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Comparative Assessment of Efficacy and Safety of Cyclosporine versus Methotrexate in Psoriasis

Saniya Fatima[1], Kumar Raja Madasu[2], Amit Singhal[3]*, Sayed Shakita Fatima[4], Nitesh Prakash[5]

[1]PG 3rd year MD, Department of Pharmacology, Santosh Medical College and Hospital, Ghaziabad

[2]Associate Professor, Department of Pharmacology, Institute of Medical Sciences & SUM Hospital II, Bhubaneswar, Odisha, India

[3]Associate Professor, Department of Pharmacology, Santosh Medical College and Hospital, Santosh Deemed to be University, Ghaziabad, India

[4]Assistant Professor, Department of Pharmacology, Saraswathi Institute of Medical Sciences, Anwarpur, India

[5]Senior Resident, Department of Pharmacology, Santosh Medical College and Hospital, Ghaziabad, India

***Address for Correspondence:** Dr. Amit Singhal, Associate Professor, Department of Pharmacology, Santosh Medical College and Hospital, Santosh Deemed to be University, Ghaziabad-201009, India
E-mail: dramitkmmc@gmail.com

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ABSTRACT

Background: Psoriasis is an immune-mediated inflammatory skin disorder that requires systemic therapy for moderate to severe cases. Methotrexate and cyclosporine are two of the most extensively used conventional systemic drugs; each has distinct safety, efficacy, and commencement of action features.

Methods: This hospital-based comparative study was conducted in the Department of Pharmacology, in collaboration with the Dept of Dermatology, Santosh Medical College and Hospital, Ghaziabad, from Oct 2024 to Oct 2025. 84 patients who satisfied the requirements for inclusion were enrolled. The methotrexate group got 2.5 mg three times at 12-hour intervals, whereas the cyclosporine group received two split doses of 3 mg/kg/day for 12 weeks. The primary efficacy indicator was the percentage decrease in the Psoriasis Area and Severity Index score at 12 weeks compared to baseline. Some laboratory tests were conducted to assess safety using haematological, hepatic, and renal parameters, as well as the documentation of adverse drug reactions.

Results: Comorbidities and baseline parameters were similar between groups ($p>0.05$). The cyclosporine group had a considerably higher mean reduction in PASI (10.33±6.12) than the methotrexate group (4.76±3.36), suggesting that cyclosporine is more effective in the short term ($p<0.001$). The most frequent ADRs were mild and included headache, dizziness, nausea, and transient hypertension, with no serious adverse events reported.

Conclusion: The study has concluded that cyclosporine has shown to be more effective than methotrexate in reducing psoriasis severity, as shown by significantly greater improvements in PASI scores.

Key-words: Psoriasis, Cyclosporine, Immune-mediated inflammatory disease, Methotrexate, PASI score, Efficacy, Safety

INTRODUCTION

Psoriasis is a chronic, immune-mediated inflammatory disease of the skin characterised by hyperproliferation of keratinocytes, dysregulated innate and adaptive immune responses, and variable systemic involvement, including psoriatic arthritis and cardiometabolic comorbidity [1].

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The clinical and psychosocial problem of moderate-to-severe plaque psoriasis is considerable: patients frequently experience persistent symptoms, functional impairment, and reduced quality of life that frequently require systemic therapy, topical agents, and phototherapy.

Because psoriasis is heterogeneous in severity, distribution, comorbid states, and patient preference, a range of systemic treatments, from conventional oral agents to biologics and newer oral small molecules, remain central to disease management worldwide [2]. Methotrexate and cyclosporine are two established

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conventional systemic agents used for moderate-to-severe psoriasis. MTX, a folate antagonist with antiproliferative and immunomodulatory effects, has been used in dermatology for decades and remains a mainstay because of its efficacy, low acquisition cost, and relative ease of administration [3]. Its mechanisms include inhibition of dihydrofolate reductase, modulation of purine/pyrimidine synthesis, anti-inflammatory effects mediated via adenosine, and suppression of activated T cells. Long-term use has an evidence base for disease control but requires monitoring for hepatotoxicity, myelosuppression, and other adverse effects [4].

