Objectives: The aim of this study was to evaluate the efficacy of comedication csDMARD and anti-TNF compared with anti-TNFs on monotherapy.

Methods: A descriptive retrospective study including 85 patients with ax-SpA according to the criteria of the group ASAS on 2009 and having received anti-TNFs between January 2000 and October 2019.

The patients were divided on two groups, those who had received combined therapy with cs-DMARDs and those who had received anti-TNFs on monotherapy.

The response to treatment was assessed with the ASAS 40 response and partial remission at 3 and 6 months of treatment and was compared between the two groups.

Results: Our populations consists of 67 men and 18 women with a mean age of 44.4 ± 10.9 years. The mean period of evolution was 12.3 ± 9.1 years and 52,2% of patients were HLA-B27 positive. The ax-SpA was associated with peripheral arthritis, enthesitis and dactylitis in 17,6%, 17,6% and 1,2% respectively.

Fifty-nine patients (69,4%) were treated with anti-TNF alpha on monotherapy and 26 patients (30,6%) had combined therapy. The ASAS 40 response was achieved in 45,6% of patients at 3 months and 64,1 % of them at 6 months of anti-TNFs treatment. Among them, 7,4% had obtained partial remission at 3 months and 20,3% at 6 months of treatment.

There was statically significant difference between the two groups on the ASAS 40 response or the partial remission at 3 and 6 months of treatments.

Conclusion: The comedication therapy with csDMARDs does not influence the efficacy of anti-TNFs in ax-SpA patients suggesting no benefit in the concomitant use of these drugs in clinical practice.

References:

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AB0638 THE EFFECT OF VITAMIN D ON QUALITY OF LIFE AND SEVERITY OF PAIN IN PATIENTS WITH ANKYLOSING SPONDYLITE

E. Komarova¹, I. Blaginina¹, N. Bludova¹, P. Bakhtoyarov¹, I. Pokryshka².

¹Lugansk State Medical University, Lugansk, Ukraine; ²Lugansk Republican Clinical Hospital, Lugansk, Ukraine

Background: The high incidence of ankylosing spondylite (AS) in people of working age, as well as the negative impact of the disease on the quality of life of patients, determine the need for adjuvants to reduce the severity of pain and thereby achieve the physical, psychological and emotional well-being of patients.

Objectives: To study the effect of vitamin D (colecalfiferol) on the quality of life and the severity of pain in patients with ankylosing spondylite.

Methods: The study included 69 patients with AS, who studied the quality of life indicators according to the Medical Outcomes Study Short Form (SF-36); pain syndrome and stiffness in the spine were assessed by a visual analogue scale by patients, and by a physician - by counting the number of painful joints (NPJ), the disease activity index (BASDAI) and the Functional Index (BASFI). All patients were receiving a basic therapy in a stable dose for at least 10 months. They were divided into 2 groups, comparable in age, disease activity; Group 1 (n = 33) additionally received colecalfiferol 1500 ME during 6 months of observation.

Results: At the end of the observation period when evaluating data on SF-36: in the 1st group, the physical health component has improved - the increase in physical functioning (PF) and bodily pain (BP) by 51.4% and 37.8% from the baseline; vital activity, psychological health, and social functioning due to emotional state have also increased by 37.6%, 33.4% and 42.5%, respectively. In the 2nd group above mentioned parameters have not changed. In the 1st group the indexes of BASDAI and BASFI have decreased by 16% and 22% (p = 0.0079, p = 0.0022, respectively), and their dynamics in the 2nd group were less significant (p = 0.013, p = 0.017, respectively) Also, in patients of the 1st group have decreased the severity of morning stiffness and the pain in the spine a highly reliable (p < 0.001), and in the 2nd group they were less significant (p = 0.043, p = 0.016, respectively). Positive dynamics of NPJ in the 1st group was more significant (p = 0.003) than it was in the 2nd group (p = 0.033).

Conclusion: In the group of patients treated with colecalfiferol was noted improvement in indicators of quality of life (the parameters of the physical component of health, vitality and social functioning) and also more significant decrease of the intensity of pain and of morning stiffness duration, of NPJ, than in not received to colecalfiferol patients. Inclusion of vitamin D in the comprehensive AS therapy promotes not only reduction the severity of the chronic pain manifestations, but also improves the quality of life of patients with this pathology.

Disclosure of Interests: None declared

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AB0639 TREATMENT EFFICACY WITH SECUKINUMAB IN A COHORT OF SPONDYLOARTHRITIS PATIENTS

A. Castilla¹, Á. García Martos², L. Sala Icardo³, A. Prada-Ojeda³, L. Barrio Nogal³, M. C. Ortega de la O⁴, C. Arconada⁴, L. González², A. Díaz Oca⁵, P. Navarro⁶. ¹University Hospital La Paz, Rheumatology, Madrid, Spain; ²Hospital del Tajo, Aranjuez, Spain; ³Hospital de Torrejón, Torrejón de Ardoz, Spain; ⁴Hospital Universitario Infanta Elena, Valdemoro, Spain; ⁵Hospital Universitario de Fuenlabrada, Fuenlabrada, Spain; ⁶Hospital Universitario de Fuenlabrada, Fuenlabrada, Spain

Background: Spondyloarthropathies are a heterogeneous group of similar diseases, with interrelated clinical manifestations, such as Psoriasis Arthritis (APs) and Ankylosing Spondylitis (EA). There are different treatments for this group of pathologies.

