Effectiveness of non-medical switch from adalimumab bio-originator to SB5 biosimilar and from ABP501 adalimumab biosimilar to SB5 biosimilar in patients with chronic inflammatory arthropathies: a monocentric observational study

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Abstract

Objective

The use of biosimilars is constantly growing, prompting healthcare payers to encourage the switch to these drugs which are less expensive than the reference bio-originator. While switching from a bio-originator to a biosimilar is supported by increasing evidence, data on the switch between different biosimilars of the same reference product are scant. Our study aimed to evaluate the effectiveness of the non-medical switch both between adalimumab (ADA) bio-originator and SB5 biosimilar and between two different ADA biosimilars in patients with inflammatory chronic arthritis.

Methods

We observed adult patients with a diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), and axial spondyloarthritis (axSpA) treated with ADA bio-originator or ABP501 ADA biosimilar (Amgevita) who switched to SB5 ADA biosimilar (Imraldi) for administrative/economic reasons. Patients were followed up for 4 months.

Results

One hundred and ten patients [33 RA, 40 PsA, 37 axSpA; F:M= 49:61; median age 56 years (25^{th}-75^{th} percentile 48-66)] switched from ADA bio-originator to SB5. After 4 months (T4), we observed a significant reduction of patients in remission/low disease activity (baseline 92.7% vs. T4 80.9%; p=0.009), with a risk of moderate-high disease activity significantly higher after the switch [RR 2.6 (95% IC 1.2 to 5.7), p=0.01]. However, no differences were found in DAS28-CRP, DAPSA, ASDAS-CRP, and BASDAI, while patients with RA and PsA experienced a worsening in the patient global assessment-VAS (p=0.04 and p=0.02, respectively), and in patients with PsA a worsening in HAQ was also observed (p=0.03). Forty patients switched from ABP501 biosimilar to SB5 [12 with RA, 25 with PsA, and 3 with axSpA; F:M=24:16; median age 56 years (25^{th}–75^{th} percentile 44–66)]. After 4 months, no differences in DAS28-CRP and DAPSA nor in the percentage of patients in remission/low disease activity were found compared to baseline. Likewise, no differences were found in patient-reported outcomes (PROs).

Conclusion

Our results provide a reassuring profile of effectiveness when switching from ADA originator to one of its biosimilars and between two different biosimilars. However, the worse outcome in PROs in patients initially treated with the bio-originator addresses the attention to a possible nocebo response, which should encourage comprehensive communication with patients.

Key words

non-medical switch, biosimilars, adalimumab, inflammatory arthropathies

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Introduction

Since the marketing of biological disease-modifying anti-rheumatic drugs (bDMARDs), a new era has begun for patients with inflammatory rheumatic diseases resistant to traditional treatments. However, bDMARDs are burdened with high costs, and the Humira originator version of adalimumab (ADA), an anti-TNF agent, was the world's best-selling drug in 2020, with full-year revenues exceeding US$20 billion (1). However, with the patent on bDMARDs expiring, the use of less expensive biosimilars is constantly growing, especially in countries with budget constraints. The economic issue is captured by the last overarching principle of the EULAR recommendation for the management of rheumatoid arthritis (RA), stating that less costly drugs should be preferred over more costly ones, provided that a similarly efficacious and safe profile has been demonstrated (2). Therefore, biosimilars could be the answer to the economic impact of the bio-originator DMARDs, ensuring better accessibility and being in line with recommendations.

Several biosimilars have now been approved and marketed, prompting healthcare payers to encourage the switch to these drugs. Notably, they may differ from the bio-originator due to minor differences in molecular structures, excipients, or injection devices (3). For this reason, a biosimilar must demonstrate equivalent clinical performance to the reference product, and much more emphasis is put on analytical and non-clinical studies than on clinical testing (4).

