Running head: Axial manifestations in PsA

Evaluation of Clinical Diagnosis of Axial Psoriatic Arthritis or Elevated Patient-Reported Spine Pain in CorEvitas' Psoriatic Arthritis/Spondyloarthritis Registry

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ABSTRACT

Objective: To determine the presence of axial symptoms in patients with psoriatic arthritis (PsA) and examine differences between those with or without a diagnosis of axial PsA (axPsA).

Methods: Patients with PsA at their CorEvitas' (formerly Corrona) Psoriatic Arthritis/Spondyloarthritis Registry enrollment visit were stratified into 4 mutually exclusive groups based on axial manifestations: physician-diagnosed axPsA only (Dx^+Sx^-), patient-reported elevated spine symptoms only (Dx^-Sx^+ ; defined as Bath Ankylosing Spondylitis Disease Activity Index ≥ 4 and spine pain visual analog scale ≥ 40), physician-diagnosed and patient-reported (Dx^+Sx^+), and no axial manifestations (Dx^-Sx^-). Patient characteristics, disease activity, and patient-reported outcomes (PROs) at enrollment in each axial manifestation group were compared with the Dx^-Sx^- group. Associations of patient characteristics with the odds of having axial manifestations were estimated using multinomial logistic regression (reference: Dx^-Sx^-).

Results: Of 3393 patients included, 226 (6.7%) had Dx^+Sx^- , 698 (20.6%) had Dx^-Sx^+ , 165 (4.9%) had Dx^+Sx^+ , and 2304 (67.9%) had Dx^-Sx^- . Patients with Dx^-Sx^+ or Dx^+Sx^+ were more frequently women and had a history of depression and fibromyalgia vs patients who had Dx^-Sx^- . Patients with Dx^+Sx^- or Dx^+Sx^+ were more frequently HLA-B27 positive than those with Dx^-Sx^- . Fibromyalgia was significantly associated with increased odds of Dx^+Sx^- or Dx^+Sx^+ . Disease activity and PROs were worse in patients with Dx^-Sx^+ or Dx^+Sx^+ than in those with Dx^-Sx^- .

Conclusion: Patients who had self-reported elevated spine symptoms, with or without physician-diagnosed axPsA, had worse quality of life and higher disease activity overall than patients without axial manifestations, suggesting an unmet need in this patient population.

INTRODUCTION

Psoriatic arthritis (PsA) is a chronic, systemic inflammatory disease with heterogeneous symptoms and presentations.(1,2). The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) recognizes 6 key disease domains that may present alone or in combination: skin disease, peripheral arthritis, nail psoriasis, enthesitis, dactylitis, and axial disease.(1) Depending on axial disease definition and study methodology, axial disease due to inflammation occurs in 25%-70% of patients with PsA.(3,4) Clinical signs and symptoms of axial PsA (axPsA) include inflammatory back pain, reduced spinal mobility, and sacroiliitis, which is often asymmetrical.(3,5-8) If untreated, patients with axPsA can experience significantly reduced spinal mobility; nearly 40% of patients without sacroiliitis have developed grade ≥ 2 sacroiliitis at 5 years of follow-up.(4) A previous study in CorEvitas' (formerly Corrona) Psoriatic Arthritis/Spondyloarthritis (PsA/SpA) Registry showed that patients who had axPsA had higher disease activity, reduced quality of life, and more impaired physical function and work productivity than those without axial involvement.(9) Thus, prompt identification and treatment of axPsA are important to prevent increasing structural damage, maintain mobility, and improve quality of life.

AxPsA is generally diagnosed based on patient history, physical examination, imaging, and laboratory testing.(5,10) However, no consensus currently exists on criteria to define axPsA. Back pain is highly prevalent in the general population and can result from numerous causes, including injury, occupational conditions, chronic pain disorders, or other conditions that affect the spine.(11) Additionally, up to 30% of patients with PsA with visible structural damage on imaging have no axial symptoms.(4,12-14) Together, these factors can result in missed or delayed diagnosis of axial disease in patients with PsA. The lack of validated classification criteria for axPsA also limits consistent evaluation and meaningful comparison of treatment efficacies for patients with axPsA in clinical research. A randomized controlled trial assessing the efficacy of secukinumab in patients with axPsA (MAXIMISE) used the following inclusion

criteria for axPsA: patients had to meet the Classification Criteria for Psoriatic Arthritis, have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score ≥ 4 (suggesting the presence of active axial manifestations), and have a patient-reported spine pain score ≥ 40 on a visual analog scale (VAS).⁽¹⁵⁾ Efforts are currently underway by GRAPPA and the Assessment of SpondyloArthritis international Society to better define axPsA.⁽¹⁶⁾ Our study evaluated characteristics of patients with PsA and physician-diagnosed axPsA, and of patients with PsA who had active elevated spine symptoms as assessed by BASDAI and patient-reported spine pain.

