PP29

There is a risk of overtreatment when the Disease Activity Score in 28 joints is based solely on subjective parameters. A cross-sectional, exploratory, DANBIO study

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Background: Rheumatoid arthritis (RA), a chronic inflammatory polyarthritis, should be treated promptly to improve clinical outcomes and prevent further joint destruction. Reaching the optimal control of RA requires regular evaluation of inflammatory activity with the aim of defined indices, such as the Disease Activity Score in 28 joints (DAS28) (1, 2).

Objective: To evaluate the reliability of DAS28 in RA, with focus on a subgroup of patients with DAS28 > 3.2.

Method: All RA patients with DAS28 > 3.2 who were registered in the local part of the DANBIO registry were categorized into two groups: (i) patients with at least one swollen joint (SJ) or elevated C-reactive protein (CRP) (the 'objective group') and (ii) patients with no swollen joints and normal CRP values (the 'subjective group'). We defined a new score, the subjective DAS28 (DAS28s), to focus on subjective parameters.

Results: Of the 230 included patients, 198 (86.1%) and 32 (13.9%) were in the objective and subjective groups, respectively. Patients in the subjective group had lower mean values of DAS28 ($p < 0.001$) and evaluator global assessment ($p < 0.001$), with less frequent IgM RF ($p < 0.001$) and anti-cyclic citrullinated peptide (anti-CCP) antibody positivity ($p = 0.02$), but higher mean values of tender joints ($p = 0.04$) and DAS28s ($p = 0.003$) compared to the objective group (Table 1).

Conclusions: DAS28 should be used cautiously in patients who are considered for treatment intensification.

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Table 1. Demographic data, disease characteristics, disease activity, and treatment modality of patients in the 'objective' and 'subjective' groups.

	Objective group	Subjective group	
	n = 198	n = 32	p-value
Age (years)	66.9 ± 15.0	61.9 ± 16.0	0.11
Gender			
Male	66 (33.3)	8 (25)	0.42
Female	132 (66.7)	24 (75)	
IgM RF			
Positive	121 (61.1)	12 (37.5)	< 0.001
Negative	35 (17.7)	19 (59.4)	
No data	42 (21.2)	1 (3.1)	
Anti-CCP antibodies			
Positive	91 (46)	11 (34.4)	0.02
Negative	65 (32.8)	21 (65.6)	
No data	42 (21.2)	0 (0)	
TJ	7.4 ± 7.1	10.1 ± 6.3	0.04
PGA	56.4 ± 22.7	57.8 ± 19.6	0.73
EGA	20.8 ± 15.2	10.7 ± 7.7	< 0.001
DAS28	4.4 ± 0.9	3.9 ± 0.5	< 0.001
HAQ	1.2 ± 0.8	1.3 ± 0.7	0.54
CDAI	15.4 ± 10.2	14.7 ± 6.9	0.63
DAS28s	2.2 ± 0.8	2.50	0.003
DMARD treatment	151 (76.3)	27 (84.4)	–
Biological treatment	48 (24.2)	9 (28.1)	–

IgM RF, immunoglobulin M rheumatoid factor; anti-CCP, anti-cyclic citrullinated peptide; TJ, tender joints; PGA, patient global assessment; EGA, evaluator global assessment; DAS28, Disease Activity Score in 28 joints; HAQ, Health Assessment Questionnaire; CDAI, Clinical Disease Activity Index; DAS28s, Disease Activity Score based on subjective parameters; DMARD, disease-modifying anti-rheumatic drug.
Values given as mean ± standard deviation or number (percentage).

PP30

The physician efficiency index (PEI) for specialists in rheumatology is significantly higher than the PEI for junior physicians in rheumatology residency training

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Background: Efficiency in the healthcare system is important (1). Junior physicians and nurses contribute under supervision to the consultations of patients with rheumatoid arthritis (RA). Patients with milder disease are referred to junior physicians.
Objectives: To evaluate the interval between planned consultations for specialists in rheumatology compared to junior physicians in rheumatology residency training, together with calculation of the physician efficacy index (PEI; the mean interval between consultations multiplied by the fraction of patients seen subsequently by a nurse).
Method: In this single-centre cohort study, data were collected for all individual rheumatologists (n = 4), physicians in the rheumatology residency programme (n = 7), and nurses' outpatient visits concerning patients with RA at the Department of Rheumatology between November 2013 and 2015. Exclusion criteria were visits to pick up medicine or steroid injection.
Results: A total of 3699 visits were included. The mean PEI for the specialists in rheumatology (69.08 ± 39.84) was significantly higher (p = 0.04) than that the junior physicians (27.20 ± 13.86), even if there was no difference in the intervals between consultations. Furthermore, a high correlation (r = 0.94) between physicians' postgraduate duration (years) and the PEI was found (Table 1).
Conclusions: Junior physicians should be supervised to delegate responsibilities to others (e.g. nurses in the workplace) so that they become more self-confident and their trust in nurses increases. As a consequence, the entire department would operate more efficiently and cost-effectively. Quality should be monitored continuously using the DANBIO database indicators.

