Outcomes in Ixekizumab Initiators By Prior Biologic Status in the Corrona Psoriasis Registry

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BACKGROUND

- The impact of psoriasis (PsO) affects quality of life, work productivity,[1] and is associated with several other comorbidities including cardiovascular disease, Crohn's disease, depression, and anxiety[2]
- Ixekizumab, a human monoclonal antibody with neutralizing activity against IL-17A, has shown significant efficacy in clinical trials for the treatment of moderate to severe PsO[3-5]
- In trials, efficacy of ixekizumab in PsO patients is similar between biologic-naïve and biologic-experienced patients,[6] yet real-world effectiveness among potentially refractory patients for whom biologics have failed is unknown

OBJECTIVE

- To examine disease characteristics and quality of life in patients with PsO six months following initiation of ixekizumab for groups defined by prior biologic failure status

METHODS

- **Study Setting**
  - The Corrona Psoriasis Registry is a prospective, multicenter observational disease-based registry launched in April 2015 in collaboration with the National Psoriasis Foundation
  - As of July 31, 2019, patients were recruited from 218 private and academic practice sites, with 448 participating dermatologists, in the US/Canada across 45 states/provinces
  - Registry inclusion criteria:
    - PsO diagnosed by a dermatologist
    - Aged ≥18 years
  - Data are collected using questionnaires from patients and providers during regular office visits at ~6-month intervals
  - 8,674 patients were enrolled and accrued 23,639 patient-visits and 8,950 patient-years of follow-up (mean 1.57 yrs, median 1.24 yrs)

METHODS

- **Study Population**
  - Analysis included the 347 patients who initiated ixekizumab between March 2016 and May 2019 and had a 6-month follow-up visit after initiation
  - Patients were classified into prior biologic therapy groups: naïve (N=56,16.1%); failure (failed to maintain/inadequate initial response to a biologic, N=213, 61.4%); non-failure (discontinued biologic for a reason other than failure, N=78, 22.5%)
- **Statistical Analysis**
  - Information on demographics, disease characteristics, treatment history, co-morbidities, and patient-reported outcomes was collected at the baseline visit and a 6-month follow-up visit
  - Logistic regression and linear regression were used to compare 6-month outcomes in the failure and non-failure groups relative to the naïve group, then adjusted for baseline age, sex, race, psoriatic arthritis (PsA), PsO duration, and outcome status

KEY RESULTS

- Mean age was 50 years, 47% were female, and 78% were white with nearly two thirds having biologic failure (Table 1)
- Biologic naïve patients had less of a history of hypertension (21.4% vs 39.0% and 38.5%), diabetes (8.9% vs 15.5% and 17.9%), psoriatic arthritis (PsA) (25.5% vs 50.7% and 59.7%), and a shorter PsO disease duration (11.6 yrs vs 17.0 yrs and 17.9 yrs) compared to the prior-biologic failure and non-failure groups, respectively, at baseline (Table 1)
- Bio-naïve patients had statistically significant changes for itch, fatigue, pain, patient global assessment, EQ-5D, work hours missed, work hours affected, impairment while working, and percent daily activities impaired (all p<0.05) at 6 months (Figures 2)
- Among all patients, 70%, 77%, 79%, and 49% maintained/achieved BSA<3%, PASI<3, IGA≤1 and DLQI ≤1, respectively, at 6 months (data not shown)

KEY RESULTS

- Compared to the naïve group:
  - The failure group was less likely to maintain/achieve BSA<3% (Odds Ratio (OR)=0.24 [0.1, 0.5]), PASI<3 [OR=0.25 (0.09, 0.6)], IGA≤1 [OR=0.28 (0.1, 0.6)], and DLQI ≤1 [OR=0.37 (0.2, 0.7)] (Table 2)
  - ORs for the non-failure group were greater: BSA<3% [OR=0.33, (0.1, 0.8)], PASI<3 [OR=0.37 (0.1, 1.0)] IGA ≤1 [OR=0.39 (0.2, 0.9)], and DLQI ≤1 [OR=0.63 (0.3, 1.4)] (Table 2)
  - Relative to the naïve group, the failure group had more significant changes in all WPAI domains compared to the non-failure group (Table 3)

