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The Association Between Patient-Reported Disease Burden and Treatment Switching in Patients with Plaque Psoriasis Treated with Nonbiologic Systemic Therapy

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Purpose: This real-world study investigated the impact of patient-reported disease burden and health-related quality of life (HRQoL) on switching from systemic nonbiologic to biologic therapy in patients with plaque psoriasis.

Patients and Methods: Biologic therapy–naive (biologic-naive) patients aged ≥18 years who were using systemic nonbiologic treatment and who enrolled in the CorEvitas Psoriasis Registry between April 2015 and August 2022 were included. Measures of patient-reported disease burden and HRQoL were collected at Registry enrollment. The primary outcome of interest was initiation of biologic therapy within 45 days of enrollment. Multivariable logistic regression models were fitted separately for each patient-reported measure, adjusting for patient, disease, and treatment characteristics, including physician-rated disease severity. Adjusted odds ratios of switching to biologic therapy were estimated for greater versus lesser burden for each measure.

Results: Of 848 included patients, 323 (38.1%) switched to biologic treatment. Greater patient-reported burden was independently associated with switching, with significantly higher adjusted odds ratios (95% confidence interval) for greater versus lesser burden as measured by the Dermatology Life Quality Index (1.55 [1.08–2.23], P=0.017), visual analog scale (VAS) for itch (2.14 [1.49–3.08], P<0.001), VAS for skin pain (2.18 [1.45–3.29], P<0.001), VAS for fatigue (1.66 [1.15–2.40], P=0.007), Patient Global Assessment-VAS (3.09 [1.94–4.91], P<0.001), and with activities impairment on the Work Productivity and Activity Impairment questionnaire (2.51 [1.72–3.65], P<0.001).

Conclusion: In addition to clinically assessed disease severity, patient-reported disease burden and quality of life may drive the switch to biologic treatment in real-world patients with plaque psoriasis.

Keywords: biological products, health-related quality of life, patient-reported outcome measures, registries, surveys and questionnaires

Introduction

As with many other immune-mediated inflammatory diseases, moderate to severe plaque psoriasis has an extensive treatment armamentarium, including systemic oral nonbiologic and injectable biologic therapies.[1] Treatment switching in psoriasis is common[2–4] and is associated with a high economic burden, primarily driven by increased pharmacy costs with subsequent lines of treatment.[2,5] A recent study of patients with psoriasis reported that within 1 year, 28.2% of those who initiated an oral systemic therapy switched treatment, and among those who switched, 79.1% switched to a costlier biologic treatment.[5] Thus, it is critically important that payers and health care system administrators, as well as clinicians, understand the factors that underlie switching behavior. Research has identified primary or secondary lack of efficacy and adverse events as the chief reasons for switching therapies, while the National Psoriasis Foundation recommends

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considering switching treatments after failure to meet treatment targets defined by body surface area involvement.[6,7] However, the impact of health-related quality of life (HRQoL), distinct from clinician-assessed disease activity, on the decision to switch from nonbiologic to biologic treatment is less well understood.[8] This real-world study evaluated the association between patient-reported disease burden and switching from systemic nonbiologic to biologic therapy in biologic-naive patients with plaque psoriasis in the CorEvitas Psoriasis Registry, a multicenter, observational registry for patients with psoriasis under the care of a dermatologist or dermatology provider.

Materials and Methods

The CorEvitas Psoriasis Registry is an independent, prospective, multicenter, observational registry for patients with psoriasis and their treating dermatologists in the United States and Canada; it includes patients aged ≥18 years with physician-diagnosed psoriasis who have initiated or switched to systemic treatments for psoriasis within the previous 12 months. Patients participating in double-blind, randomized trials for investigational psoriasis treatments are excluded from enrollment. Detailed patient demographic information, medical history, and medication history are collected at Registry enrollment; moreover, patients complete measures of HRQoL and disease burden, such as the Dermatology Life Quality Index (DLQI); visual analog scales (VAS) for itch, skin pain, and fatigue (3 separate measures); the Patient Global Assessment VAS (PGA-VAS); the 3-level EQ-5D (EQ-5D-3L) questionnaire; and the Work Productivity and Activity Impairment (WPAI) questionnaire. Clinical assessments completed at enrollment include the Psoriasis Area and Severity Index (PASI), body surface area (BSA) involvement, and Investigator's Global Assessment (IGA).

