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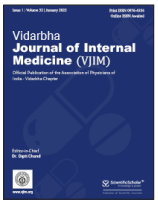

Case Series

Experience with Adalimumab Biosimilar in Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis at our District General Hospital in Shropshire, United Kingdom

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ABSTRACT

Objectives: The main objective of this article was to share our experience with Idacio (adalimumab biosimilar) in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS).

Material and Methods: We collected prospective data from the first 50 patients who were prescribed Idacio from September 2020 to August 2021. We collected their efficacy, and safety data from their subsequent visits up to 6 months. All the adverse events were recorded in our datasheet. As patients were not directly involved in the study, ethics committee approval was not needed for this study.

Results: Out of 25 RA patients, an adequate response was noted in 13 (54.2%) patients. Eleven (44%) of RA patients did not have any response to Idacio and one patient lost to follow-up due to moving out of the region hence account was closed for Idacio. Eight (57%) out of 14 patients with AS had an adequate response after Idacio treatment. Four (44.4%) out of nine patients with PsA had an adequate response and two patients with PsA lost to follow-up due to a change of address after only 1 month of treatment. Side effects noted in these 50 patients were facial rash in one patient, two patients had neutropenia (none of them had to stop the drug) and two patients had injection site pain initially on the first two injections. The patient with a severe facial rash had to stop the treatment.

Conclusion: Idacio therapy was safe and effective in our cohort of patients with few side effects.

Keywords: Biosimilar efficay and safety, Rheumatoid arthritis, Psoriatic arthritis

INTRODUCTION

Rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) are common conditions treated by a rheumatologist in the clinics with biologic disease-modifying anti-rheumatic drugs. Tumour necrosis factor-alpha is a cytokine central to the inflammatory cascade in RA, PsA, and AS.[1] TNF-α inhibitors, therefore, are indicated to treat moderately to severely active diseases.[2]

The long-term cost and high price of innovator brands were the main barriers to the use of biologic DMARDs before approval for biosimilars.[3] Therefore, the expected patent expiry of some of these therapeutics has stimulated interest in the development of biosimilars. A biosimilar is a biological medicine, that is similar, in terms of structure, function, and pharmacokinetics, to another biological medicine that has previously been approved for use.[4] At present, seven ADL biosimilars are approved in the EU and/or the USA: ABP 501, BI 695501, SB5, GP2017, MSB11022, FKB327, and PF-06410293, all of which have been proven to be similar in terms of safety and efficacy to the licensed reference product.[5,6]

Idacio or MSB11022 was approved by the EMA in 2019. Pre-clinical studies have proven its structural and functional similarities to the reference drug, which included the same amino acid sequence, N-/C-terminal modifications, the relative distribution of the intact and glycated forms of both light chain and heavy chain, as well as C-terminal lysine truncation of a heavy chain level of MBS11022. Lower oxidation levels showed in MSB11022 compared to ADL. There was also no difference in the high-order structure.[7]

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Received: 12 May 2022 **Accepted:** 27 June 2022 **Published:** 10 August 2022 **DOI**: 10.25259/VJIM_10_2022

MATERIAL AND METHODS

This study involved a prospective evaluation conducted on the first 50 patients who were prescribed Idacio (adalimumab biosimilar) for RA, PsA, and AS at our centre between September 2020 and August 2021. The criteria for prescribing Idacio were as per the NICE guidelines for biologic DMARD's prescription in RA,[8] PsA[9], and AS.[10]

For the purpose of this study, efficacy at 6 months was defined as adequate response as described below based on

a. For RA patients, an adequate response is defined as an improvement in DAS28 of 1.2 points or more
b. In PsA arthritis patients, an adequate response is defined as an improvement in at least two of the four PsARC criteria, one of which must be joint tenderness or swelling score, with no worsening in any of the four criteria
c. An adequate response in AS patients to treatment is defined as a reduction of the BASDAI score to 50% of the pre-treatment value or by 2 or more units and a reduction of the spinal pain VAS by 2 cm or more.

