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Influence of Axial Involvement on Clinical Characteristics of Psoriatic Arthritis: Analysis from the Corrona Psoriatic Arthritis/Spondyloarthritis Registry

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ABSTRACT. Objective. We analyzed the characteristics of patients with psoriatic arthritis (PsA) with and without axial involvement in the US-based Corrona Psoriatic Arthritis/Spondyloarthritis Registry.

Methods. All patients were included who had PsA and data on axial involvement, defined as physician-reported presence of spinal involvement at enrollment, and/or radiograph or magnetic resonance imaging showing sacroiliitis. Demographics, clinical measures, patient-reported outcomes, and treatment characteristics were assessed at enrollment.

Results. Of 1530 patients with PsA, 192 (12.5%) had axial involvement and 1338 (87.5%) did not. Subgroups were similar in sex, race, body mass index, disease duration, presence of dactylitis, and prevalence of most comorbidities. However, patients with axial involvement were younger and more likely to have enthesitis, a history of depression, and more frequently used biologics at enrollment. They were also more likely to have moderate/severe psoriasis (body surface area \geq 3%, 42.5% vs 31.5%) and significantly worse disease as measured by a lower prevalence of minimal disease activity (30.1% vs 46.2%) and higher nail psoriasis scores [visual analog scale (VAS) 11.4 vs 6.5], enthesitis counts (5.1 vs 3.4), Bath Ankylosing Spondylitis Disease Activity Index (4.7 vs 3.5) scores, Bath Ankylosing Spondylitis Functional Index (3.8 vs 2.5) scores, C-reactive protein levels (4.1 vs 2.4 mg/l), and scores for physical function (Health Assessment Questionnaire, 0.9 vs 0.6), pain (VAS, 47.7 vs 36.2), and fatigue (VAS, 50.2 vs 38.6).

Conclusion. Presence of axial involvement was associated with a higher likelihood of moderate/severe psoriasis, with higher disease activity and greater effect on quality of life. These findings highlight the importance of monitoring patients with PsA for signs of axial symptoms or spinal involvement. (J Rheumatol First Release July 1 2018; doi:10.3899/jrheum.171094)

Key Indexing Terms:

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J.B. Palmer is an employee of Novartis. M. Liu is an employee of Corrona LLC. R. Pandurengan and C. Karki were employees of Corrona LLC, at the time of this study. J.D. Greenberg is an employee and shareholder of Corrona LLC.

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Psoriasis is an autoimmune inflammatory disease affecting > 7 million adults in the United States and about 2% to 4% of the global population^{1,2,3}. About 30% of patients with psoriasis eventually develop psoriatic arthritis (PsA), typically described as an inflammatory disease of the skin and musculoskeletal system^{4,5,6}. The clinical spectrum of PsA is diverse in characteristics: patients may exhibit axial skeleton disorders, nail and skin changes, peripheral joint inflammation, enthesitis, and/or dactylitis; these symptoms can be found in isolation or in combination with each other. Thus the clinical heterogeneity of this disease presents a challenge in diagnosis and treatment^{7,8}.

Depending on the definition used, about 25% to 75% of patients with PsA have axial involvement (axial PsA) and experience inflammatory back pain and stiffness, along with spinal involvement on imaging (e.g., sacroiliitis, spinal ossifications)⁹. The definition of axial PsA has varied from unilateral advanced sacroiliitis to sharing similarities with ankylosing spondylitis (AS)⁹; however, axial PsA and AS differ clinically, and may be best distinguished through radiographic techniques. Axial involvement in PsA was first described > 50 years ago, with the observation of frequent sacroiliac changes (e.g., erosion, sclerosis, and ankyloses of sacroiliac joints) in patients with PsA that were not present in controls who had rheumatoid arthritis¹⁰. In studies performed several decades ago in patients with AS, psoriasis, and other rheumatic diseases, investigators observed that compared with AS, axial PsA occurred less frequently in men, manifested as less severe spinal disease, and showed reduced association with HLA-B27; however, no difference was noted in its effects on functional capacity and quality of life^{10,11,12,13,14}. To our knowledge, only 1 observational study has characterized PsA stratified by presence versus absence of physician-confirmed axial involvement; however, this study was conducted outside the United States and was not comprehensive, excluding analyses of detailed patient characteristics, laboratory assessments, and patient-reported outcomes¹⁵. Therefore very little is known about the effect of axial involvement on patient-reported outcomes and other assessments of quality of life.