This cross-sectional study included patients with plaque psoriasis who enrolled in the CorEvitas Psoriasis Registry at one of 259 clinical sites throughout 46 states and provinces in the United States and Canada between April 2015 and August 2022. Patients were included in the study if they had no previous use of biologic treatment but had used oral nonbiologic systemic therapy (ie, apremilast, acitretin, cyclosporine, or methotrexate) for at least 28 days no more than 365 days prior to their Registry enrollment. Because of its time period, the study did not include patients switching from deucravacitinib, an oral, allosteric tyrosine kinase 2 (TYK2) inhibitor approved in the United States and Canada in 2022 for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy.[9,10] Patients missing demographic information or data related to treatment history or clinician-assessed disease severity were excluded from the analysis. All participating investigators were required to obtain full board approval for conducting research involving human subjects. Sponsor (CorEvitas, LLC) approval and continuing review was obtained through a central institutional review board (IRB; Advarra, protocol number: Pro00051221). For academic investigative sites that did not receive a waiver to use the central IRB, approval was obtained from the respective governing IRBs and documentation of approval was submitted to the sponsor prior to initiating any study procedures. All patients were required to provide written informed consent prior to participating.

The main outcome of interest was a switch to biologic treatment up to 45 days after Registry enrollment, defined as the initiation of a biologic therapy in addition to or in place of the patients' current nonbiologic systemic therapy, as opposed to the continuation of their initial nonbiologic systemic treatment without any changes. Eligible biologic therapies included adalimumab, bimekizumab, brodalumab, certolizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab. Patients were excluded if they discontinued therapy or switched from one nonbiologic systemic therapy to another. Among patients who switched to biologic therapy, the reasons for switching were collected via CorEvitas Psoriasis Registry questionnaires.[11–17]

Demographics and clinical characteristics were compared between patients who did and who did not switch to biologic treatments, with standardized differences of 0.3, 0.5, and 0.8 corresponding to small, moderate, and large differences. Thresholds for greater and lesser burden on the patient-reported outcomes collected at Registry enrollment (DLQI, the VAS measures of itch, skin pain, and fatigue, PGA-VAS, EQ-5D-3L, and the activities subscale of the WPAI), were defined according to published literature[11–17] and are reported in Supplementary Table 1. Multivariable logistic regression models with biologic switch as the outcome were fitted separately for each of these patient-reported measures or subscales, adjusting for age, sex, race, ethnicity, work status, body mass index, psoriasis duration, psoriatic arthritis, number of nonbiologic systemics used before the study period began, history of psoriasis in difficult-to-treat areas, and disease severity as measured by BSA, PASI score, and IGA score. All continuous variables (age, body mass

index, psoriasis duration, BSA involvement, PASI score, and IGA score) were included as continuous variables in the models. Adjusted odds ratios (ORs) and corresponding 95% confidence intervals (CIs) from logistic regression models for switching to biologic therapy were estimated for greater versus lesser burden for each patient-reported measure or subscale. To evaluate the association between patient-reported outcomes and switching to biologic therapy in patients with limited clinician-assessed skin involvement,[18] analyses were repeated in patients with PASI scores ≤2 and in patients with PASI scores ≤4.

Results

Of 1002 biologic-naive patients enrolling in the CorEvitas Psoriasis Registry, patients were excluded from analysis because they switched from a nonbiologic systemic agent to a different nonbiologic systemic agent (n=33), because they had an uncertain start date for switching to biologic therapy that prevented defining whether a switch occurred at enrollment (n=37), or because they had a missing characteristic at enrollment (n=84). The study population included 848 patients, of whom 323 (38.1%) switched to a biologic treatment within 45 days of Registry enrollment; 54.1% were female, 78.8% were White, and the mean age was 50.4 years (Table 1). At Registry enrollment, the mean BSA was 9.3% and the mean PASI score was 5.0. Patients who switched to biologic therapy were, on average, younger and had higher BSA involvement and higher PASI and IGA scores (standardized differences >0.3) than those who did not switch. The percentages of patients who switched to biologic treatment are summarized by patient-reported disease burden indicators in Supplementary Table 2.

