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RESEARCH ARTICLE

COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF METHOTREXATE AND TOFACITINIB IN PATIENTS DIAGNOSED WITH RHEUMATOID ARTHRITIS

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ABSTRACT

Introduction: An inflammatory condition called rheumatoid arthritis (RA) results in persistent joint inflammation, which is painful and incapacitating. There are no racial or ethnic disparities in the prevalence of RA, which is believed to be between 1% and 2% worldwide. Inflammation is indicated by elevated blood levels of the C-Reactive Protein (CRP), which can be used to identify and track the illness. RA patients often experience a heavy burden of pain, disability, and limited activities, all of which have an impact on their health-related quality of life. Given the rising prevalence of RA worldwide, it is necessary to evaluate the efficacy and safety of medications and offer appropriate treatment to enhance patients' quality of life. *Methodology:* This was a prospective study conducted in orthopaedic OPD of ESIC Model Hospital Bari Brahamna in Jammu district. All the subjects (n=100) meeting the inclusion and exclusion criteria were briefed about the purpose of the study and the informed consent was obtained. The subject's demographic details and responses were collected. All the enrolled patients were assessed at the time of starting the treatment, then at 2nd month and 5th month. The collected data were entered in microsoft excel and appropriate descriptive analysis was performed. ***Results:*** A total of 100 samples were enrolled in the study based on inclusion and exclusion criteria. Out of which 50% of the participants were on Methotrexate (MTX) and the other 50% were on Tofacitinib. Majority of the subjects in the study were women (79%) and men (21%) . On comparing the effectiveness of both Methotrexate and Tofacitinib, it was found that the rate of reduction of CRP levels and ESR was better with Tofacitinib in comparison to Methotrexate. ***Conclusion:*** From this study, Tofacitinib concludes to be more effective than Methotrexate with regard to its ability to decrease CRP levels and ESR in high disease activity patients.

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INTRODUCTION

Rheumatoid Arthritis (RA) is a chronic inflammatory arthritis characterized by inflammation of the synovial lining of the joints, tendons and periarticular structures, with main disease features of joint pain, swelling and joint destruction (Lee 2001). It often begins with synovial membrane swelling and progresses to joint damage and abnormalities. If treatment is not received, it gradually affects the skin, eyes, heart, and lungs, making it a progressive disease. About 40% of RA patients experience extra-articular manifestations. It is frequently distinguished by morning stiffness lasting more than 30 minutes, fever, weight loss, swollen joints, and tenderness. Extra-articular and symmetrical joint involvement makes RA different from other types of arthritis. There is no racial preference for RA, which is thought to affect 1% to 2% of people worldwide. In the US, it impacts around 1.5 million individuals, and in India, it impacts 0.92% of adults. In the Indian population, the disease's incidence varies from 0.5% to 3.8% for males and from 0.15% to 1.37% for women, which is three to four times greater for women. Environmental and genetic variables have a major role in RA. Individuals who have differences in the Human Leukocyte Antigen (HLA) genes (HLA-DRB1*04, HLA-DRB1*10, and HLA-DRB1*01) are at risk for developing RA. Other risk factors for RA include exposure to tobacco smoke, bacterial infections, female sex, and family history of RA. Pharmacological and nonpharmacologic therapies, such as patient education, psychological interventions, weight control, and enough rest, are all part of the RA management program. The first- line therapy for RA is methotrexate (MTX), also known as a disease-modifying anti-rheumatic drug (DMARD) (Singh 2012). It suppresses inflammation and immune reactions by inhibiting amino imidazole 4-carboxamide ribonucleotide which increases adenosine levels. Tofacitinib is also found to have an increased discontinuation rate (6.9%) due to adverse drug events, including infections (Urinary tract and Herpes zoster), malignancies, increased blood creatinine, etc. Since these medications are administered over an extended period of

time, it is vital to keep an eye on their efficacy and safety. The effectiveness of drugs can be measured by evaluating C-reactive protein (CRP), Erythrocyte Sedimentation rate (ESR), Rheumatoid factor (RA FACTOR) levels which are a marker for systemic inflammation in RA, higher CRP levels, ESR levels and RA factor levels were linked with greater disease activity. Despite the severity of the disease, adverse drug reactions/adverse events also have an impact on the patient's Quality of life resulting from the individual burden of physical and mental distress.