While switching from a bio-originator to a biosimilar is supported by increasing evidence (5-8), data on the switch between different biosimilars of the same reference product are scant. Therefore, our study aimed to evaluate the effectiveness of the non-medical switch both between ADA bio-originator and SB5 biosimilar and between two different ADA biosimilars in patients with inflammatory chronic arthritis in a real-life context.

Patients and methods

Since October 2020, Humira and its ABP501 biosimilar were no longer available at AOU Policlinico Umberto I of Rome due to administrative/economic reasons. Therefore, we planned an observational cohort study on consecutive adult patients with a diagnosis of RA, psoriatic arthritis (PsA), and axial spondylarthritis (axSpA) classified according to standard criteria (9-11). We enrolled patients who switched from ADA bio-originator to SB5 biosimilar and from ABP501 ADA biosimilar to SB5 biosimilar followed up at the Arthritis Center outpatient clinic, Sapienza University of Rome.

The date of the switch was considered as the baseline (T0) and patients were followed up for 4 months (T4). At baseline, data on demographic and clinical/laboratory features were registered in an electronic database. These included: age, gender, body mass index, smoking status (yes/no/past smoker), treatment duration of the previous ADA originator or biosimilar, tender joint count (TJC), and swollen joint count, C-reactive protein (CRP). Also, patient-reported outcomes (PROs), including visual analog scale (VAS 0–10) for pain and global assessment, and functional status by Health Assessment Questionnaire (HAQ) were used, together with disease-specific scores [Disease Activity Score-28 (DAS28)-CRP for RA, PsA Disease Activity in Psoriatic Arthritis (DAPSA) for PsA, Ankylosing Spondylitis (AS) Disease Activity Score (ASDAS-CRP) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI; 0–10) for axSpA]. The same clinical and laboratory data were assessed and registered after 4 months of treatment with SB5 biosimilar or at the time of early discontinuation of SB5 for inefficacy or adverse events (AEs). Disease flare in patients with RA, PsA, and axSpA was defined as a transition from a remission/low disease activity state towards a high disease activity according to DAS28-CRP, DAPSA, and ASDAS-CRP, respectively. Part of this last group of patients resumed the treatment with ADA bio-originator or ABP501 after discontinuation of the biosimilar (back-switchers), the others were withdrawers.

The study was approved by the AOU Policlinico Umberto I Ethics Com-

Table I. Demographic and clinical data of patients with chronic inflammatory arthritis switching from adalimumab originator to SB5 biosimilar.

	All (n= 110)	RA (n=33)	PsA (n=40)	axSpA (n=37)	RA-PsA *p*-value	RA-axSpA *p*-value	PsA-axSpA *p*-value
Female sex (n/%)	49 (51.3)	23 (69.7)	14 (35)	12 (32.4)	0.03	0.004	ns
Median age (25^{th}-75^{th} percentile)	56 (48-66)	63 (53-70.75)	59 (50.5-65.5)	51 (37.75-58.25)	ns	0.0005	0.01
Median BMI (25^{th}-75^{th} percentile)	25.95 (22.03-28.65)	25 (22.03-26.81)	28.16 (24.54-31.05)	24.23 (21.13-26.26)	ns	ns	0.006
Current smokers (n/%)	28 (25.4)	8 (24)	13 (32)	7 (19)	ns	ns	ns
Median Humira treatment duration, months (25^{th}-75^{th} percentile)	48 (32-72)	49 (35-73.5)	63.5 (36-82.25)	39 (28-49.5)	ns	ns	0.02
Moderate disease activity (n/%)	3 (2.7)	2 (6)	1 (2.5)	0 (0)	ns	ns	ns
High disease activity (n/%)	5 (4.6)	0 (0)	0 (0)	5 (13.5)	ns	ns	ns
Remission/low disease activity (n/%)	102 (92.7)	31 (94)	39 (97.5)	32 (86.5)	ns	ns	ns
4 months post switch							
Moderate disease activity (n/%)	14 (12.7)	8 (24.2)	4 (10)	2 (5.4)	ns	0.02	ns
High disease activity (n/%)	7 (6.3)	1 (3)	4 (10)	2 (5.4)	ns	ns	ns
Remission/low disease activity (n/%)	89 (81)	24 (73)	32 (80)	33 (89.2)	ns	ns	ns
Back switch (n/%)	12 (11)	3 (9)	4 (10)	5 (13.5)	ns	ns	ns
Lack of efficacy (n/%)	9 (8.1)	2 (6)	4 (10)	3 (8.1)	ns	ns	ns
AEs (n/%)	3 (2.7)	0	1 (2.5)	2 (5.4)	-	-	ns