Table 1 Demographics and Disease Characteristics of Biologic Treatment–Naive Patients with Plaque Psoriasis in the CorEvitas Psoriasis Registry, by Whether They Switched from Systemic Nonbiologic to Biologic Therapy

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				0.04
White	668 (78.8)	411 (78.3)	257 (79.6)	
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 (%)				0.16
Underweight/normal	188 (22.2)	111 (21.1)	77 (23.8)	
Overweight	258 (30.4)	174 (33.1)	84 (26.0)	
Class I or higher obesity	402 (47.4)	240 (45.7)	162 (50.2)	
Any comorbidity history,[a] n/N (%)	592/846 (70.0)	370/524 (70.6)	222/322 (68.9)	0.04
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
BSA involvement, mean (SD), %	9.3 (12.8)	6.1 (10.4)	14.6 (14.5)	0.68
BSA involvement, n (%)				1.03
Mild (<3%)	262 (30.9)	235 (44.8)	27 (8.4)	
Moderate (3–10%)	382 (45.0)	224 (42.7)	158 (48.9)	
Severe (>10%)	204 (24.1)	66 (12.6)	138 (42.7)	

(*Continued*)

Table 1 (Continued).

Parameter	Total N=848	Nonswitchers n=525	Switchers n=323	Standardized Difference
PASI score				
Mean (SD)	5.0 (5.9)	3.4 (5.2)	7.5 (6.1)	0.72
>2, n (%)	518 (61.1)	247 (47.0)	271 (83.9)	0.84
>4, n (%)	341 (40.2)	139 (26.5)	202 (62.5)	0.78
IGA score, mean (SD)	2.4 (1.1)	1.9 (1.1)	3.1 (0.6)	1.27
Unique prior nonbiologic systemics, n (%)				0.13
0	739 (87.1)	469 (89.3)	270 (83.6)	
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
History of psoriasis in difficult-to-treat areas,[b] n (%)	435 (51.3)	275 (52.4)	160 (49.5)	0.06

Notes: [a]Includes patients with a history of cancer, cardiovascular disease, hypertension, hyperlipidemia, diabetes mellitus, hepatic events, gastrointestinal perforations, peptic ulcers, inflammatory bowel disease, or other gastrointestinal disorders. [b]Includes palmoplantar, genital, scalp, and nail psoriasis.
Abbreviations: BSA, body surface area; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index Score; SD, standard deviation.

After adjusting for patient, disease, and treatment characteristics, patients with lower HRQoL and greater patient-reported disease burden were more likely to switch to biologic therapy (Figure 1). Unadjusted odds of switching to biologic therapy are reported in Supplementary Table 3. Significantly higher adjusted odds of switching to biologic therapy were associated with higher disease burden, as assessed by the DLQI (OR, 1.55, 95% CI [1.08–2.23]; P=0.017), VAS itch (OR, 2.14 [1.49–3.08]; P<0.001), VAS skin pain (OR, 2.18 [1.45–3.29]; P<0.001), VAS fatigue (OR, 1.66 [1.15–2.40]; P=0.007), PGA-VAS (OR, 3.09 [1.94–4.91]; P<0.001), and WPAI activities impairment subscale (OR, 2.51 [1.72–3.65]; P<0.001). That is to say, after adjusting for patient, disease, and treatment characteristics, the odds of switching to biologic therapy were approximately 1.5–3 times higher for patients who reported greater versus lesser burden by these patient-

