Conclusion: Overall, non-infectious non-serious AEs were mild/moderate and the majority were self-limiting. Non-serious AE frequency was similar for tofacitinib monotherapy and combination therapy, and for tofacitinib and PBO.

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AB0455

FACTORS ASSOCIATED WITH DAS28 RESPONSE IN BIOLOGIC-NAÏVE PATIENTS WITH RHEUMATOID ARTHRITIS: 10 YEAR FOLLOW-UP

Daniel Xavier Xibille Friedmann¹, Maricela Escobar Román², Sandra Miriam Carrillo Vazquez³, José Luis Montiel Hernández⁴. ¹Hospital General de Cuernavaca, SSM, Rheumatology, Cuernavaca, MOR, Mexico; ²Universidad Latinoamericana, School of Medicine, Cuernavaca, MOR, Mexico; ³Hospital 1 de Octubre, ISSSTE, Rheumatology, Mexico, Mexico; ⁴Universidad Autónoma del Estado de Morelos, Faculty of Pharmacy, Cuernavaca, Mexico

Background: Access to adequate care is limited in Mexico as biologics or targeted therapies are unavailable for a proportion of patients with rheumatoid arthritis (RA) and only methotrexate and other conventional (c) DMARDs are employed as therapeutic options in many cases.

Objectives: To determine the factors associated to DAS28 response in patients with rheumatoid arthritis followed up to 10 years and who never received biologic or targeted therapy, being treated only with cDMARDs.

Methods: We analyzed a prospective cohort of 543 patients with RA followed for 10 years (March 2006 to February 2016) at the Hospital General de Cuernavaca, in central Mexico. Demographic data, shared epitope (SE; HLA-DR*0101, *0102, *0401, *0404, *0405, *0408, *0410, *1001, *1402) status, date since onset of disease and treatment, clinical and disease activity characteristics as well as treatment data was obtained and followed through time. Patients were seen by a rheumatologist every three months and blood samples obtained on each visit. The DAS28 score was determined on each visit and treatment adjusted accordingly. They were treated with prednisone (PDN; ≤10 mg/day), Methotrexate (MTX; 7.5-25 mg/week), Cloroquine (CLQ; 150-300 mg/day), Sulphasalazine (SSZ; 1-3 gr/day) or a combination of these. Descriptive statistics were used for the analysis of demographic data and parametric correlation tests (Spearman) were employed in the analysis.

Results: Of the 543, 94.3% of patients were women; mean age at baseline was 54.1 years (23-89; SD 12.4), mean time since onset of disease was 6.6 years (0-49; SD 7.9) and mean time since onset of treatment was 3 years (1-9; SD 2.12). HLA was determined in 57 patients and 36.8% of these patients were SE positive (one or two alleles). Most patients received treatment on the baseline visit based mainly on MTX (72.7%) combined with CLQ (63%) and low-dose PDN (76.4%). Less than 5% was under treatment with a non-MTX cDMARD. Baseline mean DAS28 was 4.9 (0.9-8.3; SD 1.41). At 6 months since DMARD-onset mean DAS28 was 3.8 (0.42-8.0; SD 1.46), at 12 months mean DAS28 was 3.6 (0.14-7.6; SD 1.34). At 2 years of follow-up, mean DAS28 remained at 3.6 (1.27-7.43; SD 1.35). Over the course of the next 8

years patients maintained a mean DAS28 between 3.5-3.6, with no significant changes in spite of continuing cDMARD treatment. Apart from being under treatment, which correlated with a better DAS28 score, being female correlated with a poorer DAS28 response ($p < 0.05$). The other baseline factor significantly associated to an improved long-term outcome regarding disease activity was time since onset of disease, which correlated with a higher DAS28 score during the first two years of follow up but tapered after two years of follow-up ($p < 0.001$). One of the limitations of the study was the significant drop-out rate (>20%) seen during follow up.

Conclusion: DAS28 response occurs mainly in the first 2 years of treatment. After that, cDMARD treatment is associated to a stationary effect over DAS28 in patients with no access to biologics or targeted therapies. This is an important factor to consider when establishing long-term therapeutic strategy from a cost-effective point of view.

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AB0456

PERCEPTIONS OF GLUCOSTEROID SIDE EFFECTS IN RHEUMATOID ARTHRITIS PATIENTS

Saoussen Miladi, Makhlof yasmine, Alia Fazaa, Selma Chekil, Salma Kassab, Kmar Ouenniche, Leila Souebni, Kaouther Ben Abdelghani, Ahmed Laatar. *Mongi Slim Hospital, Tunis, Tunisia*

Background: Most of the new recommendations proposed for the management of Rheumatoid arthritis (RA) emphasize the involvement of patients in therapeutic decision-making. This should encourage us to evaluate their level of information, fears and beliefs about the different treatments especially corticosteroids.

