the heel is common and occasionally is responsible for their initial symptom to seek clinics. An early or timely recognition of active enthesitis of AS from simple radiographs comes to be relevant issue.

Objectives: The purpose of current study is to assess measurement reliability and diagnostic validity for detecting the digital radiographic findings of enthesitis at the Achilles tendon insertion in patients with AS.

Methods: Current study is a blinded, matched, cross-sectional study with 44 patients (65 feet) having clinical enthesitis at the Achilles tendon insertion (Group I), and 44 healthy controls (65 feet) (Group II). Suggested findings of enthesitis including retrocalcaneal recess obliterations from retrocalcaneal bursitis, increased thickness in shadow of the Achilles tendon and posterior soft tissue at its insertion from the swellings of those soft tissues were assessed on digital radiographs of standing hindfoot lateral view, and their measurement reliabilities were determined. To investigate diagnostic validities, diagnostic odds ratio, sensitivity, specificity, positive likelihood ratio (PLR), and negative likelihood ratio (NLR) were estimated for radiographic findings of retrocalcaneal recess obliterations (RRO). For the thickness of the Achilles at its insertion (TAI) and swollen posterior soft tissue, the receiver operating characteristic (ROC) curve analysis was done.

Results: There were no significant differences between two groups in mean age, BMI and sex ratio. Intra- and inter-observer reliability of all measurements showed high degree of agreements (0.786 to 0.941). The diagnostic odds ratio of RRO for detecting enthesitis was 66.0. The sensitivity, specificity were 67.7%, 96.9%, and PLR, NLR were 22.0, 0.33, respectively. The mean TAI of Group I and II were 6.7mm±1.79, 5.01mm±0.81, respectively (p-value$<$0.001). Area under the ROC curve of the TAI was 0.806, and the optimal cut-off value predicting enthesitis was 5.47mm, and its sensitivity and specificity were both 72.3%.

Conclusions: Retrocalcaneal recess obliteration and thickened shadow of Achilles tendon at its insertion and swollen posterior soft tissue on digital radiographs of standing hindfoot lateral view are regarded as the easy and useful findings for enthesitis of the posterior heel. For searching enthesitis at the Achilles insertion in patients with AS, such findings from simple radiographs showed high measurement reliability and validity.

References:

[1] Resnick D, Feingold ML, Curd J, Niwayama G, Goergen TG. Calcaneal abnormalities in articular disorders. Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and Reiter syndrome. Radiology 1977;125:355–66.
[2] Freedman M, Steller D. Digital radiography of the musculoskeletal system: the optimal image. Journal of digital imaging 1995;8:37–42.
[3] Rudwaleit M, Khan MA, Sieper J. The challenge of diagnosis and classification in early ankylosing spondylitis: do we need new criteria? Arthritis and rheumatism 2005;52(4):1000–1008.

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FRI0443 THE EFFECT OF FIBROMYALGIA ON DISEASE ACTIVITY IN PATIENTS WITH ANKYLOSING SPONDYLITIS

I. Shapoval, M. Stanislavchuk, K. Zaichko, L. Perebetiuk. *Internal Medicine, National Pirogov Memorial Medical University, Vinnytsya, Ukraine*

Background: Ankylosing spondylitis (AS) is a chronic inflammatory rheumatic disease that affects the axial skeleton and characterized by pain, stiffness and fatigue [4]. One of the frequent concomitant condition in patients with AS is fibromyalgia (FM). FM shares some common symptoms with AS. According to the many reports concomitant FM in patients with AS has been found in 5.7 - 41.3% cases [1, 2, 3, 5]. Due to the fact that pain is a major component of the disease activity scores of the AS (Ankylosing Spondylitis Disease Activity Index (BASDAI) and Ankylosing Spondylitis Disease Activity Score (ASDAS)), concomitant FM can significantly modify the disease activity in patients with AS.

Objectives: The aim of this study was to evaluate the effect of FM on disease activity in patients with AS.

Methods: Diagnosis of AS was identified according to the modified New York criteria (1984). FM was diagnosed by ACR criteria (1990). Disease activity was assessed by BASDAI and ASDAS.