Despite first being described > 50 years ago, the characterization of axial PsA remains poorly understood, because limited data are available on this specific population. Current classification criteria for identification of axial spondyloarthritis (SpA) and PsA overlap between the Assessment of Spondyloarthritis international Society (ASAS) and Classification Criteria for Psoriatic Arthritis recommendations^{16,17}. Axial PsA is accompanied by significant clinical morbidity, the treatment of which has been addressed by both the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and the European League Against Rheumatism (EULAR)^{18,19}. The GRAPPA treatment recommendations for axial PsA are largely derived from AS literature; for patients with axial involvement, the use of nonsteroidal antiinflammatory drugs (NSAID), physiotherapy, and tumor necrosis factor inhibitors is recommended, along with conditional recommendations for the use of interleukin (IL)-17 and IL-12/23 inhibitors¹⁸. For patients with PsA with predominant active axial disease and not responding to NSAID, a biologic therapy should be initiated as per EULAR recommendations¹⁹.

Because a limited number of studies on the clinical characteristics and patient-reported outcomes of axial PsA are available, examination of the characteristics that distinguish between patients with and without axial involvement may help healthcare providers manage and improve the

quality of life in patients with PsA. In this analysis, we examined the clinical and patient-reported effect of axial involvement in patients with PsA using the Corrona Psoriatic Arthritis/Spondyloarthritis (PsA/SpA) Registry.

MATERIALS AND METHODS

Study population. The Corrona PsA/SpA Registry is a large, independent, prospective observational cohort of patients with PsA or SpA. The Corrona PsA/SpA Registry database includes information about 7476 patient visits, with a mean duration of patient followup of 1.5 years. As of July 2016, data on about 2330 patients with PsA/SpA have been collected from 28 private and academic practice sites across 25 states in the United States, with 34 participating rheumatologists. Our study included all patients with PsA enrolled in the Corrona PsA/SpA Registry between March 2013 and March 2016 with available data on axial involvement, who were further stratified based on presence vs absence of axial involvement.

Patients with axial involvement were defined as those who had a physician-reported presence of spinal involvement at enrollment, based on clinical judgment of clinical features thought to be representative of active inflammatory spondylitis, and/or radiographs or magnetic resonance imaging showing sacroiliitis. Patients without axial symptoms were defined as patients with no axial involvement.

All participating investigators were required to obtain full board approval for conducting noninterventional research involving human subjects with a limited dataset. Sponsor approval and continuing review were obtained through a central independent review board (New England IRB, NEIRB No. 120160070). For academic investigative sites that did not receive a waiver to use the central IRB, full board approval was obtained from the respective governing IRB and documentation of approval was submitted to the sponsor prior to initiating any study procedures. All research was conducted in compliance with the Helsinki Declaration of 1964 and all later amendments. All registry subjects were required to provide written informed consent and authorization prior to participating.

Outcomes and assessments. Data were collected using provider and patient questionnaires from treating rheumatologists and patients at twice-yearly office visits. All assessments, including demographics, clinical characteristics, patient-reported outcomes, and medication history, were collected at baseline (i.e., time of enrollment in the registry). Data were collected on demographics and patient characteristics [e.g., age, sex, race, body mass index (BMI)], disease duration, HLA-B27 positivity, history of comorbidities, family history, and prior and current medication [biologics, conventional synthetic disease-modifying antirheumatic drugs (csDMARD), and prednisone]. Clinical features [e.g., presence of enthesitis, Spondyloarthritis Research Consortium of Canada Enthesitis Index, presence of dactylitis, dactylitis counts, affected body surface area (BSA), tender (0-66) and swollen (0-68) joint counts, and nail psoriasis on a visual analog scale (VAS) from 0-100], disease activity measures [e.g., achievement of minimal disease activity (MDA)²⁰, Clinical Disease Activity Index, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), 28-joint Disease Activity Score using C-reactive protein (CRP), and Ankylosing Spondylitis Disease Activity Score using CRP (ASDAS-CRP)], and laboratory measurements (e.g., CRP and erythrocyte sedimentation rate) were assessed. MDA was defined as “yes” if a patient met 5 of the 7 following categories²⁰: tender joint count ≤ 1 , swollen joint count ≤ 1 , BSA $\leq 3\%$, patient pain VAS ≤ 15 , patient global activity VAS ≤ 20 , Health Assessment Questionnaire (HAQ) score ≤ 0.5 , and tender enthesal points ≤ 1 . Lastly, patient-reported outcomes were assessed at baseline: e.g., patient-reported pain (VAS 0-100) and fatigue (VAS 0-100), morning stiffness, physical function using the HAQ, quality of life using the EQ VAS and the 3-level EQ-5D questionnaire (EQ-5D-3L), and Work Productivity and Activity Impairment (WPAI).