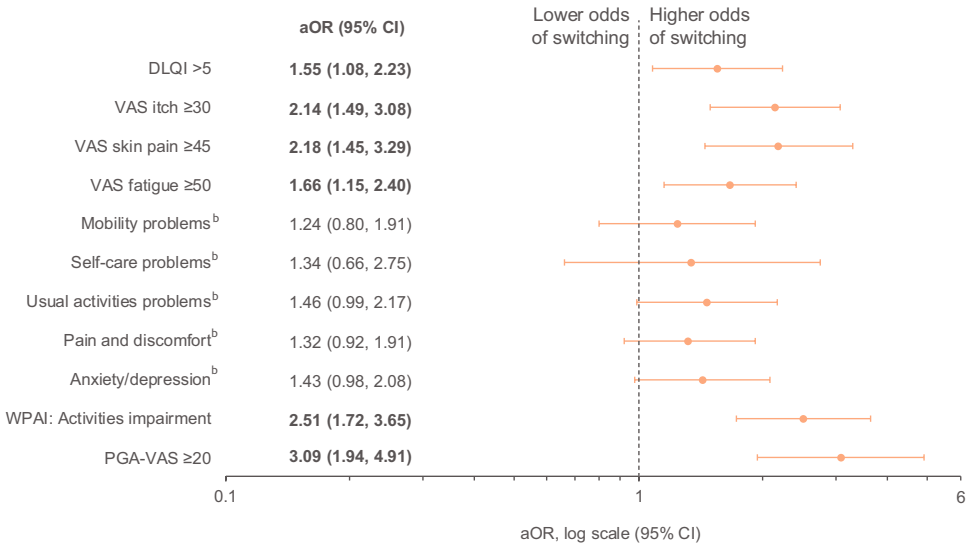

Figure 1 Adjusted associations (aOR and 95% CI) for patient-reported outcome measures and switching to biologic treatment (N=848), estimated with models specific to each measure or subscale.[a] [a]Variables adjusted for included age, sex, race, ethnicity, work status, body mass index, psoriasis duration, psoriatic arthritis, number of nonbiologic systemics used before the study period began, history of psoriasis in difficult-to-treat areas, and disease severity as measured by body surface area involvement, Psoriasis Area and Severity Index score, and Investigator's Global Assessment score. [b]Measured by the EQ-5D-3L.
Abbreviations: aOR, adjusted odds ratio; CI, confidence interval; DLQI, Dermatology Life Quality Index; EQ-5D-3L, 3-level EQ-5D; PGA-VAS, Patient Global Assessment visual analog scale; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment questionnaire.

reported outcome measures. Adjusted odds of switching were numerically higher with lower HRQoL as measured by the EQ-5D-3L subscales, but the wide CI of these results are also compatible with no effect ($P>0.05$). Recorded reasons for switching included side effects and patient requests, but the overwhelming majority of patients (91.0%) switched because of active disease, at a median of 103 days after treatment initiation (Supplementary Table 4).

Of the 330 patients (38.9%) with PASI scores ≤2, 52 patients (15.8%) switched to biologic therapy; the smaller sample size resulted in more variable odds of treatment switching estimates. However, adjusted odds of switching remained significantly higher for patients with PASI scores ≤2 who reported greater versus lesser burden for VAS itch, VAS skin pain, PGA-VAS, or impairment of usual activities item of the EQ-5D-3L (all, $P<0.05$; Supplementary Figure 1). All other measures were not found to be significantly associated with switching ($P>0.05$). Of 507 patients (59.8%) with PASI scores ≤4, 121 patients (23.9%) switched to biologic therapy. Among these patients, adjusted odds of switching were significantly higher with greater versus lesser burden reported on VAS itch, VAS skin pain, PGA-VAS, impairment of usual activities on the EQ-5D-3L, and activities impairment on the WPAI (all, $P<0.05$; Supplementary Figure 2). All other measures were not found to be significantly associated with switching ($P>0.05$). Unadjusted odds ratios are reported for patients with PASI ≤2 and ≤4 in Supplementary Table 5.

Discussion

This study demonstrates that, after adjusting for clinician-assessed disease severity, biologic-naive patients with plaque psoriasis who report greater disease burden and lower HRQoL on nonbiologic systemic therapy are significantly more likely to switch to biologic therapy than those who report less disease burden or greater HRQoL. Further, these findings applied even to patients with a low degree of clinician-rated skin involvement.[2,5,19–21] These insights should be considered in treatment algorithms: nonbiologic treatments that effectively reduce patient-reported disease burden or increase HRQoL may delay or prevent switching to costlier biologic therapies.