BMI: body mass index, AEs: adverse events.

mittee. All patients gave their written informed consent to use their data for research purposes at the start of a new therapy.

The statistical analysis was performed using GraphPad Prism v. 7 (GraphPad Software, San Diego, CA, USA). Data are presented as median/25^{th}-75^{th} percentile and percentages for continuous and categorical variables, respectively. Wilcoxon signed ranks test was used for comparisons between T0 and T4 within subjects, while the Kruskal-Wallis test with Dunn's *post-hoc* test was used for comparisons among the three groups of patients. The relative risk (RR) of changing disease activity status after the switch was calculated considering as a comparator group the baseline population, not yet exposed to the effect of switch. The comparison of percentages was performed using the χ^2 test or Fisher's exact test when appropriate. The significance of any correlation was determined by Spearman's rank correlation coefficient. *p*-values <0.05 were considered statistically significant.

Results

One hundred and fifty patients (110 treated with Humira and 40 with ABP501 biosimilar) were enrolled (45 with RA, 65 with PsA, and 40 with axSpA). Seventy-three patients (48.6%) were women, and 77 (51.3%) were men. The median age was 56 years (25^{th}–75^{th} percentile 48–66).

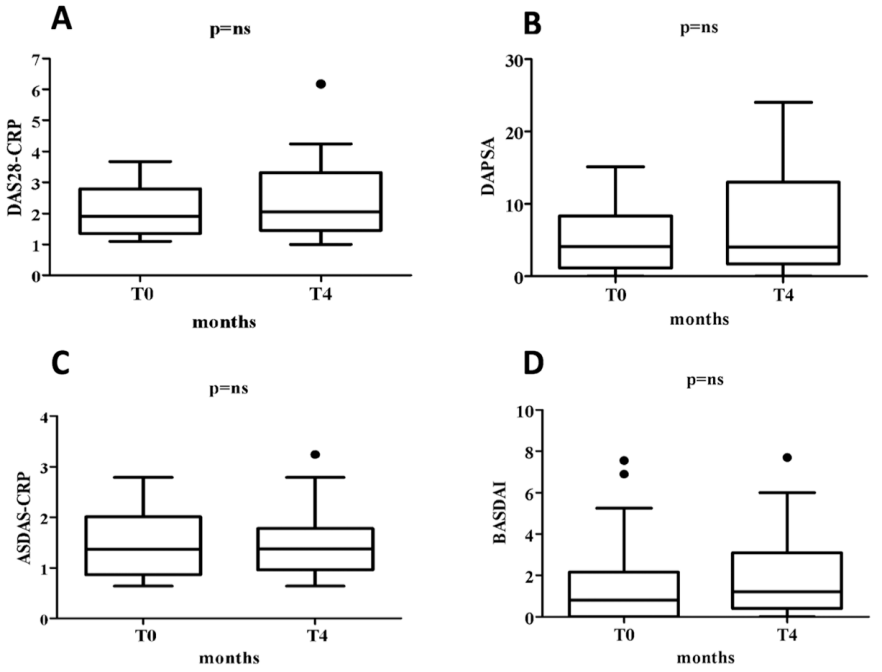

Fig. 1. DAS28-CRP, DAPSA, ASDAS-CRP, and BASDAI at baseline and after 4 months from the switch to SB5 in patients firstly treated with Humira. **A** RA, **B** PsA, **C** and **D** axSpA.
Data are shown as Tukey boxplots; lines represent the median level with 25^{th}-75^{th} percentile; data not included between the whiskers are plotted as outliers with dots.