References

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PP31

Risk of multiple sclerosis during tumour necrosis factor inhibitor treatment for arthritis: a population-based study from DANBIO and the Danish Multiple Sclerosis Registry (DMSR)

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Background: Evidence of tumour necrosis factor (TNF)-α as an important factor in the pathogenesis of multiple sclerosis (MS) has emerged. However, attempts to treat MS with a tumour necrosis factor inhibitor (TNFi) have increased disease activity.
Objectives: To investigate whether TNFi treatment in patients with arthritis is associated with an increased risk of developing MS and whether rheumatoid arthritis (RA) is associated with a decreased risk compared to the general population.
Method: Data from the national DANBIO Registry and the DMSR were linked. A cohort of 27 880 patients with arthritis (66% RA patients) was followed up for MS. During the follow-up from 2000 to 2012, 10 294 patients started TNFi therapy. Standardized incidence ratios (SIRs) of MS were estimated using standardized incidence rates from the general populations and person-years at risk.
Results: During 113 527 person-years, 12 incident MS cases occurred in the cohort (overall SIR 1.11,

Table 1. The interval between planned consultations, nurse/physician visits ratio, physician efficiency index (PEI), and physician postgraduate duration for specialists in rheumatology (P1–P4, n = 4) and junior physicians in rheumatology residency training (P5–P11, n = 7).

Physicians	Interval (days) mean ± sd	Nurse/physician visits ratio	PEI	Physician postgraduate duration (years)
P1	126.95 ± 85.06	(604/617) 0.98	124.23	29
P2	133.11 ± 105.33	(207/384) 0.54	71.75	20
P3	114.55 ± 85.23	(96/309) 0.31	35.57	11
P4	84.79 ± 83.29	(133/252) 0.53	44.76	10
P5	118.46 ± 78.44	(15/52) 0.29	34.18	9
P6	137.97 ± 101.98	(5/68) 0.07	10.15	8
P7	194.19 ± 86.28	(14/103) 0.14	26.40	8
P8	114.81 ± 78.39	(14/41) 0.34	39.20	7
P9	159.22 ± 105.51	(14/53) 0.26	42. 05	7
P10	179.13 ± 115.13	(1/16) 0.06	11.19	6
P11	0	(0/24) 0	0	3

sd, Standard deviation.

Table 1. Standardized incidence ratios (SIRs)* of MS diagnosis in ever and never TNFi-treated arthritis patients compared with the general population.

	Ever TNFi treated (53 723 person-years)		Never TNFi treated (59 804 person-years)	
	Obs/Exp	SIR (95% CI)	Obs/Exp	SIR (95% CI)
All	8/5.8	1.38 (0.69–2.77)	4/5.0	0.80 (0.30–2.12)
Males	5/1.4	3.48 (1.45–8.37)	1/0.8	1.19 (0.17–8.47)
Females	3/4.4	0.69 (0.22–2.14)	3/4.2	0.72 (0.23–2.22)
RA	2/3.0	0.67 (0.17–2.66)	2/3.2	0.64 (0.16–2.54)
Males	2/0.4	4.95 (1.24–19.8)	0/0.4	0.00 (–)
Females	0/2.6	0.00 (–)	2/2.8	0.72 (0.18–2.88)
PsA	1/0.9	1.12 (0.16–8.00)	1/0.7	1.45 (0.20–10.3)
Males	0/0.3	0.00 (–)	1/0.2	5.75 (0.81–40.8)
Females	1/0.6	1.62 (0.23–11.5)	0/0.5	0.00 (–)
AS	4/1.0	3.91 (1.47–10.42)	0/0.3	0.00 (–)
Males	3/0.6	5.32 (1.72–16.49)	0/0.1	0.00 (–)
Females	1/0.5	2.17 (0.31–15.47)	0/0.2	0.00 (–)
Other	1/0.8	1.20 (0.17–8.55)	1/0.7	1.39 (0.20–9.86)
Males	0/0.2	0.00 (–)	0/0.1	0.00 (–)
Females	1/0.6	1.56 (0.22–11.1)	1/0.6	1.68 (0.24–11.9)
Time from start of TNFi treatment/DANBIO entry (years)				
< 1	1/1.3	0.79 (1.11–5.61)	2/1.9	1.04 (0.26–4.14)
1–2	5/2.0	2.46 (1.03–5.92)	0/2.1	0.00 (–)
3–5	2/1.7	1.17 (0.29–4.67)	2/0.9	2.30 (0.57–9.19)
≥ 6	0/0.8	0.00 (–)	0/0.1	0.00 (–)

RA, Rheumatoid arthritis; PsA, psoriatic arthritis; AS, ankylosis spondylitis.
*We calculated the expected number of MS cases by multiplying the number of person-years experienced by the cobort members by the appropriate national MS incidence rates among Danish men and women in 5-year age groups and calendar time periods of observation (national rates from the DMSR). SIRs were calculated as the observed number of MS cases (Obs) divided by the expected number (Exp), and corresponding 95% confidence intervals (CIs) were calculated assuming a Poisson distribution of the observed number of MS cases.