MATERIALS AND METHODS

The present study was conducted in the orthopaedics OPD of ESIC Model Hospital Bari Brahamna Jammu. On an average, 80-100 patients visit the OPD on daily basis.

Study design: A cross-sectional hospital-based study.
Study period: The study was conducted for a period of 8 months w.e.f. 01 May 2024 to 31st December 2024.
Study population: The study population consists of patients of Rheumatoid Arthritis aged 20 years and above attending orthopaedics OPD of ESI Model Hospital Bari Brahamna Jammu.

Inclusion Criteria

Subjects willing to give consent.
Subjects of age 20 years and above.
Subjects of both the gender.
Subjects diagnosed with Rheumatoid Arthritis.
Subjects prescribed with either Methotrexate or Tofacitinib.

Exclusion Criteria

Individuals not willing to provide information.
Pregnant and lactating women.

Ethical consideration: The approval was taken from the Institutional Ethics Committee (IEC)

Sampling technique: Convenient sampling method was used to recruit the patients into the study.

Data collection: Each eligible and willing participant were explained the purpose of the study in their local dialect by the investigator and assured that all the information gathered shall be kept confidential. Thereafter, written informed consent was taken from the participants and interview was conducted in accordance to the pre-designed semi structured study proforma.

RESULTS

A Total of 100 patients diagnosed with Rheumatoid Arthritis were enrolled in the study. Out of these 100, 50 patients were put on Methotrexate (7.5mg weekly) and the 50 patients on tofacitinib (5mf BD). Table 1 shows the age distribution of the patients in the two drug groups. Mean age of the patients in the Tofacitinib drug group was found to be 47.12±10.6 whereas it was found to be 44.36±10.29 in the methotrexate group. Maximum number of the patients were in the age group 41-50 years in the both the groups.

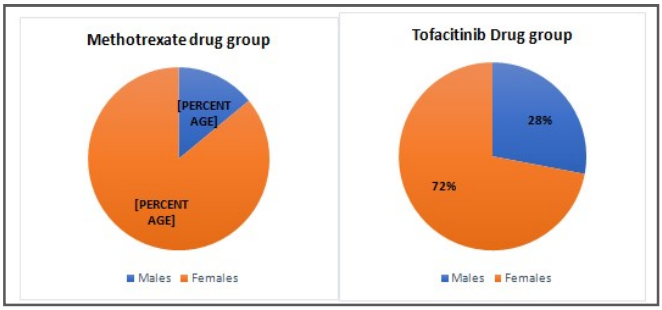

Fig. 1. Gender wise distribution of the patients in the two treatment groups

Table 1. Age distribution of patients in the two study groups

Age group	Number of patients	
	Tofacitinib group n (%)	Methotrexate groupn (%)
20-30	01 (02)	05 (10)
31-40	12 (24)	11 (22)
41-50	23 (46)	20 (40)
51-60	07 (14)	13 (26)
61-70	05 (10)	01 (02)
>70	02 (04)	00 (00)
Total	**50**	**50**

Table 2 shows the comparison of the CRP values of both the drug groups at the start of treatment, at 2nd month and 5th month of starting the treatment. Both drug groups show a reduction in CRP values over time. Tofacitinib shows a more pronounced decrease in CRP, from 14.20 at the start to 5.52 by the 5th month. Methotrexate starts at 9.79 and decreases slightly to 6.18 by the 5th month. Tofacitinib appears to have a greater overall reduction in CRP compared to Methotrexate.

