

POS0671

VALIDATION OF TWO RESPONSE AND ONE STATUS MEASURES OF THE ASAS HEALTH INDEX VERSUS EXTERNAL ANCHORS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS

Keywords: Validation, Outcome measures

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Background: Improvement in functioning and health as assessed by the ASAS Health Index (HI) is an important outcome of interventions in patients with axial spondyloarthritis (axSpA). The ability of various ASAS HI thresholds to discriminate between treatment arms of an active comparator trial have been demonstrated recently by our group with absolute improvement in the ASAS HI in general being superior to relative changes [1, 2].

Objectives: To assess whether ASAS HI response measures (absolute improvement of ≥ 3.0 and relative improvement of $\geq 30\%$) and reaching a status of good global functioning (ASAS HI ≤ 5.0) adequately discriminate between the changes and states in relevant external outcomes.

Methods: In this post-hoc analysis from the tight-controlled, treat-to-target (T2T) trial TICOSPA (2), data of active axSpA patients randomized to either the T2T arm (visits every 4 weeks, prespecified strategy of treatment intensification until achieving low disease activity) or usual care (UC; visits every 12 weeks, treatment at the rheumatologist's discretion) were used. The performance of ASAS HI response- and status scores against change (ASAS-40/ BASDAI-50 response, change in patient global/ BASDAI, and ASDAS improvement) and external status scores (ASAS partial remission, ASDAS status) was assessed, respectively. Analysis were performed by comparing the mean values and proportion of responses of continuous and dichotomous response outcomes, by t-tests. Missing data on outcomes was handled by non-responder imputation (NRI).

Results: ASAS HI was available in 160 patients, both at baseline and at week 48. At w48, an ASAS HI improvement of $\geq 30\%$, improvement of ≥ 3 points and ASAS HI ≤ 5.0 was achieved by 56 (35%), 51 (31.9%) and 54 (33.7%) patients, respectively. Patients with a meaningful improvement in global functioning had a larger reduction in patient global and disease activity as well a greater chance to reach remission compared to patients with no significant improvement in global functioning (Table 1). Health outcomes were not different between the two response measures of ASAS HI. Patients who achieved ASAS partial remission, ASDAS inactive disease or ASDAS low activity at week 48 were more likely to have an ASAS HI ≤ 5.0 compared with patients who did not achieve such states (Figure 1).

Conclusion: We demonstrated discriminant capacity of both, the relative and the absolute response measures of the ASAS HI. Both thresholds proved to have external validity and were able to discriminate between active treatment arms.

REFERENCES:

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- [2] Molto A et al. Ann Rheum Dis 2021

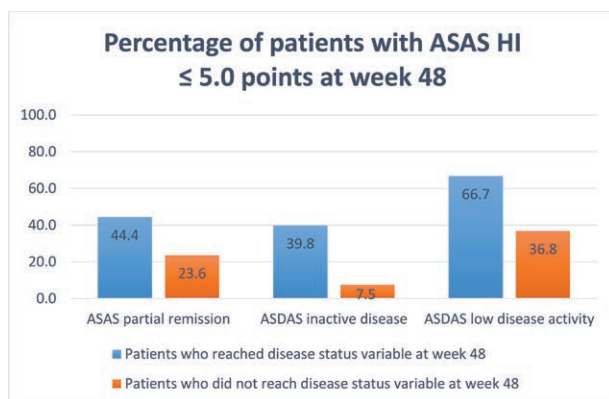


Figure 1. Proportion of patients reaching status of good global functioning at week 48