PATIENTS AND METHODS

Data source

CorEvitas' PsA/SpA Registry is a large independent, prospective, observational cohort of patients with rheumatologist-diagnosed PsA or SpA. The registry includes patients recruited by 67 participating rheumatologists from 64 private and academic practice sites across 40 US states. As of January 1, 2021, the registry included data on approximately 4683 patients with PsA/SpA from 20,230 patient visits. CorEvitas' PsA/SpA Registry and its investigators have been reviewed and approved by a central institutional review board (IRB; New England Independent Review Board No. 120160070). For academic investigative sites that did not receive a waiver to use the central IRB, approval was obtained from the respective governing IRB. All participating investigators were required to obtain full board approval for conducting noninterventional research with a limited data set involving human participants. Registry participants were required to provide written informed consent and authorization prior to participating. All research was conducted in compliance with the current (2013) Declaration of Helsinki.

Study design and patient population

This cross-sectional study included patients aged ≥ 18 years with PsA enrolled in the registry between March 2013 and November 2019. Patients were assessed for the presence of physician-diagnosed axPsA and elevated spine symptoms at registry enrollment. Physicians identified the subset of patients with axPsA based on history, physical examination, imaging, and laboratory workup. All patients completed a BASDAI questionnaire and spine pain VAS (0-100) at enrollment; the criteria for patient-reported elevated spine symptoms was a BASDAI ≥ 4 (indicating active axial manifestations) and a spine pain VAS ≥ 40 . Patients were stratified into mutually exclusive groups based on axial manifestations: physician diagnosis of axPsA only (Dx^+Sx^-), patient-reported elevated spine symptoms only (Dx^-Sx^+), both physician diagnosis of axPsA and patient-reported elevated spine symptoms (Dx^+Sx^+), and patients without physician diagnosis of axPsA or patient-reported elevated spine symptoms (Dx^-Sx^-) (**Figure S1**).

Data collection and definitions

Data were collected at registry enrollment using questionnaires from patients and their treating rheumatologists that were completed at routine office visits. Data collected included patient demographics, clinical characteristics, history of comorbidities, prior and current treatment use, disease activity and patient-reported outcome (PRO) measures, and work productivity and activity impairment. Disease activity measures included 68 tender joint count (TJC), 66 swollen joint count (SJC), physician global assessment VAS, Disease Activity Index in Psoriatic Arthritis (DAPSA), Psoriatic Arthritis Disease Activity Score (PASDAS), and minimal disease activity (MDA). MDA was defined as meeting 5 of the 7 following criteria: TJC ≤ 1 , SJC ≤ 1 , psoriasis-affected body surface area $< 3\%$, patient-reported pain VAS ≤ 15 , patient global assessment VAS ≤ 20 , Health Assessment Questionnaire Disability Index (HAQ-DI) ≤ 0.5 , and tender entheses ≤ 1 using the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index.⁽¹⁷⁾ PROs included BASDAI, spine pain VAS, patient-reported pain and fatigue VAS, patient global assessment VAS, morning stiffness VAS, EuroQoL VAS (EQ VAS), HAQ-DI,

and the Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S). Work productivity was assessed using the Work Productivity and Activity Impairment questionnaire.

The proportion of patients with Dx⁺Sx⁻, Dx⁻Sx⁺, Dx⁺Sx⁺, and Dx⁻Sx⁻ was determined in the overall population and in patients initiating a biologic at registry enrollment to reduce confounding in the assessment of disease activity in patients who were already receiving treatment at enrollment. The frequencies of other PsA manifestations (enthesitis [SPARCC Enthesitis Index count >0], dactylitis [dactylitis count >0], peripheral arthritis [TJC and/or SJC >0], nail psoriasis [global nail psoriasis VAS >0], and skin disease [percentage of affected body surface area >0%]) were reported in each axial manifestation group separately in both the overall and bioinitiator populations.

Statistical analysis

The proportion of patients with Dx⁺Sx⁻, Dx⁻Sx⁺, and other active PsA manifestations at enrollment was summarized descriptively. Patient characteristics, disease activity, and PROs at enrollment were compared between patients with Dx⁺Sx⁻, Dx⁻Sx⁺, or Dx⁺Sx⁺ and those with Dx⁻Sx⁻ using 2-sample *t* tests for continuous variables and χ^2 or Fisher exact tests for categorical variables; significance testing was not adjusted for multiple comparisons due to the descriptive nature of this study. Complete case analyses were used, with no imputation for missing data.

A multinomial logistic regression model was used to calculate odds ratios (ORs) estimating the associations of patient characteristics with having Dx⁺Sx⁻, Dx⁻Sx⁺, or Dx⁺Sx⁺ at enrollment (reference: Dx⁻Sx⁻). Covariates chosen a priori included age, sex, race, time since diagnosis, body mass index (BMI), and current and prior biologic, conventional synthetic disease-modifying antirheumatic drug (csDMARD), and prednisone use. Harrell's list of relevant covariate types was used to determine other candidate covariates(18), which were tested for collinearity (correlation coefficient $\rho \geq 0.6$) and nonlinearity ($\rho < 0.6$). Additional covariates

identified for inclusion were fibromyalgia (included as the surrogate measure TJC/SJC ratio ≥ 7 (19,20)), depression, Clinical Disease Activity Index for Psoriatic Arthritis (cDAPSA) score, and EuroQol 5-Dimensions (EQ-5D) questionnaire score. HAQ-S was excluded from the final model due to its multicollinearity with cDAPSA and EQ-5D. Time since diagnosis and cDAPSA had nonlinear associations with the outcome measures and were therefore included in the model as 4-knot restricted cubic splines.

