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Original Research Article

Evaluation of the Use of Steroid-Sparing Immunosuppressants in Dermatological Disorders: Prescription Pattern and Safety Considerations

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Abstract

Background: Chronic dermatological conditions including psoriasis, lupus, vitiligo, pemphigus, and lichen planus frequently require systemic immunosuppressive therapy. Long-term corticosteroids carry significant morbidity, prompting reliance on steroid-sparing immunosuppressants. Prospective real-world data on their prescription patterns and safety profiles from tertiary care dermatology centres in India remain limited.

Objectives: To evaluate the prescription patterns and incidence of adverse drug reactions (ADRs) of steroid-sparing immunosuppressants in patients with chronic dermatological disorders attending a tertiary care centre.

Methods: A prospective, cross-sectional observational study was conducted over six months in the Dermatology OPD and IPD of a tertiary care medical college in eastern India. A total of 183 adult patients receiving non-steroidal immunosuppressants for at least four weeks were enrolled. Socio-demographic, clinical, and pharmacological data were recorded using structured case report forms. ADRs were documented using the CDSCO ADR reporting form version 1.4 and causality assessed by the WHO-UMC scale.

Results: The mean age was 39.22 ± 16.13 years; 53% were female. Psoriasis was the most prevalent diagnosis (47.4%), followed by vitiligo (14.1%) and lupus (6.0%). Methotrexate was the most frequently prescribed agent (27.3%), followed by tacrolimus (11.5%), tofacitinib (10.9%), and cyclosporine (15.8%). The ADRs encountered were mostly mild to moderate in severity with 26.4% systemic effects and 5.1% for mucocutaneous effects. Dyslipidaemia, cough, and arthralgia were the most common systemic ADRs (3.8% each). All ADRs were mild to moderate in severity.

Conclusion: Methotrexate followed by cyclosporine dominated steroid sparing immunosuppressant prescriptions, consistent with national and international literature. The ADR profile was predominantly mild to moderate. Regular monitoring and pharmacovigilance are essential to ensure safe long-term use of these agents in dermatology practice.

Keywords: Immunosuppressants, Dermatology, Prescription Pattern, Adverse Drug Reactions, Steroid-Sparing Agents, Pharmacovigilance.

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Introduction

Chronic inflammatory and autoimmune dermatological conditions—including psoriasis, systemic lupus erythematosus (SLE), pemphigus vulgaris, vitiligo, lichen planus, and erythroderma—impose a substantial burden on the quality of life of affected individuals. These conditions, by virtue of their chronic, relapsing nature, requiring prolonged systemic therapy. [1] Though systemic corticosteroids provide rapid and reliable disease control, they carry well-documented long-term adverse effects including metabolic syndrome, osteoporosis, hypothalamic-pituitary-adrenal axis suppression, opportunistic infections, and myopathy, which collectively limit

their sustained use. [1] Steroid-sparing immunosuppressants, on the other hand, offer an effective alternative to reduce corticosteroid dependence and cumulative toxicity. Conventional agents include methotrexate (MTX), cyclosporine, azathioprine, mycophenolate mofetil (MMF), hydroxychloroquine (HCQ), dapsone, and thalidomide. [2] More recently, small-molecule inhibitors and targeted biologics like rituximab, secukinumab, infliximab, tofacitinib, and apremilast—have expanded the therapeutic armamentarium, particularly for conditions refractory to conventional therapy. [2] The global shift toward evidence-based personalised dermatologic therapy has increased the use of these agents considerably. [3] Despite their established efficacy, each immunosuppressant carries a distinct toxicity profile that demands careful patient selection, dosing, and monitoring. Thus real-world pharmacovigilance data are of paramount importance.

Dermatology practice at tertiary care centres in India serves a heterogeneous population encompassing diverse disease spectra, socio-economic backgrounds, and comorbidity profiles. Despite this, robust prospective data characterising immunosuppressant prescribing patterns and their safety in Indian dermatology practice are limited. [5,6] Existing studies are largely retrospective, and focused on limited drug classes. Bridging this evidence gap through prospective drug utilisation research is essential to guide rational prescribing, benchmarking, and pharmacovigilance.

