Conclusion: Although people living with RA or PsA acknowledge the importance of taking MTX to manage their condition, the majority of patients experience side effects, such as fatigue and nausea that they attribute to MTX.

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CARDIOVASCULAR RISK FACTORS IN RHEUMATOID ARTHRITIS

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Introduction: Rheumatoid arthritis (RA) is itself a risk factor for the development of cardiovascular diseases as a result of the interaction between traditional cardiovascular risk factors (CVR) and those associated with the state of systemic inflammation.
Objective: Describe the factors of CVR and evaluate its possible association with cardiovascular risk in patients with RA.
Methods: Descriptive and cross-sectional study in 200 patients with a diagnosis of RA. Traditional and non-traditional CVR factors were recorded as variables; Patients diagnosed with a previous cardiovascular disease were excluded.
Results: Female sex predominated (90.0%), average age of 56.9 years ± 10.4 with disease duration time of 9.6 years ± 8.6.The most frequent traditional risk factors were arterial hypertension (54, 0%) and overweight (38.5%) and non-traditional, positive rheumatoid factor (70%), disease activity index 28 joints-C-reactive protein (DAS 28-CRP) moderate-high (58%) and disease duration time> 10 years (33%). The 10-year CVR by Framingham scale was low in62.5% and moderate-high in 37.5%. Arterial hypertension, Diabetes, dyslipidemia and smoking were associated with moderate-high CVR ($p < 0.05$).
Conclusions: Most patients with RA presented low cardiovascular risk and there was an association between some traditional CVR factors with respect to moderate and high CVR.

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CLINICAL CORRELATES OF FIBROMYALGIA IN PUERTO RICANS WITH PRIMARY SJÖGREN'S SYNDROME

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Objective: Several symptoms such as tiredness, arthralgias, myalgias and sicca symptoms occur both in primary Sjögren's syndrome (pSS) and fibromyalgia (FM). However, the clinical correlates of patients with coexistent pSS and FM are not well documented. Thus, we aimed to determine the factors associated with FM in a cohort of Hispanics from Puerto Rico with pSS.
Methods: A cross-sectional study was conducted in Hispanics from Puerto Rico with pSS. All patients were ≥ 21 years of age and met the 2012 American College of Rheumatology Classification Criteria for pSS. Demographic features, health-related behaviors, pSS clinical manifestations, autoantibodies, comorbidities, disease activity (per EULAR Sjögren's Syndrome Disease Activity Index [ESSDAI]), disease damage (per Sjögren's Syndrome Disease Damage Index [SSDDI]) and, pharmacologic treatment were studied in pSS patients with and without FM. FM was ascertained using the 1990 ACR classification criteria. Patient characteristics were analyzed by bivariate and multivariate analyses adjusted for age, sex and disease duration.
Results: In total, 100 patients were studied, 94% were female. The mean (standard deviation [SD]) age was 53.6 (6.2) and the mean (SD) disease duration was 5.8 (4.2) years. Sixteen patients (16.0 %) had FM. In the bivariate analyses, patients with FM were less likely to have lymphopenia (6.3% vs. 32.5%, p=0.036), but more likely to have dyslipidemia (62.5% vs. 28.6%, p= 0.018), anxiety (50.0% vs. 20.2%, p=0.023), sleep disturbances (50.0% vs. 8.3%, p= <0.001), headaches (18.8% vs. 3.6%, p=0.050) and antidepressants exposure (68.8% vs. 21.4%, p= <0.001) than those without FM. No differences were found for smoking, exercise, body mass index, arthralgias, serologic tests, disease activity, disease damage, and exposure to nonsteroidal anti-inflammatory drugs, corticosteroids, hydroxychloroquine or immunosuppressive agents. In the multivariate analysis, dyslipidemia (OR= 3.92, 95% CI 1.24-12.40), anxiety (OR= 5.32, 95% CI 1.53-18.47), sleep disturbances (OR= 10.21, 95% CI 2.72-38.23), headaches (OR= 7.59, 95% CI 1.24-46.36), and antidepressants use (OR= 8.90, 95% CI 2.60-30.50) retained significance.
Conclusion: In this group of Puerto Ricans with pSS, 16% had FM. Clinical associations of patients with coexistent pSS and FM were more likely attributed to FM (anxiety, sleep disturbances, headaches, and antidepressants use). Conversely, FM did not appear to have an impact on the severity of pSS as no differences were observed for pSS manifestations, disease activity, damage accrual, or pharmacologic agents between patients with and without FM.