Statistical analysis. Descriptive analyses on patient demographics, clinical characteristics, patient-reported outcomes, and medication history were

conducted for all patients with PsA enrolled in Corrona at registry enrollment (baseline) and stratified by presence versus absence of axial involvement. Categorical variables (e.g., sex, race, BMI, comorbidities) were summarized using frequency counts and percentages. Continuous variables (e.g., age, clinical and disease measures) were summarized by the counts and mean (SD). Statistical comparisons between subgroups were evaluated using t tests for continuous variables and chi-square tests for categorical variables. All analyses were performed using Stata V13 (StataCorp)²¹.

RESULTS

Patient population and baseline patient characteristics. A

total of 1530 patients with PsA in the Corrona PsA/SpA Registry had available data on physician-reported axial involvement, including 192 patients (12.5%) with axial involvement and 1338 patients (87.5%) without axial involvement. Both subgroups were similar regarding most demographic characteristics, including sex, race, BMI, history of most comorbidities, and prior use of csDMARD and prednisone (Table 1). However, patients with axial involvement were significantly younger (50.4 vs 54.4 yrs; $p < 0.001$) and were significantly more likely to have

Table 1. Baseline patient demographics and characteristics. All values were calculated based on available data and are presented as mean \pm SD or n (%).

Characteristics*	Overall, n = 1530	With Axial Involvement, n = 192	Without Axial Involvement, n = 1338	p
Age, yrs	53.9 \pm 13.2	50.4 \pm 13.6	54.4 \pm 13.1	< 0.001
Female	786 (51.9)	102 (54.0)	684 (51.6)	0.55
Race				0.26
White	1397 (94.5)	170 (93.9)	1227 (94.6)	
Asian	24 (1.6)	3 (1.6)	21 (1.6)	
Black	7 (0.4)	0 (0.0)	7 (0.5)	
Pacific Islander	20 (1.3)	1 (0.5)	19 (1.5)	
Mixed race	19 (1.3)	6 (3.3)	13 (1.0)	
Native American	1 (0.1)	0 (0.0)	1 (0.1)	
Other	10 (0.7)	1 (0.5)	9 (0.7)	
BMI, kg/m ²	31.4 \pm 7.2	20.7 \pm 7.1	31.6 \pm 7.3	0.12
BMI (in kg/m ²) classifications				0.57
Normal/underweight, < 25.0	239 (16.5)	33 (18.4)	206 (16.2)	
Overweight, 25.0 to < 30.0	445 (30.8)	58 (32.4)	387 (30.5)	
Obese, \geq 30.0	763 (52.7)	88 (49.2)	675 (53.2)	
Disease duration, yrs	11.5 \pm 10.0	12.1 \pm 10.9	11.4 \pm 9.8	0.38
HLA-B27				
Patients with available HLA-B27 test result (reported on laboratory form)	340 (22.2)	84 (43.7)	256 (19.1)	
Positive test result (among patients with available test results)	62 (18.2)	20 (23.8)	42 (16.4)	0.13
HLA-B27+, physician-reported	78 (5.1)	27 (14.1)	51 (3.8)	< 0.001
History of comorbidities				
Cardiovascular disease [†]	756 (49.4)	93 (48.4)	663 (49.6)	0.77
Depression	213 (13.9)	44 (22.9)	169 (12.6)	< 0.001
Diabetes mellitus	206 (13.5)	26 (13.5)	180 (13.5)	0.97
Any cancer [‡]	106 (6.9)	14 (7.3)	92 (6.9)	0.83
Serious infections [§]	77 (5.0)	14 (7.3)	63 (4.7)	0.13
Prior medication use				
Biologics	938 (61.3)	140 (72.9)	798 (59.6)	< 0.001
csDMARD	1060 (69.3)	135 (70.3)	925 (69.1)	0.74
Prednisone	186 (12.2)	19 (9.9)	167 (12.5)	0.31
Current biologic use				0.006
None	677 (44.2)	65 (33.9)	612 (45.7)	
Monotherapy	468 (30.6)	77 (40.1)	391 (29.2)	
Concomitant MTX only	335 (21.9)	41 (21.4)	294 (22.0)	
Concomitant MTX + other csDMARD	15 (1.0)	3 (1.6)	12 (0.9)	
Concomitant other csDMARD only	35 (2.3)	6 (3.1)	29 (2.2)	
Current prednisone use	103 (6.7)	9 (4.7)	94 (7.0)	0.227

