Rheumatol Ther (2024) 11:313–329
https://doi.org/10.1007/s40744-023-00631-4

ORIGINAL RESEARCH

Effectiveness of Tofacitinib in Patients Initiating Therapy for Psoriatic Arthritis: Results from the CorEvitas Psoriatic Arthritis/Spondyloarthritis Registry

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Received: August 3, 2023 / Accepted: December 6, 2023 / Published online: January 22, 2024
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ABSTRACT

Introduction: Randomized controlled trials have demonstrated tofacitinib efficacy for psoriatic arthritis (PsA); however, real-world effectiveness data are limited. This real-world analysis assessed baseline demographics/disease characteristics and tofacitinib effectiveness in patients with PsA in the CorEvitas PsA/Spondyloarthritis Registry.

Methods: This study (NCT05195814) included patients with PsA initiating tofacitinib from December 2017–December 2021, as monotherapy or with oral small molecules (methotrexate/leflunomide/sulfasalazine/apremilast), pre-existing use, or initiated concurrently. Outcomes: mean change from baseline in disease activity/patient-reported outcomes, proportion of patients achieving low disease activity (LDA)/remission at 6 ± 3 months, and discontinuation rates.

Results: Of 222 patients with PsA who initiated tofacitinib (60.8% as monotherapy), 123 patients had 6 ± 3 months of follow-up. At initiation, 59.7% were female, 92.3% were White, mean age was 56.3 years, PsA duration since diagnosis was 8.2 years, and 25.7% were biologic disease-modifying antirheumatic drug (bDMARD)-naïve. Improvements to 6 ± 3 months were observed with tofacitinib for Clinical Disease Activity Index for PsA (cDAPSA), DAPSA, PsA Disease Activity Score (PASDAS), Clinical Disease Activity Index, body surface area (BSA), tender/swollen joint count, patient fatigue, pain, Patient Global Skin Assessment, and Health Assessment Questionnaire-Disability Index. At 6 ± 3 months, 25.0%/7.8% of patients treated with tofacitinib achieved cDAPSA-defined LDA/remission, 18.2% achieved minimal disease activity, 30.8% had PASDAS ≤ 3.2, 42.9%/29.4% had resolved enthesitis/dactylitis, and 22.5% achieved BSA = 0%. Tofacitinib discontinuation

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occurred in 51.2% of patients (51.6% of monotherapy initiators) at/prior to 6 ± 3 months (27.6%/23.6%), 57.1% of whom switched to tumor necrosis factor/interleukin-17 inhibitors. Reasons for discontinuation were not reported in 85.3%/79.3% of patients who discontinued at/prior to 6 ± 3 months.
Conclusions: This real-world US cohort analysis described patients with PsA newly initiating tofacitinib; most were bDMARD-experienced or receiving monotherapy treatment. In patients who remained on therapy (48.8%), tofacitinib was effective across multiple PsA domains at 6 ± 3 months. Limitations included small patient numbers at follow-up and potential selection bias.
Trial Registration: ClinicalTrials.gov identifier, NCT05195814.

Keywords: Effectiveness; Psoriatic arthritis; Tofacitinib

Key Summary Points

Why carry out this study?

The efficacy and safety of tofacitinib have been evaluated in randomized controlled trials (RCTs) and a long-term extension study of patients with psoriatic arthritis (PsA); however, studies assessing the effectiveness of tofacitinib in real-world settings are limited.

This observational study determined the effectiveness of tofacitinib at the 6-month follow-up visit (± 3-month window; 6 ± 3-month follow-up visit) among patients enrolled in the US CorEvitas PsA/Spondyloarthritis Registry who newly initiated tofacitinib for the treatment of PsA.

What was learned from the study?

In this analysis of a real-world US cohort, patients with PsA who initiated tofacitinib and continued on therapy showed improvements in disease activity outcomes, clinical manifestations, and patient-reported outcomes, including work productivity, which were consistent with data from previous RCTs.

Overall, 51.2% of patients discontinued tofacitinib at (27.6%) or prior to (23.6%) the 6 ± 3-month follow-up visit, which was generally consistent with previous reports of patients initiating other advanced PsA therapies in the CorEvitas PsA/Spondyloarthritis Registry; the majority of patients (> 79%) in the current study did not report a reason for discontinuations.

INTRODUCTION

Psoriatic arthritis (PsA) is a chronic, systemic, immune-mediated inflammatory disease of the musculoskeletal system [1, 2] associated with multiple physical manifestations, including peripheral arthritis, psoriasis (PsO; including nail lesions), axial disease, enthesitis, and dactylitis [1, 2]. American College of Rheumatology/National PsO Foundation guidelines recommend the use of tumor necrosis factor inhibitors (TNFi) as first-line therapy [3]. The European Alliance of Associations for Rheumatology (EULAR) recommends non-steroidal anti-inflammatory drugs and conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) for the initial treatment of PsA [4]. For patients who do not adequately respond to csDMARDs, or have poor prognostic factors and have not achieved the treatment target with rapid csDMARD initiation, EULAR advises the use of biologic (b) DMARDs, such as TNFi [4]. Janus kinase inhibitors are recommended for patients who do not adequately respond to bDMARDs [4]. The Group for Research and Assessment of PsO and PsA also

recommends the use of bDMARDs and targeted synthetic DMARDs as first-line therapy, if available [5].

Tofacitinib is an oral Janus kinase inhibitor for the treatment of PsA. The efficacy and safety of tofacitinib have been demonstrated in two phase 3 randomized controlled trials (RCTs) of patients with active PsA and an inadequate response to a csDMARD or TNFi [6, 7], and one open-label, long-term extension study [8]. While RCTs, with their well-defined patient populations, are regarded as gold standard for evaluating the efficacy and safety of therapeutic interventions [9, 10], real-world data are essential for assessing treatment characteristics, effectiveness, and therapy status in settings more representative of clinical practice [10]. Treatment patterns of patients with PsA receiving bDMARDs and targeted synthetic DMARDs have been assessed in real-world analyses using the IBM MarketScan™ US database [11, 12]. In addition, separate analyses of the CorEvitas PsA/Spondyloarthritis (SpA) Registry have evaluated the effectiveness and/or therapy status of patients with PsA initiating secukinumab, TNFi, and apremilast in clinical settings [13–15]. In another real-world study using the IBM MarketScan™ US database, demographic and baseline clinical characteristics, as well as treatment persistence and adherence, were evaluated in patients with PsA with a tofacitinib claim between December 14, 2017 and April 30, 2019 [16]. However, there is a limited number of real-world studies evaluating the effectiveness of treatment in patients with PsA receiving tofacitinib therapy.

This observational study (NCT05195814) sought to determine the effectiveness and therapy status of tofacitinib among patients enrolled in the CorEvitas PsA/SpA Registry who newly initiated tofacitinib for the treatment of PsA.