This study was therefore designed with the objectives of evaluating prescription pattern of steroid-sparing immunosuppressants in patients with chronic dermatological disorders, and to assess the safety profile of these agents through systematic documentation and causality assessment of adverse drug reactions in a real-world tertiary care setting.

Materials and Methods

Study Design and Setting: The study was carried out as a prospective, cross-sectional observational study conducted over a period of six months in the Dermatology Outpatient Department (OPD) and Inpatient Department (IPD) of a tertiary care medical college and hospital in eastern India. Ethics committee approval was obtained prior to commencement (Approval No. MC/KOL/IEC/NON-SPON/2699/04/2025).
Written informed consent was obtained from all participants.

Participants: Consecutive adult patients (aged ≥18 years) of either gender presenting to the Dermatology OPD or IPD with a confirmed diagnosis of an autoimmune or chronic inflammatory dermatological condition and receiving at least one non-steroidal immunosuppressant (steroid-sparing agent) for a minimum of four weeks were eligible for inclusion. Patients were excluded if they were using disease-modifying antirheumatic drugs (DMARDs) for non-dermatological conditions, pregnant or lactating, or had significant renal, hepatic, cardiac impairment. The sample was accrued by census method over the study period, yielding a final cohort of 183 patients.

Data Collection: Structured case report forms were used to record socio-demographic parameters (age, gender, education, occupation, income status, and marital status), clinical parameters (primary diagnosis, duration of disease, family history of autoimmunity, co-morbidities), pharmacological parameters (immunosuppressant agent(s) used, combination regimens, and concomitant medications). All adverse drug reactions (ADRs) spontaneously reported by patients or identified by the treating dermatologist during the study period were recorded using the CDSCO ADR reporting form version 1.4. Causality assessment was performed using the WHO-Uppsala Monitoring Centre (WHO-UMC) probability scale, categorizing reactions as certain, probable, possible, unlikely, conditional, or unassessable.

Statistical Analysis: Continuous data were expressed as mean ± standard deviation (SD) and median with interquartile range (IQR). Categorical data were presented as frequencies and percentages. All statistical analyses were performed using MedCalc version 11.6 (MedCalc Software, Mariakerke, Belgium).

Results

A total of 183 patients were enrolled. The mean age was 39.22 ± 16.13 years (median 40 years, IQR 28–50). Males constituted 47% of the cohort (n=86) and females 53% (n=97). Regarding educational status, the majority had secondary education (27.3%) or illiterate (22.4%) educational backgrounds. In terms of occupation, 33.3% were housewives, 31.1% employed, and 30.1% unemployed. The majority (77%) were above the poverty line (APL). Most patients were married (73.2%).

The mean disease duration was 50.28 ± 73.48 months (median 18 months, IQR 6–60 months), indicating considerable variability. A family history of autoimmunity was present in 13.7% of patients. The majority (74.9%) had no co-morbidities. Among those with comorbid conditions, type 2 diabetes mellitus (T2DM) was most prevalent (6.6%), followed by hypertension (3.8%) and hypothyroidism, rheumatoid arthritis in 2.2% patients. Psoriasis was the most common diagnosis, accounting for 87 patients (47.4%), followed by vitiligo (14.1%), lupus (6.0%), lichen planus

(4.9%), erythroderma (4.9%), and pemphigus (4.4%). Alopecia (2.7%), pyoderma gangrenosum (2.2%), morphea (1.6%), and several less common diagnoses constituted the remainder (Table 1).

