

health status, the change in patient satisfaction adjusted for CDAI at week 0 was statistically significantly correlated with changes in "symptom" and "affect" (all  $p$ -values  $< 0.05$ ). However, there were no statistically significant correlations between change in patient satisfaction and change in "physical", "role", and "social interaction".

**Conclusions:** Satisfaction was correlated with pain, PGA and psychological state in patients with RA treated with tocilizumab. On the other hand, satisfaction was not correlated with TJC, SJC and EGA. In other words, it appears that patient satisfaction is more closely linked with how symptoms are experienced physically and mentally. Further research into specific factors influencing the patients' experience could shed more light on conditions for improving patients' satisfaction and QOL.

**Disclosure of Interest:** None declared

**DOI:** 10.1136/annrheumdis-2018-eular.5999

### FRI0133 CENTRAL ROLE OF TOCILIZUMAB IN FIBROBLAST DOMINATED MODELS OF INFLAMMATORY AUTOIMMUNE ARTHRITIS

M.A. Nielsen, B. Deleuran, T.W. Kragstrup. *Biomedicine, Aarhus University (AU), Aarhus, Denmark*

**Background:** Immune mediated inflammatory arthritis including rheumatoid arthritis (RA), psoriatic arthritis (PsA) and spondyloarthritis (SpA) all characterised by joint synovitis. Disease-modifying antirheumatic drugs (bDMARDs) targeting specific components of the pathogenesis have radically improved the treatment of the diseases. However, a fair proportion of patients are non-responders.

Today, the first choice of DMARD is dependent on market pricing, regardless of the immunological target. This is due to the rather similar efficacy profile of the different DMARDs. Therefore, there is a need for stratification of patients suffering from Immune mediated inflammatory arthritis in order to reduce the fraction of DMARD non-responders.

**Objectives:** The objective of this study was to study the effects of various DMARDs on different synovial cell subsets using several human *ex vivo* models of immune mediated inflammatory arthritis. This could potentially guide future studies of personalising DMARDs in these diseases.

**Methods:** Synovial fluid was obtained from a study population of patients with active rheumatoid arthritis (RA) or peripheral spondyloarthritis (SpA). Synovial fluid mononuclear cells (SFMCs) containing primarily synovial monocytes and lymphocytes cultured for 48 hours ("Macrophage and Lymphocyte model") were used to study the effect of different biological agents on secretion of monocyte chemoattractant protein-1 (MCP-1) ( $n=14$ ). Further, fibroblast-like synovial cells (FLSs) were co-cultured with autologous PBMCs ("FLS model") to study the effects of the same biological agents ( $n=6$ ) in cultures dominated by synovial FLSs. Finally, SFMCs cultured for 21 days ("Osteoclast model") were studied to assess the effects on inflammatory osteoclastogenesis ( $n=10$ ) measured by tartrate-resistant acid phosphatase (TRAP). The DMARDs investigated are shown in table 1.

**Results:** "Macrophage and Lymphocyte model"; In SFMCs cultured for 48 hours, all DMARDs included, except anakinra, had the ability to decrease the production of MCP-1. The two TNF inhibitors (adalimumab and etanercept) ( $p < 0.05$  and  $p < 0.01$ ) and baricitinib ( $p < 0.05$ ) had the most pronounced effects and reduced the production of MCP-1 by approximately 25%. Tocilizumab had in this culture a non-significant reduction of MCP-1 production.

"FLS model"; In the FLS+PBMCs cultured for 48 hours, tocilizumab ( $p < 0.001$ ) and the two JAK inhibitors (tofacitinib and baricitinib,  $p < 0.05$  and  $p < 0.05$ ) were exclusive in decreasing the cytokine production of MCP-1 by around 50%.

"Osteoclast model"; In SFMCs cultured for 21 days, only the two TNF inhibitors, adalimumab and etanercept were able to significantly reduce the secretion of TRAP from adherent macrophage like synovial cells by roughly 25% ( $p < 0.01$ ,  $p < 0.001$ ).

