Conclusion: Confounding by indication or protopathic bias may explain the observed association of biologic therapy with the development of PsA among patients with psoriasis. Some patients may be receiving therapy because they have both psoriasis and early symptoms of PsA or their PsA diagnosis is not recorded appropriately. Given the directional discrepancy in the results between traditional modeling and propensity score analysis, further work is needed to understand the nature of this relationship.

Figure 1

Figure 3. Directed Acyclic Graph describing potential confounders in relationship between therapy prescription and diagnosis of PsA

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FR10356

BURDEN OF DISEASE IN PATIENTS INITIATING APREMILAST TREATMENT: 2014-2019 FINDINGS FROM THE CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS REGISTRY

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Background: The prospective, US-based, observational Corrona PsA/SpA Registry collects real-world data on patients (pts) with PsA provided by pts and their providers.

Objectives: To examine trends in characteristics of pts initiating apremilast (APR) from 2014-2019 and compare characteristics of treatment-naïve pts initiating APR or methotrexate (MTX).

Methods: PsA pts aged ≥18 yrs enrolled in the registry who initiated APR, MTX, and/or biologics for PsA from January 2014-August 2019 were included and stratified by year of initiation (2014-2015, 2016-2017, or 2018-2019). Demographics, clinical characteristics, treatment history, disease activity, and pt-reported outcomes (PROs) were analyzed at treatment initiation. Comparisons between treatment-naïve APR vs MTX initiators during the entire 2014-2019 study period were summarized descriptively.

Results: 1460 PsA pts initiated APR (n=238), MTX (n=178), and/or a biologic (n=1044), including treatment-naïve APR (n=20) and MTX (n=99) initiators from 2014-2019. For APR initiators in the 3 successive time periods, respectively, mean disease duration was 10.5, 12.2, and 11.4 yrs, and 87.5%, 82.5%, and 68.6% of pts had prior use of csDMARDs (similar to biologic initiators: 77.9%, 77.2%, and 68.8%). Over time, lower joint, enthesitis, and dactylitis counts, composite disease activity, and PRO measures of disease burden were observed (Table). Compared with treatment-naïve MTX initiators, treatment-naïve APR initiators had longer duration of PsA (8.5 vs 5.5 yrs) and time since PsA diagnosis (3.3 vs 1.8 yrs). Rates of comorbidities such as hypertension (50.0% vs 37.8%), diabetes mellitus (38.9% vs 13.3%), and metabolic syndrome (33.3% vs 8.9%) were higher in treatment-naïve APR vs MTX initiators. Greater proportions of treatment-naïve APR initiators had high/very high disease activity according to CDAI, DAPSA, cDAPSA, PASDAS, and DAS-28 vs MTX initiators.

Conclusion: In this Corrona Registry analysis, PsA pts initiating APR had lower disease burden in recent vs prior yrs, indicating use of APR earlier in the course of PsA is increasing in real-world practice. Treatment-naïve APR initiators had greater disease activity and severity vs MTX initiators. Comorbidities were common at APR initiation.

Table:

Disease Severity and Activity, and PROs for APR Initiators in the Corrona PsA/SpA Registry

Characteristic	2014-2015 n=72	2016-2017 n=80	2018-2019 n=86
SJC (0-66), median (IQR)	2.0 (4.0)	1.0 (3.0)	0.0 (3.0)
TJC (0-68), median (IQR)	5.0 (14.0)	2.0 (4.0)	2.0 (10.0)
SPARCC enthesitis*, mean (SD)	4.7 (3.0)	3.8 (2.2)	3.7 (3.1)
Dactylitis count†, mean (SD)	2.5 (2.5)	2.3 (1.0)	2.2 (2.3)
cDAPSA category, n (%)			
Remission	4 (7.4)	8 (14.8)	13 (15.9)
Low disease activity	12 (22.2)	18 (33.3)	30 (36.6)
Minimal disease activity, n (%)	8 (15.1)	14 (26.9)	21 (25.6)
DAS-28 remission, n (%)	5 (19.2)	8 (32.0)	24 (43.6)
Pain VAS (0-100 mm) >15, n (%)	47 (85.5)	47 (83.9)	60 (73.2)
Pt's Global Assessment of Arthritis VAS (0-100 mm) >20, n (%)	47 (82.5)	45 (77.6)	54 (65.9)
HAQ >0.5, n (%)	39 (69.6)	35 (59.3)	44 (53.7)
Fatigue VAS (0-100 mm), mean (SD)	56.7 (25.4)	49.8 (25.9)	45.6 (31.5)
Spine pain VAS (0-100 mm), mean (SD)	38.8 (27.6)	36.5 (29.6)	28.8 (34.1)
BASDAI‡, mean (SD)	5.4 (2.4)	4.9 (2.5)	4.4 (2.6)
Morning stiffness VAS (0-100 mm), mean (SD)	52.8 (27.3)	51.4 (28.3)	48.0 (31.2)

The n represents the total sample. Number of pts with data available may vary. *Among pts with enthesitis at baseline. †Among pts with dactylitis at baseline. ‡Among pts thought to have spondylitis by the investigator. IQR=interquartile range.

