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Alexis Ogdie
University of Pennsylvania

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Accepted Article

Descriptive Comparisons of the Impact of Apremilast and Methotrexate Monotherapy in Oligoarticular Psoriatic Arthritis: the Corrona Psoriatic Arthritis/Spondyloarthritis Registry Results

Alexis Ogdie (iD 0000-0002-4639-0775), Mei Liu (iD 0000-0002-2316-2606), Meghan Glynn (iD 0000-0002-3114-0423), Kelechi Emeanuru (iD 0000-0001-7097-188X), Leslie Harrold (iD 0000-0002-0170-2747), Sven Richter, Benoit Guerette, Philip J. Mease

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TNF RECEPTORS

METHOTREXATE

From the Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; Corrona, LLC, Waltham, Massachusetts; Department of Medicine, University of Massachusetts Medical School, Worcester, Massachusetts; Global Medical Affairs, Amgen Inc.; Division of Rheumatology Clinical Research, Swedish Medical Center/Providence St. Joseph Health, and Division of Rheumatology, University of Washington School of Medicine.

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statisticians completed all of the analysis; all authors contributed to the interpretation of the results.

Ethical conduct: All participating investigators were required to obtain full board approval for conducting research involving human subjects. Sponsor approval and continuing review was obtained through a central investigational review board (New England Independent Review Board, NEIRB No. 120160610); there were more than 50 study sites. For academic investigative sites that did not receive a waiver to use the central investigational review board, full board approval was obtained from the respective governing investigational review boards and documentation of approval was submitted to the sponsor before initiating any study procedures. All registry patients were required to provide written informed consent before participating.

Conflicts of interest: A. Ogdie has received grant/research support from Pfizer Inc and Novartis and has served as a consultant to AbbVie, Amgen, Bristol-Myers Squibb, Celgene Corporation, Corrona, Eli Lilly and Company, Novartis, Pfizer Inc, and Takeda. M. Liu, M. Glynn, and K. Emeanuru have worked on Corrona contracted subscriptions for AbbVie, Amgen, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene Corporation, Crescendo, Eli Lilly and Company, Genentech, Gilead, GSK, Janssen, Momenta Pharmaceuticals, Novartis, Pfizer Inc, Regeneron, Roche, Merck, UCB, and Valeant. L. R. Harrold is an employee and shareholder of Corrona, LLC, received grants from Pfizer Inc, and has served as a consultant to AbbVie, Bristol-Myers Squibb and Roche. S. Richter and B. Guerette are employees of Amgen Inc. and were employees of Celgene Corporation at the time of study conduct. P. J. Mease has received grant/research support from and served as a consultant for Abbott, Amgen, Biogen Idec, Bristol-Myers Squibb, Celgene

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A. Ogdie, MD, Departments of Medicine and Epidemiology, Perelman School of Medicine, University of Pennsylvania; M. Liu, PhD, Corrona, LLC, Waltham, Massachusetts; M. Glynn, MS, Corrona, LLC, Waltham, Massachusetts; K. Emeanuru, MPH, Corrona, LLC, Waltham, Massachusetts; L. Harrold, MD, MPH, Corrona, LLC, Waltham, Massachusetts, and Department of Medicine, University of Massachusetts Medical School, Worcester, Massachusetts; S. Richter, MD, Global Medical Affairs, Amgen Inc., Thousand Oaks, California; B. Guerette, PhD, Global Medical Affairs, Amgen Inc., Thousand Oaks, California; P. J. Mease, MD, Division of Rheumatology Clinical Research, Swedish Medical Center/Providence St. Joseph Health, and Division of Rheumatology, University of Washington School of Medicine, Seattle, Washington.

Address correspondence to: Alexis Ogdie, MD, 3400 Spruce Street, 5 White Building, Hospital of the University of Pennsylvania, Philadelphia, PA 19104.

Tel.: 215-662-4500. Email: alogdie@pennmedicine.upenn.edu.

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ABSTRACT.

