Clinical and Quality of Life Outcomes Among Ixekizumab -Treated Psoriasis Patients in a Real-World Setting: Results from a Single US Dermatology Referral Practice

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Abstract

Background: Psoriasis is a chronic immune-mediated inflammatory skin condition that has a significant negative impact on the physical, emotional, and psychosocial well-being of those affected. Ixekizumab (IXE) has demonstrated an early and high-level treatment response in the real-world setting. This study aimed to assess the rapidity and long-term disease severity and quality of life (QOL) outcomes among IXE-treated plaque psoriasis patients.

Method: A retrospective cohort study was conducted at a single US dermatology referral center. Medical charts were reviewed for adult psoriasis patients starting IXE (index date) between March 22, 2016, and February 28, 2018. Disease severity and QOL data were abstracted up to one-year pre-IXE initiation and up to 35 months post-IXE initiation. Static Physician Global Assessment (sPGA), Body Surface Area (BSA), and Dermatology Life Quality Index (DLQI) were summarized at 1-month post-index and at 3-month intervals. Logistic regressions were performed to evaluate the 1-month response in relation to long-term sPGA, BSA, DLQI outcomes. Subgroup analysis were conducted to compare outcomes among biologic naïve and biologic experienced patients.

Results: A total of 153 patients (median age at index: 47.7 years; 65.4% male; 93.5% Caucasian) were included in the study. Majority of patients (69%; n=106) were biologic experienced prior to IXE initiation. In the total study cohort, at 1-month post-index 58.8% of patients achieved sPGA (0,1), 55.9% achieved DLQI (0,1), and 66.9% achieved BSA≤1%. Patients with sPGA (0,1) at 1-month post-index had greater odds of remaining sPGA (0,1) and BSA≤1% at 24-month (sPGA 0,1: OR=10.1; 95% CI: 2.1-47.9; BSA≤1%: OR=13.3; 95% CI: 2.2-80.2). Among patients who achieved sPGA (0,1) at 1-month post-index, the proportion of patients with sPGA (0,1), DLQI (0,1), and BSA≤1% remained largely the same for the 24-month follow-up. Among biologic experienced and naïve patients, more than half achieved sPGA (0,1), DLQI (0,1), and BSA≤1% at 1-month after IXE initiation.

Conclusion: This real-world study demonstrated that majority of patients initiating IXE achieved sPGA (0,1), DLQI (0,1) and BSA ≤1% targets within the first month of treatment and were able to maintain treatment response for up to 24 months independent of prior biologic exposure.

Background

Psoriasis is a chronic immune-mediated inflammatory skin condition that has a significant negative impact on the physical, emotional, and psychosocial well-being of those affected.(1) (2) Plaque psoriasis is the most common type of psoriasis accounting for approximately 90% psoriasis cases.(3) Chronic psoriasis is characterized by recurrent flares, or the sudden and severe worsening of symptoms, often without any obvious cause. In the United States (US), the estimated prevalence of psoriasis is 3.2% among individuals aged 20 years or older with greater prevalence found among Caucasians (2.5%) compared to African Americans (1.3%).(4, 5)

The Psoriasis Area and Severity Index (PASI) is considered the gold standard measurement for psoriasis severity, yet it is rarely used in routine clinical practice due to its complexity.⁽⁶⁾ Instead, physicians routinely quantify the percentage of body surface area (BSA) affected, use the 7-point static Physician Global Assessment (sPGA) scale, and use patient perception of impairment to different aspects of their health-related quality of life (HRQoL) in order to understand disease activity and severity.⁽⁶⁾ The Dermatology Life Quality Index (DLQI) is a validated instrument which indicates the degree of reduction in patient's HRQoL.^(1, 7)

