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FRI0363

CLINICAL PREDICTORS OF SECUKINUMAB RETENTION IN A REAL WORLD COHORT OF PATIENTS WITH PSORIATIC ARTHRITIS AND AXIAL SPONDYLOARTHRITIS

A. Tindell¹, A. McGucken¹, S. Batool², S. Siebert¹. ¹University of Glasgow, Institute of Infection, Immunity and Inflammation, Glasgow, United Kingdom; ²NHS Greater Glasgow & Clyde, Glasgow, United Kingdom

Background: There are increasing treatment options for patients with psoriatic arthritis (PsA) and axial spondyloarthritis (AxSpA). Whilst there are several studies identifying predictors of response to TNF inhibitors¹ there is little data so far predicting response to the IL-17A inhibitor secukinumab which given its different mechanism of action may have different predictors of response.

Objectives: To identify demographic or clinical factors at initiation of secukinumab associated with stopping treatment due to inefficacy in PsA and in AxSpA in a real world cohort.

Methods: Retrospective analysis of all rheumatology patients' notes in Glasgow who had received secukinumab. Demographics, disease activity at baseline and retention of secukinumab were collected from medical records in patients with a diagnosis of PsA or AxSpA. Patients who discontinued due to adverse events or other events (e.g. pregnancy) were excluded. Patients who remain on secukinumab but have not yet had their six-month review to assess response or who started secukinumab via a clinical trial were also excluded. Unpaired T-test of unequal variance used to assess differences between groups with p-value ≤ 0.05 considered significant.

Results: 352 rheumatology patients in Glasgow had ever received secukinumab. 266 had PsA, 76 had AxSpA (others: SAPHO, JIA, reactive arthritis).

77 PsA patients discontinued secukinumab, 48 due to inefficacy. 157 PsA patients remain on secukinumab and have had at least an initial six-month review.

Table 1 shows results for PsA. Inefficacy was associated with higher levels of current smoking and higher levels of ESR and CRP but not tender or swollen joints.

Table 1. Demographics and clinical characteristics of PsA patients starting secukinumab

	Stopped due to Inefficacy (n=48)	Remain on Secukinumab (n=157)	Significance (p value)
Gender (M:F)	1:1.86	1:2.3	0.24
Age (years)	47.8	50.8	0.078
Current Smoking	37%	21%	0.040
Socioeconomic Decile	4.9	5.0	0.39
Weight (kg)	81.6	85.9	0.11
Number of Comorbidities	1.72	1.85	0.31
Disease Duration (years)	10.4	11.2	0.24
Number Previous bDMARDs	1.69	1.40	0.095
Tender Joint Count	16.6	16.6	0.50
Swollen Joint Count	6.4	7.3	0.29
Patient Global Score (VAS)	62.4	67.7	0.19
ESR (mm/hr)	24.1	14.8	0.017
CRP (mg/L)	12.8	6.2	0.049

Values are mean unless stated

21 AxSpA patients discontinued secukinumab, 13 due to inefficacy. 49 AxSpA patients remain on secukinumab and have had at least an initial six-month review. AxSpA patients who stopped due to inefficacy had higher mean BASDAI (8.47 vs 7.02, $p=0.007$) but there was no difference in mean ESR (31 vs 27.1, $p=0.31$) or CRP (23.6 vs 23.0, $p=0.48$). Surprisingly, disease duration was lower in inefficacy group (7.8 years vs 13.5, $p=0.003$); this could reflect a higher proportion in the inefficacy group with non-radiographic AxSpA which is known to be associated with earlier disease and to have a lower response to biologic treatments than ankylosing spondylitis. Smoking did not show significant difference in AxSpA but numbers are small and there is numerically higher level of smoking

in the inefficacy group (58% vs 32%, $p=0.063$). No other significant differences in demographics or clinical characteristics were noted.

Conclusion: Smoking predicted inefficacy in secukinumab in PsA patients, with a similar trend in AxSpA patients, reinforcing the importance of promoting smoking cessation. Higher levels of ESR and CRP negatively predicted secukinumab response in PsA. High BASDAI and low disease duration in AxSpA predicted inefficacy. These clinical factors may be helpful in informing treatment decisions in PsA and AxSpA in the absence of therapeutic biomarkers.

