significantly associated with a higher probability of non-REM at 6 months (OR: 5.0; 95% CI: 1.1-21.7) (Figure 1).

Table 1. The table shows mean±SD, median (IQR) or absolute number (percentage) for all patients included (n=62). RF, rheumatoid factor; ACPA, anti-citrullinated protein antibodies; DAS28, Disease Activity Score-28; csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; MTX, methotrexate; OD, other conventional synthetic disease-modifying anti-rheumatic drugs than methotrexate. The differences between DAS28 groups were analysed considering p-value<0.05 as statistically significant result.

Baseline patients' characteristics	Total patients (n=62)	DAS28>2.6 (n=32; 52%)	DAS28≤2.6 (n=30; 48%)	p-value
Age (years)	53±12	53±13	52±10	0.8
Female	55 (89)	30 (94)	25 (83)	0.2
Disease duration (years)	8 (4-11)	8 (4-12)	7 (3-11)	0.7
RF positive	49 (79)	23 (72)	26 (87)	0.1
ACPA positive	54 (87)	26 (81)	28 (93)	0.2
Smoking habit (n=55)				0.2
Non-smokers	26 (47)	16 (55)	10 (38)	
Smoker	29 (53)	13 (45)	16 (51)	
Body mass index (kg/m^2)	25.9±5.6	25.8±5.7	26.0±5.6	0.9
DAS28	4.9±1.0	5.4±0.9	4.3±0.9	**<0.0001**
Concomitant csDMARDs	60 (97)	32 (100)	28 (93)	0.3
MTX [±OD]	46 (74)	26 (81)	20 (67)	0.3
Only OD	14 (23)	6 (19)	8 (26)	0.3
Prednisone	36 (58)	19 (59)	17 (57)	0.9

Conclusion: Our results show that the proinflammatory IL10 B/TNF CD4 ratio is associated with non-REM status. It could be useful to analyse the success of TNFi treatment in patients with RA.

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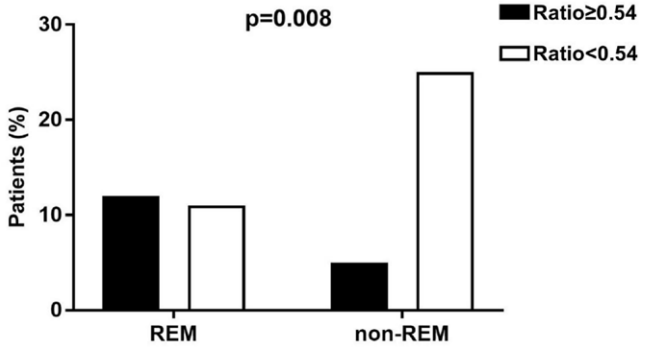

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POS0624

EFFICACY AND SAFETY OF LEVILIMAB IN COMBINATION WITH METHOTREXATE IN SUBJECTS WITH ACTIVE RHEUMATOID ARTHRITIS: PHASE III, DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED TRIAL

V. Mazurov[1], M. Korolev[2], A. Kundzer[3], N. Soroka[4], A. Kastanayan[5], T. Povarova[6], T. Plaksina[7], O. Antipova[8], D. Kretchikova[9], S. Smakotina[10], O. Tciupa[11], T. Raskina[12], T. Kropotina[13], O. Nesmeyanova[14], T. Popova[15], E. Dokukina[16], A. Plotnikova[16], A. Lutskii[17], A. Zinkina-Orihan[17]. *[1]North-Western State Medical University n.a. I.I. Mechnikov, Department of Therapy and Rheumatology of Temporary Disability and Medical Care Quality Expertise Named After E. E. Eichwald, Saint-Petersburg, Russian Federation*; *[2]Federal Research Center Institute of Cytology and Genetics, Deputy Director for Clinical Issues, Novosibirsk, Russian Federation*; *[3]Academy for Postgraduate Education, Department of Cardiology and Rheumatology, Minsk, Belarus*; *[4]Belarus State Medical University, Department of Internal Diseases No.2, Minsk, Belarus*; *[5]Rostov State Medical University, Department of Internal Diseases No.2, Rostov-on-Don, Russian Federation*; *[6]Clinical Hospital Russian Railways-Medicine of the City of Saratov, Department of Cardiology, Saratov, Russian Federation*; *[7]N. A. Semashko Nizhny Novgorod Regional Clinical Hospital, Center of Rheumatology, Nizhniy Novgorod, Russian Federation*; *[8]Irkutsk City Clinical Hospital No. 1, Medical Rheumatological Center, Irkutsk, Russian Federation*; *[9]Departmental Hospital at Smolensk Station, JSC Russian Railways, Department of Rheumatology, Smolensk, Russian Federation*; *[10]Kemerovo Regional Clinical Hospital Named After S.V. Belyaev, Regional Rheumatological Center, Kemerovo, Russian Federation*; *[11]City Hospital No.4 of the City of Barnaul, Department of Rheumatology, Barnaul, Russian Federation*; *[12]Kemerovo State Medical University, Department of Internal Medicine Propaedeutics, Kemerovo, Russian Federation*; *[13]Regional Clinical Hospital, Deputy Chief Physician for Therapy, Omsk, Russian Federation*; *[14]Chelyabinsk Regional Clinical Hospital, Department of Rheumatology, Chelyabinsk, Russian Federation*; *[15]City Clinical Hospital No.40, Department of Rheumatology, Ekaterinburg, Russian Federation*; *[16]BIOCAD, Clinical Research, Saint-Petersburg, Russian Federation*; *[17]BIOCAD, Clinical Development, Saint-Petersburg, Russian Federation*