Switchers from adalimumab bio-originator to SB5 biosimilar

The demographic and clinical data of patients switching from ADA originator to SB5 biosimilar are reported in Table I. We enrolled 110 patients [33 with RA, 40 with PsA, 37 with axSpA; F:M= 49:61; median age 56 years (25^{th}–75^{th} percentile 48–66)]. At baseline, they had been treated with Humira for a median of 48 months (25^{th}–75^{th} percentile 32–72) and 102 (92.7%) were in remission/low disease activity. After 4 months of SB5 treatment, we observed a significant reduction of patients in remission/low disease activity (89; 80.9%) (p=0.009), with a RR of moderate-high disease activity significantly higher after the switch [RR 2.6 (95% IC 1.2–5.7), p=0.01].

However, after 4 months no differences were found in DAS28-CRP, DAPSA,

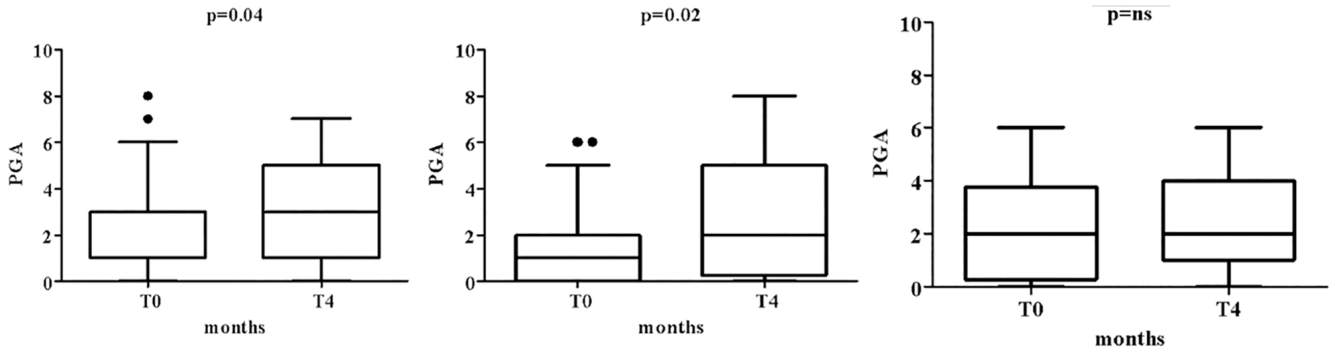

Fig. 2. PGA in patients with RA, PsA, and axSpA at baseline and after 4 months from the switch to SB5 in patients firstly treated with Humira.
Data are shown as Tukey boxplots; lines represent the median level with 25th-75th percentile; data not included between the whiskers are plotted as outliers with dots.

