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ASSESSMENT OF DRUG UTILIZATION PATTERNS USING THE AMERICAN COLLEGE OF RHEUMATOLOGY GUIDELINES FOR THE TREATMENT OF RHEUMATOID ARTHRITIS OF A TERTIARY CARE HOSPITAL IN HIMACHAL PRADESH - AN OBSERVATIONAL CROSS-SECTIONAL STUDY

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Abstract

Background: Rheumatoid arthritis (RA) is a chronic systemic autoimmune inflammatory disease characterized by progressive joint destruction and substantial morbidity. Using the established clinical guidelines of organizations such as the American College of Rheumatology (ACR) will allow for rational, evidence-based pharmacotherapy. ***Objective:*** To assess the drug utilization pattern in RA patients attending a tertiary care hospital in HP and to assess the compliance to the ACR 2021 recommendations for management of RA. ***Methods:*** A prospective observational cross-sectional study was carried out for a period of ten months in the General medicine OPD of Pt Jawahar Lal Nehru Medical College Chamba HP. 200 diagnosed RA patients were enrolled in the study after obtaining informed consent. Data were gathered on a pre-validated structured proforma.The prescriptions were analyzed using WHO core drug use indicators and compared with ACR 2021 guidelines. ***Results:*** The mean age of the patients was 42.6 ± 12.4 years with a female preponderance (72%). The most commonly prescribed DMARD was methotrexate (MTX, 78%) followed by hydroxychloroquine (HCQ, 62%) and sulfasalazine (SSZ, 44%). 38% of patients were on DMARD combination therapy (triple therapy: MTX+HCQ+SSZ). NSAIDs were co-prescribed in 64% of cases and corticosteroids in 56% of cases. Biologic DMARDs (bDMARDs) were prescribed to 8% of patients. Average number of drugs per prescription was 4.2. The patients complied with ACR 2021 disease activity-guided escalation in 71%. MTX was co-prescribed with folic acid in 82% of prescriptions. ***Conclusion:*** Pt Jawahar Lal Nehru Medical College had reasonable compliance with ACR 2021 guidelines with scope of improvement.There are gaps in treat to target monitoring, timely escalation of biologics and regular folic acid co-prescription. Periodic audits and continuing medical education are suggested to strengthen guideline-based prescribing.

Keywords: Rheumatoid Arthritis, Drug Utilization Study, ACR Guidelines, DMARDs, Methotrexate, Himachal Pradesh, Pharmacoepidemiology, Treat-to-Target

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic, progressive, systemic autoimmune condition targeting primarily synovial joints and causing irreversible structural damage if untreated[1]. It is one of the most prevalent autoimmune diseases globally, with an estimated prevalence of 0.5%–1% worldwide, and it affects women more than men at a ratio of 3:1[2]. The disease is characterized by symmetric polyarthritis, morning stiffness, fatigue and systemic features that lead to a significant negative impact on quality of life and work productivity[3].

In India, RA affects about 0.5%–0.75% of the adult population[4]. Chamba district with cold and humid climate, unique genetic make-up and altitude related environmental factors may have distinct epidemiological and clinical patterns of RA compared to those living in plains. Studies from tertiary care centers in Northern India show that RA patients present late with high disease activity scores and are suboptimally treated[5].

Drug utilization studies (DUS) are systematic studies of the marketing, distribution, prescription and use of drugs in a society with special emphasis on the medical, social and economic consequences resulting therefrom[6]. Drug

utilization research is defined by the World Health Organization (WHO) as the study of prescribing, dispensing, administration and taking of medication[7]. The main goal of drug utilization research is to understand the appropriateness of drug use. Such studies represent an important pharmacoepidemiological tool for the assessment of the rational prescribing of drugs and their compliance with the guidelines established[8].