METHODS

Data Source

The CorEvitas PsA/SpA Registry (NCT02530268) is a large, independent, prospective, multicenter, non-interventional registry, launched in March 2013, for patients diagnosed with PsA/SpA [17]. Patients are enrolled in the registry by participating rheumatologists. Questionnaires are completed by both patients and their treating rheumatologists during visits, as part of routine clinical care. While data collection is not mandated at regular intervals, rheumatologists are encouraged to complete questionnaires at least every 6 months. As of December 31, 2021, the registry included 2331 actively participating adult patients with PsA, comprising 13,342 visits to 71 rheumatologists from 66 private and academic clinical sites across 30 US states. This represents 7484.9 patient-years of data, with a mean duration of follow-up time of 3.87 years (median 3.05 years).

Study Cohort

This study (NCT05195814) included patients aged ≥ 18 years enrolled in the CorEvitas PsA/SpA Registry with rheumatologist-diagnosed PsA, who had initiated tofacitinib as monotherapy at or after registry enrollment, or in combination with oral small molecules (OSM; methotrexate, leflunomide, sulfasalazine, and apremilast [pre-existing use or initiated concurrently]), and had a 6-month follow-up visit (± 3-month window), between December 14, 2017 (date of tofacitinib US Food and Drug Administration approval for PsA) and December 31, 2021. Patients taking tofacitinib in combination with any bDMARD were excluded. The doses of tofacitinib used were not reported.

The study was performed in accordance with Good Pharmacoepidemiology Practice. All participating investigators were required to obtain full board approval for conducting research involving human patients with a limited dataset. Sponsor approval and continuing review were obtained through a central Institutional Review Board (IRB), the New England Independent Review Board (No. 120160939). For academic investigative sites that did not receive a waiver to use the central IRB, full board approval was obtained from the respective

governing IRBs and documentation of approval was submitted to CorEvitas, LLC, prior to the initiation of any study procedures. All patients in the registry were required to provide written informed consent and authorization prior to participating in the study.

Outcomes and Assessments

Data collected at the time of tofacitinib initiation (baseline) included patient demographics (age, sex, and race), comorbidities, PsA clinical features, PsA disease activity measures, and patient-reported outcome (PRO) measures. Outcomes, for which patients were required to have a 6-month follow-up visit (± 3-month window; 6 ± 3-month follow-up visit) after tofacitinib initiation, included clinical effectiveness and PROs at the 6 ± 3-month follow-up visit, and therapy status (treatment discontinuations at or prior to the 6 ± 3-month follow-up visit and reasons for discontinuation). Safety data were not assessed in this analysis.

Clinical effectiveness outcomes included mean change from baseline to month 6 ± 3 in Clinical Disease Activity Index for PsA (cDAPSA), DAPSA, PsA Disease Activity Score (PASDAS), Clinical Disease Activity Index (CDAI), body surface area (BSA), Clinical Global Assessment of PsO, tender joint count (TJC; 68-joint count), and swollen joint count (SJC; 66-joint count).

In addition, the proportions of patients achieving the following at month 6 ± 3 (among those not in each state at baseline) were analyzed: cDAPSA-based low disease activity (LDA; scores > 4 to ≤ 13) and remission (scores ≤ 4), minimal disease activity (MDA; composite measure defined as "yes" if a patient met at least 5 of the 7 following criteria: TJC ≤ 1, SJC ≤ 1, BSA $\leq 3\%$, patient pain Visual Analog Scale [VAS] ≤ 15, patient global activity VAS ≤ 20, Health Assessment Questionnaire-Disability Index [HAQ-DI] ≤ 0.5, and tender entheseal point ≤ 1), very low disease activity (VLDA; composite measure defined as "yes" if a patient met all 7 criteria included for MDA), PASDAS ≤ 3.2, resolution of enthesitis (Spondyloarthritis Research Consortium of Canada [SPARCC] = 0 for those with SPARCC > 0 at baseline), resolution of dactylitis (no dactylitis at follow-up for those with dactylitis at baseline), Clinical Global Assessment of PsO score of "clear/almost clear" (scores of 0 or 1 for those that were > 1 at baseline), and BSA = 0%. For all outcomes, patients who were in the state of interest (i.e., cDAPSA LDA/remission, MDA, VLDA, PASDAS ≤ 3.2, enthesitis/dactylitis = 0, Clinical Global Assessment of PsO of "clear/almost clear", and BSA = 0%) at initiation were excluded from the respective analysis.

PROs included mean change from baseline to month 6 ± 3 in scores for patient fatigue (0–100 VAS), patient pain (0–100 VAS), Patient Global Skin Assessment (0–100 VAS), and HAQ-DI, and the proportion of patients with overall work impairment, work time missed, impairment while working, and activity impairment, as measured by the Work Productivity and Activity Impairment (WPAI) questionnaire [18, 19].

Statistical Analysis

For patient demographics and disease characteristics, categorical variables were summarized using frequencies and proportions, and continuous variables were summarized using descriptive statistics (mean and standard deviation [SD]). Therapy status, including rates of discontinuation and reasons for discontinuation, was summarized descriptively (frequency and rate).

For the analysis of clinical effectiveness, binary outcomes were presented as response rates (%) with 95% confidence intervals (CIs) using normal approximation to binomial proportions; non-response was defined as those patients who discontinued tofacitinib prior to the 6 ± 3-month follow-up visit. Summary statistics (*n*, mean [SD]) were presented for baseline, month 6 ± 3, and difference from baseline in continuous outcomes and PROs. For patients who discontinued prior to 6 ± 3-month follow-up, values prior to discontinuation for continuous outcomes, and non-response for binary outcomes, were used.

RESULTS

Baseline Demographics, Patient, and Disease Characteristics

This analysis included 222 patients with PsA who initiated tofacitinib from December 14, 2017 to December 31, 2021, and met the inclusion criteria. At baseline, 59.7% of patients were female, most (92.3%) were White, mean (SD) age was 56.3 (11.9) years, and mean (SD) time since PsA diagnosis was 8.2 (8.2) years (Table 1). In addition, 70.7% of patients had a diagnosis of PsO, and the most common comorbidities (occurring in > 20% of the population) were hypertension (33.0%), serious infections (28.8%), and hyperlipidemia (24.3%) (Table 1).

At baseline, mean cDAPSA, DAPSA, PASDAS, and CDAI were in the moderate category. The proportion of patients with MDA and VLDA was 17.2% and 2.9%, respectively. Patients initiating tofacitinib had peripheral joint involvement (mean [SD] TJC was 9.2 [11.3] and mean [SD] SJC was 3.4 [5.5]), 40.1% had enthesitis, 14.4% had dactylitis, and most had low % BSA (69% had BSA < 3%). Mean VAS scores for patient fatigue, patient pain, and Patient Global Skin Assessment were > 50, and mean HAQ-DI was mild to moderate (0.9). The mean proportion of patients with overall work impairment, impairment while working, and activity impairment was 32.9–44.0% (Table 1).

Approximately half (53.6%) of patients had received ≥ 2 bDMARDs prior to initiating tofacitinib, 25.7% were bDMARD-naïve, 37.4% had received ≥ 2 TNFi, and 47.7% had received a non-TNFi bDMARD. While most (77.0%) patients had received ≥ 1 prior OSM, 39.2% of patients were receiving concomitant OSM therapy (Table 1).