Objectives: It is very important to differentiate between those that present predominantly axial (spine and/or sacroiliac) or peripheral involvement, since the response to treatment is very different.

In some clinical trials, secukinumab significantly improved versus placebo, the symptoms and signs, physical function and quality of life, however, at present, we do not have enough data from secukinumab in real clinical practice.

This is the real reason of this study: the use of secukinumab in clinical practice.

Methods: Multicentric longitudinal observational study of 5 Hospitals in Madrid. Patients are over 18 years old and meet the following inclusion criteria: New York criteria for AS, ASAS for EA, CASPAR for APs, and all of them are with secukinumab or have received it.

We will evaluate the effectiveness rate as well as its confidence interval at 95%. In addition, the effectiveness of secukinumab will be compared in the different pathologies by using χ^2 .

Results: 72 patients were collected, 41 of them were women (57,75%).

12 patients (16,90%) had not received FAME before secukinumab and 22 patients (33,99%) were naive to biological treatment.

In 4 patients, the reason for starting secukinumab was the patient's comorbidities, in 2 the adverse effects of previous treatment and in the rest, was the lack of efficacy of the previous treatment.

The patients were divided into 4 categories according to the level of DAS-28 or BASDAI, at the beginning of the treatment and the last recorded value, in: Absence of activity, mild, moderate and severe activity. Of the patients with data, they managed to improve the DAS-28 score (change category) by 30,95%, while only 4,76% worsened their score. With respect to BASDAI, of the total number of patients, only 3,03% worsened, while his score improved 27,27%.

According to baseline diagnosis, a greater improvement of the disease activity in peripheral APs(66,67%) and mixed APs(61,54%) is achieved.

Conclusion: In real clinical practice, treatment with secukinumab was effective in patients with spondyloarthritis, achieving improvement in previous activity rates. In this study, the most significant improvement was obtained in peripheral and mixed APs.

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AB0640 LONG-TERM EFFECTIVENESS AND DRUG SURVIVAL OF GOLIMUMAB IN PATIENTS AFFECTED BY PSORIATIC ARTHRITIS WITH CUTANEOUS INVOLVEMENT

G. L. Fonti¹, M. S. Chimenti¹, A. D'antonio¹, M. Teoli², F. Caso³, L. Costa³, M. Tasso³, A. Ortolan⁴, M. Lorenzin⁴, P. Conigliaro¹, P. Triggianese¹, R. Scarpa³, R. Perricone¹, R. Ramonda⁴. ¹Rheumatology, Allergy and Clinical Immunology, Department of Systems Medicine, University of Rome Tor Vergata, Rome, Italy; ²University of Rome Tor Vergata, Dermatology Department, Rome, Italy; ³Rheumatology Unit, Department of Clinical Medicine and Surgery, School of Medicine and Surgery, University of Naples Federico II, Naples, Italy; ⁴Rheumatology Unit, Department of Medicine-DIMED, University of Padova, Padova, Italy

Background: Psoriatic arthritis (PsA) is a chronic immune-mediated disease associated with psoriasis (PsO). Overexpression of inflammatory cytokines such as tumor necrosis factor (TNF)- α plays a key role in the pathogenic mechanisms. Golimumab (GLM) is a fully human monoclonal antibody IgG1k neutralizing TNF- α approved for PsA and PsO, but effectiveness evaluation in real life remains a crucial issue.

Objectives: In a real-life setting, to determine the survival rate of GLM (drug survival) at 48 months in the global population, in different clinical settings, and the effectiveness of GLM in improving joint symptoms and cutaneous manifestations in patients affected by moderate to severe PsA with cutaneous involvement.

Methods: We collected retrospectively from 1 January 2014 to 31 December 2019 data from 105 patients affected by PsA, according to the Classification for Psoriatic Arthritis (CASPAR) criteria, who started treatment with GLM. Inclusion criteria were age > 18 years and had a diagnosis of PsA > 6 months, the presence of peripheral arthritis (at least one active joint) and active PsO. Relevant anamnestic, clinical, biochemical data and biological treatment line were collected at baseline (T0) and after 6 (T6), 12 (T12), 24 (T24) and 48 (T48) months of GLM treatment. Comparisons between baseline and 48 months continuous variables were performed using a paired t-test or a Wilcoxon signed-rank test for paired samples. The drug survival rates were analyzed using Kaplan-Meier estimates. Drug survival rates were read from the Kaplan-Meier survival curves. Differences in drug survival between groups were analyzed using a log-rank (Mantel-Cox) test, by stratifying for sex, BMI, smoking habit and line of treatment. A p-value <0.05 was considered as statistically significant.

