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ORIGINAL RESEARCH

Outcomes of Biologic Use in Asian Compared with Non-Hispanic White Adult Psoriasis Patients from the CorEvitas Psoriasis Registry

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ABSTRACT

Introduction: Real-world data are limited comparing Asian and White patients with psoriasis using biologic therapy. This study compared the 6-month effectiveness of biologic therapy between Asian and White plaque patients with psoriasis in the CorEvitas Psoriasis Registry.

Methods: Analyses included biologic initiations and 6-month follow-up visits from self-identified Asian (n = 293) and White (n = 2314) patients in the USA/Canada (4/2015–4/2020). Outcomes included: Psoriasis Area Severity Index (PASI) 75, disease activity measures [body surface area (BSA) ≤ 1, BSA ≤ 3, PASI90, PASI100, Investigator's Global Assessment (IGA) 0/1], and patient-reported outcomes [Dermatology Life Quality Index (DLQI) 0/1, itch, fatigue, skin pain, EuroQoL visual analog scale (EQ-VAS), patient global assessment, Work Productivity Activity and Impairment (WPAI) domains]. Unadjusted regression models were used to calculate odds ratios (OR) and 95% confidence intervals (CI) for achievement of binary outcomes and difference in mean change in continuous outcomes (β, 95% CI) at 6 months, followed by adjustment for age, sex, body mass index, alcohol, smoking, health insurance, education, comorbidities, scalp psoriasis morphology, psoriatic arthritis, biologic class, previous biologics, and baseline outcome value.

Results: Asians had lower proportions of women (32.8% versus 49.1%) and obesity (27.3% versus 54.5%), and higher proportions on Medicaid (19.9% versus 8.8%), graduated college (50.9% versus 40.1%) and never smoked (67.1% versus 44.1%). In unadjusted analyses, Asians had 52% higher odds of achieving PASI75 versus White patients (OR 1.52; 95% CI 1.15, 2.02). After adjustment, the association was attenuated (OR 1.11; 0.81, 1.52). Secondary outcomes experienced similar patterns except for DLQI: Asians had 33% lower odds of achieving DLQI 0/1 in both the unadjusted

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(OR 0.67; 0.50, 0.90) and adjusted (OR 0.67; 0.49, 0.92) models.
Conclusion: Unadjusted differences in biologic therapy effectiveness between Asians compared with White patients were likely explained by differences in demographic, lifestyle, and psoriatic disease characteristics between groups. However, Asians still experienced lesser improvements in skin-related quality of life, even after adjustment.

Keywords: Psoriasis; Race/ethnicity; Biologic therapy; Effectiveness; Patient registries; Real-world evidence

Key Summary Points

Why carry out this study?

To date, phase 3 randomized trials of biologic therapies for psoriasis have included primarily White patients, but subgroup analyses of Asian patients have generally shown similar efficacy across race–ethnicity groups.

There is limited real-world data comparing the effectiveness of biologic therapy for the treatment of psoriasis between Asian and White patients.

This study compared the 6-month effectiveness of biologic therapy between patients with psoriasis who identify as Asian compared with White patients in the USA and Canada using data from the CorEvitas Psoriasis Registry.

What was learned from the study?

After 6 months of biologic treatment, effectiveness of biologics was similar between Asian and White patients.

Patient-reported outcomes improved in both groups, however Asians experienced a one-third less improvement in skin-related quality of life.

Future studies on the factors associated with the decreased quality of life in Asian patients should focus on health disparities and the social determinants of health (e.g., healthcare quality and access, education quality and access, social and community context, and economic stability) to determine how to lessen the difference.

INTRODUCTION

The advent of biologic agents over nearly two decades has dramatically enhanced the treatment of moderate to severe psoriasis. Data from randomized controlled trials (RCTs) [1–16] have demonstrated that these agents can be highly efficacious. Yet the preponderance of evidence has been garnered from studies that have primarily included White patients. Subgroup analyses in these studies have shown similar efficacy in Asian and White patients for several biologics, including ixekizumab [17], brodalumab [18, 19], guselkumab [20], and secukinumab [21]. In ixekizumab trials for plaque psoriasis, Japanese patients in the UNCOVER-J studies [22, 23] exhibited higher rates of skin response for some efficacy outcomes compared with the predominantly White (> 90%) patients in the UNCOVER-1, -2, and -3 trials [24]. While not directly comparable, these separate trials suggest response to biologics may be somewhat better among Asian patients. Recently, Zhang et al. [25] conducted a systematic review and meta-analysis (n = 16 RCTs) comparing the effectiveness of anti-interleukin-17 in Asians compared with White patients and found no significant differences between Asian and White patients [Psoriasis Area Severity Index (PASI) 75 pooled log relative risk (RR) at week 12 for the Asian group, 2.81, 95% confidence interval (CI) 2.27–3.35, $p < 0.001$, and 2.93, 95% CI 2.71–3.16, $p < 0.001$] for the White group.

However, while prior real-world evidence (RWE) studies have demonstrated the effectiveness of biologic therapies for psoriasis

[4–16], there is little published data comparing the efficacy of biologics in Asian compared with other ethnicities in RWE studies. Real-world evidence is essential for providing insight into the efficacy and safety of drug treatments across all patients with psoriasis since the typical strict inclusion criteria of RCTs often exclude many patient populations seen in routine clinical care, including those with multiple comorbidities, ethnic and racial subpopulations, older adults, and patients for whom multiple biologics have failed. An improved understanding of whether a response to biologic therapy differs between Asian and White patients with psoriasis in real-world settings will help dermatologists optimize the use of biologic therapies among their patients from both racial backgrounds. Therefore, the objective of this study was to compare outcomes at 6 months following biologic therapy initiation between self-identified Asian and White patients with psoriasis in the USA and Canada-based CorEvitas Psoriasis Registry. To demonstrate whether extraneous factors may account for any observed differences in outcomes between Asian and White patients, comparisons were conducted both unadjusted and adjusted for potential confounding variables.

METHODS

Registry Overview

The CorEvitas (formerly Corrona) Psoriasis Registry is a prospective, multicenter, observational disease-based registry launched in April 2015 in collaboration with the National Psoriasis Foundation, the design of which has been previously described [26]. Briefly, adult patients initiating a systemic therapy for the treatment for psoriasis are recruited by participating dermatologists in the USA and Canada, and data are collected from both the dermatologists and patients via questionnaires administered during routine clinical visits occurring at approximately 6-month intervals. As of 30 April 2022, CorEvitas enrolled 17,207 patients from 580 dermatologists in 40 US states and 6 Canadian provinces and collected data from 66,158 patient visits.