Table 2. Comparison of the CRP between Tofacitinib and Methotrexate group

	CRP Value		
Drug group	Start of treatment	2nd month	5th month
Tofacitinib (5mg BD)	14.20±18.23	9.90±12.95	5.52±10.50
Methotrexate (7.5mg/week)	9.79±11.41	9.12±11.87	6.18±8.42

Table 3 shows the comparison of the ESR values of both the drug groups at the start of treatment, at 2nd month and 5th month of starting the treatment. Both treatments show a reduction in ESR values over time. Tofacitinib shows a more significant decrease in ESR from the start of treatment (56.22) to the 5th month (26.02) compared to Methotrexate, which starts at 50.18 and decreases to 29.79. The reduction in ESR is more pronounced in Tofacitinib in the 2nd and 5th months.

Table 3. Comparison of the ESR between Tofacitinib and Methotrexate group

	ESR Value		
Drug group	Start of treatment	2nd month	5th month
Tofacitinib (5mg BD)	56.22±26.21	44.64±19.72	26.02±15.67
Methotrexate (7.5mg/week)	50.18±25.07	43.26±22.49	29.79±20.52

Table 4 shows the comparison of the DAS28 ESR and DAS28 CRP between Tofacitinib and Methotrexate group. Tofacitinib shows a greater reduction in DAS 28 scores (both ESR and

CRP-based) compared to Methotrexate over the 5 months. At the start of treatment, both drugs show relatively similar DAS28 scores. Tofacitinib has a noticeable reduction in both ESR and CRP DAS 28 scores by the 5th month DAS 28 ESR: 3.31, DAS 28 CRP: 2.58. Methotrexate also shows improvement, but the reduction is more gradual, with a DAS 28 ESR of 3.98 and DAS 28 CRP of 3.16 by the 5th month.

DISCUSSION

The study was a 8 month long observational study performed in orthopaedics OPD of ESIC Model Hospital Bari Brahamna Jammu. The inclusion and exclusion criteria were used to enroll 100 samples in total. The participants were split equally between the two medication groups; 50 patients received tofacitinib and 50 subjects received methotrexate. Participants in the Methotrexate group were 44.36 years old on average, whereas those in the Tofacitinib group were 47.12 years old on average. Women made up the majority of the study's participants. In this research, it was found that 79% of the subjects were women which is similar to the mean age of participants in the study conducted by Fleischmann *et al*. and only 21% of subjects were men. Comparison of the effectiveness of both Methotrexate and Tofacitinib in the study revealed that Tofacitinib had better effectiveness as it reduced C- reactive protein better than Methotrexate at 5th month from the start of the treatment, the result was similar to the study conducted by Eun Bong Lee *et al*., It was obtained from the comparison of mean values of C-reactive protein of Methotrexate and Tofacitinib groups at 5th month which was found to be 6.18 and 5.52 respectively. EKIN A *et al* evaluated the effectiveness of tofacitinib, parameters such as VAS Pain, VAS Fatigue, SDAI, CDAI, DAS28-CRP, DAS28-ESR, CRP, and ESR were assessed at the third- and sixth-month visits after the first visit. There were significant decreases in the disease activity indexes such as DAS 28-ESR AND DAS 28-CRP in both the 3rd and 6th month visits compared to the first visit, which were similar to the results of our study. In our study Tofacitinib was found to have better outcome as compared to methotrexate group whereas in a multicentre, double-blind trial, in which 999 patients were randomized to leflunomide (LEF) or oral MTX for 52 weeks [Emery *et al.* 2000]. Treatment with MTX resulted in better results for tender and swollen joint counts, physician and patient global assessments, and erythrocyte sedimentation rate (ESR).

CONCLUSION

The study aimed to compare the effectiveness of methotrexate and tofacitinib in patients with rheumatoid arthritis. The results indicated that tofacitinib is more effective than methotrexate in managing rheumatoid arthritis. With the help of the findings from our study, doctors can provide a better choice of treatment option to help patients with rheumatoid arthritis have a higher quality of life. Rheumatoid arthritis is a chronic, progressive, and long-term condition that causes severe joint deformity and functional disability, raising serious health concerns.

Limitation of the study: Our limitations were that our study was a single centered and the number of patients was small.

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