pts on TNFi. On average, pts on ABA were older and had more prior bDMARDs. Adjusting for potential confounding factors did not modify the results qualitatively (figure 1), with significantly longer time before discontinuation in seropositive vs seronegative pts on ABA (adj. HR: 0.74 (95% CI: 0.67–0.84) but not on TNFi (adj. HR: 0.99 (95% CI: 0.94–1.04)).

The proportion of pts reaching DAS28 remission or LDA at 1 year was significantly higher for seropositive vs seronegative pts on ABA (difference in proportion: remission: 5.0%; LDA: 9.7%), but similar for seropositive vs seronegative pts on TNFi (difference in proportion: remission: –2.7%; LDA: –2.3%).

Conclusions: Data from this large pooled registry suggests that seropositivity in RA pts is associated with increased drug retention and effectiveness for ABA but not for TNFi.

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Acknowledgements: Unrestricted research grant from BMS

Disclosure of Interest: D. Courvoisier Consultant for: BMS, D. Mongin: None declared, M. Hetland Consultant for: Abbvie, Biogen, BMS, CellTrion, MSD, Novartis, Orion, Pfizer, Samsung, UCB, K. Pavelka Grant/research support from: Ministry of Health, Czech Republic 023728, Consultant for: AbbVie, Roche, MSD, BMS, Amgen, Egis, Medac, UCB, Pfizer, Biogen, C. Turesson Grant/research support from: Abbvie, Bristol Myers-Squibb, Roche. Consultant for: MSD, Bristol Myers-Squibb, Roche, Paid instructor for: Abbvie, Bristol-Myers Squibb, Janssen, MSD, Pfizer, Roche, UCB, S. A. Bergstra: None declared, T. Kvien Grant/research support from: AbbVie, BMS, MSD, Pfizer, Roche, UCB, Consultant for: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly, Epirus, Hospira, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz, UCB, M. J. Santos: None declared, V. Hernandez: None declared, F. Iannone Consultant for: BMS, J.-E. Gottenberg Consultant for: BMS, X. Mariette Consultant for: BMS, S. Kubo Speakers bureau: BMS, Pfizer, Takeda, Y. Tanaka Grant/research support from: Mitsubishi-Tanabe, Takeda, Bristol-Myers, Chugai, Astellas, Abbvie, Daiichi-Sankyo, Pfizer, Eisai, Ono, Consultant for: Daiichi-Sankyo, Astellas, Pfizer, Mitsubishi-Tanabe, BMS, Chugai, YL Biologics, Eli Lilly, Sanofi, Janssen, UCB, D. Choquette: None declared, R. Ionescu: None declared, A. Finckh Grant/research support from: BMS, Consultant for: BMS, AbbVie, AB2BIO, MSD, Pfizer, Roche, UCB

DOI: 10.1136/annrheumdis-2018-eular.3312

FRI0111 ANALYSIS OF REAL-LIFE INFLIXIMAB AND ADALIMUMAB DATA: DRUG SWITCHING AND FATE OF ANTIDRUG ANTIBODIES AND TROUGH LEVELS OVER TIME

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Background: Infliximab (IFX) and adalimumab (ADL) are biological drugs used in the treatment of rheumatoid arthritis (RA), spondyloarthritis (SpA), and juvenile idiopathic arthritis (JIA). Development of antidrug antibodies (ADAb) may lead to increased drug clearance and loss of therapeutic drug trough levels (TL). Switching to another drug may be necessary after ADAb development.

Objectives: To use real-life data from a large Finnish rheumatology patient cohort to determine the association between drug switching and ADAbs and the fate of ADAbs and TLs after ADAb development.

Methods: Serum samples for IFX or ADL ADAb and TL measurements from 1345 (567 RA, 479 SpA, and 299 JIA) rheumatology patients were taken on a clinical basis in daily practice in 20 Finnish referral hospitals. ADAb analyses were performed at Sanquin laboratories (Amsterdam, The Netherlands) using radioimmunoassays; TL analyses were performed at United Medix Laboratories (Helsinki, Finland) using commercial methods (Promonitor ELISA, Progenika Biopharma). Samples were collected and analysed from January 2012 until September 2017. ADAb values ≥ 12 AU/ml were considered positive; ADAb values were classified as low (12–30 AU/ml), intermediate (30–100 AU/ml) and high (≥ 100 AU/ml).

