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Original Article

Comparative Efficacy of Janus Kinase Inhibitor (Tofacitinib) in Treatment and Disease Activity of Ankylosing Spondylitis

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ABSTRACT

Objective: To investigate the effectiveness of Janus Kinase Inhibitor (Tofacitinib) given in the treatment and disease activity of ankylosing spondylitis patients.
Study Design: Quasi-Experimental Study.
Place and Duration of Study: Rheumatology Department, Pak-Emirates Military Hospital, Rawalpindi Pakistan, from Mar to May 2023.
Methodology: Patients of either gender aged 25 to 60 years diagnosed with axSpA for at least 1 year with inadequate response to NSAIDs, lifestyle modification, exercise, and physiotherapy, and naïve to a bDMARD or JAK inhibitor were included. Patients were divided into two groups, I and II, in a ratio of 1:1 based on patient preference and clinical judgement of the treating physician. Group-I was given NSAIDs + Tofacitinib, while Group-II received NSAIDs + Etanercept. Pre- and post-treatment at 3-month clinical and inflammatory parameters, including Schober`s test, BASDAI score, ESR, CRP, and platelet count, were noted and compared for drug response.
Results: A total of 224 patients with ankylosing spondylitis having a median age of 47.00 (12.00) years, were included, with 117(52.2%) males and 107(47.8%) females. The pre-treatment Schober`s test, platelet count, and CRP were noted, which were statistically insignificant in both groups (p=0.948, p=0.504, and p=0.804, respectively. As per baseline BASDAI score, overall, 58(51.12%) was in acute flare, and 120(53.57%) patients had high/extremely high disease activity. At 3-month Tofacitinib Group showed slightly better improvement in Schober's test as compared to Etanercept Group (p<0.001). At 3-month BASDAI score showed 52(46.42%) patients improved to low disease activity or achieved remission as compared to 34(30.35%) patients in Etanercept Group.
Conclusion: The Tofacitinib Group had slightly better disease control in terms of pain, rotation of movement, and improvement in quality of life.

Keywords: Ankylosing Spondylitis, Etanercept, Janus Kinase Inhibitors, Schober's Test, Tofacitinib.

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INTRODUCTION

Ankylosing Spondylitis (AS) or Axial Spondyloarthritis (axSpA) is a clinical manifestation of Spondyloarthropathy (SpA) starting as chronic back pain and progressing to reduced mobility and ultimately vertebral fusion over years.[1] SpA occurs in the background of a particular genetic makeup that leads to complex interactions between the gut microbiome, various immune cells, and mechanical stress on certain structures. The major mediators are Tumor Necrosis Factor-α (TNF-α) and Interleukin-17 (IL-17).[2] Overall prevalence of AS in Pakistan is 0.5 to 1%, and it comprises around 5% of the cases of chronic backache presenting in OPDs.[3] The back pain and stiffness, most debilitating effects of AS, both physical and psychological, severely limit a person's ability to carry out the daily activities requiring aggressive therapy.[4] Non-pharmacological treatment, including lifestyle advice, exercise, physiotherapy, and psychosocial support, remains the initial and mainstay of the treatment.[5]

Biologic Disease Modifying Anti-Rheumatic Drugs (bDMARDs) are either monoclonal antibodies or decoy receptors that can block cytokines or their pathways implicated in disease pathogenesis with high specificity. The primary targets are IL-17, IL-23, and tumor necrosis factor (TNF) inhibitors.[6] However, they remain expensive and have somewhat cumbersome administration. Thus, new medications with the potential to delay the disease's radiological progression must be made available to ensure better compliance and a good quality of life for the patients.[7]

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In recent years, research in rheumatoid arthritis (RA) has revealed that Janus kinase inhibitors successfully overcame disease progression. Tofacitinib, classified as a novel oral Janus kinase (JAK) inhibitor, a targeted synthetic (ts)DMARD introduced in the last decade, has been used for various autoimmune diseases, including RA.[8] It favorably inhibits signaling through heterodimeric receptors allied with JAK3 and JAK1, thereby blocking several cytokines (interleukins 2, 4, 7, 9, 15, and 21) signaling integral to lymphocyte function and modulation of immune responses.[9]