Background: Previously, the results of phase II AURORA clinical study of levilimab in subjects with active rheumatoid arthritis (RA) have been reported[1]. Here we report topline 24-weeks results of preliminary primary efficacy and safety analysis of phase 3 double-blind, placebo-controlled randomized clinical study (SOLAR).

Objectives: To confirm that levilimab in combination with methotrexate is superior to placebo in combination with methotrexate in achieving ACR20 at week 12 and low disease activity (LDA) at week 24 in subjects with methotrexate (MTX) resistant active RA.

Methods: The study is ongoing at 21 clinical sites in Russia and Belarus. All randomized subjects have completed 24 weeks of study between November 2019 and January 2021.

154 adults, aged ≥18 years with the diagnosis of RA (ACR 2010) for at least 24 weeks, and confirmed disease activity at screening despite treatment with MTX for the last 12 weeks (in a stable dose 15-25 mg/week, for at least 4 weeks) were randomly assigned (2:1) to receive either levilimab (162 mg, SC, QW) + MTX (n=102) or placebo + MTX (n=52). The randomization and treatment allocation were carried out by a central computer-based system. Subjects, caregivers, and those assessing the outcomes were blinded to group assignment.

The hypothesis of superiority of levilimab over placebo was tested for two co-primary efficacy outcomes: proportion of subjects who achieved ACR20 at week 12 and proportion of subjects who achieved LDA of RA (DAS28-CRP <3.2) at Week 24 of the study.

For ethical reasons, subjects who haven't achieved minimal clinical response at week 12 (≥20% reduction in the number of tender/swollen joints; 66/68) received rescue therapy at the discretion of the Investigator, and all subsequent efficacy assessments for those were considered missing.

For the primary efficacy analysis, subjects with missing data due to study discontinuation or rescue therapy prescription were considered non-responders (non-responder imputation, NRI). Otherwise, the analysis was performed on observed cases.

Safety was assessed through monitoring of adverse events (AEs).

Results: The primary analysis was based on 149 randomized subjects (n=99 and n = 50) for ACR20 and 154 randomized subjects (n= 102 and n = 52) for LDA. 70/99 (71%) of subjects who received levilimab and 20/50 (40%) who received placebo achieved ACR20 response at week 12. The difference in proportion was 30% with a lower bound of 97.5% CI 12.8%; p=0.0003 (Pearson's chi-squared test).

53/102 (52%) of subjects received levilimab and 3/52 (6%) received placebo achieved LDA at week 24. The difference in proportion was 46% with a lower bound of 97.5% CI 31.2 %; p<0.0001 (Pearson's chi-squared test).

The safety population included all subjects, who received investigational product (n=154).

The most common adverse events (reported in ≥5% of subjects) in levilimab and placebo arms, respectively were: blood cholesterol increase (19% vs. 10%), ALT increase (11% vs. 8%), lymphocyte count decrease (9% vs. 8%), blood bilirubin increase (11% vs. 0%), blood triglycerides increase (9% vs. 2%), AST increase (7% vs. 4%), IGRA with *M.tuberculosis* antigen positive (5% vs. 6%), ANC decrease (8% vs. 0%). No deaths were occurred.

Conclusion: The study confirmed superior efficacy of levilimab + MTX over placebo + MTX in subjects with MTX resistant active RA. No new safety signals were detected.

