

(CRP, MMP-3), disease activity (Simplified Disease Activity Index; SDAI), physical function (Health Assessment Questionnaire; HAQ), and joint destruction (modified Total Sharp Score; mTSS) at baseline and 1-year follow-up.

Results: There were 9 patients in PD \geq 2/ET+ group and 31 patients in PD<2 group. PD \geq 2/ET+ group had significantly higher SDAI (p=0.027), MMP-3 (p=0.005), and PD (p<0.001) at baseline compared with PD<2 group, but their MMP-3 (p=0.019) and PD (p=0.042) were significantly decreased over 1 year. PD \geq 2/ET+ group had joint destruction before ET (p=0.022), but it was suppressed after ET and there was no significance in change in mTSS compared with PD<2 group (p>0.99) (Figure 1).

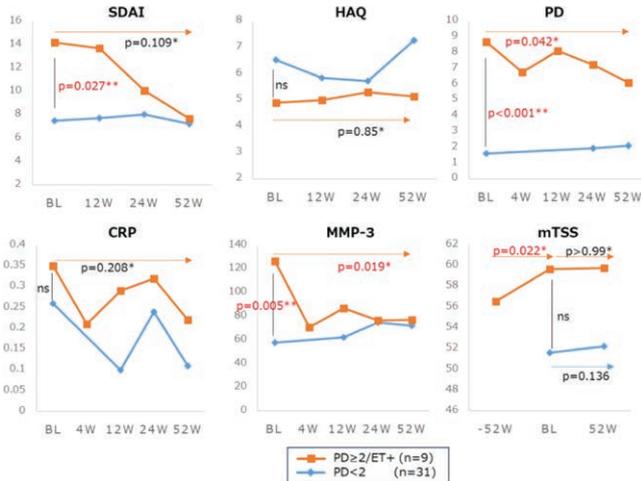


Figure 1. Disease activity, ultrasound assessment and radiographic change from baseline (BL) to 1-year follow-up in RA patients with residual synovitis who had enhanced treatment (PD \geq 2/ET+) and those without active synovitis (PD<2). *Each parameter at BL and 1-year was statistically analyzed by Wilcoxon signed rank test only in PD \geq 2/ET+ group. **Difference in two groups at BL was statistically analyzed by Student t test or Mann-Whitney U test. SDAI: simplified disease activity index, HAQ: health assessment questionnaire, PD: Power Doppler, MMP-3: matrix metalloproteinase 3, mTSS: modified Total Sharp Score.

Conclusion: In RA patients with the residual synovitis under treatment with standard dose of bDMARDs, enhanced treatment decreased the synovitis and suppressed the joint destruction.

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AB0341 EFFICACY AND DRUG SURVIVAL AFTER MULTIPLE-SWITCHING FROM ADALIMUMAB ORIGINATOR TO THE BIOSIMILARS ABP501 AND SB5: A REAL-LIFE STUDY

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Background: AntiTNF- α biosimilars are broadly available for the treatment of inflammatory arthritis. There are a lot of data concerning the maintenance of clinical efficacy after switching from originators to biosimilars. However, there is lack of data on the switch between biosimilars. The current evidence on the safety, efficacy, and immunogenicity

of switching multiple times from a biosimilar to another biosimilar comes from a limited number of randomized-controlled trials and real world evidence studies.

Objectives: The aim of our work was to evaluate the disease activity trend after multiple switching from ADA originator-Humira (oADA) to its biosimilars (bsADA; ABP 501 and SB5 subsequently) in a cohort of inflammatory arthritis patients.

Methods: In this real-life study, we selected patients with clinical diagnosis of rheumatoid Arthritis (RA), psoriatic Arthritis (PsA) and ankylosing spondylitis (AS). Patients had been previously treated with oADA and switched to the bsADA (first ABP 501 and then SB5). At each outpatient visit, we recorded demographic features (age, sex, and time since diagnosis) and the following disease activity measures: DAS28, DAPSA, BASDAI and the HAQ. Rheumatoid factor (RF), anti-citrullinated protein antibody (ACPA), C-reactive protein (CRP) and HLAB27 were also measured over the observational period (visits 0, 12, 24 and 36 months). The disease activity was evaluated during the year before the introduction of the bsADA, and then evaluated in the following 36 months during the first and the second bsADA treatment. We also examined whether some baseline characteristics, such as the duration of ADA treatment, concomitant therapy, comorbid disease and baseline disease activity, could influence the bsADA discontinuation.