There is currently no cure for psoriasis, however, based on the severity of the disease, treatments are available to help manage symptoms. These include topical agents, phototherapy, conventional systemic therapies, biologics and over-the-counter therapies. The treatment paradigm for psoriasis tends towards the use of topical agents for mild and moderate disease, systemic agents for moderate and severe disease, and biologics for the more severe cases of psoriasis.⁽⁸⁾ Current available biologic therapies are inhibitors of T lymphocytes and cytokines: TNF α , IL-12, IL-23 and IL-17A, and these have shown efficacy in reducing psoriasis symptoms in moderate to severe cases. ^(9, 10) While rapid response and long-term effectiveness were indicated to be of high importance among patients with moderate to severe disease as well as physicians making treatment decisions,^(2, 11) there is evidence that current biologic treatments may lose effectiveness over time.^{(12), (13, 14)}

The newer biologic therapies are those that inhibit the IL-17 or IL-23 pathways. Ixekizumab (Taltz®, IXE), an IL-17 antagonist, was approved in the US on March 22, 2016 for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.^(15, 16) IXE has demonstrated desired effectiveness in clinical trials^(17, 18) and in real-world clinical practice,^(9, 19) however, its speed of onset and long-term impact on patient outcomes and treatment persistence has not yet been assessed in a real-world setting.

The aims of this study are two-fold. First, to assess speed of IXE effectiveness and describe the persistency of outcomes among psoriasis patients at a single dermatology referral practice in the US. Second, to assess clinical and HRQoL outcomes in subgroups of patients who had a sPGA score of 0,1 at 1-month or were exposed to biologic treatment prior to IXE initiation. Findings from this study will provide foundational insights that can be used to inform future broader comparative effectiveness studies of IXE.

Methods

Study design

A retrospective cohort study was conducted at a single US dermatology referral center. Medical chart data were used to identify patients who initiated IXE between March 22, 2016 and February 28, 2018 (i.e. the enrolment period). The index date was defined as the date of IXE initiation. Data up to 35 months after index date and 12 months before index date were collected. The end of study period was defined as February 28, 2019, date of IXE discontinuation, or discontinuation of clinical care, whichever occurred

first. All data collected were de-identified, and the study adhered to the Guidelines for Good Pharmacoepidemiology Practices(20) as well as the Health Insurance Portability and Accountability Act (HIPAA) guidelines for protection of patient confidentiality.(21)

Data source and study population

Data were collected from Central Dermatology, a dermatology referral practice encompassing one primary investigator supported by nurse practitioners. Patients with moderate to severe psoriasis are routinely seen at one month and then every three months during active treatment stage after biologic initiation for up to one year; and are seen approximately every six months beyond one year of treatment. sPGA, BSA, and DLQI are regularly collected at clinic visits.

Study population included adult patients with physician-diagnosed plaque psoriasis who initiated IXE during the enrolment period. Patients who received IXE by participating in any clinical trials for their psoriasis before or during the enrolment period as well as patients under the age of 18 at the time of IXE initiation were excluded from the study. Medical records of psoriasis patients who initiated treatment with IXE during the enrolment period were sampled consecutively in chronological order, based on IXE initiation date. Sampled charts were then screened against study eligibility criteria. The study was reviewed and approved by Advarra institutional review board (IRB), and a waiver of informed consent was granted.

Data collection

The medical records of psoriasis patients who met the eligibility criteria were retrospectively reviewed, data were abstracted up to one year prior to IXE initiation and up to 35 months post IXE initiation using an electronic data collection form (eDCF) created with Microsoft® Access. Patients were seen at different schedules depending on the course of their disease.

Variables

Baseline demographic and clinical information including age, sex, ethnicity, insurance status, and time since psoriasis diagnosis was obtained from medical records at index date. Use of systemic, topical and phototherapy treatments as well as treatment discontinuation, and reason for discontinuation were collected during the pre-index period. Primary treatment outcomes of interest collected during post-index were sPGA, DLQI, and BSA. sPGA is a 7-point scale that classifies the severity of psoriasis from “0 = clear” to “6 = severe”. DLQI responses were classified into five categories (0–1, 2–5, 6–10, 11–20, and 21–30) from “no effect” to “extremely large effect”.(6) BSA was presented as continuous variables and also categorised using National Psoriasis Foundation (NPF) guidelines as: treat to target ($BSA \leq 1\%$), mild ($1\% < BSA < 3\%$), moderate ($3\% \leq BSA \leq 10\%$), and severe ($BSA > 10\%$).(22) These outcomes as well as the specific body regions involved were collected during the post-index period for each documented visit.