Prior targeted immune modulator use, age, and female sex have been identified as predictors of treatment switch in patients with psoriasis using biologic therapy,[22] but few studies in plaque psoriasis or other chronic diseases have assessed the association between patient-reported outcomes, independently of clinician-assessed disease severity or patient demographics, in relation to treatment switching behavior. Research in plaque psoriasis and other chronic disease areas has, however, consistently found an association between HRQoL and healthcare resource utilization,[19–21] and between patient-perceived treatment effectiveness and treatment adherence.[23] Moreover, US results from the UPLIFT survey suggest a potential misalignment between patients with psoriasis and dermatologists when considering treatment goals or factors that contribute to patient perceptions of disease severity; whereas patients ranked type of symptom as the most important factor that contributes to disease severity, dermatologists considered the proportion of body surface area involvement as the most important factor.[24] Likewise, patients identified itch relief and symptom control as the first- and second-most important treatment goals, while dermatologists ranked itch reduction eighth. Our study reinforces the critical importance of patient experiences, in addition to clinician assessments, in evaluating real-world treatment success or failure.

Among the study's strengths are both a large sample size and high-quality data, which included real-world clinical and patient-reported outcomes not available in claims databases. Limitations of this study include a lack of longitudinal data, such as patient-reported disease severity and symptomology at initiation of nonbiologic therapy prior to Registry enrollment, that could strengthen the observed association between HRQoL and treatment patterns. Further research might investigate whether these findings pertain to other disease states with a similar degree of symptom burden coupled with a large array of treatment options.

Conclusions

After adjusting for covariates that included clinician-rated disease severity measures, we found that biologic-naive patients with plaque psoriasis who reported greater disease burden (measured by VAS scales for itch, skin pain, and fatigue, and by the PGA-VAS) and lower HRQoL (measured by DLQI and WPAI) were significantly more likely to switch to biologic therapy than those who reported lesser disease burden and higher HRQoL. This association was observed even in patients who had a low degree of clinician-rated skin involvement. Nonbiologic therapies that

effectively address patient-reported disease burden and quality of life in addition to clinician-rated skin clearance may reduce treatment switching in patients with plaque psoriasis.

Abbreviations

aOR, adjusted odds ratio; BSA, body surface area; CI, confidence interval; DLQI, Dermatology Life Quality Index; EQ-5D-3L, 3-level EQ-5D; HRQoL, health-related quality of life; IGA, Investigator's Global Assessment; IRB, institutional review board; PASI, Psoriasis Area and Severity Index; PGA-VAS, Patient Global Assessment visual analog scale; TYK2, tyrosine kinase 2; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment.

Data Sharing Statement

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

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Bristol Myers Squibb employees were involved in the study design, the interpretation of data, the review of the manuscript, and the decision to submit for publication. Access to the study data was limited to CorEvitas, LLC, and CorEvitas statisticians completed all analyses.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Ms Park, Dr Zhong, and Dr Becker are employees of and may own stock options in Bristol Myers Squibb. Dr Sima is an employee of CorEvitas, LLC (formerly Corrona). Ms Roberts-Toler was an employee of CorEvitas at the time of the study. Dr Patel and Dr Hovland were employees of Bristol Myers Squibb at the time of the study and may be shareholders in the company. Dr Hovland is currently affiliated with Chiesi USA, Inc., Boston, MA. Dr Strober has served as a consultant with honoraria for AbbVie, Acelyrin, Alamar, Almirall, Alumis, Amgen, Arcutis, Arena Pharmaceuticals, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, Celltrion, CorEvitas, Dermavant, Inmagene, Janssen/J&J Innovative Medicine, Kangpu Biopharmaceuticals, Leo Pharma, Lilly, Maruho, Meiji Seika Pharma, Monte Rosa Therapeutics, Novartis, Pfizer, Protagonist, RAPT Therapeutics, Regeneron, Sanofi,

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