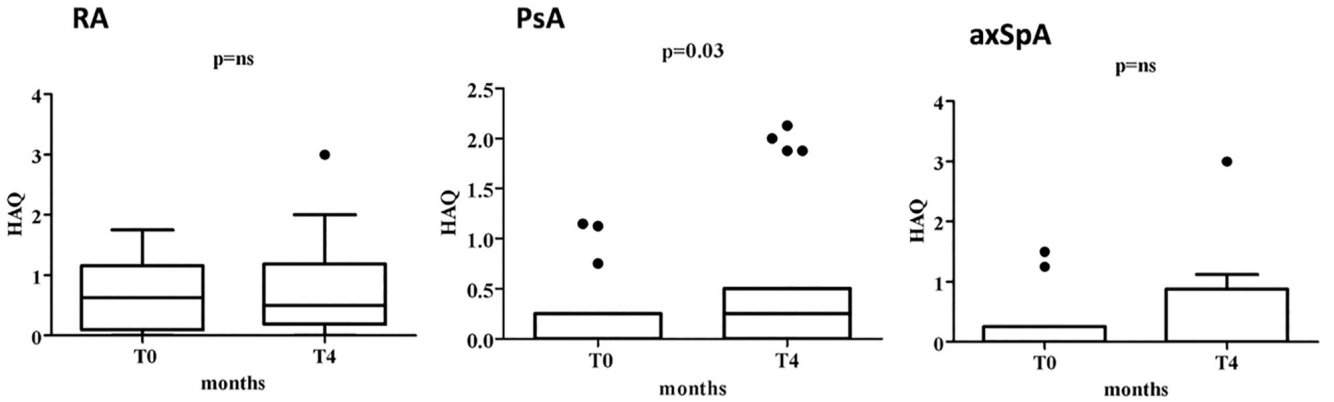

Fig. 3. HAQ in patients with RA, PsA, and axSpA at baseline and after 4 months from the switch to SB5 in patients firstly treated with Humira.
Data are shown as Tukey boxplots; lines represent the median level with 25th-75th percentile; data not included between the whiskers are plotted as outliers with dots.

ASDAS-CRP, and BASDAI in patients with RA, PsA, and axSpA, respectively (Fig. 1). At T4, patients with RA and PsA experienced a worsening in the patient global assessment-VAS (p=0.04 and p=0.02, respectively) (Fig. 2), while no differences were found in pain-VAS (not shown). In patients with PsA, a worsening in HAQ was also observed (p=0.03) (Fig. 3). No statistically significant correlation among the different demographic, clinical, and laboratory parameters was found.

Twelve patients (10.9%) switched back to Humira, mainly due to lack of efficacy in joint involvement (7; 58.3%) or recurrent uveitis (2; 16.7%), while 3 patients (2.7%) switched back because of AEs (diffuse urticarial rash in all cases). Among 21 patients (19.1%) presenting a disease flare, 14 (66.6%) continued SB5 as long as concomitant drugs were modified. A 1.5% background flare rate in the ADA originator cohort was observed and the persistence in treatment at 4 months was lower in switchers when compared to background (89.1% *vs*. 98.5%, p=0.001).

Switchers from ABP501 adalimumab biosimilar to SB5 biosimilar

The demographic and clinical data of patients switching from ABP501 ADA biosimilar to SB5 biosimilar are reported in Table II. This group included 40 patients [12 with RA, 25 with PsA, and 3 with axSpA; F:M=24:16; median age 56 years (25th–75th percentile 44–66)]. The median exposure to the previous biosimilar was 11 months (25th–75th percentile 7–18); about half of the patients were in remission/low disease activity (21; 52.5%). Due to the low number of patients with axSpA in this group, statistical analysis was conducted only on those with RA and PsA. After 4 months of SB5 treatment, no differences in DAS28-CRP and DAPSA (Fig. 4) nor in the percentage of patients in remission/low disease activity were found compared to baseline. Likewise, no differences were found in PROs (Fig. 5). No statistically significant correlation among the different demographic, clinical, and laboratory parameters was found. Out of 40 patients, 3 (7.5%) discontinued SB5 before T4 for lack of efficacy and 3 for AE (one for upper limb paresthesia, one for skin rash, and one for psoriasis relapse). The one with paresthesia and one with lack of efficacy back switched to ABP501. A 4% background flare rate in the ABP501 cohort was observed and the persistence in treatment at 4 months was not statistically different in switchers when compared to background (85% *vs*. 96%, p=0.674).

Discussion

This is one of the first studies comparing the real-world effectiveness of non-medical switching from ADA originator to ADA biosimilar and between different ADA biosimilars. The results of

Table II. Demographic and clinical data of patients with chronic inflammatory arthritis switching from adalimumab ABP501 biosimilar to SB5 biosimilar.