Study Population

Data used for this study included patients initiating a biologic from the start of the registry (15 April 2015) to 10 April 2020 who self-identified as White (non-Hispanic) or Asian, had a confirmed initiation of a biologic therapy [tumor necrosis factor inhibitor (TNFi), interleukin-17 inhibitor (IL-17i), interleukin-23 inhibitor (IL-23i) or interleukin-12/23 inhibitor (IL-12/23i)] at or post-enrollment in the registry, and had a baseline visit and a subsequent 6-month follow-up visit. For the patients who initiated therapy at enrollment or at a follow-up visit, the baseline visit was defined as that which coincided with initiation. For patients who initiated between visits, the baseline visit was defined as the last visit before initiation, provided that the last visit was within 6 weeks before initiation. The 6-month follow-up visit was defined as the visit occurring closest to 6 months following biologic initiation among all follow-up visits occurring 5–9 months after baseline. Among the 10,915 patients in the registry during the study period, 2261 patients initiated a biologic therapy, had a baseline visit and a 6-month follow-up visit, and self-identified as Asian ($n = 267$) or White ($n = 1994$). These patients made up 2607 patient-initiations, 293 among Asian patients, and 2314 among White patients (Supplemental Figure 1). Among the 8827 patients who did not meet the study inclusion criteria, 2960 patients were excluded owing to no 6-month follow-up visit.

Study Variables

Race/Ethnicity

At enrollment, patients are asked two separate questions to describe their race ("Which of the following best describes your race?") and ethnicity ("Which of the following best describes your ethnicity?"). For the race question, patients are instructed to mark all that apply among the following: American Indian or Alaskan Native, Asian, Black/African American,

Native Hawaiian or Other Pacific Islander, White, Other. For the ethnicity question, patients are instructed to mark one option: "not Hispanic or Latino" or "Hispanic or Latino." In this study, the Asian cohort was defined as patients who identified themselves as "Asian" in the race question, and White was defined as patients who identified themselves as "White" and answered "non-Hispanic" for ethnicity.

Disease Activity Outcomes

Psoriasis Area Severity Index (PASI), body surface area (BSA), and Investigator's Global Assessment (IGA) were ascertained at the baseline and 6-month follow-up visits. The PASI is measured on a scale 0–72 where a higher score indicates more severity and considers percentage of affected area and the severity of redness, thickness, and scaling of the skin [27]. A patient's BSA is reported as percent involvement on a scale of 0–100% [28]. The IGA is a 5-point tool used to measure disease severity on a scale of 0–4, where 0 is clear, 1 is almost clear, 2 is mild, 3 is moderate, and 4 is severe [29].

Study outcomes were determined at the 6-month follow-up visit. Percent change in PASI from baseline to 6 months was calculated, and patients were classified as achieving (yes/no) PASI75 if they had a 75% or more reduction in PASI. A similar approach was used to define PASI90 and PASI100. At the 6-month follow-up visit, patients were classified as achieving (yes/no) BSA $\leq$ 3% (among those with baseline BSA $>$ 3%), BSA $\leq$ 1% (among those with baseline BSA $>$ 1%), and an IGA of 0 or 1 (IGA 0/1, among those with baseline IGA $>$ 1). Absolute changes in PASI, BSA, and IGA were also calculated.

Patient-Reported Outcomes

At the baseline and 6-month follow-up visits, patients reported their levels of itch, fatigue, and skin pain on a visual analog scale (VAS) of 0 (none) to 100 (very severe), as well as the patient global assessment (PGA) for psoriasis on a VAS of 0 (very well) to 100 (very poor). Also collected was the EuroQoL Five Dimensions Questionnaire VAS (EQ-VAS), a non-disease-specific quality of life assessment for which patients rate their health state today on a scale of 0 (worst imaginable) to 100 (best imaginable) [30]. The Work Productivity and Activity Impairment (WPAI) questionnaire was administered at both visits, measuring percentage of impairment due to psoriasis in the previous week for the following domains: work hours missed (absenteeism), impairment while working (presenteeism), work productivity loss (overall work impairment), and daily activities impaired. Responses for work-related domains (absenteeism, presenteeism, overall work impairment) were collected only from patients who were employed [31]. The Dermatology Life Quality Index (DLQI), which measures patients' perception of the impact of skin diseases on various facets of their health-related quality of life was collected. A summary score is calculated across 10 different domains ranging from 0 to 30 and categorized as follows: 0–1, no effect at all on patient's life; 2–5, small effect on patient's life; 6–10, moderate effect on patient's life; 11–20, very large effect on patient's life; 21–30, extremely large effect on patient's life [32]. The absolute change from the baseline visit to the 6-month follow-up visit was calculated for all patient-reported outcomes (PROs), and patients were classified as achieving a DLQI score of 0 or 1 (DLQI 0/1: yes/no) at follow-up.

Covariates

Baseline visit variables included: sociodemographics [age, gender, education (college graduate or above: yes/no)], health insurance (Medicaid: yes/no), lifestyle characteristics [smoking status (never, former, current), alcohol use (None, 1–3 drinks per week, 4–6 drinks per week, 1–2 drinks per day, $>$ 2 drinks per day), body mass index (BMI, kg/m^2)]; history of cardiovascular disease (CVD), history of cancer, history of scalp psoriasis, comorbid dermatologist-identified psoriatic arthritis (PsA), biologic line of therapy (0, 1, or $\geq$ 2 prior biologic therapies) and current class of biologic treatment (TNFi, IL-17i, IL-12/23i, or IL-23i).

Statistical Analysis

All analyses were conducted on the patient-initiation level. Baseline characteristics were

summarized by Asian and White patient initiations, separately, using descriptive statistics. Categorical variables were summarized using frequency counts and percentages, and continuous variables by means and 95% CIs.