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FRI0364

PREVALENCE OF THE METABOLIC SYNDROME IN PSORIATIC ARTHRITIS: SYSTEMATIC LITERATURE REVIEW AND RESULTS OF THE CARMA COHORT

A. Urruticoechea-Arana¹, S. Castañeda², E. Loza³, T. Otón³, D. Benavent⁴, M. A. Martín-Martínez⁵, M. A. González-Gay⁶ on behalf of CARMA Project Collaborative Group. ¹H. Can Misses, Ibiza, Spain; ²H.U. La Princesa, Madrid, Spain; ³InMusc, Madrid, Spain; ⁴H.U. La Paz, Madrid, Spain; ⁵Spanish Society Of Rheumatology, Madrid, Spain; ⁶H.U. Marqués de Valdecilla, Santander, Spain

Background: The cardiovascular burden in psoriatic arthritis (PsA) is well recognized¹.

Objectives: To analyze the prevalence of metabolic syndrome (MetS) in patients with PsA.

Methods: We conducted a systematic literature review (SLR) and a sub-analysis of the CARMA cohort. In the SLR, we searched in Pubmed, Embase, the Cochrane Central Library, and the ClinicalTrials until March 2019 using Mesh terms and free text words. We included SLR, clinical trials and observational studies analyzing the prevalence or frequency of MetS in PsA. Two reviewers selected articles, assessed the quality of the studies and collected data independently. The CARMA cohort was designed to establish the cardiovascular (CV) morbidity and associated risk factors for CV disease. It includes data from patients with chronic inflammatory rheumatic diseases (including PsA) of 67 Spanish hospitals. A sub-analysis of the prevalence of metS in PsA was performed using the National Cholesterol Education Program Adult Treatment Panel III criteria updated in 2005, which requires the presence of ≥ 3 of the following: high waist circumference, low HDL cholesterol level, high triglyceride level, high blood pressure and high fasting glucose values.

Results: A total of 18 articles of moderate to high quality, were selected in the SLR. The included patients presented a balanced distribution by sex, with an average age ranging from 42 to 59 years. The frequency of MetS varied from 23.5% to 62.9% depending on the definition of MetS. The most widely used classification method was the National Cholesterol Education Program, followed by the method recommended by the International Diabetes Federation in 2009. A total of 724 patients with PsA were included in the CARMA study, of whom 327 (45.4%) were women and 157 (21.8%) smokers. The mean age at baseline was 51 ± 12 years and the mean duration of PsA disease 9 (4-16) years. Hypertension was the most frequently altered parameter (66.8%), followed by fasting glucose (42.6%) and hypertriglyceridemia (30.6%). Table 1 shows the frequency of patients according to the number of MetS components. A total of 222 (30.6%) PsA patients presented metabolic syndrome.

Table 1. Prevalence of metabolic syndrome.

Number of components N 0-5	Patients (n) CARMA study	Percentage of patients, SLR (%)
0	101	13.95
1	208	28.73
2	193	26.66
3	151	20.86
4	59	8.15
5	12	1.66
Total	724	100

Conclusion: The frequency of the individual components of the MetS is variable according to the method of classification, which makes it difficult to compare between studies. In the CARMA study, the prevalence of MetS was around 30%, which supports the control of individual factors to prevent CV disease.

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FRI0365

REAL-WORLD EFFECTIVENESS AND SAFETY OF APREMILAST IN A LARGE COHORT OF GERMAN PATIENTS WITH PSORIATIC ARTHRITIS: 1-YEAR ANALYSIS OF AN ONGOING MULTICENTER, PROSPECTIVE, NON-INTERVENTIONAL STUDY

J. Wollenhaupt¹, H. Strothmeyer², M. Fiene³, S. Morys⁴, C. Bach⁴, J. Roemmler-Zehrer⁴. ¹Rheumatologie im Struenseehaus, Hamburg, Germany; ²Rheumatologische Gemeinschaftspraxis Düsseldorf, Düsseldorf, Germany; ³Klinik für Rheumatologie, Demmin, Germany; ⁴Amgen Inc., München, Germany

Background: Apremilast (APR) has been studied extensively in phase III randomized, controlled trials. However, real-world information is limited on the effectiveness and safety of APR in patients with psoriatic arthritis (PsA).