#### Abstract FRI0133 – Table 1

##### Generic name:

Adalimumab  
Etanercept  
Tocilizumab  
Anakinra  
Ustekinumab  
Secukinumab  
Tofacitinib  
Baricitinib

**Conclusions:** This study reveals that most DMARDs have effects in the "Macrophage and Lymphocyte model" whereas tocilizumab, tofacitinib and baricitinib were superior in the "FLS model" and only the two TNF inhibitors were effective in

the "Osteoclast model". The findings in the "FLS model" reveals a possible beneficial effect of tocilizumab and JAK inhibitors to patients with fibroblast dominated arthritis. This study could potentially guide future studies of personalising DMARDs to treat immune mediated inflammatory arthritis.

**Disclosure of Interest:** None declared

**DOI:** 10.1136/annrheumdis-2018-eular.2930

### FRI0134 IS THERE ANY DIFFERENCE IN RA PATIENTS FOR METHOTREXATE USE VS. LEFLUNOMIDE USE AS A CONCOMITANT TREATMENT WITH BIOLOGICAL AND TARGETED SYNTHETIC DMARDs IN TURKIBIO REGISTRY?

N. Inanc<sup>1</sup>, G. Ozen<sup>1</sup>, Y. Yalcinkaya<sup>1</sup>, E. Dalkilic<sup>2</sup>, S.S. Koca<sup>3</sup>, G. Can<sup>4</sup>, A. Karataş<sup>3</sup>, Y. Pehlivan<sup>2</sup>, A. Yazici<sup>5</sup>, A. Cefle<sup>6</sup>, A. Tufan<sup>9</sup>, S. Akar<sup>7</sup>, S. Senel<sup>8</sup>, B. Oz<sup>3</sup>, N. Akkoc<sup>9</sup>, F. Onen<sup>4</sup>. <sup>1</sup>Department of Internal Medicine, Division of Rheumatology, Marmara University, School of Medicine, Istanbul; <sup>2</sup>Department of Internal Medicine, Division of Rheumatology, Uludag University, Bursa; <sup>3</sup>Department of Internal Medicine, Division of Rheumatology, Firat University, Elazığ; <sup>4</sup>Department of Internal Medicine, Division of Rheumatology, Dokuz Eylül University, İzmir; <sup>5</sup>Department of Internal Medicine, Division of Rheumatology, Kocaeli University, Kocaeli; <sup>6</sup>Department of Internal Medicine, Division of Rheumatology, Gazi University, Ankara; <sup>7</sup>Department of Internal Medicine, Division of Rheumatology, Katip Çelebi University, İzmir; <sup>8</sup>Department of Internal Medicine, Division of Rheumatology, Erciyes University, Kayseri; <sup>9</sup>Private Practice, , İzmir, Turkey

**Background:** TURKIBIO registry is the Turkish version of Danish DANBIO rheumatologic database which has been established in 2011. Demographics and previous or current treatment with conventional (csDMARD) and targeted synthetic (tsDMARD), and biological DMARDs (bDMARDs) were collected.

**Objectives:** We aimed to investigate the efficacy and safety status of methotrexate (MTX) vs. leflunomide (LEF) use as a concomitant treatment with bDMARDs and tsDMARD in this registry.

**Methods:** Frequencies of achievement of remission or remission +low disease activity (LDA) at the 6th month of bDMARD or tsDMARD treatment were compared between patients who were on these medications with MTX vs. LEF as a concomitant treatment. Drug survival and switch rates of bDMARDs and tsDMARD treatments either with MTX or LEF were compared. The adverse effects with MTX and LEF concomitant use were evaluated as well.

