between AS pts and HC (10.5; 8.3-18.0 pg/ml vs 11.9; 8.2-18.3 pg/ml, p>0.05). The same levels of IL-6 and IL-8 were detected in AS with IBD and AS without signs of IBD (p>0.05). In AS pts, serum IL-6 concentration was positively correlated with ASDAS ESR (r = 0.3), ASDAS CRP (r = 0.3), ESR (r = 0.3) and CRP (r = 0.5) (p <0.05); IL-8 was negatively associated with presence of fecal calprotectin (r = -0.3) (p <0.05).

Conclusion: Elevated serum concentration of IL-6 in AS is associated with clinical and laboratory markers of high inflammatory activity of the disease. The levels of IL-8 in the sera of AS patients were negatively correlated with the concentration of fecal calprotectin. Data on the relationship of IL-8 with the activity of the pathological process in AS require further study.

Disclosure of Interests: Elena Aleksandrova: None declared, Alexander Novikov: None declared, Polina Kulakova: None declared, Aleksey Dorofeev: None declared, Nadezhda Savenkova: None declared, Evgeniy Volnukhin: None declared, Anton Kovshik: None declared, Galina Lukina Speakers bureau: Novartis, Pfizer, UCB, Abbvie, Biocad, MSD, Roche

DOI: 10.1136/annrheumdis-2020-eular.3082

FRI0565 PREVALENCE AND SIGNIFICANCE OF ANTIBODIES AGAINST CITRULLINATED ALPHA-ENOLASE (ANTI-CEP1) IN CONNECTIVE TISSUE DISEASES.

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Background: Anti-cyclic citrullinated peptide (anti-CCP) auto-antibodies represent the current gold standard for the diagnosis of rheumatoid arthritis (RA). However, growing evidence suggests that a variety of other citrullinated self-proteins may act as autoantigens and lead to the production of autoantibodies (1). Furthermore, autoantibodies believed to be RA-specific have been detected also in patients with connective tissue diseases (CTDs). We recently demonstrated that antibodies against citrullinated alpha-enolase (anti-CEP1) are a biomarker of erosive disease and RA-associated interstitial lung disease (2).

Objectives: The purpose of this study was to investigate the prevalence and possible prognostic value of anti-CEP-1 in patients with CTDs.

Methods: Two hundred and twelve consecutive patients with CTDs (51 systemic lupus erythematosus (SLE), 85 primary Sjogren's syndrome (pSS) and 76 systemic sclerosis (SSc)) were studied and compared to 97 sex and age matched normal controls (NC) and 267 patients with RA. Anti-CEP1 IgG were detected in serum samples with a commercial ELISA kit (Euroimmun).

Results: The overall prevalence of anti-CEP1 in CTDs was 7% (15/212 patients). In detail, these antibodies were detectable in 4 out of 85 pSS (5%), 5 out of 51 SLE (10%) and 6/76 SSc (8%). The prevalence and the titer of anti-CEP1 in CTDs was significantly higher compared to NC and significantly lower compared to RA. Anti-CEP1 positive patients did not display a specific clinical and serological picture. Unlike in RA, anti-CEP1 did not correlate with CTD-associated ILD.

Conclusion: This is the first study assessing anti-CEP1 in a large cohort of patients with CTDs. We demonstrated that the association of these autoantibodies with ILD is specific for RA since it is not observed in SLE, pSS and SSc. Furthermore, although being significantly more prevalent and at higher titer compared to NC, anti-CEP1 do not allow to discriminate different patient subsets displaying peculiar clinical or serological phenotypes. Based on our results, the application of anti-CEP1 in CTDs is not advisable, however larger studies may possibly identify correlations not evident in our cohort.

