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Background: In the last 20 years, anti-tumor necrosis factor (TNF) alpha agents re-designed the management of rheumatoid arthritis (RA). Despite this, unmet needs in the management of RA brought several drugs targeting different molecules and cytokines. It is still a research question that how did these developments changed daily-practice in RA patients who are intolerant/unresponsive to the first biological disease modifying anti-rheumatic drugs (bDMARD).

Objectives: In this study, we aimed to explore the second biologic agent trends of our 20-years of single-center experience.

Methods: HUR-BIO (Hacettepe University Rheumatology Biologic Registry) is a single center biological disease modifying anti-rheumatic drug (DMARD) registry since 2005. Patients who were started biologics before 2005 were registered retrospectively. Until the end of the 2020, 21 different rheumatologists contributed to the development of HUR-BIO. Distribution of the second-line biological agents (switch from first-line biological agent because of either adverse events or unresponsiveness) was calculated according to 5-year periods starting from the 2001. Also, demographic and serologic data of RA patients were reported.

Results: A total of 776 (776/2080, 37.3%) RA patients, who was prescribed a second biological agent, was registered in HUR-BIO by the end of 2020. Of these patients, 83.7% was female. Mean age at the starting of bDMARD was 53.1 ± 13.3 years. Rate of rheumatoid factor and anti-cyclic citrullinated peptid positivity was 69.1% and 60.5%, respectively. Distribution of first-line bDMARDs was as follows: adalimumab 194 (24.9%), etanercept 209 (26.9%), infliximab 105 (13.5%), golimumab 39 (5.0%), certolizumab 35 (4.5%), abatacept 78 (10.0%), rituximab 46 (5.9%), tofacitinib 37 (4.7%), tocilizumab 33 (4.2%). 11 (1.4%), 85 (11.0%), 282 (36.3%) and 398 (51.3%) patients were prescribed with their second bDMARD in 2001-2005, 2006-2010, 2011-2015 and 2016-2020, respectively. There was a trend towards the increasing prescription of non-Anti-TNF bDMARDs as second-line over time.

Table 1. Distribution of second biologic DMARDs in RA patients according to 5-years periods

	2001-2005	2006-2010	2011-2015	2016-2020	Total
Adalimumab	3 (27.3)	15 (17.6)	69 (23.9)	77 (18.9)	164 (20.8)
Etanercept	8 (72.7)	35 (41.2)	49 (17.0)	41 (10.1)	133 (16.8)
Infliximab	0	12 (14.1)	13 (4.5)	25 (6.2)	50 (5.4)
Golimumab	0	0	19 (6.6)	8 (2.0)	27 (3.4)
Certolizumab	0	0	2 (0.7)	26 (6.4)	28 (3.5)
Anti-TNF	11 (100)	62 (72.9)	152 (53.9)	177 (44.5)	402 (51.8)
Tofacitinib	0	0	4 (1.4)	73 (17.9)	77 (9.7)
Tocilizumab	0	0	12 (4.2)	81 (19.9)	93 (11.7)
Rituximab	0	22 (25.9)	53 (18.3)	32 (7.8)	107 (13.5)
Abatacept	0	1 (1.2)	61 (21.1)	35 (8.6)	97 (12.2)
Non-Anti-TNF	0	23 (27.1)	130 (46.1)	221 (55.5)	374 (48.2)
Total	11 (100)	85 (100)	282 (100)	398 (100)	776 (100)

Approval years of drugs in Turkey; Infliximab: 2003, etanercept:2004, adalimumab: 2005, golimumab: 2013, certolizumab: 2014, abatacept: 2010, tocilizumab: 2013, rituximab:2009, tofacitinib: 2015

Conclusion: As the choice of second-line biologic and targeted synthetic DMARD, non-Anti-TNF bDMARDs, especially tofacitinib and tocilizumab becoming more frequent year-by-year. Despite that, anti-TNF agents as a group are still highly-prescribed options as second-line bDMARD.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2021-eular.694

AB0202

IMPROVEMENT IN CLINICAL DISEASE ACTIVITY AND PATIENT-REPORTED OUTCOMES AFTER 6 MONTHS OF TREATMENT WITH ABATACEPT, STRATIFIED BY LINE OF THERAPY, IN PATIENTS WITH RA: RESULTS FROM A LARGE, US, NATIONAL OBSERVATIONAL STUDY

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Background: RA is more responsive to treatment in the early stages of disease, and early treatment may lead to better long-term outcomes.^{1,2} Data on the effectiveness of specific drugs as first or later lines of therapy will help inform treatment sequencing.

