THU0697 FEASIBILITY AND RELIABILITY OF THE SPARCC SACROILIAC JOINT STRUCTURAL SCORE FOR CHILDREN WITH SPONDYLOARTHRITIS

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Background: Clinical trials in juvenile spondyloarthritis (JSpA) and axial disease are lacking. To assess the effectiveness of medications, we need measures to evaluate structural progression in the pediatric sacroiliac joint (SIJ).
Objectives: To evaluate the reliability of the SPARCC sacroiliac joint structural score (SSS) in children with suspected or confirmed JSpA.
Methods: The SSS assesses a spectrum of structural lesions of the SIJ on MRI including fat metaplasia, erosion, backfill, and ankylosis on 5 consecutive slices through the cartilaginous part of the joint. These components are scored 0–20 (backfill and ankylosis) or 0–40 (fat metaplasia, erosion). We developed a pediatric training module that included a detailed description of each SSS component plus sclerosis (0–40), scoring methodology, and numerous examples. After reviewing the module, 6 readers (mix of adult and pediatric radiologists and rheumatologists) scored 30 studies (Exercise 1). All readers then reviewed a second training module based on DICOM images and scored an additional 29 studies (Exercise 2). Inter-observer reliability was assessed using intraclass correlation (ICC).
Results: The SSS had face validity and was feasible to score in the 59 pediatric cases. 35 (59%) were male and median age was 15 years (IQR 12–16). The ICCs for the SSS components from both calibration exercises are shown in the Table. In the 1st exercise, fat metaplasia and sclerosis had good reliability ($\geq$0.4) while reliability for erosion, backfill, and ankylosis were low. During the first exercise, 31 (17%), 131 (73%), 56 (31%), 100 (56%), and 21 (12%) of the 180 ratings from 6 readers had a score$>$0 for fat metaplasia, erosion, backfill, sclerosis, and ankylosis, respectively. In the second exercise, the ICC for erosion, backfill, and sclerosis improved and had good reliability. Of the 174 ratings from 6 readers, 91 (52%), 18 (10%), and 49 (28%) of scores were $>$0 for erosion, backfill, or sclerosis in exercise 2, respectively. Reliability for fat metaplasia and ankylosis were not calculated due to low frequency of lesions (8 (5%) and 3 (2%), respectively).

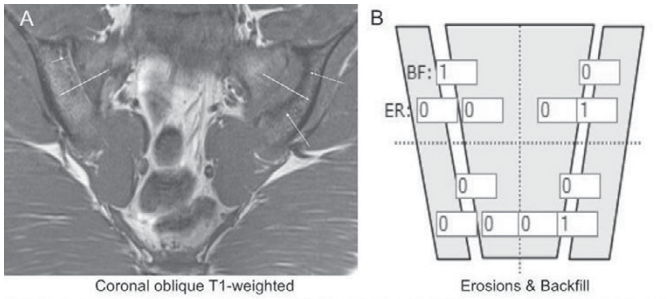

Figure 1. Sample slice and scoring methods for the sacroiliac joint structural score. A. Coronal oblique T1-weighted image of the sacroiliac joints shows each joint divided into 4 quadrants. There is backfill along the superior aspect of the right sacroiliac joint, as demonstrated by increased T1 signal in the joint space (short arrow). There is an extended erosion of the left iliac cortex affecting both upper and lower quadrants of the left iliac bone (long arrows). No sclerosis, ankylosis or fat metaplasia. B. Scoring schematic demonstrates a "1" for backfill (BF) within the R upper SIJ quadrant and "1" in both the upper and lower quadrants of the left SIJ representing erosions (ER).

Conclusions: The SSS was feasible to score and had acceptable reliability for pediatric SIJ MRI evaluation. ICC improved with additional calibration exercises based on DICOM, even for readers with limited experience.
Disclosure of Interest: None declared
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THU0698 MEASUREMENT PROPERTIES OF PRESENTEEISM MEASURES WITH DUAL ANSWER KEYS IN INFLAMMATORY ARTHRITIS

