrolled for 12 weeks. Narrow-band UVB phototherapy was administered twice a week on non-consecutive days for three months. SCORAD index was calculated by the same dermatologist at baseline, 6th, 12th, 18th and 24th treatment session. Secondary outcomes were measured using visual analog scale for pruritus and sleep loss. Patients were also followed-up for 2 years to know the length of remission after end of therapy.

RESULTS: There was a significant reduction in SCORAD index at 6th, 12th, 18th and 24th treatment session in comparison to baseline. This improvement in SCORAD was also maintained during the 2 years of post-treatment follow-up period. Consequently, pruritus and sleep loss improved significantly from baseline to end of therapy and even during the 1st and 2nd year of follow-up.

STUDY LIMITATION: Open-label trial without control group.

CONCLUSIONS: Narrow-band UVB is an efficacious and safe modality of treatment in childhood atopic dermatitis with good therapeutic index and minimal side effects.

**Keywords:** Dermatitis, atopic; Phototherapy; Pruritus

### INTRODUCTION

Atopic dermatitis (AD) is a common and distressing condition characterized by itchy, chronically relapsing inflammatory skin lesions associated with personal or family history of allergy. It is a major health problem worldwide with a prevalence of 15-20% in children and an increase by 2- to 3-fold in its incidence during the past few decades in industrialized countries has been observed.<sup>1</sup> In chronic childhood AD, emollients and topical steroids have been considered the mainstay of therapy. The long term adverse effects of topical steroids led to the development of nonsteroidal topical alternatives such as calcineurin inhibitors like tacrolimus and pimecrolimus. However, children with moderate to severe AD often fail to respond to topical therapies alone. Thus, a safe and effective treatment option is needed for moderate to severe childhood AD.

Phototherapy, particularly Narrow-band UVB (NBUVB) is considered as second line therapy for AD.<sup>2</sup> A randomized controlled trial in adult eczema has shown NBUVB to be superior to other phototherapy modalities.<sup>3</sup> As it has a good safety profile in children, it seems to be a good treatment option in childhood AD.

However, on reviewing the literature thoroughly we noticed that there are very limited studies available which have evaluated the efficacy of NBUVB phototherapy in the management of childhood AD.<sup>4,7</sup> Previous studies by Collins *et al.*<sup>4</sup>, Clayton *et al.*<sup>5</sup> and Darné *et al.*<sup>6</sup> have emphasized and refurbished the therapeutic efficacy of NBUVB in childhood AD. There is only one study in Asian patients by Mok *et al.*<sup>7</sup> who have also highlighted the usefulness of NBUVB in moderate to severe childhood AD; however, they

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have taken very small number of patients for NBUVB therapy alone (only 15). All these studies by Collin *et al.*, Clayton *et al.* and Mok *et al.* were retrospective in nature and did not include any prospective post-treatment follow-up.<sup>4,5,7</sup> Although, Darné *et al.*'s study was a prospective study, it included only 6 months of post-treatment follow-up.<sup>6</sup> However, there are no prospective studies with 2 years of post-treatment follow-up for knowing the length of remission and long-term side effects associated with NBUVB in childhood AD. Therefore, we undertook a trial to study the efficacy and safety of NBUVB in childhood AD throughout the therapy and during the post-treatment follow-up period, in terms of reduction in disease intensity, improvement in patient's grade of itch and sleep loss.

## METHODS

### Study Design

The study was a prospective, open labelled clinical trial performed at the Department of Dermatology. The study was approved by the Post-Graduate Board of Medicine and Allied Sciences, Pt. B.D. Sharma Post Graduate Institute of Medical sciences.

### Patient selection

Paediatric patients aged 4 to 14 years having atopic dermatitis diagnosed on basis of the UK refinement of Hanifin and Rajka's diagnostic criteria and having moderate to severe atopic dermatitis (Scoring Atopic Dermatitis; SCORAD index of more than 25) were included in the study.<sup>8,9</sup> Verbal and written informed consent was taken from patients, parents or guardians.

