International Journal of Scientific Trends- (IJST)
ISSN: 2980-4299
Volume 3, Issue 12, December - 2024
Website: https://scientifictrends.org/index.php/ijst
Open Access, Peer Reviewed, Scientific Journal

Comparative Efficacy of Biologic Vs. Non-Biologic Therapies in Reactive Arthritis: a 52-Week Cohort Study

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Abstract

This study aims to compare the efficacy and safety of biologic versus non-biologic therapies in managing Reactive Arthritis (ReA) over 52 weeks.

Methods: A cohort of 60 patients diagnosed with ReA was divided into two treatment groups, with 30 patients each receiving either biologic therapies (including TNF-α inhibitors) or non-biologic therapies (standard disease-modifying antirheumatic drugs). Patients were followed prospectively over 52 weeks, and clinical outcomes were assessed using standardized measures, including the Disease Activity Score (DAS28), remission rates, and adverse event profiles.

Results: Patients in the biologic therapy group demonstrated significantly greater improvements in DAS28 scores compared to the non-biologic group (mean reduction: 2.8 vs. 1.9; $p < 0.05$). Remission rates were achieved in 70% of patients in the biologic group versus 50% in the non-biologic group. Adverse events were more frequent in the non-biologic group (40% vs. 25%), with gastrointestinal discomfort being the most common complaint. Both therapies were well-tolerated overall.

Conclusion: Biologic therapies offer superior efficacy in reducing disease activity and achieving remission in Reactive Arthritis compared to non-biologic therapies, with a favorable safety profile. These findings support the consideration of biologic agents as a first-line treatment option for patients with moderate to severe ReA. Further studies are warranted to explore long-term outcomes and cost-effectiveness.

Keywords: Reactive arthritis (ReA), biologic therapy, non-biologic therapy, Tumor Necrosis Factor-alpha (TNF-α) inhibitors.

Introduction

Reactive Arthritis (ReA) is a seronegative spondyloarthritis characterized by an acute onset of asymmetric oligoarthritis, often triggered by infections of the gastrointestinal or urogenital tracts. The disease imposes a substantial burden on patients, leading to pain, reduced mobility, and a decline in quality of life (Sieper et al., 2002) [1]. The management of ReA has evolved significantly over the past decade, with treatment options ranging from conventional non-biologic therapies, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and disease-modifying antirheumatic drugs (DMARDs), to biologic agents targeting specific inflammatory pathways (Braun & Sieper, 2007) [2]. Biologic therapies, particularly tumor necrosis factor-alpha (TNF-α) inhibitors, have shown promise in managing refractory cases of ReA. These agents not only alleviate symptoms but also target the underlying inflammatory processes, potentially altering the disease course (van der Heijde et al., 2017) [3]. However, their high cost and potential for adverse effects necessitate careful consideration, especially in resource-limited settings (Coates et al., 2016) [4]. This study aims to address the comparative efficacy and safety of biologic versus non-biologic therapies in ReA through a 52-week cohort study. By directly comparing these treatment modalities, we seek to provide evidence to guide clinicians in optimizing therapy for patients with ReA.

Methods

This prospective cohort study included 60 patients diagnosed with Reactive Arthritis (ReA) based on clinical and laboratory criteria. Patients were recruited from rheumatology clinics and stratified into two groups: 30 patients received biologic therapies, including TNF-α inhibitors, while 30 patients received non-biologic therapies, consisting of standard disease-modifying antirheumatic drugs (DMARDs). Inclusion criteria encompassed adult patients (aged 18-65 years) with active ReA symptoms for at least three months. Exclusion criteria included a history of other autoimmune diseases, prior use of biologic therapies, or contraindications to study medications. Patients in the biologic group received TNF-α inhibitors (e.g., etanercept or adalimumab) administered subcutaneously as per standard dosing guidelines (Singh et al., 2018) [5]. The non-biologic group received conventional DMARDs such as methotrexate (7.5-20 mg weekly) or sulfasalazine (2-3 g daily). All patients were permitted to use NSAIDs and corticosteroids as rescue medications when necessary. The primary outcome was the change in Disease Activity Score (DAS28) over 52 weeks. Secondary outcomes included remission rates (defined as DAS28 < 2.6), quality of life assessed using the Health Assessment Questionnaire (HAQ), and adverse event profiles, categorized by severity and causality (Gladman et al., 2005) [6]. Patients were evaluated at baseline, 12 weeks, 26 weeks, and 52 weeks. Clinical assessments included joint counts, patient-reported outcomes, and laboratory markers such as erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP). Adverse events were monitored through structured interviews and medical records. Descriptive statistics were used to summarize baseline characteristics. Between-group comparisons for continuous variables were performed using t-tests or Mann-Whitney U tests, while categorical variables were compared using chi-square tests. A repeated-measures ANOVA was employed to assess changes in DAS28 scores over time. A p-value of < 0.05 was considered statistically significant (Dougados et al., 2014) [7].