Cyclosporine is a calcineurin inhibitor that acts rapidly by blocking T-cell activation and subsequent cytokine production, resulting in substantial and often rapid symptomatic improvement in psoriasis. CsA is typically used for short-term induction or intermittent rescue therapy because of concerns about cumulative nephrotoxicity, hypertension, and increased risk of non-melanoma skin cancers with prolonged exposure. Contemporary guideline statements emphasise strict patient selection, dosing limits, and careful monitoring when CsA is prescribed [5].

Clinicians face the practical decision of choosing between MTX and CsA for individual patients. The optimal is influenced by several factors, including the need for rapid disease control, long-term treatment goals, co-morbidities, potential for pregnancy, drug interactions, monitoring burden, and cost/availability. Comparative data from randomised trials and head-to-head studies are therefore critical to inform evidence-based selection and counselling for patients requiring systemic therapy [6].

Available head-to-head randomised trials and comparative studies generally show that both MTX and CsA provide clinically meaningful reductions in PASI and improvements in patient-reported outcomes. Still, they differ in onset of action, adverse-event profiles, and suitability for long-term maintenance. Some trials report a more rapid short-term PASI response with CsA, while others have found approximately equivalent efficacy over longer follow-up; equally, MTX is often chosen for longer-term disease control with established protocols for monitoring hepatotoxicity and cumulative dose considerations [7]. Safety evidence indicates that CsA is limited by renal and cardiovascular risks for prolonged use, and MTX by potential hepatotoxicity and haematologic adverse events, making individualised risk–benefit assessment essential [8].

Moreover, combination and sequential methods have been explored to exploit the rapid efficacy of CsA and the longer-term tolerability of MTX while mitigating toxicity. National and international guidelines recommend an individualised strategy grounded in disease severity, comorbidities, patient preference, and careful laboratory surveillance. Even though the emergence of biologic medicines, MTX and CsA are still widely utilised worldwide due to cost and accessibility issues, particularly in resource-limited settings, underscoring the continued importance of reliable comparative data on safety and efficacy [9].

Given these clinical realities, a targeted comparative assessment that measures differences between cyclosporine and methotrexate in treatment initiation, degree of skin clearance, patient-reported outcomes, and side effects would provide doctors and patients with proper guidance [10]. With close attention to short-term response, intermediate-term disease management, and the pattern and severity of adverse events under routine monitoring protocols, this study compares the safety and effectiveness results of CsA vs MTX in patients with moderate-to-severe plaque psoriasis.

MATERIALS AND METHODS

Research Design- The hospital-based comparison study was designed to evaluate and improve the safety and effectiveness of methotrexate and cyclosporine in patients with moderate to severe plaque psoriasis. Over the course of a year (November 2024 to November 2025), the study was conducted at the Department of Pharmacology at Santosh Medical College and Hospital in Ghaziabad, in collaboration with the Department of Dermatology. Patients who visited the Dermatology Outpatient Department and had a clinical diagnosis of recurrent or chronic plaque psoriasis were evaluated for eligibility. Participants were recruited based on predetermined inclusion and exclusion criteria. Santosh Medical College and Hospital's Institutional Ethics Committee granted ethical permission. All participants in the study provided informed consent after being fully informed about the goals and methods. No identifying information was disclosed or published, and patient confidentiality was fully maintained.

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Inclusion Criteria

- ✓ Adults aged 18–45 years.
- ✓ Newly registered patients with chronic or recurrent plaque psoriasis involving >10% body surface area.
- ✓ Patients who provided written and verbal informed consent, along with family consent.

Exclusion Criteria

- ✓ Pregnant or lactating women.
- ✓ Patients diagnosed with erythrodermic, pustular, guttate, or inverse psoriasis.
- ✓ Patients with other dermatological conditions that could interfere with psoriasis evaluation.
- ✓ Patients with malignancies, connective tissue disorders, psychiatric illness, or body weight <45 kg.
- ✓ Presence of bacterial or viral infections.
- ✓ Patients with major comorbidities such as cardiac, renal, hepatic, or respiratory disorders, hypertension, cytopenia, or alcohol/drug abuse.
- ✓ Prior use of systemic or topical psoriasis therapy, including PUVA/NBUVB, biologic agents, live vaccines, or monoclonal antibodies.
- ✓ Patients allergic to either Methotrexate or Cyclosporine.