Results: We evaluated the 3-year drug survival and efficacy of the multiple switch of bsADA in RA, PsA and AS patients, previously treated with oADA in 127 patients (Table 1). All the patients enrolled underwent a first switch lasting one year and then a second switch with a follow up of one year too. The 1-year retention rate for ABP501 was 84.4%, 78% and 76% in AS, RA and PsA patients, respectively. The 1-year retention rate for SB5 was 82.1%, 78,7% and 77,5% in AS, RA and PsA patients, respectively. Disease activity, as measured by DAS28, DAPSA and BASDAI remained stable over the 3 years (Figure 1). Comorbid disease (HR: 3.04, p < 0.001) and HAQ at baseline (HR: 2.12, p = 0.001) significantly increased the risk of ADA discontinuation, while previous ADA duration was positively associated with bsADA retention rate (HR: 0.83, p = 0.0024). 27.4% patients left the study due to the interruption of the bsADA, 76.5% discontinued due to inefficacy and 23.5% due to adverse events.

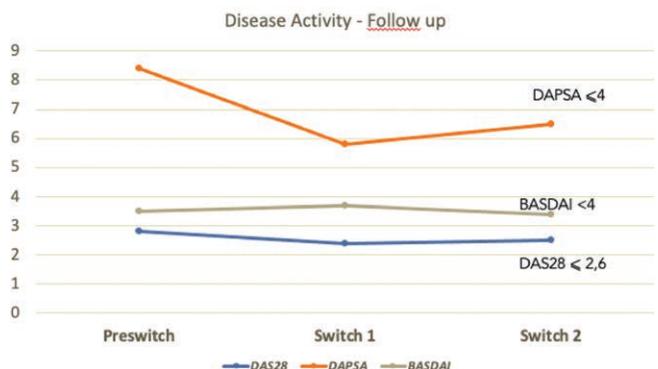
Table 1. Baseline characteristics of RA, PsA and AS patients

Characteristics	Total cohort N=127	RA N=41	PsA N=52	AS N=34
Female gender (%)	75 (60)	35 (85)	31 (59)	9 (26)
Age (years)	61.7 \pm 12.78	60.5 \pm 12.64	61.55 \pm 11.6	56.3 \pm 10.71
Disease duration (years)	15.86 \pm 9.49	17.23 \pm 10.64	13.75 \pm 6.57	14.92 \pm 9.50
Comorbidities (%)	17,8 (14)	5,7 (14)	9,8 (19)	2 (6)
ACPA+, n (%)	-	25 (63.3)	-	-
RF+, n (%)	-	24 (62.5)	-	-
HLAB27+, n (%)	-	-	8 (15)	17 (50)
CRP (mg/L)	1.65 \pm 2.27	2.31 \pm 1.90	0.42 \pm 0.27	1.36 \pm 1.91
DAS 28	-	2.65 \pm 0.75	-	-
DAPSA	-	-	8.25 \pm 3.69	-
BASDAI	-	-	-	3.23 \pm 1.58
HAQ	0.73 \pm 0.57	0.72 \pm 0.55	0.73 \pm 0.52	0.76 \pm 0.69
Prednisone, n (%)	46 (36)	23 (55)	20 (44)	3 (13)
Combo Therapy	65 (51)	29 (68)	25 (48)	11 (32)
oADA duration (months)	49.74 \pm 40.75	56.43 \pm 41.27	25.00 \pm 13.67	40.08 \pm 37.78
ABP501 duration (months)	12.42 \pm 2.41	12.77 \pm 2.34	12.82 \pm 1.49	12.49 \pm 2.95
SB501 duration (months)	11.92 \pm 1.41	12.47 \pm 1.74	12.72 \pm 1.49	12.41 \pm 1.95

ABP501 (Adalimumab biosimilar, Amgevita), SB501 (Adalimumab biosimilar, Imraldi)

Conclusion: No difference was found between oADA and bsADA in terms of efficacy. This real-life study confirms the similar efficacy profile of multiple switch bsADA with long-term retention and a good safety profile in inflammatory arthritis patients.