Objectives: The aim of this study was to evaluate the fears and beliefs of Tunisian patients with RA regarding corticosteroids.

Methods: A prospective study including 35 RA patients according to the ACR/EULAR 2010 criteria was performed. All of them were treated with corticosteroid therapy in addition to DMARDs and their usual long-term treatment. Every patient included in the study completed a questionnaire, containing sociodemographic component and evaluating corticosteroid modality use as well as side effects[1].

Results: The study included 35 patients with female predominance (74, 3%). The mean age was 57 years (29-72). The mean duration of the disease was 8 years (2-13 years). All RA patients were immunopositive for rheumatoid factor and/or for Anti-cyclic citrullinated peptide antibody (anti-CCP). Twenty-six patients were on Methotrexate, 6 on Infliximab, and 3 on Rituximab. Corticosteroid therapy was prescribed at a mean dose of 7.5 mg prednisone (5 to 10 mg). The level of education of our patients was generally low: 17 were illiterate, 10 had received a primary or secondary education, only 8 attended college. None of them was part of a medical or paramedical profession. Twenty patients, of whom eight diabetic, had an idea about the potentially harmful effect of corticosteroids on glycemic equilibrium (14 patients reported hyperglycemia and six patients mentioned hypoglycemia). Forty percent were aware of obesity as an effect correlated with corticotherapy. Moreover, 34.3% of patients talked about the hypertensive peak as a serious complication. Osteoporosis was mentioned in 17.1% of cases. About 10 patients had no idea about the adverse effects of steroids. When asking them about their source of information: they mentioned respectively television and radio programs with medical informative content, environment and medical or paramedical medical staff.

Conclusion: This study highlights the insufficiency of the level of information provided for RA patients regarding corticosteroids side effects. New awareness-raising materials should be reinforced and adapted to make full use of their potential with less likelihood of adverse effects.

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SLE, Sjögren's and APS – treatment

AB0457

AUDIT ON HYDROXYCHLOROQUINE RELATED RETINOPATHY SCREENING IN RHEUMATOLOGY PATIENTS IN SVUH

Aadil Al Ghafr, Eamonn S. Molloy. *St Vincent's University Hospital, Rheumatology, Dublin, Ireland*

Background: Hydroxychloroquine (HCQ) is a medication commonly used to treat rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), and other rheumatological conditions. A known adverse effect associated with long-term use of these medications is vision loss resulting from irreversible retinal toxic effects. Recent guidelines emphasized on routine ophthalmological examination and to adhere on real weight-based dosages.

Objectives: This audit conducted to evaluate adherence rate on standard recommendation on HCQ related retinopathy screening in rheumatology patients in St Vincent's University Hospital (SVUH).

Methods: Patient were on HCQ and attended rheumatology clinics at SVUH with rheumatic diseases selected randomly from on 01/08/2017 and end on 01/04/2018. A total sample size of 56 patients received a questionnaire that included information on HCQ dose, duration and actual body weight. Other information included precipitant factors and ophthalmology examination reports were retrieved retrospectively from patient's chart. Standards were measured against recommendations on screening for HCQ retinopathy published by American Academy of Ophthalmology, 2016 Revision.

Results: Total 56 patients on HCQ with different rheumatic disease studied. Out of 56 patients studied, 6/56 (10.7%) were <25 years (young), 45/56 (80.4%) were 25-65 years (middle age), and 5/56 (8.9%) were >65 years (elderly). Sex distribution showed that 7/56 (12.5%) were males and 49/56 (87.5%) were females. Around 35.7% (20/56) were in HCQ dose >5mg/kg, and 64.3% (36/56) were on standard HCQ dose (<=5mg/kg of real body weight. The were 44.6% (25/54) patients on HCQ for a period <5 years, the rest, 55.4% (32/56) were on HCQ for a period of 5-20years, and none of these patients were on it for >20 years duration. There were only 1/56 (1.8%) patient with history of HCQ toxicity, 98.2% (55/56) showed no history of HCQ related toxicity. None of the 56 patients had any of the following influencing factors: renal impairment, Tamoxifen usage, coagulopathies, hepatic impairment, or pre-existing retinal/macular disease. However, there were 8.9% (5/56) of this group their age was > 65years (verses 51/56 91.1% were <65years age. Only 69.6% (39/56) of these patients underwent retinal baseline screening, were 17/56 (30.4%) did not receive any baseline screening after commencing HCQ therapy. Frequency of follow up retinal screening were done annually in 19/56 (33.9%), 5 yearly in 6/56 (10.7%). However, it was not done in 21/56 (37%) and it was not due in 9/56 (16.1%). Out of those who underwent the screening at any time, 32/56 (57.1%) showed normal examination results, only 1/56 patient (1.8%) showed abnormal results. Rest of the patient data either were not available, or examination were not done.