The American College of Rheumatology (ACR) provides evidence-based recommendations for the management of RA at intervals. A treat-to-target (T2T) strategy that highlights monitoring of Disease Activity Score (DAS28) or Clinical Disease Activity Index (CDAI) is recommended in the latest ACR 2021 guidelines[9]. Treatment should be started with conventional synthetic DMARDs (csDMARDs) with Methotrexate as the anchor drug for the first 3 months after diagnosis, and escalated to biologic and targeted synthetic DMARDs (bDMARDs/tsDMARDs) in inadequate responders. The guidelines also recommend that corticosteroids be administered at the lowest effective dose for the shortest period of time[9].

However, adherence to these guidelines in real world clinical practice especially in resource limited settings like tertiary care hospitals in Chamba, HP is not well studied yet. Institutional differences in drug availability, formulary restrictions, patient affordability, physician awareness, and regional prescribing patterns can lead to important deviations from recommended guideline therapy.

Thus, the present study was planned to systematically evaluate the prescribing patterns for RA at Pt Jawahar Lal Nehru Medical College to identify deviation from ACR 2021 guidelines and generate actionable data for improving rational pharmacotherapy in this underserved patient population.

AIM AND OBJECTIVES

Aim

To assess the drug utilization patterns in patients diagnosed with Rheumatoid Arthritis attending the General medicine OPD of Pt Jawahar Lal Nehru Medical College Chamba HP, using the ACR 2021 guidelines as a reference standard.

Primary Objectives

1. To analyze the prescribing patterns of antirheumatic drugs (DMARDs, NSAIDs, corticosteroids, and biologics) in RA patients.
2. To evaluate the pattern of DMARD use (monotherapy vs. combination therapy) and assess adherence to ACR 2021 treatment algorithms.
3. To calculate WHO prescribing indicators including average number of drugs per prescription, percentage of drugs prescribed by generic name, and percentage from the Essential Medicines List (EML).
4. To assess the rate of co-prescription of folic acid with Methotrexate and corticosteroid-sparing strategies.

Secondary Objectives

1. To document the sociodemographic and clinical profiles of the study population.
2. To identify gaps in current prescribing practices for formulating targeted recommendations.

To estimate the frequency of disease-modifying therapy escalation and its accordance with treat-to-target principles.

MATERIALS AND METHODS

Study Design: A prospective, hospital-based, observational cross-sectional study was conducted over a period of ten months from January to October 2025.

Study Setting: The study was carried out in the Department of General medicine OPD of Pt Jawahar Lal Nehru Medical College Chamba HP.

STUDY POPULATION

Inclusion Criteria: (1) Patients of either sex, aged ≥18 years. (2) Patients diagnosed with RA according to the ACR/EULAR 2010 Classification Criteria for Rheumatoid Arthritis. (3) Patients who had attended at least two visits at the study centre. (4) Patients with a minimum treatment duration of 4 weeks. (5) Patients who gave written informed consent.

Exclusion Criteria: (1) Patients with overlapping connective tissue disorders (SLE, mixed connective tissue disease). (2) Pregnant or breastfeeding women. (3) Patients with active tuberculosis, malignancy, or severe hepatic/renal impairment. (4) Patients who refused consent or were unable to provide reliable history.

Sample Size: A sample size of 200 patients was determined based on a review of similar studies and practical feasibility constraints during the ten month data collection window. All eligible patients attending the general medicine OPD during the study period who met inclusion criteria were enrolled using purposive consecutive sampling until the required sample was achieved.

Data Collection Tool: A pre-validated structured proforma was designed and was piloted on 15 patients prior to the start of the study. The proforma had the following domains: sociodemographic details (age, sex, occupation, residence, BMI); clinical details (duration of disease, ACR/EULAR classification criteria, disease activity scores – DAS28-ESR, DAS28-CRP, CDAI); laboratory parameters (ESR, CRP, RF, anti-CCP, CBC, LFT, RFT); prescription details (all drugs, dose, frequency, route of administration, duration); adherence

to ACR 2021 management algorithm; and adverse drug reactions (if any).

ASSESSMENT OF PRESCRIPTIONS

WHO Core Drug Use Indicators assessed: (1) Average number of drugs per prescription. (2) Percentage of drugs prescribed by generic name. (3) Percentage of prescriptions with an antibiotic. (4) Percentage of prescriptions with an injection. (5) Percentage of drugs from the National EML.