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Background: Employment studies in arthritis have emphasised the importance of decreased productivity at work, or presenteeism. Yet, how to best measure presenteeism remains challenging. The "Work Limitations Questionnaire" (WLQ) is frequently used. A drawback is that it measures the amount of time people are limited, but not the degree to which they are limited. In contrast, the "Workplace Activity Limitations Scale" (WALS) measures the degree of limitation, but not the time. We modified the response keys to the WALS and WLQ to measure both degree of difficulty and amount of time with difficulty.
Objectives: Our objective was to evaluate measurement properties, i.e. internal consistency and construct validity, of the WALS and WLQ with combined scores from dual answer keys.
Methods: A cross-sectional study used baseline data from the RCT of an employment intervention, the "Making It Work" Program. Participants were recruited from BC, Alberta and Ontario. Inclusion criteria included: having inflammatory arthritis, currently employed, age 19–59, and having concerns about arthritis affecting ability to work. 364 participants were included (RA:195, PsA:54, SLE:46, AS:69; 77% female, mean (SD) age: 45.9 (9.8) yrs). Combined scores were obtained by i) multiplying, and ii) adding, the scores of difficulty and time answer keys at the item level. No significant differences were observed between the additive and multiplicative models. Hence, we report on the multiplicative model, which reflects consumers' preference. Internal consistency was analyzed using Cronbach's alphas; construct validity by measuring correlation (Spearman coefficients) between WALS or WLQ subscales and constructs such as work productivity activity impairment (WPAI), risk of impending work loss (work instability, RA-WIS), disease measures, and job characteristics.
Results: Analyses at the item level revealed a strong floor effect (WALS: 16% to 56%; WLQ: 27% to 81% of answers for all items except one) but no ceiling effect, likely reflecting the relatively low limitation expected in a working sample. High (i.e. $\geq$0.7) internal consistency (α 0.70–0.82) was found for WALS and all WLQ subscales except WLQ Physical Demands (0.67). As a priori hypothesized, moderate correlation was observed between the time (0.33–0.57), or combined (0.44–0.61), scores of WLQ subscales and WPAI, or WIS; and correlation was consistently higher for combined than time scores. Moderate correlation was also observed between degree of difficulty (0.70–0.77), or combined (0.60–0.69), scores of the WALS and WPAI, or WIS. Contrary to our hypothesis, the WALS combined score did not have a higher correlation with WPAI, or WIS, than degree of difficulty score. Correlations with disease (fatigue, pain, physical function, depression) and job characteristics (job demand, autonomy, social support at work, commuting difficulty) with time, difficulty, or combined scores of the WALS and WLQ met the a priori hypothesized correlation levels.
Conclusions: Our previous research confirmed the value of measuring both degree of difficulty and amount of time, showing they measure different concepts, which can serve different purposes and are both important to patients. This research demonstrates that applying a dual answer key to two validated instruments shows good initial indicators of internal consistency and construct validity.
Disclosure of Interest: None declared
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THU0699 CHARACTERIZING AND VALIDATING THE PHENOTYPE OF KNEE PAIN: A LATENT CLASS ANALYSIS

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Background: Pain in osteoarthritis (OA) is very common and often involves multiple joints. It is multifactorial and individualised with multiple factors involved in the genesis and pain experience, such as structural pathology, psychological factors and pain coping strategies. Thus it may be possible to group people together based on specific factors which are linked to experiencing pain.
Objectives: To identify and validate the phenotype of knee pain over 10.7 years.
Methods: 1099 participants (mean age 63 years; range 51–81 years) from the population-based Tasmanian Older Adult Cohort study were recruited at baseline. 875, 768 and 563 participants attended years 2.6, 5.1 and 10.7 follow-up, respectively. Demographic, psychological, lifestyle and comorbidities data were obtained at baseline. T1-weighted or T2-weighted fat saturated MRI of the right knee was performed to measure knee structural pathology–cartilage defects, bone marrow lesions (BMLs) and effusion-synovitis at baseline. Knee pain was assessed using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at each time-point. Presence of pain (yes/no) at the neck, back, hands, shoulders, hips, knees and feet was also assessed by questionnaire at each time-point. Latent class analysis, which can identify unmeasured class membership

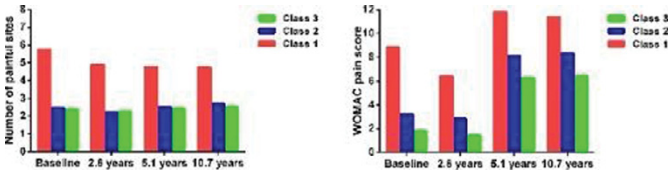
Abstract THU0697 – Table 1

	Exercise 1 ICC (95% CI)				Exercise 2 ICC (95% CI)			
	All	Pediatric Radiologists	SSS developers	Rheumatologists	All	Pediatric Radiologists	SSS developers	Rheumatologists
Fat metaplasia	0.40 (0.25–0.58)	0.46 (0.25–0.67)	0.89 (0.77–0.95)	0.82 (0.65–0.91)				
Erosion	0.37 (0.22–0.55)	0.39 (0.15–0.61)	0.72 (0.48–0.86)	0.16 (-0.17–0.47)	0.54 (0.34- 0.72)	0.51 (0.16–0.74)	0.96 (0.89–0.98)	0.61 (0.32–0.79)
Backfill	0.39 (0.25–0.58)	0.36 (0.14–0.58)	0.82 (0.56–0.92)	0.45 (0.12–0.69)	0.47 (0.31- 0.64)	0.12 (-0.08–0.38)	0.90 (0.80–0.95)	0.98 (0.95–0.99)
Sclerosis	0.42 (0.25–0.60)	0.42 (0.17–0.65)	0.61 (0.08–0.83)	0.72 (0.49–0.86)	0.47 (0.30- 0.65)	0.35 (0.13–0.58)	0.88 (0.75–0.94)	0.81 (0.63–0.90)
Ankylosis	0.31 (0.17–0.49)	0.46 (0.24–0.66)	0.72 (0.49–0.85)	0.19 (-0.16–0.51)				

