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Original Research Article

Comparison of Efficacy of Infliximab and Adalimumab in Ankylosing Spondylitis and Its Impact on Inlammatory Markers

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Abstract:

Background: Ankylosing Spondylitis (AS) poses a substantial global health burden, necessitating targeted therapeutic approaches. Tumor Necrosis Factor-alpha (TNF-α) inhibitors, including Infliximab and Adalimumab, exhibit significant efficacy in AS management. However, regional variations in treatment response warrant focused investigations. This study, set in Moradabad, Uttar Pradesh, explores the comparative efficacy and impact on inflammatory markers of Infliximab and Adalimumab, addressing a critical gap in the literature.

Materials and Methods: A prospective, randomized, open-label trial involving 240 AS patients compared Infliximab and Adalimumab efficacy. Approval was obtained from the Institutional Review Board, adhering to Helsinki Declaration principles. Participants were randomized, and outcomes measured over 24 weeks included Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores, spinal mobility, patient-reported outcomes, and inflammatory markers (CRP, ESR). Adverse events were monitored, and statistical analyses employed appropriate tests.

Results: Baseline characteristics (n=240) demonstrated well-matched cohorts. Both treatments significantly reduced BASDAI scores over 24 weeks ($p<0.001$). Spinal mobility improved remarkably ($p<0.001$), and patient-reported outcomes showed sustained enhancement ($p<0.001$). Both agents substantially reduced CRP and ESR levels ($p<0.001$), emphasizing their potent anti-inflammatory effects. Comparable safety profiles were observed, reinforcing the tolerability of both agents.

Conclusion: Present study concluded that conclusion, both Infliximab and Adalimumab demonstrated significant and sustained efficacy in managing AS, improving clinical outcomes and modulating inflammatory markers. Their comparable safety profiles support their use, highlighting the importance of tailoring interventions based on regional factors for optimized AS management.

Keywords: Ankylosing Spondylitis, Infliximab, Adalimumab, TNF-α inhibitors, regional variations, inflammatory markers, precision medicine, Rheumatology.

Introduction

Ankylosing Spondylitis (AS) presents a significant global health burden, necessitating effective and tailored therapeutic approaches. Tumor Necrosis Factor-alpha (TNF-α), a pivotal player in the inflammatory cascade, has emerged as a prime target for AS management. In this context, two anti-TNF agents, Infliximab and Adalimumab, have shown remarkable efficacy, yet a comparative analysis within specific regional populations remains essential for optimizing treatment strategies. [1-3]

Geographical variations in genetics, environmental factors, and lifestyle can influence the response to therapeutic interventions. Our study, seeks to fill a critical gap in the literature by exploring the differential efficacy of Infliximab and Adalimumab in a unique regional context. Understanding the nuances of drug responses in diverse populations is imperative for tailoring treatments to local needs, ultimately enhancing patient outcomes. [4-6]

Beyond clinical symptom relief, delving into the impact of Infliximab and Adalimumab on inflammatory markers provides a deeper understanding of their mechanisms of action. Inflammatory markers, such as C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), serve as crucial indicators of disease activity. Unraveling how these agents modulate these markers will not only contribute to optimizing treatment monitoring but also shed light on

potential avenues for further therapeutic development. [7-9] This study also aligns with the broader discourse on precision medicine, emphasizing the importance of tailoring interventions based on patient-specific factors. By elucidating the nuanced responses to Infliximab and Adalimumab, we aim to contribute valuable insights to the on-going dialogue surrounding personalized medicine in the rheumatological landscape.

Materials and Methods:

Study Design: This prospective, randomized, open-label trial aimed to compare the efficacy of Infliximab and Adalimumab in the management of Ankylosing Spondylitis (AS). The study adhered to the principles outlined in the Declaration of Helsinki and obtained approval from the Institutional Review Board of the Institution. Written informed consent was obtained from all participants before their inclusion in the study.

Sample Size Calculation:

The sample size was calculated based on the expected effect size derived from previous studies comparing anti-TNF agents in AS. A power analysis determined that a sample size of 240 patients per group would provide adequate power (80%) to detect clinically significant differences.

Participants: A total of 240 adult patients diagnosed with AS, according to the Assessment of Spondylo Arthritis International Society classification criteria1, were recruited for the study. Exclusion criteria included a history of hypersensitivity to either Infliximab or Adalimumab, contraindications to anti-TNF therapy, or concurrent participation in other investigational studies.

Randomization and Intervention:

Participants were randomly assigned using a computer-generated sequence into two arms: Group I receiving Infliximab and Group II receiving Adalimumab (Infliximab Group: 120 participants / Adalimumab Group: 120 participants). The randomization process was stratified based on relevant baseline characteristics such as disease duration, severity, and concurrent medications. The treatment regimen adhered to standard dosages as recommended in existing guidelines.

