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A COMPARATIVE STUDY OF EFFICACY AND SAFETY OF NBUVB AND ORAL BETAMETHASONE MINI PULSE IN THE TREATMENT OF GENERALISED LICHEN PLANUS.

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ABSTRACT **INTRODUCTION-** lichen planus is an idiopathic inflammatory disease of the skin and mucous membranes. Oral mini pulse therapy with betamethasone has been reported to be an effective, safe and better therapeutic approach. NBUVB may be regarded as an effective treatment for generalized lichen planus.

STUDY DESIGN- Single centre, prospective, randomized, comparative clinical study.

METHOD AND MATERIAL- 60 patients with generalized lichen planus involving more than 20% BSA of age between 10-60 years were included in this study. They were randomized to be treated either with oral betamethasone mini pulse (group A) or NBUVB (group B).Patients were followed for response to treatment, side effects and relapse.

RESULT-Mean age of onset of lichen planus was 31.8 years in group A and 32.7 in group B with female to male ratio 0.765:1 overall. Out of total 60 patients, 28(46.67%) showed relapse within 3 months after stopping therapy. In 28 patients ,18 were from group A and 10 from group B. Side effects seen in group A were gastric symptoms 40% ,weakness26.67%, facial puffiness and weight gain 16.67% each and in group B, there were tanning of skin in 80%, xerosis in 6.67%.

CONCLUSION-NBUVB may be as effective as oral mini pulse with lesser side effects for the treatment of generalized lichen planus.

KEYWORDS : Oral mini pulse, NBUVB, Lichen planus.

INTRODUCTION :

Lichen planus (LP), is an idiopathic inflammatory disease of the skin and mucous membranes characterized by pruritic, violaceous papules that favour the extremities.[1] Being self-limiting, treatment modality in lichen planus must be safe as well as effective to relieve patient's symptoms.

The management of lichen planus depends on the age of the patient, site affected and type of lichen planus.[2]Oral mini-pulse therapy with betamethasone has been reported to be an effective, safe and better therapeutic approach for the treatment of lichen planus.[3] Various studies show that NBUVB may be regarded as an effective treatment for generalized cutaneous lichen planus especially when there is contraindication for systemic corticosteroids or other immunosuppressive drugs.[4,5,6]

This study was conducted to compare the efficacy and safety of oral betamethasone mini pulse and narrow band UVB in the treatment of generalised lichen planus. To best of our knowledge this is the 1st study comparing oral mini pulse therapy with NB-UVB in the treatment of lichen planus.

MATERIALS AND METHODS :

A total number of 60 patients with confirmed diagnosis of generalised lichen planus between the age group 10-60 years involving more than 20% of body surface area attending the department of Dermatology, Dr S N Medical college, Jodhpur were randomly included in study. Clearance of ethical committee of Dr S N Medical College, Jodhpur was also taken. They were randomized using simple randomization to be treated either with oral betamethasone mini pulse (group A) or NBUVB (group B). Patients with nail involvement and lichen planopilaris were excluded from the study.

Patient's personal particulars were recorded. After informed consent, clinical photographs of the patients were taken. 30 Patients were given 36 exposures of NBUVB as per thrice weekly protocol along with emmolient over 3 months period at dose starting from 300 mj/cm^2 depending on minimum erythema dose and tolerability. 30 patients in other group were given 0.1mg/kg oral betamethasone on two consecutive days every week for 4 weeks along with emollient followed by tapering of dose over the next 8 weeks . Patients were examined for side effects during and after completion of the study. The severity of pruritus was graded on visual analogue scale 0-10.

Patients response to treatment was assessed after 3 months of therapy as follows:

The percentage of improvement in lesions was calculated as follows[2]

100% - Complete subsidence of all lesions, absence of pruritus and no new lesions.

75-99% - A few elevated lesions, itching is absent or mild, but there are no new lesions.

50-74% - Most lesions remain elevated, mild to moderate, but no new lesions.

<50% - Most lesions remain elevated, itching is moderate to severe and new lesions.

The data was analysed using IBM SPSS software programme.

RESULTS:

Mean age of onset of lichen planus was 32.25 years, group A (31.8) years group B (32.7) years. Maximum patients were seen in age range 20-40 years with 29 patients out of 60. Lichen planus was found to affect females more than males with overall male to female ratio of 0.765:1. Mean duration of illness was found to be 4.7 months with 80 percent patients presenting within 6 months of onset. There was no significance difference in the age, sex and duration of illness between both groups with p> 0.05. Out of total 60 patients 57 showed no associated dermatological or systemic disorder. Alopecia areata, hypothyroidism and diabetes mellitus were seen in 1 patients each. Family history was found in 1 patient. Severity of pruritus was measured on visual analogue scale. 95% of patients had some form of pruritus while 5% were asymptomatic. Mild pruritus was present in 16.67%, moderate pruritus was seen in 46.67% and severe pruritus was present in 31.66 % of the patients.

60% patients in the oral mini pulse group showed excellent response, 36.67% showed good response, 3.33% showed moderate response while none of the patient showed poor response. In the NB-UVB group 46.67% showed excellent response, 36.67% showed good response, 16.67% showed moderate response while there were no treatment failures in this group too. Efficacy of oral betamethasone mini pulse therapy was found to be better than NBUVB in the treatment of lichen planus but the difference was not statistically significant, P value 0.205.

In the present study out of total 60 patients 28 (46.67%) patients showed relapse when followed up for a period of 3 months after stopping therapy. In the oral mini pulse group 18 (60%) patients out of 30 showed relapse. In the NB-UVB 10 (33.33%) patients out of 30 showed relapse. Relapse was more common in oral mini-pulse group. There was significant difference in the two groups regarding presence of relapse with p value < 0.05. The response obtained by NBUVB tends to produce longer remission period as compared to oral betamethasone mini pulse therapy which is associated with higher relapse rate.