Legend: ICC$<$0.40 is poor, 0.40$\leq$ICC$<$0.75 is good, ICC$\geq$0.75 is excellent.

among participants using observed variables, was used to differentiate "pain phenotypes" considering sex, body mass index (BMI), emotional problems, comorbidities, number of painful sites and knee structural damage on MRI.

Results: Three pain phenotypes were identified: Class 1: high levels of emotional problems and low levels of structural damage (24%); Class 2: high levels of structural damage and low levels of emotional problems (20%); Class 3: relatively low levels of emotional problems and low levels of structural damage (56%). People within Class 1 were more likely to be female, had greater BMI, lower education level, more comorbidities, more severe knee pain and more painful sites as compared to Class 2 and Class 3. Furthermore, WOMAC pain scores and number of painful sites were consistently greater at baseline, 2.6, 5.1 and 10.7 years in Class 1 than Class 2 and Class 3 (all $P<0.05$).



Conclusions: Psychological and structural factors interact with each other to influence pain perception.

Disclosure of Interest: None declared

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THU0700 IMMUNOGENICITY IN PATIENTS SWITCHING FROM STABLE ORIGINATOR INFLIXIMAB TREATMENT TO CT-P13: ANALYSES ACROSS SIX DISEASES FROM THE 52-WEEK RANDOMIZED NOR-SWITCH STUDY

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Background: TNF-inhibitors (TNFi) have improved treatment of Crohn's disease (CD), ulcerative colitis (UC), spondyloarthritis (SpA), rheumatoid arthritis (RA), psoriatic arthritis (PsA) and chronic plaque psoriasis (Ps). The NOR-SWITCH study was funded by the Norwegian government to investigate if switching from originator infliximab (Remicade®, INX) to biosimilar CT-P13 (Remsima®), is safe. Previously, the primary analyses of the pooled indications have been published[1]. Immunogenicity is associated with treatment failure and has been of particular concern in switching [2].

Objectives: The NOR-SWITCH study aimed to assess if immunogenicity to infliximab differed between patients treated with continous INX vs patients switched to CT-P13.

Methods: The study was designed as a 52-week randomized, double-blind, non-inferiority, phase IV trial. Adult patients with a diagnosis of CD, UC, SpA, RA, PsA or Ps on stable treatment with the originator infliximab were eligible. Patients were randomized 1:1 to either continued INX or switch to CT-P13 treatment, using unchanged dosing regimen. Trough drug levels and neutralizing anti-drug antibodies (ADAb) measurements were done prior to every infusion, but results were not reported during the study. Assays for drug serum levels and ADAb are fully automated on the AutoDELFIA® (PerkinElmer, Waltham, MA) immunoassay platform.

Results: Twenty patients entered the study with detectable ADAb (9 in INX arm, 11 in CT-P13 arm). 36 additional patients developed detectable incident ADAb during the 52-week study period (17 in INX arm, 19 in CT-P13 arm). Incident ADAb in each disease are shown in the table. Patients with detectable ADAb at any time during the study period were more likely to discontinue study drug treatment (7/26 (26.9%) in INX arm, 5/30 (16.7%) in CT-P13 arm) than patients without detectable ADAb (17/214 (7.9%) in INX arm, 13/210 (6.2%) in CT-P13 arm) (p=0.001).

Incident ADAb during study period (total number of patients), Full Analysis Set

	INX	CT-P13
All patients in study	17 (241) 7.1%	19 (240) 7.9%
RA patients	6 (39) 15.4%	2 (38) 5.3%
SPA patients	2 (45) 4.4%	5 (46) 10.9%
PSA patients	1 (14) 7.1%	0 (16)
UC patients	5 (47) 10.6%	8 (46) 17.4%
CD patients	3 (75) 3.9%	4 (77) 5.2%
Ps patients	0 (18)	0 (17)

Conclusions: The NOR-SWITCH study demonstrated similar immunogenicity in patients switched to CT-P13 vs those who continued INX treatment, supporting that switch does not influence ADAb formation. Presence of ADAb was associated with termination of study treatment.