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Disclosure of Interests: Alessia Alunno: None declared, Francesco Carubbi Speakers bureau: Francesco Carubbi received speaker honoraria from Abbvie and Celgene outside this work., Onelia Bistoni: None declared, Matteo Antonucci: None declared, Elena Bartoloni Bocci: None declared, Roberto Giacomelli Grant/research support from: Actelion, Pfizer, Speakers bureau: Abbvie, Roche, Actelion, BMS, MSD, Ely Lilly, SOBI, Pfizer, Roberto Gerli: None declared

DOI: 10.1136/annrheumdis-2020-eular.4549

FRI0566 THE FLARE-RA QUESTIONNAIRE CAN IDENTIFY OMERACT FLARES IN PATIENTS WITH RHEUMATOID ARTHRITIS INCLUDED IN THE TAPERA TRIAL

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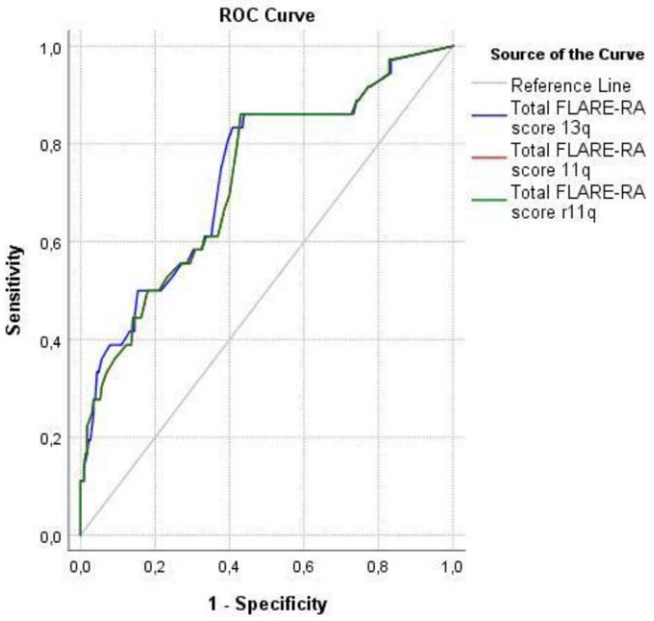

Figure 1. ROC curves of the total FLARE-RA scores (13q, 11q and r11q version) for identifying a flare according to the OMERACT definition.FLARE Q is expressed in mean ± SD. M month, FLARE Q FLARE-RA questionnaire 13q, n number, LDA low disease activity, MDA moderate disease activity, HDA high disease activity

Background: The Flare assessment in rheumatoid arthritis (FLARE-RA) questionnaire has been developed to identify flares in patients with rheumatoid arthritis (RA). The first version was published by Berthelot et al. (2012) and consisted of 13 questions on a Likert-scale of 1-6 ranging from 'completely untrue' to 'completely true'. When the FLARE-RA questionnaire was validated by Fautrel et al., 2 questions were removed, and it was rescaled to 0–10. The questionnaires' usefulness has been tested in few studies. Further external validation in a well-defined cohort of patients with RA is needed.

Objectives: To externally validate the FLARE-RA questionnaire and determine cut-offs for identifying a flare in an established RA population in which biologicals are tapered.

Methods: Patients who were in remission according to the DAS28CRP or ESR (≥6 months) and treated with etanercept 50 mg weekly (≥1 year), were enrolled between 2012 – 2014 in the pragmatic 1-year open-label randomised controlled TapERA (Tapering Etanercept in RA) trial. Patients were randomised to continue etanercept 50 mg weekly or taper to 50 mg every other week. The FLARE-RA questionnaire (version of 2012) was completed every 3 months. Outcomes were based on 3 versions of the questionnaire (13 questions (13q), 11 questions (11q) and 11 questions rescaled (r11q)). Per time point, the average of the answers was calculated to obtain a total score of the FLARE-RA questionnaire. The total scores were compared between patients in remission (DAS28CRP <2.6), low (DAS28CRP ≥2.6 - ≤3.2), moderate (DAS28CRP >3.2 - ≤5.1) and high disease activity (DAS-28CRP >5.1) using the Kruskal-Wallis test and between patients with and without a flare according to the OMERACT definition (increase in DAS28 >1.2 compared to baseline or increase in DAS28 >0.6 and current DAS28 ≥3.2) using the Mann-Whitney U test. The total FLARE-RA scores of the different time points were combined to determine the receiver operating characteristics (ROC) curves, the corresponding cut-off values and the area under the curve (AUC) for identifying an OMERACT flare. An AUC of <0.5, between 0.5 and 0.7 and >0.7 stands for having no, moderate and a good predictive value, respectively.