Table 1: Disease distribution in the study population (N = 183)

Disease	Number of Patients	% of Total
Psoriasis	87	47.4
Vitiligo	26	14.1
Lupus	11	6.0
Lichen Planus	9	4.9
Erythroderma	9	4.9
Pemphigus	8	4.4
Alopecia	5	2.7
Pyoderma Gangrenosum	4	2.2
Morphea	3	1.6
Scleroderma	2	1.1
Seborrheic Dermatitis	2	1.1
Hidradenitis Suppurativa	2	1.0
Post-Inflammatory Hypopigmentation (PIH)	2	1.1
Dermatitis	2	1.1
Others (SJS, ENL, Reiter's, Urticaria, Keloid, Prurigo, etc.)	11	6.0

A broad range of immunosuppressants was prescribed, either as monotherapy or in combination.

Methotrexate was the most commonly used agent (27.3%), followed by cyclosporine (15.8%), tacrolimus (11.5%), and tofacitinib (10.9%). Hydroxychloroquine (HCQ) was used in 6.0% of patients, rituximab in 3.3%, minocycline in 2.7%, and secukinumab/apremilast in smaller proportions. Combination regimens were employed in 29 patients (15.8%), the most common being cyclosporine + secukinumab (4.4%), tofacitinib + tacrolimus (4.4%), and cyclosporine + secukinumab + MTX (2.2%). Details of all immunosuppressant usage patterns are presented in Table 2, and combination regimens in Table 3.

Table 2: Immunosuppressant prescription pattern (N = 183)

Drug / Regimen	Number of Patients	% of Total
Methotrexate (MTX) monotherapy	50	27.3
Cyclosporine monotherapy	29	15.8
Tacrolimus monotherapy	21	11.5
Tofacitinib monotherapy	20	10.9
Hydroxychloroquine (HCQ) monotherapy	11	6.0
Cyclosporine + Secukinumab	8	4.4
Tofacitinib + Tacrolimus	8	4.4
Rituximab	6	3.3
Minocycline	5	2.7
Cyclosporine + Secukinumab + MTX	4	2.2
Apremilast	2	1.1
Rituximab + HCQ + Dapsone	2	1.1
Rituximab + MMF	2	1.1
Cyclosporine + Infliximab	2	1.1
Tacrolimus + HCQ	2	1.1
Other / Miscellaneous regimens	13	7.1

Table 3: Combination immunosuppressant regimens (N = 29)

Combination Used	Number of Patients	% of Total
Cyclosporine + Secukinumab	8	4.4
Tofacitinib + Tacrolimus	8	4.4
Cyclosporine + Secukinumab + MTX	4	2.2
Tacrolimus + HCQ	2	1.1
Rituximab + HCQ + Dapsone	2	1.1
Cyclosporine + Infliximab	2	1.1
Rituximab + MMF	2	1.1
Cyclosporine + Tofacitinib + Infliximab	1	0.5

Disease–drug associations were evaluated and for psoriasis, MTX and cyclosporine were the predominant conventional agents, while secukinumab, tofacitinib, and infliximab were the preferred targeted/biologic options. Vitiligo was managed almost exclusively with tacrolimus (topical immunosuppression) and tofacitinib. Lupus patients primarily received HCQ, with rituximab, tacrolimus, and MMF used in selected cases. Pemphigus vulgaris was treated primarily with rituximab, with MMF and azathioprine as adjuncts. Erythroderma was managed with cyclosporine, and alopecia areata predominantly with tofacitinib. Disease-drug associations are detailed in Table 4.

Table 4: Disease–drug associations in the study cohort

Disease	Conventional Agents	Targeted/Biologic Agents
Psoriasis	MTX, Cyclosporine, HCQ	Secukinumab, Tofacitinib, Infliximab, Apremilast
Vitiligo	Azathioprine	Tofacitinib, Tacrolimus
Lupus	HCQ, Dapsone	Rituximab, Tacrolimus, MMF
Pemphigus	Azathioprine, MMF	Rituximab
Erythroderma	Cyclosporine, MTX	Secukinumab, Infliximab
Lichen Planus	Cyclosporine, HCQ	Tofacitinib
Alopecia Areata	—	Tofacitinib
Pyoderma Gangrenosum	Cyclosporine, Minocycline	Tofacitinib
Scleroderma	MMF	Rituximab

Concomitant medications were prescribed alongside immunosuppressants. Antihistamines were used in 55.2% of patients (n=101). Topical steroids (clobetasol, betamethasone, mometasone) were prescribed to 52.5% of the cohort.