Results: On the basis of TL data, we identified 67 patients (5%) who switched drugs. Of these patients, 47 (70.2%) provided ADAb measurements for the first drug; 33 (49.3%) patients were ADAb positive. Most (22 patients, 63.6%) had high ADAbs. Forty-nine (73.1%) patients provided ADAb measurements for the second drug. Of these patients, 11 (16.4%) were ADAb positive against the second drug; seven (63.6%) had high ADAbs. We identified 48 (3.6%) ADAb-positive patients who provided at least one follow-up ADAb measurement. Of these patients, 32 (66.7%) experienced ADAb loss; most (24 patients, 50%) experienced complete ADAb loss (most recent ADAb value ≤ 12 AU/ml). Twenty-five

patients that experienced ADAb loss had available TL measurements both before and after ADAb loss; 23 (92%) had increased TL after ADAb loss. Of the 16 patients that experienced ADAb gain, only 3/11 (27.3%) patients that had available TL measurements both before and after ADAb gain had increased TL after ADAb gain.

Conclusions: ADAb positivity is associated with drug switching; ADAb development against a second biologic drug is common. A significant proportion of ADAb-positive patients lose ADAbs over time. ADAb loss is associated with TL increase.

Disclosure of Interest: D. Ho Consultant for: Pfizer Oy, S. Valtanen: None declared, M. Havana: None declared, L. Kröger Consultant for: Roche, K. Eklund Grant/research support from: Pfizer, Speakers bureau: Abbvie, MSD, Pfizer, BMS, T. S. Jokiranta Grant/research support from: Pfizer, Consultant for: Abbvie, MSD, Pfizer, UCB

DOI: 10.1136/annrheumdis-2018-eular.3052

FRI0112 PERSISTENCE ON TUMOUR NECROSIS FACTOR INHIBITOR (TNFI) MONOTHERAPY AFTER ACHIEVING REMISSION OR LOW DISEASE ACTIVITY (LDA) ON COMBINATION THERAPY AMONG PATIENTS WITH RHEUMATOID ARTHRITIS (RA)

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Background: Combination therapy with TNFis and conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) is standard for moderate to severe RA.

Objectives: To estimate persistence with etanercept (ETN) or other TNFi monotherapy among RA patients who achieved remission/LDA on combination TNFi +csDMARD therapy and then discontinued the csDMARD.

Methods: Data from RA patients in the Corrona registry during 10/1/2001–8/31/2017 were analysed. All patients had to be treated with TNFi +csDMARD combination therapy and to have reached Clinical Disease Activity Index remission/LDA and then discontinued the csDMARD (index date). ETN (fusion protein comprising TNF receptor and human IgG1 Fc) and other TNFi therapies (monoclonal antibodies: adalimumab, certolizumab pegol, golimumab, and infliximab) were analysed separately. Outcomes were percentages of patients persistent on index TNFi monotherapy, discontinued index TNFi, switched (to another biologic or to csDMARD monotherapy), or added csDMARD therapy (to receive combination therapy) at 6 months (primary analysis) and 12 months post-index.

Results: Data from 617 patients were analysed (182 ETN, 435 other TNFi); mean age (standard deviation [SD]) was 57.4 (13.3) years, 73% were female. Mean time (SD) in remission/LDA before csDMARD discontinuation was 17.0 (24.3) months. Rates of monotherapy persistence at 6 months were 56% for ETN and 45% for other TNFi (table 1). Patients with ≥ 6 month persistence on monotherapy had mean duration (SD) of 28.2 (22.1) months on ETN monotherapy or 27.8 (23.3) months on other TNFi monotherapy. Rates of persistence for all patients at 12 months were 46% for ETN and 33% for other TNFi. Patients with ≥ 12 month persistence had mean duration (SD) of 35.9 (22.6) months on ETN monotherapy or 39.3 (24.4) months on other TNFi monotherapy. For a subset of patients with < 6 months in remission/LDA before index date (44% of patients), rates of monotherapy persistence at 6 months were 60% for ETN and 42% for other TNFi.