Trial registration: Clinicaltrials.gov identifier NCT04397562

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POS0625 ASSOCIATIONS OF REMISSION AND PERSISTENCE OF BIOLOGICS AT 1 AND 12 YEARS

K. Murray[1], M. Turk[1], Y. Alammari[1], F. Young[1], P. Gallagher[1], T. P. Saber[1], U. Fearon[2], D. Veale[1]. [1]*Saint Vincent's University Hospital, Rheumatology, Dublin 4, Ireland*; [2]*Trinity College, Trinity Biomedical Sciences Institute, Dublin, Ireland*

Background: Biologic therapies have greatly improved outcomes in rheumatoid arthritis (RA) and psoriatic arthritis (PsA). Yet, our ability to predict long-term remission and persistence or continuation of therapy remains limited.
Objectives: To compare RA and PsA outcomes at 1 and 12 years after commencing biologic DMARDs and to identify predictors of remission and persistence of therapy.
Methods: RA and PsA patients were prospectively recruited from a biologic clinic. Outcomes on commencing therapy, at 1 year and 12 years were reviewed. Demographics, medications, morning stiffness, patient global health score, tender and swollen joint counts, antibody status, CRP and HAQ were collected. Outcomes at 1 and 12 years are reported and predictors of EULAR-defined remission (DAS28-CRP <2.6) and biologic persistence are examined with univariate and multivariate analysis.
Results: A total of 403 patients (274 RA and 129 PsA) were analysed. PsA patients were more likely to be male, in full-time employment and have completed higher education. PsA had higher remission rates than RA at both 1 year (60.3% versus 34.5%, $p<0.001$) and 12 years (91.3% versus 60.6%, $p<0.001$). This difference persisted when patients were matched for baseline disease activity ($p<0.001$). Biologic continuation rates were high for RA and PsA at 1 year (49.6% versus 58.9%) and 12 years (38.2% versus 52.3%). In PsA, patients starting on etanercept had lower CRP at 12 years ($p=0.041$). Multivariate analysis showed 1-year continuation [OR 4.28 (1.28–14.38)] and 1-year low-disease activity [OR 3.90 (95% CI 1.05–14.53)] was predictive of a 12-year persistence. Persistence with initial biologic at 12 years [OR 4.98 (95% CI 1.83–13.56)] and male gender [OR 4.48 (95% CI 1.25–16.01)] predicted 12 year remission.
Conclusion: This is the first real world data to show better response to biologic therapy in PsA compared to RA at 12 years. Long-term persistence with initial biologic agent was high and predicted by biologic persistence and low-disease activity at 1 year. Interestingly, PsA patients had higher levels of employment, educational attainment, and long-term remission rates compared to RA patients.
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POS0626 MONEY MATTERS: ASSESSING THE VALUE OF THE ADALIMUMAB BIOSIMILAR SWITCH FOR RHEUMATOLOGY PATIENTS

