

A PROSPECTIVE STUDY OF CLINICAL EFFICACY OF METHOTREXATE, CYCLOSPORINE AND AZATHIOPRINE IN PSORIASIS

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ABSTRACT

INTRODUCTION

Psoriasis is one of the most common dermatological diseases, affecting up to 2% of the world's population, In India incidence used to vary in different part of it but overall is 1.02%. This is a prospective study conducted in the department of dermatology Konaseema institute of medical science Amalapuram. out of all three drugs used for treatment of psoriasis it was found that after 12 weeks of treatment methotrexate was more effective than cyclosporine and Azathioprine in percentage reduction of PASI score.

KEYWORDS

Clinical efficacy, Methotrexate, Azathioprine, Cyclosporine.

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INTRODUCTION: Psoriasis is one of the most common dermatological diseases, affecting up to 2% of the world's population. In India incidence used to vary in different part of it, but overall is 1.02%.^(1,2) It is an immune-mediated disease clinically characterized by erythematous, sharply demarcated papules and rounded plaques covered by silvery micaceous scale.⁽³⁾ Psoriasis is not a disease of single type or a single inflammatory cytokine, it can be best conceptualized as linked to many interactive responses between infiltrating leucocytes resident skin cells and many array proinflammatory cytokines, chemokine and chemical mediators produced in the skin under the regulation of the cellular immune system.⁽⁴⁾ Both innate and acquired immune changes are thought to be responsible for the development of psoriatic plaque, different type of helper T subsets, dendritic cells, plasmacytoid dendritic cells as well as Langerhans cells have been found to play a role in psoriasis. As it is clear that this disease is a T cell-mediated disorder so various immuno-suppressive agent are used for the treatment like, methotrexate, cyclosporine and azathioprine, much attention is currently directed towards the use of biological agent, but experience with the use of these drugs are limited.⁽⁵⁾ Present study was conducted with an aim to major the clinical efficacy and of three drugs cyclosporine, methotrexate and azathioprine.

MATERIAL AND METHOD: This is a prospective study conducted in the Department of Dermatology, Konaseema Institute of Medical Science, Amalapuram.

Before start of the study prior permission for institutional ethics committee was obtained, Informed consent was obtained in written form patients in two languages, patient were enrolled in the study were divided in to three group, each group consist of twenty patient, between age group 18 to 70 yrs and both sex. The study was conducted between January 2012 to December 2015. Patients were selected on the basis of exclusion criteria.

1. Pregnancy. Lactation.
2. Hepatic and renal disorder.
3. Patient having allergy to drugs.
4. Hematological disorder.
5. Diabetes and hypertension.
6. Alcoholic.

Before start of the study detailed history of patient were taken like drug history, family history, and lifestyle. Renal function test, liver function test complete haemogram, fasting blood sugar and blood pressure measurement were done. Patients were divided into three groups after randomization Group A, Group B and Group C. Group A has been given 10mg/week methotrexate every week on fixed day, Group B have been received Azathioprine 2mg/week on fixed day of week and Group C has received cyclosporine 2mg/kg/day in two divided doses. Severity of the disease was assessed by measurement scores according to PASI score. PASI score is a tool used to measure the severity and extent of psoriasis (psoriasis Area and severity index).⁽⁶⁾ It was assessed at every week for first week after that every two weeks till 12 weeks. Interpretation of the result was done by percentage of reduction of PASI score; as follow >70% very good response, 60 to 69% good response. 50 to 59% fair response 40 to 49% poor response and less than 40% very poor response.

RESULT: In group A there were 20 patients, out of that 12 were male and 8 were female; 30% of the patients were between 18 to 30yrs, 40% of the patients were between 30

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to 50 yrs and rest were above 50 yrs of age; 20% of the patients have PASI score below 10; 30% of the patients have score between 10 to 20. Between 21 to 30 and 31 to 40 there were 20% patient each. Only 10% of the patient was above 40. After eight week of treatment with methotrexate in Group A; 30% of the patient have above 80% reduction in PASI score, 40% of the patient have 61 to 80% reduction in PASI score, 30% of the patient have 41 to 60% reduction in PASI score. After twelve weeks of treatment 60% of patients have more than 80% reduction in PASI score; 35% of the patients have reduction between 61 to 80%.