Results: FLARE-RA questionnaires of 66 patients (68% female, mean ± standard deviation (SD) age of 55 ± 11 years) were collected. The FLARE-RA score (13q) did increase when disease activity increased at month (M) 3 and M12 (p<0.01) (table 1). Patients presenting with an OMERACT flare had a statistically significantly higher total FLARE-RA score (13q) compared to patients without a flare, except at M12 (M3 and M6: p<0.05, M9: p<0.01). The AUC - ROC curve of the FLARE-RA questionnaire (13q) for identifying an OMERACT flare was 0.736 and the cut-off value was 2.3 (1-6 scale). The AUC - ROC curve was the same for the 11q and r11q version, namely 0.727. The cut-off values were 2.4 (1-6 scale) and 2.7 (0-10 scale), respectively (figure 1).

Table 1. Comparison of the total FLARE-RA scores (13q) between the disease activity groups (DAS28CRP)

		Remission	LDA	MDA	HDA	P-value
BL	Patients (n)	62	3	1	0	
	FLARE Q	1.8 ± 0.8	1.5 ± 0.3	1.3		0.800
M3	Patients (n)	50	11	5	0	
	FLARE Q	2.1 ± 1.0	3.0 ± 0.9	3.5 ± 1.4		0.004
M6	Patients (n)	52	5	9	0	
	FLARE Q	2.1 ± 0.8	3.1 ± 1.3	3.1 ± 1.9		0.057
M9	Patients (n)	48	10	7	1	
	FLARE Q	2.1 ± 0.9	2.8 ± 1.1	3.3 ± 1.6	2.4	0.079
M12	Patients (n)	52	8	6	0	
	FLARE Q	2.1 ± 1.0	3.1 ± 0.8	3.2 ± 1.0		0.002

Conclusion: The FLARE-RA scores seem to reliably discern between patients with and without an OMERACT flare. A cut-off of 2.7 on the current questionnaire (r11q) had the optimal sensitivity and specificity to identify an OMERACT flare.
Disclosure of Interests: Delphine Bertrand: None declared, Veerle Stouten: None declared, Sofia Pazmino: None declared, Diederik De Cock: None declared, Anneleen Moeyersoons: None declared, Rene Westhovens Grant/research support from: Celltrion Inc, Galapagos, Gilead, Consultant of: Celltrion Inc, Galapagos, Gilead, Speakers bureau: Celltrion Inc, Galapagos, Gilead, Johan Joly: None declared, Patrick Verschueren Grant/research support from: Pfizer unrestricted chair of early RA research, Speakers bureau: various companies
DOI: 10.1136/annrheumdis-2020-eular.2832

FRI0567 CONSTRUCT VALIDATION OF PROMIS SHORT FORM AND PROFILE-29 T-SCORES WITH SF-36 IN RHEUMATOID ARTHRITIS PATIENTS TREATED FOR 1 YEAR: RESULTS FROM A REAL-WORLD EVIDENCE-BASED STUDY IN THE UNITED STATES

