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SAT0374 IXEKIZUMAB, WITH OR WITHOUT CONCOMITANT METHOTREXATE, IMPROVES THE SIGNS AND SYMPTOMS OF PSA FOR UP TO 52 WEEKS OF TREATMENT

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Background: Ixekizumab (IXE) is a high affinity monoclonal antibody selectively targeting interleukin (IL)-17A. It was previously demonstrated

that IXE, with or without concomitant methotrexate (MTX), was superior to placebo (PBO) in improving the signs and symptoms of patients with psoriatic arthritis (PsA) for up to 24 weeks^{1,2}.

Objectives: To evaluate the efficacy of IXE, with or without continuous concomitant MTX, for up to 52 weeks of treatment in patients with active PsA.

Methods: Patients with active PsA who were biologic naïve (SPIRIT-P1, NCT01695239) or had prior inadequate response or intolerance to tumour necrosis factor inhibitors (SPIRIT-P2; NCT02349295) were randomised to PBO (N=224), 80 mg IXE every 4 weeks (IXEQ4W, N=229) or every 2 weeks (IXEQ2W, N=226), after a 160 mg starting dose. In this post-hoc analysis, efficacy was assessed up to Week 52 for the following two subgroups: (i) patients who were treated with IXE as monotherapy i.e. no concomitant conventional disease-modifying anti-rheumatic drugs and (ii) patients who received constant dose of MTX from Weeks 0 to 52. Patients who had MTX dose change were excluded. Efficacy outcome measurements included American College of Rheumatology (ACR) 20/50/70 responses, minimal disease activity (MDA), and disease activity in psoriatic arthritis (DAPSA) low disease activity (LDA) (score ≤ 14). Patients who discontinued from treatment before Week 52 were included in the analysis. Missing values were imputed using non-responder imputation. All analyses were done post-hoc.

Results: Among patients randomised to IXE at Week 0, 177 (38.9%) patients were treated with IXE monotherapy while 183 (40.2%) patients received constant dose of MTX up to Week 52. The average MTX dose was 15.7 mg/week and 16.0 mg/week for IXEQ4W and IXEQ2W, respectively. Week 52 results are presented in Table 1. At Week 52, similar results were observed between the two groups of patients for the different disease activity measures (ACR, MDA, and DAPSA LDA) and there was also a trend for a numerical higher proportion of patients achieving ACR responses with IXE monotherapy compared to patients with concomitant MTX use. Over time (Weeks 0-52), ACR 20, 50, and 70 response rates increased from baseline and were largely similar between the two subgroups (data not shown).

Conclusion: In this post-hoc analysis, IXE treatment showed sustained efficacy in patients with PsA up to one year of treatment, with or without concomitant MTX therapy.

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Table 1. Efficacy Outcomes at Week 52

	IXEQ4W N=229		IXEQ2W N=226	
Concomitant Medication:	None (n=95)	MTX (n=85)	None (n=82)	MTX (n=98)
ACR 20	66.3%	55.3%	63.4%	55.1%
ACR 50	48.4%	38.8%	48.8%	38.8%
ACR 70	35.8%	27.1%	35.4%	23.5%
DAPSA LDA*	52.6%	52.9%	54.9%	41.2%
MDA	38.9%	35.3%	36.6%	22.7%

* score ≤ 14

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SAT0375

MILD COGNITIVE IMPAIRMENT IN PSORIATIC ARTHRITIS: PREVALENCE AND ASSOCIATED FACTORS

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Background: A growing body of data demonstrated that systemic inflammation is a predisposing condition for developing cognitive impairment. Different studies highlighted that psoriasis (PsO), a multisystem chronic inflammatory disorder, is associated with cognitive impairment. No data are available regarding psoriatic arthritis (PsA).

Objectives: To assess the prevalence and the factors associated with mild cognitive impairment (MCI) in patients suffering from PsA.