Table 1. Comparison of clinical outcomes and ASAS HI response at follow up

	ASAS HI response = > 30% improvement (NRI)			ASAS HI response = > 3 points improvement (NRI)		
	Yes (n=56)	No (n=104)	p	YES (n=51)	No (n=109)	p
ASAS40 response at w48	48.2%	21.2%	<0.001	51.0%	21.1%	<0.001
BASDAI 50 at w48	71.4%	28.8%	<0.001	68.6%	32.1%	<0.001
ASDAS Major improvement (0 to 48w)	23.2%	6.7%	0.005	23.5%	7.3%	0.008
ASDAS Clinically Important Improvement (0 to 48w)	62.5%	24.0%	<0.001	60.8%	26.6%	<0.001
Change in Patient Global (0 to 48w)	Mean (SD) -3.54 (2.77)	-1.81 (2.61)	<0.001	-3.73 (2.85)	-1.80 (2.53)	<0.001
Median	-4.00	-1.00	<0.001	-4.00	-1.00	<0.001
[Min. Max]	[-10.0, 6.00]	[3.00]		[-10.0, 6.00]	[3.00]	
Missing	0 (0%)	18 (17.3%)		0 (0%)	18 (16.5%)	
Change in BASDAI (0 to 48w)	Mean (SD) -2.79 (2.09)	-1.42 (2.04)	<0.001	-2.95 (2.17)	-1.40 (1.96)	<0.001
Median	-2.60	-1.25	<0.001	-3.00	-1.20	<0.001
[Min. Max]	[-8.90, 1.40]	[3.00]		[-8.90, 1.40]	[3.00]	
Missing	0 (0%)	18 (17.3%)		0 (0%)	18 (16.5%)	

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POS0672

RHEUMATOLOGISTS OVERCALL SACROILIITIS ON X-RAY AND MRI IN AXIAL SPONDYLOARTHRITIS PATIENTS: DATA FROM THE BELGIAN INFLAMMATORY ARTHRITIS AND SPONDYLITIS COHORT (BE-GIANT)

Keywords: Imaging

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Background: Imaging of the sacroiliac joints, especially with magnetic resonance imaging (MRI), is an important tool for early diagnosis of axial spondyloarthritis (axSpA). Interpretation of sacroiliac joint imaging can vary according to readers' experience, but it is currently unknown if and how imaging assessment differs between academic hospitals and community based rheumatological care.

Objectives: To investigate (1) agreement between local and central reading of sacroiliac joint images (X-ray and MRI) from axSpA patients, and (2) to explore potential differences between patients diagnosed in an academic hospital compared to community centres.

Methods: The Belgian Inflammatory Arthritis and spondylitis cohort (Be-GI-ANT) includes newly diagnosed biological-naïve axSpA patients, that fulfil the ASAS classification criteria, at the outpatient clinic of an academic hospital and eight community centres in Flanders. X-ray and MRI of the sacroiliac joints (SIJ) of patients enrolled between November 2010 and August 2020 were assessed by the local rheumatologist ('local reading') and two calibrated central readers ('central reading') for definite radiographic sacroiliitis according to the modified New York criteria (X-SIJ) and active sacroiliitis according to the ASAS/OMERACT definition of a positive MRI (MRI-SIJ). Central readers resolved discrepant cases by consensus. Inter-reader reliability was assessed with Cohen's Kappa, and % overall, positive and negative agreement.

Results: Among the 271 included patients (n=205 academic hospital, n=66 community hospital), 231 X-SIJ and 208 MRI-SIJ were available for central reading (Table 1). Central readers disagreed with local readers on 30/231 (13%) X-SIJ images ($\kappa=0.44$, moderate); 4/231 (1.7%) were reclassified as radiographic sacroiliitis and 26/231 (11.3%) as not showing radiographic sacroiliitis. Overall agreement was higher between central readers and academic rheumatologists

compared to community rheumatologists (90.5% vs. 70.7%, $p < 0.001$). 53/208 (25.4%) MRI-SIJ images were reclassified by central readers ($\kappa = 0.36$, fair); the majority as negative for active sacroiliitis (51/208, 24.5%). Central readers agreed on the assessment of MRI-SIJ in a higher proportion with academic rheumatologists versus community rheumatologists (77.2% vs. 63.4%, $p = 0.07$).

Conclusion: In newly diagnosed axSpA patients, the prevalence of radiographic sacroiliitis is low. Sacroiliitis on MRI is overcalled by rheumatologists both in academic and non-academic settings, underscoring the need for continuous educational trainings.