Objective. Therapeutic response was evaluated among new apremilast, methotrexate, or biologic disease-modifying anti-rheumatic drug (bDMARD) initiators with oligoarticular psoriatic arthritis (PsA).

Methods. Patients with oligoarticular PsA in the Corrona PsA/Spondyloarthritis Registry initiating treatment with apremilast, methotrexate, or bDMARD and completing 6-month follow-up were included.

Results. In total, 150 patients initiated monotherapy (apremilast: n=34; methotrexate: n=15; bDMARD: n=101). Apremilast initiators had higher baseline disease activity than methotrexate initiators. At follow-up, apremilast initiators experienced numerically greater disease activity improvements than methotrexate initiators and similar improvements to bDMARD initiators.

Conclusions. Findings suggest apremilast monotherapy is an effective option for patients with oligoarticular PsA.

Oligoarticular psoriatic arthritis (PsA), defined as <5 involved joints(1, 2), affects ≈50% of patients with PsA(3). Typical randomized controlled trials have not focused on this population, and, on average, patients enrolled have swollen and tender joint counts of 12 and 21, respectively(4). Despite the high prevalence of oligoarticular PsA, data are lacking in this population, and recommendations for management remain largely unaddressed(4-6).

This study assessed baseline clinical characteristics of patients with oligoarticular PsA (≤4 swollen joints) to determine the impact of apremilast or methotrexate treatment on disease activity. Patients initiating biologic disease-modifying anti-rheumatic drug (bDMARD) monotherapy were examined as a point of reference.

MATERIALS AND METHODS

Study Design

A cohort study was performed in the Corrona Psoriatic Arthritis/Spondyloarthritis (PsA/SpA) Registry, a multicenter registry that recruited patients among >50 participating rheumatologists in the United States(7). Adults (aged ≥18 years) were included if they had PsA and oligoarthritis, defined as ≤4 swollen joints; were enrolled in the Corrona PsA/SpA Registry; initiated apremilast, methotrexate, or a bDMARD monotherapy as the first initiation within the registry between June 1, 2014, and March 1, 2018; and had a 6-month follow-up visit with a time window of 3 to 9 months within the same period. Patients were defined as having polyarticular or oligoarticular PsA at the time of therapy initiation. Patients defined as having oligoarticular PsA may have had polyarticular disease previously as they may have

had changing numbers of joints involved with therapy selection based on patient characteristics.

Outcomes

Outcomes at 6 months included assessments of disease activity and patient-reported outcome (PRO) measures. Included were the proportion of patients with >1 swollen joint or >1 tender joint at baseline achieving a swollen joint count (SJC) of 0 or 1 or a tender joint count (TJC) of 0 or 1, respectively; change from baseline in SJC and TJC; and change from baseline in the Clinical Disease Activity Index for Psoriatic Arthritis (cDAPSA) score and the cDAPSA core components.

The cDAPSA score was calculated as SJC (0–66) plus TJC (0–68) plus the Patient's Global Assessment of Disease Activity–Arthritis and Psoriasis (PtGA-PsO) visual analog scale (VAS) score (0–10 cm) plus the Overall Pain VAS (0–10 cm) score. Additional PROs included the change from baseline in Fatigue VAS (0–100 mm) score, proportion of patients achieving the minimally clinical important difference (MCID; ≥ 0.35 point decrease) in the Health Assessment Questionnaire-Disability Index (HAQ-DI) score, change from baseline in PtGA-Arthritis (PtGA-PsA) VAS score (0–100 mm), and the proportion of patients without physician-reported clinical characteristics of nail psoriasis at 6 months.

Statistical Analysis

Descriptive statistics were calculated for patients' demographics, clinical, and treatment characteristics at the index visit and outcomes at the 6-month follow-up visit. The index visit was defined as the visit in which patients reported treatment initiation with apremilast, methotrexate, or bDMARD. All data were analyzed

descriptively using means and standard deviations for continuous variables and presented as counts and percentages of patients for categorical variables.