The primary outcome for this analysis was PASI75. The proportions and 95% CIs of patient-initiations achieving PASI75, PASI90, PASI100, BSA $\leq$ 3%, BSA $\leq$ 1%, IGA 0/1, and DLQI 0/1 at 6 months were calculated. For continuous outcome measures (PASI, BSA, IGA, DLQI, itch, fatigue, skin pain, EQ-VAS, PGA, WPAI domains), means and standard deviations (SD) at baseline and follow-up were calculated, as was the mean (SD) absolute difference at 6-month follow-up visit. For patient-initiations that discontinued baseline therapy before their 6-month follow-up visit without evidence of starting a new therapy, we used observations at their follow-up visit. For those that discontinued baseline therapy and started a new therapy before the follow-up visit, we used the last observation before discontinuation (continuous measures of response) or classified these as non-responders (binary measures of response). Descriptive analyses of baseline characteristics and of outcomes at baseline and over follow-up included all patient-initiations with any data available.

To determine the association between race/ethnicity group (Asian versus White) and response to biologic therapy at 6-month follow-up, regression models with patient-initiation as the unit of analysis were utilized. Since patients may contribute multiple initiations to a single regression model, within-patient correlation was accounted for with generalized estimating equations (GEE) [33]. For binary outcomes, logistic GEE regressions were used to calculate ORs, along with 95% CI and *p*-values, for the likelihood of achieving the outcome at 6 months in Asians relative to White patients (reference group). For continuous outcomes, linear regressions with GEE were used to calculate regression coefficients (β), and corresponding 95% CI and *p*-values, estimating the relative difference in change in the outcome for the Asians compared with White patients (reference group). An exchangeable correlation structure was incorporated for all models.

Unadjusted regression models were calculated first to determine the crude association between race/ethnicity and outcome measures at 6 months following initiation of biologic therapy. To adjust for patient factors that may account for any observed associations in the crude analyses, regression models were adjusted for a set of baseline covariates (potential confounders) selected a priori on the basis of prior knowledge of differences in characteristics between Asian and White patients that could impact biologic response; specifically, age, sex, BMI, alcohol use, smoking status, health insurance, education, history of cancer, history of cardiovascular disease (CVD), history of scalp psoriasis, concomitant psoriatic arthritis, current biologic therapy class, biologic line of therapy, and the baseline value of the outcome (dependent variable). Regression models were conducted only on patient-initiations with complete information on all variables (Asians: $n = 236$, White patients: $n = 1541$).

For this study, PASI75 was considered as the primary outcome variable of interest. For all other outcomes, both nominal and multiplicity-adjusted *p*-values (Holm–Bonferroni method) were calculated for ORs and regression coefficients [34]. Confidence intervals were not adjusted for multiplicity.

R Version 4.0.4 (The R Foundation for Statistical Computing) was used for all analyses.

Ethics

The study was performed following the Guidelines for Good Pharmacoepidemiology Practice (GPP). All participating investigators were required to obtain full board approval for conducting noninterventional research involving human subjects with a limited dataset. Sponsor approval and continuing review was obtained through a central Institutional Review Board (IRB), the New England Independent Review Board (NEIRB; no. 120160610). 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.

RESULTS

Among the 10,915 patients enrolled in the registry, 2261 patients initiated a biologic therapy, had a baseline visit and a 6-month follow-up visit, and self-identified as Asian (n = 267) or White (n = 1994). These patients comprised 2607 patient-initiations, 293 among Asian patients and 2314 among White patients (Supplemental Fig. 1).

Baseline Characteristics

Compared with White patients, there were fewer females (32.8% versus 49.1%) and more patients on Medicaid (19.9% versus 8.8%) among Asians. Higher percentages of Asians were college-educated (50.9% versus 40.1%), never smoked (67.1% versus 44.1%), were not current alcohol users, (73.0% versus 54.5%), and had a lower mean BMI (27.8 kg/m^{2}versus 31.8 kg/m^2). Moreover, Asians had a lower proportion with concomitant dermatologist identified PsA (34.4% versus 43.9%) compared with White patients. However, there were similar proportions of biologic-experienced (64.5% versus 64.9%) and biologic-naïve (35.5% versus 35.1%) patients in Asian and White patients (Table 1).

Disease Activity Outcome Measures

Asian patients had higher mean PASI compared with White patients (11.2 versus 7.7) at baseline and had marginally higher mean BSA (15.8 versus 13.5) and IGA (3.0 versus 2.8) (Table 1). At 6 months following biologic initiation,

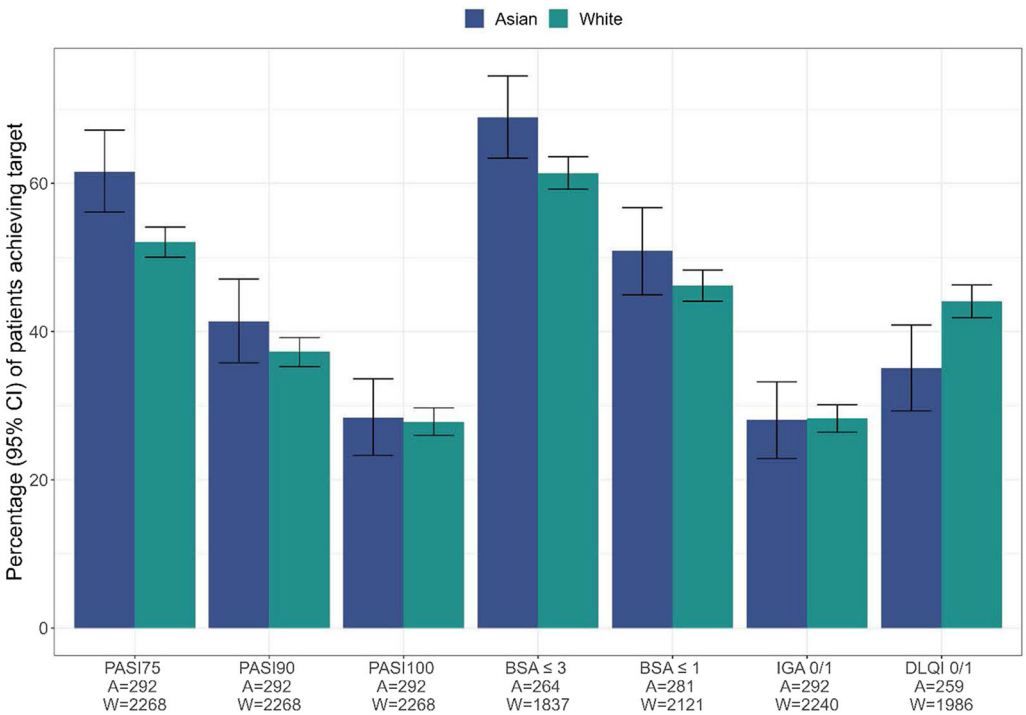

Fig. 1 Proportion of patients achieving disease response outcomes at 6 months following biologic initiation for Asian and White patients with psoriasis in the CorEvitas Psoriasis Registry. *A* Asian, *W* white, *PASI* Psoriasis Area Severity Index, *BSA* body surface area, *IGA* Investigator's Global Assessment, *CI* confidence interval

