Results: 74 patients, 63.5% males, aged mean(SD) 54.8 (14.0) years. 56 peripheral PsA and 18 mixed (peripheral predominance); with mean 94.9 (92.4) months of disease; 35.1% with previous clinical enthesitis and 37.8% previous dactylitis. Cutaneous disease consisted mainly (82.4%) in plaque psoriasis, 9.5% affecting folds, 4.1% onychopathy. 52.7% have received a previous DMARD of (31.1% MTX, 9.5% leflunomide) and 23.0% PUVA; 4.1% have received previous biological treatment. Current treatment: 83.8% DMARDs (68.9% MTX and 5.4% leflunomide) with a mean follow-up of 60.6 (55.0) months.

Disease activity:

Skin plaque psoriasis was mainly controlled: 73.4% low PASI level (23.4% moderate) median PASI 3.0 [1.5–5.0]; 50.0% mild BSA, median BSA 3.0 [1.0–6.0]. 73.1% PGA of very mild or mild-moderate disease

87.0% of patients met DAPSA criteria of remission-low disease activity (DAPSA median 3.15 [1.34–6.71]; 55.9% achieved DAPSA<4); 75.7% were in low activity/remission according to medical judgement.

Overall 63.9% of patients achieved MDA.

15.3% (10 patients) had "relative contraindications" to biological therapy (6 cases of recent cancer, 2 HBV infection).

Conclusions: Over half of PsA patients from our multidisciplinary unit achieve low cutaneous and articular disease activity under csDMARDs, mainly Methotrexate. The use of targeted DMARDs such as apremilast in this scenario, before biological therapies, may improve disease outcomes in a subgroup of patients, corresponding with the efficacy shown in different domains of the psoriatic disease. Further research is needed to compare clinical results between csDMARDs and apremilast.

Disclosure of Interest: None declared

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THU0297 EVALUATION OF CARDIOVASCULAR RISK FACTORS AMONG PATIENTS WITH PSORIASIS, PSORIATIC ARTHRITIS AND PERIPHERAL SPONDYLOARTHRITIS

M.R. Camacho-Sánchez¹, ^{1,2}C. López-Medina, L. Bautista-Aguilar^{1,2}, L. Ladehesa-Pineda^{1,2}, L. Pérez-Sánchez^{1,2}, I. Gómez-García^{1,2}, A.J. Vélez García-Nieto^{1,3}, E. Collantes-Estévez^{1,2}, M.D. López-Montilla^{1,2}. ¹Universidad de Córdoba; ²Rheumatology; ³Dermatology, Hospital Universitario Reina Sofía de Córdoba/IMBIC, Córdoba, Spain

Background: It is well known that the prevalence of Cardiovascular Risk Factors (CVRF) in patients with Psoriatic Arthritis (PsA) is higher than in the general population¹. However, there is a lack of studies comparing PsA against Psoriasis without arthritis, and also against peripheral Spondyloarthritis (SpA).

Objectives: a) To compare the prevalence of CVRF among patients with PsA, Psoriasis without arthritis and peripheral SpA without Psoriasis; and b) to evaluate the association between CVRF and the presence of arthritis and/or Psoriasis.

Methods: A cross-sectional, observational and unicenter study in which clinical, analytical and demographic data from 300 patients were analysed. Patients were divided into four groups: PsA, Psoriasis without arthritis, peripheral SpA without Psoriasis and controls. Patients with PsA and peripheral SpA met CASPAR and peripheral ASAS criteria, respectively. Hypertension, Diabetes (T2DM) and Dyslipidemia were evaluated among the four groups by using the chi-square test. In order to evaluate whether CVRF could be explained by the presence of arthritis or Psoriasis, we divided patients (by excluding control groups) in arthritis/no arthritis and Psoriasis/no Psoriasis. Univariate and multivariate logistic regressions adjusted by sex and age were performed in order to determine variables independently associated with the presence of these three CVRF.

Results: Among the 300 patients included in the analysis, 89 (29.7%), 35 (11.7%) and 87 (29%) patients reported Hypertension, T2DM and Dyslipidemia, respectively. Regarding classification, 61 (20.3%) patients, 100 (33.3%), 100 (33.3%) and 39 (13.0%) patients were classified as control group, Peripheral SpA without Psoriasis, PsA and Psoriasis without arthritis, respectively. Patients from the control group showed significantly lower prevalence of Hypertension and Dyslipidemia against the other three groups ($p<0.05$); however, there were no differences between Peripheral SpA group, PsA and Psoriasis without arthritis regarding CVRF.