Among the 222 patients with PsA who initiated tofacitinib, 123 patients had a 6 ± 3-month follow-up visit (total follow-up = 57.8 person-years). Of the patients with a 6 ± 3-month follow-up visit, 64 (52.0%) patients initiated tofacitinib as monotherapy.

Clinical Effectiveness

In patients who initiated tofacitinib and had a 6 ± 3-month follow-up visit, numerical improvements were observed in mean (SD) change from baseline at 6 ± 3 months for cDAPSA (–5.1 [12.6]), DAPSA (–6.2 [13.7]), PASDAS (–0.8 [1.4]), CDAI (–4.5 [10.6]), BSA (–1.4 [5.8]), TJC (–1.8 [8.1]), and SJC (–1.4 [4.5]) (Fig. 1).

At 6 ± 3 months, the proportions of patients achieving cDAPSA-defined LDA and remission were 25.0% and 7.8%, respectively; 18.2% and 2.9% achieved MDA and VLDA, respectively, and 30.8% had PASDAS ≤ 3.2 with tofacitinib. Resolution of enthesitis (SPARCC = 0) and dactylitis occurred in 42.9% and 29.4% of patients, respectively; 23.4% achieved Clinical Global Assessment of PsO (clear/almost clear), and 22.5% achieved BSA = 0% (Fig. 2).

Patient-Reported Outcomes

Numerical improvements in mean (SD) change from baseline at 6 ± 3 months were reported in patient-reported fatigue (–7.9 [20.9]), patient-reported pain (–9.5 [21.8]), Patient Global Skin Assessment (–9.4 [25.7]), and HAQ-DI (–0.1 [0.4]). Similarly, numerical improvements in mean (SD) change from baseline at 6 ± 3 months were observed across WPAI domains, including overall work impairment (–7.9 [19.0]), work time missed (–3.1 [15.5]), impairment while working (–5.8 [17.2]), and activity impairment (–7.8 [24.4]) (Fig. 3).

Therapy Status

Of the 123 patients with a 6 ± 3-month follow-up visit, 63 (51.2%) discontinued tofacitinib (34 [27.6%] at 6 ± 3-month follow-up, and 29 [23.6%] prior to 6 ± 3-month follow-up); the reason for discontinuation was not reported for most patients (> 79%) (Table 2). Of the 63 patients who discontinued tofacitinib at the 6 ± 3-month follow-up visit, 33 (52.4%) initiated on monotherapy.

Table 1 Demographics, baseline disease characteristics, and prior and concomitant treatment of patients with PsA in the CorEvitas PsA/SpA Registry initiating tofacitinib

	Patients initiating tofacitinib, $N = 222$[a]
Demographics	
Age (years), mean (SD) [*N1*]	56.3 (11.9) [221]
Female, *n*/*N1* (%)	132/221 (59.7)
White, *n*/*N1* (%)	203/220 (92.3)
BMI (kg/m^2), mean (SD) [*N1*]	32.2 (8.1) [218]
BMI category (kg/m^2), *n*/*N1* (%)	
< 25	35/218 (16.1)
≥ 25 to < 30	56/218 (25.7)
≥ 30	127/218 (58.3)
Duration of PsA symptoms (years), mean (SD) [*N1*]	13.3 (10.8) [217]
Time since PsA diagnosis (years), mean (SD) [*N1*]	8.2 (8.2) [218]
Diagnosis of PsO, *n* (%)	157 (70.7)
History of comorbidities, *n* (%)	
Cardiovascular disease[b]	22 (9.9)
Depression	35 (15.8)
Diabetes	35 (15.8)
Malignancy[c]	15 (6.8)
NMSC	6 (2.7)
Hypertension	74 (33.3)
Hyperlipidemia	54 (24.3)
Anxiety	16 (7.2)
Fibromyalgia[d]	34 (15.3)
Serious infection[e]	64 (28.8)
Metabolic syndrome[f]	31 (14.0)
Ulcerative colitis	2 (0.9)
Uveitis	2 (0.9)
Disease characteristics	
cDAPSA, mean (SD) [*N1*]	23.2 (17.1) [206]
cDAPSA category, *n*/*N1* (%)	
Remission ≤ 4	14/206 (6.8)
LDA > 4 to ≤ 13	42/206 (20.4)
Moderate disease activity > 13 to ≤ 27	92/206 (44.7)
HDA > 27	58/206 (28.2)
DAPSA, mean (SD) [*N1*]	24.6 (17.4) [147]

Table 1 continued

	Patients initiating tofacitinib, $N = 222$[a]
DAPSA category, *n*/*N1* (%)	
Remission ≤ 4	9/147 (6.1)
LDA > 4 to ≤ 14	33/147 (22.4)
Moderate disease activity > 14 to ≤ 28	62/147 (42.2)
HDA > 28	43/147 (29.3)
PASDAS, mean (SD) [*N1*]	4.7 (1.5) [148]
PASDAS category, *n*/*N1* (%)	
Remission ≤ 3.2	24/148 (16.2)
LDA > 3.2 to ≤ 4.2	28/148 (18.9)
Moderate disease activity > 4.2 to ≤ 6	74/148 (50.0)
HDA > 6	22/148 (14.9)
CDAI, mean (SD) [*N1*]	17.3 (11.8) [211]
CDAI category, *n*/*N1* (%)	
Remission ≤ 2.8	13/211 (6.2)
LDA > 2.8 to ≤ 10	50/211 (23.7)
Moderate disease activity > 10.0 to ≤ 22	86/211 (40.8)
HDA > 22	62/211 (29.4)
MDA,[g] *n* (%)	35/204 (17.2)
VLDA,[g] *n* (%)	6/204 (2.9)
TJC (68), mean (SD) [*N1*]	9.2 (11.3) [213]
SJC (66), mean (SD) [*N1*]	3.4 (5.5) [213]
Enthesitis, *n* (%)	89 (40.1)
SPARCC enthesitis count (in patients with count > 0), mean (SD) [*N1*]	4.2 (2.8) [89]
LEI count (in patients with count > 0), mean (SD) [*N1*]	2.2 (1.2) [65]
Dactylitis, *n* (%)	32 (14.4)
Dactylitis count (in patients with count > 0), mean (SD) [*N1*]	4.0 (4.7) [32]
BSA (in patients with BSA > 0%), mean (SD) [*N1*]	4.9 (7.9) [150]
BSA category (%), *n*/*N1* (%)	
0	66/216 (30.6)
0 to < 3	83/216 (38.4)
≥ 3 to < 10	46/216 (21.3)
≥ 10	21/216 (9.7)

