Conclusions: Obesity was more common among our patients with cutaneous psoriasis than in those with arthritis. The model that best explains obesity in this PsA series combines genetic factors (PsA family history), together with factors specific to the metabolic syndrome (dyslipidemia), with others owned to arthritis (axial evolution).

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THU0331 RELATIONSHIP BETWEEN THE NAIL ULTRASONOGRAPHIC EVALUATIONS AND CLINICAL FEATURES IN PATIENTS WITH PSORIATIC ARTHRITIS

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Background: Nail ultrasonography (US) is a favourable visualisation method to evaluate the subunits of the nail. Little is known about the relation between the properties of nail structures and the clinical characteristics of patients with psoriatic arthritis (PsA).¹

Objectives: To show the relationship between the clinical features and ultrasonographic evaluations of the nail in patients with PsA.

Methods: Patients with PsA according to the CASPAR criteria were recruited into the study. All of the hand nails and toenails were examined by grayscale and power Doppler techniques. The relations between the characteristics of the patients and the sonographic findings of the nail structures were assessed. Concerning to patient characteristics, subtypes of PsA, gender, age, height, BMI, working status, smoking, PsA duration, psoriasis duration, history of dactylitis, history of uveitis, number of tender and swollen joints, Maastricht Ankylosing Spondylitis Enthesitis Score, CRP, disease activity, haemoglobin, sacroiliitis, inspectional nail involvement (INI), Nail Psoriasis Severity Index (NAPSI), PASI, HAQ, quality of life, and the biologic treatment were recorded. The nail plate thickness (NPT), number of nails with trilaminar irregularity (NTI), nail bed thickness (NBT), and the doppler activity score (DAS) were recorded as the sonographic nail findings. The Kruskal Wallis analysis, Spearman's correlation, and Man Whitney U tests were used in statistical analysis. $p < 0.05$ was accepted as significant.

Results: 63 patients (756 nails) were evaluated. Among the PsA subtypes, 38% of patients were asymmetrical oligoarticular arthritis, 38% were symmetrical polyarthritis, 7.9% distal interphalangeal arthropathy, and 15.8% predominant spondylitis. All of the ultrasonographic nail parameters were independent of the PsA subtypes ($p > 0.05$). The mean of NPT was higher in males and correlated with age, height, and the haemoglobin levels. The NTI score was higher in patients with INI and correlated with the NAPSI score. The mean of NBT was only correlated with the haemoglobin levels. The DAS was higher in workers and correlated with age and the NAPSI score. The other clinical parameters were not associated with the sonographic findings.

Abstract THU0331 – Table 1. Relationships between the patients' characteristics and the ultrasonographic parameters*

US nail parameters	Gender	Worker	INI	Age	Height	NAPSI	Hemoglobin
NPT (mm)	$p=0.002$			$p=0.001$ rho:0.396	$p=0.021$ rho:0.290		$p=0.021$ rho:0.292
NTI (0-12)			$p<0.0001$			$p<0.0001$ rho:0.668	
NBT (mm)							$p=0.012$ rho:0.316
DAS (0-48)		$p=0.042$		$p=0.001$ rho:-0.407		$p=0.006$ rho:0.344	

(US: ultrasonography, INI: inspectional nail involvement, NAPSI: nail psoriasis severity index, NPT: nail plate thickness, NTI: nails with trilaminar irregularity, NBT: nail bed thickness, DAS: doppler activity score. *Only parameters which have statistical significant relations by Mann Whitney U test and Spearman's correlation).

Conclusions: The ultrasonographic findings of the nail structures were determined in PsA. These findings did not differ among the subtypes of the disease. Although the sonographic nail findings were not associated with the most of the clinical parameters; they had significant relations with some demographics, inspectional nail involvements, and haemoglobin levels in PsA.

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THU0332 FATIGUE REMAINS A DOMINANT SYMPTOM DESPITE TUMOUR NECROSIS FACTOR INHIBITOR THERAPY IN PSORIATIC ARTHRITIS: A POPULATION-BASED COHORT STUDY

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Background: Psoriatic arthritis (PsA) is a chronic inflammatory disorder associated with fatigue, pain and impaired function. Tumour necrosis factor inhibitor (TNFi) therapy fails among half of patients with PsA treated in routine care.

Objectives: The objective of this population-based cohort study was to investigate the association of fatigue with disease activity and adherence to therapy in PsA patients receiving their first TNFi.

