Index (BASMI), pain visual analog scale, Beck depression scale, Beck anxiety scale, Barrat impulsiveness scale, Toronto alexithymia scale, Eating attitude test, fatigue, Ankylosing spondylitis quality of life, and Nothingam health profile were administered.

Results: The frequency of depression, anxiety and non planning impulsiveness were higher in patients with AS than in healthy controls ($p<0.05$), although no difference was found in terms of alexithymia, fatigue, and eating attitude. Depression and anxiety were correlated with high disease activity, fatigue, impaired physical functioning, and lower quality of life in the patients with AS. Non planning impulsiveness was correlated with fatigue and lower quality of life while there was no correlation with disease activity and functional impairment. BASMI scores were not associated with psychiatric disorders.

Table 1. Demographic characteristics and Psychiatric disorders in Ankylosing spondylitis and healthy controls

	Ankylosing spondylitis patients (n=70)	Healthy controls (n=56)	p
Age (year)	42.85±10.46	44.75±10.04	0.363
Male (%)	57.14%	51.78%	0.548
Beck depression score	13.88±8.99	9.78±8.34	0.006*
Beck anxiety score	14.58±10.02	10.53±8.99	0.014*
Barrat impulsiveness - attentional score	15.68±3.25	15.21±2.72	0.590
Barrat impulsiveness - motor score	19.62±4.28	18.92±4.23	0.301
Barrat impulsiveness - non planning score	26.00±4.57	24.78±3.77	0.021*
Toronto alexithymia score	54.84±12.86	54.32±11.12	0.644
Eating attitude score	21.74±11.18	22.01±13.24	0.488

*$P<0.05$.

Conclusions: Depression and anxiety were associated with disease activation, while impulsivity frequency was increased independently of disease activity. Reducing in the quality of life and functional competence due to the psychiatric disorders indicates that, AS patients may require a psychological care approach during the follow up.

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FRI0440 PRESENCE OF BONE MARROW EDEMA ON MAGNETIC RESONANCE IMAGING OF THE SACROILIAC JOINTS IN MILITARY RECRUITS BEFORE AND AFTER 6 WEEKS OF INTENSIVE PHYSICAL TRAINING

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Background: Studies have shown an increase of bone marrow edema (BME) on magnetic resonance imaging (MRI), especially in feet and ankles of professional athletes and in minimally active healthy controls after mechanical stress [1]. Although this has been described for several joints and across different sport activities, information concerning BME in the sacroiliac joints (SIJ) has not been studied. In axial spondyloarthritis (AxSpA), the presence of 1 BME lesion (characteristics typical for AxSpA) on 2 consecutive slices or 2 BME lesions on 1 slice is sufficient to fulfill the definition of a positive MRI as defined by ASAS. Although this definition should only be applied on MRI of symptomatic patients with suspicion of SpA, it is unknown whether BME lesions in healthy controls could meet this definition and therefore incorrectly be interpreted as BME in the context of SpA.

Objectives: Study the effect of intense physical training in healthy subjects on the presence of BME on MRI-SIJ, by investigating whether healthy subjects meet the ASAS definition of a positive MRI and whether this is modulated by mechanical stress.

Methods: Twenty-two military recruits underwent a MRI-SIJ before and after 6 week of intense and uniform physical training. BME lesions were scored by 3 trained readers (MdH, GV and TR) blinded for time sequence and clinical findings. Additionally, the agreement with the definition of a positive MRI defined by ASAS was evaluated. Regarding the number of lesions and fulfillment of the ASAS definition of positive MRI, a consensus was made by agreement of 2 out of 3 readers.

Results: In total, 86.4% (19/22) asymptomatic recruits were male (mean age of 25.0±0.8 years). At baseline, 40.9% (9/22) of recruits presented with at least one BME lesion, whereas this number increased to 50.0% (11/22) at week 6. Indeed, 3 recruits developed BME over time, whereas in one recruit the BME lesions disappeared over time. The mean number of BME lesions was 1.0 (±0.3) at baseline, compared to 1.9 (±0.7) at week 6. Median (25th, 75th percentile) BME lesions were 0.0 (0.0, 2.25) and 0.5 (0.0, 3.0) at respectively baseline and week 6 (P=0.109). Mean change in BME lesions was 0.9 (±0.6). When applying the ASAS definition of a positive MRI, BME was present in 22.7% (5/22) of recruits at baseline, and this increased to 36.4% at follow up, of which an additional 4 initially MRI negative recruits became MRI positive and one recruit no longer fulfilled the definition.

Conclusions: In this small exploratory study we could not find a statistically significant difference in BME on MRI-SIJ after 6 weeks of training. However, over 1/5 of asymptomatic recruits displayed BME lesions, that would meet the ASAS definition of a positive MRI, increasing to more than 1/3 at follow up. Thus, in young active patients, the interpretation of BME lesions should be cautious.

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FRI0441 NECK PAIN IN ANKYLOSING SPONDYLITIS: FOCUS ON ACTIVE INFLAMMATION AT THE CRANIOCERVICAL JUNCTION ON MRI

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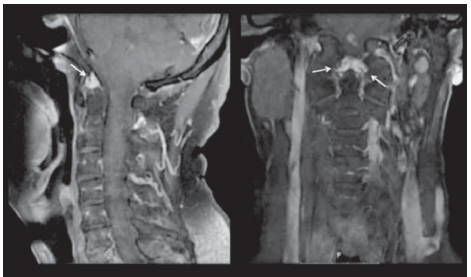
Background: A wide spectrum of structural changes in the elements of craniocervical junction in patients with ankylosing spondylitis (AS) has been recently described in a retrospective study using computed tomography [1]. The clinical significance of these findings requires further elaboration.

Objectives: To explore and describe inflammatory MR imaging findings in the craniocervical junction in patients with AS and neck pain.

Methods: Eighteen patients with AS and continuing neck pain, as well as 9 patients with fibromyalgia of the same age and similar level of severity of neck pain, who served as a control group, underwent relevant rheumatologic examination, X-ray of cervical spine and MRI study, which included STIR, CUBE T2, FSE and FSE FAT SAT sequences before and after administration of gadolinium.

Results: In the AS group, 12 males and 6 females diagnosed by 1984 New York criteria, of median age 40.5 years (range 31–61 years) and median disease duration of 8 (range 1–35) years, with 13 under treatment with anti-TNF agents were studied. All patients suffered from neck pain, with median VAS of 7 (range 2.5–10). Range of neck spine motion was limited in all but 3 patients. Seven of 18 patients had evidence of cervical syndesmophytes on X-ray. In addition to expected findings of syndesmophytes, active inflammatory lesions were seen in MR imaging in two of 18 patients with AS and in none with fibromyalgia (Fig. 1). Both AS patients with positive MRI were on anti-TNF therapy during the study and did not have syndesmophytes at the cervical spine as also by X-ray films.



Sagittal and coronal FSE T1 FAT SAT images after gadolinium injection showing enhancement of apical and alar ligaments

Conclusions: Active inflammation of both entheses and joints of the craniocervical junction was demonstrated by MRI in some patients with AS and persistent neck pain. Active lesions at the craniocervical junction should be included in the differential diagnosis of neck pain in AS.

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FRI0442 IDENTIFICATION OF ENTHESITIS AT THE ACHILLES TENDON INSERTION IN PATIENTS WITH ANKYLOSING SPONDYLITIS USING DIGITAL RADIOGRAPHY

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Background: Posterior heel pain is a common symptom in the foot and ankle region, with many different causes that need to be distinguished by differential diagnosis. Among them is ankylosing spondylitis (AS), in which enthesitis of

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.

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

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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.

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

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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