Ankylosing spondylitis (AS) management remains challenging, particularly in patients who are non-responsive to NSAIDs. While bDMARD targeting TNF-α and IL-17 have improved the outcomes, their high cost and parenteral administration limit accessibility and adherence.[10] Tofacitinib offers a promising alternative by modulating multiple cytokine pathways involved in AS pathogenesis. Approved for AS treatment in 2021, its efficacy and safety in real-world settings need further evaluation. This study aims to assess its clinical impact for AS patients in Pakistan, potentially improving treatment accessibility and patient compliance.

METHODOLOGY

This study was a Quasi-Experimental study done at Rheumatology Department, Pak Emirates Military Hospital, Rawalpindi Pakistan, from Mar to May 2023. Institutional Ethical Review Committee approval taken before starting the study (A/28/235/EC/530/23). Verbal informed consent was also taken from the participants for enrollment and publication of their data. Patient anonymity was ensured at every step of the study. Sample size was calculated based on the reported prevalence of ankylosing spondylitis as 5.3% in patients presenting to the rheumatological OPD with chronic backache.[11] Open Epi online sample size calculator was used, keeping a 95% confidence level and 5% margin of error; the sample size was calculated to be 78 patients per group.

Inclusion Criteria: Patients of either gender aged 25 to 60 years diagnosed with axSpA for at least 1 year and had been previously treated with NSAIDs, lifestyle modification, exercise, and physiotherapy with inadequate response, naïve to bDMARD or JAK inhibitors, and having no underlying contraindication for a JAK inhibitor or Anti-TNF-α agent were included.

Exclusion Criteria: AS patients with age <25 and 60 years, having Osteoarthritis, active or past history of hepatitis B or C, TB, chronic liver disease or chronic kidney disease, pregnancy, BMI > 30 kg/m2, terminal illness or malignancy were all excluded from this study.

Sampling was done using a convenience sampling technique, and all patients of axSpA presenting to the rheumatology OPD, fulfilling the criteria, were included in the study. A thorough clinical examination was done, and Schober's test was performed using a measuring tape. Patients were asked to face the wall and stand straight with feet apart to become in line with their shoulders. They were exposed from waist to a point at least 5 centimeters below the horizontal line between posterior superior iliac spine. The midpoint of this horizontal line was marked, and a second mark was made 10 centimeters above this. Patients were then asked to bend forward as much as possible with ease, and distance between these two marks was measured again. The difference was noted down, and test was performed again. Mean of the two values was recorded. The Bath Ankylosing Spondylitis Disease Severity Index (BASDAI) score was calculated using an Android mobile-based application (MDCalcR) and noted down. Patients were also advised laboratory investigations on the same day, including complete blood picture (CBC), Erythrocyte Sedimentation Rate (ESR), and C - reactive protein (CRP). The results of these investigations were recorded as well.

Patients were then divided into two groups, I and II, in a ratio of 1: 1 based on patient preference and clinical judgement of the treating physician. Both groups were given an NSAID, in addition to the second agent. Group-I was to receive NSAIDs + Tofacitinib, while Group-II received NSAIDs + Etanercept. Tofacitinib was given at a dose of 5 milligrams orally twice a day, whereas Etanercept was given at a dose of 50 milligrams weekly via the subcutaneous route. A total of 238 patients were assessed for eligibility, and only 8 were excluded. During follow-up, a few side effects, including nausea, vomiting, and gastritis, were observed in both experimental groups, and six patients were removed from the final analysis because of loss to follow-up or side effects. Patients were called for follow-up in the OPD after 3 months; the same clinical and laboratory investigations as at the time of enrollment were done, and results were jotted down (Figure).

