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LITERATURE REVIEW OF PATIENT PERSPECTIVES ON THE MANAGEMENT AND TREATMENT OF PSORIATIC ARTHRITIS

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Background: A patient-centred approach to the management and drug treatment of psoriatic arthritis (PsA) has been advocated by a multidisciplinary group of experts to improve skin and joint symptoms and health-related quality of life (HRQoL).¹

Objectives: To examine perspectives of patients with PsA on: (1) disease management and treatment goals, (2) disease management and treatment satisfaction, and (3) treatment adherence, including reasons for discontinuation. Areas of interest were those related to medication, symptom resolution, everyday living and overall HRQoL.

Methods: A targeted literature review was conducted to identify peer-reviewed literature on patient experience with PsA management and drug-treatment. English-language articles published between 1 January 2010–8 October 2018 reporting qualitative or quantitative evidence from cross-sectional or longitudinal observational studies were identified from searches conducted using MEDLINE (via PubMed) and Embase. Selection criteria included adult patients with PsA (self-reported or clinician-diagnosed); drug-treatment studies could consider only regulatory-approved treatments for PsA and other studies had to provide evidence of patient perspectives on disease management and treatment goals, experiences and/or satisfaction. Studies involving paediatric/adolescent populations were excluded, as were results for PsA were not distinguishable from other diseases.

Results: The literature search identified 266 titles, of which 48 duplicates were removed. The remaining 218 abstracts were screened: 58 full-text articles were assessed for eligibility and 16 articles were selected for full-text review. Of these 16 articles, 9 were primarily related to patient perspective on disease management, 6 to patient satisfaction and 1 to treatment adherence; some articles covered more than one of these objectives. None of the articles studied whether explicit consideration of treatment goals from the patient perspective would influence management or outcome of care. Symptom resolution, reduced fatigue, improved sexual relations, improved HRQoL and ability to participate in daily activities were consistently identified by patients as important aspects for disease management and daily living with PsA. Articles on patient satisfaction focused largely on general satisfaction with medication rather than satisfaction specifically with holistic PsA management. Notwithstanding, symptom resolution was clearly linked to greater patient satisfaction with medication. Patient dissatisfaction with PsA treatment was influenced by their attitude towards treatment, concerns about PsA medication, the physician-patient relationship and lack of patient involvement in decision-making. Treatment adherence has not been widely explored but mainly relates to perceptions about, and experiences with, medications, including efficacy and adverse events.

Conclusion: This literature review identified a lack of research on patient perspectives of PsA management and treatment goals. It also highlighted the lack of patient involvement in determining management and/or setting personal goals, which may ultimately affect satisfaction. There remains a lack of clarity on PsA symptoms and other disease- or patient-related parameters that impact patient satisfaction/dissatisfaction and patient-centred reasons for treatment discontinuation. The findings of this review will be used to develop a PsA patient survey to further explore patient perspectives to improve care in PsA.

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IXEKIZUMAB MAKES REMISSION AND LOW DISEASE ACTIVITY POSSIBLE IN PATIENTS WITH PSORIATIC ARTHRITIS: TWO-YEAR RESULTS IN TNF INADEQUATE RESPONDERS OR BIOLOGIC-NAÏVE PATIENTS

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Background: Psoriatic arthritis (PsA) is a heterogeneous inflammatory disease that can involve peripheral and axial joints, skin, and entheses. A number of validated composite indices have been developed, not only to measure overall disease activity for PsA, but also to provide thresholds for treat-to-target goals. These include MDA (Minimal Disease Activity), DAPSA (Disease Activity in PsA), and PASDAS (PsA Disease Activity Score). We have previously demonstrated that higher proportions of PsA patients treated with ixekizumab (IXE), a monoclonal antibody that selectively targets interleukin-17A, achieved therapeutic thresholds defined by MDA, DAPSA, and PASDAS versus placebo (PBO) up to Week 24.¹

Objectives: To explore the extent to which IXE can help biologic-naïve and tumor necrosis factor inhibitor (TNFi) inadequate responder patients achieve treat-to-target goals, as defined by composite indices incorporating multiple disease domains, through 108 weeks of treatment.

Methods: Data were analyzed from all patients initially randomized to 80 mg IXE every 4 weeks after a 160-mg starting dose in 2 double-blind, PBO-controlled phase III trials investigating the efficacy and safety of IXE. For SPIRIT-P1 (NCT01695239), patients (N=107) were bDMARD naïve. For SPIRIT-P2 (NCT02349295), patients (N=122) had an inadequate response or were intolerant to TNFi. The following composite measures and definitions were used: MDA and Very Low Disease Activity (VLDA) (see Figure); DAPSA Low Disease Activity (LDA) (≤ 14 and >4) and remission (≤ 4); PASDAS LDA/VLDA ($\leq 3.2/\leq 1.9$); and GRACE (GRAppa Composite score) LDA (≤ 2.3). Modified nonresponder imputation (mNRI; missing data treated as nonresponse for patients discontinued due to lack of efficacy or adverse events; multiple imputation for all other missing data) was used for all analyses.

Results: Therapeutic threshold results at Week 108 are summarized in the Figure. Whether measured using MDA, DAPSA, PASDAS, or GRACE, the proportions of IXE-treated patients achieving designated therapeutic thresholds were sustained through 2 years of treatment. Efficacy was similar between SPIRIT-P1 and SPIRIT-P2.

