Abstract SAT0348 – Table 1. Exposure-Adjusted Incidence Rate of TEAEs at 12-Week Intervals up to Week 96 (All PsA Ixekizumab Exposures Integrated Analysis Set: SPIRIT-P1, SPIRIT-P2, and SPIRIT-P3).

	Week 0-12 N=1118	Week 12-24 N=1061	Week 24-36 N=992	Week 36-48 N=777	Week 48-60 N=525	Week 60-72 N=446	Week 72-84 N=377	Week 84-96 N=315
Deaths	0.4 (0.1, 2.9)	0.0 (0.0, 3.4)	0.5 (0.1, 3.4)	0.0 (0.0, 6.0)	0.9 (0.1, 6.5)	0.0 (0.0, 8.6)	1.3 (0.2, 9.3)	0.0 (0.0, 12.2)
TEAEs	225.8 (207.9, 245.4)	180.3 (164.0, 198.4)	185.9 (168.3, 205.3)	157.7 (137.8, 180.4)	133.3 (113.1, 178.4)	117.9 (97.7, 142.2)	106.5 (85.7, 132.4)	102.5 (80.7, 130.2)
SAEs	7.7 (4.9, 12.0)	8.8 (5.5, 14.7)	4.3 (2.2, 8.3)	4.5 (2.0, 10.0)	10.0 (5.6, 18.1)	8.7 (5.1, 18.7)	15.8 (9.0, 27.8)	10.7 (5.1, 22.5)
Infections	83.2 (72.6, 95.4)	90.8 (70.1, 93.2)	101.1 (88.3, 115.7)	79.2 (65.5, 95.8)	74.8 (60.3, 92.9)	51.9 (39.1, 68.9)	46.0 (33.0, 64.1)	36.7 (24.6, 54.8)
ISRs	78.8 (68.5, 90.7)	34.0 (27.3, 42.4)	23.5 (17.7, 31.1)	20.2 (13.8, 29.4)	1.8 (0.4, 26.1)	6.5 (2.9, 14.4)	7.9 (3.5, 17.6)	7.6 (3.2, 18.4)
Hypersensitivity*	11.3 (7.8, 16.4)	8.9 (5.8, 13.7)	7.2 (4.3, 11.9)	7.5 (4.0, 13.9)	1.8 (0.5, 7.3)	2.2 (0.5, 8.6)	1.3 (0.2, 9.3)	6.1 (2.3, 16.3)
MACE	0.4 (0.1, 2.9)	0.5 (0.1, 3.0)	0.5 (0.1, 3.4)	0.0 (0.0, 6.0)	3.7 (1.4, 9.7)	0.0 (0.0, 8.6)	2.6 (0.7, 10.5)	0.0 (0.0, 12.2)

All data are IRs (95% confidence intervals) unless otherwise specified. *Potential hypersensitivity events were defined by the narrow terms within hypersensitivity SMOQ excluding local injection site reactions.
Abbreviations: BD, inflammatory bowel disease; IR=exposure-adjusted incidence rates per 100 patient-years; ISR=injection site reaction; MACE=major adverse cardiac event; N=total number of patients analyzed at each time point; SAE=serious adverse event; TEAE=treatment-emergent adverse events.

Conclusions: The safety profile of IXE in patients with PsA is consistent with previous reports as derived from the analysis of the three SPIRIT trials from a large cohort of patients. No new safety signals were identified with longer IXE treatment exposure.