FIG.1



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AB0342 EVALUATION OF SELF-CARE SAFETY SKILLS AND THERAPEUTIC KNOWLEDGE OF RHEUMATOID ARTHRITIS PATIENTS ON BIOLOGIC DRUGS

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Background: The management of rheumatoid arthritis (RA) was revolutionized by the use of biologic therapies (bDMARD). Nevertheless, bDMARDs may carry some specific risks such as infection. However, data about self-care safety skills are poor [1]. An assessment of the level of information and education is therefore essential for patients followed for RA.

Objectives: The purpose of our study was to assess knowledge and safety skills of RA patients under bDMARDs.

Methods: We conducted a descriptive, bi-centric, and cross-sectional study, including RA patients receiving intravenous (IV) or subcutaneous (SC) bDMARD for at least 3 months. Sociodemographic, clinical, and paraclinical data were collected. Knowledge and self-care safety skills were assessed by a pre-specified questionnaire.

The questionnaire was divided into three domains:

- Five questions about general theoretical knowledge domain: assessing patient's knowledge of the name of the current bDMARD, duration and rate of intake, and a question on annual cost estimation.

- Three questions about the current bDMARD management: assessing cold chain compliance and management of the biologic in SC emphasizing adherence to the steps to be taken prior to giving the injection.

- Two questions about knowledge regarding safety skills in special situations: infection, cough, contraception, surgery, vaccination, and regarding the need to inform others about the use of bDMARD.

Based on the data analysis, patients were divided into 3 groups according to their knowledge level:

- Group A (low knowledge level: percentage of correct answers <40%)

- Group B (moderate knowledge level: percentage of correct answers >40% and <60%)

- Group C (high level of knowledge: percentage of correct answers > 60%).

Results: Seventy-five patients with RA were collected. Their mean age was 56.92 ± 9.06 years [34-80]. The mean duration of bDMARD was 37.17 ± 39.44 months [4-248] with a mean rank of 1.41 ± 0.9 [1-5]. The SC route was used in 41 patients (54.7%) followed by the IV route in 34 patients (45.3%).

The most prescribed molecules were Infliximab, Certolizumab and Tocilizumab (22.7% respectively). The average order of the current biologics was 1.41 ± 0.9 [1-5] in combination with a csDMARD in 48 patients (64%).

Safety skills were low in 24 patients (32%), moderate in 36 patients (48%), and high in 15 patients (20%).

The mean percentage of correct answers for each domain was respectively: 56.53 ± 18.4% [20-100] for general theoretical knowledge domain, 68.44 ± 26.21% [0-100] for the management of current biologic treatment domain, and 40.8 ± 16.87% [6.67-80] for knowledge regarding safety skills in special situations.

Safety skills levels were significantly related to occupational status (p=0.001), DAS28 CRP (p=0.04), joint deformities (p=0.01) and radiographic erosions (p=0.006), number of previous bDMARDs (p=0.009), and the rank of the current bDMARD (p=0.009).

Conclusion: The major finding of our study was the insufficient level of knowledge and safety skills of RA patients under bDMARDs. We highlight the importance of involving patients in the decision-making process and emphasize the role of the therapeutic patient education programs.

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AB0343 LONG-TERM TOCILIZUMAB TREATMENT IN PATIENTS WITH RHEUMATOID ARTHRITIS IN DAILY CLINICAL PRACTICE

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Background: Tocilizumab (TCZ) is a humanized anti-IL-6 receptor monoclonal antibody that improves the signs and symptoms of rheumatoid arthritis (RA). In previous clinical trials, long-term outcomes have been increasingly evaluated in daily clinical practice. We report the five-year outcomes of TCZ treatment at our institute.

