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Effectiveness of 6-month Use of Secukinumab in Patients With Psoriatic Arthritis in the CorEvitas Psoriatic Arthritis/Spondyloarthritis Registry

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ABSTRACT. ***Objective.*** To evaluate clinical and patient-reported outcomes (PROs) at 6 months after secukinumab initiation in US patients with psoriatic arthritis (PsA).

Methods. Patients with PsA in the CorEvitas Psoriatic Arthritis/Spondyloarthritis Registry who initiated secukinumab between April 1, 2017, and December 2, 2019, and maintained secukinumab at their 6-month follow-up visit were included. Achievement of minimal disease activity (MDA) among patients not in MDA at initiation; resolution (ie, no evidence) of tender and swollen joint counts, enthesitis, and dactylitis among patients with ≥ 1 of these at initiation; and change in disease activity and PROs were evaluated at 6 months in all patients and in patients who received secukinumab as a first-line biologic.

Results. Of the 100 eligible patients included, most (83.0%) were biologic experienced and 17.0% initiated secukinumab as a first-line biologic. At initiation, 75/90 patients (83.3%) with available data were not in MDA; 26/71 (36.6%) with follow-up data achieved MDA at 6 months. Further, 28/68 patients (41.2%) with ≥ 1 tender joint, 24/54 (44.4%) with ≥ 1 swollen joint, 17/28 (60.7%) with enthesitis, and 9/12 (75.0%) with dactylitis at initiation achieved resolution at 6 months. Improvements in clinical manifestations, PRO measures, and work productivity and activity were observed after 6 months among patients with PsA who initiated and maintained secukinumab.

Conclusion. In this real-world population, patients with PsA who received and maintained secukinumab for 6 months achieved MDA in proportions consistent with clinical trials and demonstrated improvements in clinical manifestations and PROs.

Key Indexing Terms: effectiveness, minimal disease activity, psoriatic arthritis, registry, secukinumab

Psoriatic arthritis (PsA) is a heterogeneous, chronic inflammatory disease with diverse clinical presentations, including peripheral arthritis, axial disease, dactylitis, enthesitis, and skin and/or nail manifestations.[1,2]

Secukinumab, a fully humanized monoclonal antibody that selectively inhibits interleukin (IL)-17A, is approved for the treatment of PsA[3] and improves all PsA manifestations in the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA)–Outcome Measures in Rheumatology (OMERACT) core domain set. However, few studies in the United States have evaluated the effectiveness of secukinumab in patients with PsA in real-world settings.[4,5]

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The present study evaluated the effectiveness of secukinumab for improving disease severity and patient-reported outcome (PRO) measures from initiation to a 6-month follow-up visit in patients with PsA. Because patients with PsA often cycle through biologics and effectiveness is frequently attenuated in biologic-experienced patients, we also evaluated outcomes in patients who initiated secukinumab as first-line biologic therapy to assess if treatment effectiveness was similar regardless of prior biologic experience.

METHODS

Data source and patient population. This study included 3393 patients from the CorEvitas PsA/Spondyloarthritis Registry[6] who had a diagnosis of PsA, of whom 324 initiated secukinumab at a registry visit (initiation) between April 1, 2017, and December 2, 2019. Patients who initiated secukinumab (150 or 300 mg every 4 weeks), had a follow-up visit occurring 6 months (window: 5–8 months) after initiation, and maintained secukinumab at that time (n = 100) were included in the analysis. The study protocol was approved by a central institutional review board (IRB; New England Independent Review Board no. 120160070) for private practice sites and the local governing IRBs of participating academic sites. All registry subjects were required to provide written informed consent and authorization prior to participating.

Assessments and outcomes. Data were collected at initiation and at the 6-month follow-up visit using questionnaires completed by patients and their treating rheumatologists during office visits.