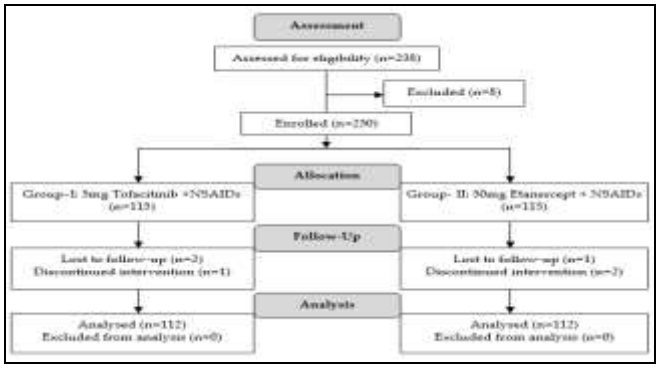

Figure: Patient Enrollment Flow Diagram (n=224)

Data were entered in the Statistical Package for Social Sciences software version 25 (SPSS v25.0) and analyzed. Normality of the data was checked using the Kolmogorov-Smirnov test. Quantitative variables were presented as median (Interquartile Range), while qualitative variables were presented as frequencies and percentages. Comparisons were made for every observation between baseline and 3 months. Intragroup comparisons were made using the Wilcoxon signed rank test, whereas for intergroup comparisons, the Mann-Whitney U test. A *p*-value of ≤0.05 was considered significant.

wise distribution of different characteristics at the beginning of the study has been summarized in Table-I.

The same parameters were compared in both groups after 3 months to see if any improvement had occurred with either treatment regimen. Both regimens were found to be effective for control of symptoms ($p<0.0001$). However, BASDAI score for disease activity showed that the Tofacitinib Group had slightly better, although statistically insignificant, disease control in terms of pain, rotation of movement, and improvement in quality of life. (Table-II).

Table-I: Characteristics of both Groups at the start of Study (n=224)

Variable		Group-I Tofacitinib + NSAIDs (n=112)	Group-II Etanercept + NSAIDs (n=112)	*p*-value
Age (years), median [IQR]		48.00(12.00)	45.50(12.00)	0.162
Gender	Male	59(52.67%)	58(51.78%)	1.00
	Female	53(47.33%)	54(48.22%)	
BASDAI Score	Moderate (1.1-2.0)	25(22.32%)	21(18.75%)	0.737
	High (2.1-4.0)	36(32.14%)	43(38.39%)	
	Very High (4.1-6.0)	20(17.85%)	21(18.75%)	
	Flare (6.1-10.0)	31(27.67%)	27(24.1%)	
Schober's Test (cm), median [IQR]		10.00(3.00)	10.00(3.00)	0.948
ESR (mm), median [IQR]		29.00(5.80)	26.00(6.80)	0.001
CRP (mg/dL), median [IQR]		10.00(4.00)	10.00(4.00)	0.504
Platelet Count (x 109/L), median [IQR]		392.00(89.00)	392.00(64.00)	0.804

BASDAI = Bath Ankylosing Spondylitis Disease Activity Index, IQR = Interquartile Ratio, ESR = Erythrocyte Sedimentation Rate, CRP = C- reactive Protein

Table-II: Intragroup Comparison of Tofacitinib and Etanercept Groups at Baseline and 3 Months (n=224)

Variable		Tofacitinib + NSAIDs (n=112)			Etanercept + NSAIDs (n=112)		
		Baseline	3 months	*p*-value	Baseline	3 months	*p*-value
BASDAI Score	Low (0.1-1.0)	0	52(46.42%)	<0.0001	0	34(30.35%)	<0.0001
	Moderate (1.1-2.0)	25(22.32%)	37(33.03%)		21(18.75%)	43(38.39%)	
	High (2.1-4.0)	36(32.14%)	22(19.64%)		43(38.39%)	29(25.89%)	
	Very High (4.1-6.0)	20(17.85%)	1(0.89%)		21(18.75%)	6(5.35%)	
	Flare (6.1-10.0)	31(27.67%)	0		27(24.1%)	0	
Schober's Test (cm), median [IQR]		10.00(3.00)	14.00(2.00)	<0.0001	10.00(3.00)	13.50(2.00)	<0.0001
ESR (mm), median [IQR]		29.00(5.80)	24.00(6.00)	<0.0001	26.00(6.80)	22.00(6.00)	<0.0001
CRP (mg/dL), median [IQR]		10.00(4.00)	7.00(3.00)	<0.0001	10.00(4.00)	8.00(3.00)	<0.0001
Platelet Count (x 109/L), median [IQR]		392.00(89.00)	341.00(58.00)	<0.0001	392.00(64.00)	345.00(64.00)	<0.0001

