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# Measurement of Clinical Outcomes in Psoriasis Patients Treated With Methotrexate and Mycophenolate Mofetil

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***Abstract***
***Objectives:*** *This study aims at measuring the clinical outcomes in Psoriasis patients treated with the drugs Methotrexate and Mycophenolate Mofetil.*
***Methods:*** *This Prospective observational study was carried out in dermatology department RIMS for 6 months. Two way ANOVA was used with the help of graph pad prism to determine the response of two drugs, PASI calculator was used for measuring PASI values, P-value was used for comparisons of clinical outcomes between methotrexate and mycophenolate mofetil.*
***Results:*** *In the present study, a total of 54 subjects met the inclusion criteria among 73 patients. Of these, 50% (n=27) patients were in methotrexate group and 50%(n=27) patients were Mycophenolate mofetil group.*
***Conclusion:*** *Based on our study results we conclude that mycophenolate group showed more improvement than methotrexate in terms of clinical outcomes.*
***Keywords:*** *Psoriasis; Methotrexate; Mycophenolate mofetil.*

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## I. Introduction

Psoriasis is a chronic inflammatory, hyper proliferative skin disease. It is characterized by well defined, erythematous scaly plaques, particularly affecting extensor surfaces and scalp, usually follows relapsing and remitting courses. The pathogenesis is multifactorial, genetic and environmental factors are important.[1] The pathogenesis of this disease is not completely understood. Multiple theories exist regarding triggers of the disease process including a infectious episode, traumatic insult and stressful life event. In many patients, no obvious trigger exits at all. However, once triggered, there appears to be substantial leukocyte recruitment to the dermis and epidermis resulting in the characteristic psoriatic plaques. Specifically, the epidermis is infiltrated by a large number of activated T cells, which appear to be capable of including keratinocyte proliferation. Treatment can be divided into three types: topical treatments, light therapy and systemic medications.[2]

Methotrexate belongs to the group of drugs known as immunosuppressant's. According to the National Psoriasis Foundation, methotrexate was first used to treat cancer in 1950's but they also found it could be used to treat psoriasis. It works to slow down the hyper proliferation of skin cells characteristic of psoriasis. Despite all the fancy new drugs out there, dermatologists still use methotrexate to control severe cases of psoriasis.[3] Anti psoriatic mechanisms of Methotrexate action include inhibition of keratinocyte differentiation and immuno modulation by destruction of lymphoid cells.[4] It is administered as weekly single dose, it can be increased gradually until an optimal response is achieved. Total dose should not ordinarily exceed 30mg per week. Doses should be reduced to the lowest possible amount of drug needed to achieve adequate control of psoriasis with concomitant topical therapy. A test dose of 2.5-5mg is recommended. Treatment can be continued for as long as necessary provided there are no meaningful signs of liver or bone marrow toxicity with adequate monitoring. Folic acid supplementation 1-5mg daily by mouth, except for the day of Methotrexate dosing, reduces the frequency of side effects.[5]

Mycophenolate mofetil is a pro-drug that is rapidly hydrolyzed to the active metabolite of mycophenolic acid (MPA). It is a suppressor of T and B cell proliferation and adhesion and inhibits inosine

monophosphate dehydrogenase (IMPDH) that eventually blocks the progression to DNA synthesis and proliferation. It does not inhibit the production of interleukins as does cyclosporine and tracolimus.[6] Mycophenolate mofetil therefore by inhibiting IMPDH, selectively inhibits lymphocyte proliferation and functions, including antibody formation, cellular adhesion and migration.[7] It is administered 1.0-1.5mg orally two times/day.[8]

