Adalimumab, Certolizumab, Golimumab, and Infliximab; and non-TNFi included Abatacept, Rituximab, Tocilizumab, and Tofacitinib.

Over a mean (SD) follow-up of 2.4 (2.0) years, bDMARD discontinuation/switching was reported for 37.6% of patients, with significant difference in time to discontinuation between TNFi and non-TNFi users (Logrank $p=0.01$). However, there was no significant difference due to non-response or loss of response (Logrank $p=0.67$) between the two groups. At 2 years, more patients remained on TNFi (71.0%) compared to non-TNFi (57.0%). At 5 years, 51.0% and 44.0% of patients still remained on TNFi and non-TNFi, respectively.

Conclusions: The overall retention rate for biologics was comparable to finding in European registries. We found that patients stay on TNFi longer compared to non-TNFi. However, no significant difference was found between the two groups, for discontinuation or switching of bDMARDs due to non-response or loss of response. Further analyses are required to adjust for the effect of potential confounders (e.g. age, sex, disease activity, and other treatment regimens) on biologic discontinuation.

REFERENCE:

- [1] Alejandro Souto José Ramón Maneiro Juan J. Gómez-Reino. Rate of discontinuation and drug survival of biologic therapies in rheumatoid arthritis: a systematic review and meta-analysis of drug registries and health care databases. *Rheumatology* 2016 March 1;55(3):523–534.

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SAT0197

ADHERENCE TO BIOLOGIC THERAPY OF RHEUMATOID ARTHRITIS PATIENTS – IS THERE ANY RELATION WITH DISEASE ACTIVITY?

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Background: In the last years, there has been an increase interest in using Patient Reported Outcomes (PROs) in clinical trials and daily clinical practice in Rheumatology to provide patient-centered care. The most frequently reported PROs are patient's pain, patient's global assessment (PGA) of disease activity and reports of functional capacity, fatigue, anxiety and depression. To date, studies that explore patient adherence to rheumatic medications are scarce.

Objectives: To study the level of adherence to biologic therapy of Rheumatoid Arthritis (RA) patients, followed at a day care hospital of Rheumatology.

Methods: Observational and cross-sectional study which took place in two months of consultation of day care hospital (5 periods per week). Patients with a diagnosis of RA according to 1987 American College of Rheumatology (ACR) and/or 2010 ACR/European League Against Rheumatism criteria, on biologic therapy, able to complete a questionnaire autonomously and who agreed to participate were included. Demographic and clinical data (DAS28, CDAI and SDAI to assess RA disease activity, HADS-A for anxiety, HADS-D for depression, FACIT-F for fatigue) were collected. To assess adherence, a Portuguese version of the Morisky Medication Adherence Scale (MMAS-8) was used and the patients were asked to apply it only to biologic therapy. Three levels of adherence were considered based on the following scores: 0 to <6 (low); 6 to <8 (medium); 8 (high). Statistics: Kruskal-Wallis and Mann-Whitney tests, $p<0.05$, SPSS® v.23.

Results: In total, 61 patients were included, 91.8% female, 82.0% on anti-Tumor Necrosis Factor (anti-TNF), the others on Tocilizumab (16.4%) or Abatacept (1.6%). Table 1 reports the means and medians of demographic and clinical variables included. The mean MMAS-8 score was 7.0 ± 1.2 , the median 7.0 (6.8–8.0), with a minimum of 2.5 and a maximum of 8. The adherence was medium in 50.8%, high in 36.1% and low in 13.1% patients. The median of current age was significantly higher for patients with high and medium levels of adherence compared to those with low levels ($p=0.030$). The time on treatment with the current biologic therapy was significantly different between the levels of adherence ($p=0.028$); the median of time on treatment for patients with medium levels of

adherence was significantly higher comparatively to the other patients ($p=0.009$). No other significant difference was found among the levels of adherence for the studied variables.