Conclusion: Above data emphasizes the need to adhere on standards HCQ retinal screening as baseline and follow up. Furthermore, adherence on real weight calculated dose rather than estimated/average body weight.

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AB0458

A PHASE II RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PROOF OF CONCEPT STUDY OF ORAL SELETALISIB IN PATIENTS WITH PRIMARY SJÖGREN'S SYNDROME (PSS)

Maria Juarez¹, Nieves Diaz¹, Geoffrey I. Johnston¹, Saba Nayar², Andrew Payne¹, Eric Helmer¹, Dionne Cain¹, Paulette Williams³, Wan Fai Ng⁴, Benjamin Fisher², Jacques-Eric Gottenberg⁵, Giuliana Guggino⁶, Xavier Mariette⁷, Marika Kvarnström⁸, Valerie Devauchelle-Pensec⁹, Jose Rosas¹⁰, Juan Sanchez-Burson¹¹, Roberto Giacomelli¹², Francesca Barone², Simon J. Bowman¹³. ¹UCB Pharma, Slough, United Kingdom; ²University of Birmingham, Birmingham, United Kingdom; ³UCB Pharma, Raleigh, United States of America; ⁴Newcastle University and NIHR Newcastle Biomedical Research Centre, Newcastle upon Tyne, United Kingdom; ⁵Strasbourg University Hospital, Strasbourg, France; ⁶University of Palermo, Palermo, Italy; ⁷Université Paris-Sud, Paris, France; ⁸Karolinska Institutet, Stockholm, Sweden; ⁹Cavale Blanche Hospital, Brest, France; ¹⁰Hospital Marina Baixa, Villajoyosa, Spain; ¹¹Infantluisa Hospital, Sevilla, Spain; ¹²University of L'Aquila, L'Aquila, Italy; ¹³University Hospitals and Birmingham Biomedical Research Centre, Birmingham, United Kingdom

Background: Seletalisib is a potent, selective oral inhibitor of phosphoinositide-3 kinase delta (PI3Kδ). Preclinical data have shown that the PI3Kδ pathway is upregulated within salivary glands of patients with PSS and contributes to disease pathogenesis.¹

Objectives: To assess the efficacy and safety of seletalisib in patients with PSS.

Methods: In this Phase II, double-blind, proof of concept study (NCT02610543), patients with PSS having an EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) score ≥5 were randomised 1:1 to seletalisib once daily or placebo (PBO) in addition to current PSS therapy for 12 weeks. The primary endpoint was change from baseline in ESSDAI at Week 12. The study was designed to have 80% power to detect a difference of 3.8 points in change from baseline in ESSDAI between seletalisib and PBO at Week 12 and required 58 patients to complete treatment. Other endpoints included EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI), salivary gland biopsy changes, Schirmer's I test, immunoglobulin concentrations and incidence of treatment-emergent adverse events (TEAEs).

Table 1. Change from baseline to Week 12 for secondary and exploratory endpoints (full analysis set)

	Seletalisib n=13, LS mean (SE)	PBO n=14, LS mean (SE)	Difference (95% CI)
ESSPRI score ^a	-2.13 (0.68)	-0.57 (0.56)	-1.55 (-3.39, 0.28)
Stimulated salivary flow rate, mL/min ^a	-0.08 (0.11)	-0.11 (0.08)	0.02 (-0.27, 0.31)
Schirmer's I test score ^b	-0.9 (3.3)	0.5 (2.6)	-1.41 (-10.35, 7.52)
Immunoglobulin G, g/L ^a	-2.36 (0.71)	1.17 (0.64)	-3.53 (-5.55, -1.51)
Immunoglobulin M, g/L ^a	-0.33 (0.10)	0.07 (0.09)	-0.40 (-0.68, -0.12)
Immunoglobulin A, g/L ^a	0.03 (0.13)	0.06 (0.12)	-0.03 (-0.40, 0.34)

LS, least squares; SE, standard error

^a Mixed model for repeated measures analysis

^b Analysis of covariance

Results: The study was terminated early due to slow recruitment, which led to study power decreasing to 36%. Twenty of 27 patients randomised (seletalisib n=13, PBO n=14) completed treatment. Demographic characteristics were generally similar between groups. Mean (SE) change from baseline in ESSDAI at Week 12 was seletalisib -5.4 (1.7) vs PBO -2.8 (1.5); treatment difference vs PBO (95% CI) was -2.59 (-7.30, 2.11; p=0.266). The percentages of patients achieving a ≥3 point reduction in ESSDAI were seletalisib 66.7% vs PBO 54.5%. Post-hoc Bayesian analyses of treatment difference showed an 86.5% probability of being superior to PBO and a 48.8% probability of a >3 point difference from PBO. Clinically notable improvements in some secondary endpoints were also observed in the seletalisib group (Table 1). Minor salivary gland biopsies had broadly similar histological features across groups at baseline. At