CONCLUSION

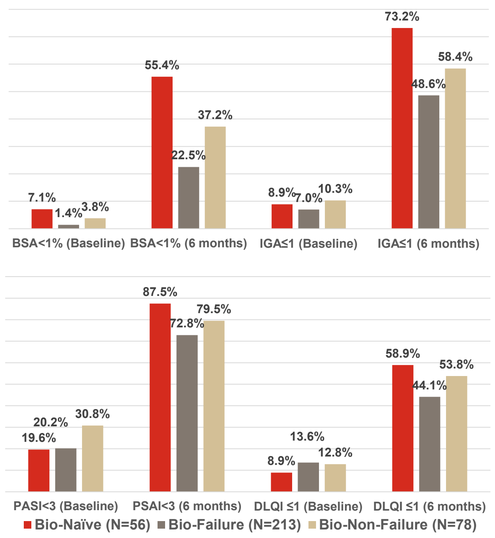
- Disease measures and quality of life improved in all groups after six months among real-world PsO patients who initiated ixekizumab, with bio-naïve patients having a more favorable response

Table 1. Demographics, co-morbidities, and disease characteristics at baseline visit for ixekizumab initiators by prior biologic status.

Characteristic	Total	Biologic Naive	Prior Biologic Failure	Prior Biologic Non-Failure
Total (N)	N=347	N=56	N=213	N=78
Age in years, Mean (SD)	50.3 (13.4)	48.1 (14.2)	50.5 (13.1)	51.4 (13.7)
Gender, Female, n (%)	163 (47.0%)	23 (41.4%)	105 (49.3%)	35 (44.9%)
Race, White, n (%)	269 (77.5%)	41 (73.2%)	166 (77.9%)	62 (79.5%)
BMI in kg/m², >30 (obese), n (%)	192 (55.3%)	29 (51.8%)	119 (55.9%)	44 (56.4%)
Hypertension, n (%)	125 (36.0%)	12 (21.4%)	83 (39.0%)	30 (38.5%)
Diabetes mellitus, n (%)	52 (15.0%)	6 (8.9%)	33 (15.5%)	14 (17.9%)
PsA– dermatologist identified, n (%)	163 (48.7%)	14 (25.5%)	103 (50.7%)	46 (59.7%)
Duration of PsO disease in years, Mean (SD)	16.3 (12.7)	11.6 (10.8)	17.0 (13.3)	17.9 (11.9)
BSA (% involvement), Mean (SD)	12.4 (14.3)	16.6 (18.5)	11.2 (11.5)	12.9 (17.0)
PASI > 10, n (%)	111 (32.0%)	24 (42.9%)	65 (30.5%)	22 (28.2%)
IGA, 0: clear, n (%)	8 (2.3%)	4 (7.1%)	2 (0.9%)	2 (2.6%)
IGA, 1: almost clear, n (%)	20 (5.8%)	1 (1.8%)	13 (6.1%)	6 (7.7%)
IGA, 2: mild, n (%)	50 (14.4%)	3 (5.4%)	29 (13.6%)	18 (23.1%)
IGA, 3: moderate, n (%)	200 (57.6%)	34 (60.7%)	132 (62.0%)	34 (43.6%)
IGA, 4: severe, n (%)	69 (19.9%)	14 (25.0%)	37 (17.4%)	18 (23.1%)
DLQI (score: 0-30) Mean (SD)	7.8 (6.2)	10.4 (7.3)	7.0 (5.3)	8.4 (7.1)

