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Efficacy of switching from originator adalimumab to biosimilar adalimumab-AACF in patients with axial spondyloarthritis: a 12-month observational study

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Abstract

Aim: The use of anti-TNF drugs is well-established for treating axial spondyloarthritis (axSpA). The introduction of biosimilars offers a more accessible alternative, but data on the switching of adalimumab biosimilars in the axSpA population remain somewhat controversial and are limited to SB5 and ABP 501 and to the European population. This study aims to evaluate the clinical efficacy of switching from originator adalimumab to the biosimilar adalimumab-AACF in Latin American axSpA patients over a 12-month period in a real-life analysis.

Methods: This observational study included patients with axSpA who had been treated with originator adalimumab for at least three months and switched to the biosimilar. Disease activity parameters and C-reactive protein (CRP) levels were assessed at baseline (T0) and compared at 6 (T6) and 12 months (T12) following the switch.

Results: Twenty-eight patients were included, with a mean duration of originator adalimumab use of 87.6 months. Ankylosing Spondylitis Disease Activity Score (ASDAS)-CRP remained stable when comparing T0 to T6 [1.56 (± 0.88) vs. 1.50 (± 0.82), $P = 0.73$] and T12 [1.56 (± 0.88) vs. 1.26 (± 0.86), $P = 0.13$]. A similar pattern was observed for ASDAS-erythrocyte sedimentation rate (ESR; $P > 0.05$) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI; $P > 0.05$). The rate of remission/low disease activity was consistent, recorded at 71.4% at baseline, 78.6% at T6 ($P = 0.62$) and 78.6% at T12 ($P = 0.68$). CRP levels did not show significant variation ($P > 0.05$) across time points. Notably, the one-year drug retention rate was 94.6%.

Conclusions: This real-world study highlights for the first time the feasibility and efficacy of transitioning from originator adalimumab to biosimilar AACF in axSpA, providing support for its use in long-term management and offering enhanced accessibility without compromising therapeutic outcomes. These results add valuable Latin American data to the body of evidence on biosimilar integration into clinical practice.

Keywords

Anti-TNF biologics, biosimilar, originator, adalimumab, axial spondyloarthritis

Introduction

Adalimumab, a fully human monoclonal antibody, is an anti-TNF biological agent that has revolutionized the treatment of chronic inflammatory diseases, such as axial spondyloarthritis (axSpA). By targeting TNF-α, adalimumab effectively reduces inflammation and helps prevent structural damage such as erosions, tissue repair, and new bone formation, which can lead to ankylosis and permanent limitations. This mechanism not only alleviates symptoms but also slows disease progression and improves quality of life and functionality of patients with axSpA [1, 2].

With the expiration of patents on originators biologics, a new wave of biosimilar agents has emerged. Designed to mirror the original efficacy, safety and quality, biosimilars provide an equally therapeutic but more affordable alternative, reducing cost for healthcare systems and broadening access to biological disease-modifying antirheumatic drugs (bDMARDs) [3, 4]. Regulatory agencies such as the European Medicines Agency (EMA), the Food and Drug Administration (FDA) and Brazilian National Health Surveillance Agency (ANVISA) have endorsed these biosimilars after rigorous review of clinical trials and real-world data [5–18].

However, the real-world evidence on switching from originator adalimumab to biosimilars for axSpA remains limited and somewhat inconsistent, with data focused mainly on biosimilars SB5 and ABP 501 [14–18]. While the PROPER registry [15] and Becciolini et al. [14] demonstrated a high long-term retention of biosimilar adalimumab of up to 85%, other studies with shorter follow-up times reported mixed outcomes [16–18]. In a six-month assessment after switching, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) indicated inactive disease, but Ankylosing Spondylitis Disease Activity Score (ASDAS) reflected mild activity and patients exhibited increased of tender joints count (TJC) and health assessment questionnaire (HAQ) at 3 and 6 months [17]. These findings highlight a need for more robust, real-world data to better understand the safety and efficacy of switching reference drugs to biosimilars in this population.

