initial MRI edema score and the level of serum CK ($p=0.028$). However, no correlation was seen between the level of improvement in MRI ES and drop in CK or with any other clinical parameters after 3 months of treatment. The intensity of muscle edema at baseline was not predictive to improvement of any clinical parameters or CK, with a tendency to a better improvement of muscle disease activity in those who had higher MRI ES at baseline (corr. coeff. 0.445, $p=0.073$).

Conclusion: We proposed a new semi-quantitative scoring system for assessment of MR images in patients with PM and DM. This system was applied to record degree of muscle edema and fatty replacement in a subpopulation of patients treated in the Prometheus study. A significant reduction of MRI ES and no relevant progression of muscle atrophy and fatty replacement after 3 months of therapy was demonstrated. Initial MRI edema score correlated with some clinical and laboratory parameters (PGA, CK) but was not predictive to a degree of improvement during treatment. The results are limited by a small sample size, particularly in the subset with longitudinal MRI. **Acknowledgement:** Supported by the project (Ministry of Health, Czech Republic) for conceptual development of research organization 00023728 (Institute of Rheumatology).

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FRI0643

SPINE AND SACROILIAC JOINTS LESIONS ON MRI IN PATIENTS WITH EARLY AXIAL SPA: CORRELATION WITH CLINICAL AND DISEASE ACTIVITY INDICES IN 24-MONTHS FOLLOW UP (ITALIAN ARM OF SPACE STUDY)

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Background: Recently several studies have focused on the use of magnetic resonance imaging (MRI) that might facilitate early diagnosis and monitor the disease activity of axial spondyloarthritis (axSpA).

Objectives: Evaluate the prevalence of spine and pelvis MRI lesions in patients (pts) with low back pain (LBP) and suspected axSpA; investigate how MRI features evolve over time and relate to radiographic damage; identify the predictive factors for a more severe disease pattern with a higher probability of radiological progression.

Methods: Seventy-five pts with LBP (≥ 3 months, ≤ 2 years, onset ≤ 45 years) underwent a physical examination, questionnaires, laboratory tests, X-rays and MRI of the spine and sacroiliac joints (SIJ) at baseline (T0) and during a follow-up (FU) period of 24 months. Two expert rheumatologists defined axSpA diagnosis and assessed fulfillment of Assessment of SpondyloArthritis International Society ASAS criteria. Disease activity and physical functioning were assessed using: Bath Ankylosing Spondylitis Metrology Index (BASMI); Maastricht Ankylosing enthesitis Spondylitis Score (MASES); Bath Ankylosing Spondylitis Disease Activity Index (BASDAI); Bath Ankylosing Spondylitis Functional Index (BASFI); Ankylosing Spondylitis disease activity score (ASDAS); Visual Analogue Scale (VAS pain); VAS night pain; VAS disease activity; Bath Ankylosing Spondylitis Patient Global Score (BASG1); BASG2; Health Assessment Questionnaire (HAQ); ESR; serum ultrasensitive CRP (hs-CRP). Spine and SIJ MRI and X-

rays were scored independently by 2 readers following the SPARCC, mSASSS and score SIJ-mNY. Pts were classified in accordance ASAS criteria as: 21 pts classified according to axSpA imaging arm; 29 pts classified according to axSpA clinical+imaging arm; 25 pts not fulfilling ASAS criteria. The Kruskal Wallis test was used to compare all indices during FU. A regression analysis was performed to identify the predictors of inflammation and radiological progression of the disease evaluated using mSASSS, score SIJ-mNY, SPARCC-SIJ and SPARCC-spine. The following independent variables were considered in this analysis: female sex, age of LBP onset, duration of LBP, presence of HLA-B27, elevated ESR/CRP, BASDAI > 4 , use of NSAIDs.

Results: The median LBP onset was 28.51 ± 8.05 years, 45.3% were male, HLA-B27 was positive in 38.7% pts; 56% pts showed bone marrow edema (BME) in spine-MRI (19%, 39%, 33% in cervical/thoracic/lumbar region) and 61.3% pts in SIJ-MRI (respectively 58% on the right SIJ and 50% on the left SIJ). Signs of enthesitis were found in 62.7% pts (respectively 8%, 58%, 11% in the cervical/thoracic/lumbar spine). Eighteen (24%) pts presented a negative BME SIJ-MRI with a positive BME spine-MRI. Predictive factors of increased radiological activity were, respectively, for a higher SPARCC-spine score, a higher use of NSAIDs and for a higher SPARCC-SIJ score, the presence of HLA-B27 and increased ESR/CRP. The prevalence of BME lesions on MRI and SPARCC-SIJ decreased during the FU period in the 2 cohorts that met the ASAS criteria for axSpA (Table 1, Figure 1a-b).