Results: 80 patients with AS were included into study (15 females and 65 males), age (M ± SD) 41.64±11.4 years. Nineteen patients (23.8%) met the criteria for FM. Patients with AS and AS+FM were representative for age and disease duration. In both groups, ESR (37.7±18.8 and 39.00±19.6 mm/h) was comparable, while ASDAS and BASDAI were significantly different. The disease activity according to both scores was higher in patients with AS+FM. According to the BASDAI in patients with AS disease activity was 5.20±1.4 whereas in patients with AS and FM - 7.14±1.7; according to the ASDAS-ESR difference in disease activity was slightly lower, but remained significant (3.6±0.8 vs 4.2±0.9).

Conclusions: The obtained data indicates that concomitant FM is a frequent condition in patients with AS. Presence of FM in patients with AS significantly modifies the disease activity determined by ASDAS. The ASDAS-ESR is more appropriate for determining the disease activity comparing to BASDAI, because included in calculation ESR diminish the distorting effect of FM.

References:

[1] Fibromyalgia in patients with axial spondyloarthritis: epidemiological profile and effect on measures of disease activity/Fausto Salaffi, Rossella De Angelis, Marina Carottiet al. Rheumatology International 2014;1103–1110.
[2] Occurrence of fibromyalgia in patients with ankylosing spondylitis. /ValderilioFeijó Azevedo, Eduardo dos Santos Paiva, Lúcio Ricardo HiurkoFelippe, Ranieri Amorim Moreira. Bras J Rheumatol 2010;50:646–654.
[3] Ankylosing spondylitis functional and activity indices in clinical practice. Popescu C, Trandafir M, Bădică AM et al. Journal of Medicine and Life 2014:78–83.
[4] Global prevalence of ankylosing spondylitis. Linda E. Dean, Gareth T. Jones, Alan G. MacDonald et al. Rheumatology 2014;53:650–657.
[5] Prevalence of fibromyalgia in patients with ankylosing spondylitis Medical Journal of Dr. D.Y. Patil University 2014:338–341.

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FRI0444 INCIDENCE OF INFLAMMATORY BOWEL DISEASE EVENTS IN ADALIMUMAB CLINICAL TRIALS ACROSS INDICATIONS

J.R. Curtis[1], D. Elewaut[2], S. Chen[3], M. Hojnik[4], N. Naveh[5], J.K. Anderson[3]. *[1]Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham, Birmingham, United States; [2]VIB Inflammation Research Center, University of Gent, Gent, Belgium; [3]AbbVie Inc., North Chicago, United States; [4]AbbVie, Ljubljana, Slovenia; [5]AbbVie, Hod HaSharon, Israel*

Background: Adalimumab (ADA) is approved for treatment of Crohn's disease (CD) and ulcerative colitis (UC); therefore, it is postulated that new onset or flare of inflammatory bowel disease (IBD) is a rare occurrence in ADA clinical trials for non-IBD indications.

Objectives: The purpose of this analysis was to determine the rates of IBD adverse events (AEs) in ADA clinical trials, particularly in spondyloarthritis (SpA) patients (pts) who are at higher risk of IBD as a feature of SpA.

Methods: The rates of IBD AEs in 73 phase 2–4 interventional ADA clinical trials in rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), pediatric enthesitis-related arthritis, uveitis (non-infectious intermediate, posterior, or pan-uveitis), hidradenitis suppurativa (HS), adult and pediatric psoriasis (Ps), psoriatic arthritis (PsA), non-PsA peripheral SpA (pSpA), non-radiographic axial spondyloarthritis (nr-axSpA), and ankylosing spondylitis (AS) were analyzed (trials in UC, CD, and intestinal Behcet's disease [BD] were excluded). The search criteria for IBD events included the following standardized MedDRA queries preferred terms: inflammatory bowel disease (IBD), ulcerative colitis (UC), Crohn's disease (CD), IBD-not otherwise specified (NOS), and ulcerative proctitis. The incidence rates (IR) for events of IBD (combined new onset and flare) in interventional clinical trials of ADA are reported as events per 100 pt-years (PY). 95% confidence intervals (CI) were based on exact Poisson confidence limits.

Results: ADA was administered to 23735 pts, representing 36404.6 PY of exposure. Overall, the IR for IBD events in all interventional ADA trials included in this analysis was 0.1/100PY (Table). The rates of IBD events varied across therapeutic indications from $<$0.1 to 0.8/100PY. There were no reports of IBD events in pediatric pts. The IR for IBD events in RA, uveitis, HS, and Ps trials were $<$0.1, 0.2, 0.4, and $<$0.1/100 PY. In SpA, the overall rates of IBD were 0.5/100 PY, while the rates were 0, 0.8, 0.5, and 0.7/100 PY in PsA, non-PsA pSpA, nr-axSpA, and AS, respectively. 2216 pts with axSpA (AS: 2026, nr-axSpA: 190) were exposed to ADA; in AS, 14 IBD events (7 new onset and 7 flares) were reported in 12 pts (7 new onset and 5 flares), while in nr-axSpA, 2 IBD events were reported in 1 pt (2 flares).