* All variables had < 20% missing data. [†] Combined histories of myocardial infarction, acute coronary syndrome, coronary artery disease, congestive heart failure, hypertension, hyperlipidemia, peripheral artery disease, cardiac revascularization procedure, ventricular arrhythmia, cardiac arrest, unstable angina, stroke, transient ischemic attack, pulmonary embolism, carotid artery disease, deep vein thrombosis, or other cardiovascular event. [‡] Excludes nonmelanoma of the skin. [§] Includes those infections that lead to hospitalization or intravenous antibiotics: joint/bursa, cellulitis, sinusitis, diverticulitis, sepsis, pneumonia bronchitis, gastroenteritis, meningitis, urinary tract infection, upper respiratory tract infection, or infection of other specified site. BMI: body mass index; csDMARD: conventional synthetic disease-modifying antirheumatic drug; MTX: methotrexate.

physician-reported HLA-B27 positivity (14.1% vs 3.8%, $p < 0.001$), a history of depression (22.9% vs 12.6%, $p < 0.001$), and prior biologic use (72.9% vs 59.6%, $p < 0.001$) at registry enrollment compared with patients without axial involvement.

Disease characteristics. Patients with axial involvement generally had more severe disease at registry enrollment compared with those patients without axial involvement (Table 2). Patients with axial involvement were significantly more likely to have moderate/severe psoriasis at enrollment as assessed by BSA $\geq 3\%$ ²² (42.5% vs 31.5%, $p = 0.005$) and worse nail psoriasis (11.4 vs 6.5, $p < 0.001$). These patients had a higher likelihood of enthesitis (30.7% vs 19.2%, $p < 0.001$), higher tender joint counts (5.2 vs 3.5, $p = 0.004$), and lower likelihood of MDA at enrollment (30.1% vs 46.2%, $p < 0.001$), with significantly worse BASDAI scores (4.7 vs 3.5, $p < 0.001$), BASFI scores (3.8 vs 2.5, $p < 0.001$), and ASDAS-CRP (2.2 vs 1.9, $p = 0.001$).

Patient-reported outcomes. Overall, patient-reported outcomes were significantly harmed by the presence of axial involvement (Table 3). Patients with axial involvement reported significantly worse mean pain (VAS 47.7 vs 36.2, $p < 0.001$) and fatigue (VAS 50.2 vs 38.6, $p < 0.001$), and were significantly more likely to experience ≥ 30 min of morning stiffness (83.2% vs 69.3%, $p < 0.001$) at enrollment, compared with patients without axial involvement. Axial

involvement was also associated with significantly impaired physical function (HAQ 0.9 vs 0.6, $p < 0.001$) and quality of life (EQ VAS 65.3 vs 73.3, $p < 0.001$). Work productivity and activity was significantly affected by axial involvement; patients with axial involvement reported a significantly higher percentage of work time missed (10.0% vs 3.3%, $p < 0.001$), with significantly higher percentages of impairment while working (29.5% vs 15.0%, $p < 0.001$), overall work impairment (32.3% vs 16.8%, $p < 0.001$), and overall activity impairment (37.0% vs 18.1%, $p < 0.001$). Additionally, patients with axial involvement were significantly more likely to experience any problems with walking, self-care, performing usual activities, pain/discomfort, and feelings of anxiety/depression at baseline compared with patients without axial involvement, as measured by EQ-5D-3L (all statistically significant, $p < 0.005$; Table 4).