The primary outcome was minimal disease activity (MDA) achievement at 6 months among patients not in MDA at the time of secukinumab initiation. MDA was achieved if a patient met ≥ 5 of 7 criteria: tender joint count in 68 joints (TJC68) ≤ 1, swollen joint count in 66 joints (SJC66) ≤ 1, psoriasis (PsO)-affected body surface area (BSA) ≤ 3%, patient pain visual analog scale (VAS; 0–100) ≤ 15, patient global assessment (PtGA) VAS ≤ 20, Health Assessment Questionnaire–Disability Index (HAQ-DI) ≤ 0.5, and tender entheseal points ≤ 1 using the Leeds Enthesitis Index (LEI; 0–6).[7] Secondary outcomes included resolution (ie, no evidence) of tender or swollen joints, enthesitis (LEI and Spondyloarthritis Research Consortium of Canada [SPARCC] Enthesitis Index [0–16]), or dactylitis among those patients who had evidence of these symptoms at initiation. Clinical outcomes (TJC68, SJC66, SPARCC count, LEI count, dactylitis count, BSA, nail PsO, Disease Activity Index for Psoriatic Arthritis [DAPSA] score, Psoriatic Arthritis Disease Activity Score [PASDAS], physician global assessment [PGA] of arthritis, and PGA of arthritis and PsO), PROs (pain, fatigue, morning stiffness, PtGA of arthritis, PtGA of arthritis and PsO, HAQ-DI, EuroQol 5-dimension [EQ-5D] questionnaire [0–1], and EQ VAS), and Work Productivity and Activity Impairment (WPAI) questionnaire were also assessed.

Data analysis. Patient demographics and clinical characteristics at baseline were summarized using counts and percentages for categorial variables, and means and SDs for continuous variables.

The proportion of patients achieving MDA at 6 months was calculated among patients not in MDA at the time of secukinumab initiation who had data for MDA available at 6-month follow-up. The proportions of patients meeting each MDA criterion at baseline and 6 months were calculated separately for patients who achieved MDA and for those who did not achieve MDA. The proportions of patients achieving resolution of tender joints, swollen joints, enthesitis, or dactylitis and mean (SD) change in continuous measures from baseline to 6-month follow-up were calculated among those patients with information available at both visits. Analyses were repeated in the subset of patients who initiated secukinumab as their first-line biologic. All analyses were performed using Stata version 15.1 (StataCorp).[8]

RESULTS

Patient characteristics at the time of secukinumab initiation. A total of 100 patients with PsA were included in this study. Mean (SD) age was 51.6 (11.6) years, 54.3% were men, and 96.8% were White (Table 1). The mean (SD) time since PsA diagnosis was 7.0 (7.0) years, and mean symptom duration was 10.8 (9.7) years (Supplementary Table 1, available with the online version of this article). Before initiation of secukinumab, 83.0% were biologic experienced, of whom 59.0% (49/83) had used ≥ 2 biologics prior to secukinumab.

Most patients had evidence of arthritis, with ≥ 1 tender joint (72.3%) or swollen joint (57.4%; Table 1). Approximately one-third of patients (LEI, 30.1% and SPARCC, 33.0%) had enthesitis, and dactylitis was reported in 12.8% of patients. Of 90 patients with available data on MDA criteria, 75 (83.3%) were not in MDA at initiation. Of patients with available DAPSA scores (n = 67), 56.7% had moderate to high disease activity, and 55.9% of patients with available PASDAS scores (n = 68) had active or very active disease at secukinumab initiation (Supplementary Table 1, available with the online version of this article).

At the time of secukinumab initiation, patients reported considerable mean (SD) pain (53.2 [26.5]), fatigue (46.7 [27.6]), and morning stiffness (51.1 [27.1]; Table 1). The mean (SD) PtGA of arthritis and PsO was 44.5 (24.5), and the HAQ-DI score was 0.87 (0.63).