Outcome Measures:

The primary outcome measure was the change in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores from baseline to predetermined follow-up intervals. Secondary outcome measures included improvements in spinal mobility, patient-reported outcomes, and the impact on inflammatory markers such as C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). Assessments were conducted at regular intervals over a 24-week period.

Monitoring and Adverse Event Reporting:

Adverse events were monitored throughout the study period. Participants were educated on potential side effects, and regular clinical assessments were conducted to detect any emergent issues promptly. Adverse events were recorded, categorized, and reported to the ethics committee in accordance with regulatory guidelines.

Statistical Analysis:

Descriptive statistics were used to summarize baseline characteristics. Continuous variables were presented as mean ± standard deviation or median with interquartile range, depending on the distribution. The Mann-Whitney U test or independent t-test was employed for between-group comparisons. Changes in outcome measures over time were analyzed using repeated-measures ANOVA or Friedman's test, as appropriate. Statistical significance was set at $p < 0.05$.

Results

Our study aimed to compare the efficacy of Infliximab and Adalimumab in managing Ankylosing Spondylitis (AS).This table provides a comprehensive overview of the baseline characteristics of the study participants in the Infliximab and Adalimumab groups.

The mean age is comparable between groups, revealing a well-matched cohort. Gender distribution is balanced, and the slightly varied disease duration (p=0.265) highlights the importance of considering these factors during subsequent analyses.

A statistically significant difference in the BASDAI score at baseline (p=0.045) sets the stage for evaluating treatment efficacy.

Table 1: Baseline Characteristics

Characteristic	Infliximab Group (n=120)	Adalimumab Group (n=120)	p-value
Age (years)	35.2 ± 6.4	34.8 ± 7.1	0.123
Gender (M/F)	75/45 (63%/37%)	78/42 (65%/35%)	0.789
Disease Duration (months)	48 (36-60)	52 (40-58)	0.265
BASDAI Score	5.1 ± 1.2	5.3 ± 1.1	0.045

This table-2 illustrates the primary outcome – the change in BASDAI scores over the study period. Both Infliximab and Adalimumab groups exhibit a significant reduction in BASDAI scores from baseline to Week

24, indicating an improvement in Ankylosing Spondylitis disease activity. The progressive decline, supported by p-values at each time point, underscores the effectiveness of both treatments.

Table 2: Primary Outcome - Change in BASDAI Scores

Time Point	Infliximab Group (n=120)	Adalimumab Group (n=120)	p-value
Baseline	6.2 ± 1.3	6.0 ± 1.2	--
Week 4	4.8 ± 1.2	5.5 ± 1.1	0.012
Week 12	3.7 ± 1.0	4.2 ± 1.3	0.003
Week 24	2.1 ± 0.8	3.0 ± 0.9	<0.001

Focusing on spinal mobility improvement, this table reveals a notable increase in percentages over time in both groups. By Week 24, both groups achieve remarkable improvement, with statistical significance ($p<0.001$). These findings underscore the positive impact of both Infliximab and Adalimumab on enhancing spinal mobility in Ankylosing Spondylitis patients.

Table 3: Secondary Outcome - Spinal Mobility Improvement

Time Point	Infliximab Group (n=120)	Adalimumab Group (n=120)	p-value
Baseline	98 (82%)	92 (76%)	--
Week 4	110 (92%)	98 (82%)	0.021
Week 12	116 (97%)	104 (87%)	0.008
Week 24	120 (100%)	114 (95%)	<0.001

Patient-reported outcomes demonstrate a consistent positive trend in both treatment groups. Scores decline progressively over the study period, reflecting an improvement in the perceived impact of Ankylosing Spondylitis on patients' lives. Statistically significant differences at Week 24 ($p<0.001$) highlight the sustained effectiveness of both Infliximab and Adalimumab in enhancing patients' well-being.

Table 4: Patient-Reported Outcomes

Time Point	Infliximab Group (n=120)	Adalimumab Group (n=120)	p-value
Baseline	65.4 ± 12.2	64.8 ± 11.8	--
Week 4	57.8 ± 10.5	61.2 ± 11.1	0.154
Week 12	49.3 ± 9.8	55.1 ± 10.3	0.029
Week 24	38.7 ± 8.3	46.2 ± 9.6	<0.001

Examining the impact on C-reactive protein (CRP) levels, both treatment groups exhibit a substantial reduction. Although statistical significance varies across time points, the overall trend underscores the anti-inflammatory efficacy of both Infliximab and Adalimumab in managing Ankylosing Spondylitis, as reflected in the CRP levels.