Objectives: This retrospective study determined the long-term trends in TCZ use in clinical practice.

Methods: Data from the Toyohashi RA database (TRAD) were used. The TRAD is single-center retrospective data. Last observation carried forward was used as a complementary method for missing data. Participants were 59 RA patients in whom TCZ therapy was started at our institute from September 2009 to May 2016. Subsequent items, baseline patient characteristics, disease activity, treatment continuation rates of TCZ using the Kaplan-Meier method, reasons for stopping TCZ, concomitant use of methotrexate (MTX) and prednisolone (PSL) were investigated.

Results: Baseline characteristics at the start of TCZ treatment were 17 men and 42 women with a mean age of 58.6 years (30–81). The mean RA duration was 8.7 years (0–31). The mean SDAI score was 27.9 ± 11.6; the mean DAS28-CRP was 5.0 ± 1.0. CRP was 4.1 ± 3.0 mg/dl and MMP-3 388.3 ± 311.5 ng/ml. Methotrexate (MTX) was administered in 37 patients (62.7%, mean 6.0 mg, mean MTX dose administered in cases, 9.6 mg/week). Prednisolone (PSL) was administered in 37 patients (62.7%, mean 3.6 mg; the mean PSL dose administered in cases 5.7 mg/day).

Regarding disease activity, the mean SDAI was 27.9 at baseline; 12.3 at three months; 8.1 at one year; 7.3 at two years; 6.5 at three years; 4.67 at four years; 5.6 at five years, and 5.2 at final observation. The SDAI significantly improved after two years compared to baseline. Remission and low disease activity also significantly improved at one year and gradually improved after one year (Figure 1). The remission rate at the final observation was 55.2%, with an SDAI ≤3.3. TCZ continuation rates were 86.9% at one year, 78.7% at three years, and 68.9% at five years (Figure 2). TCZ was discontinued due to adverse events in 11 cases (18%), and inadequate efficacy occurred in 9 (14.8%). The adverse events were respiratory infection (5), purulent arthritis (1), infectious endocarditis (1), subarachnoid hemorrhage (1), breast cancer (1), pruritis (1), and skin ulcer (1). Other reasons for discontinuation were dialysis (2), suspension of hospital visits (2), kidney transplant (1), and financial difficulties (1). Concomitant use from baseline to final observation declined from 62.7% to 15.3% for MTX and from 62.7% to 23.7% for PSL.

Conclusion: Long-term treatment with TCZ was acceptable. We found that with TCZ therapy, the remission and low disease activity rates significantly improved at one year and continued to improve after one year. Treatment persistence was high, but careful monitoring for infection is necessary.

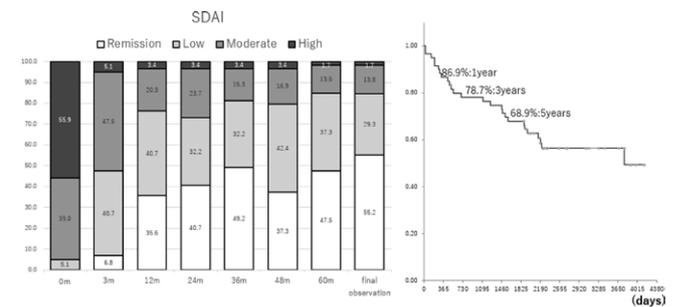


Figure 1 Time-course of Disease Activity Category in RA patients who passed 5 years after TCZ initiation (Last Observation Carried Forward, including cases who stopped TCZ therapy before 5 years after initiation)

Figure 2 Continuation rate of TCZ therapy

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AB0344 EFFICACY OF SUBCUTANEOUS INFILIXIMAB (CT-P13 SC) COMPARED WITH INTRAVENOUS INFILIXIMAB IN RHEUMATOID ARTHRITIS: A POST-HOC ANALYSIS OF A PHASE 3 RANDOMIZED CONTROLLED TRIAL

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