Association of patient-reported disease burden and treatment switching among patients with plaque psoriasis on nonbiologic systemic therapy

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Synopsis

- Psoriasis is a chronic, immune-mediated, inflammatory disease that affects up to 3.0% of the US population and can profoundly impair patients' quality of life[1,2]
- How these impairments affect psoriasis treatment patterns warrants further investigation to help guide therapeutic algorithms
- This cross-sectional, real-world study evaluated the association between patient-reported disease burden and switching from nonbiologic systemic to biologic therapy in biologic-naive patients with plaque psoriasis who enrolled in the CorEvitas Psoriasis Registry
- Odds of switching to biologic treatment were estimated with multivariable logistic regression models fitted for various patient-reported disease burden measures
  - Models were adjusted for patient demographics, clinical characteristics, and disease severity
- Significantly higher adjusted odds of switching from nonbiologic systemic to biologic treatment were observed for patients with greater vs lesser burden for several health-related quality of life (HRQoL) measures, irrespective of patients' skin clearance
- Patient-reported HRQoL burden, in addition to clinically observed disease severity, may drive the switch to biologic treatment among real-world patients with psoriasis

Objectives

- To describe and compare patient-reported disease burden of psoriasis in biologic-naive patients who were using nonbiologic systemic therapy and switched to biologic treatment vs those who continued their initial systemic therapy with no changes
- To compare the odds of switching to biologic treatment for different measures of patient-reported disease burden for patients who do and who do not have a low degree of skin involvement

Methods

Cross-sectional study design

- Inclusion criteria
  - Enrolled in the CorEvitas Psoriasis Registry
    - A prospective, multicenter, noninterventional registry for patients with psoriasis under the care of a dermatologist, the Registry includes 259 clinical sites throughout 46 states and provinces in the United States and Canada
  - History of plaque psoriasis
  - ≥18 years of age
  - No previous use of biologic treatment
  - Had used nonbiologic systemic therapy (ie, apremilast, acitretin, cyclosporine, or methotrexate) for ≥28 days and no more than 365 days prior to Registry enrollment
- The outcome measure was a switch to biologic treatment up to 45 days after Registry enrollment
  - Switching was defined as the introduction of a biologic therapy in addition to, or in place of, their current nonbiologic systemic therapy vs continuation of initial nonbiologic systemic treatment with no changes
    - Biologic therapies included adalimumab, certolizumab, etanercept, infliximab, ustekinumab, guselkumab, risankizumab, tildrakizumab, secukinumab, ixekizumab, brodalumab, and bimekizumab
  - Patients were excluded if they had switched from one nonbiologic systemic treatment to another
- The study period extended from April 2015 to August 2022
  - Because of the timeline, the study did not include switching from deucravacitinib, an oral, allosteric, selective tyrosine kinase 2 (TYK2) inhibitor approved in the United States and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy[3]

Independent variables

- At Registry enrollment, patients completed self-reported measures of disease burden
  - Dermatology Life Quality Index (DLQI)
    - 10 items assessed dermatology-specific HRQoL
    - Total scores ranged from 0-30, with higher scores indicating poorer quality of life
  - Visual analog scale (VAS) ratings for itch, skin pain, and fatigue (each considered separate measures)
    - On a 100-mm horizontal line, patients rated their perceptions of each symptom's severity over the past week, with 0 indicating absence of the symptom and 100 indicating the highest degree of symptom severity
  - EuroQol 5-Dimension 3-Level (EQ-5D-3L) questionnaire
    - A descriptive questionnaire with 5 dimensions (walking problems, self-care, usual activities, pain/discomfort, and anxiety/depression)
    - Each dimension had 3 response levels of severity: no problems, moderate problems, extreme problems
  - Work Productivity and Activity Impairment questionnaire (WPAI), activities impairment subscale
    - The activities impairment subscale corresponded to question 6 of the WPAI ("To what degree has psoriasis affected your regular activities over the past 7 days?")
    - Scores out of 10 were multiplied by 100, with higher scores indicating greater impairment
  - Patient Global Assessment VAS (PGA-VAS)
    - On a 100-mm horizontal line, patients placed a mark representing how well they were doing with respect to the ways in which psoriasis affected them
    - Scores of 0 indicated "very well" whereas scores of 100 indicated "very poorly"
- Thresholds for greater vs lesser burden for these measures, used in the published literature,[4-8] are defined in **Table 1**

Table 1. Greater vs lesser disease burden

Disease burden measure	Greater burden	Lesser burden
DLQI[4]	>5	≤5
VAS itch[5]	≥30	<30
VAS skin pain[6]	≥45	<45
VAS fatigue[7]	≥50	<50
EQ-5D-3L[a]	Moderate or extreme problems	No problems
WPAI, activities impairment	>0	0
PGA-VAS[8]	≥20	<20

[a]The 5 subscale dimensions were walking problems, self-care, usual activities, pain/discomfort, and anxiety/depression.
DLQI, Dermatology Life Quality Index; EQ-5D-3L, EuroQol 5-Dimension 3-Level questionnaire; PGA-VAS, Patient Global Assessment, visual analog scale; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment questionnaire.