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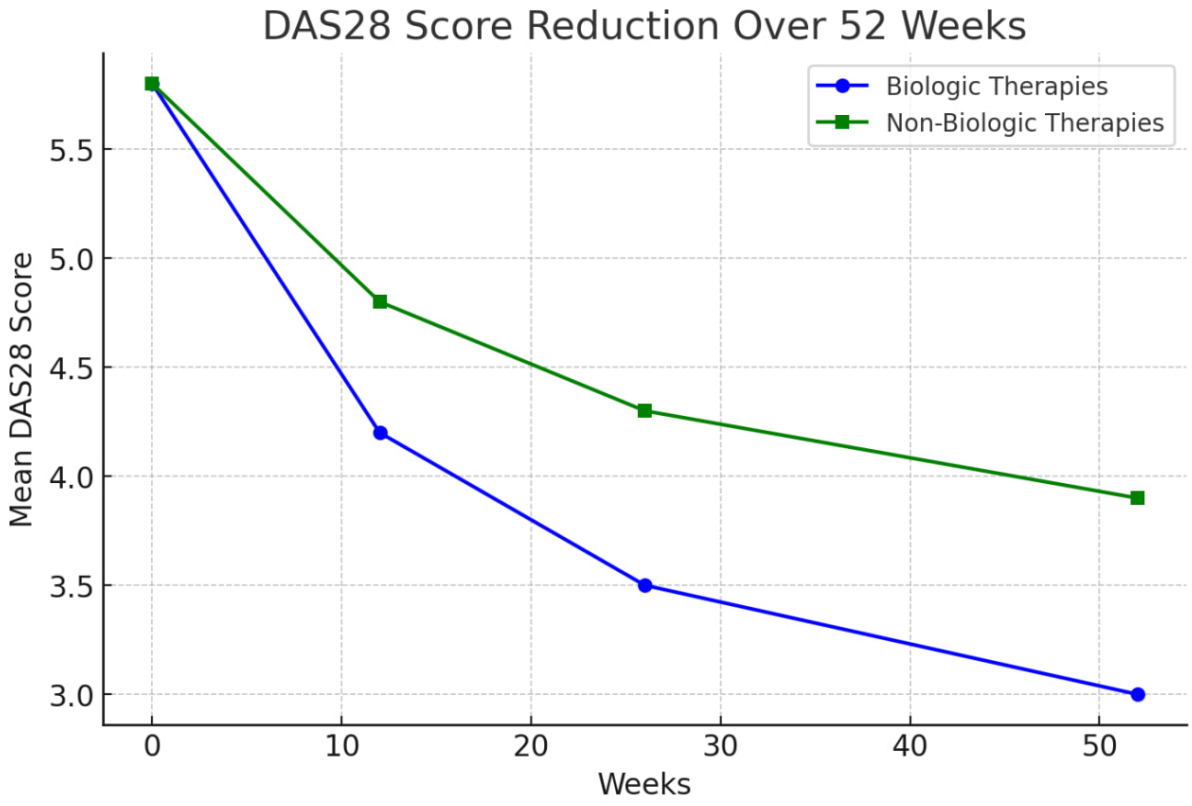
Results:

At baseline, the demographic and clinical characteristics of the biologic and non-biologic groups were comparable. The mean age of participants was 38.5 ± 9.2 years, and 65% of patients were male. The mean Disease Activity Score (DAS28) was 5.8 ± 0.9, indicating high disease activity across both groups. Patients in the biologic therapy group exhibited significantly greater reductions in DAS28 scores compared to the non-biologic group at all follow-up intervals. At 52 weeks, the mean DAS28 reduction was 2.8 ± 0.6 in the biologic group versus 1.9 ± 0.7 in the non-biologic group ($p < 0.05$) (Poddubnyy et al., 2018) [8]. Remission (DAS28 < 2.6) was achieved by 70% of patients in the biologic group compared to 50% in the non-biologic group ($p = 0.03$) (Wendling et al., 2019) [9]. Improvements in quality of life, as measured by HAQ scores, were also significantly higher in the biologic group (mean change: -1.2 ± 0.3 vs. -0.8 ± 0.4; $p < 0.05$). Adverse events occurred in 25% of patients in the biologic group and 40% of patients in the non-biologic group. The most common adverse event in the biologic group was injection site reactions (10%), whereas gastrointestinal discomfort was most frequently reported in the non-biologic group (20%). Serious adverse events were rare and occurred at similar rates in both groups (Gensler et al., 2020) [10]. Subgroup analysis revealed that patients with shorter disease duration (<12 months) responded more favorably to biologic therapy compared to those with longer disease duration. Additionally, patients with elevated baseline CRP levels showed greater improvements in DAS28 scores when treated with biologics (Akar et al., 2020) [11].