Table 1 Baseline characteristics of Asian and White patients with psoriasis who initiated a biologic and have a 6-month follow-up visit in the CorEvitas Psoriasis Registry (Patient-initiation level)

Characteristic*	Asian	White
N	293	2314
Age (years), mean (SD)	49.9 (15.3)	50.9 (14.4)
Female, *n* (%)	96 (32.8)	1135 (49.1)
Medicaid (yes/no), *n* (%)	58 (19.9)	200 (8.8)
College graduate or above, *n* (%)	149 (50.9)	927 (40.1)
Smoking status, *n* (%)		
Never	196 (67.1)	1015 (44.1)
Former smoker	53 (18.2)	856 (37.2)
Current smoker	43 (14.7)	429 (18.7)
Current alcohol use, *n* (%)		
None/occasional	214 (73.0)	1247 (54.5)
1–3 drinks per week	40 (13.7)	377 (16.5)
4–6 drinks per week	15 (5.1)	250 (10.9)
1–2 drinks per day	16 (5.5)	242 (10.6)
> 2 drinks per day	8 (2.7)	173 (7.6)
BMI (kg/m^2)[1], mean (SD)	27.8 (5.9)	31.8 (7.5)
BMI categories, *n* (%)		
< 25 (underweight/normal)	104 (35.5)	405 (17.6)
25–30 (overweight)	109 (37.2)	640 (27.8)
> 30 (obese)	80 (27.3)	1254 (54.5)
Cancer[2], *n* (%)	11 (3.8)	124 (5.4)
Cardiovascular disease[3], *n* (%)	20 (6.8)	260 (11.2)
Scalp morphology, *n* (%)	120 (41.0)	849 (36.7)
Psoriatic arthritis, dermatologist identified, *n* (%)	100 (34.4)	999 (43.9)
Initiated biologic therapy, *n* (%)		
TNFi	42 (14.3)	438 (18.9)
IL-17i	143 (48.8)	981 (42.4)
IL-12/23i	34 (11.6)	317 (13.7)
IL-23i	74 (25.3)	578 (25.0)
Previous Biologic therapies[6,7] *n* (%)		
0 prior biologics	104 (35.5)	812 (35.1)
1 prior biologic	77 (26.3)	577 (24.9)

Table 1 continued

Characteristic*	Asian	White
≥ 2 prior biologics	112 (38.2)	925 (40.0)
BSA (% involvement), mean (SD)	15.8 (15.3)	13.5 (15.1)
PASI (score: 0–72), mean (SD)	11.2 (8.0)	7.7 (6.9)
IGA (score: 0–5), mean (SD)	3.0 (0.7)	2.8 (0.9)
IGA categories, *n* (%)		
0, clear	1 (0.3%)	69 (3.0%)
1, almost clear	5 (1.7%)	116 (5.0%)
2, mild	45 (15.4%)	392 (16.9%)
3, moderate	186 (63.5)	1322 (57.2)
4, severe	56 (19.1)	414 (17.9)
DLQI (score: 0–30), mean (SD)	9.0 (6.6)	7.8 (6.1)
DLQI categories, *n* (%)		
No effect	32 (11.0%)	313 (13.6%)
Small effect	77 (26.4%)	705 (30.6%)
Moderate effect	81 (27.7%)	601 (26.1%)
Very large effect	85 (29.1%)	588 (25.5%)
Extremely large effect	17 (5.8%)	100 (4.3%)
Itch (VAS range 0–100), mean (SD)	53.6 (30.2)	51.2 (33.4)
Fatigue (VAS range 0–100), mean (SD)	35.7 (27.0)	37.4 (29.7)
Skin pain (VAS range 0–100), mean (SD)	33.7 (31.1)	33.5 (32.1)
EQ-VAS (VAS range 0–100), mean (SD)	69.5 (22.1)	70.3 (20.9)
Patient global assessment (PGA), mean (SD)	51.6 (28.2)	48.6 (28.9)
WPAI domains		
Currently employed, *n* (%)	188 (79.0)	1456 (76.8)
Absenteeism (% work hours missed), mean (SD)	5.8 (16.3)	3.5 (13.7)
Presenteeism (% impairment while at work), mean (SD)	26.3 (28.2)	13.8 (20.4)
Work productivity loss (% overall work impairment), mean (SD)	28.0 (29.5)	15.2 (21.8)

Table 1 continued

Characteristic*	Asian	White
% Activity impairment, mean (SD)	34.7 (29.4)	22.2 (27.2)

[1]On the basis of the Centers for Disease Control and Prevention (CDC) cutoffs for normal/underweight (< 25), overweight (25–29.9), and obese (≥ 30)

[2]Cancer includes lymphoma, lung, breast, skin (basal cell, squamous cell, melanoma), and any other cancers

[3]Cardiovascular disease includes baseline history of cardiac revascularization procedure, ventricular arrhythmia, cardiac arrest, myocardial infarction, acute coronary syndrome, unstable angina, coronary artery disease, congestive heart failure, cerebrovascular disease including baseline history of stroke, transient ischemic attack, peripheral vascular disease, peripheral arterial disease

*N for some characteristics differ from total N (A indicates Asian n; W indicates White n): Medicaid, A = 291, W = 2277; college graduate,
W = 2310; smoking status, A = 292, W = 2300; alcohol use, W = 2289; BMI, W = 2299; cancer, cardiovascular disease, W = 2313; PsA, A = 291, W = 2276; BSA, W = 2310; IGA, W = 2313; DLQI, A = 292, W = 2307; Itch, A = 292, W = 2312; fatigue, W = 2307; skin pain, A = 292, W = 2308; EQ-VAS, W = 2309; PGA, W = 2310; currently employed, A = 238, W = 1896; absenteeism, A = 170, W 1334; presenteeism, A = 169, W = 1322; work productivity loss, A = 168, W = 1314; activity impairment, A = 290, W = 2285