Table 5: Impact on Inflammatory Markers (CRP)

Time Point	Infliximab Group (n=120)	Adalimumab Group (n=120)	p-value
Baseline	12.4 (8.9-15.6)	13.2 (9.4-16.8)	--
Week 4	8.5 (6.1-10.9)	10.2 (7.3-13.1)	0.102
Week 12	5.3 (3.7-7.8)	8.1 (5.6-10.5)	0.006
Week 24	3.1 (1.8-4.6)	6.4 (4.3-8.7)	<0.001

This table-6 evaluates the impact on erythrocyte sedimentation rate (ESR) levels. Both Infliximab and Adalimumab groups show a consistent decline, emphasizing the effectiveness of these treatments in modulating inflammatory markers. The statistically significant reductions underscore the robust anti-inflammatory impact observed throughout the study.

Table 6: Impact on Inflammatory Markers (ESR)

Time Point	Infliximab Group (n=120)	Adalimumab Group (n=120)	p-value
Baseline	24.6 ± 4.3	25.2 ± 4.8	--
Week 4	18.8 ± 3.9	21.6 ± 4.1	0.005
Week 12	14.3 ± 3.1	19.7 ± 3.7	<0.001
Week 24	10.2 ± 2.4	15.8 ± 3.2	<0.001

In exploring adverse events, the figures indicate low incidence rates for serious infections, infusion reactions, and other side effects in both groups. Importantly, the p-values suggest no statistically significant differences, highlighting a comparable safety profile for Infliximab and Adalimumab. These results instill confidence in the tolerability and safety of both treatments in the studied population.

Table 7: Adverse Events

Adverse Event Type	Infliximab Group (n=120) - Number (%)	Adalimumab Group (n=120) - Number (%)	p-value
Serious Infections	4 (3.3%)	2 (1.7%)	0.42
Infusion Reactions	8 (6.7%)	6 (5.0%)	0.68
Other Side Effects	12 (10.0%)	10 (8.3%)	0.51

Discussion

The Present investigation delved into not only clinical outcomes but also the impact of these agents on inflammatory markers. The study revealed compelling results, shedding light on the nuanced response to these anti-TNF agents in a specific population.

The primary outcome, assessed through Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores, demonstrated a significant reduction in both Infliximab and Adalimumab groups. This sustained improvement over 24 weeks highlights the effectiveness of both agents in managing AS disease activity. The reduction in BASDAI scores aligns with previous studies, reaffirming the pivotal role of anti-TNF agents in improving clinical symptoms. [7-9]

The secondary outcomes focused on spinal mobility and patient-reported outcomes. Both Infliximab and Adalimumab groups exhibited substantial and statistically significant improvements. The observed enhancement in spinal mobility resonates with studies emphasizing the positive impact of anti-TNF therapies on the physical function of AS patients. Moreover, patient-reported outcomes reflected sustained improvements, emphasizing the holistic benefits of both treatments in enhancing the overall well-being of AS patients. [8-10]

Our study investigated the influence of Infliximab and Adalimumab on inflammatory markers, specifically C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). Both groups demonstrated a significant reduction in these markers, indicative of the potent anti-inflammatory effects of these agents. The findings align with existing literature highlighting the role of anti-TNF therapies in modulating inflammatory markers. [11,12]

Importantly, the comparable safety profiles of Infliximab and Adalimumab, as evidenced by low incidence rates of serious infections, infusion reactions, and other side effects, instill confidence in the tolerability of these agents. These results resonate with previous safety assessments of anti-TNF agents in AS. [8-10]

Our study, contributes to the growing discourse on precision medicine. By elucidating the responses to Infliximab and Adalimumab within this specific regional population, we underscore the importance of tailoring interventions based on local genetic, environmental, and lifestyle factors. This regional focus aligns with the call for personalized approaches to treatment in rheumatology. [11,12]

Limitations and Future Directions:

Despite the robust findings, our study has limitations. The generalizability of results beyond the Moradabad population warrants caution. Future research should explore larger and more diverse cohorts. Additionally, long-term follow-up studies can provide insights into the sustained efficacy and safety of these anti-TNF agents.

Conclusion:

In conclusion, our study provides compelling evidence regarding the comparative efficacy of Infliximab and Adalimumab in managing Ankylosing Spondylitis (AS) within a specific regional context. Both anti-TNF agents demonstrated significant and sustained improvements in clinical outcomes, including BASDAI scores, spinal mobility, patient-reported outcomes, and inflammatory markers (CRP and ESR).

The comparable safety profiles of Infliximab and Adalimumab further enhance their standing as well-tolerated treatments. These findings emphasize the crucial role of these agents in alleviating AS symptoms and modulating inflammatory processes, supporting their use in diverse populations.

The study contributes valuable insights to the on-going discourse on precision medicine, advocating for tailored interventions based on regional factors for optimized AS management and improved patient outcomes. However, cautious interpretation is warranted, considering the regional focus of the study, and future research should explore larger and more diverse cohorts to validate these outcomes on a broader scale.

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