

(10.9%) of the patients with DAS28 <2.6 which were on systemic corticosteroid (CS) treatment regimen.

**Conclusions:** The presence of active synovitis on PDUS in a significant part of the studied PsA patients (35.9%) which were considered as being in clinical remission for at least 6 months showed that these kind of patients need to be closely followed-up and adequately treated. The systemic CS treatment does not exclude the presence of disease activity in PsA. Further studies for assessment of the synovitis will establish correct criteria for defining and monitoring the disease activity in PsA.

**Disclosure of Interest:** None declared

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#### FRI0517 QUALITY OF LIFE IN PATIENTS WITH EARLY PSORIATIC ARTHRITIS

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**Background:** Psoriatic arthritis (PsA) is a chronic systemic inflammatory disease. Affecting skin, joints, entheses and dactylitis, its impact on health-related quality-of-life (HRQoL) could be substantial.

**Objectives:** The aim of this study was to describe HRQoL in newly diagnosed PsA patients taking into account skin involvement, swollen joints, tender entheses and dactylitis.

**Methods:** HRQoL was assessed by 8 subscales of the Short-Form 36 (SF-36) questionnaire (0–100, higher score represents a better HRQoL). Patients were classified in arthritis subtypes (i.e. mono-, oligo- or polyarthritis) by rheumatologist. Entheses were evaluated using the Leeds Enthesis Index (LEI) and Maastricht Ankylosing Spondylitis Enthesis Score (MASES; positive if tender entheses >1). Psoriasis was evaluated using the Psoriasis Area Severity Index (PASI; mild: 0–7; moderate/severe: >7) and dactylitis using the Leeds Dactylitis Index (LDI).

**Results:** 87 patients (48 male, 39 female, mean age 47,6±15,3) with PsA (21 had monoarthritis, 49 - oligoarthritis and 17 - polyarthritis) completed the SF-36 were included in the study. Psoriasis was mild in 63 (72,41%) patients and moderate/severe in 12 (13,79%) patients. At least one digit with dactylitis was present in 10 (11,49%) of the patients. A tender entheses was present in 39 (44,83%) of patients. Mean scores of the subdomains in the SF-36 were similar across the different arthritis groups, with slightly worse scores for polyarthritis compared to mono- and oligoarthritis. However, when stratifying these groups for the presence of a tender entheses, HRQoL decreased substantially for all groups across all subdomains of the SF-36, with a median difference of 12,9 points. Irrespective of joint involvement, a tender entheses decreased the mean scores of all subdomains significantly compared to the non-tender entheses group (p<0,05). Severity of psoriasis and presence of dactylitis did not lead to significantly different SF-36 values compared to those not affected.

**Conclusions:** Having tender entheses impacts HRQoL severely in both its physical and mental dimensions in incident untreated PsA.

**Disclosure of Interest:** None declared

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#### FRI0518 PRESCRIPTION PATTERNS OF TUMOUR NECROSIS FACTOR INHIBITOR AND USTEKINUMAB IN PSORIATIC ARTHRITIS: A NORDIC POPULATION-BASED COHORT STUDY

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**Background:** Psoriatic arthritis (PsA) is a chronic inflammatory disorder associated with skin and joint manifestations, several extra-articular symptoms, various comorbidities, and disability. The emergence of tumour necrosis factor inhibitor (TNFi) therapy has dramatically changed the course of disease. Over the past decade new TNFi therapies have emerged (certolizumab pegol and golimumab), and recently ustekinumab and secukinumab have also become available for PsA.

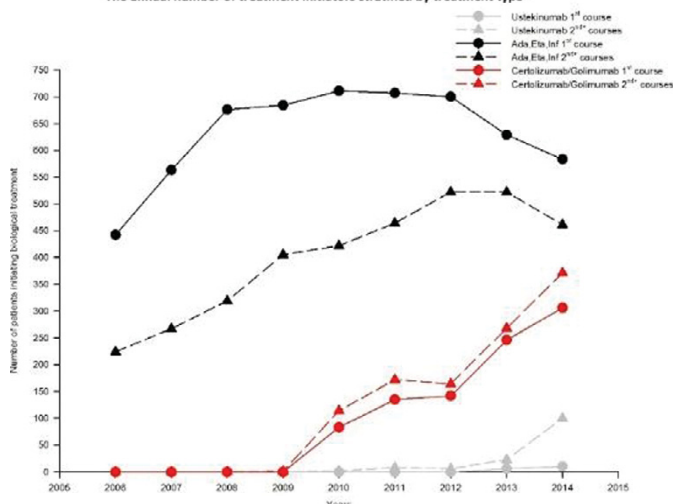
**Objectives:** The objective of this study was to assess the relative use of biological agents (bDMARDs) in PsA from 2006 through 2014, using data from the Nordic Rheumatology registers.