95% CI 0.63–1.96). SIR for arthritis patients ever treated with TNFi therapy was 1.38 (95% CI 0.69–2.77, n = 8), and 0.80 (95% CI 0.30–2.12, n = 4) in never treated. An increased risk was observed in males treated with TNFi (SIR 3.48, 95% CI 1.45–8.37) and in ankylosing spondylitis (AS) patients (SIR 3.91, 95% CI 1.47–10.42). The SIR for all RA patients was 0.65 (95% CI 0.24–1.72).

Conclusions: We found no overall association between RA and MS. No overall increased rate of MS was seen in TNFi-exposed arthritis patients, but TNFi-treated AS and male patients had an increased MS risk. However, low statistical power and diagnostic delay of MS should be taken into consideration when interpreting these results.

PP32

Significance of the lower reporting limit and intraindividual biological variability for C-reactive protein in calculating the Disease Activity Score in 28 joints (DAS28): theoretical considerations

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Background: The threshold for reporting of C-reactive protein (CRP) differs from laboratory to laboratory. CRP values are also affected by intraindividual biological variability (1). With regard to DAS28 and rheumatoid arthritis (RA), a precise threshold for reporting CRP is important because of the direct effect of CRP on the

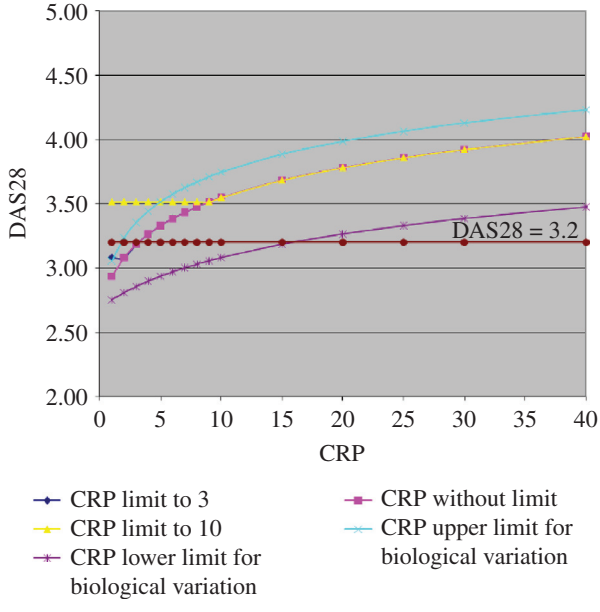

Figure 1. Dependency of DAS28 to CRP. Tender joints 3, swollen joint: 1, and visual analouge scale: 34.

calculation of DAS28, patient classification, and subsequent treatment decisions.
Objectives: To evaluate the significance of a lower reporting limit for CRP in calculating DAS28 in RA patients.
Method: DAS28 was calculated with constant values of tender joint (TJ = 3), swollen joint (SJ = 1), and global visual analogue scale (global VAS = 34) and CRP values of up to 40 mg/L with lower reporting limits of < 10 mg/L, < 3 mg/L, and without limit. Upper and lower limits of DAS28 were also calculated based on intraindividual biological variability.
Results: The lower reporting limit of CRP < 10 mg/L leads to inaccurate patient classification due to intraindividual biological variation. In addition, reducing the lower reporting limit for CRP to < 3 mg/L results in optimizing patient classification (Figure 1). Further lowering of the reporting limit does not increase the accuracy because of intraindividual variations.
Conclusions: Regarding the DAS28 calculation, the lower reporting limit for CRP of < 3 mg/L is acceptable and should be taken into consideration. However, the lower reporting limit for CRP of < 10 mg/L is too high. This is particularly relevant if treatment decisions are made solely on the basis of DAS28.

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Spondyloarthritides

PP33

Disease activity and increased risk of cardiovascular death among patients with psoriatic arthritis

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Objectives: Recent studies indicate increased cardiovascular morbidity and mortality in patients with psoriatic arthritis (PsA) but data are limited and results inconsistent. This prompted our investigation of mortality rate, cause of death, and incidence of acute cardiovascular events in a cohort of PsA patients in northern Sweden.
Method: Patients with established PsA (n = 464) were included. To calculate the standardized mortality rate ratio (SMR) and standardized incidence ratio (SIR) for cardiovascular events, data were extracted from the National Causes of Death Register and the National Inpatient Care Register in Sweden, and compared with the general population. The study period was 1995–2011. To study the impact of inflammatory activity, a composite Disease Activity Index (DAI) was used.
Results: The SMR (95% CI) for overall mortality and diseases of the circulatory system (ICD-10; I00–I99) was 1.22 (0.89–1.63) and 1.64 (1.02–2.52), respectively. In regression analysis, the DAI was significantly associated with death (OR 1.99, 95% CI 1.41–2.80) when adjusted for age and gender ($p < 0.001$), and remained significant after stratifying patients into the two major causes of death: diseases of the circulatory system and malignant neoplasms. The SIR for a cardiovascular event (MI or stroke) was 0.597 (95% CI 0.40–0.86); this association was only significant in male patients.
Conclusions: PsA patients had a small, but significant, increase in SMR for deaths due to diseases of the circulatory system compared with the general population. Among patients, death was associated with the DAI, indicative of a more aggressive disease phenotype. In addition, among male PsA patients, a reduced risk of developing a cardiovascular event compared with the general population was found.