Disease activity and PRO measures at 6 months after secukinumab initiation. Of those who had available data on MDA at follow-up, 71 patients were not in MDA at secukinumab initiation, 26 of whom (36.6%) achieved MDA at 6 months. Of these 26 patients, fewer than one-third had TJC68 ≤ 1 (26.9%), pain VAS ≤ 15 (0%), or PtGA VAS ≤ 20 (26.9%), and fewer than half (46.2%) had HAQ-DI ≤ 0.5 at initiation (Figure 1A). Most patients who achieved MDA (88.5%, 57.7%, 73.1%, and 88.5%, respectively) achieved these components at the 6-month follow-up visit. Minimal skin involvement for MDA criteria also improved among those who achieved MDA; the proportion with BSA ≤ 3% increased from 57.7% at initiation to 96.2% at 6 months.

The proportions of patients with TJC68 ≤ 1 (31.1%), pain VAS ≤ 15 (6.7%), PtGA VAS ≤ 20 (6.7%), and HAQ-DI ≤ 0.5 (2.2%) at initiation were also low among patients who did not achieve MDA at 6 months, although these proportions remained low (26.7%, 6.7%, 15.6%, and 13.3%, respectively) at 6-month follow-up. Among patients who did not achieve MDA at 6 months, 46.7% had minimal skin involvement (MDA component of BSA ≤ 3%) at initiation, and nearly two-thirds (64.4%) had BSA ≤ 3% at follow-up.

Improvements were observed in PsA disease activity measures at 6 months, including TJC68, SJC66, PsO-affected BSA, nail PsO VAS, DAPSA, PASDAS, and PGA of arthritis and PsO (Figure 1B). Among all patients who initiated secukinumab, 28/68 with TJC68 ≥ 1, 24/54 with SJC66 ≥ 1, 17/28 with LEI ≥ 1, and 9/12 with dactylitis at initiation achieved resolution at 6 months (Figure 1C).

Improvements in PRO measures were seen at 6 months, including decreased pain, fatigue, PtGA of arthritis and PsO, morning stiffness, HAQ-DI, and EQ-5D scores (Figure 2A).

Table 1. Demographics, clinical measures, and PROs at secukinumab initiation (baseline) of patients with PsA who maintained secukinumab at the 6-month follow-up visit.

Characteristic[a]	Patients, N = 100
Age, yrs, mean (SD) [n]	51.6 (11.6) [94]
Male sex, [n]	51 (54.3) [94]
White, [n]	90 (96.8) [93]
BMI, kg/m^2, mean (SD), [n]	33.0 (7.9) [92]
Disease duration, yrs, mean (SD) [n]	7.0 (7.0) [93]
Secukinumab dose	
150 mg	30 (30.0)
300 mg	70 (70.0)
Prior biologic use	83 (83.0)
No. prior biologics	
0	17 (17.0)
1	34 (34.0)
2	26 (26.0)
≥ 3	23 (23.0)
Prior csDMARD use	79 (79.0)
Prior tsDMARD use	20 (20.0)
Prior prednisone use	17 (17.0)
Current secukinumab use[b]	
Secukinumab monotherapy	67 (67.0)
Secukinumab + csDMARD/tsDMARD combination	33 (33.0)
Current csDMARD use[b,c]	31 (31.0)
Current tsDMARD use (total)	4 (4.0)
Current prednisone use, [n]	6 (6.4) [94]
Tender joint count (0–68), mean (SD) [n]	6.5 (9.2) [94]
Tender joint count ≥ 1	68 (72.3)
Tender joint count (1–68), mean (SD)	9.0 (9.7)
Swollen joint count (0–66), mean (SD) [n]	2.7 (4.0) [94]
Swollen joint count ≥ 1	54 (57.4)
Enthesitis (LEI), [n]	28 (30.1) [93]
LEI count (1–6), mean (SD)	1.9 (1.1)
Enthesitis (SPARCC Enthesitis Index), [n]	31 (33.0) [94]
SPARCC Enthesitis Index (1–16), mean (SD)	4.3 (3.0)
Dactylitis, [n]	12 (12.8) [94]
Dactylitis count (1–20), mean (SD)	2.1 (1.3)
BSA, % affected, mean (SD) [n]	7.3 (13.6) [93]
BSA > 3%	33 (35.5)
Nail psoriasis VAS (1–100), [n]	32 (34.8) [92]
Nail psoriasis VAS (1–100), mean (SD)	35.0 (32.9)
MDA, [n][d]	15 (16.7) [90]
DAPSA, mean (SD) [n]	20.2 (15.6) [67]
PASDAS, mean (SD) [n]	4.3 (1.4) [68]
PGA of arthritis (0–100), mean (SD) [n]	32.8 (22.2) [94]
PGA of arthritis and psoriasis (0–100), mean (SD) [n]	38.3 (22.4) [94]
Patient-reported pain (VAS 0–100), mean (SD) [n]	53.2 (26.5) [93]
Patient-reported fatigue (VAS 0–100), mean (SD) [n]	46.7 (27.6) [94]
Morning stiffness (VAS 0–100), mean (SD) [n]	51.1 (27.1) [94]
PtGA of arthritis (VAS 0–100), mean (SD) [n]	44.3 (23.2) [93]
PtGA of arthritis and psoriasis (VAS 0–100), mean (SD) [n]	44.5 (24.5) [93]
HAQ-DI (0–3), mean (SD) [n]	0.87 (0.63) [94]
WPAI domains[e]	
Current employment	66 (70.2) [94]
% Work time missed, mean (SD) [n]	12.1 (26.8) [61]
% Impairment while working, mean (SD) [n]	29.4 (29.0) [65]
% Overall work impairment, mean (SD) [n]	36.4 (32.7) [61]
% Activity impairment, mean (SD) [n]	43.0 (29.8) [93]