Exclusion criteria include patients with history of having impaired renal or hepatic function, uncontrolled infected eczema, claustrophobia, intolerance or previous failure to phototherapy, photosensitivity or photo-mediated disorders. Patients who had taken other forms of treatment for AD like psoralen therapy, NBUVB, systemic steroids and other immunosuppressant within 3 months were excluded.

A detailed history was taken and dermatological examination was performed to measure the disease intensity and extent. SCORAD index was then calculated to assess the severity of disease.<sup>9</sup> Presence of any other dermatological condition was also noted.

### Treatment schedule

Patients were treated with phototherapy in a whole body NBUVB unit (V care UV therapy unit, Bangalore, India) of wavelengths from 310 to 315 nm, containing 16 fluorescent tubes (TL-01) with 100 watts and 6 ft. The initial dose of UV-B was 50 mJ/cm<sup>2</sup>, which was determined on the basis of patient's skin type, according to the classification by Pathak *et al.*<sup>10</sup> The irradiation dose was increased by 10% of the previous dose on each subsequent visit. The dose was not increased if there was any trace of erythema. In case of symptomatic erythema with or without oedema/blistering, further treatment was withheld till symptoms subsided. After resolution of symptoms, the dose was reduced to 50% of the last dose and subsequent increments were by 10%.

During the entire study, no other topical therapy was used other than coconut oil because it does not interfere significantly with NBUVB transmission.<sup>11</sup> During each treatment, eyes were pro-

TECTED by UV blocking goggles, genitalia and other uninvolved area were shielded.

### Clinical assessment

All the patients were examined by the same dermatologist at each visit. We used a validated scoring system SCORAD index<sup>9</sup> to accurately monitor AD disease activity and response to treatment. SCORAD index was calculated at baseline i.e. before starting the therapy and then after 6<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup> and 24<sup>th</sup> treatment session. Patients were also followed-up for 2 years and the SCORAD index was calculated at 6 months, 1 year and 2 years of post-treatment follow-up period. During this follow-up period patients did not undergo any phototherapy session and did not receive any other systemic therapy.

We also determined the mean cumulative dose of NBUVB and number of treatment sessions required for clearance. "Clearance" was defined when more than 90% of body surface area was free of the disease.<sup>12</sup> In our study, the secondary outcomes were measured as improvement in pruritus and reduction in sleep loss. The rating was obtained by using visual analogue score (VAS) consisting of 10 cm line on which patient indicated a point between "worst itch imaginable/no sleep" and "no itch/ normal sleep".<sup>13</sup> Adverse effects were looked for at each visit.

### Statistical analysis

All statistical analysis was carried out with Statistical Package for Social Sciences (SPSS) for Microsoft windows 20<sup>th</sup> version. Descriptive statistics were analysed on the parameters of range, mean  $\pm$  standard deviation, frequencies (number of cases), ratio or percentages, whichever was appropriate. The change in mean SCORAD index as compared to baseline at each treatment session and at 6 months, 1 and 2 years of follow-up period was analysed using One-way ANOVA. The improvement in pruritus and reduction in sleep loss from baseline to end of therapy and during the follow-up period was compared using Wilcoxon Signed Ranks test.

### Significance of results

All tests were performed at a 5% level of significance; thus, an association was significant (S) if the p value was less than 0.05 and p value < 0.001 as highly significant. The p-value more than 0.05 considered as non-significant (NS).

## RESULTS

### Patient's Demographic

Demographics of all the patients are given in table 1. Personal history of atopy was present in 24% of patients while family history of atopy was present in 16% of patients. Out of 30 patients, 27 (90%) patients had moderate AD (SCORAD index ranging from 25-50<sup>9</sup>) while 3 (10%) patients had severe AD (SCORAD index >50<sup>9</sup>).

### Efficacy evaluation

All the patients showed improvement in terms of extent of disease, intensity of disease, pruritus and sleep loss. In our study, we observed that SCORAD index had considerably reduced at the 6<sup>th</sup>, 12<sup>th</sup> and 18<sup>th</sup> treatment session in comparison to baseline (Table 2).