The associations of Dx^+Sx^- , Dx^-Sx^+ , or Dx^+Sx^+ with disease activity and PRO measures were analyzed using multivariable linear or logistic regression models with Dx^-Sx^- as the reference group (**Table S1**). Models were adjusted for age, sex, race, BMI, time since diagnosis, fibromyalgia (TJC/SJC ratio ≥ 7), depression, cDAPSA score, EQ-5D score, and prior and current biologic, csDMARD, and prednisone use. All statistical analyses were performed using Stata 15.1 (StataCorp LP, College Station, TX).

RESULTS

Frequency of axial and other PsA manifestations

Of 3393 patients with PsA enrolled in the registry, 226 (6.7%) had Dx^+Sx^- , 698 (20.6%) had Dx^-Sx^+ , and 165 (4.9%) had Dx^+Sx^+ (**Figure 1A**); 2304 patients (67.9%) were Dx^-Sx^- . Of the 769 patients who initiated a biologic at registry enrollment, 55 (7.2%) had Dx^+Sx^- , 216 (28.1%) had Dx^-Sx^+ , and 54 (7.0%) had Dx^+Sx^+ (**Figure 1B**); 444 biologic initiators (57.7%) were Dx^-Sx^- .

The frequency of coexisting PsA manifestations was higher in patients with Dx^+Sx^- , Dx^-Sx^+ , or Dx^+Sx^+ than in those with Dx^-Sx^- in both the overall population and in patients initiating a biologic at registry enrollment, except for dactylitis, which was reported less often in patients with Dx^+Sx^- than in those with Dx^-Sx^- (**Figure 2**). Most patients across all study groups had active skin disease and peripheral arthritis at registry enrollment, with the highest frequency in patients with Dx^-Sx^+ (skin disease: overall, 76.8%; biointiators, 82.9%; peripheral arthritis:

overall, 78.1%; bioinitiators, 88.4%). The frequency of active nail psoriasis, enthesitis, and dactylitis was highest in patients with Dx⁺Sx⁺, with more than half having active nail psoriasis (overall, 56.4%; bioinitiators, 55.6%) and enthesitis (overall, 50.3%; bioinitiators, 51.9%).

Patient demographics and clinical characteristics at enrollment

Higher proportions of patients with Dx⁻Sx⁺ (64.3%) or Dx⁺Sx⁺ (61.0%) were female compared with patients with Dx⁻Sx⁻ (50.6%; both $P < 0.05$; **Table 1**). Patients with Dx⁻Sx⁺ or Dx⁺Sx⁺ had a higher prevalence of depression (22.1% and 28.5%, respectively), and fibromyalgia (both 13.3%) compared with patients with Dx⁻Sx⁻ (depression, 13.1%; fibromyalgia, 3.2%; both $P < 0.05$). Patients with Dx⁻Sx⁺ had a higher prevalence of hypertension, metabolic syndrome, diabetes mellitus, and cardiovascular disease than those with Dx⁻Sx⁻. Patients with Dx⁺Sx⁻ or Dx⁺Sx⁺ were more likely to be HLA-B27 positive (among those with available HLA-B27 test results) than patients with Dx⁻Sx⁻ (Dx⁺Sx⁻, 34.3%; Dx⁺Sx⁺, 39.2%; Dx⁻Sx⁻, 20.2%; $P < 0.05$).

Higher proportions of patients with Dx⁺Sx⁻, Dx⁻Sx⁺, or Dx⁺Sx⁺ had prior biologic experience compared with patients with Dx⁻Sx⁻ (all $P < 0.05$; **Table 1**). The proportion of patients currently using biologics was higher in the Dx⁺Sx⁻, Dx⁻Sx⁺, or Dx⁺Sx⁺ groups compared with the Dx⁻Sx⁻ group, although the difference only reached statistical significance in the Dx⁺Sx⁺ group (71.5% vs 63.8%; $P < 0.05$). Prior and current tsDMARD and prednisone use were more frequent among patients with Dx⁻Sx⁺ than among those with Dx⁻Sx⁻ (all $P < 0.05$). Fewer patients with Dx⁺Sx⁻ or Dx⁻Sx⁺ were currently receiving csDMARDs compared with patients with Dx⁻Sx⁻ (both $P < 0.05$).