Objectives: To assess the effectiveness and safety of APR in a large cohort of patients with active PsA from routine clinical practice settings in Germany.

Methods: In this multicenter, prospective, non-interventional study, the primary endpoint was the proportion of patients reaching ≥ 1 point ($\geq 20\%$) improvement from baseline (BL) in the Physician's Global Assessment of Disease Activity (PhGA) score. Other endpoints included effects on swollen and tender joint counts (SJC/TJC), psoriasis-involved body surface area (BSA), enthesitis, dactylitis, Patient's Global Assessment of Disease Activity score (PtGA), Psoriatic Arthritis Impact of Disease (PsAID) tool, pain, and pruritus. The current analysis is based on observed data through 1 year of study duration.

Results: A total of 545 German patients were enrolled and followed up to 12 months of APR treatment; 488 patients were included in the safety analysis and 418 in the final analysis set. The mean age was 55 years, mean body mass index was 29.5 kg/m², and 60% were female. The mean duration of psoriasis and PsA was 26 years and 18 years, respectively. At BL, 46.7% of patients had enthesitis based on the Leeds Enthesitis Index (LEI; mean [SD]: 2.9 [1.72]) and 23% had dactylitis (mean [SD]: 2.2±2.03); 74% of patients were biologic-naïve. Effectiveness is shown after ~1 month (Visit 1 [V1]) and ~4 months (Visit 2 [V2]) and for up to 225 patients after 12 months (Visit 5 [V5]) of treatment (Table). Improvements were also seen in PtGA, overall pain, and pruritus. A subanalysis suggests APR was associated with greater benefits in biologic-naïve patients compared with patients who previously received biologic therapy. Observed safety and tolerability through V5 were consistent with the known overall safety profile of APR. Common adverse events in clinical trials were similar, with a lower incidence of diarrhea (11.1%), nausea (7.0%), headache (3.9%), and respiratory tract infection (0.8%).

Conclusion: Data from this large, real-world cohort of patients with PsA show the effectiveness of APR. In patients with up to 12 months of follow-up, APR was associated with rapid and maintained improvements in physician-assessed and patient-reported outcomes. Safety and tolerability were consistent with the known profile of APR.

Table. Effectiveness of APR Treatment

	BL n=418*	V1 n=326*	V2 n=360*	V5 n=214*
≥ 1 -point PhGA improvement, %	NA	56.2	77.2	86.4
PhGA score, mean (95% CI)	2.5 (2.4, 2.5)	1.8 (1.7, 1.9)	1.4 (1.3, 1.5)	1.1 (1.0, 1.2)
PhGA score=0-1, %	NA	34.3	60.8	77.0
SJC mean improvement, % (95% CI)	NA	42.1 (34.7, 49.5)	54.7 (45.4, 64.1)	75.7 (65.5, 86.0)
TJC mean improvement, % (95% CI)	NA	38.3 (27.2, 40.4)	36.0 (23.8, 48.3)	57.1 (41.1, 73.1)
Psoriasis-involved BSA (%), mean (95% CI)	10.0 (8.6, 11.4)	7.7 (6.3, 9.1)	4.7 (3.8, 5.7)	2.4 (1.8, 2.9)
Achievement of LEI=0 [†] , %	NA	38	50	58
Achievement of dactylitis count=0 [†] , %	NA	48	71	88
PsAID score, mean (95% CI)	5.33 (5.12, 5.53)	4.65 (4.41, 4.89)	3.97 (3.73, 4.20)	3.22 (2.94, 3.50)

*Based on the number of patients with data available at the given visit; the n may vary for individual parameters at a given visit. [†]In patients affected at BL. CI=confidence interval; NA=not applicable.