Table. Incidence of IBD events in patients from ADA clinical trials.

Indication	N (PYs)	All IBD AEs, n[§]	IR/100 PY (95% CI)
All ADA trials[†]	23735 (36404.6)	40	0.1 (0.1 – 0.2)
Rheumatoid Arthritis	15152 (24813.0)	16	<0.1 (0.0 – 0.1)
Uveitis	387 (538.8)	1	0.2 (0.0 – 1.0)
Hidradenitis suppurativa	733 (836.3)	3	0.4 (0.1 – 1.1)
Psoriasis	3500 (5268.7)	1	<0.1 (0.0 – 0.1)
All SpA[‡]	3218 (3919.9)	19	0.5 (0.3 – 0.8)
PsA	837 (997.5)	0	0.0 (0.0 – 0.4)
Non-PsA pSpA	165 (390.7)	3	0.8 (0.2 – 2.2)
All axSpA[?]	2216 (2531.7)	16	0.6 (0.4 – 1.0)
nr-axSpA	190 (412.2)	2	0.5 (0.1 – 1.8)
AS	2026 (2119.5)	14	0.7 (0.4 – 1.1)

[§]No IBD events were reported in pediatric patients.
[†]All ADA adult and pediatric patients in all interventional studies excluding Crohn's disease, ulcerative colitis, and intestinal Behcet's disease.
[‡]All ADA patients in all interventional studies of PsA, non -PsA pSpA, nr-axSpA, and AS.
[?]All ADA patients in all interventional studies of nr -axSpA and AS.
Abbreviations: IBD = inflammatory bowel disease; ADA = adalimumab; PY = patient years; AEs = adverse events; IR = incidence rates; CI = confidence interval; SpA = spondyloarthritis; PsA = psoriatic arthritis; pSpA = non-PsA peripheral spondyloarthritis; axSpA = axial spondyloarthritis; nr-axSpA = non-radiographic axSpA; AS = ankylosing spondylitis.

Conclusions: The rates of IBD AEs in ADA clinical trials were generally low across all indications, with all events occurring in adult pts. In AS pts, who are at increased risk of manifesting IBD, the rates of IBD for pts treated with ADA (0.7/100 PY [95% CI, 0.4–1.1]) were similar to published placebo rates pooled

across multiple clinical trials (1.3/100 PY [95% CI, 0.2–4.8]).[1] In pts at risk for IBD requiring biologic therapy, ADA is a reasonable therapeutic option based on the observed low IBD event rates in ADA clinical trials and its demonstrated efficacy in treating UC and CD pts.

References:
[1] Braun, J. et al., Arthritis & Rheum, 2007; 57:639–47.

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FRI0445 FAECAL CALPROTECTIN, BUT NOT ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES, IS LINKED TO WORSE DISEASE STATUS IN AXIAL SPONDYLOARTHRITIS PATIENTS WITHOUT INFLAMMATORY BOWEL DISEASE: RESULTS FROM THE SPARTAKUS COHORT

T. Olofsson[1], E. Mogard[1], K. Andréasson[1], J. Marsal[2], M. Geijer[3], L.-E. Kristensen[1,4], E. Lindqvist[1], J.K. Wallman[1]. *[1]Department of clinical sciences Lund, Rheumatology; [2]Department of clinical sciences Lund, Gastroenterology, Lund University, Lund; [3]Department of Radiology, Faculty of Medicine and Health, Örebro University, Örebro, Sweden; [4]The Parker Institute, Department of Rheumatology, Copenhagen University Hospital, Frederiksberg and Bispebjerg, Copenhagen, Denmark*