RESULTS

A total of 224 patients of ankylosing spondylitis having a median age of 47.00 (12.00) years, were included in the study, with 117(52.2%) males and 107(47.8%) females. The pre-treatment Schober's test, platelet count, and CRP were noted, which were statistically insignificant in both groups ($p=0.948$, $p=0.504$, and $p=0.804$, respectively). However, ESR was slightly higher in Tofacitinib Group median of 29.00(5.80), as compared to Etanercept group, 26.00(6.80). BASDAI score was also statistically insignificant in both groups, and noted that overall, 58(51.12%) was in acute flare, and 120(53.57%) patients had high/extremely high disease activity. The group-

Table-III: Comparison of Tofacitinib/NSAIDs and Etanercept/ NSAIDs Groups at 3 months (n=224)

Variable		Tofacitinib + NSAIDs (n=112)	Etanercept + NSAIDs (n=112)	*p*-value
BASDAI Score	Low (0.1-1.0)	52(46.42%)	34(30.35%)	0.737
	Moderate (1.1-2.0)	37(33.03%)	43(38.39%)	
	High (2.1-4.0)	22(19.64%)	29(25.89%)	
	Very High (4.1-6.0)	1(0.89%)	6(5.35%)	
Schober's Test (cm), median [IQR]		14.00(2.00)	13.50(2.00)	<0.0001
ESR (mm), median [IQR]		24.00(6.00)	22.00(6.00)	0.129
CRP (mg/dL), median [IQR]		7.00(3.00)	8.00(3.00)	0.307
Platelet Count (x 109/L), median [IQR]		341.00(58.00)	345.00(64.00)	0.063

The Tofacitinib Group showed slightly better improvement in Schober's test as compared to

Etanercept Group (p<0.001). BASDAI score calculated at 3 months showed 52(46.42%) patients improving to low disease activity or achieving remission as compared to 34(30.35%) patients in Etanercept Group. Comparison of 3-month characteristics between both treatment groups showed comparable results with non-significant p-values (Table-III).

DISCUSSION

In our study comparing Tofacitinib plus NSAIDs versus Etanercept plus NSAIDs in ankylosing spondylitis patients with inadequate NSAID alone response, both treatment regimens demonstrated significant improvements over three months. It was observed that ankylosing spondylitis patients had good pain control with better functional status when treated with bDMARDs along with NSAIDs in comparison to only NSAID treatment. Although NSAIDs were first pharmacological treatment for SpAs, as explained by Nander *et al.,* bDMARDs like TNF-α inhibitors, IL-17i, and JAK inhibitors have shown better efficacy in improving symptoms, controlling pain, preventing axial damage, and improving quality of life.[12] Similar results were shown by Deodhar *et al.,* that in NSAID non-responders patients of ankylosing spondylitis, bDMARDs had better results and efficacy in controlling disease flare and maintaining remission.[13]

This study showed that Tofacitinib and Etanercept, both biological agents, had statistically insignificant but better efficacy in terms of pain control, reducing inflammatory markers, and improving skeletal mobility. In a randomized control trail by Garcia *et al.,* substantial improvements were seen in terms of pain control and disease activity in AS patients at week 14 of treatment with Upadacitinib (JAK inhibitor), a bDMARDs (45%) vs placebo (18%) (p<0.0001).[14]