	Treatment pattern, n (%)			
	Persistent on index TNFi monotherapy		Not persistent on index TNFi monotherapy	
	Discontinued index TNFi	Switched to new biologic or csDMARD	Added csDMARD	
6 months				
ETN (n=182)	102 (56)	6 (3)	10 (6)	64
Other TNFi (n=435)	195 (45)	21 (5)	23 (5)	(35) 196 (45)
12 months				
ETN (n=120)	55 (46)	1 (1)	8 (7)	56
Other TNFi (n=307)	102 (33)	22 (7)	19 (7)	(47) 164 (53)

Conclusions: Monotherapy with ETN or other TNFi is an option for patients in remission/LDA; $> 50\%$ of patients on ETN remained on monotherapy 6 months after discontinuing their csDMARD.

Acknowledgements: This study was sponsored by Corrona, LLC and the analysis was funded by Amgen Inc.

Disclosure of Interest: D. Pappas Employee of: Corrona, LLC, H. Litman Employee of: Corrona, LLC, T. Lesperance Consultant for: Amgen Inc., S. Rebello Employee of: Corrona, LLC, E. Karis Shareholder of: Amgen Inc., Employee of:

Amgen Inc., G. Kricorian Shareholder of: Amgen Inc., Employee of: Amgen Inc., W. Hua Employee of: Corrona, LLC, N. Accortt: None declared
DOI: 10.1136/annrheumdis-2018-eular.1509

FRI0113 SWITCHING TO ANTI-IL-6 BIOLOGICS AFTER ANTI-TNF THERAPY IN CHILDREN WITH JIA

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Background: Development of biologics gives rise to novel classes of drugs, offering more options for treating children with primary or secondary failure of anti-TNF therapy. However, the question of whether or not previous exposure to biologic therapy and the number of previously administered biologics influence the efficacy of current treatment still needs to be solved.

Objectives: To compare tocilizumab efficacy in biologics-naïve and biologics-switched patients with JIA.

Methods: Comparative analysis involved patients who had initiated TOC treatment at the National Medical Research Centre of Children's Health (Moscow) depending on previous history of biologics therapy. Treatment efficacy was evaluated according to the dynamics of clinical and laboratory signs using the ACR-Pedi criteria. The Wallace criteria were used to evaluate whether or not remission had been achieved.

Results: Thirty-two patients were biologics-naïve and 43 patients switched to TOC were previously treated with ETA (n=10), ADA (n=34), certolizumab (n=2), and infliximab (n=1). Children in the biologics-naïve group differed from the switchers in a number of important baseline parameters: shorter disease duration (2.13 [1.25:5.34] and 7.42 [3:10.75] years, respectively; p<0.001) and lower arthritis severity indices (the number of joints affected, the CHAQ and JADAS scores). Therapy with TOC in children was found very effective. The CHAQ and JADAS disease activity scores, the CRP and ESR laboratory values, morning stiffness duration, and the VAS score (assessed by both patient and physician), and the number of affected joints (swollen or painful joints, joints with the limited range of motion and with active arthritis) significantly decreased after 4 week therapy in all patients (p<0.01). The percentages of biologics-naïve patients and switchers who achieved ACR90 after the first 12 months of therapy were 31.25% and 25.6%, respectively (p=0.613). A smaller percentage of children achieved stable remission: 4.65% of switchers and 6.25% of biologics-naïve patients (p>0.999).

Conclusions: Tocilizumab therapy is highly efficient both as the first and subsequent biologic agent. Children with history of therapy with at least one biologic agent have lower chances for achieving remission during the first 12 months of therapy. However, this difference is most likely caused by the longer and more severe arthritis course in children allocated to the group of biologics-switched patients compared to biologics-naïve ones. Further matched large-cohort study is needed to identify predictors of response to therapy.

Disclosure of Interest: E. Alexeeva: None declared, T. Dvoryakovskaya Grant/research support from: Roche, Pfizer, M. Soloshenko: None declared, R. Denisova: None declared, K. Isaeva: None declared, A. Mamutova: None declared, V. Gladikh: None declared, A. Moskalev: None declared

DOI: 10.1136/annrheumdis-2018-eular.6526

FRI0114 EFFICACY AND RETENTION RATE OF CERTOLIZUMAB PEGOL IN RHEUMATOID ARTHRITIS: DATA FROM A LARGE REAL-LIFE MULTICENTRE RETROSPECTIVE COHORT

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Background: Even though certolizumab pegol (CZP) has been licensed for the treatment of rheumatoid arthritis (RA) since longtime, observational data in a real-life setting are still lacking.

Objectives: To retrospectively evaluate the use of CZP in a multicentric observational cohort of Northern Italy (the LORHEN registry), calculating both clinical response and retention rate. To explore the effectiveness of CZP in childbearing age female.