Side effects observed with oral mini-pulse were gastric Symptoms 12 (40%), Weakness 8 (26.67%), Facial Puffiness 5 (16.67%), Acneform Eruption 2 (6.67%), Raised BP 1 (3.33%), Secondary Infection 1 (3.33%), Weight Gain 5 (16.67%) & Menstrual Abnormalities in 1 (3.33%) patient.

Most common complaint with NBUVB therapy was of tanning of skin which was seen in 24 (80%) patients. Xerosis was seen in 5 (6.67%) of the patients. Erythema was seen in 4 (13.33%) of the patients and blistering was seen in 3 (10%). No laboratory anomalies were seen in both groups during or after therapy. Side effects observed with NBUVB were less than oral betamethasone mini pulse therapy. NBUVB was found to be safer than oral mini pulse in the treatment of lichen planus.

DISCUSSION :

Oral mini pulse therapy is usually prescribed using a longer acting corticosteroids like betamethasone for 1-2 days in a week which probably would have an effect equivalent to prednisolone but with reduced side effects. In the present study 60% patients in the oral mini pulse group showed excellent response, 36.67% showed good response, 3.33% showed moderate response while none of the patient showed poor response[fig. 1]. In the similar study conducted by al-muntari et al[7] a good to excellent response was seen in 68% of the patients. Ramesh et al[8] noted excellent response in 57% of the patients which is similar to present study. No patient in the present study showed treatment failure which is similar to results obtained by Mittal and Verma[9] who noted there was no patient without some response.

In the NB-UVB group 46.67% showed excellent response, 36.67% showed good response, 16.67% showed moderate response while there were no treatment failures in this group too [table.1]. In the similar study conducted by Fariba ebaji et al[6] complete response was seen in 52% of the patients while none of the patients showed no response which was similar to our study. Pavlotsky et al[5] obtained complete response (100%) in 70% of the patients which is far more than the present study. Habib et al[4] reported complete response in 55 % of patients, Saricaoglu et al[10] reported complete response in 50 % of their patients which is similar to our study. In the present study oral-mini pulse was found to be slightly more effective than NB-UVB in the treatment of generalised lichen planus but the difference in treatment was not found to be significant. Since the study duration was 3 months, for studying the efficacy of NB-UVB prospective controlled study of longer duration are required.

Relapses after treatment are common in lichen planus. In the present study out of total 60 patients 28 (46.67%) patients showed relapse when followed up for a period of 3 months after stopping therapy, patients with appearance of new lesions and increase in severity of itching were considered in relapse. Relapses were more common in oral mini-pulse group. In the oral mini pulse group 18 (60%) patients out of 30 showed relapse [table.2]. Which was in contrast to the study by Ramesh et al[8] in which only 12 % patients showed relapse after 3 months of stopping therapy.

In the NB-UVB 10 (33.33%) patients out of 30 showed relapse. There was significant difference in the two groups regarding presence of relapse. The response obtained by NBUVB tends to produce longer remission period as compared to oral betamethasone mini pulse therapy which is associated with higher relapse rate. This was consistent with the results obtained by Pavlotsky et al[5] whose 85% patients were in remission on stopping therapy after a median of 34.7 months.

Side effects profile of oral mini pulse therapy and NBUVB are completely different as these are different forms of therapy. Oral mini pulse therapy is used in an attempt to reduce side effects but these are frequently present. In the present study side effects observed with oral mini-pulse were Gastric Symptoms 12 (40%), Weakness 8 (26.67%), Facial Puffiness 5 (16.67%), Acneform Eruption 2 (6.67%), Raised BP 1 (3.33%), Secondary Infection 1 (3.33%), Weight Gain 5 (16.67%) & Menstrual Abnormalities in 1 (3.33%) patient. Laboratory parameters did not show any abnormalities during or after oral mini pulse therapy which was consistent with study by mittal et al.[9] In the present study side effects observed in the narrow band UVB group were less and narrow band UVB was more tolerable to the patients than oral mini pulse group. Most common complaint was of tanning of skin which was seen in 24 (80%) patients. Xerosis was seen in 5 (6.67%) of the patients. Erythema was seen in 4 (13.33%) of the patients and blistering was seen in 3 (10%).

CONCLUSION:

Thus in conclusion for the treatment of generalized lichen planus NBUVB may be as effective as oral mini pulse with lesser side effects. Oral mini pulse therapy produces a more dramatic response but NB-UVB has advantage over oral mini pulse as it can be given in patients with pregnancy and systemic disorders in which systemic steroids are contraindicated. However a larger study should be performed to confirm these findings.

Table.1 showing response to therapy at the end of months

Group	Response to Therapy				Total	P-Value
	<50 Poor	50-74% Moderate	75-99% Good	100% Excellent		
Oral Mini Pulse	0(0%)	1(3.33%)	11 (36.67%)	18(60%)	30(100%)	.205
NBUVB	0(0%)	5 (16.67%)	11 (36.67%)	14(46.67%)	30(100%)	
Total	0(0%)	6(10%)	22 (36.67%)	32(53.33%)	60(100%)	

Table.2 showing comparison in frequency of relapse

Group	Relapse		Total	P-Value
	Present	Absent		
Oral Mini Pulse	18(60%)	12(40%)	30(100%)	.038
NBUVB	10(33.33%)	20(66.67%)	30(100%)	
Total	28(46.67%)	32(53.33%)	60(100%)	

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