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Background: Use of patient-reported outcomes (PROs) to assess health-related quality of life in clinical practice, research studies, and clinical trials in rheumatoid arthritis (RA) remains an ongoing area of research. SF-36 is commonly used in RA trials but is not feasible for routine use in clinical practice settings. The **P**atient **R**eported **O**utcomes **M**easurement **I**nformation **S**ystem (PROMIS) may address this gap but has not been widely assessed in RA patients starting therapy in a real-world comparative effectiveness study, nor examined in that setting in relation to the SF36 and Clinical Disease Activity Index (CDAI).
Objectives: To assess validity of PROMIS based on Comparative and Pragmatic Study of Golimumab Intravenous (IV) Versus Infliximab in Rheumatoid Arthritis (AWARE), an ongoing Phase 4 study providing real-world assessment of IV tumor necrosis factor inhibitor (TNFi) medications in RA patients.
Methods: AWARE is a prospective, non-interventional, 3-year study conducted at 88 US sites. RA patients were enrolled when initiating TNFi treatment. Treatment decisions were made by treating rheumatologists. We report baseline PROMIS-29 (7 domains and pain intensity), PROMIS Pain Interference (PI) Short Form (SF) 6b (PI6b) and PROMIS Fatigue (F) Short Form 7a (F7a), domain T-Scores, and SF-36 subdomain and Component Scores (CS) in AWARE patients. Here we report baseline data obtained from the final 1-year AWARE dataset. Correlations between PROMIS measures and comparable SF-36 component scores were calculated using Pearson correlations. Data is shown as mean ± standard deviation (SD).
Results: At baseline, mean CDAI of all patients (n=1262) was 32.3±15.6, with 70.4% in high disease activity (HDA, CDAI>22), 22.8% in moderate disease activity (MDA, CDAI: >10 and ≤22), 6.1% in low disease activity (LDA, CDAI: >2.8 and ≤10), and 0.7% in remission (CDAI ≤2.8). Mean PROMIS scores were >0.5 SD worse than population means for Physical Function (PF, 38.1±6.84), PI (63.4±7.68), F (58.8±9.95), Sleep Disturbance (55.1±8.68); and Ability to Participate in Social Roles/Activities (PSRA, 43.4±8.58). Baseline Depression and Anxiety were within 0.5 SD of population T-scores. PI6b, F7a, and P29 domain T-scores correlated with the comparable SF-36 subdomain and component scores (r's >0.58), except sleep for which no comparable SF-36 element was applicable. Examples include: P6b (r=-0.80) and P29-PI (0.81) with SF-36 Bodily Pain; F7a (-0.77) and P29-F (-0.77) with SF-36 Vitality; P29-PF with SF-36 PF (0.77), Role-Physical (0.69), and Physical CS (0.73); P29 Anxiety with SF-36 Mental Health (-0.72), Role-Emotional (-0.56), Mental CS (-0.70); and P29-PRSA with SF-36-Social Functioning (0.71). Mean PROMIS-29 T-scores (except Anxiety and Sleep Disturbance) among patients with HDA were significantly different from patients with MDA, LDA or remission ($p < 0.001$ for all). Further, mean PROMIS T-scores of PF, F, PSRA, PI, Pain Intensity, PI6b and P7a among patients with MDA were significantly different from patients with more or less active RA (by CDAI category).
Conclusion: Analysis of baseline results from a large cohort of RA patients indicates high correlations between individual P29 domain T-scores and SF-36 component scores, as well as categorical CDAI, providing strong evidence of PROMIS construct validity in a real-world population of RA patients.
Disclosure of Interests: Clifton Bingham Grant/research support from: Bristol-Myers Squibb, Consultant of: Bristol-Myers Squibb, Shelly Kafka Employee of: Janssen Scientific Affairs, LLC, Shawn Black Employee of: Janssen Research & Development, LLC, Janssen Scientific Affairs, LLC, Stephen Xu Employee of: Janssen Research & Development, LLC, Wayne Langholff Employee of: Janssen Research & Development, LLC, Jeffrey Curtis Grant/research support from: AbbVie, Amgen, Bristol-Myers Squibb, Corrona, Janssen, Lilly, Myriad, Pfizer, Regeneron, Roche, UCB, Consultant of: AbbVie, Amgen, Bristol-Myers Squibb, Corrona, Janssen, Lilly, Myriad, Pfizer, Regeneron, Roche, UCB
DOI: 10.1136/annrheumdis-2020-eular.2255