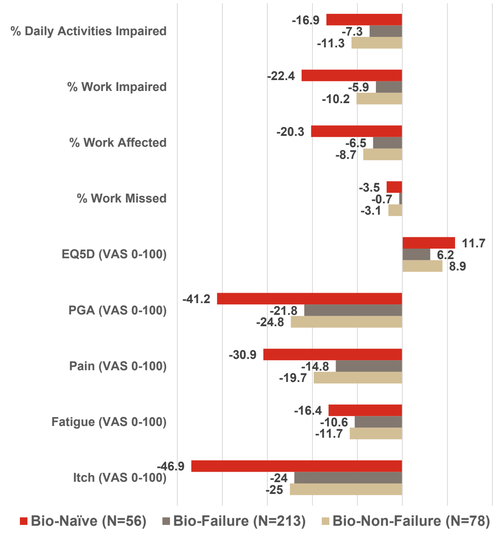
Body Mass Index (BMI), Body Surface Area (BSA), Psoriasis Area Severity Index (PASI), Investigator's Global Assessment (IGA), and Dermatology Life Quality Index (DLQI)

Figure 1. Proportion of patients with BSA<1%, IGA≤1, PASI<3, and DLQI ≤1 at baseline and 6-month follow-up visit for ixekizumab initiators by prior biologic status.



Body Surface Area (BSA), Investigator's Global Assessment (IGA), Psoriasis Activity Severity Index (PASI), and Dermatology Life Quality Index (DLQI)

Figure 2. Mean absolute difference in patient-reported outcome response from baseline to 6-month follow-up visit for ixekizumab initiators by prior biologic status.



For EQ5D: Health Status, a higher mean absolute change indicates patient improvement; Patient Global Assessment (PGA)

Table 2. Multivariable-adjusted odds ratios (OR) for maintaining/achieving disease and patient-reported outcome response, for the difference in change at 6-month follow-up visit for ixekizumab initiators with prior biologic failure and non-failure, relative to bio-naïve patients.

Outcomes	Prior Biologic Failure	Prior Biologic Non-Failure
	OR (95% CI)*	OR (95% CI)*
Disease Characteristics		
BSA <3%	0.24 (0.10, 0.54)	0.33 (0.12, 0.83)
BSA <1%	0.17 (0.09, 0.34)	0.36 (0.17, 0.77)
PASI 75	0.18 (0.07, 0.41)	0.42 (0.16, 1.06)
PASI 90	0.16 (0.08, 0.32)	0.36 (0.16, 0.79)
PASI 100	0.19 (0.09, 0.37)	0.39 (0.17, 0.84)
PASI <3	0.25 (0.09, 0.59)	0.37 (0.12, 1.01)
IGA ≤1	0.28 (0.14, 0.55)	0.39 (0.17, 0.85)
Patient-Reported Outcomes		
DLQI ≤1	0.37 (0.19, 0.73)	0.63 (0.29, 1.35)
Itch 0	0.54 (0.27, 1.11)	0.93 (0.41, 2.09)
Fatigue 0	0.90 (0.44, 1.90)	0.72 (0.29, 1.77)
Pain 0	0.47 (0.24, 0.89)	0.45 (0.21, 0.95)

Body surface area (BSA), Psoriasis Area Severity Index (PASI), Investigator's Global Assessment (IGA), Dermatology Life Quality Index (DLQI); *Odds Ratio (95% Confidence Interval) from multivariable logistic regression adjusted *a priori* for age, gender, race (white vs non-white), PsA, PsO duration, and baseline outcome

Table 3. Multivariable-adjusted linear regression coefficients for Work Productivity Activity Impairment (WPAI) response, for the difference in change at 6-month follow-up visit for ixekizumab initiators with prior biologic failure and non-failure, relative to bio-naïve patients.

Outcomes	Prior Biologic Failure	Prior Biologic Non-Failure
	β (95% CI)*	β (95% CI)*
WPAI		
% Work Missed	1.01 (-3.26, 5.28)	4.36 (-0.67, 9.39)
% Work Impaired	8.5 (2.73, 14.28)	5.86 (-1.02, 12.74)
% Work Affected	9.56 (2.96, 16.17)	7.02 (-0.77, 14.8)
% Daily Activities Impaired	4.8 (-1.34, 10.94)	3.73 (-3.43, 10.88)

* β (95% Confidence Interval) from multivariable linear regression adjusted *a priori* for age, gender, race (white vs non-white), PsA, PsO duration, and baseline outcome

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