Table 1 continued

	Patients initiating tofacitinib, *N* = 222[a]
Clinical Global Assessment of PsO (0–4),[h] mean (SD) [*N1*]	1.3 (1.2) [217]
Clinical Global Assessment of PsO category, *n*/*N1* (%)	
Clear (0)/almost clear (1)	133/217 (61.3)
Mild (2)	43/217 (19.8)
Moderate (3)	33/217 (15.2)
Severe (4)	8/217 (3.7)
Patient fatigue (0–100 VAS),[i] mean (SD) [*N1*]	55.6 (27.8) [220]
Patient pain (0–100 VAS),[i] mean (SD) [*N1*]	58.0 (26.6) [219]
Patient Global Skin Assessment (0–100 VAS),[i] mean (SD) [*N1*]	50.4 (26.9) [217]
HAQ-DI, mean (SD) [*N1*]	0.9 (0.7) [219]
WPAI domains %,[j] mean (SD) [*N1*]	
Overall work impairment	37.9 (29.5) [107]
Work time missed	8.0 (18.0) [107]
Impairment while working	32.9 (26.7) [114]
Activity impairment	44.0 (29.4) [213]
Prior and concomitant treatment	
Prior bDMARD, mean (SD)	2.0 (1.7)
Number of prior bDMARDs, [k] *n* (%)	
0	57 (25.7)
1	46 (20.7)
2+	119 (53.6)
Prior TNFi, mean (SD)	1.3 (1.2)
Number of prior TNFi, [k] *n* (%)	
0	74 (33.3)
1	65 (29.3)
2+	83 (37.4)
Prior non-TNFi, mean (SD)	0.7 (0.9)
Number of prior non-TNFi, [k] *n* (%)	
0	116 (52.3)
1	70 (31.5)
2+	36 (16.2)
Prior OSM, mean (SD)	1.2 (0.9)

Table 1 continued

	Patients initiating tofacitinib, $N = 222$[a]
Number of prior OSM, [k] *n* (%)	
0	51 (23.0)
1	101 (45.5)
2+	70 (31.5)
Current OSM use, [k] *n* (%)	87 (39.2)

bDMARD biologic disease-modifying antirheumatic drug, *BMI* body mass index, *BSA* body surface area, *CDAI* Clinical Disease Activity Index, *cDAPSA* Clinical Disease Activity Index for PsA, *DAPSA* Disease Activity Index for PsA, *HAQ-DI* Health Assessment Questionnaire-Disability Index, *HDA* high disease activity, *LDA* low disease activity, *LEI* Leeds Enthesitis Index, *MDA* minimal disease activity, *N* total number of patients, *N1* number of evaluable patients, *n* number of patients with each outcome, *NMSC* non-melanoma skin cancer, *OSM* oral small molecules, *PASDAS* PsA Disease Activity Score, *PsA* psoriatic arthritis, *PsO* psoriasis, *SD* standard deviation, *SJC (66)* swollen joint count, 66 joints, *SpA* spondyloarthritis, *SPARCC* Spondyloarthritis Research Consortium of Canada, *TJC (68)* tender joint count, 68 joints, *TNFi* tumor necrosis factor inhibitor, *VAS* Visual Analog Scale, *VLDA* very low disease activity, *WPAI* Work Productivity and Activity Impairment

[a]$N = 222$ unless otherwise stated; 123 patients had a 6 ± 3-month follow-up visit

[b]History of cardiovascular disease includes history of cardiac revascularization procedure (coronary artery bypass graft, stent, angioplasty), ventricular arrythmia, cardiac arrest, myocardial infarction, acute coronary syndrome, unstable angina, congestive heart failure (with and without hospitalization), stroke, transient ischemic attack, other cardiovascular disease, deep vein thrombosis, peripheral arterial disease, peripheral arterial thrombosis, urgent peripheral revascularization, peripheral ischemia/gangrene, pulmonary embolism, carotid artery disease, and hemorrhage

[c]Malignancy includes breast cancer, lung cancer, lymphoma, skin cancer (excluding NMSC), and other cancers

[d]Patients were defined as having fibromyalgia if reported on physician or patient forms, or if the definition of fibromyalgia was met using Widespread Pain Index and Symptom Severity Score measures with published criteria [20]

[e]Serious infections include joint/bursa infection, cellulitis, sinusitis, diverticulitis, sepsis, pneumonia, bronchitis, gastroenteritis, meningitis, urinary tract infection, tuberculosis, and other infections

[f]Metabolic syndrome was defined as presence of ≥ 3 of hypertension, hyperlipidemia, diabetes, and obesity

[g]MDA is a composite measure defined as "yes" if a patient met at least 5 of the 7 following criteria: TJC ≤ 1, SJC ≤ 1, BSA ≤ 3%, patient pain VAS ≤ 15, patient global activity VAS ≤ 20, HAQ-DI ≤ 0.5, and tender entheseal point ≤ 1. VLDA is a composite measure defined as "yes" if a patient met all 7 of the 7 criteria for MDA

[h]Clinical Global Assessment of PsO scored from 0 to 4 (clear to severe)

[i]Patient fatigue, pain, and Patient Global Skin Assessment scored from 0 to 100 (higher scores indicate higher severity)

[j]Among those reporting current employment

[k]TNFi: adalimumab, certolizumab, etanercept, golimumab, and infliximab; non-TNFi bDMARDs: abatacept, guselkumab, ixekizumab, secukinumab, and ustekinumab; OSM: leflunomide, methotrexate, sulfasalazine, and apremilast

Of patients who discontinued tofacitinib at 6 ± 3-month follow-up, 10 (29.4%) switched to a TNFi and 7 (20.6%) switched to an anti-interleukin (IL)-17 therapy; for those taking tofacitinib in combination with OSM, 7 (20.6%) patients continued OSM treatment. For those who discontinued tofacitinib prior to the 6 ± 3-month follow-up visit, 8 (27.6%) patients switched to a TNFi and 11 (37.9%) patients switched to anti-IL-17 therapy; for those taking tofacitinib in combination with OSM, 6 (20.7%) patients continued OSM therapy (Table 2).

DISCUSSION

The efficacy and safety of tofacitinib have been demonstrated in RCTs of patients with PsA [6, 7]; however, the strict inclusion/exclusion criteria used in RCTs may limit the generalizability of the results to real-world clinical