PP34

Do male psoriatic arthritis patients get easier access to biological DMARDs?

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Background: Among patients with rheumatoid arthritis it has been reported that the likelihood of receiving tumour necrosis factor inhibitor (TNFi) treatment may be lower for females than males. Whether this may also be true in PsA remains to be explored.
Objectives: To explore if the likelihood of receiving TNFi treatment is higher for male than for female PsA patients.
Method: In this retrospective study we included all PsA patients visiting the Hospital of Southern Norway Trust between 1 January 2013 and 30 April 2014. Descriptive statistics were used to calculate patients' demographic variables. A χ^2 test was used to explore differences in proportions. A gender difference in access to TNFi treatment was explored in a logistic regression model adjusted for age and disease duration.
Results: A total of 471 patients were included. Mean (sd) age was 56.2 (12.6) years, disease duration 10.2 (8.4) years, 240 (51%) were females, 87 (18.5%) current smokers, and 221 (46.9%) currently in full- or part-time work. Age and disease duration were similar between the sexes. A higher percentage of females were current smokers and currently not working; 23.9% vs. 13.8%, $p = 0.006$ and 61.7% vs. 44.2%, $p < 0.001$, respectively. A higher percentage of males had previously received and were currently receiving TNFi treatment; 94 (56%) vs. 74 (44%), $p = 0.026$ and 78 (59.1%) vs. 54 (40.9%), $p = 0.006$, respectively. In a logistic regression model adjusted for disease duration and age, males had a higher likelihood of being currently under TNFi treatment (OR 1.67, 95% CI 1.1–2.5, $p = 0.018$).

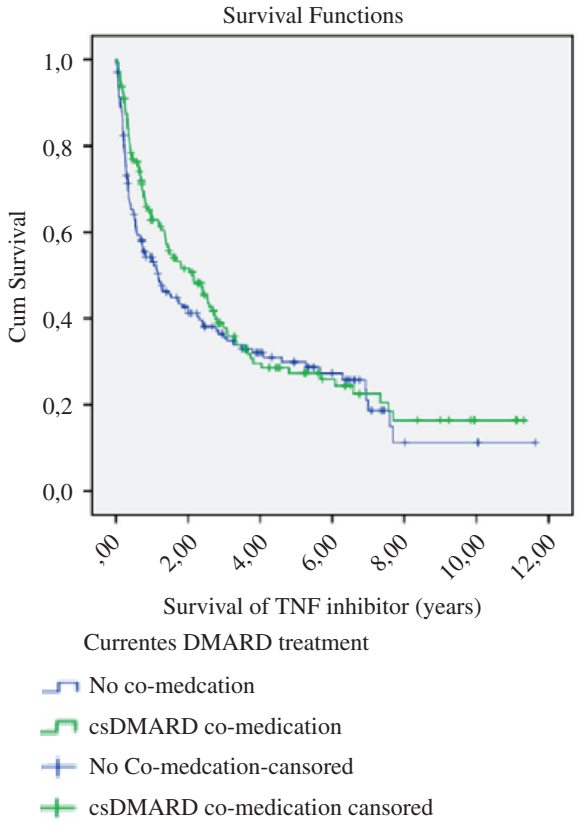

Figure 1. Survival functions.

Conclusions: Males were found to have a higher likelihood of being currently under TNFi treatment in both the unadjusted and adjusted analyses.

PP35

Tumour necrosis factor inhibitor treatment in psoriatic arthritis: need for co-medication?

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Objectives: To investigate the role of concomitant csDMARDs on survival of subcutaneous TNFi in PsA.
Method: We included all PsA patients initiating first-time treatment with subcutaneous TNFi between 2000 and 2015 at the Hospital of Southern Norway Trust. The χ^2 test, independent t-test, and the Mann–Whitney U test were used for group comparisons. Drug survival was explored by Kaplan–Meier analysis, patients receiving vs. not receiving co-medication were compared using the log rank test. Univariable and multivariable Cox regression analyses were used to identify predictors of discontinuation.
Results: Among 371 TNFi-treated PsA patients, 145 received csDMARD co-medication; 58/118 with etanercept, 48/106 with adalimumab, 21/47 with certolizumab, and 18/47 with golimumab. Mean (sd) age was 54.0 (11.5) years, disease duration 13.1 (9.1) years, years of education 12.9 (3.4), baseline DAS28 4.1 (1.4), and 45.7% were female. Baseline characteristics were similar for patients with and without co-medication, except for a higher percentage of first-time TNFi users (67.6% vs. 32.4%) in the co-medication group ($p = 0.001$). Drug survival of TNFi was similar for patients receiving vs. not receiving concomitant csDMARDs (log rank test $p = 0.181$, Figure 1). In the Cox regression analysis, identified predictors for TNFi discontinuation were previous use of TNFi (HR 1.68, 95% CI 1.25–2.26, $p < 0.001$) and TNFi type ($p < 0.001$). Separate analyses for first-time TNFi users did not change the primary outcome.
Conclusions: We found similar drug survival rates for TNFi-treated patients with and without csDMARD co-medication. Predictors for TNFi discontinuation were previous use of TNFi and TNFi type.