S. Gohil[1]. [1]*University Hospitals of Coventry and Warwickshire NHS Trust, Pharmacy, Coventry, United Kingdom*

Background: The adalimumab biosimilar switch plan, actioned 2018-19 was one of the most complex of all biologic switches across several specialties. Non-medical switches are considered to ensure the best value medicines are prescribed for patients in line with NICE Technology Appraisals.
Objectives: This 2 year follow up review explores the value of the switch for Rheumatology (R) patients in comparison to two other major specialisms; Dermatology (R) and Gastroenterology (G).
Methods: 403 homecare (HC) patients had been identified as eligible for switch to a citrate containing biosimilar (R;189, G;176, D;38) between April-December 2019. 35 hospital FP10 patients receiving the citrate-free originator biologic were also identified for switch to the citrate containing biosimilar and prescription processing via HC (R; 24, G; 9, D;2). Biosimilar switch information was communicated via patient letters/clinic reviews. FP10 patients also received remote pharmacist telephone support, as part of a PDSA (Plan, Do, Study, Act) quality improvement pilot. Data in regard to switch refusal, treatment cessation, withheld treatment and patient satisfaction ratings for pharmacist phonecalls (1 = unsatisfactory, 5=very satisfied) was documented.
Results: 235/403 HC patients successfully switched (R;99, G;107, D;29). 64/403 HC patients switched back to the originator (R;47, G;12; D;5). Of the 64 switch back HC patients; 52% = reported lack of efficacy; 27% = injection site pain and 21% = various other factors such as blepharitis, insomnia and hair loss. 38/403 HC patients refused the switch and remained on the originator biologic (R;11, G;27, D;0). 31/403 HC patients switched to an alternative biologic (R;19, G;9, D;3). 32/403 HC patients stopped treatment (R;13, G;19, D;0). Treatment was withheld for 3/403 HC patients (R;0, G;2, D;1). 100% of FP10 patients switched to HC. 31/35 FP10 patients switched to the biosimilar (R; 22, G; 7, D; 2). 3/31 patients switched back to the originator due to lack of efficacy or side effects. 4 patients refused the switch to biosimilar (R;3, G;1, D;0). 89% of patients were very satisfied with the pharmacist telephone support.
Conclusion: In summary, 58% of all eligible HC patients switched in comparison to 89% of FP10 patients who received pharmacist telephone support; total cost saving following HC and FP10 switch = £270,000. Rheumatology demonstrated the least success in HC switching (52%) and the highest HC switch back figure (25%). Injection site pain and subjective lack of efficacy appear to be the main reasons for ongoing switch backs. The PDSA project demonstrates that a thorough pharmacist assessment of patient concerns in rationalising the use of a biologic agent versus biosimilar can be valuable for patients. Further cost effective adalimumab biosimilars have recently been launched. This seminal review emphasises the ongoing need for robust critical appraisals of biosimilars, with consideration for both clinical and cost effective parameters, before establishing their placement in treatment pathways.
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POS0627 SHORT-TERM EFFECT OF ANTI-IL-6 THERAPY ON ADIPONECTIN SERUM LEVELS IN PATIENTS WITH RHEUMATOID ARTHRITIS

S. Remuzgo-Martínez[1], V. Pulito-Cueto[1], F. Genre[1], J. Calvo[2], E. Aurrecoechea[3], I. Llorente[4], A. Triguero-Martinez[4], R. Blanco[1], J. Llorca[5], M. E. Ruiz[6], N. Rivera[6], O. Gualillo[7], R. López-Mejías[1], S. Castañeda[4,8], M. A. González-Gay[1,9,10]. [1]*IDIVAL, Hospital Universitario Marqués de Valdecilla, Genetic Epidemiology and Atherosclerosis in Systemic Diseases and in Metabolic Bone Diseases of the Musculoskeletal System, Santander, Spain*; [2]*Hospital Universitario Txagorritxu, University of Basque Country, Rheumatology Division, Araba, Spain*; [3]*Hospital Universitario Sierrallana, Rheumatology Division, Torrelavega, Cantabria, Spain*; [4]*Hospital Universitario de la Princesa, IIS-IP, Rheumatology Division, Madrid, Spain*; [5]*School of Medicine, University of Cantabria, and CIBER Epidemiología y Salud Pública (CIBERESP), IDIVAL, Epidemiology and Computational Biology Department, Santander, Spain*; [6]*Hospital Universitario Basurto, Rheumatology Division, Bilbao, Spain*; [7]*Santiago University Clinical Hospital, SERGAS (Servizo Galego de Saude) and IDIS (Instituto de Investigación Sanitaria de Santiago), NEIRID Lab (Neuroendocrine Interactions in Rheumatology and Inflammatory Diseases), Research Laboratory 9, Santiago de Compostela, Spain*; [8]*Universidad Autónoma de Madrid (UAM), Cátedra UAM-ROCHE, EPID Future, Department of Medicine, Madrid, Spain*; [9]*University of Cantabria, School of Medicine, Santander, Spain*; [10]*University of the Witwatersrand, Cardiovascular Pathophysiology and Genomics Research Unit, School of Physiology, Faculty of Health Sciences, Johannesburg, South Africa*

Background: Adiponectin is an adipokine with anti-inflammatory, anti-atherosclerotic and cardioprotective effects that also contributes to the pathogenesis of metabolic syndrome (MetS) [1]. MetS is frequently observed in patients with rheumatoid arthritis (RA), increasing the risk of cardiovascular (CV) morbidity and mortality in these patients [1-3]. A recent study of our group disclosed a short-term effect of anti-IL-6 therapy on serum levels of leptin (another adipokine with pro-inflammatory functions, related with MetS and CV disease) in RA patients [4]. Accordingly, it is plausible to think that such treatment may also have an effect in adiponectin levels.
Objectives: To determine the short-term effect of the anti-IL-6 receptor tocilizumab (TCZ) administration on circulating adiponectin serum levels in patients with RA, as well as the potential association of adiponectin with demographic and clinical features of these patients.