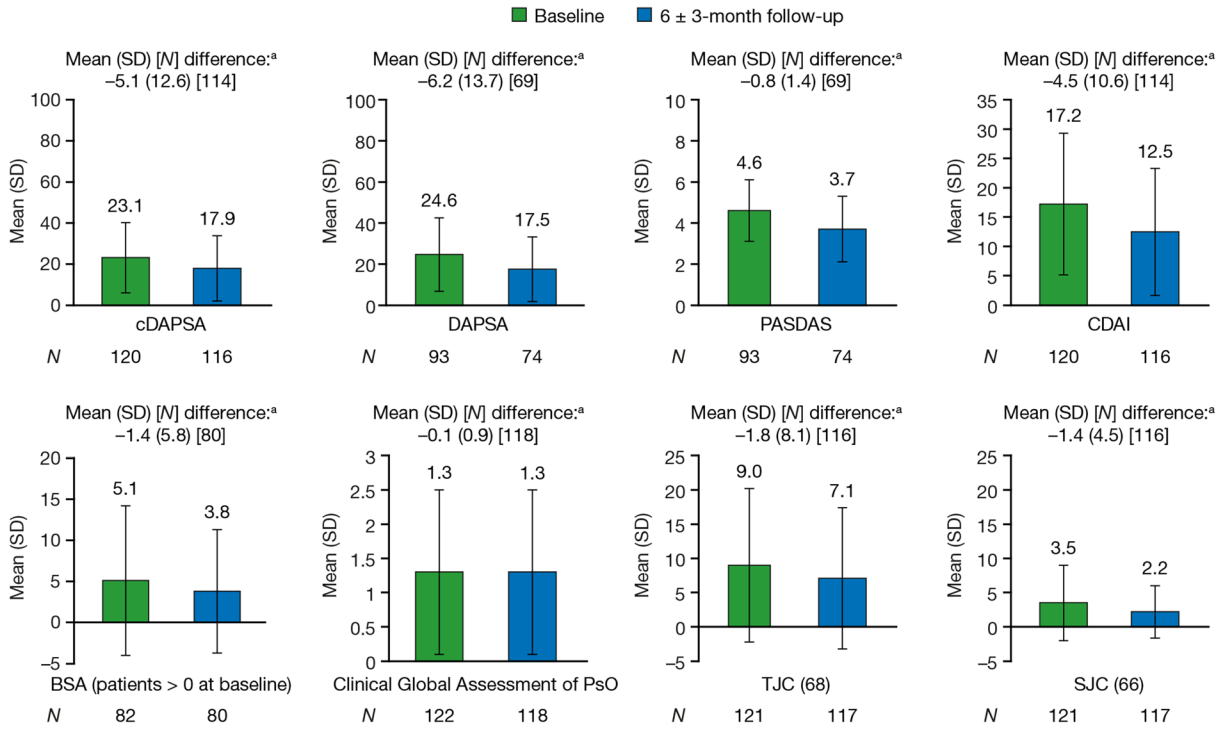

Fig. 1 Change from baseline in effectiveness outcomes at the 6 ± 3-month follow-up visit for patients with PsA in the CorEvitas PsA/SpA Registry initiating tofacitinib. [a]Calculated as 6 ± 3-month value minus baseline value. Outcomes summarized descriptively. For patients who discontinued prior to 6 ± 3-month follow-up, values prior to discontinuation were used. *BSA* body surface area, *CDAI* Clinical Disease Activity Index, *cDAPSA* Clinical Disease Activity Index for PsA, *DAPSA* Disease Activity Index for PsA, *N* number of patients eligible to achieve outcome, *PASDAS* PsA Disease Activity Score, *PsA* psoriatic arthritis, *PsO* psoriasis, *SD* standard deviation, *SJC (66)* swollen joint count, 66 joints, *SpA* spondyloarthritis, *TJC (68)* tender joint count, 68 joints

practice [9, 10]. Real-world evidence therefore complements RCT results, providing patient characteristics and treatment effectiveness in real-world settings [9, 10].

This observational study used data from the CorEvitas PsA/SpA Registry to characterize demographics and disease characteristics and determine the effectiveness and rates of discontinuation of tofacitinib in patients with PsA who newly initiated tofacitinib. To our knowledge, this is one of the first real-world studies that evaluated the effectiveness of tofacitinib for PsA in the US.

Overall, patients with PsA who initiated tofacitinib in the registry had heterogeneous disease characteristics and showed improvements in disease activity and PROs, including WPAI domains, after 6 ± 3 months of follow-up, consistent with tofacitinib PsA phase 3 RCTs and post hoc analyses [6, 7, 21, 22].

There were some notable differences in the demographic and disease characteristics of patients in the CorEvitas PsA/SpA Registry who had initiated tofacitinib, compared with those in tofacitinib PsA RCTs [6, 7]. For example, the majority (60.8%) of patients in the CorEvitas PsA/SpA Registry were not receiving concomitant OSM, while patients receiving tofacitinib 5 or 10 mg twice daily (BID) were required to receive a concomitant csDMARD in the phase 3 OPAL Broaden and OPAL Beyond trials [6, 7]. Patients initiating tofacitinib in the registry had less joint involvement (TJC [9.2 vs. 20.5/23.2] and SJC [3.4 vs. 12.5/12.3]), and fewer patients had BSA ≥ 3% (31% vs. 68/64%), enthesitis (40% vs. 74/80% [SPARCC]), and dactylitis (14%

