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 (± 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 MUSCULOESKELETAL INVOLVEMENT IN PATIENTSWITH POLYMYALGIA REUMATICA

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Background: Fluorine-18-fluorodeoxyglucose (^{18}F-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 ^{18}F-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 ^{18}F-FDG uptake to discern if ^{18}F 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 ^{18}F-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 ± SD: 68.2 ± 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 ^{18}F-FDG uptake was more frequently detected in steroid-naïve patients. In regard with musculoskeletal ^{18}F-FDG uptake, no statistically significant differences were seen between both groups (**TABLE**).