Systemic steroids were used concomitantly in 10.9% of patients (n=20), primarily to achieve rapid initial disease control (prednisolone being most common at 4.9%).

Vitamins and minerals (folic acid, calcium, and vitamin D3) were prescribed to 46.4%, and antimicrobials to 13.1% of patients.

Adverse Drug Reactions: Mucocutaneous ADRs were observed in 10 (5.1%) patients. Rash and hypersensitivity reactions were most frequent (1.6%), followed by paraesthesia ± erythema and oral ulcers (1.0% each). Alopecia, erythema, and angioedema occurred in 0.5% each. By WHO-UMC causality assessment, oral ulcers (methotrexate), alopecia (MMF), erythema (tofacitinib), and angioedema (hydroxychloroquine) were rated as probable. Rash/hypersensitivity and paraesthesia/erythema were rated as possible. The mucocutaneous ADRs are presented in Table 5a.

Table 5a: Mucocutaneous ADRs and causality assessment

Mucocutaneous ADR	N	% of Total	Implicated Drug(s)	WHO-UMC Causality
Rash / Hypersensitivity	3	1.6	Rituximab + HCQ + Dapsone; Cyclosporine; Cyclosporine + Tofacitinib + Infliximab	Possible
Paraesthesia ± Erythema	2	1.0	Tacrolimus ± HCQ	Possible
Oral Ulcers	2	1.0	Methotrexate	Probable
Alopecia	1	0.5	Mycophenolate Mofetil	Probable
Erythema	1	0.5	Tofacitinib	Probable
Angioedema	1	0.5	Hydroxychloroquine	Probable

Systemic ADRs were recorded in 44 patients, yielding an overall systemic ADR incidence of approximately 24.6% (though 75.6% of patients had no systemic ADRs). Dyslipidaemia, cough, and arthralgia were the most common, each occurring in 3.8% of patients (n=7). Anaemia and abdominal pain were recorded in 2.2% each (n=4), and dyselectrolytaemia in 1.6% (n=3). Rarer adverse events included hypertension, vertigo, low platelet count (1.0–1.1%), and single cases of proteinuria, colour vision loss, uremia, malaise/fatigue, tuberculosis, and megaloblastic anaemia.

All ADRs were mild to moderate in severity (Table 5b).

Table 5b: Systemic ADRs and causality assessment

Systemic ADR	N	% of Total	Implicated Drug(s)	WHO-UMC Causality
Dyslipidaemia	7	3.8	Cyclosporine, MTX, Secukinumab, Rituximab, Cyclosporine + MTX + Secukinumab	Possible
Cough	7	3.8	Rituximab + HCQ + Dapsone; MTX; Tofacitinib; Rituximab + MMF	Possible
Arthralgia	7	3.8	Cyclosporine; Rituximab + MMF; Rituximab + HCQ + Dapsone; MTX	Possible
Anaemia	4	2.2	Rituximab; Cyclosporine + Tofacitinib + Infliximab; Cyclosporine + Secukinumab + MTX	Possible
Abdominal Pain	4	2.2	Cyclosporine, MTX, Tofacitinib + HCQ	Possible
Dyselectrolytaemia	3	1.6	Rituximab; Cyclosporine + MTX + Secukinumab	Possible
Hypertension	2	1.1	Cyclosporine + Secukinumab; Cyclosporine + Infliximab; Rituximab	Possible
Vertigo	2	1.0	Methotrexate, Tofacitinib	Possible
Low Platelet Count	2	1.1	Hydroxychloroquine, Methotrexate	Possible
Proteinuria	1	0.5	Hydroxychloroquine	Probable
Colour Vision Loss	1	0.5	Hydroxychloroquine + MMF	Possible
Uremia	1	0.5	Cyclosporine + MTX + Secukinumab	Possible
Malaise + Fatigue	1	0.5	Cyclosporine	Probable
Tuberculosis	1	0.5	Tofacitinib	Probable
Megaloblastic Anaemia	1	0.5	Cyclosporine	Probable