DISCUSSION

In our analysis of 1530 patients with PsA enrolled in the US Corrona PsA/SpA Registry who had axial data available, 12.5% of patients exhibited axial involvement at baseline, which was associated with significantly worse disease as measured by several clinical variables, including more severe skin manifestations, more severe joint disease, more enthesitis, and worse disease activity (i.e., decreased presence of MDA and higher BASDAI scores, BASFI scores, and CRP

Table 2. Baseline clinical characteristics of patients with psoriatic arthritis stratified by presence of axial involvement. Values are mean \pm SD or n (%).

Characteristics*	Overall, n = 1530	With Axial Involvement, n = 192	Without Axial Involvement, n = 1338	P
Enthesitis	316 (20.7)	59 (30.7)	257 (19.2)	< 0.001
SPARCC Enthesitis Index, 1–16	3.8 \pm 3.3	5.1 \pm 3.9	3.4 \pm 3.0	0.001
Dactylitis	194 (12.7)	19 (9.9)	175 (13.1)	0.22
Dactylitis count, 1–20	2.4 \pm 1.8	3.3 \pm 2.5	2.3 \pm 1.7	0.08
BSA, % affected	5.7 \pm 11.3	6.7 \pm 12.5	5.5 \pm 11.1	0.19
BSA, categorical				0.005
Mild disease, 0 to < 3%	969 (67.2)	104 (57.5)	865 (68.5)	
Moderate disease, ≥ 3 to $\leq 10\%$	296 (20.5)	53 (29.3)	243 (19.3)	
Severe disease, > 10%	178 (12.3)	24 (13.3)	154 (12.2)	
MDA [†]	554 (44.2)	46 (30.1)	508 (46.2)	< 0.001
CDAI	11.6 \pm 8.7	12.4 \pm 9.3	11.6 \pm 8.6	0.25
Tender joint count, 68	3.7 \pm 7.8	5.2 \pm 9.2	3.5 \pm 7.5	0.004
Swollen joint count, 66	2.0 \pm 4.1	2.3 \pm 4.9	2.0 \pm 3.9	0.37
Nail psoriasis, VAS 0–100	7.1 \pm 15.1	11.4 \pm 18.8	6.5 \pm 14.4	< 0.001
BASDAI, 0–10	3.6 \pm 2.6	4.7 \pm 2.5	3.5 \pm 2.5	< 0.001
BASFI, 0–10	2.7 \pm 2.6	3.8 \pm 2.8	2.5 \pm 2.5	< 0.001
DAS28-CRP	2.7 \pm 1.0	2.8 \pm 1.1	2.7 \pm 1.0	0.48
ASDAS-CRP	2.0 \pm 0.8	2.2 \pm 0.9	1.9 \pm 0.8	0.001
CRP, mg/l	2.6 \pm 7.3	4.1 \pm 11.2	2.4 \pm 6.5	0.02
ESR, mm/h	15.5 \pm 16.1	16.5 \pm 17.4	15.4 \pm 15.9	0.51

* All values were calculated based on available data. All variables had < 20% missing data except for CRP (n = 934) and ESR (n = 926). [†] MDA was defined as “Yes” if a patient met ≥ 5 of the 7 following categories²⁰: tender joint count ≤ 1 , swollen joint count ≤ 1 , BSA $\leq 3\%$, patient pain VAS ≤ 15 , patient global activity VAS ≤ 20 , HAQ ≤ 0.5 , tender enthesal points ≤ 1 . ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BSA: body surface area; CDAI: Clinical Disease Activity Index; CRP: C-reactive protein; DAS28: 28-joint Disease Activity Score; ESR: erythrocyte sedimentation rate; HAQ: Health Assessment Questionnaire; MDA: minimal disease activity; SPARCC: Spondyloarthritis Research Consortium of Canada; VAS: visual analog scale.

Table 3. Baseline patient-reported outcomes. Values are mean ± SD or n (%).