Objectives: Data from patients enrolled in the Corrona RA Registry were used to compare the effectiveness of abatacept across lines of therapy overall (primary cohort) and in a subset of patients who were anti-citrullinated protein antibody positive (ACPA+).

Methods: Patients with RA who initiated abatacept (January 2006 to October 2020), had 6 months' follow-up (within 4–9 months of starting abatacept), had baseline (BL) and follow-up CDAI scores available, and had BL CDAI >2.8 were included. Outcomes were compared for first-, second- and third or higher-line therapy: 0, 1 or ≥2 prior biologic DMARDs or Janus kinase inhibitors, respectively. Continuous outcomes included change from BL to 6 months in mean CDAI and patient-reported pain, fatigue, and HAQ. Binary outcomes included rate of achieving minimal clinically important difference (MCID) in CDAI or modified ACR20/50/70 at 6 months. Continuous and binary outcomes were analysed using multiple linear and logistic regression, respectively. The models included line of therapy, age, sex, disease duration, work status, SC nodules, history of hypertension and depression, BL CDAI, BL patient-reported pain and BL fatigue. Additional subgroup analyses were carried out in patients with moderate/high disease activity (CDAI >10) at BL.

Results: In total, 2876 patients (2327 with BL CDAI >10; 890 ACPA+) were included; 442, 911, and 1523 patients initiated first-, second- or third/higher-line abatacept, respectively. Compared with patients on second/third/higher-line abatacept therapy, those on first-line abatacept were significantly older, had shorter disease duration, and had lower BL CDAI, pain and fatigue (all p<0.001). In adjusted analyses, patients receiving abatacept as earlier lines of therapy had significantly greater improvement from BL in mean CDAI and in patient-reported fatigue and HAQ (Table 1). There was no significant difference between lines of therapy in change in patient-reported pain. Patients receiving first-line abatacept had significantly higher odds of achieving a MCID in CDAI or modified ACR20/50/70 response (Figure 1). Similar patterns were seen when the sample was limited to patients with moderate/high disease activity or in patients who were ACPA+.

Conclusion: There were significant differences in improvement in clinical disease activity and patient-reported outcomes across lines of therapy. Better treatment responses were observed with earlier lines of abatacept therapy in the overall population, in patients who were ACPA+ and in those with moderate/high BL disease activity.

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Table 1. Adjusted mean change in CDAI and patient-reported outcomes from BL to 6 months after initiation of abatacept by line of therapy (primary cohort)

Adjusted outcome, mean change (SE)	First-line (n=440)	Second-line (n=898)	Third/higher-line (n=1515)	p value ^a
CDAI	-7.96 (0.33)	-7.49 (0.27)	-5.74 (0.19)	<0.001
Patient-reported pain (VAS 0–100)	-9.43 (0.69)	-7.98 (0.47)	-7.70 (0.35)	0.074
Patient-reported fatigue (VAS 0–100)	-7.49 (0.71)	-5.87 (0.51)	-4.81 (0.36)	0.002
Patient-reported HAQ	-0.16 (0.01)	-0.12 (0.01)	-0.08 (0.01)	<0.001

^aEstimated by multiple linear regression model adjusted for age, sex, disease duration, work status, SC nodules, history of hypertension and depression, BL CDAI, BL patient-reported pain and BL fatigue (factors that were identified *a priori* based on clinical experience or that differed significantly by line of therapy); p values reflect ANOVA overall test of differences across lines of therapy. VAS=visual analogue scale.