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Disclosure of Interest: P. Goupille Consultant for: Abbvie, BMS, Biogaran, Celgene, Eli Lilly and Company, Janssen, MSD, Novartis, Pfizer, UCB, E. Roussou Grant/research support from: Pfizer, MERCK, Eli-Lilly, TAKEDA, UCB, G. Burmester Grant/research support from: Eli Lilly and company, Consultant for: Novartis, Pfizer, Janssen, Eli Lilly, P. Mease Grant/research support from: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, SUN, Eli Lilly, Genentech, Janssen, Merck, Novartis, Pfizer, UCB, Consultant for: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, SUN, Eli Lilly, Genentech, Janssen, Merck, Novartis, Pfizer, UCB, Speakers bureau: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Novartis, Eli Lilly, Genentech, Janssen, Pfizer, and UCB, A. B. Gottlieb Grant/research support from: Janssen, Incyte, Consultant for: Celgene Corp., Bristol Myers Squibb Co., Beiersdorf, Inc., Abbvie, UCB, Novartis, Incyte, Lilly, Reddy Labs, Valeant, Dermira, Allergan, Sun Pharmaceutical Industries, S. Garces Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, O. Benichou Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, D. Adams Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, W. Xu Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, P. Nash Grant/research support from: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Hospira, Janssen, MSD, Novartis, Pfizer, Roche, Sanofi, UCB, Consultant for: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Hospira, Janssen, MSD, Novartis, Pfizer, Roche, Sanofi, UCB, Speakers bureau: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Hospira, Janssen, MSD, Novartis, Pfizer, Roche, Sanofi, UCB

DOI: 10.1136/annrheumdis-2018-eular.2132

SAT0349 A NOVEL SCORING SYSTEM TO DIFFERENTIATE PSORIATIC ARTHRITIS FROM NODAL OSTEOARTHRITIS ON PLAIN-FILM RADIOGRAPHS

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Background: Differentiating Psoriatic Arthritis (PsA) and Nodal Osteoarthritis (NOA) in patients with interphalangeal joint (IPJ) involvement is often challenging.¹⁻³ Yet, the distinction is important to make, especially as the treatment for these conditions is vastly different. Here we present a novel scoring system based on identifying often subtle but characteristic radiographic features of both conditions on bilateral hand plain-film radiographs.

Objectives: To describe the key radiographic discriminating features that underpin a new scoring system aimed primarily to differentiate PsA from NOA.

Methods: The initial scoring methodology was tested through blind analysis and scoring of 99 bilateral hand radiographs of patients with a confirmed clinical diagnosis of PsA, NOA and RA.⁴ In this initial study, anonymised radiographs were read by a Musculoskeletal Radiologist blinded to all clinical information. The reader correctly identified the clinical diagnosis in 100% of radiographs. The analysis method was taught to 3 specialist trainees, in a 1 hour training session. They assessed the same radiograph series with an accuracy of 67%–88%.

We refined the radiograph analysis method to develop a scoring system by developing weighted scores for different PsA arthropathic features. These include periarticular erosions and new bone formation (NBF), reduced joint space, soft tissue

oedema and asymmetry of findings. Osteoarthritis features included marginal osteophytes, subchondral sclerosis/cysts and reduced joint space.

Results: All bilateral interphalangeal joints and 1 st metacarpophalangeal (MCP) joint are assessed – (20 joints in total). First carpo-metacarpal joint changes were more common in NOA, but had little discriminatory value. Periarticular erosion and NBF are the key indicators and either feature must be present on the radiographs. Asymmetry of the findings and soft tissue oedema are also included.

Each radiographic feature is scored between 0 and 2 (0=normal, 1=mild/moderate, 2=severe). The scoring system allows the identification of PsA features, even in the presence of background NOA. This scoring system is currently undergoing validation.

Conclusions: This radiographic interpretation and scoring system provides a clear framework with key discriminators and relative major and minor weighting. Once validated, it could be taught and used as a readily available, low-cost imaging tool, by both radiologists and non-radiologists alike.