**Methods:** Based on data from the observational registers DANBIO, ICEBIO, NOR-DMARD, ROB-FIN, and SRQ registers, PsA patients initiating treatment with bDMARDs as a first or subsequent biological therapy were identified. Adalimumab, etanercept and infliximab were grouped as "first generation TNFi therapies"; certolizumab pegol and golimumab were grouped as "second generation TNFi". Treatments with ustekinumab during the study period were also identified. Descriptive statistics for prescription patterns of bDMARD therapy were calculated.

**Results:** A total of 11,458 treatment initiations were identified (DANBIO 3,068, ICEBIO 357, NOR-DMARD 1,113, ROB-FIN 708, SRQ 6,212). 54% of the patients were female. Overall, 5,695 patients initiated a first generation TNFi, 912

a second generation TNFi, and 16 ustekinumab, as their first course of biological treatment. The corresponding numbers for those initiating a second (or more) biological treatment were 3,606, 1,090 and 139 patients, respectively. The figure displays the annual number of treatment initiations stratified by treatment type. The total yearly number of first course biological treatment increased significantly throughout the period (p<0.001), and this was also the case for patients switching therapy (p<0.001), indicating a previously unmet need for biological therapies in the Nordic population. The annual number of patients initiating first generation TNFi both as first and subsequent course of therapy decreased significantly towards the end of the study period (p<0.001). This drop was more than offset by a rapid increase in initiation of second generation TNFi treatments (p<0.001). Ustekinumab was primarily used as second or subsequent course of therapy in PsA. The same pattern was seen when stratified for country (data not shown).

The annual number of treatment initiators stratified by treatment type



**Conclusions:** Across the Nordic countries the prescription pattern for biological therapies for PsA has changed significantly over time. After 2012 initiation of the first generation TNFi is decreasing both as first and second course therapy, whereas second generation TNFi are increasing both as first and second course of biologic intervention. Collaboration across registers will allow for robust assessment of the uptake of newer biological therapies.

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#### FRI0519 EFFECT OF BIOLOGICS ON FATIGUE IN PSORIATIC ARTHRITIS: A SYSTEMATIC LITERATURE REVIEW WITH META-ANALYSIS

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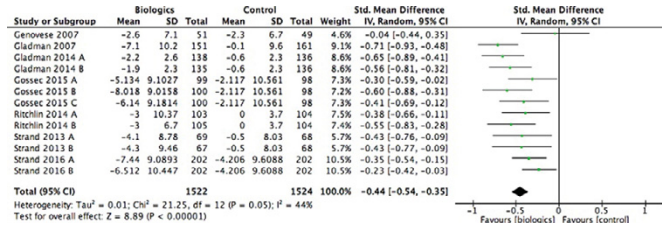
**Background:** Fatigue is an important aspect of disease both in rheumatoid arthritis (RA) and in psoriatic arthritis (PsA) and is of high priority for patients. In RA, a recent Cochrane meta-analysis found a small effect of biologics on fatigue (standardized mean difference, SMD, 0.43; 95% confidence interval, CI: 0.38–0.49).(1) Little is known about this effect in PsA.

**Objectives:** To assess the effect of biologics on fatigue in PsA randomised controlled trials (RCTs) and to compare this effect with the effect in the same trials, on pain, through a systematic literature review (SLR) and meta-analysis (MA).