Measuring clinical outcomes plays a pivotal role in influencing the way critical care is practiced and used to drive changes in interventions or treatments.[9] There are four major clinical outcome measures are used in our study, (1) Psoriasis area and severity index (PASI), (2) Dermatological life quality index (DLQI), (3) Overall lesion severity scale (OLS), (4) Physician's global assessment of change (PGA). A PASI score is a tool used to measure the severity and extent of psoriasis. It takes a few minutes and experience to calculate it accurately. A representative area of psoriasis is selected for each body region. The intensity of redness, thickness and scaling of the psoriasis is assessed as none(0), mild (1), moderate(2), severe(3), very severe(4).[10] The Dermatological life quality index (DLQI), the first dermatology-specific health-related quality of life (HRQoL) instrument, has helped enormously to introduce and assess HRQoL in dermatology.[11] It is designed for use in adults, i.e. patients aged 16 years and over. It is self explanatory and can be simply handed to the patient who is asked to fill it in without the need for detailed explanation. It is usually completed in one or two minutes. The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired. The DLQI can also be expressed as a percentage of the maximum possible score of 30. Scores (0-1) no effect, (2-5) small effect, (6-10) moderate effect, (11-20) very large effect, (21-30) extremely large effect on patient's life.[12] For general inflammatory skin conditions a change in DLQI score of at least 4 points is considered clinically important.[13] This means that a patient's DLQI score has to either increase or decrease by at least 4 points in order to suggest that there has actually been a meaningful change in that patient's quality of life since the previous measurement of his/her DLQI scores.[14] Overall lesion severity scale is a tool used to assess the severity of the lesion by plaque elevation, erythema, scaling an given scores from 0 to 5. The scores from 0-5 categorizes as clear, minimal, mild, moderate, severe and very severe respectively.[15] Physician's global assessment (PGA) can be used to show improvement by a comparison with baseline disease severity which is termed as a dynamic PGA or it can be an assessment made at one movement in time which is termed as a static PGA.[16] Because the latter requires the dubious assumption that physicians can remember the severity of psoriasis at baseline over the course of the trial, the static PGA has become the standard.[17]

## II. Materials And Methods

A prospective observational study was carried out in dermatology outpatient department of Rajiv Gandhi Institute of Medical Sciences (RIMS), a 750 bedded tertiary care teaching hospital, Kadapa. Our study was approved by the human institutional ethics committee(IEC), RIMS, Kadapa. It was planned to compare the clinical outcomes from baseline to three follow ups with time interval of one month between each follow up.

Approximately 54 patients were taken as sample size. this study included the subjects satisfying the following criteria: all the patients of either sex with psoriasis and aged 18 years and older, patients receiving either methotrexate or mycophenolate mofetil in the treatment of psoriasis and who had attended 3 follow ups. this study excluded pregnant, breast feeding, Alcoholics.

Data was collected from treatment charts, prescription and questionnaire forms from subjects included in the study. Data collection, measurement of PASI, DLQI, OLS and PGA was done using following documents.

Statistical analysis:

Two way ANOVA was used with the help of graph pad prism to determine the response of two drugs, PASI calculator was used for measuring PASI values, P-value was used for comparisons of clinical outcomes between methotrexate and mycophenolate mofetil.

## III. Results

In the present study, a total of 54 subjects met the inclusion criteria among 73 patients. Of these, 50% (n=27) patients were in methotrexate group and 50%(n=27) patients were Mycophenolate mofetil group.

**Table 1** shows the participants were divided into 2 groups by gender i.e., male and female, in methotrexate group 12(22.2%) were males and 15(27.7%) were females, in Mycophenolate mofetil group 18(33.3%) were males and 9(16.6%) were females. The majority of patients in methotrexate group were females 15(27.7%), and in mycophenolate mofetil group were males 18(33.3%).

| **Table:1** Gender wise distribution of patients (n=54) | | | | |
|---|---|---|---|---|
| | **Methotrexate (27)** | | **Mycophenolate mofetil (27)** | |
| Gender | **Male** | **Female** | **Male** | **Female** |
| No of Patients | 12 | 15 | 18 | 9 |
| Percentage | 22.2% | 27.7% | 33.3% | 16.6% |

**Table 2** shows improvement of Psoriasis area and severity index (PASI) scores from baseline to 3rd follow up in methotrexate group was 21.15% while in mycophenolate mofetil group was 22.57%. Psoriasis area and severity index (PASI) values of methotrexate and mycophenolate mofetil were found to be significant.

| **Table 2: Average PASI scores** | | | |
|---|---|---|---|
| | **Methotrexate** | **Mycophenolate Mofetil** | **P-Value** |
| Baseline | 18.68±7.44 | 19.50±5.77 | <0.0001 (Significant) |
| 1st Follow up | 17.61±6.81 | 17.80±4.69 | |
| 2nd Follow up | 16.75±6.52 | 17.17±4.82 | |
| 3rd Follow up | 14.73±5.68 | 15.10±4.02 | |

**Table 3** shows improvement of Dermatological life quality index (DLQI) scores from baseline to 3rd follow up in methotrexate group was 4.29% while in mycophenolate mofetil group was 17.39%. Dermatological life quality index (DLQI) values of methotrexate and mycophenolate mofetil were found to be significant.