Figure 1. Adjusted odds ratio of achieving MCID CDAI or modified ACR20/50/70 at 6 months after initiation of abatacept by line of therapy (primary cohort)

*Estimated by multiple logistic regression analysis adjusted for age, sex, disease duration, work status, SC modules, history of hypertension and depression, BL CDAI, BL patient-reported pain and BL fatigue (factors that were selected a priori based on clinical experience or differed significantly by line of therapy); p values reflect overall difference across lines of therapy.
^bReduction in CDAI score of 2 if BL disease activity was low (CDAI score ≤10); of 6 if BL disease activity was moderate (CDAI score >10 and ≤22); and of 11 if BL disease activity was high (CDAI score >22).
^cModified ACR criteria is based on 2 out of 4 measures (not using ESR or CRP).
 Modified ACR20/50/70=20/50/70% improvement in modified ACR criteria; MCID=minimal clinically important difference; OR=odds ratio.

Acknowledgements: Professional medical writing and editorial assistance was provided by Claire Line, PhD, at Caudex and was funded by Bristol Myers Squibb. The poster was a collaborative effort between Corrona and Bristol Myers Squibb, with financial support provided by Bristol Myers Squibb. This study was sponsored by Corrona, LLC. Corrona is supported through contracted subscriptions with multiple pharmaceutical companies.

Disclosure of Interests: Leslie Harrold Consultant of: AbbVie, Bristol Myers Squibb, Genentech/Roche, Grant/research support from: Pfizer, Keith Wittstock Employee of: Bristol Myers Squibb, Sheila Kelly Shareholder of: Bristol Myers Squibb, Employee of: Bristol Myers Squibb, Sang Hee Park Employee of: Bristol Myers Squibb, Xue Han Employee of: Bristol Myers Squibb, Ying Shan: None declared, Carla Roberts-Toler: None declared, Nicole Middaugh: None declared, Vadim Khaychuk Shareholder of: Bristol Myers Squibb, Employee of: Bristol Myers Squibb

DOI: 10.1136/annrheumdis-2021-eular.701

AB0203

EFFECT OF DOSE ESCALATION OF SUBCUTANEOUS TOCILIZUMAB ON DISEASE ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS IN A RANDOMIZED CONTROLLED TRIAL

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Background: In patients with RA, subcutaneous tocilizumab (TCZ-SC) is administered every 2 weeks (q2w) or every week (qw), based on the patient's weight and clinical response.

Objectives: To compare the effects on disease activity at week 24, when the dosing schedule of TCZ-SC was escalated from q2w to qw, in patients who did not achieve LDA (DAS28-ESR > 3.2) at week 12 in COMP-ACT with patients who, despite not achieving LDA, continued TCZ-SC qw in SUMMACTA and q2w in BREVACTA.

Methods: US patients in COMP-ACT who weighed < 100kg at baseline and who received TCZ-SC 162mg q2w + methotrexate escalated to qw if they did not achieve LDA at week 12. DAS28-ESR remission (< 2.6) and LDA (< 3.2), CDAI remission (< 2.8) and LDA (< 10) and SDAI remission (< 3.3) and LDA (< 11) at week 24 were compared between patients who switched from q2w to qw and North American patients in SUMMACTA who initiated TCZ qw + csDMARDs and continued a qw dose (baseline body weight < 100kg and DAS28 > 3.2 at week 12). A secondary analysis compared COMP-ACT patients who escalated from q2w to qw with all SUMMACTA patients who continued a qw dose and all BREVACTA patients who initiated a TCZ-SC q2w dose + csDMARDs and continued a q2w dose (baseline body weight < 100kg and DAS28 > 3.2 at week 12). DAS28 was standardized to DAS28-ESR, and comparisons were calculated using a mixed model with repeated-measures logistic regression, including the following covariates: CDAI, SDAI and/or DAS28 at the reference visit (week 12),

as well as study baseline values of CDAI, SDAI and/or DAS28, baseline age, sex, TNFi use prior to the study (yes or no) and weight category.