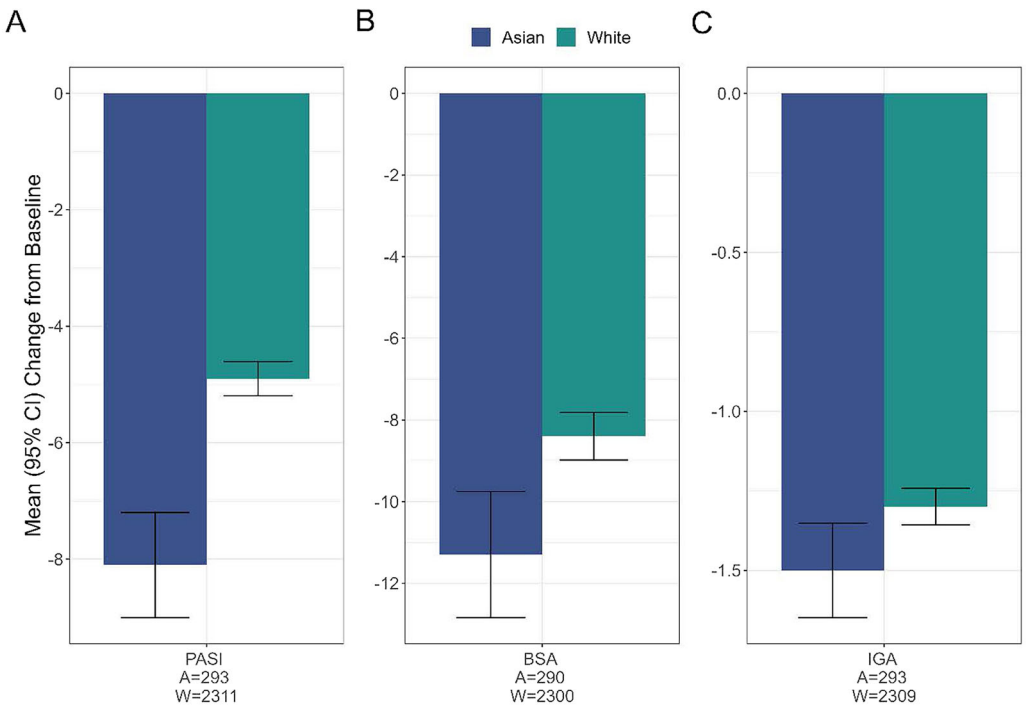

Fig. 2 Mean change (SD) in patient disease activity at 6 months following biologic initiation for Asian and White patients with psoriasis in the CorEvitas Psoriasis Registry. *A* Asian, *W* White, *PASI* Psoriasis Area Severity Index, *BSA* body surface area, *IGA* Investigator's Global Assessment, *CI* confidence interval

Table 2 Unadjusted and multivariable-adjusted odds ratios for achieving binary outcomes at 6 months following biologic initiation in Asian versus White patients (reference group)

Outcome	Unadjusted			Multivariable-adjusted*		
	OR (95% CI)	*p*-value	Multiplicity-adjusted** *p*-value	OR (95% CI)	*p*-value	Multiplicity-adjusted** *p*-value
PASI75	1.52 (1.15, 2.02)	0.004	n/a	1.11 (0.81, 1.52)	0.532	n/a
BSA $\leq$ 1	1.35 (1.02, 1.79)	0.036	0.146	1.13 (0.83, 1.53)	0.452	$>$ 0.999
BSA $\leq$ 3	1.47 (1.09, 1.99)	0.011	0.057	1.29 (0.92, 1.79)	0.136	0.679
PASI90	1.22 (0.92, 1.62)	0.176	0.527	0.88 (0.64, 1.21)	0.430	$>$ 0.999
PASI100	1.04 (0.76, 1.43)	0.813	$>$ 0.999	0.86 (0.60, 1.23)	0.406	$>$ 0.999
IGA 0/1	0.98 (0.71, 1.36)	0.917	$>$ 0.999	0.81 (0.56, 1.15)	0.238	0.952
DLQI 0/1	0.67 (0.50, 0.90)	0.007	0.041	0.67 (0.49, 0.92)	0.014	0.084

PASI Psoriasis Area Severity Index, *BSA* body surface area, *IGA* Investigator's Global Assessment, *DLQI* Dermatology Life Quality Index, *OR* odds ratio, *CI* confidence interval

*Multivariable logistic GEE regression adjusted for: age, sex, body mass index, alcohol use, smoking status, health insurance—Medicaid, education, history of cancer, history of cardiovascular disease, scalp morphology, psoriatic arthritis, biologic therapy class, previous biologic therapies (0 versus $\geq$ 1), and baseline value of the outcome variable

**P-values adjusted for multiplicity using Holm–Bonferroni method

substantial proportions of patients achieved response for all outcomes. For example, 62% (95% CI 56, 67) of Asians and 52% (95% CI 50, 54) of White patients achieved PASI75, and 69% (95% CI 63, 75) of Asians and 61% (95% CI 59, 64) of White patients achieved BSA $\leq$ 3% (Fig. 1). Mean disease activity measures improved over the 6-month follow-up in both Asian and White patients. Mean (SD) decreases in PASI, BSA, and IGA among Asians were 8.1 (7.9), 11.3 (13.4), and 1.5 (1.3), respectively, and among White patients were 4.9 (7.2), 8.4 (14.3), and 1.3 (1.4), respectively (Fig. 2).

When comparing the likelihood of achieving PASI75 at 6 months between Asian and White patients in logistic regression analyses, Asians had 52% higher odds in unadjusted analyses (OR 1.52; 95% CI 1.15, 2.02; $p = 0.004$), though this association was attenuated and was not statistically significant after adjustment for potential confounders (OR 1.11; 95% CI 0.81, 1.52; $p = 0.532$) (Table 2). A similar pattern was observed for BSA outcomes such that Asians had higher odds of achieving BSA $\leq$ 1% (OR 1.35; 95% CI 1.02, 1.79; $p = 0.036$) and BSA $\leq$ 3% (OR 1.47; 95% CI 1.09, 1.99; $p = 0.011$) in unadjusted analyses, but associations were attenuated after covariate adjustment (BSA $\leq$ 1%: OR 1.13; 95% CI 0.83, 1.53; $p = 0.452$; BSA $\leq$ 3%: OR 1.29; 95% CI 0.92, 1.79; $p = 0.136$). The odds of achieving PASI90, PASI100, and IGA 0/1 were similar between Asian and White patients. Similarly, when comparing mean changes in disease activity over follow-up in linear regression analyses, Asians had greater mean decreases in PASI ($\beta = -3.02$; 95% CI -4.13, -1.90; $p < 0.001$) and BSA ($\beta = -2.26$; 95% CI -4.23, -0.29; $p = 0.025$) compared with White patients in unadjusted analyses, but there were no associations after adjustment for covariates (PASI: $\beta = -0.03$; 95% CI -0.73, 0.68; $p = 0.942$; BSA: $\beta = -0.73$; 95% CI -2.13, 0.67; $p = 0.307$) (Table 3). There was no association with mean change in IGA. For all secondary disease activity outcomes, there were no statistically significant associations after adjustment for multiple comparisons (Tables 2 and 3).