All participating investigators were required to obtain full board approval for conducting research involving human subjects. Sponsor approval and continuing review was obtained through a central investigational review board (New England Independent Review Board, NEIRB No. 120160610); there were >50 study sites. For academic investigative sites that did not receive a waiver to use the central investigational review board, full board approval was obtained from the respective governing investigational review boards and documentation of approval was submitted to the sponsor before initiating any study procedures. All registry patients were required to provide written informed consent before participating.

RESULTS

Index Visit: Patient Demographics and Clinical Characteristics

A total of 1593 patients with oligoarticular PsA were listed in the Corrona PsA/SpA Registry between June 2014 and March 2018. Of these patients, 150 had initiated monotherapy with apremilast (n = 34), methotrexate (n = 15), or bDMARD (n = 101) as the first initiation during follow-up for oligoarticular PsA (**Supplementary Figure 1**). Patient demographic, clinical, and treatment characteristics at index visit are presented in **Table 1**. Patients who initiated methotrexate monotherapy were slightly older and a higher proportion were female compared with patients in the apremilast and bDMARD monotherapy groups. More than half of patients in all 3 monotherapy groups were obese. Mean disease duration was generally similar among monotherapy groups.

Overall, treatment and clinical characteristics of apremilast initiators were suggestive of more refractory oligoarticular PsA compared with methotrexate initiators (**Table 1**). Among apremilast and methotrexate initiators, 79% and 20% received ≥ 1 prior bDMARD, respectively. Patients who initiated apremilast had higher levels of disease activity at baseline, measured by a cDAPSA score >13 (moderate or high disease activity), and fewer had minimal disease activity (MDA) at baseline compared with patients who initiated methotrexate or bDMARDs. Patients initiating apremilast monotherapy also reported numerically higher mean scores of PRO measures at baseline, including PtGA-PsA and Fatigue VAS scores; likewise, the proportion of patients with a HAQ-DI score >0.5 was also higher with apremilast monotherapy.

Disease Activity Assessments

A numerically greater proportion of patients with an SJC >1 or TJC >1 at baseline who received apremilast monotherapy achieved an SJC ≤ 1 or TJC ≤ 1 at 6 months than those who received monotherapy with methotrexate or bDMARDs (**Figure 1**). Achievement of an SJC ≤ 1 or TJC ≤ 1 in the apremilast monotherapy group was more similar to the bDMARD monotherapy group than to the methotrexate monotherapy group (**Figure 1**). Mean changes in SJC and TJC, respectively, from baseline were numerically greater with apremilast monotherapy (-0.4 and -0.4) compared with methotrexate (0.1 and -0.3) or bDMARD (0.2 and -0.1) monotherapy. A numerically greater proportion of apremilast monotherapy initiators who were in a moderate or high disease activity cDAPSA category at baseline achieved low disease activity (LDA) or remission (REM) at 6 months compared with methotrexate and bDMARD monotherapy initiators (**Figure 2**). Achievement of LDA

or REM in the apremilast monotherapy initiators was more comparable to bDMARD monotherapy initiators than to methotrexate monotherapy initiators (**Figure 2**). Of those patients who did not have MDA at initiation, 8.7% (2/23) in the apremilast monotherapy group, 0% (0/7) in the methotrexate group, and 17.9% (10/56) in the bDMARD monotherapy group achieved MDA at the 6-month visit. None of the patients receiving apremilast monotherapy or methotrexate who did not have very LDA (VLDA) at initiation achieved VLDA at the 6-month visit; 4.8% (4/84) initiating bDMARD monotherapy achieved VLDA. The mean improvement from baseline in cDAPSA score was numerically greater in patients receiving apremilast monotherapy (-1.5) compared with those receiving methotrexate (-0.2) or bDMARD (-0.1) monotherapy.