Table 1. The prevalence of inflammatory and structural lesions at T0 and 24 months in three cohorts (axSpA imaging arm, axSpA clinical+imaging arm, not full ASAS axSpA).

	axSpA imaging arm	axSpA clinical+imaging arm	not full ASAS axSpA
T0 MRI evaluation			
Total number of patients	21 (100%)	29 (100%)	25 (100%)
SIJ total lesions	21 (100%)	27 (93%)	4 (16%)
BMD lesions	21 (100%)	21 (72%)	0 (0%)
vertebrae lesions	17 (81%)	18 (62%)	0 (0%)
fatty lesions	7 (33%)	8 (28%)	4 (16%)
erosions lesions	0 (0%)	3 (10%)	0 (0%)
Spine total lesions	20 (95%)	28 (97%)	13 (52%)
BMD lesions	18 (85%)	15 (52%)	9 (36%)
vertebrae lesions	17 (81%)	19 (65%)	11 (44%)
fatty lesions	6 (28%)	7 (24%)	4 (16%)
vertebrae/fundamentophysis lesions	4 (20%)	6 (21%)	3 (12%)
erosions lesions	2 (10%)	2 (7%)	1 (4%)
24 months MRI evaluation			
Total number of patients	18 (100%)	22 (100%)	18 (100%)
SIJ total lesions	18 (100%)	15 (68%)	1 (6%)
BMD lesions	17 (94%)	13 (59%)	0 (0%)
vertebrae lesions	7 (39%)	10 (45%)	0 (0%)
fatty lesions	4 (22%)	4 (18%)	1 (6%)
erosions lesions	0 (0%)	2 (9%)	0 (0%)
Spine total lesions	13 (72%)	4 (18%)	7 (39%)
BMD lesions	7 (39%)	3 (14%)	5 (27%)
vertebrae lesions	7 (39%)	6 (27%)	7 (39%)
fatty lesions	4 (22%)	4 (18%)	4 (22%)
vertebrae/fundamentophysis lesions	7 (39%)	9 (41%)	2 (11%)
erosions lesions	1 (6%)	2 (9%)	0 (0%)

Conclusion: At T0 a significant prevalence of BME lesions was observed both for SIJ and the spine, with predominant involvement of thoracic district. Since positive spine-MRI images were observed in absence of sacroiliitis, we can hypothesize that this finding could have a diagnostic significance in suspected axSpA. Further studies are warranted to assess in a more exhaustive manner the role of imaging in the monitoring of activity disease and radiological progression. **Disclosure of Interests:** None declared
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FRI0644

ANALYSIS OF CARDIOVASCULAR RISK AND CAROTID INTIMA-MEDIA THICKNESS IN PATIENTS WITH PSORIASIS

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Background: Psoriasis (Ps) is associated with atherosclerosis and an increased risk of cardiovascular disease (CVR). Currently, a new automated ultrasound software, based on radio frequency, called QIMT (quantitative intima media thickness) technology, proved to be a useful method for assessing subclinical atherosclerosis with the measurement of the intima-media thickness (IMT) in carotid arteries^{1,2}.

Objectives: To analyze the ultrasound results of the QIMT and Framingham score for psoriasis patients submitted to two types of treatments: methotrexate (MTX) and tumor necrosis factor inhibitor (TNF- α).

Methods: Fifty patients with psoriasis in plaques, were divided into two groups, using MTX and using TNF- α (infliximab and adalimumab). We

evaluated the measurement of abdominal circumference, blood pressure, body mass index (BMI) and presence of metabolic syndrome (SM). In addition, we evaluated cardiovascular risk with the Framingham score and IMT of the two common carotid arteries using automatic software (QIMT) and laboratory tests, including fasting glycemia and total cholesterol, fractions and triglycerides. Data were analyzed using the t-student, chi-square test and the Mann-Whitney test. For the evaluation of the CVR, univariate and multivariate logistic regression analyzes were performed. The level of significance (α) adopted was 5%, being considered statistically significant values of $p < 0.05$.

Results: Total of 50 patients in the study, 25 were on MTX (group 1) and 25 were on anti-TNF- α (group 2). Mean age was 54.8 ($\pm$ 12.5) with a slight male predominance (58%). Total cholesterol, HDL, LDL and triglycerides were altered in 50%, 76%, 30% and 42% of patients, respectively. Overall, 84% of the patients had high waist circumference and 82% had a BMI above the ideal. There was a statistically significant difference ($p < 0.05$) between the groups for metabolic syndrome results (68% vs. 32%); 44% of the patients in group 1 presented Framingham score intermediate to high and 28% of group 2, and in relation to the QIMT, 56% of group 1 and 72% of group 2 showed higher than expected ($p > 0.05$). For the correlation between QIMT and Framingham Score, the Pearson (r) linear correlation coefficient found was 0.617 ($p < 0.001$), indicating a moderate to strong positive association. The cross-sectional analysis does not provide information on causality and the protective or non-protective effect of the aforementioned therapies in relation to cardiovascular risk was not evaluated.

Conclusion: The results show that patients with Ps have high rates of metabolic syndrome and subclinical atherosclerosis. There was a positive association correlating the Framingham score values with the QIMT measurement, providing evidence for the use of ultrasound in clinical practice.

