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Background: Italy and ties of U2016 EULAR/ACR criteria and are followed up in 5 clinical centers ([University CV criteria and in comparison with the classical CV of HCV patients.

Objectives: well characterized patients is required.

picture of CV in HCV negative SS, but the number of studied patients was rather small. CV has been well documented in HCV patients without SS, and shares Sjögren’s syndrome (SS) and is closely associated with type II IgMk cryoglobulins. SS-CV patients were purpura (90%) followed by arthralgias (70%), fatigue (59%), Raynaud’s phenomenon (48%), lymphadenopathy (31%), peripheral neuropathy (29%), vasculitis ulcer (11.3%), and pulmonar y cryoglobulinemia (11.3%). Interestingly, almost 50% of SS related CV patients developed lymphoma and displayed high frequency of strong predators including purpura, low C4 complement (88.6%) and salivary gland enlargement (SGE). Compared to HCV-CV patients, SS-CV patients had higher frequency of sicca manifestations, SGE, fatigue, arthritis, Raynaud’s phenomenon, lymphadenopathy, type II IgMk cryoglobulins and lymphoma.

Conclusion: The prevalence of cryoglobulinemia and CV among SS patients is about 10% and 6-7% respectively. SS-CV patients are mainly middle-aged females with purpura as the main clinical manifestation, and up to one half of them may develop lymphoma, which is rarer in HCV-CV. Compared to HCV-CV patients, SS patients with CV have more frequently sicca symptoms, SGE and type II IgMk cryoglobulins.

Disclosure of Interests: Oaura Angyropoulou: None declared, Vasileios Pezoulas: None declared, Luca Quaruccio: None declared, Francesco Ferrn: None declared, Savanida Gofolono: None declared, Valentina Donati: None declared, Aliki Venetanopoulou: None declared, Loukas Chatzisis: None declared, Evangelia Zampeli: None declared, Maria Mavromati: None declared, Paraskevi Vougiou: None declared, Chiai Baldini: None declared, Fotini Skopoulis: None declared, Dimitris Fotiadis: None declared, Massimo Galli: None declared, Salvatore De Vita Consultant of: Roche, Human Genome Science, Glaxo Smith Kline and Novartis, Haralampos M. Moutsopoulos: None declared, Andreas Goulis: None declared, Athanasios Tziolous: None declared.

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THU0294

THE DIFFERENCES IN THE CLINICAL SPECTRUM OF CRYoglobulinemic VASCULITIS BETWEEN SJÖGREN’S SYNDROME AND HCV HEPATITIS

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Background: Cryoglobulinemic vasculitis (CV) is a serious complication of Sjögren’s syndrome (SS) and is closely associated with type II IgMk cryoglobulinemia. CV has been well documented in HCV patients without SS, and shares common features with CV in SS. So far, few studies have described the clinical picture of CV in HCV negative SS, but the number of studied patients was rather small and CV was not well defined. To better describe the clinical spectrum of CV in SS and explore the differences compared to HCV-related CV, a large cohort of well characterized patients is required.

Objectives: To study the clinical phenotype of CV in HCV-negative SS patients, in a large cohort of well characterized patients, after applying stringent classification criteria and in comparison with the classical CV of HCV patients.

Methods: From a total cohort of 199 consecutive SS patients who fulfilled the 2016 EULAR/ACR criteria and are followed up in 5 clinical centers ([Universities of Udine, Pisa and Athens, Harokopio and Ioannina, (UAPHI)], those who fulfilled the 2011 classification criteria for CV were identified and compared with matched HCV-CV patients according to age and gender. Glandular, extra-glandular manifestations and serologic features were compared between the 2 CV groups. Statistical analysis for categorical variables was performed by Fisher exact or chi-square tests and for continuous variables with t test or Mann-Whitney exactly.