Patients with arthritis showed similar prevalence of CVRF than those without arthritis, as well as patients with Psoriasis vs. no Psoriasis.

Univariate analysis showed that Hypertension is significantly associated ($p<0.05$) to AINEs intake [OR 1.79 (95%CI 1.06–2.99)] as well as with disease duration [OR 1.02 (95%CI 1.01–1.05)]; however, the multivariate analysis adjusted by age and sex did not show significant differences. Regarding T2DM and dyslipidemia, the presence of arthritis or Psoriasis was not associated with the development of these comorbidities.

Conclusions: Our data suggest that the prevalence of CVRF among patients with Psoriasis, PsA and peripheral SpA are similar, although it is higher than in the general population. The presence of Hypertension in these patients is associated

with the use of NSAIDs; however, greater new studies would be necessary in order to determine specific associations.

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THU0298 PERITENON EXTENSOR TENDON INFLAMMATION, SYNOVITIS AND ENTHESOPATHY IN PSORIATIC ARTHRITIS: WHAT IS THE CONNEXION?

¹C. Macía Villa, S. Falcao², H.B. Hammer³, M. Gutierrez⁴, E. De Miguel⁵.

¹Rheumatology, Hospital Universitario Severo Ochoa, Madrid, Spain;

²Rheumatology, Chronic Diseases Study Center, NOVA Medical School, UNL, HEM. CHLO., Lisboa, Portugal; ³Rheumatology, Diakonhjemmet Hospital, Oslo, Norway; ⁴Division of Musculoskeletal and Rheumatic Disorders, Instituto Nacional de Rehabilitación, Mexico, Mexico; ⁵Rheumatology, Hospital Universitario La Paz, Madrid, Spain

Background: Metacarpophalangeal joint (MCPj) swelling in Psoriatic Arthritis (PsA) can be produced both by intra-articular synovitis (IAS) and peritenon extensor tendon inflammation (PTI). This last lesion has been reported as an enthesitis-like lesion.

Objectives: To evaluate if PTI is a synovitis or enthesitis related lesion using MASEI (Madrid Sonographic Enthesis Index) to analyse the existence of association with IAS and PTI.

Methods: 27 consecutive non selected PsA patients were included. An expert rheumatologist obtained the US images from the dorsal aspect of 2nd to 5th MCPj of both hands evaluating IAS and PTI, and also performed the MASEI examination. In addition to the PD item of MASEI (defined as signal in bone profile or intra-tendon or bursa at the enthesitis), PD OMERACT was evaluated as present or absent (defined as signal in the enthesitis ≤ 2 mm to the bone profile). We used a MyLab 70 XVG machine, Esaote, Genova, Italy, with a greyscale (GS) 13 MHz probe and 7.1 MHz power Doppler (PD) frequency, PRF 750 Hz and 60 Gain. 3–5 s videos of each MCPj and enthesitis were obtained in transverse and longitudinal views for further reliability analysis. Reliability of IAS and PTI was performed by 5 readers (true US result was the consensus of at least three) and MASEI's reliability was performed by 3 readers (true US result was the consensus of at least two). For reliability analysis, mean Cohen kappa was used for IAS and PTI, and intraclass correlation coefficient (ICC) for MASEI based on a mean-rating three readers, absolute-agreement, two-way mixed effect model. Statistical association between IAS, PTI and MASEI was analysed with T student test. SPSS statistical package version 20 (SPSS Inc, Chicago, IL) was used.

Results: Eighteen patients had PTI PD (66.7%), same for SIA PD. Inter-reader reliability for PTI and SIA was 0.685 and 0.680 kappa values respectively. Inter-reader reliability for MASEI was excellent ICC 0.922 (IC 95% 0.852–0.962), similar to PD MASEI ICC 0.921 (IC 95% 0.851–0.962) and PD OMERACT ICC 0.895 (IC 95% 0.802–0.949). Association data are shown in table 1.

Abstract THU0298 – Table 1. Association between IAS and PTI with MASEI and different PD subgroups.