	All (n=40)	RA (n=12)	PsA (n=25)	axSpA (n=3)	RA-PsA *p*-value	RA-axSpA *p*-value	PsA-axSpA *p*-value
Female sex (n/%)	24 (60)	8 (66.7)	13 (52)	3 (100)	ns	ns	ns
Median age (25^{th}-75^{th} percentile)	56 (44-66)	66.5 (48.75-80.5)	50 (43-61.5)	57 (36-78)	ns	ns	ns
Median BMI (25^{th}-75^{th} percentile)	25.95 (22.03-28.65)	23.83 (22.63-28.77)	25.06 (22.05-28.17)	23.38 (20.58-32.05)	ns	ns	ns
Current smokers (n/%)	12 (30)	2 (16.6)	9 (36)	1 (33.3)	ns	ns	ns
Median APB501 treatment duration, months (25^{th}-75^{th} percentile)	11 (7-18)	16 (8-21)	10 (7-15.75)	16 (11-17)	ns	ns	ns
Moderate disease activity (n/%)	5 (12.5)	1 (8.3)	4 (16)	0 (0)	ns	ns	ns
High disease activity (n/%)	4 (10)	0 (0)	2 (8)	2 (66.7)	ns	ns	ns
Remission/low disease activity (n/%)	21 (52.5)	8 (66.7)	12 (48)	1 (33.3)	ns	ns	ns
4 months post switch							
Moderate disease activity (n/%)	5 (12.5)	3 (25)	2 (8)	0 (0)	ns	ns	ns
High disease activity (n/%)	3 (7.5)	2 (16.6)	0 (0)	1 (33.3)	ns	ns	ns
Remission/low disease activity (n/%)	28 (70)	7 (58.3)	20 (80)	1 (33.3)	ns	ns	ns
Back switch (n/%)	2 (5)	0 (0)	1 (4)	1 (33)	ns	ns	ns
Lack of efficacy (n/%)	3 (7.5)	3 (25)	0 (0)	0 (0)	ns	ns	ns
AEs (n/%)	3 (7.5)	0 (0)	2 (8)	1 (33)	ns	ns	ns

BMI: body mass index, AEs: adverse events. DAPSA of 7 PsA patients and DAS28 of 3 RA patients were not available at T0.
DAPSA of 3 PsA patients and ASDAS of 1 axSpA patient were not available at T4.

our study suggest that the two types of switches are successful in terms of effectiveness measured by the standardised clinimetric indexes, although the switch from the bio-originator to a biosimilar may be negatively perceived by the patients, as indicated by a worsening in PROs. Also, a good safety profile was observed in both groups.

Regarding ADA SB5 biosimilar, premarketing registration studies have demonstrated a similar profile of efficacy and safety with respect to reference ADA (5, 6). Furthermore, two meta-analyses of randomised controlled trials (RCTs) have shown similar efficacy and safety in RA patients treated with the bio-originator ADA or its biosimilars (7, 8), while no RCT is available on ADA switch in patients with other chronic inflammatory rheumatic diseases. In a real-life context, conflicting results have been published. A recent Italian study analysed 82 patients who switched from Humira to SB5 for medical and non-medical reasons. At 3 months, patients with RA had a significant increase in TJC, and those with PsA and axSpA showed an increase in DAPSA and ASDAS, with a return to the original results at 6 months, after minor adjustment in concomitant treatment (12). Conversely, in a larger Danish cohort, 1318 patients who switched from ADA bio-originator to two different biosimilars (GP2017 or SB5) showed a higher risk of withdrawal and lower remission rates if treated with SB5 compared to GP2017. These differences between biosimilars may be due to minor variations in molecular structures, excipients, or injection devices, though the role of different clusters and residual confounding variables could not be excluded (13).