ACR 2021 Guideline Compliance Assessment: Each prescription was reviewed against the ACR 2021 algorithm for treatment-naive patients and established RA patients with active/stable disease. Specific metrics included: use of MTX as anchor DMARD, csDMARD combination therapy in moderate-to-high disease activity, escalation to bDMARDs/tsDMARDs in csDMARD failure, T2T monitoring documentation, folic acid co-prescription with MTX, and appropriate corticosteroid tapering strategy.

Statistical Analysis: The data were entered using Microsoft Excel 2019 and analyzed using SPSS version 26.0. Categorical variables were reported as frequencies and percentages. Continuous variables were presented as mean ± standard deviation (SD) or median (interquartile range, IQR) as appropriate. Categorical variables were compared with the Chi-square test and continuous variables with the independent samples t-test or the Mann-Whitney U test. Statistical significance was defined as a p-value of < 0.05.

Ethical Considerations: All participants gave written informed consent before being enrolled. Patient confidentiality was maintained by strict anonymisation of data with unique identification codes. The study was conducted as per Declaration of Helsinki (2013 revision) and ICMR Ethical Guidelines for Biomedical and Health Research (2017).

RESULTS

A total of 200 patients diagnosed with Rheumatoid Arthritis were enrolled in the study from January to octobar 2025. The findings are presented in the following tables.

Table 1: Sociodemographic Profile of Study Participants (n = 200)

Parameter	Category	n (%)
Age Group (years)	18–30	28 (14.0%)
	31–45	78 (39.0%)
	46–60	64 (32.0%)
	>60	30 (15.0%)
	Mean age: 42.6 ± 12.4 yrs	
Sex	Female	144 (72.0%)
	Male	56 (28.0%)
Residence	Urban	112 (56.0%)
	Rural	88 (44.0%)
Disease Duration	< 1 year	32 (16.0%)
	1–5 years	90 (45.0%)
	> 5 years	78 (39.0%)
Disease Activity (DAS28)	Remission (<2.6)	18 (9.0%)
	Low (2.6–3.2)	34 (17.0%)
	Moderate (3.2–5.1)	96 (48.0%)
Seropositivity (RF/anti-CCP)	High (>5.1)	52 (26.0%)
	Seropositive	156 (78.0%)
	Seronegative	44 (22.0%)

Table 2: Frequency of DMARD Prescriptions (n = 200)

Drug	No. of Patients	Percentage (%)
Methotrexate (MTX)	156	78.0%
Hydroxychloroquine (HCQ)	124	62.0%
Sulfasalazine (SSZ)	88	44.0%
Leflunomide (LEF)	36	18.0%
Triple Therapy (MTX+HCQ+SSZ)	76	38.0%
MTX + HCQ (Dual)	52	26.0%
MTX Monotherapy	28	14.0%
bDMARDs (Rituximab/Adalimumab/Etanercept)	16	8.0%

JAK Inhibitors (Baricitinib/Tofacitinib)	6	3.0%

Table 3: Pattern of Adjunct Medications (n = 200)

Drug Class / Agent	No. of Patients	Percentage (%)
NSAIDs	128	64.0%
— Diclofenac	54	27.0%
— Etoricoxib	44	22.0%
— Ibuprofen	30	15.0%
Corticosteroids	112	56.0%
— Prednisolone (oral)	88	44.0%
— Methylprednisolone (IV pulse)	24	12.0%
Folic Acid (co-prescribed with MTX)	128/156*	82.1%*
Proton Pump Inhibitors (PPIs)	102	51.0%
Calcium + Vitamin D	86	43.0%
Analgesics (Paracetamol)	62	31.0%

*Denominator: 156 patients receiving MTX

Table 4: WHO Prescribing Indicators

WHO Indicator	Observed Value	Standard Value
Average No. of Drugs per Prescription	4.2	1.6–1.8
% Drugs Prescribed by Generic Name	56.4%	>80%
% Prescriptions with Antibiotic	8.5%	<30%
% Prescriptions with Injection	18.0%	<10%
% Drugs from National EML	74.2%	>90%
% Patients on DMARD (any)	96.0%	100%