References:

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Disclosure of Interest: G. Goll Consultant for: Novartis, Pfizer, Orion Pharma, AbbVie, I. Olsen: None declared, K. Lundin Consultant for: Orion Pharma, MSD, Takeda, K. Jørgensen Consultant for: Orion Pharma, AbbVie, Tillott, Intercept, M. Lorentzen: None declared, R. Klaasen: None declared, D. Warren: None declared, C. Mørk Consultant for: Novartis, LeoPharma, ACOhud, AbbVie, Galderma Nordic, Cellgene, J. Jahnsen Consultant for: Orion Pharma, Celltrion, Pfizer, MSD, AbbVie, Takeda, Napp Pharm, AstroPharma, E. Haavardsholm Consultant for: AbbVie, UCB, Pfizer, MSD, Roche, T. Kvien Consultant for: Biogen, BMS, Boehringer Ingelheim, Celltrion, Eli Lily, Epirus, Hospira, Merck-Serono, Novartis, Orion Pharma, Pfizer, Sandoz, UCB, N. Bolstad: None declared

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THU0701 THE EFFECTS OF STRUCTURAL DAMAGE ON FUNCTIONAL DISABILITY IN PSORIATIC ARTHRITIS

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Background: Functional outcomes are central in patients with chronic inflammatory musculoskeletal diseases. It has been shown in rheumatoid arthritis that functional outcomes are impaired in the presence of structural damage, a finding that has not yet been investigated in psoriatic arthritis (PsA), which has a more complex phenotype than rheumatoid arthritis (RA).

Objectives: To quantify the association of radiographic damage with physical function in PsA patients.

Methods: We analysed patients enrolled in the GO-REVEAL study[1] who had received golimumab. We obtained modified Sharp-van-der-Heijde scores (mSvDHS) from X-rays, performed at week 0, 24, 52 and week 104 (n=262). In longitudinal data analysis, we then used generalized estimating equations (GEE) on all patients in DAPSA remission (n=96), utilising all their remission visits, whereby the health assessment questionnaire (HAQ) disability index of each patients visit was used as dependent variable and mSvDHS, joint space narrowing (JSN) and erosion (ERO) scores, respectively, were used as independent variables in separate models.

To analyse effects of structural damage on changeability of functional limitations, we identified a subgroup of patients who had functional limitations at baseline (HAQ$\geq$1) and who showed a major response of DAPSA (improvement of $\geq$85% from baseline). In this model we assess the effect of mSvDHS on changes in HAQ, while adjusting for HAQ at baseline (n=54).

As validation cohort, we analysed a routine clinic PsA cohort with complete cDAPSA (the clinical version of the DAPSA without CRP) and mSvDHS (n=99). A cDAPSA cutoff of $\leq$4 was used to define the remission cohort in an analogous way as decribed above (n=32).

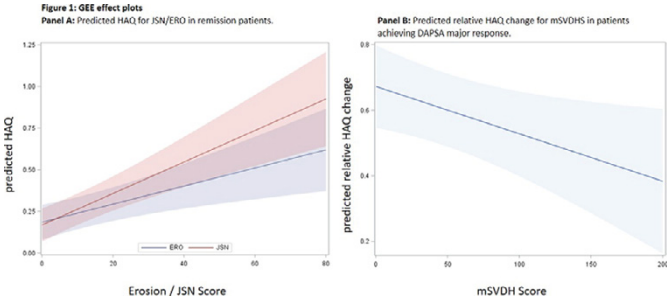
Results: As shown in table 1 and visualised in figure 1A, for patients in DAPSA remission, significant effects were seen for mSvDHS, JSN and ERO. These results could be confirmed in the validation cohort with patients achieving cDAPSA remission and showed a significant association of HAQ and mSvDHS (Estimate=0.0044, p=0.0176) as well as JSN (Estimate=0.0078, p=0.0165).

In the second analysis, looking at patients achieving DAPSA major response, again, results were significant for the association total mSVDHS and JSN. Additionally, higher estimates of JSN, compared to mSvDHS could be observed, with relative HAQ change as outcome parameter (see table 1 and figure 1B).

Table 1. Association of radiographic damage and HAQ in separate GEE models

Dependent variable	DAPSA remission (n=96) HAQ		DAPSA Major Response (n=54) relative HAQ change*	
Independent variable	Estimate	p	Estimate	p
mSVDHS	0.0037 (0.0018 to 0.0055)	**<0.001**	-0.0014 (-0.0027 to -0.0002)	**0.024**
Erosion	0.0054 (0.0021 to 0.0088)	**0.001**	-0.0021 (-0.0043 to 0.0002)	0.075
JSN	0.0095 (0.0057 to 0.013)	**<0.001**	-0.0039 (-0.0067 to -0.0012)	**0.005**

*Adjusted for HAQ at baseline.



Conclusions: Our results suggest that in JSN is functionally more important than