	PTI		p value	IAS		p value
	Present	Absent		Present	Absent	
Mean MASEI±SD	32,44 ±15,62	27±9,33	0270	32±6,16 ±7,72	27,89 ±7,72	0380
Mean PD MASEI±SD	8±6	3,67 ±3,28	0023	6,83 ±6,15	6±4,5	0694
Mean PD OMERACT ±SD	1,61±1,33	0,56 ±1,01	0033	1,39 ±1,46	1±1	0426

Conclusions: In PsA, IAS at MCPj didn't show any association with enthesitis. However, PTI showed a significant statistically association with active enthesitis (PD MASEI and PD OMERACT). This finding reinforces the idea that PTI at MCPj level is related with the swelling of the functional enthesitis related to the retinaculum pulley structure.

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THU0299

AN INTEGRATED ANALYSIS OF CHANGES IN LIPID LEVELS AND INCIDENCE OF CARDIOVASCULAR EVENTS FOLLOWING TOFACITINIB TREATMENT IN PATIENTS WITH PSORIATIC ARTHRITIS ACROSS PHASE 3 AND LONG-TERM EXTENSION STUDIES

¹D.D. Gladman, C. Charles-Schoeman², I.B. McInnes³, D.J. Veale⁴, B. Thiers⁵, D. Graham⁶, C. Wang⁶, T.V. Jones⁷, R. Wolk⁸, R. DeMasi⁷. ¹University of Toronto, Toronto Western Hospital, Toronto, ON, Canada; ²University of California, Los Angeles, CA, USA; ³University of Glasgow, Glasgow, UK; ⁴St. Vincent's University Hospital and University College Dublin, Dublin, Ireland; ⁵Medical University of South Carolina, Charleston, SC; ⁶Pfizer Inc, Groton, CT; ⁷Pfizer Inc, Collegeville, PA, USA

Background: Cardiovascular (CV) disease and cardiometabolic syndrome are common comorbidities/causes of mortality in patients (pts) with psoriatic arthritis (PsA). Tofacitinib is an oral JAK inhibitor for the treatment of PsA.

Objectives: To investigate changes in lipid levels and incidence of CV events in pts with PsA treated with tofacitinib in Phase (P) 3 and long-term extension (LTE) studies.

Methods: Data were analysed for pts who received ≥ 1 dose of tofacitinib 5 or 10 mg BID or placebo (PBO), integrated across 2 P3 studies (OPAL Broaden [12 months (m); NCT01877668, including adalimumab control]; OPAL Beyond [6 m; NCT01882439]) and 1 LTE study (OPAL Balance [data cut-off May 2016; ongoing, database not locked; NCT01976364]). Lipid levels were assessed throughout P3 and LTE studies; this analysis included data from the PBO-controlled period (M0–3) of P3 studies. Blood pressure, hypertension events (standardised MedDRA query [narrow]) and adjudicated (independent/blinded to treatment) major adverse cardiovascular events (MACE) are reported for all pts who received ≥ 1 dose of tofacitinib (pooled across doses for hypertension and MACE). Incidence rates (IR; pts with events/100 pt-years [PY]) and 95% CI are reported.

Results: Overall, 783 pts (776 PY of tofacitinib exposure) were included in P3 and LTE studies; treatment duration was 1–927 days. After 3 m of tofacitinib treatment in P3 studies, dose-dependent increases in lipid levels were observed with tofacitinib; minimal changes were observed with PBO, except for triglycerides (figure 1). Concurrent increases in high-density and low-density lipoprotein (HDL/LDL) and no change in the total cholesterol/HDL ratio were shown. Across P3 and LTE studies, no clinically significant changes in mean systolic or diastolic blood pressure were seen to 24 m. Hypertension events were reported in 38 (4.9%) pts: IR 4.93 [95% CI 3.49, 6.77]. Of these events, 4 led to pt discontinuation and 2 were serious adverse events. MACE were reported for 3 (0.4%) pts receiving tofacitinib (IR 0.38 [95% CI 0.08, 1.11]) and included sudden cardiac death (57 days of exposure at time of event), myocardial infarction (197 days) and ischaemic stroke (80 days). This is within the range reported in tofacitinib studies in pts with psoriasis (IR 0.24 [0.15, 0.37]; 8,759 PY of exposure) and rheumatoid arthritis (RA) (IR 0.38 [0.30, 0.47]; 21,286 PY of exposure). No dose-dependent effects on blood pressure were apparent.