**Results:** The study included 725 bDMARD or tsDMARD receiving RA patients from 8 participating centres of the TURKIBIO registry. Of these patients, 462 (63.7%) were receiving concomitant MTX and 263 (36.3%) LEF. Demographic findings are given in the table 1. Achievement of remission and remission +LDA at the 6th month of bDMARD or tsDMARD initiation was similar in concomitant MTX vs LEF groups (51.4% vs. 53%,  $p=0.683$ ). When each bDMARD and tsDMARD was evaluated separately, achievement of remission were again similar in MTX and LEF concomitant users (TNFi: 53% vs. 54%; ABA: 50% vs. 59%; RTX: 53% vs. 61%; TCZ: 42% vs. 35%;  $p > 0.05$  for all). For TOFA, although remission +LDA rate was numerically higher in MTX concomitant group than LEF group (42% vs. 21%), the difference was not statistically significant due to the smaller sample size of TOFA ( $n=33$ ). The results were similar for all DMARD groups when remission was evaluated alone. Drug survival ( $17 \pm 12$  vs.  $16 \pm 11$  months,  $p > 0.05$ ) and drug discontinuation (42,2 vs 38,  $p > 0.05$ ) rates of bDMARDs or tsDMARD were also not different in MTX vs. LEF concomitant users. Adverse effects rate (19.5% vs 20.5%,  $p > 0.05$ ) were similar between MTX vs. LEF concomitant users as well.

#### Abstract FRI0134 – Table 1. Demographic findings of patients.

Sex, n (%)	Female	596 (82,2)
	Male	129 (17,8)
Age, Median (Q1-Q3)		55 (45-62)
Age, Mean±SD		54±13
Disease duration, Orntanca (Q1-Q3)		12 (8-17)
Disease duration, OrttSD		13±8
Biological and targeted synthetic drugs, n (%)	TNFi*	354 (48,8)
	RITUXIMAB	144 (19,9)
	ABATACEPT	127 (17,5)
	TOCILIZUMAB	61 (8,4)
	TOFACITINIB	36 (5,0)
	ANAKINRA	3 (0,4)
Biological+MTX, n (%)		462 (63,7)
Biological+LEF, n (%)		263 (36,3)

\*TNFi: ETANERCEPT, ADALIMUMAB, CERTOLIZUMAB, GOLIMUMAB, INFILIXIMAB, REMSIMA.

**Conclusions:** Achievement of remission or remission +LDA was not different with the concomitant use of MTX vs. LEF with any bDMARD or tsDMARD treatment in RA patients with a similar safety profile. LEF might be an alternative as a concomitant DMARD in MTX-intolerant RA patients initiating bDMARDs or tsDMARD.

**Disclosure of Interest:** None declared

DOI: 10.1136/annrheumdis-2018-eular.5662

FRI0135

### HAVE PREVALENCE OF JOINT SURGERY DECREASED WITH THE USE OF BIOTHERAPY IN RHEUMATOID ARTHRITIS?

O. Saidane, M. Sellami, R. Barhoumi, A. Ben Tekaya, H. Ajlani, R. Tekaya, I. Mahmoud, L. Abdelmoula. *Rheumatology, Charles Nicolle Hospital, Tunisia, Tunisia*

**Background:** Biological response modifiers have greatly expanded therapeutic arsenal of rheumatoid arthritis (RA) leading to a better control of inflammation, a reduced long-term complications and a prevention of joint damage.

**Objectives:** Our objective was to assess the impact of use of biologics on joint surgery during RA.

**Methods:** This is a retrospective study including patients with RA according to American College of Rheumatology (1987) followed- over 15 years period [2000–2014]. We excluded patients who underwent joint surgery without direct relevance to RA. The significance level was set at 0.05.