This study aims to address this gap by evaluating the clinical efficacy of the adalimumab-AACF biosimilar (MSB11022) in axSpA patients transitioning from the originator, analyzing disease activity parameters and drug survival over a 12 months period.

Materials and methods

Study design

This single-center, retrospective, longitudinal, observational study evaluated axSpA patients who transitioned from originator adalimumab to its biosimilar starting in September 2022, when the biosimilar became available at our center. The study is based on data from a prospective database collected through electronic medical records, which included regular clinical and laboratory assessments every three months or at any necessary intervals at our Biological Center. To be included in the analysis, patients needed to have been on the originator for at least three months and to have experienced no interruption in treatment at the time of the switch.

Population

Twenty-eight patients over 18 years old, with confirmed axSpA according to the Assessment of SpondyloArthritis international Society (ASAS) Expert Classification Criteria [19], followed at the Spondyloarthritis Outpatient Clinic and the Immunobiological Drugs Infusion Center (CEDMAC—Centro de Dispensação de Medicação de Alto Custo) of the Hospital das Clínicas, Faculty of Medicine, University of Sao Paulo, were evaluated.

Informed consent to participate in the study was obtained from all participants.

Data collection

Clinical data were collected retrospectively from our electronic prospective database at baseline (T0), 6 months (T6), and 12 months (T12) after the switch from originator to biosimilar. Disease activity parameters such as the ASDAS based on C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), as well as the BASDAI and CRP were assessed. Remission/low disease activity rates for axSpA according to ASDAS-CRP (< 2.1) [20, 21] and information on allergic reactions during the period were recorded.

Statistical analysis

The results were presented as mean [standard deviation (SD)] or median [interquartile range (IQR)] for continuous variables and compared using paired *t*-test or Wilcoxon when indicated. Categorical variables were shown as a percentage and evaluated through the McNemar's test. Statistical significance was considered when $P < 0.05$. Statistical analyses were performed using SigmaStat version 3.1 (2005) and GraphPad/Prisma Software.

Results

Patient characteristics

A total of 28 patients were included in the final adalimumab-AACF efficacy evaluation six and 12 months following the switch. The mean age of axSpA patients was 50.4 years (± 13.2), predominantly male (75.0%) and 64.3% (9/14) were HLA-B27 positive. The average duration of treatment with originator adalimumab before study entry was 87.6 months (± 56.6 months). Notably, 85.7% of the patients had been treated for more than one year before transitioning to the biosimilar, and of these, 53.6% had been on treatment for over seven years. These long-term users were advised by specialists to continue the therapy, with some receiving reduced doses administered at intervals longer than the standard 14 days. This adjusted dosing regimen was maintained following the switch to the biosimilar. The recorded use of concomitant medications was 28.6% (8/28) and 22.2% (6/27) for nonsteroidal anti-inflammatory drugs and 57.1% (16/28) and 55.6% (15/27) for synthetic DMARDs, retrospectively at the beginning and at the final assessment. One patient discontinued adalimumab-AACF before the last evaluation due to recurrent uveitis.

Disease activity parameters

ASDAS-CRP remained stable at 6 months [1.56 (± 0.88) vs. 1.50 (± 0.82), $P = 0.73$] and 12 months [1.56 (± 0.88) vs. 1.26 (± 0.86), $P = 0.13$] compared to baseline (T0). Similar results were observed for ASDAS-ESR and BASDAI as demonstrated in Table 1. The assessment of inflammatory markers also revealed stable levels of CRP at all-time points ($P > 0.05$; Table 1).