Background: Inflammatory bowel disease (IBD) is a common comorbidity in axial spondyloarthritis.
Objectives: To study faecal calprotectin (F-calprotectin) levels and anti-*Saccharomyces cerevisiae* antibodies (ASCA) and their associations with disease status and gastrointestinal (GI) symptoms in axial spondyloarthritis.
Methods: Consecutive patients with a clinical axial spondyloarthritis diagnosis were examined and classified as non-radiographic axial spondyloarthritis (nr-axSpA; Assessment of SpondyloArthritis international Society [ASAS] criteria; n=26) or ankylosing spondylitis (AS; modified New York criteria; n=45). Only patients without known IBD were included. F-calprotectin and ASCA IgA and IgG antibodies in serum were measured by commercially available enzyme-linked immunosorbent assay kits (Calpro AS; ORGENTEC Diagnostika).
Results: Elevated levels of F-calprotectin (≥50 mg/kg) were observed in 15% of nr-axSpA and 40% of AS patients (non-significant difference, with reservation for small groups). Overall, worse mean disease activity/disability scores were observed among patients with elevated versus normal F-calprotectin levels (Table), whereas no association was seen between F-calprotectin and GI symptoms. Similar results remained after exclusion of patients with monoclonal antibody type anti-TNF therapy. Elevated levels of ASCA IgA were observed in 8%/2% of nr-axSpA/AS patients, and IgG in 28%/26%. Only 2 subjects were ASCA double positive. Neither disease activity/disability measures nor GI symptoms were associated with ASCA status.

	Nr-axSpA (n=26)	AS (n=45)	F-Calprotectin <50 mg/kg (n=38)	F-Calprotectin ≥50 mg/kg (n=18)	p-value*
Male sex	10 (39%)	26 (59%)	16 (42%)	10 (56%)	0.346
Age, years	45 (10)	58 (13)	54 (13)	55 (14)	0.847
Disease duration, years	18 (10)	32 (14)	26 (14)	31 (15)	0.339
HLA-B27 positive, y/n	24 (92%)	38 (86%)	32 (84%)	17 (100%)	0.083
ASAS 3m NSAID score	25 (37)	31 (36)	21 (33)	37 (40)	0.221
Antibody anti-TNF, y/n	10 (39%)	12 (27%)	14 (36%)	4 (22%)	0.274
VAS global	41 (21)	35 (25)	32 (25)	45 (16)	0.023
VAS pain	40 (23)	37 (28)	34 (26)	42 (23)	0.142
VAS fatigue	41 (28)	39 (27)	34 (28)	46 (21)	0.056
BASDAI	3.5 (1.7)	3.5 (2.6)	3.1 (2.3)	4.2 (2.3)	0.076
BASFI	1.9 (1.4)	3.0 (2.9)	2.2 (2.2)	3.9 (3.1)	0.029
ASDAS-CRP	2.0 (0.8)	2.2 (1.1)	1.8 (0.9)	2.6 (0.9)	0.034
CRP, mg/L	3.1 (3.0)	4.7 (4.6)	3.0 (2.7)	5.7 (5.5)	0.157
F-calprotectin, mg/kg	45 (64)	84 (117)	21 (13)	172 (129)	NA
ASCA IgA, E/ml	3.7 (7.3)	2.1 (1.9)	2.9 (5.8)	3.0 (3.8)	0.175
ASCA IgG, E/ml	10 (20)	6.5 (6.3)	6.9 (6.8)	11 (24)	0.854
Often stomach pain, y/n	17 (65%)	25 (56%)	23 (61%)	11 (61%)	0.967
Frequent defecation, y/n	7 (27%)	9 (20%)	9 (24%)	5 (28%)	0.741
Frequent diarrhoea, y/n	12 (46%)	12 (27%)	12 (32%)	8 (44%)	0.348

N (%) or mean (SD). *Chi^2/Mann-Whitney U-test for comparison of categorical/continuous variables between the F-calprotectin groups. Missing data: ASCA IgA/IgG 4%, F-calprotectin 21%. y/n, yes/no; 3m, 3 months; NA, not applicable.

Conclusions: Elevated levels of F-calprotectin and ASCA IgG antibodies are both common in axial spondyloarthritis patients without IBD, and elevated F-calprotectin may be a marker of more severe spondyloarthritis. Neither F-calprotectin nor ASCA levels were associated with self-reported GI symptoms.