Patient Reported Outcomes

Baseline mean self-reported itch, skin pain and fatigue, as well as EQ-VAS, were similar in Asian

Table 3 Unadjusted and multivariable-adjusted regression coefficients (β) estimating the difference in mean change in outcomes at 6 months following biologic initiation in Asian versus White patients (reference group)

Outcome	Unadjusted			Multivariable-adjusted*		
	β (95% CI)	*p*-value	Multiplicity-adjusted** *p*-value	β (95% CI)	*p*-value	Multiplicity-adjusted** *p*-value
PASI (score: 0–72)	−3.02 (−4.13, −1.90)	< 0.001	< 0.001	−0.03 (−0.73, 0.68)	0.942	> 0.999
BSA (% involvement)	−2.26 (−4.23, −0.29)	0.025	0.199	−0.73 (−2.13, 0.67)	0.307	> 0.999
IGA (score: 0–5)	−0.11 (−0.29, 0.07)	0.224	0.896	0.03 (−0.15, 0.21)	0.743	> 0.999
DLQI (score: 0–30)	−0.14 (−1.03, 0.75)	0.759	> 0.999	0.94 (0.21, 1.67)	0.012	0.151
Itch (VAS-100)	−3.65 (−8.30, 0.99)	0.123	0.617	−0.63 (−4.70, 3.44)	0.760	> 0.999
Fatigue (VAS-100)	−3.85 (−7.47, −0.22)	0.037	0.262	−2.83 (−6.19, 0.54)	0.099	> 0.999
Pain (VAS-100)	−1.53 (−5.79, 2.74)	0.483	> 0.999	0.68 (−2.61, 3.96)	0.686	> 0.999
EQ-VAS (VAS-100)	4.64 (1.57, 7.71)	0.003	0.034	1.89 (−0.42, 4.21)	0.109	> 0.999
PGA (VAS-100)	−1.93 (−6.56, 2.70)	0.414	> 0.999	3.04 (−1.06, 7.14)	0.146	> 0.999
WPAI domains						
Absenteeism (% work hours missed)	−1.78 (−3.66, 0.10)	0.064	0.385	−0.04 (−1.10, 1.01)	0.934	> 0.999
Presenteeism (% impairment while at work)	−5.19 (−9.03, −1.36)	0.008	0.080	1.59 (−1.26, 4.44)	0.273	> 0.999
Work productivity loss (% overall work impairment)	−5.40 (−9.46, −1.35)	0.009	0.081	1.64 (−1.37, 4.65)	0.285	> 0.999
% Activity impairment	−7.24 (−11.58, −2.90)	0.001	0.013	0.83 (−2.36, 4.03)	0.609	> 0.999

PASI Psoriasis Area Severity Index, *BSA* body surface area, *IGA* Investigator's Global Assessment, *DLQI* Dermatology Life Quality Index, *CI* confidence interval, *PGA* patient global assessment, *WPAI* Work Productivity Activity Impairment Questionnaire

*Multivariable GEE linear regression adjusted for: age, sex, body mass index, alcohol use, smoking status, health insurance—Medicaid, education, history of cancer, history of cardiovascular disease, scalp morphology, psoriatic arthritis, biologic therapy class, previous biologic therapies (0 versus ≥ 1), and baseline value of the outcome variable