PP36

The impact of obesity on response and adherence to tumour necrosis factor-α inhibitors in psoriatic arthritis: results from the DANBIO and ICEBIO registries

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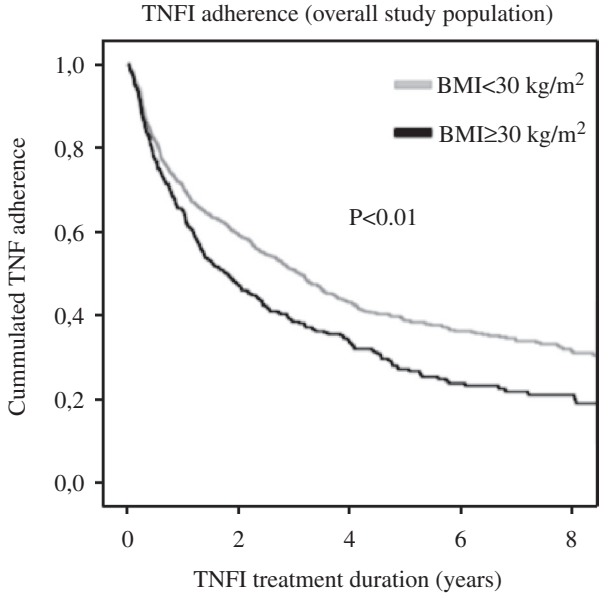
Objectives: To investigate the impact of obesity on response to first tumour necrosis factor-α inhibitor



(TNFi) treatment course in patients with psoriatic arthritis (PsA) followed in routine care.

Method: This was an observational cohort study based on the Danish (DANBIO) and Icelandic (ICEBIO) registries. Kaplan–Meier plots and Cox and logistic regression analyses were performed to study the impact of obesity (BMI ≥ 30 kg/m^2) on TNFi adherence and response after 6 months (according to ACR20/50/70 and EULAR criteria). Subanalyses studied the impact of obesity according to gender, TNFi type, and nationality.

Results: Among 1943 PsA patients (193 Icelandic/1750 Danish) identified in the registries, 1271 (65%) had available BMI and 408 (32%) of these were obese. The median follow-up time was 1.5 (IQR 0.5–3.9) years. Obese patients had higher baseline disease activity [e.g. DAS28 (mean ± sd): 4.6 ± 1.2 vs. 4.4 ± 1.2; CRP median (IQR): 9 (5–19) vs. 7 (3–18) mg/L; and VAS pain: 66 (48–76) vs. 60 (38–74) mm] compared to non-obese (all $p < 0.05$). TNFi adherence was shorter in obese patients, especially among men, where median TNFi duration was 2.5 (95% CI 1.7–3.2) years in obese vs. 5.9 (95% CI 4.1–7.7) years in non-obese men($p < 0.01$). A EULAR good or moderate response was achieved by 55% of obese vs. 65% of non-obese patients after 6 months ($p = 0.02$). In multivariable analyses, obesity increased the risk of TNFi withdrawal (HR 1.6, 95% CI 1.3–2.0) and reduced the odds for a EULAR good or moderate response (OR 0.45, 95% CI 0.29–0.72). The influence of obesity was seen across genders, TNFi types, and nationality.

Conclusions: Obesity is associated with higher disease activity and diminished response and adherence to TNFi treatment in PsA.

PP37

The majority of patients with psoriatic arthritis are not eligible for controlled clinical trials

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Objectives: To elucidate the proportion of patients with psoriatic arthritis (PsA) who would meet inclusion criteria of the controlled clinical studies that were performed leading up to the registration of the TNF inhibitors.

Method: Data from 329 patients with PsA were obtained from ICEBIO and medical records at the University Hospital of Iceland and Laeknasetrid (a private out-patient clinic). The patients were classified according to whether they met inclusion criteria of the clinical trials that were used as data for the registration of each respective TNFi. The reasons for exclusion were also explored.

Results: The percentage of patients with complete data available who met the inclusion criteria was 34%. There were insufficient clinical data with respect to exclusion and inclusion criteria for 13% of the cases. The proportion of patients who met the inclusion criteria was highest among those who received adalimumab and etanercept (53%). Patients who received infliximab had the highest exclusion rate (77%). The main reason why patients did not meet the inclusion criteria was that their PsA disease was not sufficiently active (45%).