Statistical analysis

Analyses were performed based on available patient data at each clinic visit. Descriptive analysis was used to summarize baseline demographic and clinical characteristics, treatment details, and study outcomes. Mean, standard deviation (SD), median, and range were summarized for continuous variables, and counts and percentages were summarized for categorical variables.

Disease severity measures were summarized from index date up to 24 months post-index. sPGA, DLQI, BSA and specific body regions involved were summarized by counts and percentages at 1-month post-index, at 3-month intervals for up to 12 months post-index, and at 6-month intervals in the second year following IXE initiation among patients with available data at each post-index time point (+/-45 days). Percentage of BSA and number of body regions involved were summarized by mean, SD, median, and range. Additionally, two subgroup analyses were performed: 1) comparing early responders, defined as patients who had achieved a sPGA (0,1) at 1-month with those who did not; and 2) comparing patients who had used biologic systemic treatment prior to IXE initiation with patients who were biologic naïve.

Unadjusted logistic regressions were performed to explore the potential determinants of sPGA, DLQI, and BSA outcomes at 12 and 24 months after IXE initiation. The outcomes were $BSA \leq 1\%$ versus $BSA > 1\%$, sPGA (0, 1) versus sPGA > 1, and DLQI (0, 1) versus DLQI > 1. Odds ratios (OR) were presented alongside 95% CI. Analyses were performed in SAS 9.4 (SAS Institute, Inc., Cary, NC).

Results

A total of 153 psoriasis patients treated with IXE between March 22, 2016 and February 28, 2018 and who met the study eligibility criteria were included in the study. Among patients seen at each individual study follow-up visit, nearly all patients had sPGA (98%), BSA (99%), and DLQI (96%) documented. The median age at IXE-initiation was 47.7 years (range: 19.7–74.5), 65.4% of the study population was male, and 93.5% of patients were Caucasian (Table 1). The median time since psoriasis diagnosis was 11.9 years (range: 0.1–41.1). A total of 106 patients received prior biologic therapy for psoriasis; adalimumab was the most commonly used biologic prior to IXE initiation (n = 40), followed by secukinumab (n = 35). Almost half of the study cohort received prior non-biologic systemic treatment (n = 69, 45.1%) with the majority receiving methotrexate (n = 66, 43.1%). 38.6% (n = 59) patients received topical treatment during the pre-index period while only two patients (1.3%) received phototherapy. Among patients who switched to IXE from other biologic therapies, the majority of the patients discontinued their prior biologics due to inadequate response to treatment (TNF- α inhibitor: 90.8%, IL-12/23 inhibitor: 100%, IL-17 inhibitor: 82.9%, Table 2)

Table 1
Baseline demographic and clinical characteristics

Demographic characteristics	All patients (n = 153)
Age at study index date (years)	
Mean (SD)	47.2 (13.1)
Median (Min-Max)	47.7 (19.7–74.5)
Unknown	0 (0.0)
Sex, n (%)	
Male	100 (65.4)
Female	53 (34.6)
Race/ethnicity, n (%)	
Caucasian	143 (93.5)
African-American	5 (3.3)
Multi-racial	1 (0.7)
Unknown	4 (2.6)
Insurance status at study index date, n (%)	
Private	143 (93.5)
Medicaid	1 (0.7)
Medicare	3 (2.0)
Medicare;Private	4 (2.6)
None	2 (1.3)
Time since psoriasis diagnosis (years)*	
Mean (SD)	14.8 (10.5)
Median (Min-Max)	11.9 (0.1–41.1)
Unknown	34 (22.2)
Treatment during pre-index**	
Non-biologic systemic medications, n (%)	69 (45.1)
Methotrexate	66 (43.1)
Cyclosporine	3 (2.0)
Biologic systemic medications, n (%)	106 (69.3)

