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Efficacy and Safety of Ixekizumab in Patients with Psoriatic Arthritis and Inadequate Response to TNF Inhibitors: Three Year Results from a Phase 3 Study (SPIRIT-P2)

J. Gratacos-Masmithi1, A. Turciwiekz2, E. Dokoupilova3, A. M. Gelleit4, A. T. Sprabery5, V. J. Geneus5, A. Constantin6, University Hospital Parc Taulí Sabadell, Barcelona, Spain; Dermatology Unit, Department of Medicine-DIMED, Padova, Italy; University of Veterinary and Pharmaceutical Sciences, Faculty of Pharmacy, Department of Pharmacoeconomics, Brno, Czech Republic; Eli Lilly and Company, Indianapolis, United States of America; Medical Plus s.r.o., Uherske Hradiste, Czech Republic; University of Veterinary and Pharmaceutical Sciences, Faculty of Pharmacy, Department of Pharmacoeconomics, Brno, Czech Republic; Eli Lilly and Company, Indianapolis, United States of America; Hospital Pierre Paul Riquet, Toulouse, France

Background: Ixekizumab (IXE) is a high affinity monoclonal antibody that selectively targets interleukin-17A. In the SPIRIT-P2 study, IXE every 4 (Q4W) or 2 (Q2W) weeks was superior to placebo (PBO) in improving the signs and symptoms of psoriatic arthritis (PsA) at Week 24 in patients (pts) with prior inadequate response or intolerance to 1 or 2 tumour necrosis factor inhibitors (TNFi).

Objectives: To determine efficacy and safety of IXE treatment up to 3 years in pts with PsA.

Methods: In SPIRIT-P2 (NCT02349295), 310 pts entered the extension period where pts maintained their original ixekizumab dose, and placebo pts received IxEQ4W or IXEQ2W (1:1). Pts failing to demonstrate ≥20% improvement in both tender and swollen joint counts at Week 32, or any subsequent visit, were discontinued (mandatory discontinuation criteria). Efficacy outcomes were ACR20/50/70 response, Psoriasis Area and Severity Index (PASI) 75/90/100 response, Leeds Enthesitis Index (LEI), Leeds Dactylitis Index-Basic (LDI-B), Minimal Disease Activity (MDA), and Disease Activity in Psoriatic Arthritis (DAPSA). Ad-hoc efficacy data are presented for intent-to-treat (ITT) pts initially randomized to IXE at Week 0. Observed and modified non-responder imputation (mNRI); missing data treated as non-response for pts discontinued due to lack of efficacy or adverse events (AEs) was applied to categorical measures. Observed and modified baseline observation carried forward (mBOCF) was applied to continuous efficacy measures. Safety was analysed in pts exposed to at least one dose of ixekizumab. During the double-blind treatment period (Weeks 0-24), one patient reported serious adverse events of anal fistula and anal abscess, which were considered by the sponsor to be IBD; however, an independent adjudication committee of external experts reviewed the case and determined the events to be ‘Not IBD.’

Conclusion: In pts treated with IXE who had prior inadequate response or intolerance to 1 or 2 TNFi, improvements in the signs and symptoms of PsA persisted up to 3 years. No unexpected safety signals were observed, and the safety profile was consistent with previous studies of IXE.

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Accuracy of an Instrument for Screening Psoriatic Arthritis Among Psoriatic Patients: Results from the Multicentre Italian Study HERACLES (Screening Strategies for Rheumatological Referral of Psoriatic Subjects Aimed to Disclose Psoriatic Arthritis)

G. De Marco1, M. Manara2, P. Gisondi3, L. Idioli4, R. Ramonda5, S. Piaserico6, A. Cauil7, M. A. Cimmino8, V. Tomatis9, C. Salvarani10, R. Scirocco11, A. Zanetti11, G. Carrara11, C. A. Sciri1, A. Cattaneo12, A. Marchesoni13, 1NIHR Leeds Biomedical Research Centre, Leeds Teaching Hospitals NHS Trust, Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, United Kingdom; 2ASST Gaetano Pini-CTO, Milano, Italy; 3University of Verona, Dermatology and Venereology Section, Verona, Italy; 4University of Verona, Rheumatology Unit, Department of Medicine, Verona, Italy; 5University of Padova, Rheumatology Unit, Department of Medicine-DIMED, Padova, Italy; 6University of Padova, Dermatology Unit, Department of Medicine-DIMED, Padova, Italy; 7Università
Background: Identifying psoriatic arthritis (PsA) among people with psoriasis is often challenging due to low specificity of symptoms at early PsA stage and/or delayed referral to the rheumatologist. Screening instruments -assisting the dermatologist to decide when rheumatological assessment is beneficial- have potential to reduce the diagnostic delay.