Disease activity, PROs, and work productivity at enrollment

Patients with Dx⁺Sx⁻, Dx⁻Sx⁺, or Dx⁺Sx⁺ had higher physician global assessment scores than those with Dx⁻Sx⁻ (all $P < 0.01$; **Figure 3**). Additionally, patients with Dx⁻Sx⁺ or Dx⁺Sx⁺ had higher TJC and SJC, worse DAPSA and PASDAS scores, and were less likely to be in MDA at

enrollment than those with Dx⁻Sx⁻ (all $P < 0.01$). Patients with Dx⁻Sx⁺ or Dx⁺Sx⁺ also had worse PRO scores than those with Dx⁻Sx⁻, including pain, fatigue, patient global assessment, morning stiffness, spine pain, EQ VAS, HAQ-DI, HAQ-S, BASDAI, and work productivity and activity impairment (all $P < 0.01$; **Figure 4**). Results were generally consistent in multivariable adjusted regression models (**Table S1**).

Patient characteristics associated with axial manifestations

In the multinomial logistic regression model, age was not significantly associated with having Dx⁺Sx⁻ or Dx⁻Sx⁺; however, for each 1-year increase in age, a patient's odds of having Dx⁺Sx⁺ decreased relative to the presence of Dx⁻Sx⁻ (OR [95% CI], 0.98 [0.96, 0.99]; $P < 0.01$) (**Figure 5**). The odds of having Dx⁻Sx⁺ were comparable between Black and White patients; however, relative to White patients, patients of other races had higher odds of reporting Dx⁻Sx⁺ (OR [95% CI], 1.75 [1.11, 2.74]; $P = 0.02$) compared with Dx⁻Sx⁻. BMI was not associated with having Dx⁻Sx⁺ or Dx⁺Sx⁺, but the odds of having Dx⁺Sx⁻ decreased for each unit increase in BMI (OR [95% CI], 0.96 [0.94, 0.98]; $P < 0.01$) relative to Dx⁻Sx⁻. Patients with fibromyalgia had significantly higher odds of having Dx⁺Sx⁻ (OR [95% CI], 2.20 [1.24, 3.91]; $P < 0.01$) or Dx⁺Sx⁺ (OR [95% CI], 2.35 [1.44, 3.85]; $P < 0.01$). Prior csDMARD and prednisone use was associated with decreased odds of having Dx⁺Sx⁺ (OR [95% CI]: csDMARDs, 0.61 [0.41, 0.91]; prednisone, 0.40 [0.19, 0.84]; both $P < 0.05$) compared with Dx⁻Sx⁻.

DISCUSSION

Approximately one-third of patients in this real-world PsA population had axial manifestations. The proportion of patients reporting elevated spine symptoms (Dx⁻Sx⁺ and Dx⁺Sx⁺ combined) was higher than those who had a physician diagnosis of axPsA (Dx⁺Sx⁻ and Dx⁺Sx⁺ combined). Patients with Dx⁻Sx⁺ or Dx⁺Sx⁺ had higher unadjusted disease activity and worse PRO scores than patients with Dx⁻Sx⁻, whereas disease activity and PRO scores were generally comparable

in patients with Dx⁺Sx⁻ and those with Dx⁻Sx⁻. These results suggest that managing spine symptoms is important for improving patient quality of life and disease outcomes.

The proportion of patients with a physician diagnosis of axPsA (Dx⁺Sx⁻ or Dx⁺Sx⁺) in CorEvitas' PsA/SpA Registry was 11.5%, which is lower than that observed in other real-world studies. Estimates of the prevalence of axPsA among patients with PsA generally range from 5%-28% for patients with early disease(6,21-27) and 25%-70% in patients with established PsA.(3,8,12) Additionally, >50% of patients in our study population with physician-diagnosed axPsA did not have patient-reported elevated spine symptoms (ie, were Dx⁺Sx⁻), although most were currently on therapy at the time of sampling; it is possible that some of these patients may have been asymptomatic despite having imaging evidence of axPsA and may have been switching therapies for control of other disease manifestations at the time of registry enrollment. Additionally, treating physicians may not take into account other more objectively measured characteristics in their diagnosis of axPsA—for example, increases in BMI were associated with decreased presence of Dx⁺Sx⁻ relative to Dx⁻Sx⁻. Previous studies indicate that 20%-30% of patients with PsA with visible structural damage on imaging have no axial symptoms.(4,12-14) In contrast, nearly one-quarter of patients in our study had patient-reported elevated spine symptoms, of whom only 19% also had physician-diagnosed axPsA. Many of the previous studies investigating the prevalence of axPsA required imaging confirmation. There are no clear guidelines to suggest that rheumatologists always obtain imaging in the workup of PsA. As such, there was no imaging requirement in the registry; the presence of a physician diagnosis of axPsA was based on the judgment of the treating physician. The diagnosis of axPsA may have been missed in some patients with patient-reported elevated spine symptoms, contributing to the relatively low prevalence of axial disease in our cohort. This study emphasizes the need to establish a clinically relevant set of criteria defining axPsA and for the development of sensitive screening tools that allow accurate diagnosis of the underlying conditions causing patients' back pain.