[a] Values are expressed as n (%) unless stated otherwise; [n] represents the number of patients with nonmissing data available. [b] Current drug use included the drug initiated at secukinumab initiation among incident users and last medication used among prevalent users. [c] One patient was prescribed 2 csDMARDs at secukinumab initiation. [d] MDA is defined as meeting ≥ 5 of the 7 following criteria: tender joint count ≤ 1, swollen joint count ≤ 1, BSA ≤ 3%, patient pain VAS ≤ 15, PtGA VAS ≤ 20, HAQ-DI ≤ 0.5, and tender entheseal points ≤ 1 using LEI. [e] Work time missed, impairment while working, and overall work impairment reported among patients who were employed. Current drug use included the drug initiated at secukinumab initiation among incident users and last medication used among prevalent users. BSA: body surface area; csDMARD: conventional synthetic disease-modifying antirheumatic drug; DAPSA: Disease Activity in Psoriatic Arthritis; HAQ-DI: Health Assessment Questionnaire–Disability Index; LEI: Leeds Enthesitis Index; MDA: minimal disease activity; PASDAS: Psoriatic Arthritis Disease Activity Score; PGA: physician global assessment; PRO: patient-reported outcome; PsA: psoriatic arthritis; PtGA: patient global assessment; SPARCC: Spondyloarthritis Research Consortium of Canada; tsDMARD: targeted synthetic disease-modifying antirheumatic drug; VAS: visual analog scale; WPAI: Work Productivity and Activity Impairment questionnaire.