**P-values adjusted for multiplicity using Holm–Bonferroni method

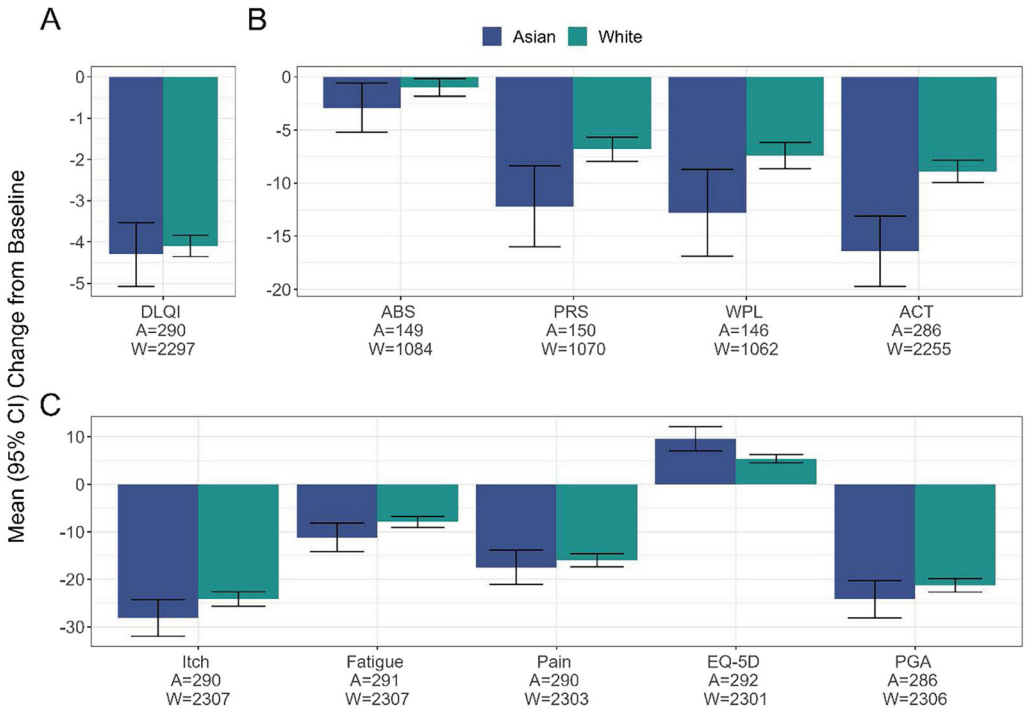

Fig. 3 Mean change (SD) in PRO measures at 6 months following biologic initiation for Asian and White patients with psoriasis in the CorEvitas Psoriasis Registry. *Multivariable GEE linear regression adjusted for: age, sex, body mass index, alcohol use, smoking status, health insurance—Medicaid, education, history of cancer, history of cardiovascular disease, scalp morphology, psoriatic arthritis, biologic therapy class, previous biologic therapies (0 versus $\geq$ 1), and baseline value of the outcome variable. **P-values adjusted for multiplicity using Holm–Bonferroni method. *PASI* Psoriasis Area Severity Index, *BSA* body surface area, *IGA* Investigator's Global Assessment, *DLQI* Dermatology Life Quality Index, *CI* confidence interval, *PGA* patient global assessment, *WPAI* Work Productivity Activity Impairment Questionnaire, *A* Asian, *W* White, *PASI* Psoriasis Area Severity Index, *BSA* body surface area, *IGA* Investigator's Global Assessment, *CI* confidence interval, *EQ-5D* Euroquol Five Dimensions Questionnaire, *PGA* patient global assessment, *ABS* absenteeism (work hours missed), *PRS* presenteeism (impairment at work/reduced on-the-job effectiveness), *WPL* work productivity loss, *ACT* activity impairment

and White patients, although mean DLQI was slightly higher in Asians (9.0 versus 7.8) (Table 1). Among patients who were currently employed, Asians had higher mean percent impairment while at work (26.3% versus 13.8%) and percent overall work impairment (28.0% versus 15.2%). Additionally, among all patients mean percent activity impairment was higher in Asian versus White patients (34.7% versus 22.2%) (Table 1; Fig. 3). At the 6-month follow-up visit, 35% (95% CI 29, 41) of Asians and 44% (95% CI 42, 46) of White patients achieved DLQI 0/1 (Fig. 1). For all PROs, there were mean improvements over the 6-month follow-up period among both Asian and White patients (Fig. 2).

In the unadjusted logistic regression analysis, Asians had 33% lower odds (OR 0.67; 95% CI 0.50, 0.90; $p = 0.007$) of achieving DLQI 0/1 at 6 months compared with White patients, and this association was unchanged (OR 0.67; 95% CI 0.49, 0.92; $p = 0.014$) after adjustment for covariates (Table 2). From the unadjusted linear regression models comparing mean changes in PROs over 6 months, Asians had statistically significant greater improvements in fatigue ($\beta = -3.85$; 95% CI -7.47, -0.22; $p = 0.037$) and EQ-VAS ($\beta = 4.64$; 95% CI 1.57, 7.71; $p = 0.003$) than White patients (Table 3). Asians

had greater improvements in mean percent impairment while at work (β = −5.19; 95% CI −9.03, −1.36; p = 0.008) and percent overall work impairment (β = −5.40; 95% CI −9.46, −1.35; p = 0.009) among employed patients, and in activity impairment among all patients (β = −7.24; 95% CI −11.58, −2.90; p = 0.001). In the multivariable-adjusted models, all the associations observed in the unadjusted models were attenuated and no longer statistically significant. Mean change in DLQI was not different between Asian and White patients in unadjusted analyses (β = −0.14; 95% CI −1.03, 0.75; p = 0.759), yet after accounting for covariates Asians had a lesser mean decrease in DLQI over follow-up compared with White patients (β = 0.94; 95% CI 0.21, 1.67; p = 0.012). Except for DLQI 0/1 in the logistic model unadjusted for covariates, associations for all outcomes were not statistically significant after multiplicity adjustment (Table 2).

DISCUSSION

In this real-world cohort of patients with psoriasis in the USA and Canada, both self-identified Asian and White patients demonstrated improvements in all disease activity and PROs at 6 months following initiation of biologic therapy. In crude analyses, Asians had better improvements than White patients for several outcome measures. There were, however, differences between the groups for patient characteristics that have previously been shown to impact response to biologic therapy. After accounting for these factors in adjusted analyses, improvements in outcomes were similar for Asian and White patients. The one exception was DLQI, for which Asians had reduced mean improvement and a lower likelihood of achieving a meaningful response than White patients, even after accounting for potential confounders.

Conducting RCTs is a well-established methodology that provides evidence of therapeutic efficacy, while RWE studies confirm therapeutic treatment effectiveness in real-world practice settings [35, 36]. Randomized clinical trials utilize randomization with strict inclusion and exclusion criteria to reduce bias and increase internal validity. However, increased internal validity may decrease external validity (e.g., generalizability) [37] and diminish the ability to replicate the study effect [38]. Further, the strict inclusion criteria of RCTs may exclude many patient populations seen in routine clinical care (i.e., patients with multiple comorbidities, ethnic and racial subpopulations, the elderly, biologic multi-failure patients). To assuage this dichotomy, RWE is complementary to RCTs and provides insight into the efficacy and safety of drug treatments during real-life routine clinical care [8, 37, 38]. Real-world evidence studies can generate hypotheses requiring further investigation in RCTs while also providing answers to questions RCTs cannot adequately address [37]. To our knowledge, this study is among the first using RWE to compare outcomes in biologic therapy between Asian and White patients with psoriasis.

Our findings are consistent with subgroup analyses in clinical trials of several different biologic therapies, demonstrating Asians have similar efficacy to White patients for several biologics [25]. Wu et al. found the efficacy of secukinumab in Taiwanese patients was consistent with the overall patient population in the global phase III ERASURE study [21]. Nakagawa et al. reported that the rapid efficacy of brodalumab in Japanese patients [19], which confirmed the previous findings of studies conducted with White populations [18, 39]. In subpopulation analyses of the guselkumab trials VOYAGE 1 and VOYAGE 2, Reich et al. found comparable responses in Asian and non-Asian populations [20]. As with the findings from the UNCOVER 1–3 studies with ~ 92% White patients [24], investigators from the UNCOVER-J open-label study have shown ixekizumab to be safe and efficacious in Japanese patients [23]. These findings of the effectiveness in Asian subpopulations may assist clinical decision making and more patient-centered care.

Our results suggest that response to biologic therapy for psoriasis is similar between Asian and White patients across both disease activity measures and PROs. We did find, however, a difference between the two groups for health-

related quality of life as measured by the DLQI, suggesting improvement in patient-reported quality of life related to the impact of skin symptoms, as measured by DLQI, was worse for Asians. It should be noted that the association with DLQI was no longer statistically significant ($p = 0.084$) after adjustment for multiple comparisons.