**Results:** A total of 500 RA patients (422 women and 78 men) were enrolled in this period. The mean age was 53.3 years (21–83) and the mean disease duration was 12 years (2–40). Rheumatoid factor was positive in 71.4% cases. A high disease activity was noted at diagnosis with a mean disease activity score of 5.90 ± 1.38. The mean Health Assessment Questionnaire index was 1.62 [0.2 à 3]. All patients received at least 2 conventional disease-modifying antirheumatic drugs, one of which was methotrexate. Twenty seven per cent of RA patients (135 patients) received biologics: 35 patients received Rituximab (7%) and 100 patients (20%) received anti TNF  $\alpha$  (infliximab, etanercept and adalimumab in 10%, 6.8% and 3.2% respectively). The trend curve of biologics use showed a linear increase with spikes of use in 2008, 2011 and 2014. A surgical act was considered necessary in 59 cases (11.8%) mainly total knee arthroplasty (56%). The mean duration between the onset of RA and surgery was 7.02 (1–33). Patients who received biologics had less joint surgery without significant association ( $p=0.350$ ). The joint surgery showed a decrease in the number of procedures from 2004, concomitantly with promoting biologics.

**Conclusions:** Our study concluded that joint surgery was less frequent in RA patients who received biologics without a significant association.

**Disclosure of Interest:** None declared

DOI: 10.1136/annrheumdis-2018-eular.4671

FRI0136

### PERSISTENCE OF MONOTHERAPY OR COMBINATION THERAPY WITH DISEASE-MODIFYING AGENTS IN PATIENTS WITH PSORIATIC ARTHRITIS IN A REAL-WORLD SETTING

P.J. Mease<sup>1</sup>, N.A. Accortt<sup>2</sup>, S. Rebello<sup>3</sup>, C. Etzel<sup>3</sup>, R.W. Harrison<sup>3</sup>, G.A. Aras<sup>2</sup>, M. M.F. Gharaibeh<sup>2</sup>, J.D. Greenberg<sup>3</sup>, D.H. Collier<sup>2</sup>. <sup>1</sup>Swedish Medical Center and University of Washington, Seattle; <sup>2</sup>Amgen Inc., Thousand Oaks; <sup>3</sup>Corrona LLC, Waltham, USA

**Background:** Until recently, treatment for moderate to severe psoriatic arthritis (PsA) mainly focused on conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) and tumour necrosis factor inhibitors (TNFis). However, the persistence of TNFis alone or in combination with csDMARDs is not well understood.

**Objectives:** To assess real-world treatment patterns among patients with PsA receiving TNFi monotherapy, csDMARD monotherapy, or TNFi and csDMARD combination therapy.

**Methods:** This retrospective study utilised data from patients with PsA aged  $\geq 18$  years, enrolled in the Corrona PsA registry between March 21, 2013, and July 31, 2017, treated with a TNFi and/or csDMARD (index therapy), and with  $\geq 6$  months of follow-up time. Patients were stratified by prevalent (initiation before enrollment) or incident (initiation after enrollment) therapy use; cohorts were based on index therapy: TNFi monotherapy, csDMARD monotherapy, or combination therapy. Outcomes of interest were the percentage of patients who were persistent on their index therapy or had a therapy change (discontinued, switched, or restarted) 12 months after the index visit.

**Results:** There were 1266 patients in this study: 1144 prevalent and 122 incident (table 1). Patient characteristics at the index date were similar among patients; however, csDMARD monotherapy patients had higher disease activity than either TNFi group. Among prevalent patients, TNFi monotherapy patients were likely to be female (59%) and younger (51.9 years), nearly all patients had psoriasis, and BSA was similar and  $\leq 5$ . At month 12, among patients with a follow-up visit within the 9–15-month window, the vast majority of prevalent patients and half of incident patients were persistent on their index therapy, and one quarter to one third of incident patients discontinued or switched therapy (table 1).