Data Collection- Age, sex, weight, BMI, length of illness, plaque location and size, and other clinical and demographic information were noted at baseline. The Psoriasis Area and Severity Index was used to measure the degree of psoriasis.

To approve patient eligibility, extensive laboratory tests were carried out at baseline, including:

- Complete Blood Count
- Liver Function Tests
- Kidney Function Tests
- Hepatitis B and C serology
- HIV test
- Urinalysis

Treatment Protocol- Two groups of eligible patients (n=42 per group) were created:

Methotrexate Group: Received three 2.5 mg doses of methotrexate spaced 12 hours apart each week, for a weekly total of 7.5 mg. Folic acid supplementation was given to reduce side effects.

Cyclosporine Group: Received Cyclosporine 3 mg/kg/day, divided into two doses 12 hours apart.

Dosage adjustments were made depending on clinical response and laboratory data at each follow-up visit during the 12-week treatment period. Four-week intervals were used to monitor the patients (Weeks 0, 4, 8, and 12). At every visit, PASI scores were reassessed, and CBC, LFT, and KFT were reevaluated to monitor safety and treatment response. Following a 12-week course of treatment, individuals in both treatment groups stopped taking their medications for two months while the PASI evaluation was used to track any recurrence or relapse.

Outcome Measures- The Psoriasis Area and Severity Index score at 12 weeks relative to baseline was the study's main outcome and the primary metric for assessing the treatment's effectiveness. Several significant clinical and safety factors were among the secondary results. These included laboratory abnormalities reflecting hepatic, renal, and haematological functions to evaluate systemic safety, as well as the frequency and type of adverse medication responses observed throughout the treatment period. To assess the durability of remission following therapy withdrawal, the recurrence or relapse rate of psoriasis was also noted throughout the two-month post-treatment follow-up period. To compare the overall treatment acceptability of cyclosporine and methotrexate, another critical secondary measure was patient preference and tolerability, established based on subjective input and clinical assessment. In compliance with the U.S. Food and Drug Administration's standards for psoriasis clinical studies, a PASI 75 response served as the baseline for clinical effectiveness.

Statistical Analysis- Data were analysed using SPSS software version 27. Baseline clinical and demographic variables were summarised using descriptive statistics. Categorical variables were expressed as frequencies and percentages, while quantitative variables were presented as mean ± standard deviation. Student's *t*-test or Mann–Whitney U test was used to compare continuous variables between the two treatment groups, depending on data distribution. The Chi-square test was applied for comparison of categorical variables, including treatment response and adverse effects. A p-value<0.05 was considered statistically significant.

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Ethical Approval- The Institutional Ethical Committee granted ethical approval, and the study adhered to the Declaration of Helsinki. All participants provided written and verbal informed consent after being fully informed about the goals, methods, possible risks, and advantages of the study.

RESULTS

There were no statistically significant differences in comorbidities between the cyclosporine and methotrexate groups in any of the evaluated situations ($p>0.05$). Methotrexate-treated patients had a slightly larger proportion of patients with diabetes mellitus (6 cases) than the cyclosporine group (3 cases), although this difference was not statistically significant ($\chi^2=1.12$, $p=0.29$). In a similar vein, the two groups' rates of dyslipidaemia and hypertension were identical, with each group exhibiting a small number of instances that were not statistically significant ($p=0.55$). There was no treatment-related bias or differential hepatic risk, since both therapy groups had an equal number of patients with liver illness (7 cases each). Similarly, the incidence of kidney disease was somewhat higher in the cyclosporine group (4 cases) than in the methotrexate group (2 cases), but this difference was not significant ($\chi^2=0.71$, $p=0.39$) (Table 1).