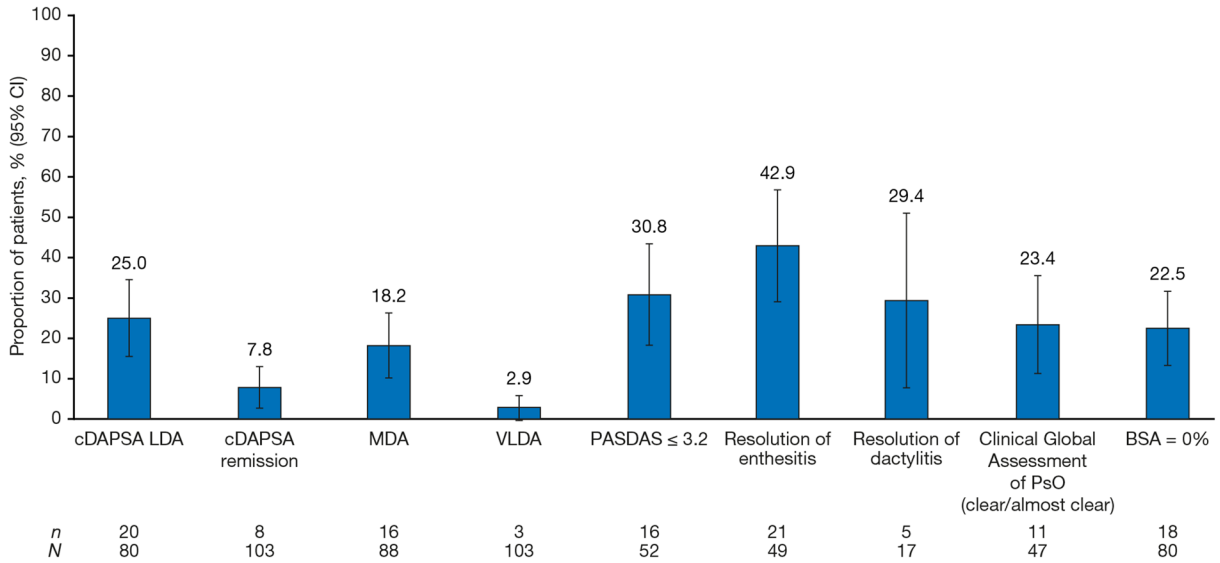

Fig. 2 Proportion (95% CI) of patients with PsA achieving effectiveness outcomes at the 6 ± 3-month follow-up visit[a] for patients in the CorEvitas PsA/SpA Registry initiating tofacitinib. [a]Patients who were in the state of interest at baseline (cDAPSA LDA/remission, MDA, VLDA, PASDAS ≤ 3.2, enthesitis/dactylitis = 0, Clinical Global Assessment of PsO of "clear/almost clear", and BSA = 0%) were excluded from the respective analysis. 95% CIs for response rates were calculated using normal approximation to binominal proportions. Patients who discontinued prior to the 6 ± 3-month follow-up visit were considered non-responders. cDAPSA LDA is achievement of a score > 4 to ≤ 13. cDAPSA remission is achievement of cDAPSA ≤ 4. MDA is a composite measure defined as "yes" if a patient met at least 5 of the 7 following criteria: tender joint count ≤ 1, swollen joint count ≤ 1, BSA ≤ 3%, patient pain VAS ≤ 15, patient global activity VAS ≤ 20, HAQ-DI ≤ 0.5, and tender entheseal point ≤ 1. VLDA is a composite measure defined as "yes" if a patient met all 7 of the above 7 criteria. Resolution of enthesitis: no enthesitis (SPARCC = 0) at the 6 ± 3-month follow-up visit for those who had enthesitis (SPARCC > 0) at baseline. Resolution of dactylitis: no dactylitis at the 6 ± 3-month follow-up visit for those who had dactylitis at baseline. Clinical Global Assessment of PsO = 0 or 1 for those who had a score of > 1 at baseline. Patients who had cDAPSA LDA or were in remission at initiation were excluded from the achievement of LDA analysis. Patients who were in cDAPSA remission were excluded from the achievement of remission analysis. Patients who were in MDA at initiation were excluded from the achievement of MDA analysis. Patients who were in VLDA at initiation were excluded from the achievement of VLDA analysis. Patients who had PASDAS ≤ 3.2 at initiation were excluded from the achievement of PASDAS ≤ 3.2 analysis. Patients who had enthesitis (SPARCC) = 0 at initiation were excluded from the resolution of enthesitis analysis. Patients who had dactylitis = 0 at initiation were excluded from the resolution of dactylitis analysis. Patients who had BSA = 0% at initiation were excluded from the achievement of BSA = 0% analysis. Patients who had a Clinical Global Assessment of PsO of "clear/almost clear" at initiation were excluded from the analysis of its achievement. *BSA* body surface area, *cDAPSA LDA* Clinical Disease Activity Index for PsA-defined low disease activity, *CI* confidence interval, *HAQ-DI* Health Assessment Questionnaire-Disability Index, *MDA* minimal disease activity, *N* number of patients eligible to achieve outcome, *n* number of patients achieving outcome, *PASDAS* PsA Disease Activity Score, *PsA* psoriatic arthritis, *PsO* psoriasis, *SpA* spondyloarthritis, *SPARCC* Spondyloarthritis Research Consortium of Canada, *VAS* Visual Analog Scale, *VLDA* very low disease activity

vs. 53% [for both tofacitinib 5 and 10 mg BID]) versus those receiving tofacitinib 5 or 10 mg BID in a pooled data analysis of the PsA RCTs [22]. In addition, mean PASDAS (4.7 vs. 6.0 [tofacitinib 5 and 10 mg BID]) and DAPSA (24.6 vs. 45.6/43.7) at tofacitinib initiation were also lower in the analysis presented here versus tofacitinib 5 or 10 mg BID in an analysis of disease-specific composite endpoints from the tofacitinib PsA RCTs [21]. These results suggest

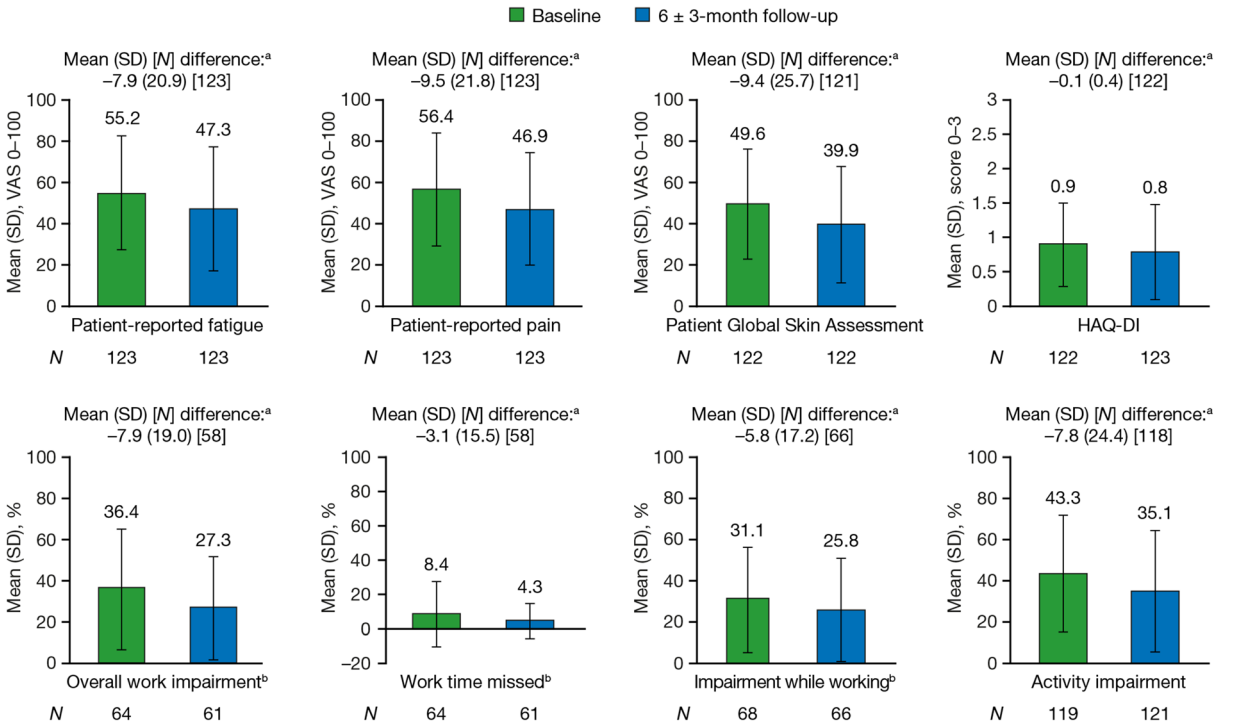

Fig. 3 Change from baseline in PROs at the 6 ± 3-month follow-up visit for patients with PsA in the CorEvitas PsA/SpA Registry initiating tofacitinib. [a]Calculated as 6 ± 3-month value minus baseline value. [b]Overall work impairment, work time missed, and impairment while working reported among patients who were employed. Outcomes summarized descriptively. For patients who discontinued prior to 6 ± 3-month follow-up, values prior to discontinuation were used. *HAQ-DI* Health Assessment Questionnaire-Disability Index, *N* number of patients eligible to achieve outcome, *PRO* patient-reported outcome, *PsA* psoriatic arthritis, *SD* standard deviation, *SpA* spondyloarthritis, *VAS* Visual Analog Scale

that patients with PsA who initiated tofacitinib in a real-world setting had lower disease activity than patients at baseline enrolled in the tofacitinib PsA RCTs.