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Disclosure of Interest: R. Mandegaran: None declared, E. Nikiphorou: None declared, S. Bahadur: None declared, C. Hughes: None declared, B. Kirkham Grant/research support from: Abbvie, Novartis, Roche, UCB, Paid instructor for: Eli Lilly and Co, Janssen, Novartis, A. Zavareh: None declared

DOI: 10.1136/annrheumdis-2018-eular.7462

SAT0350

CONTENT AND FACE VALIDITY AND FEASIBILITY OF FIVE CANDIDATE INSTRUMENTS FOR PSORIATIC ARTHRITIS RANDOMISED CONTROLLED TRIALS: RESULTS FROM THE PSA OMERACT CORE SET WORKSHOP AT THE GRAPPA 2017 ANNUAL MEETING

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Background: The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) – Outcome Measures in Rheumatology (OMERACT) Psoriatic Arthritis (PsA) Core Set working group is developing a core instrument set to guide selection of outcome measures (instruments) for PsA randomised controlled trials (RCTs) and longitudinal observational studies (LOS). Candidate instrument measurement properties are being appraised in systematic literature reviews by working group members.

Objectives: Appraise the content and face validity (domain match) and feasibility of PsA instruments with GRAPPA stakeholders using the OMERACT Filter 2.1 instrument selection process¹.

Methods: The PsA Core set workshop held at the GRAPPA 2017 annual meeting comprised an introductory plenary session and breakout group discussions. Working group members facilitated six breakout groups, with two patient research partners (PRPs) per group, discussing pre-selected domain-instrument pairs. Participants individually reviewed the instrument(s). After group discussion, they completed anonymised paper-based OMERACT questionnaires examining domain match and feasibility, with votes for each aspect of domain match and feasibility centralised by instrument. A final vote (show of hands) on whether the assigned instrument met the requirements for domain match and feasibility using the OMERACT traffic-light scoring system was taken. Consensus was defined as more than 70% agreement, and majority as more than 50% agreement within a group. Consensus represents stronger evidence than majority agreement.

Results: There were 145 participants across all breakout groups and 116 returned completed questionnaires. Anonymized votes are summarised across groups and instruments in figure 1. More than 70% in the respective breakout groups endorsed the PsA instrument 66 swollen and 68 tender joint count (66/68 SJC/TJC) as a good match with the target domain of arthritis, a subset of MSK disease activity, FACIT-Fatigue as a good match with fatigue, and PsAID12 as a good match with HRQoL. There was consensus or majority agreement for all feasibility questions for the 66/68 SJC/TJC, HAQ-DI and PsAID9 and PsAID12. For the SPARCC enthesitis index only one item in both domain match and feasibility did not reach majority agreement.

Abstract SAT0350 – Figure 1. GRAPPA stakeholders' ratings for OMERACT domain match and feasibility for 6 PsA instruments

Conclusions: The first two steps of the OMERACT Filter 2.1 instrument selection process for five candidate instruments have been completed. The first set of candidate instruments selected to undergo the next phase of the OMERACT Filter 2.1, construct validity and discrimination appraisal are 66/68 SJC/TJC, SPARCC enthesitis index, PsAID9, PsAID12, HAQ-DI and FACIT-Fatigue. Additional PsA instruments will undergo the OMERACT selection process.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.1906

SAT0351 VERY LOW DISEASE ACTIVITY, DAPSA REMISSION, AND PATIENT-ACCEPTABLE SYMPTOM STATE IN PSORIATIC ARTHRITIS

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Background: The goal of treatment in psoriatic arthritis (PsA) according to the T2T strategy is remission, or at least, a low disease activity state¹. Currently there is no clear agreement on how to measure these treatment goals.

Objectives: To explore the relationship between very low disease activity (VLDA) state, according to the MDA 7/7 criteria², and DAPSA remission³, as well as its association with the impact of the disease evaluated by the PsAID questionnaire⁴, in patients with PsA in routine clinical practice.

Methods: Post-hoc analysis of the MAAp's study⁵. We included patients who met CASPAR criteria, with at least one year of disease evolution, and treated with biological and/or synthetic DMARDs according to the usual clinical practice in Spain. Patients were considered in VLDA if they met 7/7 of the MDA criteria, and in DAPSA/cDAPSA remission (this last without CRP) if they had a value ≤ 4 . A PsAID < 4 represented a patient-acceptable symptom state (PASS). The frequency of these states and kappa (κ) agreement between them were analysed.