Characteristics*	Overall, n = 1530	With Axial Involvement, n = 192	Without Axial Involvement, n = 1338	p
Patient pain, VAS 0–100	37.6 ± 29.3	47.7 ± 29.1	36.2 ± 29.1	< 0.001
Patient-reported fatigue, VAS 0–100	40.0 ± 29.5	50.2 ± 29.6	38.6 ± 29.2	< 0.001
Morning stiffness				< 0.001
Yes	1301 (88.6)	173 (93.5)	1128 (87.9)	
< 30 min	375 (28.8)	29 (16.8)	346 (30.7)	
≥ 30 min	926 (71.2)	144 (83.2)	782 (69.3)	
HAQ, 0–3	0.6 ± 0.6	0.9 ± 0.7	0.6 ± 0.6	< 0.001
HAQ-S, 0–3	0.6 ± 0.7	0.9 ± 0.7	0.6 ± 0.6	< 0.001
EQ VAS, 0–100	72.3 ± 21.3	65.3 ± 22.0	73.3 ± 21.0	< 0.001
WPAI, % impairment				
Work time missed	4.0 ± 14.6	10.0 ± 23.4	3.3 ± 13.0	< 0.001
Impairment while working	16.7 ± 21.7	29.5 ± 27.6	15.0 ± 20.2	< 0.001
Overall work impairment	18.5 ± 23.6	32.3 ± 29.7	16.8 ± 22.1	< 0.001
Activity impairment	20.4 ± 24.3	37.0 ± 29.8	18.1 ± 22.5	< 0.001
Current employment	911 (62.1)	103 (55.1)	808 (63.2)	0.03

* All values were calculated based on available data. All variables had < 20% missing data except for WPAI (n, range 689–837). EQ VAS: EQ-5D visual analog scale; HAQ: Health Assessment Questionnaire; HAQ-S: HAQ for Spondyloarthropathies; VAS: visual analog scale; WPAI: Work Productivity and Activity Impairment questionnaire.

Table 4. Baseline EQ-5D-3L domains for patients with psoriatic arthritis. Values are n (%) unless otherwise specified.

Characteristics*	Overall, n = 1530	With Axial Involvement, n = 192	Without Axial Involvement, n = 1338	p
EQ-5D-3L index, mean ± SD	0.8 ± 0.2	0.7 ± 0.2	0.8 ± 0.2	< 0.001
Walking about				0.003
No problems	868 (58.1)	88 (47.3)	780 (59.6)	
Some problems	622 (41.6)	97 (52.2)	525 (40.1)	
Confined to bed	4 (0.3)	1 (0.5)	3 (0.2)	
Self-care				0.003
No problems	1184 (81.8)	129 (72.5)	1055 (83.1)	
Some problems washing or dressing	258 (17.8)	48 (27.0)	210 (16.5)	
Unable to wash or dress self	6 (0.4)	1 (0.6)	5 (0.4)	
Usual activities				< 0.001
No problems	750 (50.7)	66 (35.5)	684 (52.9)	
Some problems	671 (45.4)	107 (57.5)	564 (43.6)	
Unable to perform usual activities	58 (3.9)	13 (7.0)	45 (3.5)	
Pain/discomfort				< 0.001
No pain or discomfort	331 (22.4)	24 (13.0)	307 (23.8)	
Moderate pain or discomfort	1007 (68.3)	132 (71.7)	875 (67.8)	
Extreme pain or discomfort	137 (9.3)	28 (15.2)	109 (8.4)	
Feeling anxious/depressed				< 0.001
Not anxious or depressed	977 (65.7)	96 (51.6)	881 (67.8)	
Moderately anxious or depressed	467 (31.4)	81 (43.5)	386 (29.7)	
Extremely anxious or depressed	42 (2.8)	9 (4.8)	33 (2.5)	

* All values were calculated based on available data and had < 20% missing data. EQ-5D-3L: 3-level EQ-5D questionnaire.

levels). Patients with axial involvement were also younger and more likely to have prior biologic use, with a history of depression and a greater effect on patient-reported outcomes, physical function, and quality of life at enrollment. The prevalence of axial PsA in our study is lower than the 25% to 70% reported⁹; however, other cohorts of patients with early disease/newly diagnosed PsA have reported prevalence of axial involvement (using terms such as axial arthritis, axial

involvement, axial symptoms, spondylitis, and SpA) in the 4.5% to 26.8% range^{23–30}. Further, because radiograph confirmation of axial PsA was not required, the number of patients with axial PsA may have been underestimated (asymptomatic patients with radiographic changes) or overestimated (symptomatic patients without radiographic changes). Given the general lack of consensus on the definition of axial PsA and the broad spectrum of both

inclusion criteria and timing of patient evaluations across multiple studies, the wide range of estimates is not surprising.