Methods: Data were retrospectively extracted from the LORHEN registry which includes all RA patients treated with CZP as first or second-line biologic agent between December 2010 and April 2017. The 2 year clinical response was evaluated as EULAR response and proportion of patients achieving Disease Activity Score 28 (DAS28-ESR) remission. The 5 year retention rate was calculated by Kaplan-Meier method. Cox proportional hazard models were developed to examine potential predictors of CZP persistence, including sex, line of CZP treatment (naïve vs switchers), childbearing age, and concomitant MTX as categorical variables, whereas age, disease duration, and baseline DAS28-ESR as continuous variables.

Results: The overall study population included 242 RA patients (78.9% female; mean $\pm$ standard deviation, SD] age 54.2 $\pm$ 13.8 years; mean disease duration 10 $\pm$ 13.1 years; baseline DAS28-ESR 4.58 $\pm$ 1.39), who received CZP as first- (64%) or second-line (36%) biologic agent, as monotherapy (40.9%) or in combination with methotrexate (MTX, 59.1%). Two-year EULAR good +moderate response and remission rates were similar in first- and second-line patients (66% vs 60.7% [p=0.65] and 39.6% vs 32.1% [p=0.52], respectively). The overall 5 year retention rate was 42.5%, with no difference between first- and second-line therapy (43.5% vs 40.5%, respectively; p=0.98), but with a clear trend in favour of childbearing subpopulation versus older women (62.8% vs 32.3%, respectively; p=0.07). Concomitant MTX was a predictor of CZP persistence (Hazard Ratio [HR] 1.79, 95% confidence interval [95% CI] 1.08–2.95; p=0.02), whereas sex (HR 1.35, 95% CI 0.71–2.54, p=0.35), age (HR 1.01, 95% CI 0.99–1.03; p=0.14), mean disease duration (HR 0.99, 95% CI 0.97–1.02; p=0.87), and baseline DAS28-ESR (HR 1.15, 95% CI 0.96–1.38; p=0.12) were not associated with CZP retention rate. The most frequent reason for discontinuation was inefficacy (60%), whereas only 21% of patients stopped the drug because of adverse events.

Conclusions: In our real-life experience, CZP showed a very good clinical response, with more than one third of patients achieving 2 year clinical remission and more than 40% persisting on treatment after 5 years. Unexpectedly, no significant difference was found between first and second line of treatment. The use of CZP in childbearing women seems to be associated with a higher retention rate.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.4160

FRI0115 INDIRECT STANDARDISED ASSESSMENT OF INJECTION SITE PAIN FOLLOWING SUBCUTANEOUS ADMINISTRATION OF CITRATE-FREE FORMULATION OF ADALIMUMAB AND ITS BIOSIMILAR ABP 501

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Background: In randomised double-blind studies in patients with rheumatoid arthritis (RA) and psoriasis (PsO), ABP 501, an approved adalimumab biosimilar, had significantly lower injection site pain (ISP) perception compared with the citrate-containing formulation (CCF) of adalimumab reference product (RP) (40 mg/0.8 mL); however, there have been no direct or indirect comparisons of ISP perception between ABP 501 and the CCF of the RP (40 mg/0.4 mL).

Objectives: To demonstrate that pain perception after injection of both the ABP 501 formulation and the CFF-RP formulation was lower than after CCF-RP.

Methods: We analysed ISP perception data after injection from two ABP 501 phase 3 studies, one in patients with RA (NCT01970475) and another in patients with PsO (NCT01970488) and 2 citrate-free RP formulation studies (NCT01561313, NCT01502423) where the "control" group received the CCF-RP. In all studies, patients were equally randomised between the 2 treatment arms. Patients were asked to rate the ISP perception on a visual analogue scale (VAS) on which the current pain level was marked from 0 cm (no pain) to 10 cm (worst possible pain). We calculated Cohen's d-statistic for difference in ISP perception with ABP 501 compared with CCF-RP for the 2 ABP 501 studies. Similar comparisons were performed between the ISP perception associated with CFF-RF and CCF-RF. These measures were subsequently compared in a descriptive manner.

Results: Both ABP 501 and CFF-RF were associated with lower ISP perception after injection with maximum reduction observed immediately post-injection. The 95% confidence intervals of relative reduction in ISP perception for ABP 501 formulation and the CFF-RP (table 1) were provided descriptively.