Table 1. Disease activity parameters in axSpA patients at baseline and 6 and 12 months post-switch from originator adalimumab to adalimumab-AACF

Disease activity parameters at baseline and after switching	Baseline (*n* = 28)	6 months (*n* = 27)	*P*	12 months (*n* = 27)	*P*
ASDAS-CRP	1.56 (± 0.88)	1.50 (± 0.82)	0.732	1.26 (± 0.86)	0.133
ASDAS-ESR	1.47 (± 0.93)	1.57 (± 0.78)	0.876	1.27 (± 0.87)	0.979
BASDAI	1.30 (± 1.43)	1.26 (± 1.63)	0.176	0.99 (± 1.28)	0.331
CRP (mg/L)	3.9 (1.9; 8.1)	2.6 (1.8; 4.9)	0.310	2.6 (1.63; 6.9)	0.494

Data are presented as mean (± standard deviation) or median (interquartile range); statistical significance was considered when $P < 0.05$. axSpA: axial spondyloarthritis; ASDAS-CRP: Ankylosing Spondylitis Disease Activity Score-C-reactive protein; ASDAS-ESR: Ankylosing Spondylitis Disease Activity Score-erythrocyte sedimentation rate; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index

Remission/low disease activity

At baseline, 71.4% of patients had remission/low disease activity (ASDAS-CRP < 2.1), and this rate was maintained at 6 months ($P = 0.62$) and at 12 months ($P = 0.68$; Table 2). For the patient who discontinued the medication before the 6M visit the last observation carried forward was considered. Among the patients with high disease activity at the time of the switch, 50% (4/8) achieved ASDAS-CRP < 2.1 after 12 months of follow-up. Among those who did not achieve at least low disease activity were the patient who switched to another immunobiological therapy and three others who did not have a viable therapeutic option available at that time. Among the patients with ASDAS < 2.1 at the start of the study, 90% remained in the same disease activity category at the final assessment.

Table 2. Remission/low disease activity frequency in axSpA patients at baseline and 6 and 12 months post-switch from originator adalimumab to adalimumab-AACF

Remission/low disease activity frequency at baseline and after switching ($n = 28$)	Baseline	6 months	*P*	12 months	*P*
ASDAS-CRP < 2.1	20 (71.4%)	22 (78.6%)	0.617	22 (78.6%)	0.683

Data are presented as number (%); statistical significance was considered when $P < 0.05$. ASDAS-CRP: Ankylosing Spondylitis Disease Activity Score-C-reactive protein

Retention rate

The drug retention rate at 12 months was 96.4%. The only patient who discontinued biosimilar adalimumab before completing one year of treatment did so within three months of starting adalimumab-AACF. This patient had been on originator adalimumab for only 3.5 months prior to the switch and developed a new episode of uveitis while tapering corticosteroids during biosimilar use. This was deemed a failure of adalimumab (both originator and biosimilar), leading to a switch to another monoclonal anti-TNF biologic.

Allergic reactions

No allergic reactions were recorded among the 28 patients included in the evaluation.

Discussion

This study represents the first experience of switching from originator adalimumab to the AACF biosimilar in axSpA, reinforcing the disease stability previously shown with other biosimilars and adding to the literature more assurance that this effect can also be applied in real-world long-term scenarios in Latin American patients.

One key strength of this study is its long-term evaluation (12 months) conducted at a single center enabling a highly systematic disease activity assessment. The short-term evaluation reported in other studies may not allow the full impact of the switching [16–18]. Moreover, the baseline population was homogeneous including only axSpA mainly under low disease activity, resulting in a more accurate assessment of efficacy and safety of the switching. The inclusion of a more heterogeneous population regarding disease activity status [14] and distinct inflammatory diseases [14–18] may hamper the interpretation of the findings. Another important aspect of this study is the evaluation of Latin American axSpA patients, since all previous studies of adalimumab biosimilars reported are from India, China and Europe [7, 12–18]. In fact, it has been demonstrated relevant regional differences in clinical phenotype of axSpA [22].