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FRI0446 PREVALENCE AND CHARACTERISTICS OF SPONDYLOARTHRITIS ACCORDING TO ASAS CRITERIA IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE – RESULTS FROM THE SPICE COHORT

J. Haschka[1,2], S. Hirschmann[3], A. Kleyer[1], M. Englbrecht[1], J. Zimmermann[1], F. Faustini[1], D. Simon[1], C.P. Figueiredo[1], A. Cavallaro[1,4], C. Muschitz[2], R. Kocijan[2], H. Resch[2], R. Atreya[3], J. Rech[1], M.F. Neurath[3], G. Schett[1]. *[1]Department of Internal Medicine 3, University of Erlangen-Nuremberg, Erlangen, Germany; [2]Medical Department 2, St. Vincent Hospital, The VINFORCE Study Group, Vienna, Austria; [3]Department of Internal Medicine 1, University of Erlangen-Nuremberg, Erlangen, Germany; [4]Div. of Rheumatology, Faculdade de Medicina da Universidade de São Paulo, São Paulo, Brazil*

Background: Musculoskeletal symptoms are considered as one of the most frequent extra-intestinal manifestation in Inflammatory Bowel Disease (IBD) patients with a prevalence of up to 40% involving axial and/or peripheral joints. Data on the prevalence of musculoskeletal disease, in particular of SpA are limited and vary considerably due to different criteria the studies have used to define musculoskeletal disease in IBD patients.
Objectives: To define the prevalence of axial and peripheral spondyloarthritis (SpA) according to Assessment of Spondyloarthritis International Society (ASAS) in patients with Crohn's disease (CD) and ulcerative colitis (UC).
Methods: The SPICE cohort (Spondyloarthritis in Inflammatory Bowel Disease Cohort Erlangen) comprises prospectively recruited colonoscopy- proven Crohn's Disease (CD) or Ulcerative Colitis (UC) patients, who received a pre-defined and standardized musculoskeletal assessment by the rheumatologist. Duration and activity of gastrointestinal and rheumatic disease (axial and peripheral) was documented and fulfillment of ASAS classification criteria for axial and peripheral SpA was tested.
Results: 102 IBD patients (62 with CD and 40 with UC) with a median (IQR) disease of 11.0 (18.0) years were assessed. 38.2% fulfilled ASAS criteria for SpA with no difference between CD and UC. ASAS axial SpA criteria were fulfilled by 12%, ASAS peripheral SpA criteria by 31.4% of the IBD patients. Inflammatory back pain was present in 24.5% with MRI signs of sacroiliitis in 48% of IBD patients with inflammatory back pain. Disease activity according to ASDAS-CRP was moderate to high in 91% of the patients with axial SpA. Peripheral arthralgia was present in 71.6%, while arthritis was found in 18.6% of the IBD patients.
Conclusions: Both major forms of IBD show a similar burden of musculoskeletal disease. More than one third of inflammatory bowel disease patients show axial or peripheral SpA according to ASAS criteria. Peripheral SpA is more commonly found than axial SpA.

References:
[1] Harbord M, Annese V, Vavricka SR, et al. The first European evidence-based consensus on extra-intestinal manifestations in inflammatory bowel disease. J Crohn Colitis 2016; 239–254.
[2] Karreman MC, Luime JJ, Hazes JMW, Weel AEAM. The prevalence and incidence of axial and peripheral spondyloarthritis in inflammatory bowel disease: a systematic literature review and meta-analysis. J Crohn Colitis 2016; 1–12.

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FRI0447 SEVERITY OF SACROILIITIS AND ERYTHROCYTE SEDIMENTATION RATE ARE ASSOCIATED WITH A LOW TRABECULAR BONE SCORE IN YOUNG MALE PATIENTS WITH ANKYLOSING SPONDYLITIS

K.Y. Kang. *Division of Rheumatology, Internal Medicine, Catholic University of Korea, Seoul, Korea, Republic Of*

Background: The trabecular bone score (TBS) is a novel method used to evaluate bone microarchitecture. To date, the risk factors associated with a low TBS in AS are unknown and no study has examined the association between TBS and vertebral fracture in ankylosing spondylitis (AS) patients.
Objectives: To examine factors related to a low trabecular bone score (TBS) and the association between TBS and vertebral fracture in patients with (AS).
Methods: One hundred patients (all male, aged <50 years) who fulfilled the modified New York criteria for the classification of AS were enrolled. The TBS and bone mineral density (BMD) were assessed using dual-energy X-ray absorptiometry (DXA). Clinical variables, inflammatory markers, and the presence of vertebral fracture were also assessed. Spinal radiographic progression was measured using the Stokes AS spine score (SASSS). Multivariate linear regression analysis was performed to identify factors associated with TBS.