In our study, it was seen that 52(46.42%) out of 112 patients in Tofacitinib Group went into remission with low disease activity at 3 months of treatment, as compared to 34(30.35%) in Etanercept group. Similarly, Viswanath *et al.,* showed in a randomized control trail that at week 16 of treatment with Tofacitinib (JAK inhibitor), the AS disease activity response rate was significantly higher (56.4%, 75/133) versus placebo (29.4%, 40/136) (p<0.0001).[15]

The BASDAI score, ESR, and C-reactive protein (CRP) are three commonly used clinical indicators for assessing and monitoring disease activity in AS, which were studied and compared in this study. After treatment, both groups showed marked reductions in disease and inflammatory markers, with many patients achieving remission or low disease activity. These findings confirm that bDMARDs such as Tofacitinib and Etanercept effectively reduce symptoms in AS patients. The use of new treatment strategies, including bDMARDs, for ankylosing spondylitis and other spondyloarthropathies (SpA) had notable improvement in quality of life and functional status of patients with SpA, as explained by Kyriokou *et al*.[16]

The pre-treatment mean CRP was 10.30±2.35 vs 10.14±2.67, and following 3-month treatment, the mean CRP was reduced in both groups, slightly more in Tofacitinib group as compared to the Etanercept group, 7.29±1.90 vs 7.62±2.13, respectively. Ward *et al.,* studied the effect of Tofacitinib in ankylosing spondylitis patients and concluded that the mean ASDAS-CRP score was 0.9±0.6 at 6-month post-treatment, which was reduced from the pre-treatment mean ASDAS-CRP score of 2.24±1.13, with remission in 77.27% (17/22) patients.[17]

Notably, the improvement in spinal mobility, as assessed by Schober's test, was significantly greater in the Tofacitinib Group compared to the Etanercept group (p<0.001). This suggests that while both treatments are beneficial, Tofacitinib may offer an additional advantage in enhancing spinal flexibility. In another study by Perrotta *et al.,* Tofacitinib exhibited favorable effects in clinical as well as radiological outcomes of axial SpA after 12 weeks of therapy.[18] Similarly, Ogdie *et al.,* also explained that despite TNF inhibitors being first-line bDMARDs in AS and SpA, IL-17 inhibitors and JAK inhibitors displayed better efficacy and safety profile in terms of pain relief and improvement in joint inflammation, stiffness, articular function, and life quality.[19]

Given the fact that Tofacitinib is an oral agent, its efficacy combined with the ease of administration positions it as a promising alternative to parenteral biologics, particularly in settings where cost and accessibility are key concerns. The efficacy of Tofacitinib in AS in terms of better pain control and low BASDAI score at 3-month treatment with oral 5mg or 10mg Tofacitinib.[20] The findings of our study were in accordance with national and international studies on AS treatment. However, these findings underscore the potential of Tofacitinib to become a preferred treatment in the management of AS, warranting further exploration and consideration in clinical practice.

LIMITATION OF STUDY

The study included a small sample size due to the low prevalence of diagnosed disease in the country. The findings yielded fewer objective endpoints for dose response and were challenging to interpret. Some patients missed scheduled follow-ups, resulting in incomplete clinical examinations, BASDAI score calculations, and Schober's test results. Additionally, some patients who improved after two months of treatment did not obtain laboratory markers (ESR and CRP) as advised, and others missed doses, potentially affecting the study outcomes. The cost-effectiveness of biological agents was not assessed. Further research is recommended, especially on patients with more prevalent peripheral spondylitis symptoms, as current data are limited nationally and internationally.

CONCLUSION

In conclusion, our study highlights Tofacitinib as a more effective option for alleviating the symptoms in patients with Ankylosing Spondylitis (AS). By providing superior symptom relief, Tofacitinib offers a promising alternative for improving the quality of life in individuals affected by this chronic condition. Hence, providing better efficacy and being an oral agent, Tofacitinib is a potential candidate for the treatment of ankylosing spondylitis.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AM & AF: Data acquisition, data analysis, critical review, approval of the final version to be published.

BR & IA: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

FH & GAKN: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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