Methods: Data on patient characteristics, disease activity and treatment adherence were obtained from the DANBIO register. Information on comorbidities according to the Charlson Comorbidity Index (CCI) and psychiatric comorbidities was obtained through linkage with the Danish National Patient Register. We performed Kaplan-Meier plots and univariate Cox proportional hazard regression analysis. Percentages of patients achieving relevant clinical responses were calculated.

Results: From 2006 thru 2016, we identified 880 patients eligible for analyses. Patients with upper median fatigue scores had statistically significantly higher disease activity measures, higher pain and HAQ scores, more comorbidities and current smoking status at baseline compared with patients with lower median fatigue scores (table 1). After treatment initiation the mean VAS fatigue score decreased from 62 mm (SD 25) to 44 mm (SD 30) at six months ($p < 0.001$). Kaplan-Meier curves showed shorter adherence to treatment in patients with higher baseline fatigue scores compared with patients with lower fatigue scores (HR 1.43 [1.2 to 1.7], $p < 0.001$) (figure 1). ACR20, 50 and 70 responses at six months were 49%, 35% and 18% respectively. VASfatigue20, 50 and 70 responses were 57%, 39% and 20%, respectively. The kappa value between ACR20, 50, 70 and VASfatigue responses were 0.37, 0.40 and 0.48 ($p < 0.001$), respectively.

Abstract THU0332 – Table 1. Baseline characteristics according to median fatigue stratification

	Lower median VAS fatigue (n=430)	Upper median VAS fatigue (n=450)	p value
Age, years	47.8 (39.4–57.3)	49.0 (40.0–56.1)	$p=0.905$
Male gender	51%	40%	$p<0.001$
DAS28-CRP (0–10)	4.0 (3.2–3.7)	4.8 (3.9–5.5)	$p<0.001$
HAQ score (0–3)	0.75 (0.38–1.13)	1.38 (0.88–1.75)	$p<0.001$
VAS patient pain (0–100)	45 (29–62)	74 (63–84)	$p<0.001$
BMI	26.8 (23.7–30.7)	27.7 (24.3–31.2)	$p=0.118$
Current smoking	28%	36%	$p=0.034$
Comorbidities (%)	66%	61%	$p=0.049$
CCI=0	27%	27%	
CCI=1	7%	12%	
CCI≥2			
Depression treated in hospital, n (%)	18 (4.2)	31 (6.8)	$p=0.105$

Values are the mean and SD except where stated otherwise. Comparisons were assessed by χ^2 /Mann-Whitney test. Lower median fatigue <64 mm, higher median fatigue ≥64 mm

Years of TNFi treatment	0	1	2	3	4	5	6	7	8	9
LowerMedianFatigue (n)	430	387	337	283	238	166	94	47	28	19
HigherMedianFatigue (n)	450	410	341	273	216	155	92	43	28	16

Conclusions: Fatigue remains a dominating symptom after TNFi treatment, and is associated with higher baseline disease activity, more comorbidities, smoking, higher pain and HAQ scores, and increased risk of TNFi treatment discontinuation in a cohort of Danish patients with PsA. The agreement between ACR responses and VASfatigue responses is weak to moderate suggesting heterogeneity between experienced fatigue and joint inflammation.

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THU0333 EFFICACY AND SAFETY OF IXEKIZUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: THREE YEAR RESULTS FROM A PHASE 3 STUDY (SPIRIT-P1)

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Background: Ixekizumab (IXE) is a high affinity monoclonal antibody that selectively targets interleukin-17A. IXE, every 4 (Q4W) or 2 (Q2W) weeks, was superior to placebo (PBO) in improving the signs and symptoms of psoriatic arthritis (PsA) at Week 24 in biologic-naïve patients (pts).

Objectives: To determine the efficacy and safety of IXE treatment up to 3 years in biologic-naïve pts with PsA.

Methods: In SPIRIT-P1 (NCT01695239), 381 pts entered the extension period (EP; Weeks 24–156). Pts failing to demonstrate $\geq 20\%$ improvement in both tender and swollen joint counts at Week 32, or any subsequent visit, were discontinued (mandatory discontinuation criteria). Ad-hoc efficacy data are presented for intent-to-treat (ITT) pts initially randomised to IXE at Week 0. Modified non-responder imputation (mNRI; missing data treated as non-response for pts discontinued due to lack of efficacy or adverse events [AEs]; multiple imputation (MI) for all other missing data) was applied to categorical measures. Modified baseline observation carried forward (mBOCF) was applied to continuous efficacy measures. Safety assessments are presented for all pts who entered the EP; baseline was the first IXE dose during the EP.