The main limitation was the modest sample size that may have contributed to potential over or underestimation of certain outcomes, such as therapy discontinuation. Lastly, serum trough levels and antidrug antibodies were not measured at baseline or during the follow-up period precluding the analysis of the role of immunogenicity in drug retention.

Our study provides the first demonstration of sustained stability in disease activity parameters over 12 months following the switch from originator adalimumab to its biosimilar AACF, with consistent measures such as ASDAS-CRP, ASDAS-ESR, and BASDAI. Additionally, the high and persistent rate of remission/low disease activity of more than 70% throughout this period aligns with data from the PROPER study [15], which also showed disease stability in European patients with axSpA, with 81% in low disease activity at baseline and 78% one year after switching to the biosimilar SB5, in a real-life observation.

In addition to this clinical stability, our biosimilar retention rate after one year was high, reaching 96.4%. Large registries have demonstrated similar one-year survival rates for both originator and diverse biosimilar drugs in axSpA [6, 9, 11]. Studies involving the adalimumab biosimilar have also shown comparable results, with high retention rates even after switching, such as 72% in the PROPER registry [15] and over 80% reported by Becciolini et al. [14], but this study evaluated this rate by assessing switchers patients not only with axSpA.

A particularly relevant finding from the COMPACT study [6], which evaluated the use of biosimilar etanercept in patients with rheumatic diseases, was that patients who were more likely to retain the medication were those in remission or low disease activity before switching, compared to patients who were naïve to the same medication. Our findings on disease activity stability reinforces the notion that patients with controlled disease are the best candidates for successfully switching from originator drugs to biosimilars, broadening this observation to include the adalimumab AACF and Latin American patients.

Another critical factor to consider is the impact of the nocebo effect during the transition to biosimilars. Studies indicate that inadequate communication or a lack of understanding about biosimilars can lead to negative outcomes attributed to the nocebo effect, affecting both treatment adherence and response [17, 18, 23]. Improvements in education and communication between doctors and patients are essential to overcome this obstacle and ensure a smooth, uninterrupted transition [3, 24]. In this study, the switch was conducted at a supervised infusion center in a large teaching hospital, with a specialized medical and multidisciplinary care team, and all patients were informed and guided about the procedure. The high retention rate of the adalimumab biosimilar and the stability in disease activity scores suggest that, in our population, the nocebo effect had no impact. Real-world data are essential for further enhancing knowledge and building confidence among prescribers and patients.

In conclusion, this real-world study highlights for the first time the feasibility and efficacy of transitioning from originator adalimumab to biosimilar AACF in axSpA, providing support for its use in long-term management. These results add valuable Latin American data to the body of evidence on biosimilar integration into clinical practice.

Abbreviations

ASDAS: Ankylosing Spondylitis Disease Activity Score

axSpA: axial spondyloarthritis

BASDAI: Bath Ankylosing Spondylitis Disease Activity Index

CRP: C-reactive protein

ESR: erythrocyte sedimentation rate

Declarations

Author contributions

FARN and BB: Conceptualization, Investigation, Writing—original draft. KRB and NEA: Conceptualization, Investigation, Writing—review & editing. APLA, FHCdS, CEI, HAMG and EFVNY: Investigation, Validation, Writing—review & editing. RM: Investigation, Writing—review & editing. EB: Conceptualization, Validation, Writing—review & editing, Supervision. CGSS and ACdMR: Conceptualization, Investigation, Writing—review & editing, Supervision. JCBdM and AYS: Conceptualization, Investigation, Writing—original draft, Writing—review & editing, Supervision. All authors read and approved the submitted version.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical approval

This study was approved by the Local Ethics Committee on Human Research of the University of São Paulo (CAPPesq), under number 1298/06.

Consent to participate

Informed consent to participate in the study was obtained from all participants.

Consent to publication

Not applicable.

Availability of data and materials

The raw data supporting the conclusions of this manuscript will be made available by the authors, without undue reservation, to any qualified researcher.

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Publisher's note

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