Results: Of the 227 patients included in the original study, 26 (11.5%), 52 (30.6%), 65 (36.9%) and 125 (55%) were in VLDA, DAPSA remission, cDAPSA remission, and PASS, respectively. There was a moderate agreement between VLDA and DAPSA remission ($\kappa=0.52$) or the cDAPSA remission ($\kappa=0.42$). Patients in VLDA had a lower impact of the disease measured by PsAID [mean total score (SD): VLDA 1.1 (1.2); DAPSA remission 1.3 (1.5); cDAPSA remission 1.7 (1.6)]. There was a moderate agreement between DAPSA remission or cDAPSA remission and PASS ($\kappa=0.55$ and $\kappa=0.58$ respectively), while fair agreement was found between VLDA and PASS ($\kappa=0.18$).

Conclusions: About one third of this series reached DAPSA remission, while only 11.5% reached VLDA state. On the other hand, more than half were in PASS situation. Agreement between VLDA and DAPSA was moderate. Although the MDA 7/7 criteria seem to be more stringent criteria for assessing remission, DAPSA remission shows better agreement with PASS. DAPSA and VLDA would be adequate treatment targets in daily practice.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.2955

SAT0352 PREVALENCE AND CHARACTERISTICS OF CORONARY DISEASE AND CARDIOVASCULAR RISK FACTORS IN A COHORT OF PATIENTS WITH PSORIATIC ARTHRITIS

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Background: We performed a descriptive study of our patients with psoriatic arthritis (PsA) over 40 years old, attending to the presence of coronary disease and cardiovascular risk factors in each group of treatment (DMARDs vs biologic therapy).

Methods: Patients older than 40 years, diagnosed with psoriatic arthritis attending clinics at the Department of Rheumatology were analysed to determine how many of them presented coronary disease. The following information was recorded: age, sex, disease duration and age at the coronary event, HLA-B27 positivity, hypertension, type II diabetes and hyperlipidemia, on medical records and discharge reports for each patient.

Results: All 137 patients were identified from an electronic database. We found a male predominance: 57% versus 43% of women. Mean age 57.05 ± 10.6 years. Of the 137 patients, 82% had only peripheral arthritis, while 18% also showed axial involvement. With regard to the latter subgroup, 16% patients had a positive HLA-B27 test, 56% were HLA-B27 negative and 28% showed lack of HLA-B27 test. Almost all patients (87%) were in DMARDs therapy, while 31% received biologic therapy: etanercept 42%, secukinumab 16%, adalimumab 12%, ustekinumab 12%, infliximab 9.5%, golimumab 4.7% and certolizumab 2%. About 7% of patients didn't receive DMARDs neither biologic therapy, because of intolerance. Results regarding to cardiovascular risk factors, and coronary disease are as follows:

	DMARD therapy	Biologic therapy ($\pm$ DMARDs)
Arterial Hypertension	43%	26%
Diabetes	19.5%	7%
Hyperlipidemia	47.5%	38%
Coronary disease	10.9%	2.4%

In DMARD subgroup, we found 6 myocardial infarction (all of them revascularized) and 3 angina, versus 1 myocardial infarction in biologic subgroup.

Conclusions: There is solid epidemiologic evidence linking PsA to cardiovascular risk factors and an increased risk of developing cardiovascular disease¹. Furthermore, over the past two decades it has become increasingly clear that chronic inflammation is an independent risk factor for cardiovascular events. In our study the ratio of ischaemic heart disease for patients with PsA in DMARD therapy is four times higher than that of biologic treatment group. This may be due to the greater percentage of cardiovascular risk factors in the first group, although, the cardioprotective effect of biologic therapies, must be taken into account, as there are some studies that show association between anti-TNF and significant reduction in carotid IMT². Proper management of cardiovascular risk requires aggressive control of disease activity.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.7146