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FRI0366

CARDIOVASCULAR RISK RECLASSIFICATION USING CAROTID ULTRASOUND IN PSORIATIC ARTHRITIS: A CASE-CONTROL STUDY

D. Á. Galarza-Delgado¹, J. R. Azpiri-López², I. J. Colunga-Pedraza¹, D. E. Flores Alvarado¹, O. Ilizaliturri Guerra¹, I. C. Zárate Salinas², P. F. Frausto Lerma¹, A. Pérez Villar², M. A. Reyes Soto¹, A. C. Garza Acosta³. ¹Hospital Universitario "Dr. José Eleuterio González"; UANL, Rheumatology, Monterrey, Mexico; ²Hospital Universitario "Dr. José Eleuterio González"; UANL, Cardiology, Monterrey, Mexico; ³Hospital Universitario "Dr. José Eleuterio González"; UANL, Radiology, Monterrey, Mexico

Background: Patients with psoriatic arthritis (PsA) have an increased risk of cardiovascular disease (CVD). Risk stratification algorithms for general population, such as cardiovascular risk calculators, have been developed to improve primary prevention and early detection of CVD; however, it underestimates cardiovascular risk in PsA patients¹. Carotid ultrasound, which measures both carotid intima-media thickness (cIMT) and carotid plaque (CP), is useful in the detection of subclinical carotid atherosclerosis improving risk stratification.

Objectives: This study aimed to evaluate the use of carotid ultrasound in the reclassification of cardiovascular risk in PsA patients and compare it with controls.

Methods: This cross-sectional study included 70 PsA patients that fulfilled the CASPAR criteria and 70 controls subjects matched by age and comorbidities. Patients with a history of previous atherosclerotic CVD and pregnancy were excluded. Clinical examination, blood tests and Framingham Risk Score Lipids and BMI based (FRS-Lipids/FRS-BMI) and ACC/AHA 2013 calculators were performed. Carotid B-mode ultrasonography was used for measurements of cIMT and CP presence. *Increased cIMT was defined as ≥ 0.9 mm. CP was defined as a focal narrowing ≥ 0.5 mm of the surrounding lumen or a cIMT ≥ 1.2 mm.* Descriptive analysis was done with measures of central tendency and dispersion and comparisons with Chi-square, Student's t and Mann-Whitney U tests.

Results: A total of 138 subjects were included. Clinical and demographic characteristics are shown in Table 1. Differences were found in the cardiovascular risk classification between the calculators and the carotid ultrasound. However, these were not significant when compared to controls, with the exception of the FRS-Lipids which had a significant difference when recategorized as high risk by the increase in the cIMT ($p = 0.016$). A 70.8% and a 56% of patients with PsA who had CP were not classified as high risk according to FRS-Lipids ($p = 0.010$) and ACC / AHA 2013 ($p < 0.001$) respectively.

Table 1. Clinical and demographic characteristics.

	PsA (n=69)	Controls (n=69)	P
Age, (mean±SD)	53.58±10.946	53.86±7.313	NS
Women, n (%)	38(55.1)	59(85.5)	<0.001
Type 2 Diabetes Mellitus, n (%)	14(20.3)	9(13)	NS
Hypertension, n (%)	27(39.1)	19(27.5)	NS
Dyslipidemia, n (%)	29(42)	24(34.8)	NS
Obese, n (%)	26(37.7)	28(40.6)	NS
Active smoker, n (%)	15(21.7)	12(17.4)	NS
Disease duration, median (q25-q75)	5(2.5-8)	-	-
DAS28-ESR, (mean±SD)	3.74±1.477	-	-
DAPSA, median (q25-q75)	35(27.5-58.5)	-	-

Conclusion: None of the traditional calculators used in the general population correctly estimates cardiovascular risk in patients with PsA. Among the calculators we performed, FRS-Lipids was the worst, underestimating PsA individuals with CP up to 70.8%. Therefore, it is advisable to perform a carotid ultrasound without relying on the results obtained by any of these calculators in order to achieve an adequate classification and accomplish a correct management of the disease.

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