**Methods:** SLR up to January 2017 in PubMed, Embase and Cochrane trials database and in recent congress abstracts, using key words related to PsA and biologics. All RCTs in PsA of any biologic therapy, assessing fatigue (whatever the

score used), with data available for fatigue were included. Data were collected by 2 regarding levels of fatigue (6 trials used FACIT, 1 VAS) and pain (if available) at baseline and at the timepoint closest to 24 weeks after the biologic introduction. A MA was performed using RevMan and SMDs were calculated for each trial and each study dose, for fatigue and for pain. A SMD <0.5 is usually considered small, between 0.5 and 0.8 moderate and >0.8 as important.

**Results:** After screening 295 publications, 7 RCTs were included in the meta-analysis and assessed TNF blockers (N=3: adalimumab N=2, certolizumab pegol, N=1), secukinumab (N=2), apremilast (N=1) and ustekinumab (N=1) with or without methotrexate, compared to placebo. The studies included 2340 PsA patients: weighted mean age ± standard deviation (SD), 48.7±1.3 years, disease duration 7.7±1.3 years, 53.3% were females. At baseline, joint disease activity was high (weighted mean swollen joint count: 13.0±3.1, HAQ-DI: 1.2±0.1, PASI: 10.4±3.3). Fatigue levels were high at baseline (weighted mean FACIT score: 29.2±1.5). The pooled SMD for fatigue was 0.44 (95% CI -0.35, 0.54) and it ranged 0.04 to 0.71 across drugs and trials with a small to moderate effect (Graph). In 6 of the same studies, the pooled SMD for pain was 0.62 (95% CI 0.52, 0.73) and ranged 0.46 to 0.84.



**Conclusions:** Biologics had a mild to moderate effect on fatigue at 24 weeks in PsA RCTs. No notable differences across drugs were apparent. Effect sizes were higher on pain with a moderate effect. This effect seems similar to effects noted in RA in the Cochrane meta-analysis (1). These results confirm fatigue may be multifactorial in PsA; biologics bring some improvement at the group level but other treatment modalities should be further explored also.

**References:**

- [1] Almeida C, Choy EHS, He wlett S, Kirwan JR, Cramp F, Chalder T, Pollock J, Christensen R. Biologic interventions for fatigue in rheumatoid arthritis. Cochrane Database of Systematic Reviews 2016, Issue 6. Art. No. CD008334. DOI:10.1002/14651858.CD008334.pub2.

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**FRI0520 IMPROVED PATIENT-REPORTED OUTCOMES IN PSORIATIC ARTHRITIS PATIENTS TREATED WITH ABACEPT: RESULTS FROM A PHASE III TRIAL**

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**Background:** In the Phase III ASTRAEA study (NCT01860976), abatacept (ABA) significantly increased ACR20 responses, with benefits on other musculoskeletal symptoms in patients (pts) with active psoriatic arthritis (PsA).<sup>1</sup> As PsA impacts HRQoL, assessing treatment (tmt) effect using patient-reported outcomes (PROs) is important.

**Objectives:** To explore the effect of ABA tmt using PROs in intent-to-treat and *post hoc* analyses of ASTRAEA.

**Methods:** Pts were randomized (1:1) to SC ABA 125 mg weekly or placebo (PBO) for 24 weeks (W). At W16, pts without ≥20% improvement in joint counts started open-label ABA. Adjusted mean changes from baseline (BL) to W16 (all pts) and W24 (responder analysis) in Short Form-36 (SF-36; physical and mental component summary [PCS, MCS] and individual domains using spidergrams), pain VAS and HAQ-DI scores, Dermatology QoL Index (DLQI) and FACIT-Fatigue scale (FACIT-F) were evaluated in the total population and subgroups stratified by BL CRP level and prior TNFi use. Proportions of pts reporting improvements ≥minimal clinically important difference (MCID) in SF-36 summary (≥2.5) and domain (≥5.0), FACIT-F (≥40) and HAQ-DI (<-0.22) scores and ≥normative values in SF-36 summary (≥50) and domains, FACIT-F (<40) and HAQ-DI (<0.5) at W16 were analysed in the total population.

