

Original Research Article

Comparative study of oral methotrexate and narrow band ultraviolet-B in chronic plaque psoriasis: a study from urban Karnataka

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ABSTRACT

Background: Treatment of psoriasis continues to be a challenge. It is often frustrating experience for dermatologists. Methotrexate or PUVA or NBUVB when used properly, can produce good to excellent clinical benefit with minimal side effects. The objective of the study was to compare the efficacy and safety of oral methotrexate and NBUVB in the treatment of chronic plaque psoriasis.

Methods: 100 patients of chronic plaque psoriasis attending the skin department of Navodaya Medical College and Hospital, Raichur from November 2012 to April 2014 were included in the study. Group A exhibited to Oral methotrexate and group B to NBUVB. Outcome was measured in terms of PASI 75 (it means 75% reduction in original PASI). Data was analysed using SPSS 19.0 version.

Results: In Group A mean age was 33.68 years and in Group B mean age 33.7 years. The difference in mean PASI at baseline, at 4 and 8 weeks using oral methotrexate as well as NBUVB was found to be highly significant (<0.001). PASI score was less in-group using methotrexate at 4 and 8 weeks interval (<0.05). Mean time taken for PASI 75 in the baseline PASI score in Group A was 9.62±1.3 weeks whereas in Group B it was 11.3±0.7 weeks. Side effects were higher in group B (60%) compared to group A (36%).

Conclusions: Improvement in the PASI score was best with methotrexate than NBUVB. The side effects observed in a methotrexate were minimal compared to NBUVB.

Keywords: Oral methotrexate, Narrow band ultraviolet-B, Chronic plaque psoriasis

INTRODUCTION

Psoriasis is a chronic, disfiguring, inflammatory and proliferative condition of the skin. Genetic and environmental influences plays vital role in its etiology.¹ Commonly observed lesions consist of red, scaly, sharply demarcated, plaques over extensor surfaces and scalp.¹ The disease is variable in duration, periodicity of flares and its extent. It has a bimodal distribution of age. It affects both males and females equally. Its etiology is unknown. Its clinical diagnosis is easy but difficult to

treat satisfactorily.¹ Newer therapeutic approaches are added frequently.¹ All therapies have merits and demerits and often no single treatment is ideal.²

The management includes laboratory investigations and treatment. The treatment depends upon age, sex, occupation, general health, intelligence of the patient, clinical type, extent and duration of the disease. Treatment of psoriasis is a challenge for health system. Its cure is not ensured. Therapy should be simpler, potentially less toxic and more effective.³

Pruritus is the main symptom in psoriasis subjects. In surveys, the majority of psoriatic patients indicate a serious impairment in their quality of life. They feel that the current treatment, although often effective, do not provide a satisfactory long-term cure. Usually simpler and potentially less toxic therapies tried first, including phototherapy with tar and ultraviolet B radiation. Other therapies to be considered if (1) cumulative amount of phototherapy becomes excessive with respect to potential toxicity, (2) psoriasis does not respond to it and (3) psoriasis is life threatening. In such conditions, methotrexate or PUVA or NBUBV when used rationally, can produce better clinical benefit.

So, in view of availability of many modalities of treatment it is worthwhile to study and compare the effects of oral methotrexate and NBUBV in the most common type chronic plaque psoriasis, which would add to the future trends in the management of the same and would help the suffering patients.

Objectives

- To compare the efficacy and safety of oral methotrexate and NBUBV in the treatment of chronic plaque psoriasis.

METHODS

Hundred patients of chronic plaque psoriasis attending the skin department of Navodaya Medical College and Hospital, Raichur from November 2012 to April 2014 were included in the study. The hundred patients were consecutively selected and allocated according to inclusion and exclusion criteria which were mentioned below into two groups, fifty each Viz group A and B exhibited to oral methotrexate and NBUBV respectively.

Patients of chronic plaque psoriasis were included adopting the following criteria.

Inclusion criteria

Inclusion criteria were patients with normal liver function, renal function, haemogram; patients willing for treatment, investigations and regular follow up are included in the study after taking consent.

Exclusion criteria

Exclusion criteria were pregnancy, lactation, children; abnormal liver function, renal function, excessive alcoholism; photo aggravated psoriasis; previous cutaneous malignancy; patients with photosensitivity disorders like SLE etc.; patients unsure about attending treatment schedule regularly; patients who failed to come for follow up after initial therapy.

A detailed cutaneous and systemic examination was done in all the patients. Complete haemogram, urine for

albumin, sugar and microscopy, skin biopsy, blood sugar, liver function test, renal function test were done in all the patients before initiation of therapy. The patients were explained regarding the duration of treatment, the need for regular follow up to therapy clinic and probable side effects that could be encountered during treatment. Complete haemogram, urine for albumin, sugar and microscopy, blood sugar, liver function test, renal function test were done periodically to observe for any systemic involvement and the response to treatment was evaluated every week by PASI score and also the patients were observed clinically for any cutaneous or systemic side effects.