Conclusions: The adherence to biologic therapy was at least medium for 86.9% of patients. Differences between levels of adherence were found only for current age and time on treatment. Disease activity of RA does not seem to influence the levels of adherence.

Table 1 Means and medians of demographic and clinical variables.

	Mean ±SD	Median (IQR)
Current age – years	56.1 ±11.1	58.1 (48.1– 62.8)
Disease duration – years	15.0±7.5	13.1 (10.1– 18.2)
Time on treatment with the current biologic therapy – years	3.5±2.7	2.8 (1.0–5.6)
DAS28–4V	3.4±1.2	3.3 (2.6–4.2)
CDAI	9.7±7.8	7.0 (3.6–15.1)
SDAI	10.1±8.0	7.0 (4.0–15.7)
HAQ	0.9±0.6	0.9 (0.4–1.4)
HADS-A	6.5±3.9	6.0 (3.0–9.0)
HADS-D	5.4±3.7	5.0 (2.0–8.0)
FACIT-F	36.5±8.8	37.0 (29.1– 43.5)

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SAT0198

DRUG SURVIVAL AND EFFICACY OF ABATACEPT IN RHEUMATOID ARTHRITIS PATIENTS IN ROUTINE CARE – 7 YEAR EXPERIENCE FROM A SINGLE CENTRE IN THE UNITED KINGDOM

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Background: Even after the advent of multiple biologic drugs, optimum treatment of rheumatoid arthritis (RA) in a real-world situation continues to be challenging. The data on long-term drug survival of biologic drugs in routine clinical practice is lacking. We extended our earlier analysis of abatacept use in RA patients^{1,2} from a single centre in the United Kingdom over 7 years.

Objectives: To assess the efficacy, tolerability and drug survival of abatacept use in RA patients in a routine clinical setting like ours.

Methods: From November 2010 to December 2017, all RA patients with at least 6 months of follow up after abatacept initiation were included in the analysis. Data on demographics, disease duration, previous biologics, mode of administration, reasons for discontinuation and length of abatacept therapy were retrospectively collected from biologics database and medical records. Effectiveness was assessed by change in Disease activity scores (DAS 28) and European League Against Rheumatism response criteria (EULAR) after 6 months of therapy.

Results: 220 patients had received abatacept with at least 6 months follow up until December 2017. 176 were females and 44 males with mean age of 67.83 years (SD = 10.32). Mean disease duration in these patients was 14.42 years (SD = 8.11). 152 (69%) patients were seropositive (Rheumatoid factor and/or anti-CCP antibody). 207 (94%) patients had received a prior biologic and only 13 (6%) patients were biologic naïve. 193 (87.7%) patients were initiated on intravenous (iv) abatacept and 27 (12.2%) patients on subcutaneous (s/c) abatacept. 90 (40.9%) patients were successfully switched from iv to s/c abatacept.

The mean number of prior biologic drugs use per patient was 1.70 (SD = 1.03). 83.6% patients were co-prescribed DMARDs at the initiation of abatacept therapy. Mean baseline DAS 28 score was 6.02 (SD = 3.11). Average DAS 28 change at 6 months was -1.5 (95% CI -1.27, -1.33). 75% patients had a positive EULAR response (38% good, 37% moderate) and 25% had no response at 6 months.

Overall 57 (25.9%) patients discontinued treatment. 43 (19.5%) patients discontinued abatacept early (<9 months) due to primary inefficacy (10.9%) and adverse reactions (8.6%). 24 (10.9%) patients discontinued abatacept later, after a mean 27.46 (SD = 12.9) months of use, due to secondary loss of efficacy (6.3%) and adverse reactions (4.5%).

82% (180/220) of RA patients continued taking abatacept beyond 6 months. 61.5% (91/148) patients were still adherent at 2 years, 51.3% (39/76) retained the drug beyond 48 months.