Figure. Mean % change from baseline in lipid levels to Month 3 integrated across Phase 3 studies

BID, twice daily; SE, standard error

Abstract THU0299 – Figure 1. Mean% change from baseline in lipid levels to Month 3 integrated across Phase 3 studies. BID, twice daily; SE, standard error

Conclusions: In pts with PsA, the magnitude and dose dependency of increases in lipid levels to M3 were consistent with findings in tofacitinib studies in pts with psoriasis and RA. In P3 and LTE studies, no clinically significant changes were seen in blood pressure or incidence of hypertension. Incidence of MACE was within the range reported in prior tofacitinib studies in psoriasis and RA; however, the long latency of MACE requires longer-term observation.

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THU0300

NETWORK META-ANALYSIS OF TOFACITINIB VS bDMARDS OR APREMILAST FOR THE TREATMENT OF TNF INHIBITOR-NAÏVE PATIENTS WITH PSORIATIC ARTHRITIS

¹D.D. Gladman, A.-M. Orba², J. Gomez-Reino³, S. Chang-Douglass⁴, E. Leoncini⁴, H.E. Burton⁴, K.S. Kanik⁵, T. Hendrikx⁶, J.C. Cappelleri⁵, M.-A. Hsu⁵. ¹University of Toronto, Toronto Western Hospital, Toronto, ON, Canada; ²Johns Hopkins University School of Medicine, Baltimore, MD, USA; ³Hospital Clínico Universitario, Santiago de Compostela, Spain; ⁴Decision Resources Group, London, UK; ⁵Pfizer Inc, Groton, CT; ⁶Pfizer Inc, Collegeville, PA, USA

Background: Tofacitinib is an oral JAK inhibitor for the treatment of psoriatic arthritis (PsA).

Objectives: To perform a systematic literature review (SLR) and network meta-analysis (NMA) to evaluate the efficacy of tofacitinib 5 and 10 mg BID relative to biologic disease-modifying antirheumatic drugs (bDMARDs) or a targeted synthetic DMARD (apremilast [APR]) in tumour necrosis factor inhibitor-naïve (TNFi-N) patients with active PsA.

Methods: The SLR identified randomised controlled clinical trials (RCTs) evaluating tofacitinib, bDMARDs or APR to treat patients with active PsA who were TNFi-N. Outcomes included American College of Rheumatology (ACR)20 response and change from baseline in Health Assessment Questionnaire-Disability Index (Δ HAQ-DI), Dactylitis Severity Score (Δ DSS) and Leeds Enthesitis Index (Δ LEI). Treatment effects were only evaluated during placebo (PBO)-controlled trial phases. The Bayesian NMA (with non-informative priors) was conducted using WinBUGS. The binomial logit model was used for ACR20, Δ HAQ-DI, Δ DSS and Δ LEI were analysed using the normal identify link model. A fixed-effect model was fitted to the data. Median treatment rankings represent data from each iteration of the model from which inferences are based, following model convergence.

Results: The SLR identified 25 RCTs and 21 were included in the NMA (see treatments in table 1). All trials allowed methotrexate use. PBO-controlled treatment durations ranged from 12–24 weeks. In general, patient characteristics were similar across trials. All treatments were associated with improvements in ACR20 and Δ HAQ-DI vs PBO. Tofacitinib 5 mg BID was associated with substantially decreased odds ratios (ORs) for ACR20 vs golimumab 50 and 100 mg Q4W, etanercept 25 mg BW, infliximab 5 mg/kg and secukinumab 150 mg QW-Q4W (table 1); ORs for all remaining comparators were not substantially different. Tofacitinib 10 mg BID was associated with a substantially increased OR for ACR20 vs APR 20 mg BID. Etanercept was associated with an improvement in Δ HAQ-DI for tofacitinib 5 and 10 mg BID. There was no difference in Δ HAQ-DI for tofacitinib vs other bDMARDs. For ACR20, tofacitinib 5 and 10 mg BID were median ranked 14 (95% credible interval: 8, 17) and 9, ^{5, 14} respectively, among 18 comparators. For Δ HAQ-DI, tofacitinib 5 and 10 mg BID were median ranked 11 ^{4, 13} and 8, ^{2, 13} respectively, among 14 comparators. Two studies evaluated Δ DSS and Δ LEI; there were no substantial differences in Δ DSS and Δ LEI for tofacitinib 5 and 10 mg BID vs adalimumab 40 mg Q2W and ixekizumab 80 mg Q2W and Q4W.