TABLE 1: The demographic data of the patients included in the study

	Patients (n=30)
Age (years) Mean + SD; Range	8.13+3.22 (4-14)
Sex ratio (male: female)	1:1
Duration of disease (years) Mean + SD; Range	4.23 + 3.02 (1-12)
Age at onset (years) Mean + SD; Range	3.90 + 3.44 (0.1-12)
Body surface area (percentage) Mean + SD; Range	34.13+16.90 (12-77)

TABLE 2: SCORAD index at baseline, during and after the therapy

SCORAD index	Range	Mean + SD	p-value
Baseline	20-56	30.42+7.90	-
6th treatment session	7.2-30	14.01+5.80	<0.001
12th treatment session	0-22.5	11.41+5.89	<0.001
18th treatment session	0- 19.1	8.89+4.25	<0.001
24th treatment session	0-18.0	7.82+3.72	<0.001
After 6 month of post-treatment	0-19	8.09+3.41	<0.001
After 1 year of post-treatment	0-20	10.29+3.85	<0.001
After 2 years of post-treatment	0-22.4	15.34+5.08	<0.001

At baseline, mean SCORAD index was  $30.42 \pm 7.90$  while at the end of three months the mean SCORAD index was  $7.82 \pm 3.72$ . The difference between them was found to be highly significant with p-value  $<0.001$ . Similarly, when the baseline SCORAD index was compared with SCORAD index at the 6<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup> and 24<sup>th</sup> treatment session, the reduction was again found to be highly significant with p-value of  $<0.001$  at all the sessions respectively (Figures 1, 2 and 3).

Out of the 30 patients included in our study, 27 patients (90%) showed clearance of disease. Most patients (i.e. 13) cleared at the 18<sup>th</sup> treatment session, while 5, 3 and 6 patients cleared at the 6<sup>th</sup>, 12<sup>th</sup> and 24<sup>th</sup> treatment session respectively. In our study, the maximum cumulative dose of NBUVB required for clearance ranged from 388-4450mJ/cm<sup>2</sup> and the mean cumulative dose for clearance was  $2137.077 \pm 1414.32$  mJ/cm<sup>2</sup>.

Pruritus significantly improved from baseline (mean  $5.83 \pm 1.44$ ) to end of the therapy (mean  $0.76 \pm 1.56$ ) as measured by VAS (p-value  $<0.001$ ). The reduction in sleep loss measured on VAS scale from baseline ( $2.73 \pm 2.099$ ) to 24<sup>th</sup> treatment session ( $0.1 \pm 0.402$ ) was also found to be statistically significant.

On follow up of the patients, we observed a clinically and statistically significant reduction in SCORAD index at 6 months, 1 year and 2 years after completion of treatment as compared to the

baseline (Table 1). Similarly, during the 1<sup>st</sup> and 2<sup>nd</sup> year of post-treatment follow-up period the improvement in pruritus and reduction in sleep loss was maintained both clinically and statistically (p value  $<0.001$ ). Although from the baseline the difference of reduction in SCORAD and VAS for pruritus and sleep loss at 6 months was higher in comparison to 1<sup>st</sup> and 2<sup>nd</sup> year of post-treatment follow-up, the statistical significance was maintained throughout the whole 2 years of follow-up period (Figure 1, 4 and 5).

#### Safety evaluation

Side effects were reported in 5 patients (16.67%). Grade II erythema was seen in 3 patients. Reactivation of herpes labialis and chickenpox were reported in one patient each. All these patients required temporary cessation of therapy and were restarted on NBUVB at lower doses. During the follow-up period of 2 years the patients were also examined for any side-effects related to NBUVB phototherapy and we did not find any significant adverse effects in this follow-up period.