Results: Among the 1083 SS patients who have been evaluated for cryoglobulin, 114 (9.8%) were found positive. Seventy-one (6.5%) SS patients met the 2011 CV criteria while 44 patients presented with type II IgMk cryoglobulinemia without CV. Sixty nine of 71 (97%) SS related CV patients were females and 2 of 71 (3%) males. Forty eight of 71 (68%) had SS disease onset 35 and 65 years old while 14/71 (19.7%) and 9/71 (12.7%) had SS disease onset <35 and >65 years old respectively. The most common clinical manifestations of CV among SS patients were purpura (90%) followed by arthralgias (70%), fatigue (59%), Raynaud’s phenomenon (48%), lymphadenopathy (31%), peripheral neuropathy (29%), vasculitis ulcer (11.3%) and pulmonary cryoglobulinemia (11.3%). Interestingly, almost 50% of SS related CV patients develop lymphoma and displayed high frequency of strong predators including purpura, low C4 complement (88.6%) and salivary gland enlargement (SGE). Compared to HCV-CV patients, SS-CV patients had higher frequency of sicca manifestations, SGE, fatigue, arthritis, Raynaud’s phenomenon, lymphadenopathy, type II IgMk cryoglobulins and lymphoma.

Conclusion: The prevalence of cryoglobulinemia and CV among SS patients is about 10% and 6-7% respectively. SS-CV patients are mainly middle-aged females with purpura as the main clinical manifestation, and up to one half of them may develop lymphoma, which is rarer in HCV-CV. Compared to HCV-CV patients, SS patients with CV have more frequently sicca symptoms, SGE and type II IgMk cryoglobulins.

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THU0295

LOW IMMUNOCOMPETENCE IN PATIENTS WITH GIANT CELL ARTERITIS TREATED WITH TOCILIZUMAB: 3-YEAR RESULTS FROM THE RANDOMIZED CONTROLLED PORTION AND OPEN-LABEL FOLLOW-UP OF A PHASE 3 TRIAL

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Background: Tocilizumab (TCZ) has low immunogenicity in patients with rheumatoid arthritis. The risk for immunogenicity remains to be determined in patients with giant cell arteritis (GCA) treated with TCZ. TCZ administered subcutaneously every week (QW) or every other week (Q2W) with 26-week prednisone tapering was superior to placebo (PBO) plus 26-week (PBO+26) or 52-week (PBO+52) prednisone tapering for the achievement of sustained remission in patients with GCA in the 52-week, double-blind part 1 of the GIACTA trial. Part 2 was a 2-year open-label, long-term follow-up in which patients were treated at the investigators’ discretion; part 2 treatment could include initiation/termination of TCZ QW with or without glucocorticoids or methotrexate.

Objectives: To investigate immunogenicity of TCZ QW and Q2W regimens in patients with GCA in combination with a 26-week prednisone taper regimen versus PBO+26 or PBO+52 over the course of the GIACTA study in the randomized controlled part 1 and long-term follow-up part 2.

Methods: In parts 1 and 2 combined, anti–TCZ antibodies (ADA) and corresponding pharmacokinetic (PK) parameters were assessed in serum samples taken at scheduled times during the study and at any early withdrawal. Additional assessments were made for patients who interrupted blinded TCZ treatment for ≥4 weeks in part 1 and those who withdrew from the study because of anaphylaxis/hypersensitivity. All samples were tested by screening assay, and samples that were ADA positive were further analyzed by a confirmation assay to verify specificity. If the confirmation assay was positive, 2 additional tests were performed to characterize the detected ADA: a neutralizing assay to test the neutralizing potency of ADAs, and an assay to determine whether the detected ADA were of the IgE isotype. Proportions of patients in whom ADA developed were summarized for the safety population.

Results: Among evaluable patients (had baseline and ≥1 postbaseline ADA assessments and received ≥1 dose of study treatment) in part 1, ADA developed in 1 of 95 (1.1%) and 3 of 46 (6.5%) patients after TCZ QW and Q2W dosing, respectively. One of 49 (2.0%) and 1 of 47 (2.1%) in the PBO+26 and PBO+52 groups, respectively, tested positive for ADA but had not received TCZ and were considered false positives. In parts 1 and 2 combined, among 199 patients who received ≥1 dose of TCZ, 193 (97%) were evaluable (Table); TCZ-induced ADA developed in 13 of these patients (6.7%) postbaseline (4 during part 1, 9 during part 2). Of these 13 patients, 8 (6.1%) had ADA with neutralizing potential and 1 (0.5%) had IgE ADA. Most TCZ-induced ADA were transient. There was no clear impact of TCZ-induced ADA on TCZ PK (Figure). No patients with TCZ-induced ADA experienced anaphylaxis or hypersensitivity or injection site reactions, and none withdrew because of lack of efficacy.

Conclusion: In patients with GCA, treatment-induced ADA developed in a minority of patients and had no impact on TCZ PK, efficacy, or safety. The...