Objectives: To evaluate the accuracy of a dermatologist-filled-out questionnaire designed for screening PsA among psoriatic patients under dermatology care.

Methods: HERACLES is a multicentre, cross-sectional study running at 9 Italian dermatology and rheumatology tertiary centres. All participants were under dermatology care for skin psoriasis. Previous diagnosis of PsA precluded eligibility. Dermatologists at each site assessed consecutive psoriatic subjects, filled in the specifically-designed HERACLES questionnaire (HQ, Figure 1) and finally referred the participants to rheumatologists for clinical evaluation. All participants filled in the ToPAS, PASE, PEST and EARP questionnaires. Rheumatologists assessed the participants regardless of the questionnaires’ scores. The gold standard applied to assess the instruments’ accuracy was the diagnosis of PsA as established by the rheumatologists. ROC curve analysis evaluated the performance of the scores associated with the clinical criteria listed in the HQ, estimating the sensitivity and specificity of different cut-off levels. Further exploratory ROC curve analysis compared HQ performance to that of the other four questionnaires tested.

Results: Out of 759 subjects enrolled, 524 (69%) attended rheumatology assessment. Rheumatologists diagnosed PsA in 73/524 patients (13.9%, Figure 2). Mean age was 53 (SD 16) years and 46% were female. Mean psoriasis duration was 20 (SD 19) years. The area under the ROC curve of HQ was 0.757. The HQ score cut-off value of 2 yielded a sensitivity of 92% and a specificity of 77%; a cut-off value of 3 yielded a sensitivity of 66% and a specificity of 75%. The comparison between the ROC curve of the HQ and those of the other four questionnaires evaluated did not show any significant difference (p=0.523 versus TOPAS; p=0.201 versus PASE; p=0.345 versus PEST and p=0.240 versus EARP).

Flow Chart, HERACLES study

Figure 2.

Conclusion: The HERACLES questionnaire, a tool designed for dermatologists, showed good sensitivity and specificity in identifying PsA cases among subjects with cutaneous psoriasis.

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SAT0413 DACTYLITIS IS ASSOCIATED WITH DISEASE SEVERITY AND ULTRASOUND DEFINED EROSIIVE DAMAGE IN VERY EARLY, DMARD NAIVE PSORIATIC ARTHRITIS

S. Dubash1, O. Alabas1, X. Michelena1, G. De Marco1, L. Garcia-Montoya1, R. Wakefield1, A. L. Tan1, P. Helliwell1, P. Emery1, D. Mcgonagle1, H. Marzo-Ortega1, NHIR LBRC, Leeds Teaching Hospitals Trust & LIRMM, University of Leeds, Leeds, United Kingdom

Background: Dactylitis is a hallmark feature of Psoriatic arthritis (PsA) and Spondyloarthritis (SpA) defined as a uniform swelling of a digit (“sausage digit”). Dactylitis is associated with radiographic damage in chronic PsA. However, there are a paucity of data on the significance of dactylitis and its potential impact in disease burden in early PsA.

Objectives: To characterize a very early DMARD naive PsA cohort based on clinical presence or absence of dactylitis at disease onset.

Methods: PsA subjects fulfilling the CASPAR classification criteria, were recruited into a prospective observational cohort, the Leeds Spondyloarthritis Registry for Research and Observation (SpARRO) after providing informed written consent. Clinical data including tender (TJC) and swollen joint counts (SJC) were independently assessed. Dactylitis was recorded per digit (finger or toe) as tender (hot) or non-tender (cold). Differences in baseline characteristics were evaluated using percentages to describe categorical variables and means and standard deviations for continuous variables, p value of the mean/proportion difference was calculated. Ultrasound (US) examination was conducted by trained ultrasonographers blinded to clinical details. Bone erosions were defined on US if intra-articular discontinuity was present in two perpendicular planes at any of 46 joints: wrists, MCP1-5, PIP2-5, DIP2-5, MTP1-5, knees, ankles, subtalar, talonavicular.

Results: A total of 177 PsA patients were recruited. Dactylitis was seen in nearly half the cohort (n=83 (47%)). Patients with dactylitis had significantly more early morning stiffness, higher TJC and SJC, compared with non-dactylitis (Table 1). A total of 211 digits with dactylitis were recorded in 83 patients. Dactylitis of multiple digits was seen in 47/83 (57%) patients whilst a single dactylitic digit occurred in 36/83 (43%). Foot involvement was more prevalent (141/211, 67%) than hands (70/211, 33%). "Hot" or tender dactylitis was more frequently detected (153/211,