| **Table 3:** Average DLQI scores | | | |
|---|---|---|---|
| | **Methotrexate** | **Mycophenolate Mofetil** | **P-Value** |
| Baseline | 10.48±3.45 | 12.59±3.64 | <0.0001 (Significant) |
| 1st Follow up | 10.48±2.63 | 12.11±3.44 | |
| 2nd Follow up | 10.44±2.81 | 11.81±3.37 | |
| 3rd Follow up | 10.03±2.15 | 10.40±2.67 | |

**Table 4** shows improvement of Overall lesion severity scale (OLS) scores from baseline to 3rd follow up in methotrexate group was 21.06% while in mycophenolate mofetil group was 25.29%. Overall lesion severity scale (OLS) values of methotrexate and mycophenolate mofetil were found to be significant.

| **Table 4:** Average OLS scores | | | |
|---|---|---|---|
| | **Methotrexate** | **Mycophenolate Mofetil** | **P-Value** |
| Baseline | 3.37±0.83 | 3.40±0.57 | 0.0003 (Significant) |
| 1st Follow up | 3.25±0.65 | 3.48±0.57 | |
| 2nd Follow up | 3±0.55 | 3.29±0.54 | |
| 3rd Follow up | 2.66±0.48 | 2.54±0.44 | |

**Table 5** shows improvement of Physician's global assessment of change (PGA) scores from baseline to 3rd follow up in methotrexate group was 28.82% while in mycophenolate mofetil group was 27.87%. Physician's global assessment of change (PGA) values of methotrexate and mycophenolate mofetil were found to be statistically not significant.

| **Table 5:** Average PGA scores | | | |
|---|---|---|---|
| | **Methotrexate** | **Mycophenolate Mofetil** | **P-Value** |
| Baseline | 3.33±0.62 | 3.48±0.57 | 0.2427 (Not Significant) |
| 1st Follow up | 3.22±0.57 | 3.44±0.57 | |
| 2nd Follow up | 2.88±0.50 | 3.18±0.55 | |
| 3rd Follow up | 2.37±0.49 | 2.51±0.50 | |

## IV. Discussion

In the present study total number of Psoriasis patients during baseline were 73. The patients who met the inclusion criteria after 3 follow ups were 54 patients. These patients were divided into two groups based on their treated drug i.e., methotrexate and mycophenolate mofetil group. Each group in the study contains 27 patients. The majority of patients in methotrexate group were females 15(27.7%), and in mycophenolate mofetil group were males 18(33.3%) also in a study conducted by David hagg, et.al, psoriasis occurred to be more common in males when compared to the disease in females.[40] In our present study, PASI decreased significantly to 21.15% in methotrexate group whereas 22.57% in mycophenolate group. But in a study of comparing methotrexate and mycophenolate mofetil, conducted by M. Akhyani et.al, PASI decreased to 53.3% among 15 patients who were treated with methotrexate, whereas the score decreased to 33.3% among the 17 patients who were treated with mycophenolate mofetil.[32] Dermatological life quality index (DLQI) in the present study significantly decreased to 4.29% in methotrexate group and 17.39% in mycophenolate group. Overall lesion

severity scale (OLS) scores from baseline to 3rd follow up in methotrexate group was 21.06% while in mycophenolate mofetil group was 25.29%. Overall lesion severity scale (OLS) values of methotrexate and mycophenolate mofetil were found to be significant. Physician's global assessment of change (PGA) scores from baseline to 3rd follow up in methotrexate group was 28.82% while in mycophenolate mofetil group was 27.87%. Physician's global assessment of change (PGA) values of methotrexate and mycophenolate mofetil were found to be statistically not significant.

From the reports of world health organization(WHO), out of 7 billion individuals who populate the earth, more than 125 millions of them are living with psoriatic disease, according to the International Federation of Psoriasis Associations (IFPA), of which national psoriasis foundation is a part. On the basis of current evidence derived from hospital-based studies, mostly from North India, the prevalence of psoriasis in adults varies from 0.44 to 2.8%, with much lower prevalence in children. The peak age at onset in adults is in the third and fourth decade of life, with a slight male preponderance. It is recommended that population-based large epidemiologic studies should be undertaken in different parts of the country for estimating the correct prevalence of psoriasis in general population. Chronic plaque-type psoriasis is the most common morphologic presentation of psoriasis, accounting for more than 90% of all cases.[18]

## V. Conclusion

Based on Psoriasis area and severity index (PASI), Dermatological life quality index (DLQI), Overall lesion severity scale (OLS) scores, mycophenolate mofetil is more efficacious then methotrexate, In physicians global assessment (PGA) scale methotrexate group showed slight better improvement when compared to mycophenolate group. Based on our study results we conclude that mycophenolate group showed more improvement than methotrexate in terms of clinical outcomes.

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