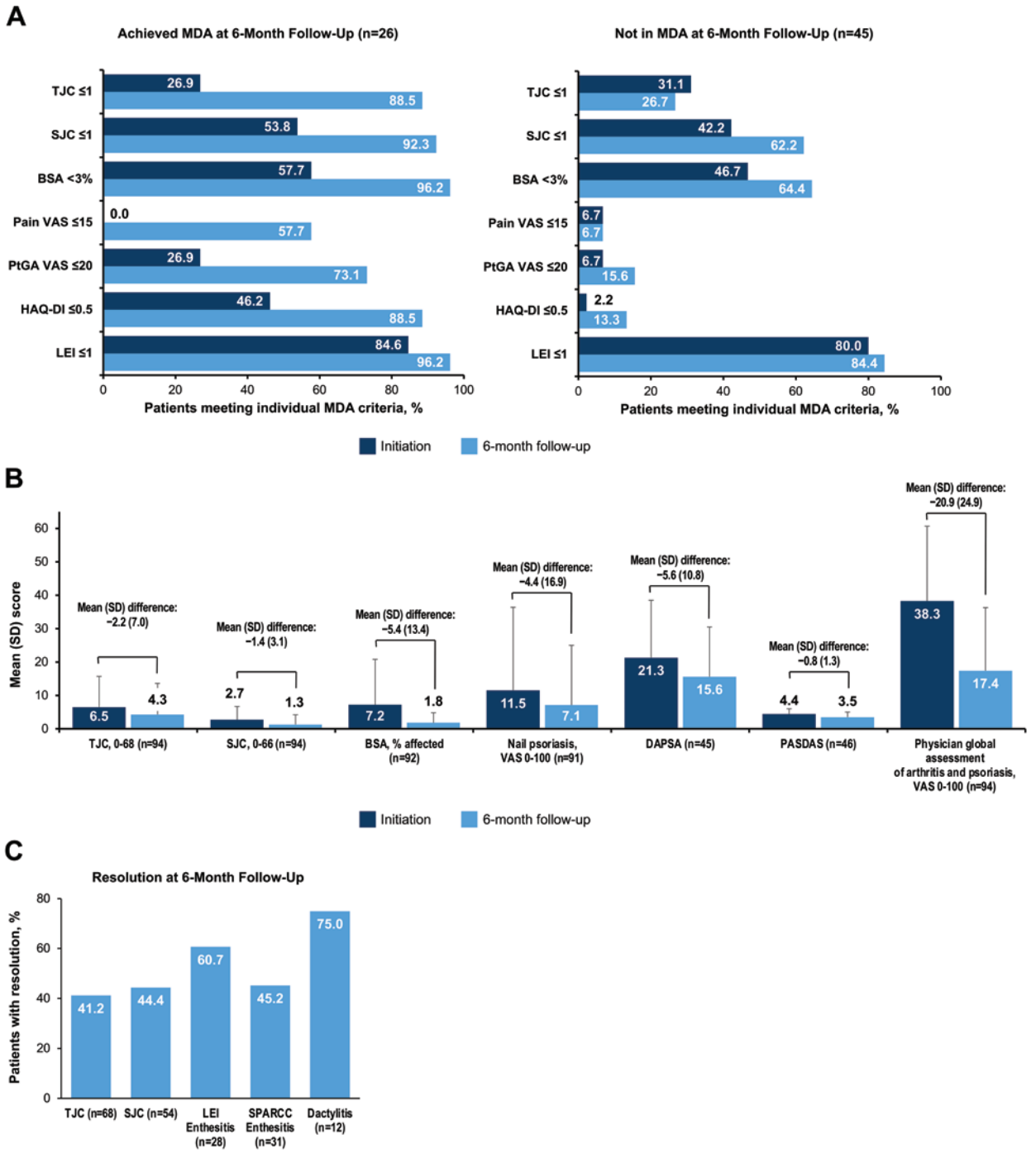

Figure 1. Clinical outcomes at initiation and at 6-month follow-up for patients with PsA who initiated and maintained secukinumab. (A) Achievement of individual MDA components in patients who achieved MDA and those who did not achieve MDA (the proportion of patients meeting each MDA criterion at initiation and 6-month follow-up among patients who were not in MDA at initiation and had 6-month follow-up data available [n = 71], stratified by achievement of MDA at 6 months). (B) Change in clinical outcomes from initiation to 6-month follow-up. (C) Resolution (count = 0) of peripheral arthritis, enthesitis, and dactylitis at 6 months among patients with ≥ 1 site at initiation. BSA: body surface area; DAPSA: Disease Activity in Psoriatic Arthritis; HAQ-DI: Health Assessment Questionnaire–Disability Index; LEI: Leeds Enthesitis Index; MDA: minimal disease activity; PASDAS: Psoriatic Arthritis Disease Activity Score; PsA: psoriatic arthritis; PtGA: patient global assessment; SJC: swollen joint count; SPARCC: Spondyloarthritis Research Consortium of Canada; TJC: tender joint count; VAS: visual analog scale.

