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Review Article

Observational Study on Evaluation of the Side Effects of Tofacitinib in Patients with Rheumatoid Arthritis

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ABSTRACT

Rheumatoid arthritis is a chronic autoimmune inflammatory disease that primarily affects synovial joints and may lead to progressive joint damage and disability. Tofacitinib is an oral Janus kinase inhibitor used in the management of rheumatoid arthritis, either alone or in combination with disease-modifying antirheumatic drugs. The purpose of this study was to evaluate the side effects of tofacitinib in patients with rheumatoid arthritis in a real-world clinical setting. An ambispective observational study was conducted for six months in the Department of Rheumatology, Krishna Institute of Medical Sciences, Secunderabad. A total of one hundred adult patients receiving tofacitinib were included. Demographic details, diagnosis, comorbidities, treatment pattern, reported side effects, vital parameters, and laboratory values were collected and analyzed using repeated measures analysis of variance and descriptive statistics. Females constituted eighty-eight percent of the study population. Rheumatoid arthritis seropositive cases accounted for eighty-six percent. The reported side effects included weight gain in twenty-one percent, urinary tract infection in one percent, and vertigo in two percent of patients. No statistically significant changes were observed in systolic blood pressure, diastolic blood pressure, pulse rate, hemoglobin, white blood cell count, platelet count, serum glutamic pyruvic transaminase, or body weight across visits. Creatinine showed a p value of 0.042, but no clinically meaningful renal impairment was identified. Tofacitinib was generally well tolerated in this study population, with no major adverse effects observed based on vital and laboratory parameters.

INTRODUCTION

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Rheumatoid arthritis is a chronic systemic autoimmune disease characterized by persistent synovial inflammation, progressive joint destruction, pain, swelling, stiffness, and functional disability. It commonly affects small joints in a symmetrical pattern and may progress to involve larger joints. If not treated appropriately, chronic inflammation can result in cartilage damage, bone erosion, deformity, and reduced quality of life.

The pathogenesis of rheumatoid arthritis involves genetic, environmental, and immunological factors. Genetic susceptibility, especially involving human leukocyte antigen-DRB1 alleles, plays an important role in disease development. Environmental factors such as smoking, infections, silica exposure, and oral microbial factors may contribute to immune dysregulation. Autoantibodies such as rheumatoid factor and anti-cyclic citrullinated peptide antibodies are commonly associated with rheumatoid arthritis and may indicate more severe disease.

The management of rheumatoid arthritis has evolved significantly with the introduction of disease-modifying antirheumatic drugs, biological agents, and targeted synthetic drugs. Conventional disease-modifying antirheumatic drugs such as methotrexate, hydroxychloroquine, sulfasalazine, and leflunomide are commonly used as first-line agents. However, some patients fail to respond adequately or develop intolerance to these therapies. In such cases, biological and targeted synthetic therapies are considered.

Tofacitinib is an oral targeted synthetic disease-modifying antirheumatic drug belonging to the Janus kinase inhibitor class. It inhibits intracellular signaling pathways involved in inflammatory cytokine activity. Tofacitinib is used in patients with moderate to severe rheumatoid arthritis and may be prescribed as monotherapy or in combination with conventional disease-modifying antirheumatic drugs such as methotrexate. Although it is effective in reducing disease activity, tofacitinib may be associated with adverse effects such as infections, gastrointestinal symptoms, hematological abnormalities, altered liver enzymes, lipid abnormalities, and rare serious events.

The purpose of this study was to evaluate the side effects of tofacitinib in patients with rheumatoid arthritis in a real-world outpatient setting.

MATERIALS AND METHODS

Study design:

This was an ambispective observational study conducted over a period of six months.

Study site:

The study was conducted in the outpatient Department of Rheumatology and Clinical Immunology, Krishna Institute of Medical Sciences, Secunderabad, Telangana, India.

Study population:

A total of one hundred adult patients diagnosed with rheumatoid arthritis and receiving tofacitinib therapy were included in the study.