Demographic characteristics	All patients (n = 153)
TNF-a inhibitor	66 (43.1)
Etanercept	2 (1.3)
Infliximab	9 (5.9)
Adalimumab	40 (26.1)
Certolizumab	8 (5.2)
Ampremilast	9 (5.9)
IL-12/23 inhibitor	14 (9.2)
Ustekinumab	14 (9.2)
IL-17 inhibitor	35 (22.9)
Secukinumab	35 (22.9)
Topical medications, n (%)	59 (38.6)
Phototherapy, n (%)	2 (1.3)
<p>Abbreviations: IL = Interleukin; n = Number; SD = Standard deviationAbbreviations: TNF = Tumor necrosis factor</p> <p>*The study index date is the date of ixekizumab initiation</p> <p>**Patients may have received more than one treatment concomitantly or sequentially during pre-index period; number of treatments received can be higher than number of patients that received the treatment</p>	

Table 2

Reasons for treatment choice and treatment discontinuation of biologics in the pre-index period

Reasons [^]	TNF- α inhibitor (n = 66)*	IL-12/23 inhibitor (n = 14)*	IL-17 inhibitor (n = 35)*
	n (%)	n (%)	n (%)
Treatment discontinuation			
Treatment ongoing at end of pre-index period	1 (1.5)	0 (0.0)	0 (0.0)
Treatment switch/discontinuation	65 (98.5)	14 (100.0)	35 (100.0)
Reason for treatment switch/discontinuation~			
Inadequate response to treatment	59 (90.8)	14 (100.0)	29 (82.9)
Adverse event	2 (3.1)	0 (0.0)	1 (2.9)
Insurance coverage	1 (1.5)	0 (0.0)	1 (2.9)
Patient preference	2 (3.1)	0 (0.0)	1 (2.9)
Doctor preference	26 (40.0)	4 (28.6)	15 (42.9)
Side effect profile of biologic	1 (1.5)	0 (0.0)	0 (0.0)
Other	10 (15.4)	0 (0.0)	0 (0.0)
Abbreviations: IL = Interleukin; n = Number; TNF = Tumor necrosis factor			
[^] Patients may have had more than one reason for treatment choice or discontinuation or switch; number of reasons can be higher than number of patients receiving treatment.			
*Denominator: total number of patients receiving the treatment.			
~Denominator for this variable is number of patients who discontinued the biologics.			

Speed of treatment effect

Disease severity during follow-up was summarized (Fig. 1). At index, 7.2%, 20.9%, and 19.6% of patients had sPGA (0, 1), DLQI (0,1), and BSA $\leq$ 1%, respectively. By 1-month post-index (n = 136), 58.8% of patients achieved clear or almost clear skin (sPGA 0, 1), 29.4% clear skin (sPGA 0), 55.9% DLQI (0, 1) and 66.9% BSA $\leq$ 1%. The proportion of patients achieving sPGA (0, 1), DLQI (0, 1), and BSA $\leq$ 1% (NPF target) during follow-up are shown in Fig. 1. At 3-month post-index, nearly three-quarters (73.5%) of patients had sPGA (0, 1), while 68.4% had DLQI (0,1), and 86% had BSA $\leq$ 1%. The median change during 24 months post-index period was approximately 3% reduction for BSA, -3 points for sPGA, and -2 points for DLQI scores for the overall study cohort.

Subgroup analysis was done on early responders (defined as achieving sPGA 0, 1 at 1 month) and non-early responders (not achieving sPGA (0, 1) at 1 month). Among 135 patients with 1-month post-index sPGA data available, 59.2% (n = 80) of patients were early responders, among which 70% (n = 56) achieved DLQI (0, 1), and 85% (n = 68) achieved BSA $\leq$ 1%. Over 85%, 75%, and 65% of patients met the targets for BSA, sPGA, and DLQI, respectively, at all the time points after 1-month post-index among early-responders (Fig. 2). Among non-early responders (n = 55), 46.8%, 55.3%, and 74.5% of them achieved the targets for sPGA, DLQI, and BSA at 3-month post-index, respectively. The proportions remained largely the same for 24-month post-index (Fig. 2).