Variables	Characteristics	Group-A	Group-B	Group-C
Age	18-30	6(30%)	8(40%)	7(35%)
	30-50	8(40%)	8(40%)	8(40%)
	50 to 70	6(30%)	4(20%)	5(25%)
Sex	Male	12(60%)	9(45%)	11(55%)
	Female	8(40%)	11(55%)	9(45%)

Table 1: Age and Sex distribution of patient

PASI Score	Group-A	Group-B	Group-C
1-10	4(20%)	3 (15%)	3 (15%)
10-20	6(30%)	7 (35%)	8 (40%)
21-30	4(20%)	6(30%)	4 (20%)
31-40	4(20%)	3(15%)	4 (20%)
>40	2(10%)	1 (5%)	1 (5%)

Table 2: PASI score at the start of study

In Group B; there was 45% of male and 65% of female. 40% of the patients were between 18 to 30 yrs of age, 40% of the patients were between 30 to 50% of age rest were between 50 to 70 years of age. 15% of the patients have PASI score below 10. 35% of patient have PASI score between 11 to 20, 21 to 30, 31 to 40 and above 40 were 35%, 30%, 15% and 5% respectively.

After 8 weeks of treatment with Azathioprine 20% of the patient more than 80% reduction in PASI score; 30% of the patients have 61 to 80% reduction in PASI score; 45% of the patients have 41 to 60% reduction in PASI score.

After 12 weeks of treatment 35% of the patients have more than 80% reduction in PASI score, 60% of the patients have reduction in PASI score between 61 to 80%.

Response	Group A	Group B	Group C
80 to 100%	6(30%)	4(20%)	5(25%)
61 to 80%	8(40%)	6(30%)	7(35%)
41 to 60%	6(30%)	9(45%)	8(40%)
> 40%	0	1(5%)	0

Table 3: Response after 8 weeks treatment

In Group C out of 20 patients 11 were male and 9 were female, 35% of the patient were below 30 yrs, 40% were between 30 to 50 yrs, 25% were between 50 to 70 yrs, 15% of the patient have PASI score below 10, 40% of the patient have PASI score 10 to 20. Between 20 to 30, 30 to 40 and above 40 were 20%, 20% and 5% respectively. After 8 weeks of treatment with cyclosporine, 25% of the patient have more than 80% reduction, 35% of the patients have

reduction between 61 to 80% and 40% of the patients have reduction between 41 to 60. After of 12 weeks of treatment 50% of the patient have reduction above 80%, 40% of the patients have reduction between 61 to 80%.

Response	Group A	Group B	Group C
80 to 100%	12(60%)	7(35%)	10(50%)
61 to 80%	7(35%)	12(60%)	8(40%)
41 to 60%	1(5%)	1(5%)	1(5%)
>40%	0	0	1(5%)

Table 4: Response after 12 weeks of treatment

DISCUSSION: Out of all three drugs used for treatment of psoriasis it was found that after 12 weeks of treatment methotrexate was more effective than cyclosporine and Azathioprine in percentage reduction of PASI score; which is as per the study of Sandhuk et al.⁽⁷⁾ Azathioprine is not as effective as cyclosporine and methotrexate which similar to other studies.^(8,9,10,11,12) cyclosporine is less effective than methotrexate in percentage reduction of PASI score.^(13,14)

CONCLUSION: All three drugs are effective for treatment of psoriasis but they are different in there efficacy and safety. Now a day biological agents are used for treatment of psoriasis but limitation with the use of this drug is less experience and cost of treatment. As we know that psoriasis is a chronic disease long term treatment required so cost of treatment matters.

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