Results: Of the 210 pts initially randomised to IXE at Week 0 (ITT), 125 (60%) pts completed 156 weeks of treatment; 27 pts discontinued due to AEs, and 26 pts met the mandatory discontinuation criteria. Efficacy results are summarised (table 1). Improvements in ACR (American College of Rheumatology) and PASI (Psoriasis Area and Severity Index) responses, resolution in enthesitis and dactylitis, and improvements from baseline HAQ-DI (Health Assessment Questionnaire Disability Index), enthesitis, and dactylitis persisted up to Week 156. Safety

assessments for all pts who entered the EP are summarised (table 2). Frequencies of treatment-emergent AEs (TEAEs) were similar between IXE Q4W and Q2W. The majority of TEAEs were mild or moderate in severity; serious AEs occurred in 47 pts.

Abstract THU0333 – Table 1. Efficacy Overview at Week 156 (ITT Population)

	IXE Q4W (n=107)	IXE Q2W (n=103)
Responder Rates (n/Nx [%]): mNRI		
ACR20	74/107 (69%)	64/103 (62%)
ACR50	55/107 (51%)	58/103 (56%)
ACR70	35/107 (33%)	45/102 (44%)
PASI75 ^a	46/73 (63%)	41/59 (69%)
PASI90 ^a	37/73 (51%)	38/59 (65%)
PASI100 ^a	32/73 (44%)	36/59 (61%)
LEI= ^b	32/68 (47%)	23/57 (40%)
LDI-B= ^c	23/37 (62%)	17/25 (68%)
Mean Change from Baseline (SD): mBOCF		
HAQ-DI	-0.4 (0.6)	-0.5 (0.6)
LEI ^b	-1.7 (1.8)	-1.7 (1.7)
LDI-B ^c	-51.2 (91.0)	-55.4 (61.3)

LEI=Leeds Enthesitis Index; LDI-B=Leeds Dactylitis Index-Basic; Nx=pts with non-missing data; n=responders. With mNRI, missing data were treated as non-response for pts discontinued due to lack of efficacy or AEs. All other missing data were imputed with MI. With MI analysis, 32 patients were considered ACR20 responders. ^aPts with psoriatic lesions $\geq 3\%$ of body surface area at baseline. ^bPts with LEI >0 at baseline. ^cPts with LDI-B >0 at baseline.

Abstract THU0333 – Table 2. Safety Outcome Measures (Weeks 24–156)

	Total IXE Q4W (N=191)	Total IXE Q2W (N=190)
TEAEs	146 (76%)	144 (76%)
Serious AEs	28 (15%)	19 (10%)
Serious Infections	5 (3%)	1 (<1%)
Discontinued due to AE	16 (8%)	21 (11%)
Death	1* (<1%)	0
Infections	92 (48%)	94 (49%)
Injection-Site Reactions	21 (11%)	23 (12%)
Hypersensitivities	8 (4%)	11 (6%)

n=pts with ≥ 1 designated AE. Data presented as n (%). For safety analyses, baseline was defined as the time of first study drug injection during the EP (Weeks 24–156). *Pt experienced a cerebrocardiovascular accident.

Conclusions: In pts treated with IXE, improvements in the signs and symptoms of PsA persisted up to 3 years. No unexpected safety signals were observed, and the safety profile was consistent with previous studies of IXE.

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THURSDAY, 14 JUNE 2018

SLE, Sjögren's and APS – clinical aspects (other than treatment)

THU0334 PATTERNS OF ASPIRIN USE IN SLE PREGNANCIES WITHIN A MULTINATIONAL INCEPTION COHORT AND RELATIONSHIP TO PREECLAMPSIA RISK FACTORS

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Background: Aspirin reduces the risk of preeclampsia in pregnancies at high risk, and is recommended in pregnant women with ≥ 1 risk factors for preeclampsia, including systemic lupus erythematosus (SLE).

Objectives: To assess the prevalence of aspirin use in SLE pregnancies within a multinational inception cohort and compare aspirin use among those with and without additional preeclampsia risk factors.

Methods: Premenopausal women aged 18–45 enrolled in the Systemic Lupus International Collaborating Clinics (SLICC) Registry (2000–2017) within 15