Analytic strategy

- Characteristics were descriptively compared between patients who did and who did not switch
- Multivariable logistic regression models were fitted separately for DLQI, VAS itch, VAS skin pain, VAS fatigue, PGA-VAS, the activities impairment subscale of the WPAI, and the 5 EQ-5D-3L subscales
  - Models were adjusted for age, sex, race, ethnicity, work status, body mass index, psoriasis duration, psoriatic arthritis status, number of prior nonbiologic systemics used prior to the study period, history of difficult-to-treat areas, and disease severity, as measured by body surface area (BSA) involvement, Psoriasis Area and Severity Index (PASI) score, and Investigator's Global Assessment (IGA) score
  - Adjusted odds of a switch with greater vs lesser burden were estimated for each measure/subscale
- A secondary analysis stratified each model by whether patients had or did not have a low degree of skin involvement, defined as a PASI score ≤2 or >2, respectively

Results

Descriptive comparisons of switchers and nonswitchers

- The analytic sample included 848 patients, of whom 323 (38.1%) switched to biologic treatment
- Mean age at enrollment was 50.4 years, 54.1% of patients were female, and 78.8% of patients were White (**Table 2**)
- Mean BSA involvement was 9.3% and mean PASI score was 5.0 (**Table 3**)
- Mean age was lower in patients who switched, while BSA involvement, PASI score, and IGA score were higher, with standardized differences >0.3 (**Tables 2 and 3**)
  - Psoriatic arthritis was reported in 29.0% of patients who did not switch and 41.2% of patients who switched to biologic treatment (standardized difference: 0.26)

Table 2. Demographics and Clinical Characteristics

Parameter	Total N = 848	Nonswitchers n = 525	Switchers n = 323	Standardized difference
Age, mean (SD), years	50.4 (15.6)	52.3 (15.3)	47.3 (15.6)	0.32
Female, n (%)	459 (54.1)	288 (54.9)	171 (52.9)	0.04
Race, n (%)				
White	668 (78.8)	411 (78.3)	257 (79.6)	0.04
Black	29 (3.4)	19 (3.6)	10 (3.1)	
Asian	89 (10.5)	55 (10.5)	34 (10.5)	
Other	62 (7.3)	40 (7.6)	22 (6.8)	
Hispanic ethnicity, n (%)	76 (9.0)	52 (9.9)	24 (7.4)	0.09
Employed full-time, n (%)	450 (53.1)	263 (50.1)	187 (57.9)	0.16
Body mass index, n (%)				
Underweight/normal	188 (22.2)	111 (21.1)	77 (23.8)	0.16
Overweight	258 (30.4)	174 (33.1)	84 (26.0)	
≥ Class 1 obesity	402 (47.4)	240 (45.7)	162 (50.2)	
Any comorbidity history, n (%)	592/846 (70.0)	370/524 (70.6)	222/322 (68.9)	0.04

SD, standard deviation.