Among those with available HLA-B27 status, the proportion HLA-B27–positive patients was significantly higher in patients with Dx⁺Sx⁻ (34.3%) or Dx⁺Sx⁺ (39.2%) than in those with Dx⁻Sx⁻ (20.2%), and numerically higher than in those with Dx⁻Sx⁺ (25.1%; statistical comparisons not performed). HLA-B27 positivity has been associated with a higher prevalence of axPsA among patients with PsA.(14,28) Approximately 20% of patients with PsA overall are HLA-B27 positive,(29) but the prevalence of HLA-B27 is substantially higher in those with vs without axial involvement (23%-40% vs 7%-17%, respectively).(8,9,14,28) Although HLA-B27 testing is not recommended for all patients with suspected PsA, it may be helpful in diagnosing axial disease due to PsA among patients with PsA.

Although some patients classified as having Dx⁻Sx⁺ may have also had physician-diagnosed axPsA (and could have been in the Dx⁺Sx⁺ group), many may have had back pain due to other underlying conditions. Back pain is highly prevalent in the general population—the lifetime prevalence of spinal pain is estimated to be 54%-80%, and 25%-60% of patients with low back or neck pain experience pain lasting ≥1 year.(11) There are many causes of chronic back pain, including degenerative spine disease, injury, occupational conditions, and chronic pain disorders such as fibromyalgia.(11) Causes of chronic back pain are not mutually exclusive; patients may have a combination of conditions, such as degenerative spine disease and axPsA. The presence of other conditions that cause chronic back pain in patients with PsA could result in increased spine pain VAS scores, regardless of the presence of axPsA.

The BASDAI assesses both axial symptoms and symptoms consistent with those of peripheral PsA, including pain and swelling in other joints, areas tender to touch or pressure (eg, enthesitis), fatigue, and morning stiffness.(30) Patients with Dx⁻Sx⁺ in our study population had higher TJC, SJC, and fatigue and morning stiffness VAS scores than those with Dx⁺Sx⁻ or Dx⁻Sx⁻. Patients with a greater burden of peripheral symptoms and higher overall disease activity may have had higher BASDAI scores and thus were eligible for inclusion in the Dx⁻Sx⁺ group, despite the absence of true axPsA. Together with the frequency of chronic back pain in

the general population, the potential impact of peripheral symptoms on BASDAI scores may have contributed to the higher frequency of Dx⁻Sx⁺ compared with Dx⁺Sx⁻ or Dx⁺Sx⁺. Establishing consensus criteria to identify axPsA and the development of screening tools to more easily differentiate between axPsA and other causes of back pain are important to ensure accurate diagnosis and appropriate management of the underlying cause of patients' back pain.

The higher frequency of Dx⁻Sx⁺ may also have been influenced by the presence of central sensitization, a hypersensitivity to painful or inflammatory stimuli caused by dysregulation of the central nervous system.(31) Central sensitization can lead to chronic pain, perceived pain intensity disproportionate to the intensity of the stimulus, or pain perceived in areas where injury or inflammation has not occurred.(32) Central sensitization contributes to the pain hypersensitivity characteristic of several disorders including fibromyalgia, which is characterized by chronic widespread pain, fatigue, sleep disturbance, and cognitive disfunction.(33) Fibromyalgia is more common in women than in men and is more prevalent in patients with rheumatic disease than in the general population.(34,35) Patients with PsA and comorbid fibromyalgia have worse disease activity when assessed using measures with subjective or patient-reported components, including DAPSA, Leeds Enthesitis Index, BASDAI, HAQ, pain, and fatigue scores.(31,36,37) In our study cohort, history of fibromyalgia was significantly associated with a patient's odds of having axial manifestations by either definition, which may support the difficulty in differentiating fibromyalgia from axial symptoms in PsA. However, patients with Dx⁻Sx⁺ were more likely to be female and had higher TJC and worse BASDAI, pain, and fatigue scores than patients with Dx⁺Sx⁻ or Dx⁻Sx⁻. The presence of central sensitization in some patients in our study population may have increased their pain and fatigue, resulting in higher BASDAI and spine pain scores and contributing to their eligibility for the Dx⁻Sx⁺ cohort in the absence of axPsA. CorEvitas' PsA/SpA Registry is currently incorporating the Widespread Pain Index and Symptom Severity Scale, a validated, quantitative measure of central sensitization,(38,39) to better identify fibromyalgia in future analyses.

Our study has several strengths. The observational design of CorEvitas' PsA/SpA Registry captures real-world practice patterns and data on patients seen in routine clinical practice, which may provide information more representative of the general population of patients with PsA than the stringent protocols and patient populations in clinical trials. Additionally, the registry collects an extensive number of demographic, clinical, and PRO variables, which allows a detailed characterization of the registry's patient population. The sample size of patients with PsA was large enough to allow adjustment for confounding variables. We collected PRO data on axial symptoms in patients without a clinical diagnosis of axPsA, which provides a broader view of the impact of axial symptoms on quality of life in patients with PsA, regardless of the presence of axPsA.