FRI0568 MEASURING DAILY PHYSICAL ACTIVITY IN AXSPA PATIENTS: CONTENT VALIDITY AND MEASUREMENT PROPERTIES OF THE NEW AXSPA-SQUASH

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Background: The ASAS-EULAR recommendations for management of axial Spondyloarthritis (axSpA) includes that patients should be encouraged to exercise.[1] So far, there is no validated instrument for measuring daily physical activity in axSpA. Our previous study recommends to adapt the Short QUestionnaire to Assess Health-enhancing physical activity (SQUASH) to improve the validity in axSpA patients.[2]
Objectives: AxSpA-disease specific adaptation of the physical activity questionnaire SQUASH to improve content validity and measurement properties.
Methods: This study was conducted according to the OMERACT-filter within the Groningen Leeuwarden AxSpA (GLAS) cohort and was performed in two parts. Part 1: adaptation and evaluation of content validity using a qualitative stepwise approach with in-depth interviews with different healthcare professionals (n=9) and patients (n=8), field testing in patients (n=10), and consensus meeting for final adaptations. Thereafter, content validity (n=45) was tested by filling out axSpA-SQUASH and SQUASH in random order two weeks apart. Part 2: measurement properties were tested using the International Physical Activity Questionnaire (IPAQ) as comparator. Criterion validity (n=40): Spearman's correlation with accelerometer as golden standard and classification accuracy of intensity. Construct validity (n=106): Spearman's correlation with disease activity, physical functioning and quality of life as clinical outcome with expected fair to moderated associations. Test-retest reliability (n=45): intraclass correlation coefficients (ICC) after 2 weeks. Responsiveness (n=47): standardized response mean (SRM) after 3 months stratified by Ancor method.
Results: In total 156 patients were included: mean age 48±13 years, 56% males, 72% HLA-B27 positive, symptom duration 21±13.3 years and ASDAS 2.0±1.0. Part 1: main adaptations were better explanation of intensities, adding answer option "not applicable", examples were modernized, physiotherapy and activity "shopping" were added. Compared to the original SQUASH, the adapted axSpA-SQUASH measured a systematically higher activity count and had less missing values (8% vs. 32%). Part 2: criterion validity: axSpA-SQUASH correlated better with accelerometer compared to IPAQ (ρ=0.51 vs. ρ=0.35). Classification accuracy: accelerometer defined most activity as light (97%), whereas axSpA-SQUASH and IPAQ defined most activity as moderate intensity (55% and 62% resp.). Construct validity: correlations were low to moderate and strongest for axSpA-SQUASH compared to IPAQ. Construct validity: correlations were low to moderate and stronger for axSpA-SQUASH compared to IPAQ (BASDAI -0.27 vs -0.15, BASDAI –0.27 vs. -0.15, ASDAS -0.24 vs -0.09, BASFI -0.39vs. -0.21, ASQoL -0.39 vs. -0.35). Test-retest reliability: ICC axSpA-SQUASH: 0.80. Responsiveness: axSpA-SQUASH changed over time in the corresponding direction (Table 1). Feasibility: considered comprehensible and average completion time was 7 minutes.

Table 1. Responsiveness of the axSpA-SQUASH versus change in BASDAI

	SRM	95% CI	BASDAI T1	BASDAI T2
Improved (n=12)	-0.36	-0.99 to 0.28	5.01 (2.10)	3.93 (1.60)
Stable (n=21)	0.28	-0.18 to 0.73	3.76 (2.05)	3.76 (2.05)
Decreased (n=14)	0.75	0.18 to 1.33	4.71 (1.96)	5.79 (2.42)