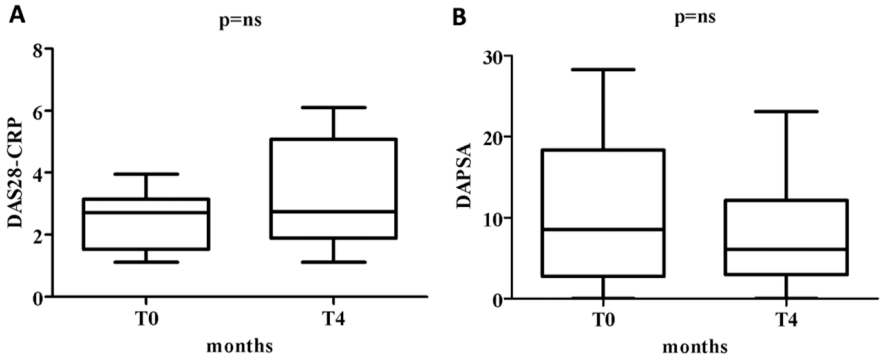

Fig. 4. DAS28-CRP and DAPSA, at baseline and after 4 months from the switch to SB5 in patients firstly treated with ABP501. **A** RA, **B** PsA.
Data are shown as Tukey boxplots; lines represent the median level with 25^{th}-75^{th} percentile; data not included between the whiskers are plotted as outliers with dots.

In our study, we did not find any differences in terms of DAS28-CRP, DAPSA, ASDAS-CRP, and BASDAI in patients who switched from Humira to SB5. However, after 4 months of SB5 treatment, we observed a significant reduction in the percentage of patients in remission/low disease activity, with a risk of moderate-high disease activity significantly higher after the switch, likely due to the observation that 11.7% did no longer maintain the remission/low disease activity status, which represents the therapeutic target in the management of inflammatory arthropathies as stated by the EULAR recommendations (2, 14, 15). Furthermore, 6.3% of patients were in a high disease activity status, 12.7% in moderate disease activity and overall 8.1% presented a disease flare (7 with high disease activity and 2 with recurrent uveitis). AEs were reported in 2.7% and all of them switched back to Humira. Interestingly, patients with RA and PsA experienced a worsening of the PGA, and those with PsA also a worsening in HAQ.

As far as the switch between the two different ADA biosimilars is concerned, no significant differences in DAS28-CRP and DAPSA, as well as in PROs,