Discussion

This prospective observational study provides a real-world, contemporary snapshot of immunosuppressant prescribing patterns and their safety in a tertiary care dermatology setting in eastern India. The cohort of 183 patients with a mean age of approximately 39 years and a slight female preponderance broadly reflects the demographic profile of patients attending dermatology services for chronic inflammatory and autoimmune conditions in this region. [6]

Psoriasis was the dominant diagnosis (47.4%) in our cohort, followed by vitiligo and lupus. This contrasts with the distribution reported by Swathi and Sirisha (2022), who reported pemphigus and lichen planus as the most common immunosuppressant-requiring diagnoses in their cohort, [5] and Shakur et al. (2023) from Bihar, where psoriasis and pemphigus were the predominant conditions.[6] Disease distribution at referral centres is shaped by local epidemiology and referral patterns, which likely accounts for these inter-study differences.

Methotrexate emerged as the most frequently prescribed immunosuppressant (27.3%), followed by cyclosporine (15.8%), tacrolimus (11.5%), and tofacitinib (10.9%). The primacy of methotrexate is consistent with existing literature from India. Shakur et al. reported methotrexate as the most commonly used immunosuppressant (60.4%) in their Bihar cohort, [6] while Swathi and Sirisha similarly identified it as the leading agent. [5] This prescription preference reflects methotrexate's established efficacy across multiple dermatological indications including psoriasis, pemphigus, and various inflammatory dermatoses, its oral route of administration, low cost, and long-standing familiarity among clinicians. [2,3] The relatively high use of tofacitinib (10.9%)—a JAK inhibitor—and tacrolimus (11.5%) in our cohort is noteworthy and reflective of evolving prescribing trends. Tofacitinib has gained significant traction for alopecia areata and vitiligo, indications for which conventional immunosuppressants offer limited efficacy. [2] This is consistent with the disease-drug association observed in our study, where tofacitinib was the primary agent for alopecia areata patients and a major agent for vitiligo. The use of biologics such as secukinumab (for psoriasis) and rituximab (for pemphigus and scleroderma) underscores increasing biologic uptake even in resource-limited settings. Kanatoula et al. (2024) reviewed the evidence base for non-biologic immunosuppressives and highlighted the growing integration of targeted agents to complement or replace conventional therapies, a trend validated by our prescribing data. [2]

Combination immunosuppressant regimens were employed in approximately 15.8% of patients, most commonly cyclosporine combined with secukinumab or MTX, and tofacitinib with tacrolimus. This practice is appropriate when disease severity demands faster control but carries the attendant risk of compounding immunosuppression, particularly regarding infection susceptibility. The simultaneous use of systemic steroids in 10.9% of the cohort reflects the clinical practice of bridging with corticosteroids to achieve rapid initial disease control while allowing

the steroid-sparing agent to reach therapeutic efficacy—a strategy commonly described in the management of pemphigus and severe psoriasis. This approach aligns with recommendations in contemporary dermatology guidelines and reflects the challenge of balancing speed of control against cumulative toxicity. [1,2]

Regarding safety, the overall systemic ADR incidence of approximately 24.6% and mucocutaneous ADR incidence of 5.1% are broadly consistent with published reports. Shakur et al. reported an ADR incidence of 47.5% in their cohort, though their inclusion criteria and monitoring methods may account for the higher figure. [6] Zeng et al., in their systematic review of steroid-sparing agents in bullous pemphigoid and pemphigus, highlighted the considerable adverse effect burden of conventional agents including azathioprine and dapsone, and noted that dyslipidaemia, bone marrow suppression, and hepatotoxicity were among the most clinically significant concerns. [1] Our study similarly identified dyslipidaemia as the leading systemic ADR (3.8%), implicated with cyclosporine, methotrexate, secukinumab, and rituximab—drugs each independently associated with lipid metabolic disturbances.