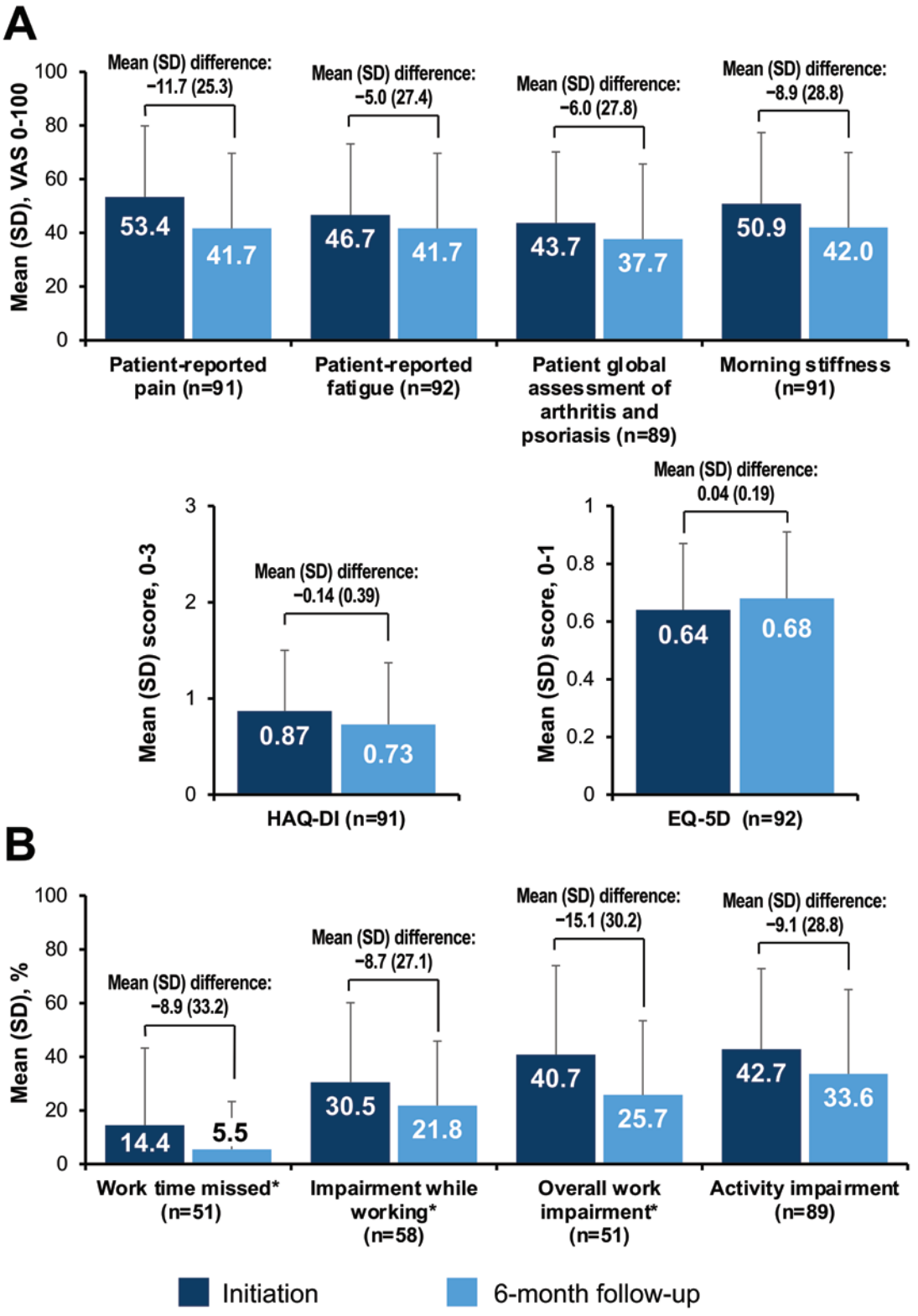

Figure 2. Change from initiation in (A) patient-reported outcome measures and (B) WPAI at the 6-month follow-up visit among patients with psoriatic arthritis who initiated and maintained secukinumab. * Work time missed, impairment while working, and overall work impairment reported among patients who were employed. EQ-5D: EuroQol 5-dimension; HAQ-DI: Health Assessment Questionnaire–Disability Index; VAS: visual analog scale; WPAI: Work Productivity and Activity Impairment questionnaire.

Patients also reported improvement in work productivity and activity measures at the 6-month follow-up (Figure 2B).

Secukinumab as a first-line biologic. Patient characteristics for the biologic-naïve cohort at initiation were similar to the overall population's, with the exception of shorter mean (SD) symptom and disease duration (6.9 [9.5] years and 2.8 [4.3] years, respectively; Supplementary Table 2, available with the online version of this article). Biologic-naïve patients had lower mean (SD) patient-reported pain (46.1 [27.3]), fatigue (36.4 [25.8]), PtGA of arthritis and PsO (35.9 [27.0]), and morning stiffness (40.0 [28.1]), as well as higher PGA of arthritis and PsO (46.6 [26.2]) and percentage of work time missed (19.7% [37.9%]) than the overall study population; all other characteristics were similar between cohorts (Supplementary Table 3).

There were 12 patients who initiated secukinumab as a first-line biologic who were not in MDA at initiation and had 6-month follow-up data available. Of these patients, 7 (58.3%) achieved MDA at 6 months. In this cohort, 8/13 patients with TJC68 ≥ 1 and 3/10 with SJC66 ≥ 1 at initiation achieved resolution at 6 months (Supplementary Table 4, available with the online version of this article). Although available patient numbers were low, similar trends were seen for enthesitis and dactylitis resolution: 4/5 with enthesitis (LEI), and 2/2 with dactylitis at initiation achieved resolution at 6 months. Improvements from baseline were observed at the 6-month follow-up in most disease activity and PRO measures (Supplementary Table 5).

DISCUSSION