Our study also has some limitations. Active PsA disease manifestations at the time of registry enrollment were physician reported and may not reflect all PsA presentations experienced by patients throughout the course of their disease. Laboratory tests (eg, HLA-B27) are not required at all visits and are reported only when collected, these missing data may reflect practice patterns of the enrolling providers. Although used as an assessment of axial involvement in clinical trials of PsA, the BASDAI has not been validated as a disease activity measure in patients with PsA without clearly defined axial disease. Dx^+Sx^- was physician reported and patients may have been misclassified. For example, imaging prior to enrollment in the registry may not have been adequately recorded or preserved, particularly if the imaging was conducted long before enrollment. Additionally, because imaging confirmation of axPsA was not required, this could have led to overestimation (patients with Dx^+Sx^- who would not have had imaging findings) or underestimation (missed axPsA in patients with Dx^-Sx^+) of the prevalence of axPsA.

In CorEvitas' PsA/SpA Registry, a higher prevalence of Dx^-Sx^+ than Dx^+Sx^- was observed. Patients with Dx^-Sx^+ or Dx^+Sx^+ had significantly higher disease activity and worse PRO scores than those with Dx^-Sx^- and numerically worse scores than those with Dx^+Sx^- .

Although patients with Dx⁻Sx⁺ may have had other reasons for back pain, such as degenerative spine disease or central sensitization, it is possible that axPsA was present in some of these patients, which warrants further evaluation. These findings highlight the need to establish standardized assessment tools for axPsA to facilitate the accurate identification and effective management of axial disease in patients with PsA.

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FIGURE LEGENDS

Figure 1. Frequency of axial manifestations in **(A)** the overall population of patients with psoriatic arthritis and **(B)** patients with psoriatic arthritis who initiated a biologic at registry enrollment. AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; Dx, diagnosis; Sx, symptoms; VAS, visual analog scale.

* Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup.

† Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

‡ Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only.

Figure 2. Frequency of other active PsA manifestations by study group in the **(A)** overall population of patients with PsA and **(B)** patients with PsA who initiated a biologic at registry enrollment. AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; Dx, diagnosis; PsA, psoriatic arthritis; Sx, symptoms; VAS, visual analog scale.

* Patients who did not have a physician diagnosis of axPsA or elevated spine symptoms.

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§ Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

Figure 3. Unadjusted mean disease activity measures at enrollment in mutually exclusive axial manifestation groups. AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Score; DAPSA, Disease Activity Index in Psoriatic Arthritis; Dx, diagnosis; PASDAS, Psoriatic Arthritis Disease Activity Score; Sx, symptoms; VAS, visual analog scale.

* $P < 0.01$ for comparison with the Dx⁻Sx⁻ group.

† In patients with ≥ 1 tender/swollen joint.

‡ Minimal disease activity was defined as meeting 5 of the 7 following criteria: tender joint count ≤ 1 , swollen joint count ≤ 1 , psoriasis-affected body surface area $< 3\%$, patient-reported pain VAS ≤ 15 , patient global assessment VAS ≤ 20 , Health Assessment Questionnaire Disability Index ≤ 0.5 , and tender entheses points ≤ 1 using the Spondyloarthritis Research Consortium of Canada Enthesitis Index.

§ Patients who did not have a physician diagnosis of axPsA or elevated spine symptoms.

|| Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup.

¶ Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only.

Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

Figure 4. Unadjusted mean patient-reported outcome measures at enrollment in mutually exclusive axial manifestation groups. AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; Dx, diagnosis; EQ VAS, EuroQol visual analogue scale; HAQ-S, Health Assessment Questionnaire for the Spondyloarthropathies; Dx, symptoms; WPAI, Work Productivity and Activity Impairment.

* $P < 0.01$ for comparison with the Dx⁻Sx⁻ group.

† Patients who did not have a physician diagnosis of axPsA or elevated spine symptoms.

‡ Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup.

§ Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only.

|| Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

Figure 5. Adjusted ORs estimating the association of patient characteristics with having Dx⁺Sx⁻, Dx⁻Sx⁺, or Dx⁺Sx⁺ relative to Dx⁻Sx⁻, at enrollment.* AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Score; BMI, body mass index; cDAPSA, Clinical

Disease Activity Index for Psoriatic Arthritis; csDMARD, conventional synthetic disease-modifying antirheumatic drug; Dx, diagnosis; EQ-5D, EuroQol 5-Dimensions questionnaire; OR, odds ratio; Sx, symptoms; VAS, visual analog scale.

* Multivariable logistic regression model with Dx⁻Sx⁻ as the reference group. Model included age, sex, race, time since diagnosis, BMI, fibromyalgia, depression, cDAPSA, EQ-5D score, and current and prior biologic, csDMARD, and prednisone use.

† $P < 0.05$.

‡ Effects on Dx⁺Sx⁻ or Dx⁺Sx⁺ could not be estimated due to separation of data.

§ Defined as tender/swollen joint count ratio ≥ 7 .

|| Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup.

¶ Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only.

Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

Table 1. Demographics, clinical characteristics, and treatment profiles at enrollment of patients with psoriatic arthritis with vs without axial manifestations (unadjusted).

	Axial manifestation category at enrollment			
Characteristic*	Dx ⁻ Sx ⁻ [†] (n = 2304)	Dx ⁺ Sx ⁻ [‡] (n = 226)	Dx ⁻ Sx ⁺ [§] (n = 698)	Dx ⁺ Sx ⁺ (n = 165)
Age, mean (SD), years	54.1 (13.3)	51.7 (13.9) [¶]	53.5 (12.2)	50.2 (12.6) [¶]
Female, n (%)	1157 (50.6)	113 (50.7)	448 (64.3) [¶]	100 (61.0) [¶]
Race, n (%)				
White	2132 (94.8)	205 (94.5)	627 (91.1) [#]	150 (92.6)
Black	16 (0.7)	0	10 (1.5) [#]	0
Other	102 (4.5)	12 (5.5)	51 (7.4) [#]	12 (7.4)
Work status, n (%)				
Full-time	1324 (58.0)	123 (55.4)	290 (41.8) [#]	71 (43.6) [#]
Part-time	192 (8.4)	27 (12.2)	57 (8.2) [#]	15 (9.2) [#]
Disabled	132 (5.8)	16 (7.2)	150 (21.6) [#]	30 (18.4) [#]
Retired	492 (21.6)	42 (18.9)	136 (19.6) [#]	28 (17.2) [#]
Other	143 (6.3)	14 (6.3)	60 (8.7) [#]	19 (11.7) [#]
BMI, mean (SD), kg/m ²	31.6 (7.4)	29.8 (6.8) [¶]	33.4 (7.9) [¶]	31.7 (7.1)
BMI category (in kg/m ²), n (%)				
Normal/underweight (<25)	394 (17.5)	49 (22.3)	85 (12.3) [#]	26 (16.0)
Overweight (25 to <30)	672 (30.0)	72 (32.7)	169 (24.5) [#]	46 (28.2)
Obese (≥30)	1185 (52.6)	99 (45.0)	435 (63.1) [#]	91 (55.8)
HLA-B27 positive, n/N (%)**	100/496 (20.2)	37/108 (34.3) [¶]	47/187 (25.1)	31/79 (39.2) [¶]

Symptom duration, mean (SD), years	10.8 (10.1)	12.4 (11.2) [¶]	10.3 (9.9)	11.7 (11.6)
Time since diagnosis, mean (SD), years	8.0 (8.7)	7.5 (8.8)	6.6 (7.6) [¶]	6.4 (9.0) [¶]
History of comorbidities, n (%)				
Hypertension	859 (37.2)	70 (31.0)	298 (42.7) [¶]	57 (34.5)
Hyperlipidemia	520 (22.6)	51 (22.6)	168 (24.1)	34 (20.6)
Metabolic syndrome	333 (14.5)	20 (8.8) [¶]	130 (18.6) [¶]	29 (17.6)
Diabetes mellitus	315 (13.7)	25 (11.1)	119 (17.0) [¶]	25 (15.2)
Depression	301 (13.1)	32 (14.2)	154 (22.1) [¶]	47 (28.5) [¶]
Cardiovascular disease	246 (10.7)	23 (10.2)	94 (13.5) [¶]	24 (14.5)
Any cancer (excluding NMSC)	179 (7.8)	19 (8.4)	43 (6.2)	16 (9.7)
Serious infections	133 (5.8)	14 (6.2)	53 (7.6)	13 (7.9)
Anxiety	91 (3.9)	11 (4.9)	70 (10.0) [¶]	16 (9.7) [¶]
Fibromyalgia	74 (3.2)	10 (4.4)	93 (13.3) [¶]	22 (13.3) [¶]
Uveitis	23 (1.0)	10 (4.4) [¶]	17 (2.4) [¶]	8 (4.8) [¶]
Crohn's disease	20 (0.9)	1 (0.4)	10 (1.4)	3 (1.8)
Ulcerative colitis	19 (0.8)	4 (1.8)	8 (1.1)	0
Prior medication use, n (%)				
Biologic	694 (30.1)	88 (38.9) [¶]	274 (39.3) [¶]	62 (37.6) [¶]
tsDMARD	120 (5.2)	18 (8.0)	60 (8.6) [¶]	10 (6.1)
csDMARD	671 (29.1)	74 (32.7)	230 (33.0)	47 (28.5)
Prednisone	330 (14.3)	20 (8.8) [¶]	130 (18.6) [¶]	19 (11.5)
Current medication use, n (%)				

Biologic	1469 (63.8)	157 (69.5)	452 (64.8)	118 (71.5) [¶]
tsDMARD	157 (6.8)	18 (8.0)	68 (9.7) [¶]	10 (6.1)
csDMARD	1204 (52.3)	94 (41.6) [¶]	331 (47.4) [¶]	74 (44.8)
Prednisone	172 (7.5)	11 (4.9)	87 (12.5) [¶]	15 (9.1)

AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BMI, body mass index; csDMARD, conventional synthetic disease-modifying antirheumatic drug; Dx, diagnosis; HLA-B27, human leukocyte antigen B27; NMSC, nonmelanoma skin cancer; Sx, symptoms; tsDMARD, targeted synthetic disease-modifying antirheumatic drug; VAS, visual analog scale.