Conclusions: Abatacept continues to be a safe and effective treatment option for patients with RA who are biologic naïve or after discontinuation of prior biologic due to failure or intolerance. A significant number of patients continue on abatacept even after 4 years.

REFERENCES:

- [1] Joshi P, Sheeran T, Venkatachalam S, et al. AB0370 Real Life Experience with Abatacept in Patients with Rheumatoid Arthritis from A Regional Centre in UK. *Annals of the Rheumatic Diseases* 2016;75:1030.
- [2] Ahmed N, Roskell S, Passey K, et al. AB0441 Abatacept in Rheumatoid Arthritis (RA) Patients: Real-Life Experience in A Subregional Centre in UK. *Annals of the Rheumatic Diseases* 2014;73:954.

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SAT0199

SWITCH FROM INNOVATOR ETANERCEPT TO BIOSIMILAR ETANERCEPT IN INFLAMMATORY RHEUMATIC DISEASES: THE EXPERIENCE OF COCHIN UNIVERSITY HOSPITAL PARIS-FRANCE.

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Background: Etanercept biosimilar (bETN) is available for treatment of spondyloarthritis (SpA) and rheumatoid arthritis (RA) since 2016 in France. Data showing effectiveness and safety of bETN are still limited.

Objectives: 1/To evaluate the RA and SpA patients' and treating rheumatologists' characteristics associated with the switch 2/To evaluate the safety and efficiency of bETN.

Methods: **Patients:** All the patients receiving innovator etanercept for at least 3 months on October 2016 and monitored in the department of rheumatology B of Cochin hospital. **Physicians:** All the 9 physicians in charge of at least one patient. **Study design:** After information (one hour session) on the biosimilars, all the physicians were invited to propose a switch from innovator etanercept to bETN. **Data collected:** physicians' characteristics, patients' characteristics (demographics, diagnosis of the rheumatic disease, disease activity parameters).

Results: Of the 435 outpatients who had received etanercept; 304 were receiving etanercept in 2016 and 183 were eligible for a potential switch (the remaining 121 patients did not attend any out-patient-clinic between October 1st 2016 and April 1st 2017).

The percentage of patients who switched to bETN was 51.6% (94 patients).

This switch was more frequently performed in patients monitored by older physicians (mean age: 50.4±14.3 vs 44.8±11.3, p=0.005) and by physicians with a full-time academical position (56.4 % vs 13.5 %, p<0.001)

The patients' characteristics were similar: % RA (51.1% vs 44.9%), age (52.1±15 vs 50.5±15), female gender (57.4% vs 51.6%), disease duration (16.8±11.9 vs 14.8±11.3) except for the NSAID intake (28.3 % vs 12.3 %, p=0.014) and the global evaluation (25.2±19.4 vs 19.1±21.8, p=0.02) in the switchers vs non-switchers, respectively. However, no independent factors were associated with the switch in the multivariate analysis.

The bETN retention rate was 83 % [0.76–0.92] after a 6 month follow-up period. The bETN was discontinued in 26 patients with the following reasons: inefficiency 13 patients, adverse event 13 patients (painful injection site n = 4, fatigue = 2, pruritus n = 2, "allergic reaction" n = 1, headache n = 1, pollakiuria n = 1, dizziness n = 1, supply problem n = 1).

The univariate analysis aimed at evaluating the baseline predisposing factors of bETN discontinuation overtime picked up the baseline objective sign of inflammation (defined by CRP≥6 mg/L or ESA ≥28 mm) (OR=4.18 [1.19 – 14.66] p=0.0256), p=0.002) and global disease activity score (OR = 1.57 [1.04 – 2.36], p=0.03). Nevertheless, no independent factors were associated with the switch in the multivariate analysis.

There was no difference in the changes in the disease activity parameters in both the completer and ITT population.