Table 1. Agreement between local and central readers on X-SIJ and MRI-SIJ of axSpA patients in academic and community centers.

	All axSpA patients		Academic hospital		Community centres	
	Local reading	Central reading	Local reading	Central reading	Local reading	Central reading
X-SIJ (N=231)						
X-SIJ +	41 (18%)	19 (8%)	30 (16%)	14 (7%)	11 (27%)	5 (12%)
X-SIJ -	190 (82%)	212 (92%)	160 (84%)	176 (93%)	30 (73%)	36 (88%)
Overall agreement	87.0%		90.5%		70.7%	
Positive agreement	50.0%		59.1%		25.0%	
Negative agreement	92.5%		94.6%		81.8%	
Kappa (95% CI)	0.44 (0.28 – 0.60)		0.55 (0.37 – 0.72)		0.10 (-0.20, 0.40)	
MRI-SIJ (N=208)						
MRI-SIJ +	181 (87%)	132 (63%)	151 (90%)	115 (69%)	30 (73%)	17 (41%)
MRI-SIJ -	27 (13%)	76 (37%)	16 (10%)	52 (31%)	11 (27%)	24 (59%)
Overall agreement	74.5%		77.2%		63.4%	
Positive agreement	83.1%		85.7%		68.1%	
Negative agreement	48.5%		44.1%		57.1%	
Kappa (95% CI)	0.36 (0.25 – 0.48)		0.35 (0.20 – 0.49)		0.32 (0.10 – 0.55)	

REFERENCES: NIL.

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POS0673 ARE PATIENTS WITH AXIAL SPONDYLOARTHRITIS WHO WERE BREASTFED LESS PRONE TO MORE ACTIVE AND SEVERE DISEASE?

Keywords: Spondyloarthritis

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Background: Breast milk is the first source of microorganisms that colonize the gastrointestinal tract and a key factor in shaping the intestinal microbiome. It is currently believed that alterations in the intestinal microbiota are key in the pathogenesis of spondyloarthritis (SpA). It has been postulated that breastfeeding could reduce the risk of ankylosing spondylitis, although this claim needs further support [1].

Objectives: To analyze the potential effect of having received breastfeeding on activity and other disease outcomes in patients with axial SpA (axSpA).

Methods: Retrospective longitudinal study of 105 consecutive patients with axSpA. Only patients with reliable information about a history of breastfeeding were included. The following disease outcomes were collected: BASDAI, ASDAS-CRP, BASFI, structural damage (syndesmophytes), and ASAS-HI. The group was divided according to the history or not of breastfeeding, as well as its duration. Both groups were compared by univariate and multivariate regression methods.

Results: Forty-six women and 59 men were included, mean age 43.3 ± 12.5 years, mean age at diagnosis 34.3 ± 10.9 years. Fifty-eight percent had been breastfed for a mean of 5.5 ± 4.6 months, while 42% had not received breast milk. The main characteristics of both groups are shown in Table 1. In the raw estimate, all disease outcomes analyzed were significantly better in patients who had been breastfed. Regardless of sex, disease duration, family history, HLA-B27, use of biologics, obesity, and smoking, patients who were breastfed had a mean 1.13 points less (95% CI: -2.04, -0.23) in the estimate of BASDAI, $p < 0.05$, and an average of 0.38 points less (95% CI: -0.72, -0.04) in the ASDAS estimate, $p < 0.05$. After these same adjustments, no association was found between BASFI or structural damage and lactation. Regarding ASAS HI, breastfeeding was associated with a lower impact of the disease with 1.43 points less on average (95% CI: -2.98, 0.11), although the significance was borderline, $p = 0.06$. Breastfed patients were associated with less severe disease, severity being understood as a sustained combined outcome of BASDAI > 4 and/or ASDAS $> 2.1 + \text{ASAS-HI} > 5 + \text{BASFI} > 4$ [OR 0.22 (95% CI 0.08-0.57), $p < 0.01$].