Characteristic at index date	Prevalent TNFi mono N=421	Prevalent csDMARD mono N=347	Prevalent combo N=376	Incident TNFi mono N=43	Incident csDMARD mono N=56	Incident combo N=23
Sex (female), n (%)	244 (59)	158 (46)	185 (50)	19 (44)	24 (43)	11 (48)
Age, mean (SD)	51.9 (12.3)	57.7 (13.3)	53.9 (11.3)	50.7 (14.0)	55.8 (14.1)	52.3 (13.5)
BMI (obese), n (%)	202 (51)	182 (54)	204 (56)	18 (44)	37 (70)	8 (47)
Current psoriasis, n (%)	366 (93)	300 (90)	312 (90)	38 (93)	49 (94)	15 (68)
HAQ, mean (SD)	0.2 (0.4)	0.3 (0.4)	0.3 (0.4)	0.3 (0.4)	0.3 (0.3)	0.4 (0.6)
CDAI, mean (SD)	9.7 (6.6)	11.6 (8.2)	11.7 (8.4)	12.6 (7.3)	16.2 (8.5)	15.7 (13.9)
DAS28 CRP, mean (SD)	2.4 (0.9)	2.7 (1.0)	2.8 (1.0)	3.0 (0.7)	3.4 (0.8)	2.8 (1.4)
Anesthetics, n (%)	74 (18)	52 (15)	75 (20)	14 (32)	8 (14)	3 (13)
Dactylitis, n (%)	27 (6)	25 (7)	12 (3)	7 (16)	14 (25)	4 (17)
BSA (%), mean (SD)	4.9 (8.7)	4.8 (9.3)	5.0 (11.9)	6.2 (8.8)	5.4 (8.9)	1.3 (2.1)
Nail psoriasis VAS, mean (SD)	5.6 (12.4)	8.1 (22.6)	7.2 (14.3)	11.9 (18.8)	5.9 (15.2)	10.3 (23.3)
History of biologic, n (%)	421 (100)	0	375 (100)	2 (5)	0	0
History of csDMARD, n (%)	192 (46)	347 (100)	369 (98)	13 (30)	0	13 (57)
Treatment pattern, n (%)						
Persistent, n (%)	233/251 (92.8)	196/225 (87.1)	186/214 (86.9)	13/26 (50.0)	15/35 (42.9)	8/15 (53.3)
Time on drug (mo), mean (SD)	68.8 (46.4)	82.5 (78.1)	49.8 (37.7)	15.9 (5.4)	16.9 (8.7)	16.0 (5.0)
Discontinuation, n (%)	3 (1.2)	8 (3.6)	17 (7.9)	5 (19.2)	9 (25.7)	4 (26.7)
Switch (to another biologic), n (%)	2 (0.8)	2 (0.9)	4 (1.9)	1 (3.8)	4 (11.4)	2 (13.3)
Restart, n (%)	0	3 (1.3)	1 (0.5)	0	0	0

**Conclusions:** Most patients who were prevalent on therapy at the time of enrollment in Corrona remained persistent on their therapy for 12 months in this study, while roughly half of patients initiating therapy after enrollment remained persistent over the same period. Young, female patients were more likely to receive TNFi monotherapy; the TNFi monotherapy cohort was associated with the least disease activity. The incident group was not different from the prevalent group. Although the prevalent group is more likely to have patients who responded to treatment, the data suggest that most therapy changes occur within the first year of PsA treatment.

**Disclosure of Interest:** P. Mease Grant/research support from: AbbVie, Amgen, Bristol Myers Squibb, Celgene, Janssen, Lilly, Novartis, Pfizer, Sun, and UCB, Consultant for: AbbVie, Amgen, Bristol Myers Squibb, Celgene, Janssen, Lilly, Novartis, Pfizer, Sun, and UCB, Speakers bureau: AbbVie, Amgen, Bristol Myers Squibb, Celgene, Genentech, Janssen, Novartis, Pfizer, and UCB, N. Accortt Shareholder of: Amgen Inc., Employee of: Amgen Inc., S. Rebello Employee of: Corrona LLC, C. Etzel Consultant for: Merck, Employee of: Corrona LLC, R. Harrison Employee of: Corrona LLC, G. Aras Shareholder of: Amgen Inc., Employee of: Amgen Inc., M. Gharaibeh Shareholder of: Amgen Inc., Employee of: Amgen Inc., J. Greenberg Shareholder of: Corrona LLC, Consultant for: Genentech, Janssen, Novartis, Pfizer, and Eli Lilly, Employee of: Corrona LLC, D. Collier Shareholder of: Amgen Inc., Employee of: Amgen Inc.