Although we cannot directly compare outcomes owing to differences in the type of studies (RWE versus RCTs), these findings are in line with a prior study that found that Asians report a lower health-related quality of life than White patients regardless of psoriasis severity at baseline [41]. In a retrospective study to investigate the ethnic variations in psoriasis treatment with etanercept (EASE Study), Shah et al. found that Asians had a higher DLQI when compared with White patients at baseline, yet after controlling for percent of BSA affected and PGA, percent improvement in DLQI for the two groups were no longer different [40].

We observed similar effectiveness for biologics between White patients and Asians for objectively measured outcomes such as skin clearance, while effectiveness differed between the groups for the self-reported measure of skin-related quality of life. Decreased quality of life in the Asian population may be attributable to the psychosocial burden of the disease, including cultural issues, higher levels of social stigma, and discrimination owing to the misunderstanding of psoriasis [42–44]. This psychosocial burden may also vary among different Asian subpopulations, though we were unable to explore this given the CorEvitas Psoriasis Registry does not collect information on these specific groups. One should note, however, that in the current study, Asian and White patients reported similar improvements for the EQ-VAS, a more general assessment of health-related quality of life. Nevertheless, the observed discrepancy between the impact of biologics on objective outcomes and self-reported quality of life suggests that dermatologists should consider attitudes, knowledge, and behaviors of cultural subgroups when developing treatment plans for their patients.

There is evidence that the DLQI may have limited cross-cultural equivalence as it has been shown that patients with similar levels of underlying health-related quality of life respond differently to DLQI items [45, 46]. The psychometric properties of the DLQI have been studied in different ethnic populations to determine if the instrument meets the requirements of modern test theory [46–48]. Research has found that the DLQI has not evolved and introduces a form of selection bias [46, 49, 50] since more than half the questions are affected by external factors such as age, gender, diagnosis, and nationality [46]. Therefore, Asian and White patients with similar overall health-related quality of life impairment should be compared with caution when using the DLQI as these two ethnicities likely respond differently to some of the items based on variation in cultural norms [49, 50]. Therefore, it is possible that the differences in DLQI observed in the current study may be at least partly explained by cultural biases inherent in the instrument [46, 54].

In the unadjusted analyses in this study, Asians demonstrated greater improvements in PASI, BSA, fatigue, EQ-VAS, and WPAI domains. A recent study using data from the British Association of Dermatologists Biologic Interventions Register (BADBIR) identified several demographic, social, and clinical factors associated with poor response to biologics, including female sex, non-White ethnicity, unemployment, current or former smoking, higher weight, and psoriasis of the palms or soles [51]. In the current analysis, White patients had higher proportions of females and current/former smokers, as well as higher mean BMI at baseline compared with Asians. Once we accounted for these and other variables in our multivariable analyses, the observed associations were attenuated. As expected, covariates that were most consistently significantly associated with worse response in multivariable models across all outcomes were female sex, current smoking, and higher BMI (data not shown). For example, in the regression model for the primary outcome of PASI75, among all patients, female sex was associated with 17% lower odds of achievement versus male sex, current smoking was associated with 27% lower odds versus never smoking, and a 1 kg/m^2 increase in BMI was associated with 4% lower

odds. While there were other baseline characteristics that differed between Asian and White patients, including Asians having higher proportions of college graduates and nondrinkers and a lower proportion with concomitant PsA, these factors were not consistently associated with response across all outcome measures in the multivariable models. Our analyses could not determine whether individual characteristics may have explained the observed associations in the unadjusted analyses, thus further studies are required to elucidate the specific factors that account for the crude differences in response to biologics observed between Asian and White patients.

This study has some limitations. Collection of racial/ethnic information in the CorEvitas Psoriasis Registry is limited to a broad category of "Asian." Patients in the USA and Canada who self-identify as Asian could comprise 24 different ethnic groups originating from several regions (e.g., Indian subcontinent, Southeast Asia, East Asia) [52]; however, we were unable to identify which patients belong to specific Asian subpopulations. Thus, the results from this study may not be generalizable to specific Asian subpopulations. The size of the Asian cohort was small compared with the White cohort, which likely impacted the precision of effect estimates. While we adjusted for the most important covariates, we were unable to adjust for potential genetic factors that may drive response [e.g., the role of the human leukocyte antigen (HLA)-Cw1 associated with psoriasis in some Asian populations [53]].

Nevertheless, after adjustment for non-genetic factors, there were no associations with effectiveness. Since our Asian cohort had a very heterogeneous genetic makeup (i.e., a myriad of Asian populations), we would not expect further adjustment for genetic factors to impact our results. Until RWE studies are conducted in Asian subgroup populations and other marginalized patient populations [i.e., the elderly, patients with histories of comorbidities, biologic multi-failure patients, patients who suffer from other forms of plaque psoriasis (e.g., erythrodermic psoriasis)], addressing this health disparity in quality of life outcomes will continue to be a puzzle for the medical community (55, 56). Results from such studies will be an essential component of a patient-centered care paradigm for dermatologists and patients when developing a psoriasis treatment plan. Finally, CorEvitas dermatologists and their patients are voluntary participants in the registry, thus findings may have limited generalizability to the larger population of patients with psoriasis using biologic therapy.

Despite these limitations, this study has several strengths. This study is among the first to investigate differences in biological response between Asian and White patients in a real-world setting. Since CorEvitas collects data from academic and private practice dermatologists across the USA and Canada, these patients are more likely to reflect the typical real-world patient population than those participating in clinical trials. Additionally, the CorEvitas Registry collects data on a wide range of patient characteristics and outcomes, including disease activity measures and PROs that are not available in other real-world data sources such as claims databases.

CONCLUSION

In this study of patients with psoriasis from the USA and Canada who initiated biologic therapy, Asian and White patients demonstrated improvements in disease activity and PROs after 6 months. Although crude analyses suggested Asians may have greater improvements, changes were similar in both groups after accounting for differences in baseline characteristics. However, results indicated that Asians might have lesser skin-related quality of life improvements. These findings suggest that biologics continue to provide dermatologists with viable options for treating Asian and White patients with psoriasis who are candidates for systemic therapy.

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Compliance with Ethics Guidelines. The study was performed following Good Pharmacoepidemiology Practice. All participating investigators were required to obtain full board approval for conducting noninterventional research involving human subjects with a limited dataset. Sponsor approval and continuing review was obtained through a central Institutional Review Board (IRB), the New England Independent Review Board (NEIRB; no. 120160610). 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.

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.

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