Additional subgroup analyses were done among biologic naïve patients and biologic experience patients prior to index date (Fig. 2). Of the 109 patients who received biologic treatments for psoriasis at any time prior to IXE initiation, 6.5% had sPGA (0, 1), 25.7% had DLQI (0, 1), and 22% had BSA $\leq$ 1% at IXE initiation. 95 patients in the biologic experienced group had data available at 1-month post-index, and 58.9% had sPGA (0, 1) including 28.4% with sPGA 0; 55.8% of the patients achieved DLQI (0, 1); and 66.3% achieved BSA $\leq$ 1%. At 3-month, the proportions of patients achieving sPGA, DLQI and BSA targets increased to 72.6% (52.6% patients had sPGA 0), 68.4%, and 83.2%, respectively. Of 44 biologic naïve patients, 41 patients had data available at 1- and 3-months post-index. The proportions of patients achieving sPGA, DLQI, and BSA targets were 58.5% and 75.7%, 68.3% and 75.7%, 68.3% and 92.7%, respectively at 1- and 3-months.

Long-term treatment effect

Disease severity and quality of life outcomes at 24-month post-index were available for 49 patients from the overall study cohort. Among the 49 patients, 75.5%, 69.4%, and 83.7% had treatment outcomes of sPGA (0, 1), DLQI (0,1), and BSA $\leq$ 1%, at 24-month post index respectively. Among early responders, 87.9% of patients had sPGA (0, 1), including 66.7% with sPGA 0; 75.8% patients had DLQI (0, 1); and 93.9% BSA $\leq$ 1% at 24 month.

Logistics regression model results showed that at 24 months post-index, early sPGA responders at 1-month not only had greater odds of achieving sPGA (0, 1) (OR = 10.1; 95% CI: 2.1–47.9; p-value = 0.003), but also greater odds of achieving BSA $\leq$ 1% (OR = 13.3; 95% CI: 2.2–80.2; p-value = 0.005) than non-early responders. No association was found for DLQI (0,1) at 24 months. Also, early sPGA responders were more likely to achieve the sPGA (0,1) outcome at 12 months than non-early responders (OR = 4.4; 95%CI: 1.7–11.1; p-value = 0.002, data not shown).

Discussion

This is the first observational study reporting 1- to 24-month real-world severity and quality of life outcomes following IXE initiation among patients with moderate-to-severe psoriasis in a US referral clinic. The current study showed that in the real-world setting, a high level of effectiveness can be observed as early as 1-month following IXE initiation and maintained for up to 24 months. We found that the majority of patients met the treatment targets of sPGA (0, 1), DLQI (0, 1) and BSA $\leq$ 1% at 1-month after initiating

IXE. Most patients not achieving sPGA (0, 1) after 1-month of IXE treatment were still able to achieve response of sPGA (0,1) by 3 months. Most of the study cohort were on a prior biologic before switching to IXE with mean treatment duration of 9.8 months (SD: 6.7 months). Despite inadequate response to previous biologics, more than half of patients achieved a rapid response at 1-month after IXE initiation, and the proportion of patients meeting treatment targets increased at 3-month and remained relatively stable onward.

The current study found that the majority of patients from the overall study cohort as well as in the subgroups of early responders and non-early responders all maintained high levels of responses of sPGA, DLQI, and BSA outcomes throughout the 24-month follow-up period. These findings were consistent with the 5-year results from the UNCOVER-1 and 2 studies, reported by Leonardi et al, in which clinical and quality of life responses of IXE were maintained throughout the 5-year period.(23, 24) Similar rapid response results were found in other real-world studies outside the US, where significant improvement in disease severity measured by PASI was observed at one-month after IXE initiation and continued to improve at 3-month and at 6-months.(9, 19)²⁸ In the current study, BSA percentage at IXE initiation and a rapid response to IXE at one month were found to be strongly associated with the 24-month IXE treatment outcomes in the study.