Table 5: Compliance with ACR 2021 Guideline Recommendations

ACR 2021 Recommendation	Compliant (n)	Compliance (%)
MTX as first-line DMARD (treatment-naive)	148/158	93.7%
Combination csDMARD in moderate-high disease activity	108/148	73.0%
Folic acid co-prescription with MTX	128/156	82.1%
Corticosteroid dose ≤10 mg/day prednisolone equivalent	86/112	76.8%
Disease activity score (DAS28) documented at visit	142/200	71.0%
Escalation to bDMARD in csDMARD failure (≥2 DMARDs)	16/38	42.1%
Radiographic evaluation (annual X-ray hands/feet)	76/200	38.0%
Overall Guideline Adherence (composite score ≥5/7)	142/200	71.0%

Table 6: Adverse Drug Reactions (ADRs) Reported (n = 38 patients)

Adverse Drug Reaction	Causative Drug	n (%)*
Nausea / Vomiting	MTX, NSAIDs	14 (36.8%)
Elevated Liver Enzymes	MTX, Leflunomide	8 (21.1%)
GI Upset / Gastritis	NSAIDs, Steroids	7 (18.4%)
Oral Ulcers	MTX	4 (10.5%)
Hyperglycemia	Corticosteroids	3 (7.9%)
Injection Site Reaction	Adalimumab	2 (5.3%)

*Denominator: 38 patients who reported ADRs

DISCUSSION

This prospective cross-sectional study of 200 RA patients is the first systematic drug utilization analysis in this population with reference to the ACR 2021 guidelines. The key findings are discussed below in the light of existing national and international literature.

Socio-demographic:

The mean age in our study was 42.6 ± 12.4 years with a female to male ratio of 2.57:1, which is in keeping with published epidemiology[2,3]. Misra et al. (2012) from AIIMS Delhi reported female predominance of 3:1 with mean age of 44 years[10]. The majority of patients were in the age group of 31–60 years (71%), which coincides with the most economically productive years and underlines the socioeconomic impact of the disease in

this region. The high percentage (44%) of rural patients points to the role of Pt Jawahar Lal Nehru Medical College as a primary referral centre for rural populations. A similar pattern was observed by Sharma et al. (2019)[11].

Disease Activity Profile:
Remarkably, 74% of the patients had a moderate to high activity of disease (DAS28 >3.2) at the time of inclusion in the study. This is higher than the 58% found by Singh et al. (2018) in a similar study in Chandigarh[12] and could indicate delayed specialist referral patterns in Chamba. Late presentation and referral delays are well known barriers in resource limited settings and are associated with higher disease burden at first contact in tertiary care[5].

DMARD Utilization:
Methotrexate was prescribed in 78% patients which is a significant improvement over earlier Indian studies (38–65%)[13,14,11] and comparable to Western registries (70–80%)[15]. Such a finding is of particular encouragement and most probably reflects the impact of institutional training in ACR guidelines at study setting. The high use of MTX is in keeping with the ACR 2021 first-line recommendation of MTX as the anchor DMARD for all patients with moderate-to-high disease activity without contraindications[9].

Combination DMARD therapy (triple therapy: MTX+HCQ+SSZ) was prescribed in 38% patients, which is in line with the approach recommended for moderate-to-high disease activity by ACR 2021[9]. This is higher than 29% reported by Sharma et al. (2019) from Jammu[11] and reflects progressive adoption of evidence based combination strategies in this region. However, considering that 74% of our study population had moderate-to-high disease activity, the ideal rate of combination therapy should be much higher, suggesting a gap in the implementation of ACR 2021.

The usage of biologic DMARDs (8%) and JAK inhibitors (3%) was low compared to high-income countries (30–40%). This is in keeping with the findings by Malaviya et al. (2011)[14], and is due to cost, limited formulary availability and lack of a structured biologics monitoring programme. The ACR 2021 guidelines recommend escalation to bDMARDs or tsDMARDs in patients who fail two or more csDMARDs with inadequate response; however, only 42.1% of eligible patients in our study received this escalation, revealing a significant treatment gap[9].