Conclusions: Our results demonstrate that two-thirds of patients with PsA in Iceland who are treated with biologics would not have qualified for the pharmacotherapy trials performed leading up to the registration of the medications. Further studies with regard to whether outcomes are different between those who met the inclusion criteria and those who did not remain to be performed.

PP38

The efficacy and safety of ixekizumab, adalimumab, and placebo in patients with psoriatic arthritis naïve to biological disease-modifying anti-rheumatic drugs: a double-blind phase 3 study

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Objectives: Ixekizumab (IXE) is an anti-IL-17A monoclonal antibody under investigation for the treatment of psoriatic arthritis (PsA). In this double-blind phase 3 study, we investigated the efficacy and safety of IXE, adalimumab (ADA), and placebo (PBO) in PsA patients naïve to biological disease-modifying anti-rheumatic drugs (bDMARDs).

Method: A total of 417 bDMARD-naive patients with active PsA were randomized to PBO (n = 106), ADA 40 mg Q2 W (n = 101), or IXE 80 mg Q2 W (n = 103) or Q4 W (n = 107) after an initial 160 mg dose. Endpoints included ACR20 response at 24 weeks (primary), ACR50/70, PASI75/90/100, DAS28-CRP, LDI-B, LEI, and HAQ-DI (12 and 24 weeks), and mTSS (16 and 24 weeks).

Results: Among the 382 patients who completed 24 weeks, 30.2%, 57.4%, 62.1%, and 57.9% of PBO, ADA, IXE Q2 W, and IXE Q4 W patients, respectively, had ACR20 responses. At 12 (ACR70 not eligible for comparison) and 24 weeks, a higher percentage of IXE Q2 W/IXE Q4 W than PBO patients achieved ACR20/50/70 and PASI75/90/100 responses ($p \leq 0.001$). IXE groups experienced

Table 1. Efficacy, patient-reported outcomes, and safety outcome measures in an intent-to-treat population.

	Placebo		Adalimumab 40 mg Q2W		Ixekizumab 80 mg Q4W		Ixekizumab 80 mg Q2W	
	12 weeks	24 weeks	12 weeks	24 weeks	12 weeks	24 weeks	12 weeks	24 weeks
	n = 106		n = 101		n = 107		n = 103	
ACR 20, %	31.1	30.2	51.5**	57.4***	57.0***	57.9***	60.2***	62.1***
ACR 50, %	4.7	15.1	29.7***	38.6***	33.6***	40.2***	39.8***	46.6***
ACR 70, %	0	5.7	17.8	25.7***	15.0	23.4***	16.5	34.0***
	n = 67		n = 68		n = 73		n = 59	
PASI 75, %†	7.5	10.4	33.8***	54.4***	75.3***	71.2***	69.5***	79.7***
PASI 90, %	1.5	6.0	22.1**	36.8***	52.1***	56.2***	57.6***	67.8***
PASI 100, %†	1.5	3.0	14.7*	23.5**	31.5***	42.5***	40.7***	52.5***
LS mean (se) change from baseline								
	n = 106		n = 101		n = 107		n = 103	
DAS28-CRP	−0.56 (0.11)	−0.85 (0.13)	−1.51 (0.12)***	−1.68 (0.12)***	−1.58 (0.11)***	−1.92 (0.12)***	−1.61 (0.12)***	−2.04 (0.12)***
	n = 39		n = 23		n = 54		n = 41	
LDI-B (dactylitis)‡	−1.5 (0.47)	−2.1 (0.42)	−2.2 (0.57)	−3.3 (0.47)	−3.0 (0.41)*	−3.4 (0.35)**	−3.2 (0.45)**	−3.5 (0.38)**
	n = 57		n = 56		n = 70		n = 59	
LEI (enthesitis)‡	−0.8 (0.24)	−0.8 (0.26)	−0.8 (0.24)	−0.9 (0.23)	−0.9 (0.21)	−1.3 (0.21)	−1.5 (0.24)	−1.4 (0.24)
	n = 106		n = 101		n = 107		n = 103	
mTSS§	0.36 (0.07)	0.49 (0.09)	0.12 (0.08)*	0.10 (0.09)***	0.13 (0.07)*	0.17 (0.08)**	0.06 (0.07)**	0.08 (0.08)***
HAQ-DI	−0.13 (0.05)	−0.18 (0.05)	−0.35 (0.05)***	−0.37 (0.05)**	−0.37 (0.05)***	−0.44 (0.05)***	−0.47 (0.05)***	−0 50 (0.05)***
	n = 106		n = 101		n = 107		n = 102	
TEAE, %	47.2		64.4*		66.4**		65.7**	
SAE, n (%)	2 (1.9)		5 (5.0)		6 (5.6)		3 (2.9)	
Discontinued due to TEAE, %	1.9		2.0		1.9		3.9	

ACR 20/50/70, American College of Rheumatology Improvement Responder Index (RI) improvement response for 20/50/70%; DAS28-CRP, Disease Activity Score (28 diarthrodial joint counts) based on C-reactive protein; HAQ-DI, Health Assessment Questionnaire Disability Index; LDI-B, Leeds Dactylitis Index – Basic; LEI, Leeds Enthesitis Index; LS, least squares; n, number of responders; mTSS, modified van der Heijde Total Sharp Score; PASI 75/90/100, Psoriasis Area and Severity Index improvement response for 75/90/100%; Q2W, once every 2 weeks; Q4W, once every 4 weeks; TEAE, treatment-emergent adverse event; se, standard error.