Inclusion criteria:

Patients aged eighteen years and above, diagnosed with rheumatoid arthritis according to clinical criteria, currently receiving tofacitinib therapy, and willing to provide informed consent were included.

Exclusion criteria:

Pregnant women, lactating women, and patients below eighteen years of age were excluded from the study.

Data collection:

Relevant data were collected from patient records, laboratory reports, prescriptions, and communication with healthcare professionals. The collected data included demographic details, diagnosis, comorbidities, treatment pattern, reported side effects, vital parameters, and laboratory investigations.

Parameters assessed:

The following parameters were assessed across visits: systolic blood pressure, diastolic blood pressure, pulse rate, hemoglobin, white blood cell count, platelet count, serum glutamic pyruvic transaminase, creatinine, and body weight. Reported side effects such as weight gain, urinary tract infection, and vertigo were also documented.

Ethical considerations:

The study was conducted after approval from the Institutional Ethics Committee of Krishna Institute of Medical Sciences. Written informed consent was obtained from participants before enrollment. Patient confidentiality was maintained throughout the study.

Statistical analysis:

Data were analyzed using descriptive statistics, standard deviation, and repeated measures analysis of variance. A p value less than 0.05 was considered statistically significant.

RESULTS

A total of one hundred patients receiving generic tofacitinib were included in the study.

Demographic characteristics:

The mean age of the study population was 50.67 years with a standard deviation of 11.545 years. The minimum age was twenty-two years and the maximum age was seventy-nine years. Females constituted eighty-eight percent of the study population, while males constituted twelve percent.

Table 1. Distribution of gender

Gender	Frequency	Percentage
Female	88	88
Male	12	12
Total	100	100

Distribution of diagnosis:

Among the study population, eighty-six percent of patients were rheumatoid arthritis seropositive, while fourteen percent were rheumatoid arthritis seronegative.

Table 2. Distribution of diagnosis

Diagnosis	Frequency	Percentage
Rheumatoid arthritis seropositive	86	86
Rheumatoid arthritis seronegative	14	14
Total	100	100

Distribution of comorbidities:

The most common comorbidity was osteoarthritis, observed in twenty-one percent of patients, followed by hypothyroidism in seventeen percent, anemia in fifteen percent, Sjogren's syndrome in fifteen percent, hypertension in thirteen percent, osteoporosis in nine percent, diabetes mellitus in six percent, hypovitaminosis D in five percent, and coronary artery disease in two percent.

Table 3. Distribution of comorbidities

Comorbidity	Frequency	Percentage
Osteoarthritis	21	21
Hypothyroidism	17	17
Anemia	15	15

Sjogren's syndrome	15	15
Hypertension	13	13
Osteoporosis	9	9
Diabetes mellitus	6	6
Hypovitaminosis D	5	5
Coronary artery disease	2	2

Distribution of side effects:

The side effects reported during the study were weight gain in twenty-one percent of patients, vertigo in two percent, and urinary tract infection in one percent.

Table 4. Distribution of side effects

Side effect	Frequency	Percentage
Weight gain	21	21
Vertigo	2	2
Urinary tract infection	1	1

Distribution of treatment:

During the first visit, forty-seven patients were receiving tofacitinib alone, while fifty-three patients were receiving tofacitinib with methotrexate. During the second visit, forty-two patients were receiving tofacitinib alone, while fifty-eight patients were receiving tofacitinib with methotrexate. During the third visit, forty-seven patients were receiving tofacitinib alone, while fifty-three patients were receiving tofacitinib with methotrexate.

Table 5. Distribution of treatment pattern

Treatment	Visit 1	Visit 2	Visit 3
Tofacitinib	47	42	47
Tofacitinib with methotrexate	53	58	53
Total	100	100	100

Vital parameters and laboratory findings:

No statistically significant changes were observed in systolic blood pressure, diastolic blood pressure, pulse rate, hemoglobin, white blood cell count, platelet count, serum glutamic pyruvic transaminase, or body weight across visits. Creatinine showed a p value of 0.042. However, the observed values did not indicate clinically meaningful renal dysfunction.