In this analysis, 18.2% of patients who initiated tofacitinib achieved MDA at 6 ± 3 months, compared with 26% and 38% of patients receiving tofacitinib 5 and 10 mg BID, respectively, achieving MDA at 6 months in OPAL Broaden, and 24% for both tofacitinib 5 and 10 mg BID at 6 months in OPAL Beyond [6, 7]. Improvements (mean difference) in DAPSA, PASDAS, TJC, and SJC were also recorded in this analysis. Furthermore, in the analysis of disease-specific composite endpoints using data from OPAL Broaden and OPAL Beyond, improved DAPSA and PASDAS scores from baseline were reported after 6 months of tofacitinib treatment [21]. In a separate analysis of patients with PsA treated with secukinumab from the CorEvitas PsA/SpA Registry, higher rates of MDA (36.6%) and greater improvements (mean difference) across disease activity outcomes after 6 months of follow-up were observed [13]. Differences in responses to treatment in these two independent studies may be due to variations in the characteristics of the populations when initiating treatment. Of note, patients newly initiating tofacitinib in this analysis were older (56.3 years vs. 51.6 years), a greater proportion were female (59.7% vs. 45.7%) and had numerically higher mean DAPSA (24.6 vs. 20.2) and PASDAS (4.7 vs. 4.3) at baseline versus the analysis of patients who initiated secukinumab [13].

Multiple PsA disease domains, including enthesitis and dactylitis, should be controlled to improve patient outcomes [1, 2, 5]. Here, 42.9%

Table 2 Therapy status at or prior to the 6 ± 3-month follow-up visit for patients with PsA in the CorEvitas PsA/SpA Registry initiating tofacitinib

	All patients with 6 ± 3-month follow-up visit, *N* = 123
Remained on tofacitinib, *n* (%)	60 (48.8)
Remained on tofacitinib (monotherapy initiators), *n* (%)	31 (51.7)
Discontinued tofacitinib, *n* (%)	63 (51.2)
Discontinued tofacitinib (monotherapy initiators), *n* (%)	33 (52.4)
Discontinued tofacitinib at the 6 ± 3-month follow-up visit, *n* (%)[a]	34 (27.6)
Did not switch to any other DMARD therapy	6 (17.6)
Switched to OSM[b] (monotherapy initiators)	2 (5.9)
Switched to TNFi[b]	10 (29.4)
Switched to anti-IL-17 therapy[b]	7 (20.6)
Switched to other bDMARD[b]	2 (5.9)
Continued OSM[b] (combination therapy initiators)	7 (20.6)
Reasons for discontinuation among those who discontinued at the 6 ± 3-month follow-up visit, *n* (%)	
No reported reason	29 (85.3)
Lack of effectiveness[c]	4 (11.8)
Safety[d]	0
Other[c]	1 (2.9)
Discontinued tofacitinib prior to 6 ± 3-month follow-up, *n* (%)[f]	29 (23.6)
Did not switch to any other DMARD therapy	2 (6.9)
Switched to OSM[b] (monotherapy initiators)	0
Switched to TNFi[b]	8 (27.6)
Switched to anti-IL-17 therapy[b]	11 (37.9)
Switched to other bDMARD[b]	2 (6.9)
Continued OSM[b] (combination therapy initiators)	6 (20.7)
Reasons for discontinuation among those who discontinued prior to the 6 ± 3-month follow-up visit, *n* (%)[f]	
No reported reason	23 (79.3)
Lack of effectiveness[c]	3 (10.3)
Safety[d]	2 (6.9)
Other[c]	1 (3.4)

bDMARD biologic disease-modifying antirheumatic drug, *COVID-19* coronavirus disease 2019, *DMARD* disease-modifying antirheumatic drug, *IL* interleukin, *N* number of evaluable patients, *n* number of patients with each outcome, *OSM* oral small molecules, *PsA* psoriatic arthritis, *SpA* spondyloarthritis, *TNFi* tumor necrosis factor inhibitor

[a]The denominator for the % calculation was the number of patients who discontinued tofacitinib at the 6 ± 3-month follow-up visit

[b]Anti-IL-17 therapies: ixekizumab and secukinumab; TNFi: adalimumab, certolizumab, etanercept, golimumab, and infliximab; non-anti-IL-17 and TNFi bDMARDs: abatacept, guselkumab, and ustekinumab; OSM: apremilast, leflunomide, methotrexate, and sulfasalazine

[c]Effectiveness reasons included inadequate initial response, failure to maintain initial response, and active disease

[d]Safety reasons included serious side effects, minor side effects, and fear of future side effects

[e]Other reasons included COVID-19 concerns, temporary interruption, patient preference, need to improve compliance and/or tolerability, denied by insurance, co-pay/patient cost, patient doing well, frequency of administration, route of administration, alternative mechanism of action, and "other"

[f]The denominator for the % calculation was the number of patients who discontinued tofacitinib prior to the 6 ± 3-month follow-up visit

and 29.4% of patients initiating tofacitinib reported a resolution of enthesitis (SPARCC = 0) and dactylitis at 6 ± 3 months, respectively. In an analysis of pooled data of the PsA phase 3 RCTs, at 6 months, 39.0/40.2% and 55.9/60.8% of patients receiving tofacitinib 5/10 mg BID achieved a resolution of enthesitis (SPARCC = 0) and dactylitis, respectively [22]. In the separate CorEvitas PsA/SpA Registry study of secukinumab, 45.2% of patients reported resolution of enthesitis (SPARCC = 0), and 75.0% reported a resolution of dactylitis at 6 months [13]. Furthermore, in the real-world prospective APOLO study of patients with PsA in Belgium initiating apremilast, at 6 months, 37.5% and 71.4% of patients achieved a resolution of enthesitis (Leeds Enthesitis Index = 0) and dactylitis, respectively [23].

In patients with PsA, impairment in physical function can result in a reduced ability to work, contributing to the economic burden of disease. In this study, improvements across WPAI domains were reported. Additionally, slight improvements were observed at 6 ± 3 months in HAQ-DI scores (–0.1), lower than those observed with tofacitinib 5/10 mg BID in the pooled analysis of OPAL Beyond and OPAL Broaden at 6 months (–0.5 and –0.4, respectively) [22]. The smaller improvement in HAQ-DI may be due to the lower level of HAQ-DI at tofacitinib initiation in this analysis (0.9) versus baseline values in the tofacitinib 5/10 mg BID groups in OPAL Beyond (1.3/1.4) and OPAL Broaden (1.2/1.1) [6, 7]. It should be noted that HAQ-DI scores ranged from 0 to 3 in this analysis and the RCTs, with a minimal clinically important difference of approximately 0.35 [24]. Improved HAQ-DI scores have been reported with apremilast (–0.5) in the real-world Belgian APOLO study [23], and in the independent CorEvitas PsA/SpA Registry secukinumab analysis (–0.1) [13]. Reduced patient fatigue (mean difference –7.9) and patient pain (mean difference –9.5) scores at 6 ± 3 months were also recorded in this analysis, comparable with reductions observed with secukinumab under real-world conditions (mean differences –5.0 and –11.7, respectively) [13]. Findings from the tofacitinib CorEvitas study indicate that tofacitinib is effective in improving PROs in real-world settings.