#### DISCUSSION

Children with moderate to severe AD often fail to respond to topical therapy such as emollients, corticosteroids and tacrolim-

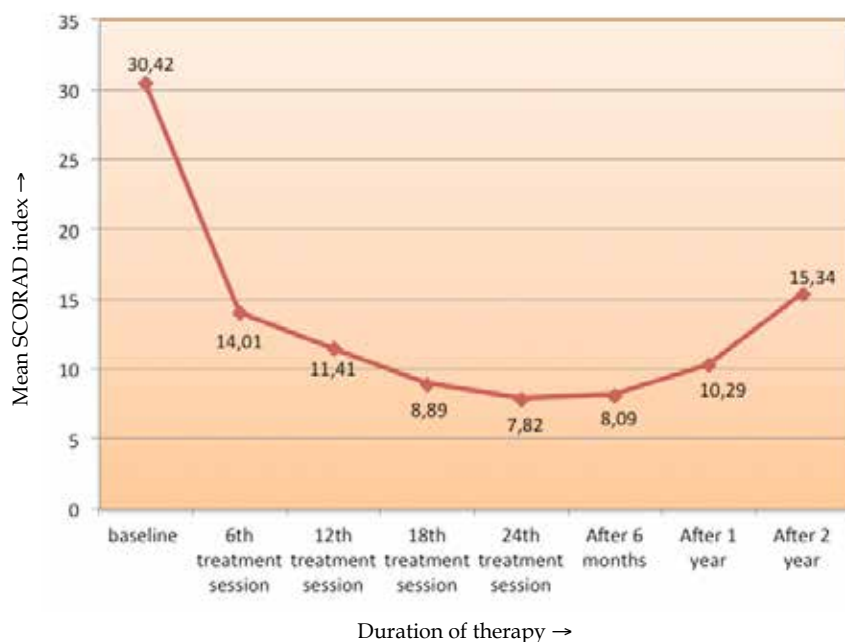


FIGURE 1: Improvement in SCORAD index with therapy and during post-treatment follow-up period



**FIGURE 2:** A. Before NBUVB: showing atopic dermatitis lesion on the left side of the face in a 3 year old male; B. After NBUVB: showing clearance of lesion on the left side of the face

mus. Thus, phototherapy has been regarded as another alternative for the treatment of moderate to severe AD. PUVA with oral 8-Methoxypsoralen has been shown to be an effective treatment option for adult AD, although there are concerns regarding its long-term safety.<sup>14</sup> According to a recent review by Dogra *et al.*<sup>15</sup> both UVA1 and NBUVB are equally effective in the treatment of patients with moderate to severe atopic dermatitis. However, UVA1 is preferable for controlling acute flare of atopic dermatitis while NBUVB is most effective in managing chronic disease. Another systematic review by Pérez-Ferriols *et al.*<sup>16</sup>, described two studies according to which NBUVB was found to be superior than medium dose UV-A1, with a better reduction of pruritus compared to medium dose UVA1. Moreover, UVA1 has potential association with photo-carcinogenesis like melanoma and Merkel cell carcinoma.<sup>15</sup>

NBUVB has been reported to be effective in the management of AD in adults resulting in prolonged remission.<sup>3</sup> In AD, there is an inappropriate balance between  $CD_4^+CD_{25}^{high}$  Tregs and  $Th_2$  T effs. This imbalance may result from a deficiency in suppression by Tregs or by strong activation signals that supersede the regulatory mechanism.<sup>17</sup> Samahy *et al.*<sup>18</sup> has recently reported a significant reduction of clinical severity grades according to the Leicester score after NB-UVB therapy, with overall significant elevation of Tregs



**FIGURE 3:** A. Before NBUVB: lesions of atopic dermatitis on the cubital fossae bilaterally in a 6 year old male; B. After NBUVB: showing clearance of lesions on the cubital fossae

FoxP<sub>3</sub> expression%. Comparing pre- and post-phototherapy data, there was a statistically significant elevation of Tregs% and Tregs/Teffs ratio in mild grade patients and significant elevation of Tregs FoxP<sub>3</sub> expression% and Tregs/Teffs ratio in the moderate group. However, no significant change was detected in the severe group which could be attributed due to the small sample size as well as the high pretreatment Tregs% in the patients of severe group.