*$p \leq 0.025$, **$p \leq 0.01$, and ***$p \leq 0.001$ vs. placebo.

†Analysis restricted to patients with baseline psoriatic lesions involving ≥ 3% of body surface area.

‡Only patients with dactylitis or enthesitis present at baseline were included in the respective analyses.

§Value shown for 12 weeks was collected at 16 weeks.

greater reductions than PBO in LDI-B ($p \leq 0.025$) and LEI (week 12 Q2 W only; $p \leq 0.05$) (Table 1). DAS28-CRP and HAQ-DI scores improved, and both IXE doses inhibited radiographic progression of joint structural damage (mTSS) ($p \leq 0.025$ compared to PBO). The 24-week incidence of treatment-emergent adverse events (TEAEs) and of serious adverse events (SAEs) was greater ($p < 0.05$ and $p > 0.27$) with IXE and ADA compared to PBO. Discontinuation due to TEAEs was similar across groups. No deaths occurred.

Conclusions: IXE patients showed greater disease marker improvement than PBO and no unexpected safety findings were observed in bDMARD-naive patients with PsA.

PP39

Reduction in fatigue in patients with active psoriatic arthritis is sustained over 2 years: long-term results of two phase 3 studies of secukinumab

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Background: Fatigue is an important symptom associated with active psoriatic arthritis (PsA). Secukinumab (SEC) has resulted in rapid improvements in signs and symptoms, physical functioning, and HRQoL in patients with active PsA.

Objectives: To assess 1- and 2-year data on the effects of SEC on fatigue in patients with PsA and to investigate correlations between fatigue and baseline characteristics or clinical endpoints.

Method: Patients with active PsA (FUTURE1, n = 606; FUTURE2, n = 397) received SEC or PBO every 4 weeks. Fatigue was assessed using the FACIT-F scale. A change in FACIT-F score of ≥ 4 from baseline was used to define fatigue response. Logistic regression was used to explore the relationship between fatigue response (weeks 16 and 52) and baseline characteristics and clinical response.

Results: A fatigue response at week 16 was achieved by 58.4% (FUTURE1) and 70.0% (FUTURE2) of patients receiving SEC 150 mg and 50.5% receiving SEC 300 mg (FUTURE2) compared with 51.6% (FUTURE1) and 43.2% (FUTURE2) of those receiving PBO. Responses were sustained at weeks 52 and 104. Age and baseline HAQ-DI scores were associated with fatigue response. Achieving a fatigue response was correlated with clinical response criteria (including ACR, HAQ-DI, and PASI).

Conclusions: SEC provided rapid and sustained improvements in fatigue for up to 104 weeks in patients with active PsA, regardless of prior biologic exposure. Fatigue response was correlated with improvement in clinical response criteria, indicating a relationship between fatigue and disease activity. Age and physical functioning may predict fatigue response.

PP40

Disease activity and quality of life of patients with psoriatic arthritis mutilans: the Nordic PAM study

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Objectives: To determine the disease activity, social status, and health-related quality of life in patients with psoriatic arthritis mutilans (PAM) in the Nordic countries.

Method: Patients with at least one mutilated joint verified radiologically were included in the study. Disease activity including joints and skin, physician-estimated disease activity, and patients' education and work status was recorded. SF-36, mHAQ, and DLQI scores were obtained and correlated to disease duration, pain, and general well-being (VAS).

Results: This study included 64 patients (30 from Sweden, 19 from Denmark, 12 from Norway, and three from Iceland), all with a very early onset of disease (25 ± 14 years) and a mean disease history of 33 years. The overall inflammatory activity was low, the number of mean mutilated joints was 8.2, and gross deformity was found in 16% of the patients. Forty per cent of patients were treated with bDMARDs and 32% with csDMARDs. Forty-two per cent were early retired or on sick leave. Reduced functional capacity with almost no ability to perform self-care or daily duties was reported by 21%. Quality of life was most reduced in patients aged 45 to 60 years.

Conclusions: PAM has a substantial impact on social functions. Whether early recognition of PAM and novel therapies will improve the disease outcome and its consequences on quality of life remains to be studied.