Table 3. Psoriatic disease characteristics

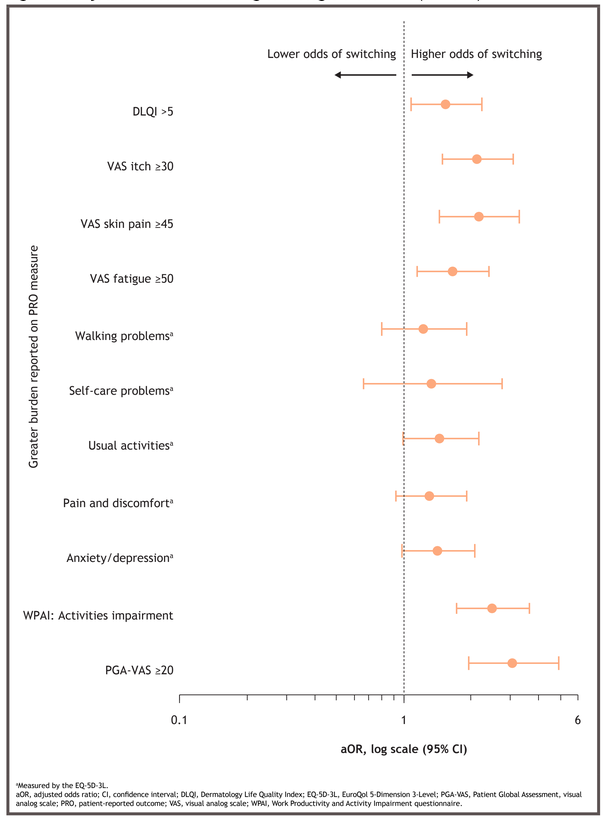
Characteristic	Total N = 848	Nonswitchers n = 525	Switchers n = 323	Standardized difference
Psoriasis duration, mean (SD), years	8.9 (12.0)	9.4 (12.2)	8.1 (11.6)	0.11
Psoriatic arthritis, n (%)	285 (33.6)	152 (29.0)	133 (41.2)	0.26
Body surface area involvement, %				
Mean (SD)	9.3 (12.8)	6.1 (10.4)	14.6 (14.5)	0.68
Mild (0-3), n (%)	262 (30.9)	235 (44.8)	27 (8.4)	1.03
Moderate (3-10), n (%)	382 (45.0)	224 (42.7)	158 (48.9)	
Severe (10-100), n (%)	204 (24.1)	66 (12.6)	138 (42.7)	
PASI score, mean (SD)	5.0 (5.9)	3.4 (5.2)	7.5 (6.1)	0.72
IGA score, mean (SD)	2.4 (1.1)	1.9 (1.1)	3.1 (0.6)	1.27
Unique nonbiologic systemics used prior to current systemic, n (%)				
0	739 (87.1)	469 (89.3)	270 (83.6)	0.13
1	90 (10.6)	43 (8.2)	47 (14.6)	
≥2	19 (2.2)	13 (2.5)	6 (1.9)	
Duration of current therapy (<90 days), n (%)	386 (45.5)	241 (45.9)	145 (44.9)	0.02

IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; SD, standard deviation.

Odds of switching to biologic treatment, overall analysis

- Unadjusted odds of switching were significantly higher in patients who reported greater vs lesser burden as measured by the DLQI or by VAS itch, skin pain, fatigue, or PGA; in those who reported activities impairment on the WPAI; and in those who reported moderate or extreme pain and discomfort, activities impairment, or anxiety/depression on the EQ-5D-3L ($P \leq 0.003$)
  - Odds of switching were numerically higher among patients who reported moderate or extreme problems with walking or self-care on the EQ-5D-3L
- After adjusting for disease severity and baseline characteristics, greater disease burden was an independent predictor for treatment switching to biologics (**Figure 1**)
  - Patients with DLQI scores >5 had 55% higher odds of switching than those with DLQI scores ≤5 (adjusted odds ratio [aOR] = 1.55 [95% CI, 1.08-2.23], $P = 0.017$)
  - Patients with greater burden for itch or skin pain had approximately twice the odds of switching compared with patients with less burden for these symptoms (itch aOR = 2.14 [95% CI, 1.49-3.08], $P < 0.001$; skin pain aOR = 2.18 [95% CI, 1.45-3.29], $P < 0.001$)
  - Patients with greater burden for fatigue had 66% higher odds of switching than those with less burden for fatigue (aOR = 1.66 [95% CI, 1.15-2.40], $P = 0.007$)
  - Patients with activities impairment measured by the WPAI had 2.5 times the odds of switching than those whose activities were not impaired on this measure (aOR = 2.51 [95% CI, 1.72-3.65], $P < 0.001$)
  - Patients who reported greater burden on the PGA-VAS had more than 3 times the odds of switching than those who reported lesser burden (aOR = 3.09 [95% CI, 1.94-4.91], $P < 0.001$)
- Adjusted odds of switching to biologic treatment were numerically higher with greater burden measured by the EQ-5D-3L, but these results' wide confidence intervals merit interpretative caution

Figure 1. Adjusted odds of switching to biologic treatment (N = 848)