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FRI0645

EVALUATION OF MARKETED KITS FOR MEASUREMENT OF ABP 501, THE FIRST APPROVED ADALIMUMAB BIOSIMILAR, DRUG CONCENTRATION AND ANTI-DRUG ANTIBODY LEVELS IN PATIENT SERUM

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Background: Adalimumab and its biosimilars are anti-tumour necrosis factor (TNF)- monoclonal antibodies that are approved in Europe as treatment for various autoimmune-related indications, including Crohn's disease and ulcerative colitis. Despite the clinical success of adalimumab, some patients show a diminished response after prolonged treatment. It is known that serum adalimumab trough levels are correlated with clinical response and the development of anti-adalimumab antibodies (AAA) may negatively impact trough levels. Currently, therapeutic drug monitoring (TDM) is used to measure adalimumab concentration and/or AAA allowing individualized optimization of treatment regimens. This then facilitates better clinical outcomes by avoiding delay in treatment decisions. Therefore, having a single assay that provides reliable TDM for both adalimumab and adalimumab biosimilars is important for physicians and patients. ABP 501, the first adalimumab biosimilar, is approved for the same indications as adalimumab (except those protected by regulatory exclusivity).

Objectives: The aim of this study was to evaluate the Promonitor[®] TDM kits for measurement of drug levels and AAA in serum samples from a

selected representative subset of subjects, treated with ABP 501 or adalimumab reference product (RP) in the phase 3 study (NCT01970475).

Methods: A total of 30 subjects (15 ADA-positive; 15 ADA-negative) served as a representative subset in this evaluation. AAA positive control antibody and serum samples from subjects treated with either ABP 501 or adalimumab RP in the Phase 3 study were used to assess the suitability of the TDM (Promonitor[®]) kits for AAA (Promonitor[®] ANTI-ADL) and quantitative drug detection (Promonitor[®] ADL).

Results: The Promonitor[®]-ANTI-ADL TDM kit was able to detect a low level (10 ng/ml) of AAA positive control antibodies for ABP 501. In subjects whose serum was evaluated (18 treated with ABP 501 adalimumab biosimilar and 10 treated with adalimumab RP), the TDM kit produced 100% concordant positive or negative AAA results when compared to the assay that had been used in the phase 3 study. The quantitative drug assessment in subjects whose serum was evaluated (11 treated with ABP 501 and 9 treated with adalimumab RP) using the Promonitor[®] ADL TDM kit displayed a high degree of correlation (average Pearson's $r = 0.987$) compared with results obtained in the phase 3 study.

Conclusion: This evaluation indicates that the Promonitor[®] kits are suitable for use in routine detection of AAA and in quantitating serum levels of the ABP 501 adalimumab biosimilar in patients.

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FRI0646

EFFECT OF LONG-TERM MEDIUM-DOSE STEROID TREATMENT ON 18F-FDG PET/CT FINDINGS TO ASSESS VASCULAR AND MUSCULOSKELETAL INVOLVEMENT IN PATIENTSWITH POLYMYALGIA REUMATICA

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Background: Fluorine-18-fluorodeoxyglucose (¹⁸F-FDG) PET/CT has been proposed as a promising tool for assessing both musculoskeletal and vascular involvement in patients with polymyalgia rheumatica (PMR). Glucocorticoids (GC) may decrease the intensity of ¹⁸F-FDG uptake. Therefore, performance of PET/CT before steroid therapy is recommended. However, in many patients with PMR, large vessel vasculitis (LVV) is precisely suspected because of steroid resistance after a long-term treatment with GC ¹.

Objectives: Our aim was to assess the influence of long-term medium-dose treatment on ¹⁸F-FDG uptake to discern if ¹⁸F FDG PET/CT could be useful to evaluate musculoskeletal and vascular involvement in patients under treatment with GC.

Methods: Single-center study of 75 patients with PMR diagnosis based on 2012 EULAR/ACR criteria. All patients underwent a PET/CT scan due to LVV suspicion based on the presence of atypical symptoms and/or persistent symptoms despite steroid therapy. We considered two groups: a) Steroid-naïve PMR patients. b) Steroid-resistant PMR patients. Both musculoskeletal and vascular ¹⁸F-FDG uptake was assessed. The statistical analysis was performed with SPSS. Student's t test or Mann-Whitney U test was used to compare continuous variables, and Chi-squared test or Fisher's exact test for categorical variables as appropriate.

Results: We evaluated 75 patients, 27 men and 48 women (mean age $\pm$ SD: 68.2 $\pm$ 10.7 years). PET/CT was performed in 14 steroid-naïve PMR patients (18.7%) and 61 steroid-resistant PMR patients (81.3%). Patients under steroid treatment had received a median dose of Prednisone of 10.0 [5.0-15.0] mg/day during 9.0 [2.0-22.0] months. Vascular ¹⁸F-FDG uptake was more frequently detected in steroid-naïve patients. In regard with musculoskeletal ¹⁸F-FDG uptake, no statistically significant differences were seen between both groups (TABLE).