Patient-Reported Outcomes

At 6 months, patients in all 3 monotherapy groups experienced minimal changes from baseline in mean PtGA-PsA VAS, Overall Pain VAS, Fatigue VAS, and PtGA-PsO VAS scores. Changes from baseline in the apremilast, methotrexate, and bDMARD monotherapy groups were -0.2, 2.5, and 0.4 for mean PtGA-PsA VAS scores, 0.2, -0.1, and 0.1 for Overall Pain VAS scores, -1.4, 0.3, and -0.3 for mean Fatigue VAS scores, and -2.3, 1.7, and -2.0 for PtGA-PsO VAS scores, respectively. The proportions of patients achieving at least a 0.35-point improvement in HAQ-DI MCID were similar in the apremilast, methotrexate, and bDMARD monotherapy groups (**Supplementary Figure 2**). A numerically greater proportion of patients with physician-reported nail psoriasis at baseline were without physician-reported nail psoriasis at 6 months in the apremilast monotherapy group compared with the methotrexate and bDMARD monotherapy groups (**Supplementary Figure**

3). Improvement in nail psoriasis in the apremilast monotherapy group was more similar to the bDMARD monotherapy group than to the methotrexate monotherapy group (**Supplementary Figure 3**).

DISCUSSION

Although oligoarticular PsA, by definition, involves fewer joints than polyarticular PsA, the 2 subgroups had comparable disease burden (8-10). Oligoarticular PsA, while common(11-16), remains understudied and identification of effective management of this PsA phenotype is warranted. Despite use in a more often treatment-refractory patient population, the apremilast monotherapy group experienced improvements in disease activity measures and PROs; improvements were also experienced in the methotrexate group. The improvements observed with apremilast monotherapy in this population were comparable with bDMARD monotherapy. Our comparison of the 3 groups was descriptive, without statistical testing because we cannot fully address confounding by indication when comparing different therapy classes across different lines of therapy. Of note, in many cases, patients included in this study were receiving apremilast shortly after its approval. As is generally observed, due to physician comfort with a new medication and payer preference, new-to-market therapies are often used in a more recalcitrant patient population. Overtime, apremilast has been more commonly used earlier in the disease course(17). A limitation of this study is the small sample size and therefore statistical testing was not performed. Furthermore, only patients who completed the 6-month follow-up visit were analyzed, which can introduce selection bias. A larger phase 4, multicenter, randomized, double-blind, placebo-controlled, parallel-group study (NCT03747939) is currently assessing the efficacy of apremilast in patients

with early oligoarticular PsA despite initial stable treatment with either non-steroidal anti-inflammatory drugs and/or 1 conventional synthetic DMARD. Overall, findings from this exploratory analysis suggest that apremilast monotherapy is an effective treatment option for oligoarticular PsA.

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DATA SHARING

The Corrona dataset is based on a large US multicenter study adhering to a number of institutional review boards, with complex logistics. Patients did not provide consent to raw data sharing during the data collection for this purpose, and the Corrona data sharing policies do not permit raw data sharing for this purpose. An aggregated limited dataset from the current analyses is available to qualified investigators with an approved protocol. Data requests may be sent to Corrona, represented by Dr. Jeffrey Greenberg, e-mail jgreenberg@corrona.org.

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FIGURE LEGENDS

Figure 1. The proportions of patients with >1 swollen joint or >1 tender joint at baseline achieving (A) swollen joint count (SJC) ≤ 1 and (B) tender joint count (TJC) ≤ 1 at 6 months. n/N=number of responders/number of patients with sufficient data for evaluation. bDMARD: biologic disease-modifying anti-rheumatic drug; MDA: minimal disease activity; SJC: swollen joint count; TJC: tender joint count.

Figure 2. Achievement of LDA/REM: Proportions of patients in moderate or high Clinical Disease Activity Index for Psoriatic Arthritis (cDAPSA) categories at baseline achieving cDAPSA low disease activity (LDA) or remission (REM) categories at 6 months. bDMARD: biologic disease-modifying anti-rheumatic drug; n/N: number of responders/number of patients with sufficient data for evaluation.

Table 1. Baseline patient characteristics.