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A PHASE 3 CLINICAL PROGRAM OF THREE, RANDOMIZED, DOUBLE-BLIND, PLACEBO- AND COMPARATOR-CONTROLLED STUDIES TO ASSESS THE EFFICACY AND SAFETY OF OTILIMAB IN RA: STUDY DESIGN AND METHODOLOGY

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Objectives: Otilimab (GSK3196165) is a human monoclonal antibody that inhibits GM-CSF and has shown efficacy in Phase 2 randomized controlled trials (RCTs) in patients with RA. The contRAst Phase 3 clinical program comprises 3 ongoing multicenter RCTs that will assess the efficacy and safety of otilimab in patients with moderate to severely active RA.
Methods: contRAst-1 (N=1500–1700) and contRAst-2 (N=1500–1800) are the first RA trials to include the oral targeted synthetic (ts) DMARD tofacitinib as a comparator with a 52-week duration (contRAst-1: otilimab vs tofacitinib or placebo, plus MTX; contRAst-2: otilimab vs tofacitinib or placebo, plus conventional synthetic [cs]DMARDs). ContRAst-3 (N=525–600) is a 24-week trial that will assess otilimab vs the anti-IL-6 monoclonal antibody sarilumab or placebo, plus csDMARDs. The program will enroll patients with an inadequate response to MTX (contRAst-1), cs/bDMARD (contRAst-2) or bDMARD-IR and/or JAKi-IR (contRAst-3). Otilimab dose selection was based on pharmacokinetic/pharmacodynamic modelling and simulation of Phase 2 data. Patients will be randomized 6:6:3:1:1:1 (contRAst-1 and -2) or 6:6:6:1:1:1 (contRAst-3) to weekly subcutaneous otilimab 150 mg or 90 mg, active comparator (approved dose and route), or placebo (3 arms). At Week 12 all patients in the placebo arms will switch to active treatment, randomized equally to the two otilimab doses and active comparator. Primary endpoint: proportion of ACR20 responders at Week 12. Secondary endpoints include: health assessment questionnaire disability index and clinical disease activity index (CDAI); CDAI was chosen based on findings from the BAROQUE Phase 2 study to provide an alternative to DAS28(CRP), which is heavily influenced by changes in CRP. Radiographic changes, patient-reported outcomes (including pain), and safety will also be assessed. The primary endpoint will be compared separately between each otilimab dose and the pooled placebo group up to Week 12, with additional comparisons between the original randomized otilimab groups and tofacitinib at Weeks 12, 24, and 52. The analysis will include a comprehensive safety evaluation of the two otilimab doses and a comparison vs an oral tsDMARD over 1 year, and vs bDMARD over 24 weeks.
Conclusions: The novel aspects of the contRAst program plus a wide geographical coverage (USA, Central and South America, western and eastern Europe, Asia [including Japan and China]) will provide a robust global dataset. Recruitment is ongoing.

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THE ANTIPHOSPHOLIPID ANTIBODIES REGISTRY OF THE ARGENTINEAN SOCIETY OF RHEUMATOLOGY (GESAF-SAR): BASELINE DATA OF THE FIRST 162 PATIENTS

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Objective: Antiphospholipid antibodies registry of the Argentinean Society of Rheumatology (GESAF-SAR) was created to study long-term disease characteristics and outcomes in persistently antiphospholipid antibody (aPL)-positive patients. The objective was to report baseline demographic, clinical, laboratory and treatment characteristics of aPL-positive patients enrolled in the registry.

Materials and Methods: GESAF-SAR is a multicenter, multidisciplinary and longitudinal study. Thirty centers from Argentina participated. Data collection was performed by review of medical records and interview with individuals/patients, after signing an informed consent. A web-based data capture system (ARTHROS) was used. Inclusion criteria: aPL with at least one positive determination of Lupus Anticoagulant (LAC) and/or positive Anticardiolipin Antibodies (aCL) and Anti-βeta 2 Glycoprotein I (aβ2GLPI) IgG and IgM greater 40 or positive aCL and/or aβ2GLPI with levels 20-40 GPL or MPL (at least two determinations) separated by 12 weeks. Patients were followed every 12±3 months. Descriptive cross-sectional analysis of data collected from May to October 2019 was performed.

Results: Overall 162 patients were enrolled, 139 (86%) were women with a mean age at entry of 40.3 years (SD 12.9); 76 (47%) patients were Mestizo, 72 (44%) Caucasians and 14 (9%) others. The socioeconomic level was Medium-Low in 47 patients (29%), Medium in 58 (36%) and Medium-High in 25 (15%). Seventy-four patients (46%) met classification criteria for Primary APS, 37 (23%) were APS associated with autoimmune disease and 2 (1%) were catastrophic APS (CAPS). Of the 111 APS patients, 50 (45%) presented thrombotic manifestations, 44 (40%) obstetric and 16 (15%) both. Forty-nine patients (30%) did not meet classification criteria of APS. A total of 40 (24.7%) venous events, 34 (21%) arterial, 70 (43.2%) obstetric morbidity and 55 (34%) non-criteria manifestations were recorded. Seventy-seven women presented at least one pregnancy with a total 265 gestations, resulting in 104 (39%) live births. Of all gestations, 80 (30%) were miscarriages <10 weeks, 53 (20%) premature births, 42 (16%) placental insufficiency, 24 (9%) preeclampsia and only 2 (1%) eclampsia. Based on aPL profile, 88 (54%) were positive for LAC, 110 (68%) aCL and 74 (46%) for aβ2GLPI. Regarding treatments, 117 (72%) patients received Aspirin, 71 (43.8%) oral anticoagulation, 53 (32.7%) prophylactic heparin, 46 (28.4%) therapeutic heparin, 92 (56.8%) hydroxychloroquine.