Our findings are among the first to provide evidence of the effectiveness of secukinumab in US patients with PsA who initiated and maintained secukinumab after 6 months in a real-world setting. Further, we ascertained effectiveness in multiple PsA disease domains with MDA. Most patients who initiated secukinumab were biologic experienced and were not in MDA at initiation. MDA is a multidomain composite measure that assesses a range of symptoms, and patients who achieve MDA have been reported to experience overall better clinical benefit.[9,10] More than one-third of patients achieved MDA, and the overall cohort of secukinumab initiators included in this analysis achieved improvements in clinical manifestations, PRO measures, and work productivity with 6 months of continuous treatment.

Findings from our study also show similar proportions of patients who maintained secukinumab for 6 months achieved MDA as seen in clinical trials, and patients experienced improvements in functional status, quality of life (QOL), and work productivity measures, despite a larger proportion of biologic-experienced patients in this study population (83%) compared with clinical trial populations (range 29.6–45%).[11,12,13,14,15]

European studies have shown that secukinumab improves disease activity and PRO measures in biologic-naïve and -experienced patients seen in routine clinical practice.[4,16,17,18,19] In a study comprising data for 2017 patients with PsA from 13 rheumatology registries, 78.1% were biologic/targeted synthetic DMARD (b/tsDMARD)-experienced.[17] Improvements from baseline were reported with secukinumab in multiple clinical disease measures sustained up to 12 months, regardless of prior treatment experience. The study also reported significant differences in improvements between b/tsDMARD-naïve and -experienced patients for each of these measures of treatment effectiveness, with response rates significantly better for b/tsDMARD-naïve patients. Further, a prospective study of patients with PsA, which included 62.7% biologic-experienced patients, demonstrated that MDA was achieved by 75.7% and 70.4% of biologic-naïve and -experienced patients, respectively, with 24 months of secukinumab treatment.[19] This prospective study also reported improvements in outcome measures across PsA disease domains. Variability in the effectiveness of secukinumab in patients with PsA across real-world studies may be due to the differences between study populations in clinical trials and patient populations seen in routine clinical practice, the latter of whom may have had multiple failed lines of therapy.