Group A: Oral methotrexate

In this group initial dose of 7.5 mg per week was given in 3 equal divided doses spaced at 12 hours apart and dose was gradually increased by 2.5 mg/week to a maximum of 15 mg/week, till PASI achieves 75 or for 12 weeks whichever was first.

Group B: NBUBV⁴

Minimal erythema dose (MED) was done using six test doses (200, 280, 390, 550, 770, 1100 mj/cm). Result read after 24 hours.

Phototherapy regimen

Determination of MED, first exposure – 70% of MED and subsequent exposures. If no erythema – increase by 20% at each visit. Minimal erythema – same dose. Asymptomatic, well-defined erythema – postpone exposure till next visit; then same dose; thereafter 10% increment at each visit. Painful erythema – omit further exposures till recovery, reduce exposure dose by half, then 10% increment at each visit. It was given thrice weekly.⁵

Outcome measures

PASI 75 (it means 75% reduction in original PASI) Cumulative dose. Assessment of side effects of each modality/group

Statistical analysis

Data was analysed using SPSS 19.0 version. Quantitative data was expressed as mean and standard deviation. Qualitative data was expressed as percentages. Unpaired t test was used to compare the difference in the mean of two groups. One way ANOVA was used for multiple group comparisons.

RESULTS

In Group A patients belonged to age group between 18-53 yrs with mean age 33.68 years. In Group B belonged to age group between 20-52 yrs with mean age 33.7

years. In both the two groups males constituted majority of patients. In Group A duration of illness was 1-20 yrs and in Group B was 1-10 yrs.

Table 1: Baseline information of study subjects.

	Group A Methotrexate (n=50) (%)	Group B NBUVB (n=50) (%)
Mean age in years	33.68	33.7
Male	31 (62)	32 (64)
Female	19 (38)	18 (36)

Table 2: Comparison of PASI at different time intervals using methotrexate.

	Mean	SD	P value	Inference
PASI	Baseline	36.2	6.6	0.0001 Highly significant
	At 4 weeks	27.1	5.4	
	At 8 weeks	14.3	4.9	

Baseline PASI was observed to be 36.2±6.6, at 4 weeks 27.1±5.4 and at 8 weeks 14.3±4.9. The difference in mean PASI was found to be highly significant (p<0.001).

Table 3 Comparison of PASI at different time intervals using NBUVB.

	Mean	SD	P	Inference
PASI	Baseline	33.9	4.7	0.0001 Highly significant
	At 4 weeks	30	4.7	
	At 8 weeks	16.65	3.2	

Baseline PASI was observed to be 33.9±4.7, at 4 weeks 30.0±4.7 and at 8 weeks 16.65±3.2. The difference in mean PASI was found to be highly significant (p<0.001).

Table 4 Comparison of psoriasis area and severity index score (PASI) at different time intervals between methotrexate and NBUVB.

Groups	Baseline	At 4 weeks	At 8 weeks
Group A (MTX)	36.2±6.6	27.1±5.4	14.37±4.9
Group B (NBUVB)	33.9±4.7	30.0±4.7	16.65±3.2
t test	1.4	4.2	5.1
P value	0.052	0.006	0.008
Inference	Not significant	Significant	Significant

In our study, baseline PASI score in Group A was 36.2±6.6 and in Group B was 33.9±4.7. The difference in PASI score was found to be not significant (p>0.05). PASI score at 4 weeks in Group A was 27.1±5.4 and in Group B was 30.0±4.7. The difference in PASI score was found to be significant. (p<0.05) PASI score at 8 weeks in Group A was 14.37±4.9 and in Group B was

16.65±3.2. The difference in PASI score was found to be significant. (p<0.05) It means PASI score was less in group using methotrexate at 4 and 8 weeks interval.

Table 5: Comparison of time for 75% reduction in PASI score between methotrexate and NBUVB.

Groups	Mean	SD	t	P value	Inference
Group A (MTX)	9.62	1.3	3.7	0.04 (<0.05)	Significant
Group B (NBUVB)	11.3	0.7			

In our study mean time taken for PASI 75 i.e. 75% reduction in the baseline PASI score in Group A was 9.62±1.3 weeks whereas in Group B it was 11.3±0.7 weeks. When we compared the PASI score between two groups, it was found to be significant (p<0.05). It means faster achievement of PASI 75 was seen in Group A as compared to patients who were included in Group B.

Table 6: Comparison of side effects between methotrexate and NBUVB.