Results: Peripheral arthritis was present in 67 (63.8%) cases, axial disease in 37 (35.3%), enthesitis and PsO as prominent manifestations in 82 (78%) and 84 (80%) patients respectively. Erosive disease was present in 38 (36.2%) of patients at baseline. The most frequent comorbidities were MetS described in 20 (19%) patients and cardiovascular disease described in 33 (31.4%) patients, probably due to the high incidence of smokers (33 (31.4%) of patients) and to the elevated BMI score (27.1 ± 6.0). At 48 months, the 42% (44 of 105) (figure 1A) of the patients have discontinued therapy; the most frequent reason was insufficient response/loss of efficacy (30 patients (28.6%) out of 105). Unexpectedly, no statistical significant difference emerged according to gender ($p=0.652$), BMI ($p=0.655$), smoking habit ($p=0.466$) and line of treatment ($p=0.208$) (figure 1B-E). Finally, the effectiveness of GLM in improving joint symptoms and cutaneous manifestations was confirmed once again, with a statistical significant improvement at 48 months in clinical (BASDAI $p<0.0001$; PASI $p<0.01$; DAPSA $p<0.0001$) and biochemical (CRP<0.05) data.

Conclusion: This multicentric study revealed a high drug persistence of GLM in real-life patients, although the presence of comorbidities. Unlike what is known in literature, our study population presented no differences in terms of clinical response and efficacy between male and female, smokers and no-smokers, obese and health-weight patients, different line of treatment. On the other hand, efficacy and safety of GLM has been demonstrated once again also in real-life treatments.

References: No references.

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AB0641

MANAGING ANKYLOSING SPONDYLITIS (AS) WITH SHORT TERM BIOSIMILAR ADALIMUMAB REGIMEN IN A RESOURCE STRAPPED SETTING: A PROTOCOL DRIVEN COMMUNITY CLINIC ORIENTED STUDY

A. Chopra¹, N. Khadke¹, M. Saluja¹, T. Kianifard¹, A. Venugopalan¹. ¹Center For Rheumatic Diseases, Pune, India

Background: We were handicapped by the exorbitant cost of innovator anti-Tumour Necrosis Factor (TNF) drugs. Despite limited use, we sometimes observed

long-term benefits following short term induction like use. Emboldened by advent of biosimilars, we carried out an investigational study.

Objectives: To evaluate the effectiveness of a short regimen of biosimilar (Bs) Adalimumab in AS

Methods: 50 consenting patients (86% B27+) naïve for biologics and negative for latent TB screen were enrolled into an observational design study of one year; Baseline mean values for age, duration, ASDAS and CRP was 31 years, 98.8 months, 4.6 and 64 mg per dl respectively. During the first year, patients were begun with 40 mg Bs Adalimumab (Bs-ADL) (Exemptia™), injected fortnight, for 12-16 weeks. No patient received DMARD or steroid in the first year of study. Patients continued standard of care follow up program in the clinic. The ASAS (Assessment Spondyloarthritis International Society) improvement indices were used. Standard intention-to-treat analysis was performed; significant $p < 0.05$.

Results: Optimum ASAS 40 improvement was observed at week 12 (68%); substantial improvement lasted till week 36. At one year, the ASAS 40 was 38%; ASAS partial remission 22% patients. Pro-inflammatory cytokines (IL-6, TNF α and IL-17) showed conspicuous reduction; maximum drop in IL-6 at week 24 (See Figure). 11 patients withdrew in the first year. 30 patients completed two years and 22 patients completed 3 year follow up. Over time, there was substantial loss in the ASAS 20 and 40 responses but patients seemed satisfied with the on-going symptomatic relief and improved function. Admittedly, patients showed more adherences to advice on physical exercise and stress reduction. Flares were more frequent after 1 year requiring short term round the clock NSAID; only 5 patients could afford to repeat a short term Bs-ADL regimen and one patient underwent hip arthroplasty. None received steroids and 5 patients were begun on Sulfasalazine in the second year and monitored. We could not evaluate structural modification (AS). Selected outcomes over 2 and 3 years from the current study will be compared to matched control (derived from the clinic database). None developed TB or any serious drug related toxicity. 2 patients developed recurrent uveitis.

Conclusion: This real life documented experience unravelled impressive long term benefits following a kick start short term induction regimen of Biosimilar Adalimumab in AS. Though contrary to standard practice, this seemed a practical solution in our setting. We speculate a psychological and motivational boost rather than a prolonged real time biological effect (Bs-ADL) for this phenomenon. Our study has important socioeconomic bearing and merits validation.

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AB0642

SACROILIAC JOINT INJECTIONS PERFORMED WITH ULTRASOUND GUIDANCE IN PATIENTS WITH SACROILIITIS

A.R. Cunha¹, C. Mazedo¹, R. Aguiar¹, A. Barcelos¹. ¹Rheumatology Department, Centro Hospitalar do Baixo Vouga, Aveiro, Aveiro, Portugal

Background: Sacroiliitis is the hallmark of axial Spondyloarthritis (axSpA). ASAS-EULAR management recommendations for axSpA, consider glucocorticoid injections directed to the local site of musculoskeletal inflammation as a