Clinical studies have shown NBUVB phototherapy as an effective and well-tolerated treatment in childhood AD; however, its long-term adverse effects and length of remission have not been thoroughly assessed.<sup>4,7,12</sup> Furthermore, on perusal of literature, there are very few studies observing the effect of NBUVB in childhood AD of which most of the studies are retrospective and have included small number of patients.<sup>4,5,7,12</sup> The present study was, therefore, undertaken to determine the response and safety of NBUVB in children with AD, in terms of efficacy, reduction in disease intensity and extent of disease, adverse effects, amelioration in pruritus and sleep loss.

In our study, out of 30 patients, 90% had moderate AD and 10% had severe AD. This is in concordance with the earlier Indian studies which have also highlighted that severity of AD in Indian patients is much less as compared to that in the West.<sup>19,20</sup>

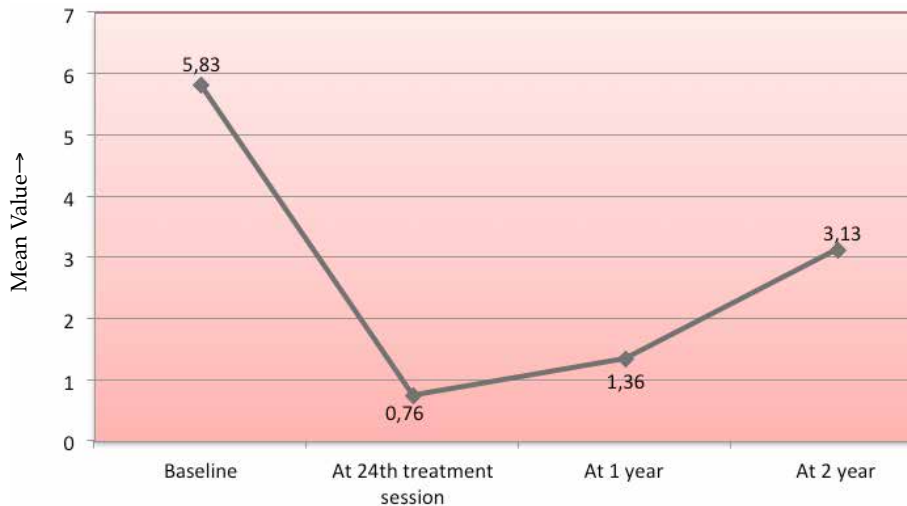


FIGURE 4: Improvement in pruritus measured on VAS during and after the treatment

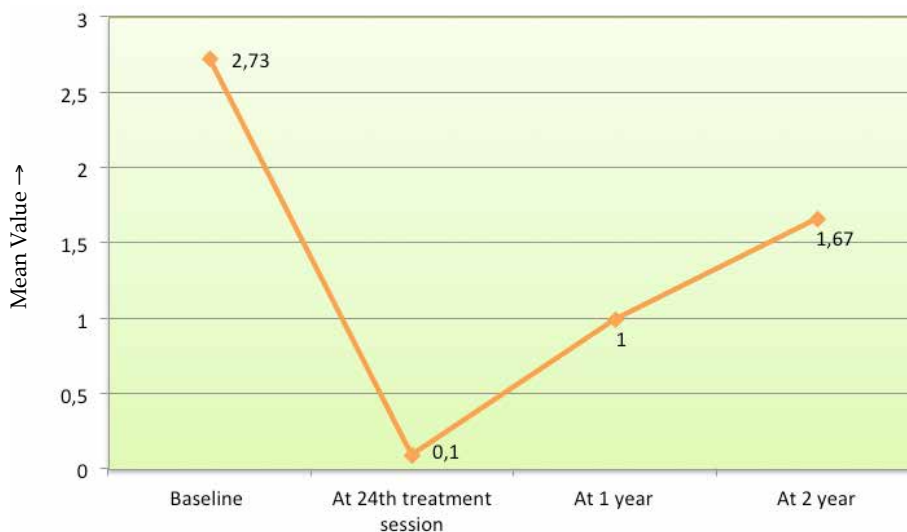


FIGURE 5: Reduction in sleep loss measured on VAS during and after the treatment

In the present study, we observed that SCORAD index had considerably reduced at the 6<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup> and 24<sup>th</sup> treatment session in comparison to baseline. This was in concordance to a recent study by Darné *et al.*<sup>6</sup> who had also showed a significant decrease in SCORAD index at 12 weeks of treatment (i.e. end of treatment) as compared to baseline. Besides the study by Darné *et al.*, all other previous studies were retrospective studies and have not used such validated scoring system to measure the improvement in response to NBUVB.<sup>4,5,7</sup>

The results of our study reveal that clearance of disease was seen in 90% of patients. Maximum number of patients achieved clearance at the 18<sup>th</sup> treatment session, while Darné *et al.* had observed that only 41% of children with AD achieved clearance or minimal residual disease at the end of therapy, i.e., 12 weeks. In our study, all the patients were of Indian origin while in Darné *et al.* study there was predominance of patients of western origin. Thus, the higher rates of clearance in our study can be explained by the

fact that patients of western origin have been reported to have more treatment resistant eczema.<sup>6</sup>

In our study, the maximum cumulative dose of NBUVB for clearance was 2.267J/cm<sup>2</sup>. The cumulative dose in our study is relatively less as compared to other studies because we have given twice weekly NBUVB starting with 50mJ/cm<sup>2</sup> and session wise increment of 10% only while in other studies therapy was either given thrice weekly or doses were given according to MED values with 20% increments three times in a week.<sup>5,6,12</sup>