PP41

Achilles enthesitis defined by ultrasound is not associated with clinical enthesitis in patients with psoriatic arthritis

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Background: Clinical examination may overestimate Achilles enthesitis. Ultrasonography (US) is valuable for the assessment of musculoskeletal inflammation including subclinical enthesitis.
Objectives: To compare clinical and US evaluation of Achilles enthesitis in psoriatic arthritis (PsA).
Method: The Achilles insertion was examined by assessment of tenderness and an ultrasound evaluation was performed of (i) inflammatory activity defined as the power Doppler (PD) signal, tendon thickening, hypoechogenicity, and bursal swelling and (ii) structural damage defined as erosions at tendon insertion, calcifications, and enthesophytes. US sum scores of inflammatory activity and structural damage were assessed. Proportions were analysed by the χ^2 test. Correlations were assessed by Spearman's rank correlation test (non-parametric data distribution).
Results: A total of 141 PsA outpatients fulfilling the CASPAR criteria were included consecutively during 1.5 years. The mean (sd) age of the patients was 52.4 (10.2) years, disease duration was 9.5 (6.6) years, BMI 28.3 (4.3) kg/m^2, 50.4% were female, 10.6% used steroids, 57.4% conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs), 32.6% tumour necrosis factor inhibitors (TNFi), and 20.6% both TNFi and csDMARDs. Of the 282 Achilles tendons, 88 (33.2%) were tender on palpation. By US, six (17%) had hypoechogenicity, 37 (13.1%) thickening, two (0.8%) PD activity, 14 (5%) bursal swelling, 112 (39.7%) calcifications, 77 (27.3%) enthesophytes, and four (1.4%) erosions at tendon insertion. Inflammatory activity was found in 55 (19.5%) of the examined Achilles tendons and 148 (52.5%) had structural damage. No significantly correlation was found between US sum scores and tenderness on palpation. Subclinical inflammation was shown by 36 (18.6%) of the Achilles tendons on US.
Conclusions: We report a lack of association between tenderness to palpation and US signs of Achilles enthesitis in PsA.

PP42

Reactive arthritis caused by a weever fish sting: a case report

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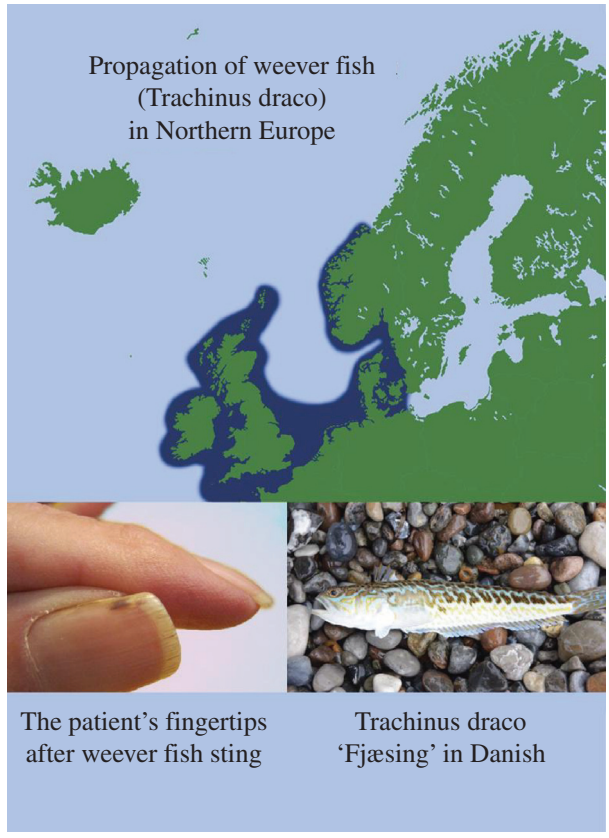
A human leucocyte antigen (HLA)-B27-positive 65-year-old man who was fishing in the local harbour in August 2015 was stung on the first and second fingertips of the left hand by a weever fish. Afterwards he was treated with phenoxymethylpenicillin for 14 days.

Two months after the weever sting he developed 1 week of fever (38.0°C), weight loss (8 kg), balanitis circinata, arthritis of the left wrist, left knee, and



right ankle, and elevated C-reactive protein (94 mg/L) and erythrocyte sedimentation rate (94 mm/h). Despite treatment with NSAIDs, the oligoarthritis persisted and was treated with intra-articular steroid injections. Results of examination of the joint fluid by culture and 16S polymerase chain reaction (PCR) were negative.

Thoracic and abdominal computed tomography were without pathological findings. Urine tests for chlamydia and gonorrhoea were negative. Standard stool cultures and faecal PCR investigations were negative for known causes of reactive arthritis.

Based on the history and the clinical work-up, it was concluded that the weever fish sting had caused reactive arthritis.
Discussion: Sting by weever fish (*Trachinus draco*) is known to cause sequelae such as infection, ischaemic aseptic necrosis, irreversible tissue damage, complex regional pain syndrome, chemical bursitis, tendinitis, and tetanus (1). The literature has not previously described reactive arthritis due to a weever fish sting. The described case is the first known of reactive arthritis caused by an infection transferred by a weever fish sting.

Reference

1. Rasmussen AM, Steffensen HM. [Weever fish stings and their sequelae], in Danish. Ugeskr Laeger 1985;147:1982–5.