Statistical analysis

Continuous variables were summarised using mean and standard deviation, and median with range. Categorical values were estimated using frequencies and percentages.

RESULTS

Baseline demographic and clinical characteristics of patients are shown in [Figure 1].

Adequate response to Adalimimab(Idacio) as per [Figure 2].

DISCUSSION

Out of 25 RA patients, an adequate response was noted in 13 (54.2%) patients. Eleven (44%) of RA patients did not have any response to Idacio and one patient lost to follow-up due to moving out of the region hence account was closed for Idacio.

Eight (57%) out of 14 patients with AS had an adequate response after Idacio treatment.

Four (44.4%) out of nine patients with PsA had an adequate response and two patients with PsA lost to follow-up due to change of address after only 1 month of treatment.

Neutropenia and injection site pains were the common adverse effects noted in our patients. No major adverse effects were noted in our study. No serious infections or life-threatening cardiovascular events were noted during this study period.[11] One patient had a severe facial rash.

CONCLUSION

Overall Idacio therapy was effective and safe in patients with RA, PsA, and AS patients.

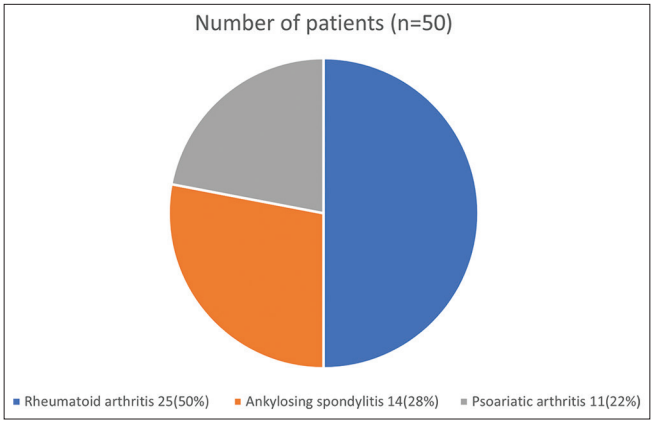

Figure 1: Number of Patients

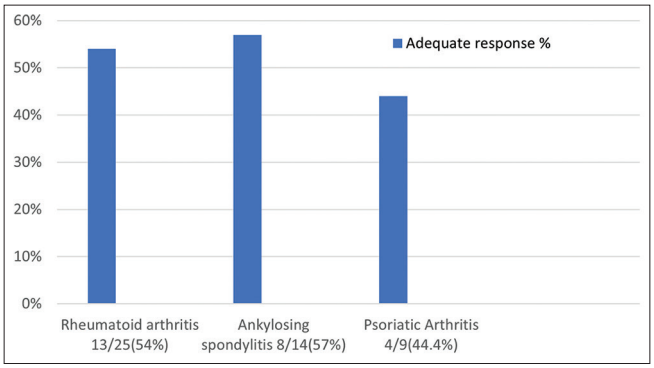

Figure 2: Efficacy of Idacio.

Limitations of this study

This was a small study with a short duration of follow-up. This study was carried out in a single centre during the COVID-19 pandemic and some of the follow-up consultations were virtual (telephone or video clinics) which was also another limiting factor for the study.

Acknowledgments

We thank all the consultant colleagues in the rheumatology department at Robert jones and Agnes Hunt orthopaedic hospitals NHS foundation trust for accessing the electronic patient records of their patients on Idacio for the data collection for this study. We also thank the pharmacist Katy Ryan in our department for providing the list of patients on Idacio.

Declaration of patient consent

Patients' consent not required as patients' identity is not disclosed or compromised.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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How to cite this article: Sagdeo A, Sagdeo A, Amarasena R. Experience with adalimumab biosimilar in rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis at our District General Hospital in Shropshire, United Kingdom. Vidarbha J Intern Med 2022;32:135-7.