Figure. Therapeutic threshold results by Instrument and SPIRIT study

Data labels show proportion of patients achieving the indicated treatment threshold. P-1 and P-2, SPIRIT-P1 and -P2; n, patients included in the analysis (modified nonresponder imputation applied). *MDA was achieved if 5 to 6, and VLDA was achieved if 7 of 7, of the following criteria were met: tender joint count ≤ 1 ; swollen joint count ≤ 1 ; Psoriasis Area and Severity Index total score ≤ 1 or body surface area $\leq 3\%$; patient's assessment of pain visual analog scale (VAS) ≤ 15 ; patient's global assessment of disease activity VAS ≤ 20 ; Health Assessment Questionnaire Disability Index ≤ 5 ; and tender entheses points ≤ 2 (assessed by the Leeds Enthesitis Index). *N=106 for MDA; 107 for VLDA.

Conclusion: High proportions of IXE-treated patients, whether biologic naïve or TNFi inadequate responders, achieved treat-to-target goals, as defined by composite indices incorporating multiple disease domains, through 2 years of treatment.

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IS THE CLINICAL AND THERAPEUTIC PROFILE RELATED TO SATISFACTORY RESPONSE TO APREMILAST IN PSORIATIC ARTHRITIS?

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Methods: An observational and analytical multicenter retrospective study. There are included PsA patients treated with APR after two years of commercialization. Clinical and demographic data were collected: disease duration, previous treatments, cutaneous and joint involvement pattern defined as: joint exclusively, non joint and mixed (by several domains combination). It was collected: duration of treatment, tolerance, adverse events, and reason for APR choice: intolerance or toxicity to csDMARD, preference before bDMARD contraindication or caution to bDMARD, csDMARD and bDMARD inefficacy, csDMARD and bDMARD intolerance. The effectiveness was considered as a dicotomic variable (Yes/No) by clinical criteria.

Results: There were included 89 patients, 46(51.7%) males, the mean age was 53.99±12.3 years, and the PsA disease duration was 7.28±6.25 years. The PsA pattern was: joint 29(32.6%), non joint, 12(13.5%) and mixed 48(53.9%). The reason for APR choice was: intolerance or toxicity to csDMARD 13 patients, preference before BT 28, contraindication or caution to BT 22, inefficacy to csDMARD or BT 18, intolerance to csDMARD and BT 1, and due to clinical profile 1. After a mean treatment duration with APR of 8.13(0-23) months a total of 33 withdrawals were found (17 due to inefficacy and 16 due to intolerance), treatment was maintained on them a mean of 4.3(0-12) months. 56 patients keep with APR a mean of 10.4(2-23) months, 22 of them among 1 and 2 years of evolution. The treatment was effective in 61(68.5%) patients. Comparisons of the different variables analyzed did not show significant differences among the responders and non responders patients.

Conclusion: We have not found a specific profile that relates with a satisfactory response to APR.

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PSORIATIC ARTHRITIS AND DEPRESSIVE SYMPTOMS: DOES SYSTEMIC INFLAMMATION PLAY A ROLE?

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Background: Depression is one of the most common comorbidities in patients with Psoriatic Arthritis (PsA) but risk factors for mood disorders in these patients are still largely unrecognized. Pro-inflammatory cytokines involved in the pathogenesis of PsA have been also associated with depressive symptoms in patients without systemic autoimmune diseases.

Objectives: The aim of this study is to determine risk factors for depressive symptoms and compare serum cytokines concentrations in subjects with and without depressive symptoms in a cohort of PsA patients.

Methods: Eighty consecutive patients with PsA were screened for depressive symptoms with depression subscale of the Hospital Anxiety and Depression Scale (HADS-D). A validated cut-off of 8 was used to define patients with significant depressive mood. Patients with and without depressive symptoms were compared for the prevalence of general risk factors for depression, comorbidity, psoriatic disease age of onset, duration, activity and domains affected, treatment and serum levels of IL-6, TNF- α and IL-17A.

Results: Mean disease duration of skin disease and articular disease was 18.8 $\pm$ 15.3 years and 9.0 $\pm$ 11.1 years, respectively. All patients had a history of peripheral arthritis, 41.3% had dactylitis, 38.8% had enthesitis, 21.3% had spondylitis 82.5% had a psoriatic skin disease and 51.2% had psoriatic nail disease. According to DAPSA index, 20.0% were in remission, 50.0% in Low Disease Activity, 20.0% in Moderate Disease Activity and 10.0% in High Disease Activity. Thirty-five (43.8%) were in Minimal Disease Activity. Thirty-three patients (41.3%) had depressive symptoms according to HADS. Patients with and without depressive symptoms did not differ in terms of age, gender, comorbidity, general risk factors of depression, psoriatic disease age of onset, duration, domains affected, DAPSA activity, MDA achievement, PASI, HAQ, VAS pain, the intensity of treatment, serum TNF- α IL-17A and IL-23. Serum levels of IL-6 were higher in patients with depressive symptoms. (2.99 $\pm$ 2.58 vs 1.54 $\pm$ 1.60 pg/dl; p=0.006). A cut-off of 2.27 pg/ml of serum IL-6 had the best ability to predict a HADS $\geq$ 8 according to higher Youden Index of the ROC curve (AUC 0.682 $\pm$ 0.061; p=0.006). Multivariate logistic regression analysis revealed that serum IL-6 $\geq$ 2.27 pg/ml was a predictor of depressive symptoms even when adjusted for DAPSA, HAQ and PASI (OR 3.06; CI 1.14-8.20; p = 0.026).

Conclusion: Higher serum IL-6 is associated with depressive symptoms independently from articular and cutaneous disease activity and degree of disability. This association suggest a direct role of systemic inflammation in the modulation of mood in PsA patients.

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