Table 1: Comorbidities in each group and their analysis of the patients

Comorbidities	Cyclosporine	Methotrexate	χ^2	p-value
Diabetes	3	6	1.12	0.29
Hypertension	2	1	0.34	0.55
Dyslipidemia	1	2	0.34	0.55
Liver Disease	7	7	0	1
Kidney Disease	4	2	0.71	0.39

There were no statistically significant differences in most haematological, hepatic, and renal parameters between the methotrexate and cyclosporine groups, suggesting that both medications maintained a similar systemic safety profile throughout the course of therapy. There was no indication of substantial haematological toxicity ($p>0.05$), and haemoglobin, total and differential white blood cell counts, red blood cell counts, and platelet counts were all within normal ranges in both groups. Similarly, there were no significant differences between the two therapies in liver function indicators such as ALT, AST, ALP, and total bilirubin, indicating that both methotrexate and cyclosporine were well tolerated hepatically under carefully controlled dosing. There were no visible intergroup changes in renal function tests, such as blood urea nitrogen and serum uric acid levels, suggesting that renal integrity was maintained in both treatment groups. Moreover, screening for viral markers revealed similar distributions between the groups, confirming the absence of drug-related hepatotoxicity or viral reactivation during treatment (Table 2).

Table 2: Comparison of Haematological, Hepatic, and Renal Parameters between Methotrexate and Cyclosporine Groups

Parameter	Group	Mean	SD	F	t	p-value
Haemoglobin (Hb)	Methotrexate	14.69	1.75	1.43	-0.50	0.61
	Cyclosporine	14.89	1.92			
WBC Count ($\times10^9$/L)	Methotrexate	6.98	1.70	0	0.37	0.70
	Cyclosporine	6.84	1.72			
Platelet Count ($\times10^3$/µL)	Methotrexate	305566	91805.8	0.60	0.72	0.47
	Cyclosporine	291801	83058.4			
RBC Count ($\times10^6$/µL)	Methotrexate	4.98	0.64	5.28	-0.40	0.68
	Cyclosporine	5.03	0.49			
ALT (U/L)	Methotrexate	53.52	3.02	0.23	0.18	0.85

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	Cyclosporine	53.40	2.91			
AST (U/L)	Methotrexate	40.09	3.17	3.36	-0.55	0.58
	Cyclosporine	40.45	2.75			
ALP (U/L)	Methotrexate	79.07	24.11	0.08	0.38	0.69
	Cyclosporine	77	24.65			
Total Bilirubin (mg/dL)	Methotrexate	1.20	0.24	0.52	-1.49	0.13
	Cyclosporine	1.27	0.22			
Hepatitis B (Positive cases)	Methotrexate	0.47	0.50	0.09	-0.21	0.83
	Cyclosporine	0.50	0.50			
Hepatitis C (Positive cases)	Methotrexate	0.50	0.50	2.46	1.09	0.27
	Cyclosporine	0.38	0.49			
Blood Urea Nitrogen (BUN, mg/dL)	Methotrexate	19.05	3.85	1.01	0.98	0.32
	Cyclosporine	18.27	3.49			
Uric Acid (mg/dL)	Methotrexate	7.41	0.92	0.24	-0.32	0.744
	Cyclosporine	7.48	0.94			

SD= Standard Deviation

The comparative evaluation of treatment efficacy between the methotrexate and cyclosporine groups exposed a significant difference in the reduction of disease severity as measured by the Psoriasis Area and Severity Index. The mean change in PASI score from baseline was decidedly greater in the cyclosporine group (10.33±6.12) compared to the methotrexate group (4.76±3.36), and this difference was highly significant ($p<0.001$). This indicates that cyclosporine achieved a faster and greater improvement in psoriasis symptoms within the treatment duration. Even though the baseline PASI scores were comparable between the two groups (methotrexate: 20.02±5.66; cyclosporine: 18.93±7.43; $p=0.45$), suggesting similar initial disease severity, the follow-up PASI scores established a clear distinction. After 12 weeks of therapy, patients in the cyclosporine group showed a lower mean PASI score (8.59±4.17) compared to those receiving methotrexate (15.26±4.70), with $p<0.001$, confirming the superior short-term efficacy of cyclosporine in achieving disease control (Table 3).