Methods: Consecutive PsA patients, classified as suffering from PsA with the CIASification criteria for Psoriatic ARthritis (CASPAR), were enrolled in this study. For each patient were collected the sociodemographic data (age, gender, years of school attendance, years of articular disease duration, years of cutaneous disease duration, treatment), the values of C-reactive protein (CRP) and the following clinical variables: 68 tender joint count (TJC), 66 swollen joint count (TJC), the Leeds Enthesitis Index (LEI), the dactylitis digit count, the Psoriasis Area and Severity Index (PASI), 10 cm numerical rating scale (NRS) for pain and for assessment of disease activity (PaGA), the Dermatology Life Quality Index (DLQI), the 12-item Psoriatic Arthritis Impact of Disease (PsAID-12), the Health Assessment Questionnaire (HAQ), and the Self-administered Comorbidity Questionnaire (SCQ). Cognitive impairment was assessed through the Montreal Cognitive Assessment (MoCA). The exclusion criteria were represented by the presence of: age older than 70 years, major depressive disorder, dementia, Parkinson's disease, active skin disease other than PsO, concomitant inflammatory joint conditions (such as gout or calcium pyrophosphate deposition), and comorbid fibromyalgia.

Results: The study involved 96 PsA patients, with a mean age of 52.8 years. Twenty (20.8%) patients were suffering from PsA sine PsO. The mean articular disease duration was 9.9 years, and the mean cutaneous disease duration was 14.9 years. The mean Disease Activity index for Psoriatic Arthritis (DAPSA) was 11.8, and the mean PASI was 0.95. MCI (defined as a MoCA score <26/30) was detected in 47 (48.9%) patients, with a mean value of MoCA of 25.1±3.1. Short-term memory was the most affected domain (mean value 2.6 on 0-5 point scale). The variables under investigation significantly correlated with a worsening cognitive performance (Spearman's Rho) were functional capacity (MoCA vs HAQ, $r_s = -0.227$, $p = 0.026$) and fatigue (MoCA vs PsAID item 2, $r_s = -0.222$, $p = 0.029$).

Conclusion: MCI is present in a significant proportion of PsA patients, and is present in a relative young age. MCI occurrence is associated with the presence of a worse functional capacity and a greater fatigue. Short-term memory is the more frequently affected domain. Although not predominantly of rheumatological interest, the MCI presence should be carried out in all patients with PsA.

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SAT0376

MAKING THE NEXT STEPS IN PSORIATIC ARTHRITIS MANAGEMENT: DOMAIN DRIVEN, TREAT-TO-TARGET, TAILORED MANAGEMENT APPROACH

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Background: The diverse clinical picture of psoriatic arthritis (PsA) suggests the need to identify suitable therapies to address the different combinations of clinical manifestations and comorbidities. The current treatment paradigms recommend early diagnosis and treatment, and a strategic, target orientated approach, aiming at a low disease activity status. The introduction of new treatment modalities highlighted the need for guidelines to prioritize these options for doctors and patients.

Objectives: To develop an evidence-based recommendation for the management and treatment of PsA. The management paradigm should cover all domains of psoriatic disease and provide a stepwise tailored treatment options giving clear advice on treatment from the initial diagnosis, including inclusion/exclusion criteria for treatment, monitoring requirements and how to quantify response to treatment.

Methods: A Steering Committee formulated a set of overarching principles for the management of PsA based on evidence derived from a systematic literature review. These were subsequently discussed, amended and voted on by a Task Force of 20 rheumatologists, dermatologists and patient research partners. Using the nominal group technique and Delphi method, 7 domains were identified (peripheral arthritis, axial disease, enthesitis, dactylitis, skin and nails as well as comorbidities including uveitis). A multidisciplinary, evidence- and consensus-based treatment recommendations for PsA were developed for each of the domains based on three consensus discussions. A set of recommendations for a sequential DMARD/biologic treatment algorithm for patients with PsA was also set.

Results: literature review provided evidence regarding an optimised domain specific, treat-to- target approach to management. The guidelines addressed both drug and non-drug interventions. 20-statements regarding diagnosis, disease activity scoring, US/MRI scanning, and drug therapy were generated. Percentage of positive votes ranged between 86-100%; whereas mean±SD level of agreement was 9.6±0.3. The main treatment outcome is to achieve remission status or at least low disease activity state, which should be based on a shared decision with parents/patients. Treatment should be adapted according to disease activity. Treatment should be also adapted if the remission state got lost.

Conclusion: Although no clear correlation exists between joint inflammation and the skin in every patient, the skin and joint aspects of the disease often must be treated simultaneously. Treatment recommendations for the cardinal physical manifestations of PsA were developed based on a literature review and consensus between rheumatologists, dermatologists and patients. It is anticipated that periodic updates will take place using this framework as new data become available.

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