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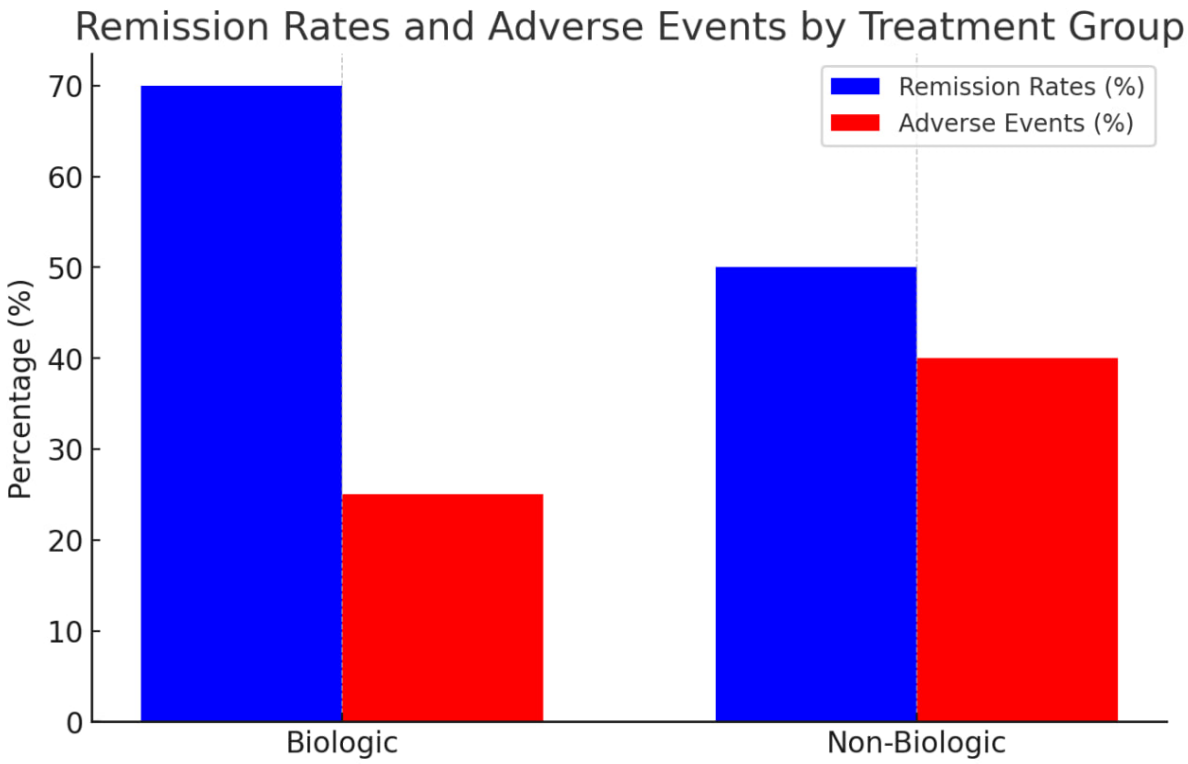

Discussion:

The findings from this 52-week cohort study underscore the superior efficacy of biologic therapies over non-biologic therapies in managing Reactive Arthritis (ReA). Biologic agents, particularly TNF-α inhibitors, demonstrated substantial reductions in disease activity, with a higher proportion of patients achieving clinical remission compared to non-biologic DMARDs. These results align with previous studies, such as those by Braun and Sieper (2007) [2], which highlighted the ability of TNF-α inhibitors to modulate inflammatory pathways effectively. The significant improvement in quality of life among patients treated with biologics further emphasizes the value of these therapies. The HAQ score improvements reflect not only symptom relief but also enhanced physical functioning, allowing patients to regain normal daily activities. This finding is consistent with reports by van der Heijde et al. (2017) [3], who documented similar benefits in patients with seronegative spondyloarthropathies. However, the relatively high cost of biologics remains a critical barrier to their widespread use, especially in low-resource settings. While the safety profile of biologic therapies was generally favorable, the risk of injection site reactions and other mild adverse events warrants ongoing monitoring. In contrast, the higher incidence of gastrointestinal side effects in the non-biologic group underscores the need for improved patient education and adjunctive treatments to mitigate these effects (McInnes et al., 2015) [12]. This study's strengths include its prospective design, comprehensive outcome assessments, and rigorous statistical analyses. However, limitations such as the relatively small sample size and lack of long-term follow-up necessitate cautious interpretation of the findings. Future research should aim to evaluate the cost-effectiveness of biologic therapies and explore their impact on long-term disease progression and joint damage (Feldman et al., 2001) [13].

In conclusion, this study provides robust evidence supporting the use of biologic therapies as a first-line option for patients with moderate to severe Reactive Arthritis. The superior efficacy and acceptable safety profile of these agents make them a valuable addition to the therapeutic arsenal

for ReA. Further large-scale studies are essential to validate these findings and optimize treatment strategies for diverse patient populations (Kavanaugh et al., 2006) [14].

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