Adjunct Medications:
NSAIDs were co-prescribed in 64% of patients, mainly for symptom control in the lag period before DMARD efficacy. This is in line with 61% reported by Saikia et al. (2014)[16]. ACR 2021 guidelines recommend NSAIDs at the lowest effective dose for the shortest duration[9]. Etoricoxib (22%) and Diclofenac (27%) were the most commonly consumed NSAIDs. Selective COX-2 inhibitors like Etoricoxib have lesser GI risk but need evaluation of cardiovascular risk which was not uniformly documented in our study. 56% cases were treated with corticosteroids. The ACR 2021 guidelines conditionally recommend low-dose corticosteroids (≤10 mg prednisolone/day equivalent) as a bridge therapy, but advise against their prolonged use[9]. In our study, 76.8% of patients receiving corticosteroids were maintained at ≤10 mg/day, suggesting reasonable but improvable adherence. The other 23.2% at higher doses are a patient safety concern and require active monitoring of metabolic, osteoporotic and adrenal complications.

Folic acid co-prescription with MTX was recorded in 82.1% of cases, which is higher than the 71% reported by Badyal et al. (2007)[13] but still below the 100% recommended by the ACR[9]. Folic acid supplementation markedly decreases MTX-related gastrointestinal adverse effects, hepatotoxicity, and oral mucositis without compromising clinical efficacy and is a mandatory co-prescription in all patients treated with MTX.

WHO Prescribing Indicators:
The average number of drugs per prescription (4.2) is understandably higher than WHO standards (1.6–1.8) for acute care facilities, given the inherent polypharmacy required in managing chronic autoimmune disease[7,8]. This figure is comparable with reports from other Indian rheumatology centres (3.8-5.2)[16,11]. The percentage of drugs prescribed generically (56.4%) is far below the recommended target ((>80%) suggesting the need for institutional generic prescribing policies. Drugs prescribed from the National EML (74.2%) are also inadequate, mainly because bDMARDs and targeted synthetic DMARDs are not included in the current National EML.

Overall ACR 2021 Guideline Compliance:
Overall composite guideline compliance (≥5 of 7 key metrics) was observed in 71% of patients. This is comparable to that of 67% reported by Misra et al. (2020) from AIIMS[17] but significantly lower than the 81% achieved following structured audit cycles in EULAR registries[18]. The greatest gaps were in: (a) escalation to bDMARDs/tsDMARDs in csDMARD failure (42.1% compliant), and (b) annual radiographic monitoring (38% compliant) to detect subclinical joint damage and inform escalation of therapy.

Adverse Drug Reactions:
Adverse Drug Reactions in 19% of patients (n=38) mainly related to MTX (GI symptoms, hepatotoxicity) and corticosteroids this value is in agreement with the literature. The relatively high rate of ADRs related to MTX compared with the rate of incomplete co-prescription of folic acid reinforces the imperative for

universal supplementation of folic acid. Study setting should strengthen systematic monitoring and reporting of ADRs through Pharmacovigilance Programme of India (PvPI).

CONCLUSION

This drug utilization study of 200 RA patients in Pt Jawahar Lal Nehru Medical College highlights that the pattern of prescribing is reasonable but can be improved with the adherence of ACR 2021 guidelines. Methotrexate has been appropriately established as the cornerstone DMARD and triple DMARD therapy is increasingly used. However, there are significant gaps in escalation of biologic therapy, co-prescription of folic acid, documentation of disease activity score, annual radiographic monitoring and generic name prescribing.

This study provides a much needed pharmacoepidemiological baseline for the Chamba region to enable evidence based quality improvement interventions. Next steps include systematic audits, physician education programs and a structured treat-to-target monitoring protocol. With proper institutional support, Pt Jawahar Lal Nehru Medical College is well positioned for higher levels of guideline adherence and ultimately better clinical outcomes and quality of life for RA patients in the Chamba region.

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