Characteristics	Apremilast, n = 34	Methotrexate, n = 15	bDMARD, n = 101
Age, yrs, mean (SD)	55.7 (12.6), n = 33	61.5 (16.6), n = 15	52.9 (11.5), n = 99
Female, n (%)	20 (58.8), n = 34	10 (71.4), n = 14	59 (59.0), n = 100
Body mass index, kg/m ² , mean (SD)	34.4 (9.3), n = 34	30.6 (8.1), n = 14	32.7 (6.8), n = 96
Obese*, n (%)	22 (64.7), n = 34	8 (57.1), n = 14	58 (60.4), n = 96
Duration since PsA diagnosis, yrs, mean (SD)	8.0 (6.7), n = 33	5.4 (7.8), n = 14	9.7 (9.4), n = 96
Prior non-bDMARD use, n (%)	23 (67.6), n = 34	2 (13.3), n = 15	73 (72.3), n = 101
Prior biologic use (≥1), n (%)	27 (79.4), n = 34	3 (20.0), n = 15	76 (75.2), n = 101
SJC [†] (0–66), mean (SD)	1.5 (1.5), n = 34	1.0 (1.1), n = 15	0.8 (1.3), n = 101
SJC >1, n (%)	17 (50.0), n = 34	4 (26.7), n = 15	26 (25.7), n = 101
TJC (0–68), mean (SD)	2.7 (3.9), n = 34	2.5 (3.3), n = 15	3.1 (5.9), n = 101
TJC >1, n (%)	17 (50.0), n = 34	8 (53.3), n = 15	39 (38.6), n = 101
SPARCC enthesitis >0, n (%)	6.0 (17.6)	2.0 (13.3)	20 (19.8)
Dactylitis count >0, n (%)	6.0 (17.6)	2.0 (13.3)	6.0 (5.9)
Axial disease, n (%)	6 (17.6)	3 (20.0)	22 (21.8)
MDA, n (%)	6 (20.0), n = 30	4 (36.4), n = 11	35 (37.2), n = 94
VLDA, n (%)	3 (10.0), n = 30	1 (9.1), n = 11	7 (7.4), n = 94
cDAPSA score (0–154), mean (SD)	14.0 (8.5), n = 34	11.5 (4.9), n = 11	12.3 (9.1), n = 98
cDAPSA category			

Remission (≤ 4), n (%)	5 (14.7), n = 34	1 (9.1), n = 11	17 (17.3), n = 98
Low disease activity ($>4-\leq 13$), n (%)	12 (35.3), n = 34	7 (63.6), n = 11	45 (45.9), n = 98
Moderate disease activity ($>13-\leq 27$), n (%)	14 (41.2), n = 34	3 (27.3), n = 11	30 (30.6), n = 98
High disease activity (>27), n (%)	3 (8.8), n = 34	0 (0.0), n = 11	6 (6.1), n = 98
PtGA-PsA VAS score (0–100 mm), mean (SD)	47.1 (29.8), n = 34	32.5 (26.3), n = 13	42.9 (27.7), n = 99
Patient-reported Overall Pain VAS score (0–100 mm), mean (SD)	50.5 (31.1), n = 34	46.7 (26.5), n = 14	42.7 (29.6), n = 99
Patient-reported Fatigue VAS score (0–100 mm), mean (SD)	55.9 (30.0), n = 34	37.8 (31.9), n = 15	41.2 (29.0), n = 101
HAQ-DI score, mean (SD)	1.0 (0.7), n = 34	0.5 (0.4), n = 14	0.7 (0.6), n = 100
HAQ-DI score >0.5 , n (%)	21 (61.8), n = 34	6 (42.9), n = 14	45 (45.0), n = 100
Psoriasis-affected body surface area, %, mean (SD)	7.1 (17.6), n = 30	4.8 (9.4), n = 14	4.1 (7.8), n = 97
PtGA-PsO VAS score (0–100 mm), mean (SD)	47.1 (29.4), n = 34	28.4 (16.6), n = 12	41.2 (26.8), n = 99
Presence of physician- reported nail psoriasis, n (%)	8 (23.5), n = 34	3 (20.0), n = 15	25 (24.8), n = 101