Results: A total of 328 US patients in COMP-ACT did not achieve LDA at week 12 and escalated from q2w to qw TCZ-SC. In SUMMACTA, 285 patients did not achieve LDA at week 12 and continued TCZ-SC qw, of whom 71 were from North America. Baseline demographic and clinical characteristics were comparable between patients in COMP-ACT and North American patients in SUMMACTA. A significantly higher proportion of patients in COMP-ACT achieved DAS28-ESR, CDAI and SDAI remission and LDA 12 weeks after TCZ dose escalation (week 24) than North American SUMMACTA patients (Table 1). Similar results were seen when the proportion of patients who achieved DAS28 remission and LDA was compared at week 24 between patients in COMP-ACT and patients from all geographic regions who did not escalate dosing in SUMMACTA and BREVACTA (N=196).

Conclusion: US patients with RA who did not achieve LDA and escalated from q2w to qw TCZ-SC at week 12 in COMP-ACT had better disease activity outcomes at week 24 than North American patients who did not achieve LDA and continued qw dosing in SUMMACTA. These results provide some evidence that escalation from q2w to qw has more effect than expected without dose change for patients who do not achieve LDA by week 12.

Table 1. Comparison at Week 24 of Clinical Response After Week 12 Dose Escalation or Continuation Between Patients Who Did Not Achieve LDA at Week 12

	All COMP-ACT (N = 328)	North American SUMMACTA (n = 71)	All SUMMACTA (N = 285)	All BREVACTA (N = 196)
DAS28-ESR remission, n (%)	66 (20.1)	7 (9.9)	44 (15.4)	36 (18.4)
Adjusted OR (95% CI)	Ref	5.76 (1.92, 17.32)	3.29 (2.11, 5.12)	2.35 (1.44, 3.84)
P value	Ref	0.0018	< 0.0001	0.0006
DAS28-ESR LDA, n (%)	122 (37.2)	17 (23.9)	90 (31.6)	60 (30.6)
Adjusted OR (95% CI)	Ref	3.36 (1.61, 7.00)	2.81 (1.97, 4.01)	2.24 (1.50, 3.33)
P value	Ref	0.0012	< 0.0001	< 0.0001
CDAI remission, n (%)	12 (3.7)	2 (2.8)	13 (4.6)	11 (5.6)
Adjusted OR (95% CI)	Ref	4.50 (1.32, 15.32)	2.93 (1.37, 6.27)	1.45 (0.69, 3.05)
P value	Ref	0.0161	0.0056	0.3325
CDAI LDA, n (%)	80 (24.4)	11 (15.5)	81 (28.4)	66 (33.7)
Adjusted OR (95% CI)	Ref	4.19 (1.88, 9.35)	2.35 (1.63, 3.39)	1.32 (0.88, 1.97)
P value	Ref	0.0005	< 0.0001	0.1825
SDAI remission, n (%)	16 (4.9)	2 (2.8)	15 (5.3)	11 (5.6)
Adjusted OR (95% CI)	Ref	5.23 (1.44, 19.01)	3.23 (1.54, 6.76)	1.64 (0.81, 3.30)
P value	Ref	0.0120	0.0019	0.1670
SDAI LDA, n (%)	89 (27.1)	11 (15.5)	91 (31.9)	72 (36.7)
Adjusted OR (95% CI)	Ref	4.68 (2.20, 9.99)	2.20 (1.56, 3.11)	1.47 (0.99, 2.17)
P value	Ref	< 0.0001	< 0.0001	0.0540

Acknowledgements: This study was funded by Genentech, Inc. Support for third-party writing assistance, furnished by Health Interactions, Inc., was provided by Genentech, Inc.

Disclosure of Interests: Nora Singer Grant/research support from: Genentech/Roche, Merck and Pfizer, Shalini Mohan Shareholder of: Genentech, Inc., Employee of: Genentech, Inc., Jian Han Shareholder of: Genentech, Inc., Employee of: Genentech, Inc., Michael Edwardes Employee of: Everest Clinical Research, Margaret Michalska Shareholder of: Genentech, Inc., Employee of: Genentech, Inc.

DOI: 10.1136/annrheumdis-2021-eular.795

AB0204

THE PROPER STUDY: INTERIM ANALYSIS OF A PAN-EU REAL-WORLD STUDY OF SB5 BIOSIMILAR FOLLOWING TRANSITION FROM REFERENCE ADALIMUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS, AXIAL SPONDYLOARTHRITIS, OR PSORIATIC ARTHRITIS

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