Conclusion: This study points to a potential benefit of breastfeeding on certain disease outcomes (activity and disease impact) in patients with axSpA. This

potential beneficial effect of breastfeeding should be confirmed with larger and prospective studies.

REFERENCE:

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Table 1. Characteristics of the study population based on breastfeeding.

	Breastfeeding: no N=44	Breastfeeding: yes N=61
Age, years (mean \pm SD)	44.4 (11.7)	42.5 (13.1)
Male	56.8%	55.7%
Radiographic axSpA	75%	49.2%
Non-radiographic axSpA	13.6%	32.8%
Mixed forms	6.8%	6.6%
HLA-B27	79.5%	70.5%
Age at diagnosis, years (mean \pm SD)	34.8 (10.8)	33.9 (11)
Family history	45.5%	32.8%
Smoking	50%	27.9%
Obesity	15.9%	11.5%
Uveitis	18.2%	18%
IBD	13.6%	6.6%
BASDAI (mean \pm SD)	4.41 (2.24)	3.06 (2.53)
ASDAS (mean \pm SD)	2.31 (0.8)	1.84 (0.9)
ASAS HI (mean \pm SD)	6.3 (4.2)	4.3 (4.1)
BASFI (mean \pm SD)	3.2 (2.2)	2.4 (2.5)
Syndesmophytes (% of patients)	27.3%	19.7%
NSAIDs	81.8%	78.7%
Biologics	56.8%	60.7%

IBD: inflammatory bowel disease. The other acronyms and abbreviations as usual.

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POS0674 RENAL SAFETY OF LONG TERM NSAID USE IN PATIENTS WITH ANKYLOSING SPONDYLITIS

Keywords: Spondyloarthritis

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Background: Nonsteroidal anti-inflammatory drugs (NSAIDs) are the basis of treatment for patients with ankylosing spondylitis (AS) to reduce pain and inflammation. However, long-term NSAID use may cause deterioration of renal function.

Objectives: We aimed to investigate the renal safety from long-term NSAID exposure in patients with AS.

Methods: We extracted clinical information from the electronic medical records of patients with newly diagnosed AS with an observation period of more than one year who were treated at Asan Medical Center from January 1, 2000, to December 31, 2020, excluding patients with chronic kidney disease Stage 4–5, known kidney disease, and malignancy. Renal function was determined by calculation of the estimated glomerular filtration rate (GFR) using the Modification of Diet in Renal Disease (MDRD) and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equations. Patients were stratified into three groups according to initial GFR: Stage 1 (GFR ≥ 90), Stage 2 ($60 \leq \text{GFR} < 90$), and Stage 3 ($30 \leq \text{GFR} < 60$). The GFR values for every 3-year interval were imputed by the linear interpolation method using the measured values before and after each point, and NSAID use in each interval was estimated as the medication possession rate (MPR). To evaluate the association between NSAID use and annual changes in GFR, linear mixed effects models were used and adjusted for key covariates including age, sex, body mass index, baseline GFR, relative dosage of NSAIDs, comorbidities, and comedications.

Results: Among 1,838 patients with AS, the mean age was 38.0 (SD, 13.8) years with a median 6.1 years of follow-up. The majority of 1,386 (75.4%) patients belonged to the Stage 1 group, and the number of patients in the Stage 2 and Stage 3 groups was 442 (24.0%) and 10 (0.5%), respectively. In the multivariable models, the mean annual decrease in GFR was significant (model 1: $\beta = -0.684$, 95% CI -0.980 to -0.389, $p < 0.001$; model 2: $\beta = -0.387$, 95% CI -0.770 to -0.004, $p = 0.048$), and the MPR of NSAID use was significantly associated with an additional decrease in GFR (model 1: for 100% vs. 0% of MPR, $\beta = -0.5$, 95% CI, -0.8 to -0.1, $p = 0.008$; model 2: for highest vs. lowest tertile of MPR, $\beta = -0.519$, 95% CI -0.906 to -0.132, $p = 0.009$) in the Stage 1 group but not in patients in the Stage 2 group (Table 1).