Table 3: Efficacy of the drugs as found from the PASI score and their analysis

Efficiency Parameter	Group	Mean	Std. Deviation	F	t	p-value
Change PASI	Methotrexate	4.76	3.35	14.88	-5.16	<0.001
	Cyclosporine	10.33	6.12			
Score	Methotrexate	20.02	5.66	8.79	0.75	0.45
	Cyclosporine	18.92	7.43			
Follow-up Score	Methotrexate	15.26	4.70	1.47	6.87	<0.001
	Cyclosporine	8.59	4.17			

The comparative analysis of adverse drug reactions between the cyclosporine and methotrexate groups established no statistically significant difference in the overall incidence or pattern of adverse effects ($p>0.05$). The most reported ADRs in both groups were recurrence of lesions, headache, dizziness, and nausea, all of which were mild to moderate in severity and manageable with supportive care.

Recurrence of psoriasis was slightly higher in the methotrexate group (16.7%) compared to the cyclosporine group (11.9%), although the difference was not significant ($\chi^2=0.38$, $p=0.53$). Similarly, headache (14.3% vs. 7.1%), dizziness (16.7% vs. 7.1%), and nausea (14.3% vs. 9.5%) were somewhat more frequent in the methotrexate group, but none reached statistical significance. Other ADRs such as fever, vomiting, and

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flare-up reactions occurred infrequently and were equally distributed between the two groups (p=1.0).

Stimulatingly, hypertension was observed slightly more often among patients receiving cyclosporine (9.5%) compared to methotrexate (2.4%), consistent with cyclosporine's known effect on vascular tone and renal haemodynamics, but again without statistical significance (p=0.16) (Table 4).

Table 4: Adverse Drug Reactions of the patients in each group and their analysis

ADR	Cyclosporine (n=42)	Methotrexate (n=42)	Chi-Square	p-value
Recurrence	5 (11.9%)	7 (16.7%)	0.38	0.53
Headache	3 (7.1%)	6 (14.3%)	1.12	0.29
Dizziness	3 (7.1%)	7 (16.7%)	1.81	0.17
Fever	1 (2.4%)	1 (2.4%)	<0.001	1
Vomiting	2 (4.8%)	3 (7.1%)	0.21	0.64
Nausea	4 (9.5%)	6 (14.3%)	0.45	0.5
Hypertension	4 (9.5%)	1 (2.4%)	1.9	0.16
Flare-Up Reaction	1 (2.4%)	1 (2.4%)	<0.001	1

DISCUSSION

This study's findings should be interpreted within the situation of considerable but heterogeneous evidence base comparing methotrexate and cyclosporine for moderate-to-severe plaque psoriasis. Randomised trials and real-world series show that both agents produce clinically meaningful skin clearance, but they differ in onset of action, suitability for maintenance therapy, and dominant safety apprehensions. Several head-to-head trials reported broadly similar overall efficacy at intermediate timepoints, while some found CsA produces faster short-term improvement and others favoured MTX or showed no significant difference, suggesting that the optimal agent is frequently subject to on the clinical scenario rather than large absolute efficacy differences [10].

On efficacy, the NEJM randomised trial by Heydendael *et al*. found no significant difference in overall effectiveness between MTX and CsA over 16 weeks, suggesting comparable short-term disease control when using usual dosing schemes [11]. Other trials, such as Heydendael *et al.* reported a statistically greater short-term response with CsA versus MTX, consistent with CsA's well-described rapid onset due to calcineurin blockade of T-cell activation [12]. Smaller single-centre studies have at times reported faster or deeper early clearance with MTX, emphasising that dosing schedules, patient selection, and outcome timing materially affect comparative results.

Clinically, this means CsA may be preferred when rapid control is required, whereas MTX is frequently chosen when longer-term maintenance and cumulative safety considerations dominate [13].