Side effects	Group A (n=18)	Group B (n=30)
Erythema	-	16 (32)
Headache	3 (6)	-
Malaise	5 (10)	-
Nausea	10 (20)	-
Pruritis	-	14 (28)

Side effects were higher in group B (60%) compared to group A (36%). Majority side effects in methotrexate group were non-cutaneous including nausea, malaise and headache. In Group B using NBUVB, majority side effects were cutaneous i.e. erythema and pruritis.

DISCUSSION

Age wise distribution

In Group A (oral methotrexate) patients belonged to age group between 18-53 years. Mean age of the patients in group was 33.6 years, in group B (NBUVB) patients age varied 20-52 years with mean of 33.7 years. This correlates with the age incidence of earlier studies of Faber et al which showed mean age of onset 28 years, Sharma et al and Lal showing highest incidence to be in the second decade or in the reproductive age group.^{6,7,29}

In the present study the youngest patient was 18 years old and eldest was 53 years old.

Sex distribution

In the current study, in all the two groups males constitute the majority of number of patients, this

concurrency with most of the Indian studies in which higher prevalence in males has been noted.⁶⁻⁸

The higher incidence in males could be explained by the fact that though there is no strict variation in the occurrence of the disease in both sexes, the male patients come forward for examination and treatment whereas, there is a hesitancy on the part of females to come forward for treatment, for fear of social stigma and rejection.

PASI measurement

The baseline PASI score in all the two groups was almost equal but it was slightly higher in group A and it showed significant reduction ($p < 0.05$, Significant) at the end of 4 and weeks in group A (oral methotrexate) as compared to group B. In group A Mean \pm SD base line PASI score was 36.2 ± 6.6 , in group B Mean \pm SD base line PASI score was 33.9 ± 4.7 , so there was no significant difference in all the two groups at baseline level but severity of involvement was more in all the two groups.

In group A Mean \pm SD PASI score at the end 4 weeks was 27.1 ± 5.4 , in group B Mean \pm SD PASI score at the end 4 weeks was 30.0 ± 4.7 , so it showed significant reduction ($P < 0.05$, significant) in group A. This is in consistent to response to monotherapy seen in 1-4 weeks with at least 50% reduction in PASI in 70-80% of treated patients.⁹

In group A Mean \pm SD PASI Score at the end 8 weeks was 14.4 ± 4.9 , In group B Mean \pm SD PASI Score at the end 8 weeks was 16.6 ± 3.2 , so there was significant reduction ($p < 0.005$, significant) to baseline PASI score in group A compared to group B. So there was a faster reduction in PASI Score at the end of 4 and 8 weeks in group A compared to group B.

Time taken for PASI 75 in weeks

In this study time taken for PASI 75 (75% reduction in the baseline PASI score) in group A was 7-12 weeks with mean of 9.6 weeks, this is in concurrence with the study of Dhir et al.¹⁰

In group B it was 9-12 weeks with mean of 11.3 weeks, which correlates with the observation which is made by Dayal et al.¹¹

Side effects in two groups

In this study the side effects in group A were nausea in 20%, followed by malaise 10% and headache in 6%, overall 36% patients encountered with side effects. Dhir et al found nausea, vomiting, mild to moderate headache in 7% of patients on the day of administration of the drug, 3 patients each experienced pain abdomen, diffuse alopecia, loss of appetite and giddiness.¹⁰ Radmanesh et al comparing weekly MTX (15 mg/week) with daily MTX (2.5 mg/day for 6 days/week) found the weekly

regimen to be significantly more effective, with fewer side effects.¹²

In group B the most common side effect was erythema which was seen in 32% of patients followed by pruritus in 28% of patients, overall side effects were seen in 60% cases in group B. The higher incidence of erythema and pruritus could be attributed to higher doses were required and comparatively prolonged phototherapy exposures in these groups of the patients.

In the study side effects were controlled with symptomatic treatment and stoppage of treatment was not required. In the present study as the dosage of methotrexate was comparatively small, the incidence of side effects was minimal and did not require stoppage of therapy in any of the patients.

So the side effects were encountered higher in patients included in group B as compared to group A, but they were significantly less in patients who were included in group A. This is consistent with observations made by Paul et al.¹³

CONCLUSION

Improvement in the PASI score was best with methotrexate than NBUVB, which emphasizing the superiority of the methotrexate over NBUVB. Time taken to achieve PASI 75 was shortest with methotrexate compared to NBUVB therapy. This will improve compliance of the patients. Average number of sittings were required with methotrexate therapy was significantly less as compared to NBUVB therapy. The side effects observed in a methotrexate were minimal compared to NBUVB and none of the patients discontinued the treatment.

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Ethical approval: The study was approved by the institutional ethics committee

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