Table 6. Comparison of vital and laboratory parameters across visits

Parameter	Visit 1 mean	Visit 2 mean	Visit 3 mean	p value
Systolic blood pressure	123.36	120.47	120.84	0.332
Diastolic blood pressure	77.29	77.21	76.97	0.945
Pulse rate	90.11	91.40	91.40	0.655
Hemoglobin	12.1189	12.1689	11.36	0.508
White blood cell count	7649.01	7465.71	7754.73	0.390
Platelet count	2.9788	2.9290	2.95	0.775
Serum glutamic pyruvic transaminase	21.95	22.79	20.04	0.118
Creatinine	0.8154	0.7933	0.75	0.042

Body weight:

The total body weight at visit one was 6204.88, while the total body weight at visit three was 6383.41. The calculated percentage change was below the five percent threshold used to define significant weight gain. Therefore, no significant treatment-related body weight change was observed.

DISCUSSION

Tofacitinib is an oral Janus kinase inhibitor used in the treatment of rheumatoid arthritis, particularly in patients who have inadequate response or intolerance to conventional disease-modifying antirheumatic drugs. It acts by inhibiting intracellular Janus kinase pathways involved in

cytokine signaling and inflammatory responses. As an oral targeted synthetic therapy, tofacitinib offers an alternative to injectable biological agents.

In the present study, the majority of patients were female, accounting for eighty-eight percent of the study population. This finding is consistent with the known epidemiology of rheumatoid arthritis, which is more common in females than males. Most patients were rheumatoid arthritis seropositive, which may reflect the common clinical presentation of patients attending rheumatology outpatient care.

The reported side effects in this study were limited. Weight gain was observed in twenty-one percent of patients, urinary tract infection in one percent, and vertigo in two percent. No cases of tuberculosis, malignancy, thromboembolic events, or major cardiovascular complications were reported during the study period. These findings suggest that tofacitinib was generally well tolerated in the observed population.

The analysis of vital parameters showed no significant changes in systolic blood pressure, diastolic blood pressure, or pulse rate across visits. This indicates that tofacitinib did not produce clinically relevant changes in cardiovascular vital parameters during the study period.

Laboratory parameters, including hemoglobin, white blood cell count, platelet count, and serum glutamic pyruvic transaminase, remained stable across visits. This suggests that no major hematological or hepatic abnormalities were observed in the study population. Creatinine showed a p value of 0.042, but the observed values remained within a clinically acceptable range and did not indicate significant renal impairment.

The weight analysis showed no significant change based on the defined cut-off of five percent. Although weight gain was reported in some patients, the overall change in weight did not qualify as clinically significant at the group level.

The findings of this study are generally consistent with previous clinical and real-world studies showing that tofacitinib is effective and generally tolerable in patients with rheumatoid arthritis. However, previous literature has reported potential risks such as serious infections, lipid abnormalities, cardiovascular events, malignancy, and thromboembolic events in selected high-risk populations. Therefore, continued monitoring remains important during tofacitinib therapy.

Limitations:

This study had some limitations. The sample size was limited to one hundred patients. The study duration was six months, which may not be sufficient to detect delayed or rare adverse effects. Lipid profile changes were not included in the presented results, although lipid monitoring is clinically important during tofacitinib therapy. The study was conducted at a single center, which may limit generalizability.

CONCLUSION

This observational study found that tofacitinib was generally well tolerated among patients with rheumatoid arthritis. The most commonly reported side effect was weight gain, followed by vertigo and urinary tract infection. No major adverse effects were observed based on vital parameters and laboratory results during the study period.

No significant changes were observed in systolic blood pressure, diastolic blood pressure, pulse rate, hemoglobin, white blood cell count, platelet count, serum glutamic pyruvic transaminase, or

body weight. Creatinine showed statistical variation but no clinically meaningful renal impairment. Overall, the findings suggest that tofacitinib has an acceptable short-term safety profile in the studied rheumatoid arthritis population, although long-term monitoring is necessary.

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