Similar to previous studies, our study population included 83% biologic-experienced patients, of whom 59% had initiated secukinumab as at least a third-line biologic. Although patients with prior biologic treatment may be difficult to treat, we found that the proportion of patients who achieved MDA was similar to that seen in clinical trials, regardless of prior biologic use. Additionally, we observed improvements in DAPSA and HAQ-DI scores, TJC68, and SJC66, as well as resolution of enthesitis and dactylitis among most patients with ≥ 1 site at initiation; comparable improvements were observed for the overall cohort, of whom the majority were biologic-experienced, and patients in the biologic-naïve cohort. The totality of evidence addresses a knowledge gap by providing information on secukinumab effectiveness in patients with PsA who are predominantly biologic-experienced and increased effectiveness in biologic-naïve patients. These findings offer further evidence of the utility of secukinumab as an option for patients at all points along their treatment journey.

Further, the majority of patients who achieved MDA at 6-month follow-up also achieved each individual MDA criterion at 6 months, with improvements from initiation in the proportion of patients who met TJC68 ≤ 1, pain VAS ≤ 15, PtGA VAS ≤ 20, and HAQ-DI ≤ 0.5. In contrast, among patients who did not achieve MDA at follow-up, the proportions of patients who met TJC, pain, PtGA, and HAQ-DI cut-offs remained low at 6 months, indicating that these components may drive changes in overall MDA achievement in this population. Future studies with larger sample sizes and longer study durations should be conducted to evaluate the long-term effect of secukinumab on maintenance of MDA. These findings provide additional evidence of the effectiveness of secukinumab for achievement of MDA in patients with PsA, regardless of prior biologic use.

The results of this study may not be representative of all patients with PsA worldwide since the data source was a US-based registry and participation is voluntary for patients and rheumatologists, which may predispose the registry population to selection of patients who may have a more active role in management of their disease. Nevertheless, this cohort is more representative of patients seen in US clinical practice compared with patients typically selected for clinical trials.[20] Patients who experienced

extended time without treatment for PsA and those with no gaps in treatment could both be included in this study population, which may influence patient characteristics and disease activity. Additionally, patients who discontinued or switched treatment prior to follow-up were excluded from this study due to the difficulty of accurately capturing outcomes at the time of discontinuation or switching treatment for each patient. This exclusion limits the generalizability of our findings and may introduce an inclination for treatment effectiveness since patients who remain persistent are more likely to respond favorably to treatment. The size of our cohort was modest, particularly the subgroup of first-line secukinumab initiators. Results from this subset should be considered as suggestive. However, to our knowledge, this is one of the first real-world studies of secukinumab effectiveness in the US. As the population of patients treated with secukinumab in the registry increases, larger sample sizes will be available for more robust testing and allow for stratification by line of therapy.

In summary, more than one-third of real-world patients with PsA who were not in MDA at secukinumab initiation and remained on treatment for 6 months achieved MDA and experienced improvements in clinical manifestations, PRO measures, and work productivity at 6-month follow-up, which is consistent with findings from clinical trials. Additionally, our results suggest that secukinumab may be effective as biologic therapy for those patients both with and without prior biologic use. The results presented here provide evidence of the effectiveness of secukinumab for improving disease activity and QOL in patients with active PsA seen in routine clinical practice, regardless of prior biologic experience.

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ONLINE SUPPLEMENT

Supplementary material accompanies the online version of this article.

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