In our study, secondary outcomes were assessed using restoration of sleep and reduction in pruritus. Pruritus showed significant improvement from baseline to the end of three months of therapy and during two years of post-treatment follow-up period. Similarly, significant restoration in normal sleep pattern was seen at the end of therapy, i.e., 3 months, and during the two years post-treatment follow-up period. These results were in agreement

with Darné *et al.* study where they also mentioned amelioration of pruritus and restoration of normal sleep pattern by the patients and parents as treatment benefits during and after 6 months of therapy.<sup>6</sup>

In the present study, when we assessed the adverse effects, we found that the therapy was generally well tolerated during and after the treatment. The side effect profile observed in our study was in agreement with the earlier studies. Clayton *et al.* have reported that NBUVB phototherapy was generally well tolerated except for short term adverse effects in few patients like grade II erythema and reactivation of Herpes simplex virus, etc.<sup>5</sup> Likewise, Mok *et al.* had reported minor side effects like erythema, skin peeling and itch.<sup>7</sup> Darné *et al.* had also concluded that side effects were mild, mainly in the form of erythema.<sup>6</sup> But concern remains about the long-term carcinogenesis potential of NBUVB. This made us follow-up these patients for two years after NBUVB, however we did not find any side effects during this period.

Our study holds considerable importance because the study group was made of children, and therefore there is need for a treatment that is effective as well as safe. The use of validated scoring system, i.e., SCORAD in our study has ensured the accurate

monitoring of AD disease activity. Furthermore, to the best of our knowledge, there are no prospective studies available in the literature with such a long term, i.e., 2 years of post-treatment follow-up period. However, there were some limitations in our study. Firstly, the study was an open-label trial, not randomized nor controlled. A control group was not used as we felt it was unethical not to give any treatment to children afflicted with moderate to severe atopic dermatitis. Secondly, the study period was relatively short, in terms of post-treatment follow-up period. Thus, one would require large multicentric studies involving several thousand new patients per year followed-up for 10 years or more, to determine its carcinogenic potential.

## CONCLUSIONS

Our study proves that NBUVB phototherapy is an efficacious and safe modality of treatment in childhood AD. It also reaffirms the school of thought that it could be relied upon as the first line therapy in moderate to severe AD in the pediatric age group before opting for more toxic therapies as it has a good therapeutic index and low profile of acute and possibly long-term side effects. □

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