Cough and arthralgia (3.8% each) were the next most common systemic ADRs. Cough in the setting of methotrexate and rituximab use warrants consideration of drug-induced pneumonitis, a recognised though infrequent complication of both agents.[2] Arthralgia, particularly in the context of cyclosporine and rituximab use, may represent musculoskeletal adverse effects or immune reconstitution phenomena. The occurrence of a single case of tuberculosis in a tofacitinib-treated patient (causality: probable) is consistent with the established risk of opportunistic infections, particularly mycobacterial reactivation, associated with JAK inhibitor therapy. [2] Khurana and Saxena (2020) specifically cautioned against the use of JAK inhibitors in regions with high tuberculosis burden, advocating for tuberculosis screening prior to initiation—a recommendation that must be rigorously followed in the Indian context. [4]

Mucocutaneous ADRs were generally mild. Oral ulcers attributed to methotrexate (probable causality) are a well-recognised and folic acid-responsive adverse effect, underscoring the importance of routine folic acid co-prescription with methotrexate. [3]

Angioedema attributed to hydroxychloroquine (probable) was an infrequent but clinically important reaction, aligning with rare hypersensitivity reactions reported in the literature. The absence of severe or life-threatening ADRs in our cohort may reflect the relatively controlled outpatient setting, proactive monitoring by dermatologists, and early intervention upon ADR detection.

When benchmarked against Swathi and Sirisha (2022), our study shares methodological similarities in terms of observational cross-sectional design and ADR documentation methodology but differs in the breadth of biologics and JAK inhibitors represented, reflecting temporal shifts in prescribing practices. [5] The study by Shakur et al. (2023) from a comparable eastern Indian tertiary care setting identified drug cost as an important determinant of prescribing choices—an aspect we could not systematically evaluate, which constitutes a limitation of our work. [6] Bose and Madke's comprehensive review (2022) of immunosuppressants in paediatric dermatoses provided a useful pharmacological reference for interpreting observed adverse effects, particularly for cyclosporine and azathioprine. [3]

A key observation is that all ADRs recorded in the present study were mild to moderate in severity, with no life-threatening events detected over the six-month observation window. This is reassuring but should be interpreted cautiously, given the relatively short follow-up duration and the fact that some serious ADRs (hepatotoxicity, nephrotoxicity, malignancy) are characteristically delayed and may only emerge with prolonged use. Continued pharmacovigilance and longer observational studies are necessary.

The overall cost of immunosuppressants was not systematically analysed in this study, constituting its primary limitation. Additionally, the single-centre design limits generalisability; a multi-centre study with a larger, geographically diverse sample would provide more representative data. The six-month observation period may be insufficient to capture delayed or cumulative toxicities. These limitations notwithstanding, this study adds to the sparse prospective evidence base on immunosuppressant use in Indian dermatology practice.

Conclusion

This prospective observational study characterises the real-world prescribing patterns of steroid-sparing immunosuppressants in a tertiary care dermatology centre in India. Psoriasis was the predominant indication, and methotrexate followed by cyclosporine were the most frequently prescribed agents, consistent with existing literature.

The increasing use of targeted agents such as tofacitinib, secukinumab, and rituximab reflects the evolution of dermatological therapeutics toward precision immunotherapy. Adverse drug reactions

occurred in approximately one quarter of patients for systemic effects and 5.1% for mucocutaneous effects, but were predominantly mild to moderate and consistent with known drug toxicity profiles.

The identification of tuberculosis in a tofacitinib-treated patient highlights the need for stringent pre-treatment screening, particularly in endemic regions.

Regular clinical monitoring, systematic pharmacovigilance, and patient education are essential to optimise the benefit-risk ratio of immunosuppressant therapy in dermatology practice. Future studies incorporating cost analysis, longer follow-up, and multi-centre designs will further strengthen the evidence base in this important domain.

Ethical Approval: Ethics committee approval was obtained prior to commencement of the study (Approval No. 2699/04/2025). Written informed consent was obtained from all participants. The study was conducted in accordance with the Declaration of Helsinki.

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