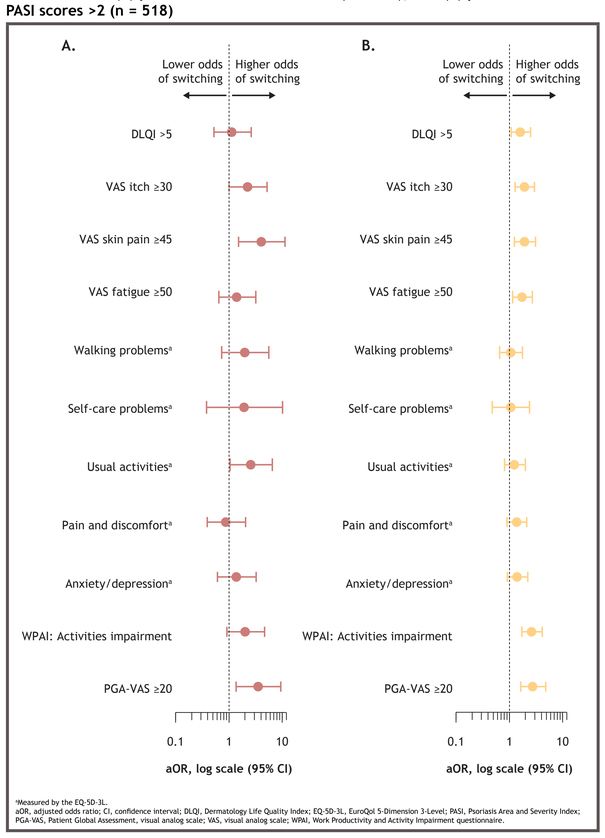


[a]Measured by the EQ-5D-3L.
aOR, adjusted odds ratio; CI, confidence interval; DLQI, Dermatology Life Quality Index; EQ-5D-3L, EuroQol 5-Dimension 3-Level; PGA-VAS, Patient Global Assessment, visual analog scale; PRO, patient-reported outcome; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment questionnaire.

Adjusted odds of switching to biologic treatment, secondary analysis

- Of the 330 patients with PASI scores ≤2, 52 (15.8%) switched to biologic therapy
- Of the 518 patients with PASI scores >2, 271 (52.3%) switched to biologic therapy
- Irrespective of stratification by PASI scores ≤2 or >2, aORs were significantly higher for patients with greater burden for VAS itch, skin pain, or PGA ($P < 0.05$)
- **Figure 2** displays aORs for switching for each measure in both subgroups
  - Adjusted odds of switching were significantly higher for patients with PASI scores ≤2 who reported greater vs lesser burden for VAS itch, skin pain, or PGA, or impairment of usual activities on the EQ-5D-3L ($P < 0.05$)
  - Stratifying the sample by the skin clearance threshold reduced the sample size, resulting in more variable odds of switch estimates

Figure 2. Adjusted odds of switching to biologic treatment by degree of skin involvement in (A) patients with PASI scores ≤2 (n = 330), and (B) patients with PASI scores >2 (n = 518)



[a]Measured by the EQ-5D-3L.
aOR, adjusted odds ratio; CI, confidence interval; DLQI, Dermatology Life Quality Index; EQ-5D-3L, EuroQol 5-Dimension 3-Level; PASI, Psoriasis Area and Severity Index; PGA-VAS, Patient Global Assessment, visual analog scale; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment questionnaire.

Conclusions

- The real-world evidence included in this study contains clinical data and patient-reported outcomes not available in claims databases; however, this study does not include longitudinal data
- After adjusting for covariates that included disease severity measures, biologic-naive patients with psoriasis who reported greater HRQoL burden had higher odds of switching to biologic therapy than those who reported lesser HRQoL burden
- The observed association of HRQoL burden with a switch to biologic therapy was similar, irrespective of whether patients had a low degree of skin involvement (PASI scores ≤2)
  - Even among patients with PASI scores ≤2, a switch to biologic therapy was observed for patients who reported greater HRQoL burden
- Patient-reported HRQoL burden, as well as clinically observed disease severity, may drive the switch to biologic treatment among patients with psoriasis

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Disclosures

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- **AS, CR-T:** Employees of CorEvitas
- **BS:** Consultant (honoraria): AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly, Equillium, GlaxoSmithKline, Immunic Therapeutics, Janssen, Leo Pharma, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB, Ventyx Biosciences, and vTv Therapeutics; Speaker: AbbVie, Eli Lilly, Janssen, and Sanofi Genzyme; Co-scientific director (consulting fee): CorEvitas' (Corrona) Psoriasis Registry; Investigator: AbbVie, Cara, CorEvitas' (Corrona) Psoriasis Registry, Dermavant, Dermira, and Novartis

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