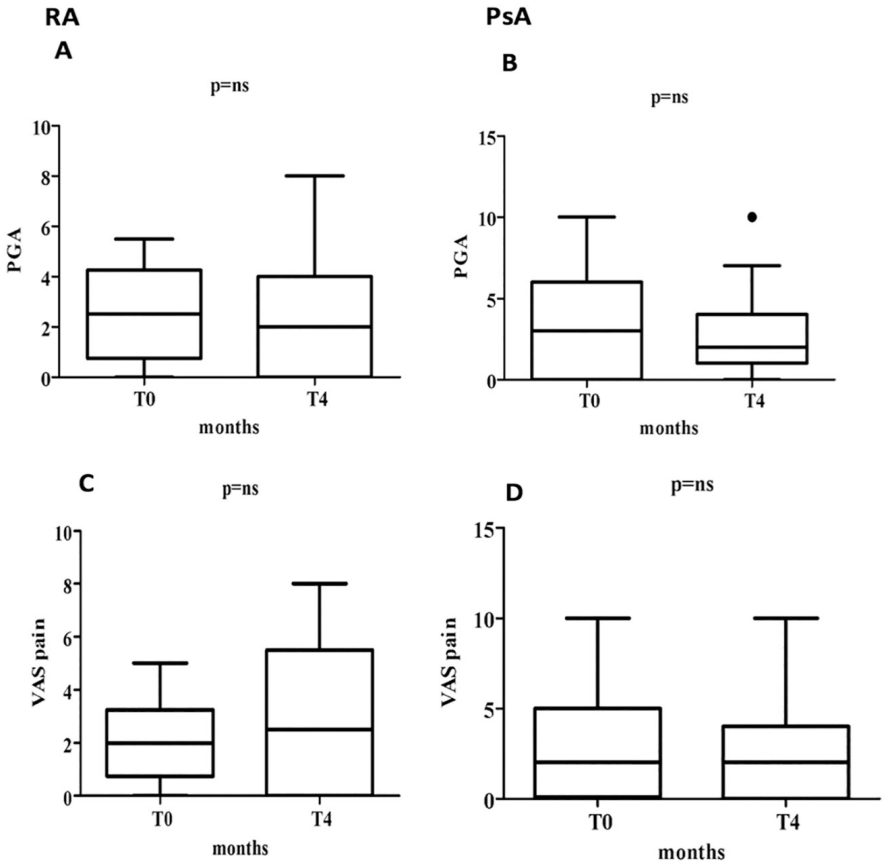

Fig. 5. PGA and pain-VAS at baseline and after 4 months from the switch to SB5 in patients firstly treated with ABP501. **A** and **C** RA, **B** and **D** PsA.
Data are shown as Tukey boxplots; lines represent the median level with 25th-75th percentile; data not included between the whiskers are plotted as outliers with dots.

were observed in our study. Among the patients who discontinued SB5, 5% back switched to ABP501, and 6.7% were switched to another drug. This is consistent with preliminary results published in the literature, albeit mainly in the form of abstracts and characterised by small cohorts and short follow-up. In the ADA bio-originator to biosimilar group, the percentage of back-switchers was high when compared with the background flare rates but is in line with the data in the literature (13).This is probably due to the combination of the nocebo effect, differences in molecular structures, excipients, and injection devices. In particular, no clinical differences in disease activity were found in a French cohort of patients with RA, PsA, and AS previously treated with infliximab originator or CT-P13 (an infliximab biosimilar) and then switched to SB2 (another infliximab biosimilar) (16). In another study from France, a retention rate from CT-P13 to SB2 of 66.7% was reported in patients with chronic inflammatory rheumatic diseases, but no data about efficacy and safety were reported (17). Similar data come from patients with gastrointestinal and dermatologic diseases. In a 2019 study, the switch from CT-P13 to SB2 in a cohort of 133 patients with inflammatory bowel disease did not significantly change disease activity after 16 or 18 weeks (18). In an Italian cohort of 24 patients with psoriasis, no difference in efficacy was shown at 6 months after the switch from CT-P13 to SB2 (19).

In our study, based on the different results obtained after the switch in the two groups, we cannot rule out that patients treated with ABP501 biosimilar may be less affected by the nocebo effect than patients initially treated with the bio-originator. Indeed, it is known that switching from an originator to a biosimilar can result in nocebo responses, including a subjective increase in disease activity and pain-related AEs (4). This hypothesis was firstly advanced in a Danish study on one-year treatment outcomes in 2061 patients with inflammatory arthropathies who switched from etanercept (ETA) originator to ETA biosimilar. Because the disease activity did not change three months after the switch and reasons for withdrawal were mainly subjective, it was suggested that the switch outcomes may be affected by both patient-related factors and non-specific drug effects, rather than the drug effects themselves (20). However, in another recent study, no changes in disease activity or function were registered following the non-medical switch from ETA bio-originator to its biosimilar in 84 patients with inflammatory arthropathies (21).

The main limitations of our study are the population size, the disparities between the 2 groups, and the short-term follow up. Nevertheless, our results replicate those reported in the literature, providing a reassuring profile of effectiveness when switching from ADA originator to one of its biosimilars and between 2 different biosimilars. However, the worse outcome in PROs in patients initially treated with the bio-originator addresses the attention to a possible nocebo response, which should encourage comprehensive communication with patients.

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