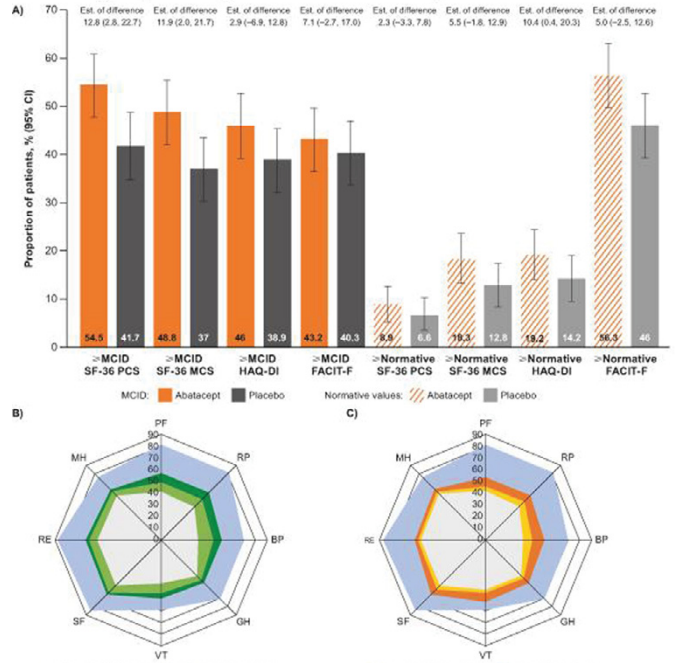
**Results:** In the total population, improvements in all PROs were numerically greater for ABA (n=213) vs PBO (n=211) at W16 and W24 and significant for SF-36 PCS at W16 and HAQ-DI at W24 (Table). At W16, improvements in all SF-36 domains were numerically greater with ABA, and significant for physical function, bodily pain and vitality. A higher proportion of pts receiving ABA vs PBO reported improvements ≥MCID in SF-36 PCS, MCS, SF-36 domains, FACIT-F, HAQ-DI (Fig) and DLQI (not shown) at W16. The proportion of pts whose scores were ≥normative values at W16 was higher with ABA vs PBO in SF-36 PCS, MCS, FACIT-F and HAQ-DI scores. At W24, improvements in SF-36 domain scores accrued in both groups, with numerical differences in favour of ABA except in social function. Improvements in PROs were greater with ABA tmt in BL CRP>upper limit of normal (ULN) vs CRP≤ULN and in TNFi-naïve vs -exposed subpopulations.

Table 1. Change from Baseline in PROs at 16 and 24 Weeks

PRO	Week 16 (total population)		Week 24 (responder analysis)	
	Abatacept	Placebo	Abatacept	Placebo
SF-36	n=202	n=186	n=124	n=97
PCS	3.76 (0.55)*	2.02 (0.57)	5.11 (0.64)	3.69 (0.71)
MCS	2.42 (0.70)	1.15 (0.73)	2.56 (0.83)	2.62 (0.92)
HAQ-DI	n=202	n=187	n=124	n=98
	-0.25 (0.04)	-0.15 (0.04)	-0.33 (0.04)*	-0.20 (0.05)
DLQI	n=212	n=189	n=126	n=98
	-2.28 (0.34)*	-1.24 (0.35)	-2.49 (0.42)*	-0.71 (0.48)
FACIT-F	n=202	n=189	n=126	n=99
	-3.67 (0.65)	-2.61 (0.67)	-4.58 (0.80)	-4.49 (0.89)

Data are adjusted mean change (SE). \*95% CI of difference vs placebo did not cross 0.

Figure. Percentage of Patients Reporting Improvements ≥MCID or ≥Normative Values on PROs at Week 16 (A) and SF-36 Domain Scores at Baseline, Week 16 and Week 24 for Abatacept (B) and Placebo (C) Groups Versus Age/Gender Matched Normative Population



AG=age/gender; BP=body pain; FACIT-F=Functional Assessment of Chronic Illness Therapy-Fatigue scale; GH=general health; MCID=minimal clinically important difference; MCS=mental component summary; MH=mental health; PCS=physical component summary; PF=physical function; RE=role emotional; RP=role physical; SF=SF-36; SF-36=Short-Form 36; VT=vitality

**Conclusions:** Abatacept treatment improved many PROs in pts with active PsA, with larger benefits in the CRP>ULN and TNFi-naïve subpopulations.

**References:**

- [1] Mease P, et al. Arthritis Rheumatol 2016;68(suppl 10): [Abstract 1041].

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