Conclusions: This study suggests that:

- 1/The probability to switch from etanercept innovator to bETN was mainly related to physicians' behavior
- 2/Using an open design, the percentage of patients complaining of a lower efficiency and/or a worse safety profile of the biosimilar was high
- 3/There was no objective parameter permitting to conclude at a lower efficiency and/or a worse safety profile of the bETN in comparison to the innovator etanercept.

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SAT0200

LONG TERM SAFETY OF FILGOTINIB IN THE TREATMENT OF RHEUMATOID ARTHRITIS: WEEK 108 DATA FROM A PHASE 2B OPEN-LABEL EXTENSION STUDY

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Background: Filgotinib (FIL) is an orally administered, selective inhibitor of Janus Kinase 1 (JAK1) in Phase 3 development for the treatment of rheumatoid arthritis (RA).

Objectives: Assess the long-term safety and efficacy of FIL in the DARWIN 3 open-label extension study.

Methods: Two 24-week Phase 2b studies were completed in patients (pts) with moderately to severely active RA (DARWIN 1, DARWIN 2; Ref 1, 2). Following study completion, pts were offered FIL in the ongoing DARWIN 3 extension study: 100 mg QD (US males), 200 mg QD, or 100 mg BID. This report summarizes safety data from the first dose of FIL in the DARWIN program to 11 Oct 2017 and efficacy data from the DARWIN 3 baseline visit to Week 108, which all ongoing pts have completed.

Results: Of 877 pts, 790 (90%) completed DARWIN 1/2, and 739 (84%) enrolled in DARWIN 3; 603 (82%) were female, mean age 53 years. At analysis, 491/739 (66%) were on study. Cumulative patient years of exposure (PYE) was 1931, median time on study drug was 1072 days. Key data are summarized in table 1. 87%, 68%, and 48% of pts achieved ACR20/50/70, respectively, and 72% achieved DAS28-CRP≤3.2 (by observed case analysis).

Table 1 Key Safety Events and Lab Abnormalities per 100 PYE*

Events Per 100 PYE	Filgotinib + MTX		Filgotinib Monotherapy	Total* (N=739)
	100 mg BID (N=249)	200 mg QD (N=250)	200 mg QD (N=222)	
Treatment-emergent AEs (TEAEs)	146.7	141.7	150.3	146.2
Serious TEAEs	5.9	3.9	7.4	5.7
TEAEs for Infections	44.5	39.3	37.2	40.0
Serious TEAEs for Infections	1.2	0.6	2.2	1.3
Malignancy (excl. NMSC [†])	0.8	0.4	0.7	0.6
Herpes Zoster	1.2	1.5	1.1	1.2
Deep Vein Thrombosis [‡]	0.2	0	0	0.1
Pulmonary Embolism [‡]	0.2	0	0	0.1
Active Tuberculosis	0	0	0	0
≥ Grade 3 Laboratory Abnormalities				
Hemoglobin ↓	0.5	0.1	0	0.2
Lymphocytes ↓	1.2	0.9	0.4	0.8
Neutrophils ↓	0.3	0.1	0.2	0.2
Platelets ↓	0	0.3	0	0.1
ALT ↑	0.2	0.1	0.2	0.2
Creatinine ↑	0.3	0	0	0.1
LDL ≥ 190 mg/dL	17.0	5.5	18.4	13.1
HDL <40 mg/dL	5.4	7.3	6.9	7.1

*Treatment groups with fewer than 10 subjects were omitted for clarity; [†]Non-melanoma skin cancer;

[‡]Single patient DVT leading to PE

*Treatment groups with fewer than 10 subjects were omitted for clarity; [†]Non-melanoma skin cancer; [‡]Single patient DVT leading to PE

Conclusions: Filgotinib long-term RA data demonstrates an acceptable safety and durable efficacy profile.

REFERENCES:

- [1] Westhovens R, et al. *Ann Rheum Dis* 2017;76:998–1008.
- [2] Kavanaugh A, et al. *Ann Rheum Dis* 2017;76:1009–1019.

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