* All values were calculated based on available data and had <10% missing data except HLA-B27 (n = 870).

† Patients who did not have a physician diagnosis of axPsA or elevated spine symptoms.

‡ Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup.

§ Patients with elevated spine symptoms (BASDAI ≥4 and spine pain VAS ≥40) only.

|| Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

¶ $P < 0.05$ for comparison with the Dx⁻Sx⁻ group. P values were calculated using 2-sample t tests for continuous variables and χ^2 or Fisher exact tests for categorical variables.

$P < 0.05$ for distribution across categories compared with the Dx⁻Sx⁻ group. P values were calculated using χ^2 or Fisher exact tests.

** Number of patients with positive test result (n) among those with known test result (N).

Figure 1. Frequency of axial manifestations in **(A)** the overall population of patients with psoriatic arthritis and **(B)** patients with psoriatic arthritis who initiated a biologic at registry enrollment. AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; Dx, diagnosis; Sx, symptoms; VAS, visual analog scale. * Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup. † Patients who had both a physician diagnosis of axPsA and elevated spine symptoms. ‡ Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only.

338x190mm (300 x 300 DPI)

Figure 2. Frequency of other active PsA manifestations by study group in the **(A)** overall population of patients with PsA and **(B)** patients with PsA who initiated a biologic at registry enrollment. AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; Dx, diagnosis; PsA, psoriatic arthritis; Sx, symptoms; VAS, visual analog scale. * Patients who did not have a physician diagnosis of axPsA or elevated spine symptoms. [†] Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup. [‡] Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only. [§] Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

215x279mm (300 x 300 DPI)

Figure 3. Unadjusted mean disease activity measures at enrollment in mutually exclusive axial manifestation groups. AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Score; DAPSA, Disease Activity Index in Psoriatic Arthritis; Dx, diagnosis; PASDAS, Psoriatic Arthritis Disease Activity Score; Sx, symptoms; VAS, visual analog scale. * $P < 0.01$ for comparison with the Dx-Sx- group. † In patients with ≥ 1 tender/swollen joint. ‡ Minimal disease activity was defined as meeting 5 of the 7 following criteria: tender joint count ≤ 1 , swollen joint count ≤ 1 , psoriasis-affected body surface area $< 3\%$, patient-reported pain VAS ≤ 15 , patient global assessment VAS ≤ 20 , Health Assessment Questionnaire Disability Index ≤ 0.5 , and tender entheses points ≤ 1 using the Spondyloarthritis Research Consortium of Canada Enthesitis Index. § Patients who did not have a physician diagnosis of axPsA or elevated spine symptoms. || Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup. ¶ Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only. # Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

190x203mm (300 x 300 DPI)

Figure 4. Unadjusted mean patient-reported outcome measures at enrollment in mutually exclusive axial manifestation groups. AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; Dx, diagnosis; EQ VAS, EuroQol visual analogue scale; HAQ-S, Health Assessment Questionnaire for the Spondyloarthropathies; Dx, symptoms; WPAI, Work Productivity and Activity Impairment. * $P < 0.01$ for comparison with the Dx-Sx- group. † Patients who did not have a physician diagnosis of axPsA or elevated spine symptoms. ‡ Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup. § Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only. || Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

304x330mm (300 x 300 DPI)

Figure 5. Adjusted ORs estimating the association of patient characteristics with having Dx+Sx–, Dx–Sx+, or Dx+Sx+ relative to Dx–Sx–, at enrollment. * AxPsA, axial psoriatic arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Score; BMI, body mass index; cDAPSA, Clinical Disease Activity Index for Psoriatic Arthritis; csDMARD, conventional synthetic disease-modifying antirheumatic drug; Dx, diagnosis; EQ-5D, EuroQol 5-Dimensions questionnaire; OR, odds ratio; Sx, symptoms; VAS, visual analog scale. * Multivariable logistic regression model with Dx–Sx– as the reference group. Model included age, sex, race, time since diagnosis, BMI, fibromyalgia, depression, cDAPSA, EQ-5D score, and current and prior biologic, csDMARD, and prednisone use. [†] $P < 0.05$. [‡] Effects on Dx+Sx– or Dx+Sx+ could not be estimated due to separation of data. [§] Defined as tender/swollen joint count ratio ≥ 7 . ^{||} Patients with physician-diagnosed axPsA only based on clinical assessments, imaging, and laboratory workup. [¶] Patients with elevated spine symptoms (BASDAI ≥ 4 and spine pain VAS ≥ 40) only. [#] Patients who had both a physician diagnosis of axPsA and elevated spine symptoms.

Accepted Article

165x228mm (300 x 300 DPI)