Conclusions: In our multi-center Argentinean aPL-positive cohort, at baseline: a) 30% of patients did not meet classification criteria of APS, b) 46% met classification criteria for Primary APS, c) one-fourth were APS associated with autoimmune disease, d) 45% presented thrombotic manifestations, e) the most frequent obstetric morbidity were miscarriages <10 weeks. Future longitudinal analysis of GESAF-SAR Registry will help clarify the risk profiles of aPL in Argentina.

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CIRCULATING CELL-FREE DNA AND DNASE I Q222R GENETIC VARIANT AS POTENTIAL BIOMARKERS IN SYSTEMIC LUPUS ERYTHEMATOUS

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Introduction: Excessive formation and/or insufficient clearance of neutrophil extracellular traps (NETs) have been reported in systemic lupus erythematous (SLE) and which could be associated with an increased disease activity. Therefore, increased levels of circulating cell-free DNA (cfDNA) could potentially be a disease activity biomarker. The insufficient clearance of NETs could mainly be due to a decreased DNAse I activity that could result from single-nucleotide polymorphisms in its gene, like the genetic variant Q222R.

Aims: To study cfDNA plasmatic levels and the distribution of the DNAseI-Q222R genetic variant to evaluate their predictive value both in the development and evolution of SLE in an Argentinian cohort.

Methods: We studied 54 SLE patients [(32 years (23-40), female 89%] who fulfilled the ACR criteria for SLE (2012), 95% were treated with hydroxychloroquine and 52% with prednisone. The control group consisted of 86 unrelated healthy subjects from the general population who had no personal history of chronic inflammatory and/or autoimmune diseases [(30 years (25-39), female 60%]. cfDNA levels were measured with the Quant-iT™ PicoGreen® dsDNA Assay Kit, (Thermo Fisher Scientific), and the DNAseI-Q222R genotyping was assessed by PCR-RFLP. The statistical analysis was performed using the SPSS statistical package (Version 23.0 IBM SPSS Statistics).

Results: cfDNA plasmatic levels were found to be significantly higher ($p<0.005$, Mann-Whitney test) in SLE patients (1,22 ng/ul (1,06-1,42) with regard to the controls 1,00 ng/ul (0,92-1,06). However, no differences were found among SLE patients grouped according to clinical manifestations, laboratory, damage and disease activity.

The distribution of the DNAseI-Q222R genotypic frequencies in SLE patients and controls did not show significant differences ($p=0.78$) even under different models of allelic dominance. Due to the small sample size, no analysis of its distribution within SLE groups could be performed.

Conclusion: While SLE patients had higher levels of cfDNA than controls, we did not find cfDNA increased levels in patients with lupus nephritis or other clinical manifestation of SLE. Therefore, it would not be useful as a biomarker to identify risk groups. As almost all of our patients were being treated with hydroxycholoroquine, which inhibits NETosis at physiologic concentrations, we consider that these results highlight a limitation of cfDNA as a potential biomarker in SLE patients under treatment. On the other hand, DNAseI-Q222R genetic variant was not found to be associated with the onset of SLE.

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ASSESSMENT OF SIX CARDIOVASCULAR RISK CALCULATORS IN MEXICAN PATIENTS WITH PSORIATIC ARTHRITIS

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Objectives: Patients with psoriatic arthritis (PsA) have an increased risk of cardiovascular (CV) morbidity and mortality. CV risk evaluation is performed by CV risk calculators such as the Framingham Risk Score (FRS) using lipids, FRS using body mass index (BMI), Reynolds Risk Score (RRS), QRISK3, and an algorithm developed by the American College of Cardiology and the American Heart Association in 2013 (ACC/AHA). However, these models underestimate CV risk in PsA patients. We aimed to compare these six CV risk scales in PsA patients (FRS Lipids, FRS BMI, RRS, ACC/AHA 2013, QRISK3, JBS3).

Methods: Cross-sectional study, which included 91 PsA patients, aged 40-75, who fulfilled the CASPAR classification criteria. Predicted CV risk global comparison was performed using the Friedman test, considering a p value ≤ 0.05 as statistically significant. Individual comparisons were made using the Wilcoxon signed-rank test, and a p value ≤ 0.05 was considered statistically significant.

Results: A total of 91 patients were included: Median of age was 53 (46-61) years, 53 (58.2%) were female. Disease duration median was 4 (2-8) years. Concerning cardiovascular risk factors, 17 (18.7%) had type 2 Diabetes Mellitus, 33 (36.3%) had hypertension, 37 (40.7%) had dyslipidemia, 33 (36.3%) had a BMI