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FRI0357

IMPROVED PAIN AND FATIGUE WITH IXEKIZUMAB TREATMENT IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AND PREVIOUS INADEQUATE RESPONSE TO TNF INHIBITORS: THREE YEAR FOLLOW-UP FROM A PHASE 3 STUDY (SPIRIT-P2)

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Background: Psoriatic arthritis (PsA) is a chronic and complex inflammatory disease with both articular and extra-articular symptoms. Pain and fatigue are two of the most common patient-reported symptoms. Improvements in pain and fatigue have been demonstrated with up to 2 years of treatment with ixekizumab (IXE) in patients who had an inadequate response or intolerance to tumor necrosis factor inhibitors (TNFi).^{1,2}

Objectives: To report improvements in pain and fatigue in TNFi-experienced patients with PsA who were treated with IXE for 3 years (156 weeks).

Methods: SPIRIT-P2 (NCT02349295) was a 156-week, Phase 3 study that included patients who met the Classification Criteria for Psoriatic Arthritis (CASPAR) and had an inadequate response or intolerance to 1 or 2 TNFi. Although there was a placebo group through Week 24, these data were derived only from patients in the intent-to-treat population randomized to IXE at baseline. After a 160-mg starting dose, patients received 80mg subcutaneous IXE every 2 or 4 weeks (Q2W or Q4W). Patients self-rated their symptoms using the Joint Pain Visual Analog Scale (Joint Pain VAS; 0 [none] to 100 [worst imaginable]), the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36; with the domains ranging from 0 [worst] to 100 [best]), and the Fatigue Severity Numeric Rating Scale (Fatigue NRS; 0 [none] to 10 [worst imaginable]). Minimum clinically important difference (MCID) cutoffs were ≥ 10 for Joint Pain VAS, ≥ 5 for SF-36 domains, and ≥ 3 for Fatigue NRS. Missing values were imputed by modified baseline observation carried forward for continuous variables and modified non-responder imputation for categorical variables.

Figure. Pain and fatigue outcomes after 156 weeks of treatment with ixekizumab. Mean change from baseline is shown for (A) Joint pain VAS, (B) SF-36 bodily pain domain, (C) Fatigue NRS, and (D) SF-36 vitality domain. IXE=ixekizumab; NRS=numeric rating scale; Q2W=every 2 weeks; Q4W=every 4 weeks; SF-36= Medical Outcomes Study 36-Item Short Form Health Survey; VAS=visual analog scale.

Results: The proportions of patients who completed Week 156 were 70/122 (57.4%) in the IXE Q4W group and 55/123 (44.7%) in the IXE Q2W group. At Week 156, mean change from baseline for the Joint Pain VAS was -28.9 (IXE Q4W) and -25.3 (IXE Q2W) (Fig. A). In addition, 51.8% of patients on IXE reported clinically meaningful improvement of joint pain (56.1% IXE Q4W, 47.5% IXE Q2W) at Week 156. Patients reported an 18-point mean improvement in the SF-36 bodily pain domain at Week 156 (Fig. B). Patients also reported improvements in fatigue up to Week 156 (Fig. C), with 35.0% of patients achieving the MCID on the Fatigue NRS (39.4% IXE Q4W, 30.6% IXE Q2W). Improvement in fatigue was supported by a 14-point mean improvement in the vitality domain of the SF-36 at Week 156 (Fig. D).

Conclusion: In patients with PsA who had an inadequate response or intolerance to TNFi, improvements in pain and fatigue were sustained through 3 years of IXE treatment in both the Q2W and Q4W treatment groups.

References:

- [1] Kavanaugh A, Marzo-Ortega H, Vender R, et al. *Clin Exp Rheumatol*. 2019;37(4):566-574.
- [2] Turkiewicz A, Gellett A, Kerr L, et al. [abstract] *Arthritis Rheumatol*. 2018;70(S9):2577.

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FRI0358

USAGE OF C-REACTIVE PROTEIN TESTING IN THE DIAGNOSIS AND MONITORING OF PSORIATIC ARTHRITIS (PSA): RESULTS FROM A REAL-WORLD SURVEY IN THE US AND EUROPE

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Background: C-reactive protein (CRP) is an important non-specific marker of both acute and chronic inflammation and can be elevated in patients with PsA. The role of CRP in the management of PsA is unclear.

Objectives: To describe how CRP testing is implemented in real-world clinical practice for disease management of PsA.

Methods: A cross-sectional study among patients with PsA recruited by rheumatologists and dermatologists was conducted in France, Germany, Italy, Spain, UK and US. Data were collected from Jun-Aug 2018 via physician-completed patient record forms. Use of CRP testing was obtained by asking the physician to state (yes/no) whether CRP was used to aid PsA diagnosis, confirm the patient's PsA and to monitor the patient's PsA. Where physicians stated use of CRP testing, they were then asked to provide the number of CRP tests conducted in the last 12 months.

Results: Data were collected for 2270 patients with PsA (595 US, 1675 EU). In EU, 78.7% of patients had CRP conducted to aid diagnosis (vs 43.4% in US) and 72.0% had CRP conducted to monitor their condition (vs 34.6% in US). Patients seen by rheumatologists (vs dermatologists) were at least 50% more likely to have CRP used for monitoring purposes, this difference being most pronounced in the US. In EU, CRP was conducted a mean [SD] of 2.7 [1.7] times in the last 12 months, versus 2.0 [1.4] in the US. Country level usage of CRP testing is shown in Table 2.