*Body mass index ≥ 30 kg/m². †Patients had oligoarticular PsA, defined as ≤ 4 swollen joints. bDMARD: biologic disease-modifying anti-rheumatic drug; MDA: minimal disease activity; PtGA-PsA: Patient's Global Assessment of Disease Activity–Arthritis; PtGA-PsO: Patient's Global Assessment of Disease Activity–Arthritis and Psoriasis; SJC: swollen joint count; TJC: tender joint count; VAS: visual analog scale; VLDA: very low disease activity.

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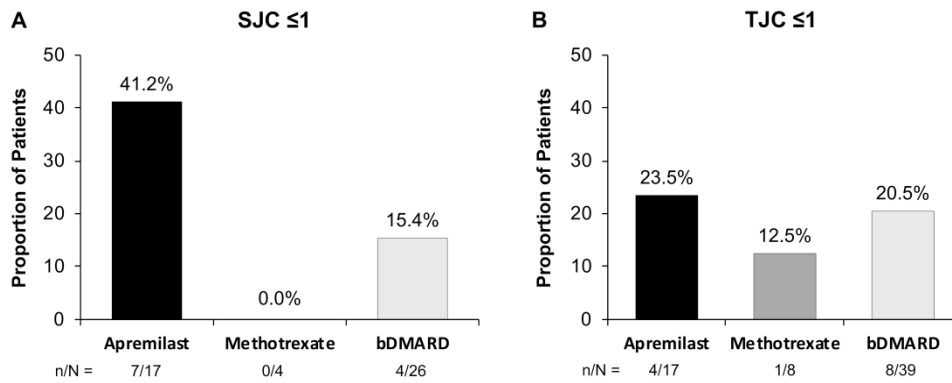


Figure 1. Achievement of SJC/TJC MDA criteria: The proportions of patients with >1 swollen joint or >1 tender joint at baseline achieving (A) swollen joint count (SJC) ≤ 1 and (B) tender joint count (TJC) ≤ 1 at 6 months. n/N=number of responders/number of patients with sufficient data for evaluation. bDMARD: biologic disease-modifying anti-rheumatic drug; MDA: minimal disease activity; SJC: swollen joint count; TJC: tender joint count.

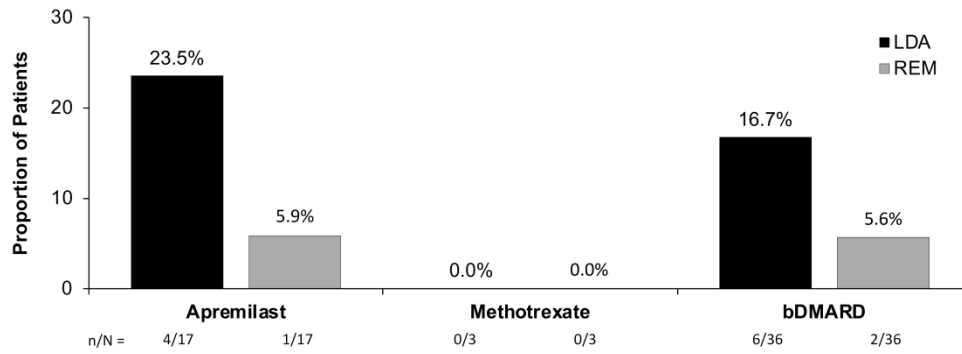


Figure 2. Achievement of LDA/REM: Proportions of patients in moderate or high Clinical Disease Activity Index for Psoriatic Arthritis (cDAPSA) categories at baseline achieving cDAPSA low disease activity (LDA) or remission (REM) categories at 6 months. bDMARD: biologic disease-modifying anti-rheumatic drug; n/N: number of responders/number of patients with sufficient data for evaluation.