Of patients with a 6 ± 3-month follow-up visit, 51.2% discontinued tofacitinib (27.6% at follow-up and 23.6% prior to follow-up), with patients tending to switch to TNFi or anti-IL-17 therapy and/or continue concomitant OSM treatment. Interestingly, 33 of 64 (51.6%) patients who initiated tofacitinib as monotherapy discontinued at or prior to 6 ± 3-month follow-up. Overall, 52 of 63 patients (82.5%) who discontinued tofacitinib at (85.3%) or prior to (79.3%) the 6 ± 3-month follow-up visit did not report a reason for discontinuation. Of the very limited number of patients who did report a reason for discontinuation, lack of effectiveness accounted for the highest proportion of all discontinuations (n/N = 7/63 [11.1%]). Interestingly, in a real-world study of the IBM MarketScan^{TM} US database of patients with PsA with a tofacitinib claim, 12.9% (n/N = 41/318) discontinued therapy 6 months post-index [16]. Rates of discontinuation of other advanced PsA therapies in the CorEvitas PsA/SpA Registry have been investigated [14, 15]. Of the 279 patients with PsA enrolled in the CorEvitas PsA/SpA Registry who initiated apremilast and had a 6-month visit, 44% discontinued prior to or at the 6-month follow-up visit [15]. Additionally, in a separate analysis of the CorEvitas PsA/SpA Registry of patients with PsA receiving TNFi, 43.9% (n/N = 75/171) of patients who were TNFi-naïve discontinued TNFi treatment during follow-up (mean follow-up time 21.9 months; total follow-up 579 person-years [overall study cohort]) [14]. Of those who discontinued and had a provider-reported reason, > 90% of patients who were TNFi-naïve discontinued TNFi due to lack of effectiveness [14]. Most patients in this study (total follow-up = 57.8 person-years) did not report a specific reason for discontinuation, while in the CorEvitas PsA/SpA Registry of patients with PsA receiving TNFi, approximately half of patients who discontinued their index TNFi by the first follow-up visit had a provider-reported reason [14].

The results of this study should be considered in the context of several limitations. The analysis was limited by a small number of patients remaining on tofacitinib at the

6 ± 3-month follow-up visit. Data from patients who initiated tofacitinib as monotherapy or in combination with OSM were not assessed separately, as the number of patients included in the analysis would be further reduced when stratified. Patients enrolled in the CorEvitas PsA/SpA Registry were registered by participating rheumatologists from 66 private and academic clinical sites across 30 states; this registry includes a sample of adult patients with PsA who may not necessarily be representative of all adults with PsA in the US and/or the rest of the world. Medical history prior to registry enrollment is reported by patients and their current rheumatologist within the registry, and data might be missing. The number of patients with missing data is small (< 5%) and expected to be non-differential. Registry reporting is not based on a fixed visit schedule; thus, a ± 3-month time window was used to determine eligible visits, meaning that not all visits necessarily occurred at 6 months. In addition, the cause of each visit was not captured. Lastly, the registry captures provider-reported prescribing; hence, there are no measures of patient adherence.

CONCLUSIONS

In this analysis of a real-world cohort of patients in the US with PsA who newly initiated tofacitinib, the majority of patients had prior use of bDMARDs or were receiving tofacitinib as monotherapy. Tofacitinib treatment demonstrated improvements across multiple domains of PsA and PROs, including work productivity, in patients who continued therapy. These results showed that, in patients who remained on therapy, tofacitinib was effective in real-world settings, consistent with findings from previous RCTs.

ACKNOWLEDGEMENTS

Medical Writing, Editorial, and Other Assistance. Medical writing support, under the direction of the authors, was provided by Lewis C. Rodgers, PhD, CMC Connect, a division of IPG Health Medical Communications, and was funded by Pfizer, New York, NY, USA, in accordance with Good Publication Practice (GPP 2022) guidelines (Ann Intern Med. 2022;175:1298–304).

Author Contributions. Conceptualization of study and design: Philip J. Mease, Pamela Young, Lara Fallon, Oluwaseyi Dina, Taylor Blachley, Nicole Middaugh, and Alexis Ogdie. Patient recruitment: Philip J. Mease. Data acquisition: Philip J. Mease. Data analysis: Philip J. Mease, Pamela Young, Lara Fallon, Rajiv Mundayat, Oluwaseyi Dina, Taylor Blachley, Nicole Middaugh, and Alexis Ogdie. All authors were involved in the drafting of the article or revising it critically for important intellectual content; all authors approved the final version to be submitted for publication.

Funding. The registry is sponsored by CorEvitas, LLC, and the analyses based on secondary analysis of registry data were funded and sponsored by Pfizer. The journal's Rapid Service Fee was funded by Pfizer. Access to study data was limited to CorEvitas, and CorEvitas statisticians completed all the analysis. All authors contributed to the interpretation of the results. CorEvitas has been supported through contracted subscriptions in the past 2 years by AbbVie, Amgen, Arena, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai, Eli Lilly, Genentech, Gilead Sciences, GlaxoSmithKline, Janssen, LEO Pharma, Novartis, Ortho Dermatologics, Pfizer Inc, Regeneron, Sanofi, Sun, and UCB.

Data Availability. Data are available from CorEvitas, LLC through a commercial subscription agreement and are not publicly available. No additional data are available from the authors.

Declarations

Conflict of Interest. Philip J. Mease has acted as a consultant for and/or has received

grant/research support from AbbVie, Acelyrin, Aclaris, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, CorEvitas, LLC, Eli Lilly, Galapagos, Gilead Sciences, Inmagene, Janssen, MoonLake, Novartis, Pfizer Inc, Sun, and UCB. Pamela Young, Lara Fallon, Rajiv Mundayat, and Oluwaseyi Dina are employees and stockholders of Pfizer Inc. Taylor Blachley and Nicole Middaugh are employees of CorEvitas, LLC. Alexis Ogdie is a stockholder of Amgen, Novartis, and Pfizer Inc, and has received grant/research support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, CorEvitas, LLC, Eli Lilly, Novartis, and Pfizer Inc.

Ethical Approval. The study was performed in accordance with Good Pharmacoepidemiology Practice. All participating investigators were required to obtain full board approval for conducting research involving human patients with a limited dataset. Sponsor approval and continuing review were obtained through a central Institutional Review Board (IRB), the New England Independent Review Board (No. 120160939). For academic investigative sites that did not receive a waiver to use the central IRB, full board approval was obtained from the respective governing IRBs and documentation of approval was submitted to CorEvitas, LLC, prior to the initiation of any study procedures. All patients in the registry were required to provide written informed consent and authorization prior to participating in the study.

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