Safety profiles represent the principal axis of differentiation. CsA's principal risks are nephrotoxicity and hypertension, which correlate with dose and duration and typically limit continuous use; methods consequently recommend limiting duration or using intermittent/sequential methods and careful blood-pressure and renal monitoring. MTX's dominant safety apprehensions are hepatotoxicity and bone-marrow suppression, influenced by cumulative dose, alcohol use, and metabolic comorbidities; routine laboratory surveillance and folate supplementation mitigate but do not eliminate these risks [14]. Meta-analytic and pooled safety data confirm that both drugs have treatment-limiting adverse events in a minority of patients over months of follow-up, but the nature of those events guides agent selection based on individual comorbidities [15].

Combination and sequential strategies have attracted interest as pragmatic approaches to combine the rapid induction of CsA with the maintenance advantages of MTX. Randomised and non-randomised studies have shown that combination regimens can achieve earlier and sometimes greater PASI responses without a clear increase in short-term laboratory toxicity when carefully monitored, though longer-term safety data are limited

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and pharmacologic interactions must be respected. Where available, such strategies may be mainly useful in resource-limited settings where biologic therapies are inaccessible but rapid disease control plus reasonable maintenance is desired [16].

When comparing trials, heterogeneity must be recognised: differences in MTX dosing, CsA dosing schedules, baseline disease severity, result timing, and monitoring protocols make pooled interpretation stimulating. The PLoS One meta-analysis of MTX trials and other systematic reviews emphasises that older trials predate modern biologic comparators and that direct, contemporary head-to-head evidence between MTX and CsA remains limited in scale. Thus, findings from individual RCTs should be integrated with patient comorbidities, treatment goals, and local availability when forming recommendations [17].

Implications for practice are select CsA when rapid clearance is clinically necessary, and select MTX when planning longer-term therapy where hepatotoxicity monitoring and folate cover are acceptable. Consider combination or sequential regimens in refractory or severe presentations when close monitoring is feasible, and reserve long-term use of either drug for patients in whom biologics are contraindicated, poorly accessible, or unacceptable. Shared decision-making should emphasise expected time to response, monitoring burden, reproductive considerations, and comorbidity-related risks [18].

Limitations and future research of the comparative literature contain relatively small RCTs with short follow-up; larger pragmatic trials with longer safety surveillance would be valuable, as would direct comparisons that standardise dosing regimens and include patient-reported outcomes and health-economic endpoints. In addition, research on optimal sequencing or low-dose combination protocols, and on their long-term safety, would directly inform clinical practice in settings where biologics are not an option.

MTX and CsA remain effective, complementary systemic selections for moderate-to-severe psoriasis. The balance between speed of onset and long-term tolerability, combined with individual patient comorbidity, should guide therapeutic choice. Healthy, long-term comparative safety data and trials of combination/sequential methods are priorities for refining evidence-based treatment pathways.

CONCLUSIONS

The present study concludes that both methotrexate and cyclosporine are effective and generally well-tolerated options for the management of psoriasis. However, cyclosporine demonstrated superior efficacy compared to methotrexate, as evidenced by a significantly greater and faster reduction in Psoriasis Area and Severity Index (PASI) scores. This rapid improvement highlights the advantage of cyclosporine in achieving quicker disease control, making it particularly suitable for short-term treatment of moderate to severe psoriasis. Both treatment groups showed comparable effects on haematological, hepatic, and renal parameters, indicating similar safety profiles. Adverse drug reactions were mostly mild to moderate and manageable, with no statistically significant difference in overall incidence between the two groups. While hypertension was observed slightly more frequently in the cyclosporine group, this finding was consistent with its known pharmacological effects and did not reach statistical significance. Overall, cyclosporine may be preferred when rapid symptom reduction is desired. In contrast, the choice of therapy should ultimately be individualized based on clinical presentation, treatment goals, and patient-specific risk factors.

CONTRIBUTION OF AUTHORS

Research concept – Saniya Fatima
Research design – Saniya Fatima, Kumar Raja Madasu
Supervision – Amit Singhal
Materials – Kumar Raja Madasu
Data collection – Saniya Fatima, Sayed Shakita Fatima
Data analysis and interpretation – Nitesh Prakash, Kumar Raja Madasu
Literature search – Saniya Fatima, Sayed Shakita Fatima
Writing article – Saniya Fatima
Critical review – Amit Singhal
Article editing – Amit Singhal
Final approval – Amit Singhal

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