The key strength of the study was the availability of long-term clinical and DLQI data collection, which enables the investigation of long-term treatment outcomes, as well as the frequency of outcomes collected at each time point. In the current study, a third (n = 49) of the study cohort had 24-month post-index data, and treatment outcomes were collected at 1-month and as frequently as every 3 months during the first year following IXE initiation. This density of follow-up visits is not available from other real-world data sources. For example, the CORRONA registry, established in April 2015 to collect prospective real-world data on patients with autoimmune diseases, including those with psoriasis who are treated with biologic therapies in the US and Canada only collects data on clinical and patient reported outcomes (i.e. BSA, sPGA) at six-month intervals.(25) This makes it difficult to assess speed of treatment response. This single-arm retrospective chart review study was able to address this knowledge gap. Additionally, the outcomes reported in our study were measured by a single physician at study site which limit the inter-rater variations. Other strengths of this study include the use of a consecutive sampling approach based on treatment initiation date to reduce selection bias, and the unique study design that allows the collection of both pre-index data of up to 12 months and post-index data of up to 35 months. Such study design allows the exploration of treatment history and its impact on subsequent IXE treatment outcomes. The overall patient population and results in this study were consistent to clinical trials,(26) and the two real-world studies conducted in Europe and one in Canada which used PASI as disease severity measure.(9, 19)²⁸

There are several limitations to the current study. First, a single study site was chosen based on the availability of relevant data at the site, however, efforts were made to randomly select charts within the stratifications of interest, and the findings of this study are expected to reflect the real-world outcomes of the target patient population. Second, this study looked at cross-sectional clinical and HRQoL data at

each follow-up time point. Although the use of patient medical records offers many potential advantages over other data sources such as administrative data, in research studies that require detailed clinical information,(27) the use of retrospective data has the inherent limitation of having been collected for purposes independent of the study objectives. The level of detail available depends largely on the charting practices of the study site. For the changes in disease severity and HRQoL analysis performed in this study, only patients with available data at each study time point were used; therefore, the sample size declined over time due to infrequent clinic visits or losses to follow-up. The regression analyses performed in the study were unadjusted due to this sample size constraint, and further investigations on the strength of these results are needed in larger study populations.

In conclusion, the findings of the current real-world study support the speed of response and persistency of effect seen in IXE clinical trials.(23, 24) Results from this study demonstrated that the majority of patients achieved sPGA (0,1), DLQI (0,1) and BSA $\leq$ 1% targets within the first month of treatment which were also achieved at each follow-up time point up to 24 months. Findings from this study provide valuable information on speed of treatment response and long-term outcomes in IXE-treated psoriasis patients and in other subgroup populations.

List Of Abbreviations

Abbreviation	Full description
BSA	Body surface area
CM	Centimetre
eDCF	Electronic data collection form
DLQI	Dermatology Life Quality Index
HRQoL	Health-related quality of life
IL	Interleukin
IXE	Ixekizumab
NPF	National Psoriasis Foundation
sPGA	Static Physician Global Assessment
PASI	Psoriasis Area and Severity Index
TNF	Tumour necrosis factor

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from Advarra, Inc., prior to beginning data collection. A Waiver of informed consent was granted.

All analyses and reporting were carried out using de-identified data. This study adhered to the Guidelines for Good Pharmacoepidemiology Practices⁽²⁰⁾ as well as the Health Insurance Portability and Accountability Act (HIPAA) guidelines for protection of patient confidentiality.⁽²¹⁾

Consent for publication

Not applicable, the manuscript does not contain individual person's data

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

C. Leonardi has received honoraria from Eli Lilly for the following: Advisory Board, Speaker, and Consultant.

RT, SS, SW, SM are employees of ICON plc., a company contracted by Eli Lilly to conduct this study.

RB, BZ, and WNM are employees of Eli Lilly.

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Author's contributions

CL: conception of the study.

WNM, RT, SW: conception of the study, design of the study.

SS: Statistical analysis.

All authors involved in interpretation of data and critical revision of the work.

All authors read and approved the final manuscript.

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Figures

Figure 1

Figure 1

Percentage of patients achieving treatment targets during 24-month post-index, among overall study cohort (n=153)

Figure 2.

Figure 2

Percentage of patients achieving treatment targets during post-index among subgroups