Limited real-world studies exist on the characterization of axial PsA, and current classifications of this disease overlap with that of AS, thus obscuring the clinical and therapeutic implications of axial PsA. This analysis represents the first national-level query, to our knowledge, of patients with PsA from a broad geographic distribution of a primary-to-tertiary mix of clinical centers across the United States. Within a US-based registry, we have described the demographic, clinical, and treatment characteristics of patients with PsA at the time of enrollment. Data from the Corrona PsA/SpA Registry showed that in patients with PsA, presence of axial involvement was associated with significantly worse disease and widespread impairment of patient-reported outcomes at the time of registry enrollment. Patients with axial PsA also demonstrated greater overall work impairment with higher percentages of impairment across all WPAI domains compared to patients without axial involvement. Because of the lack of studies evaluating axial PsA effects on work performance, our study provides valuable information that helps to address the effects of axial PsA-related work productivity and activity loss. The findings from our present study suggest that patients with PsA who have axial involvement have more severe disease than those patients without axial involvement; however, the effect of axial involvement on progression of disease remains unclear. There have been few studies or clinical trials that have examined the progression of disease and management of patients with axial PsA^{11,12,13,14}. These observations are in line with another report indicating that patients with confirmed radiographic diagnosis of axial PsA failed to show improvements in back symptoms after a 10-year prospective followup, and demonstrated worsening cervical and lumbar mobility and radiographic changes over time³¹.

Current treatment recommendations for PsA were developed by GRAPPA based on a review of the literature and agreement between rheumatologists and dermatologists in accordance with ASAS guidelines¹⁸; accordingly, several biologics have been approved for patients with axial SpA, which may be used to inform treatment decisions for patients with axial PsA³²⁻³⁷. There have been only 2 observational studies that have evaluated the use of biologic therapy in patients with axial PsA^{15,38}. A large, retrospective analysis of 1455 patients with PsA (296 with axial involvement and 1159 without axial involvement, based on clinical examination by the treating physician) in Germany demonstrated that treatment with adalimumab was effective for patients regardless of presence or absence of axial involvement¹⁵. Aside from the presence of axial involvement, the authors did not observe any obvious differences between patients with and without axial involvement at baseline; however, their analysis did not include comprehensive assessments of disease activity or patient-reported outcomes at baseline. In

a 12-month observational study of patients with refractory axial PsA, treatment with etanercept led to significant improvement in BASDAI scores, suggesting that biologic therapy may be effective in patients with axial PsA³⁸. Because of the lack of consensus on how axial PsA is identified and characterized, as well as the limited amount of data from the axial PsA patient population, many investigators have applied spinal measurements developed for use in AS to assess spinal mobility in PsA^{12,39}. An examination of available radiographic scoring methods demonstrated that while some tools routinely used for axial SpA may be reliable for axial PsA (e.g., the Bath Ankylosing Spondylitis Radiology Index, the modified Stoke Ankylosing Spondylitis Spinal Score, and the Radiographic Ankylosing Spondylitis Spinal Score), the Psoriatic Arthritis Spondylitis Radiology Index, developed for axial PsA, may be superior for assessing structural damage^{40,41}. Other metrics for assessing disease activity and inflammation in axial PsA continue to be adapted from AS, including BASDAI scores and the ASDAS^{42,43}; however, although BASDAI scores could reliably be used in AS and peripheral PsA, these were not sufficient in evaluating axial involvement⁴². The lack of specific tools to assess disease activity in axial PsA highlights the need for additional data to support the development of specific and substantiated clinical tools for the appropriate monitoring and management of these patients.

As with any observational study, there are possibilities of other unmeasured confounders. The patients in our study routinely see their rheumatologists, which may not be indicative of the frequency or type of care received by the average patient. Patients were recruited by their rheumatologist, who was required to indicate diagnosis upon enrollment. Presence of axial involvement was determined based on physician diagnosis of inflammatory SpA, but imaging documentation was not required; therefore, it is possible that the proportion of patients with axial involvement may have been underestimated or overestimated.

These data highlight the need to monitor patients with PsA for axial symptoms to ameliorate disease development and progression of patient-reported measures. More formal studies in axial PsA are critical to assess specifications for diagnosis, treatment, response, and outcome measures.

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