DOI: 10.1136/annrheumdis-2018-eular.1929

FRI0137

### EFFICACY, SAFETY AND IMMUNOGENICITY FROM WEEK 30 TO WEEK 54 IN A RANDOMISED, DOUBLE-BLIND PHASE III STUDY COMPARING A PROPOSED INFLIXIMAB BIOSIMILAR (PF-06438179/GP1111) WITH REFERENCE INFLIXIMAB

B. Alten<sup>1</sup>, V. Tseluyko<sup>2</sup>, T. Hala<sup>3</sup>, S. Mehmedagic<sup>4</sup>, M. Pileckyte<sup>5</sup>, E. Dokoupilová<sup>6</sup>, D. Jovic<sup>7</sup>, M. Rehman<sup>8</sup>, M. Zhang<sup>9</sup>, L. Sewell<sup>10</sup>, S. Hackley<sup>11</sup>, S. Salts<sup>9</sup>, C. Cronenberger<sup>12</sup>, K. Schumacher<sup>13</sup>, O. von Richter<sup>13</sup>, B. Batko<sup>14</sup>, <sup>1</sup>Schlosspark Klinik, Berlin, Germany; <sup>2</sup>Kharkiv Medical Academy of Postgraduate Education, Kharkiv, Ukraine; <sup>3</sup>Center for Clinical and Basic Research, Pardubice, Czech Republic; <sup>4</sup>Clinical Center University of Sarajevo, Sarajevo, Bosnia and Herzegovina; <sup>5</sup>Hospital of Lithuanian University of Health Sciences, Kaunas, Lithuania; <sup>6</sup>Medical Plus s.r.o., Uherske Hradiste, University of Veterinary and Pharmaceutical Sciences, Brno, Czech Republic; <sup>7</sup>University Clinical Centre of the Republic of Srpska, Banja Luka, Bosnia and Herzegovina; <sup>8</sup>Pfizer Inc., Andover, MA; <sup>9</sup>Pfizer Inc., La Jolla, CA; <sup>10</sup>Pfizer Inc., Cambridge, MA, USA; <sup>11</sup>Pfizer Ltd, Sandwich, UK; <sup>12</sup>Pfizer Inc., Collegetown, PA, USA; <sup>13</sup>Sandoz Biopharmaceuticals, Holzkirchen, Germany; <sup>14</sup>J. Dietl Specialist Hospital, Krakow, Poland

**Background:** PF-06438179/GP1111 (GP1111) is an infliximab (IFX) biosimilar in development for the treatment of immune-mediated inflammatory diseases, including rheumatoid arthritis (RA). The efficacy, safety and immunogenicity of GP1111 and European reference IFX (IFX-EU) have been reported to be similar over 30 weeks (Wks).

**Objectives:** To evaluate the efficacy, safety and immunogenicity of GP1111 and IFX-EU with longer-term treatment, and after treatment transition from IFX-EU to GP1111.

**Methods:** A randomised, double-blind, parallel-group study compared GP1111 with IFX-EU in biologic-naïve, adult patients with moderate-to-severe active RA on a stable dose of methotrexate (MTX). Patients were randomised (1:1) to GP1111 or IFX-EU (3 mg/kg IV at Wks 0, 2, 6, and then every 8 wks, with one dose escalation to 5 mg/kg allowed at or after Wk 14 for inadequate responders)