Real-world effectiveness of ixekizumab in mild, moderate, and severe psoriasis: The patient perspective

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BACKGROUND

- Ixekizumab, a highly selective IL-17A monoclonal antibody, has been approved for the treatment of moderate to severe plaque psoriasis[1]
- There are limited real-world data available on patient-reported outcomes (PROs) shortly after ixekizumab initiation, particularly among patients with mild psoriasis
- Data collection from the US Ixekizumab Customer Support Program (CSP) aims to create a large, patient-reported US database to fill this information gap

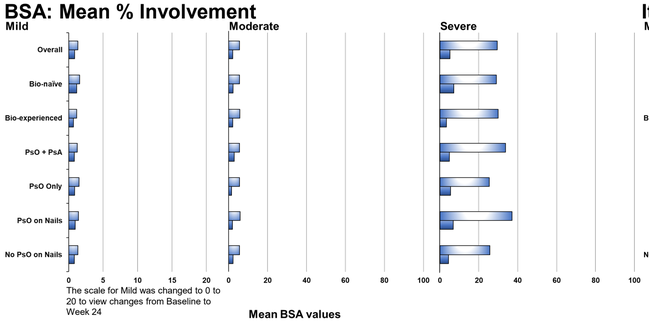
OBJECTIVE

- This analysis evaluated the real-world effectiveness of ixekizumab, as measured by PROs at baseline and Week 24 among patients with mild, moderate, or severe psoriasis who were enrolled in the Taltz CSP
  - We assessed the overall sample and selected subgroups of clinical interest

KEY RESULTS AT BASELINE AND WEEK 24

Baseline ■ Week 24 P < 0.001 for all within-group comparisons of responses at baseline and at Week 24

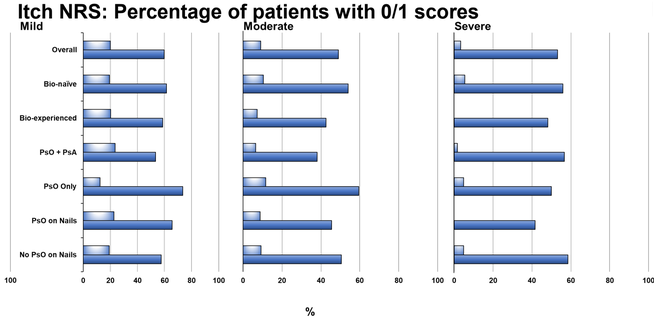
BSA: Mean % Involvement



The scale for Mild was changed to 0 to 20 to view changes from Baseline to Week 24

Mean BSA values

Itch NRS: Percentage of patients with 0/1 scores



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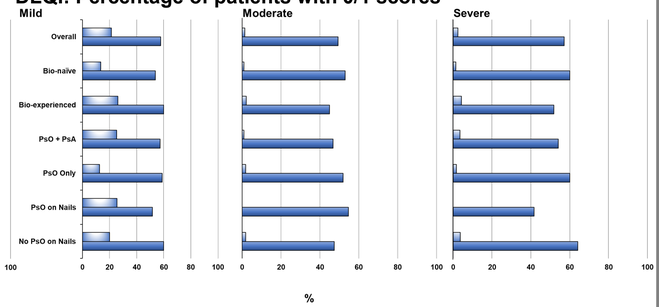
DLQI: Percentage of patients with 0/1 scores



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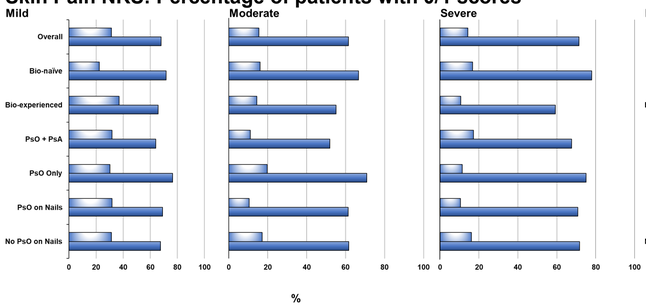
Skin Pain NRS: Percentage of patients with 0/1 scores



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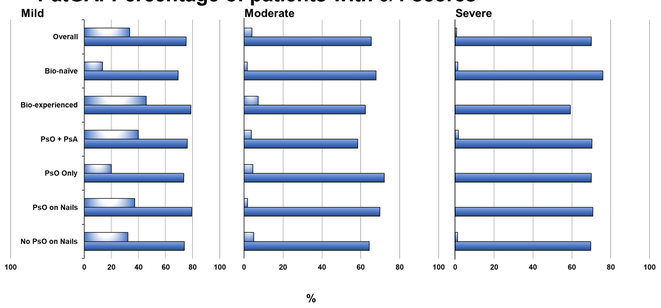
PatGA: Percentage of patients with 0/1 scores



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PROMIS Sleep-related Impairment Total Score*: Mean Values at Baseline and at Week 24

	Mild (N=180)		Moderate (N= 223)		Severe (N=120)	
	Baseline	Week 24	Baseline	Week 24	Baseline	Week 24
Overall	9.9	8.0	10.6	7.9	10.4	7.7
Bio-naïve	9.3	7.6	10.0	7.2	10.2	7.8
Bio-experienced	10.3	8.3	11.2	8.8	10.9	7.5
PsO + PsA	10.3	8.6	11.6	8.6	11.1	7.9
PsO Only	9.2	6.9	9.5	7.2	9.8	7.5
PsO on Nails	10.2	8.6	11.3	7.5	11.2	7.4
No PsO on Nails	9.9	7.8	10.3	8.1	10.1	7.8

*Measures self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours, and the perceived functional impairments during wakefulness associated with sleep problems/impaired alertness; 4 items on a scale from "not at all" (1) to "very much" (5)

DISCUSSION

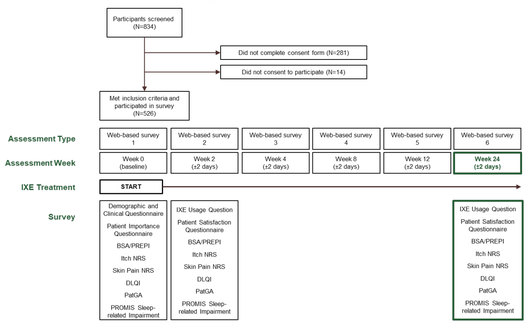
- Improvement in all outcome measures were observed by Week 24 across all severities of psoriasis
  - Similar improvements were observed across the subgroups: biologic use, PsA status, and PsO nail involvement at baseline
- With a real-world study population, factors influencing outcomes may include, but are not limited to, self-reported psoriasis, compliance with medications, and experience with biologics

CONCLUSIONS

- In a real-world setting, PRO improvements have been observed across all severities of psoriasis, with the greatest improvements observed in patients with severe psoriasis

METHODS

US Ixekizumab CSP Design



Key Eligibility Criteria

- Patients with psoriasis enrolled in the US Ixekizumab CSP
- ≥18 years of age
- Commercial insurance
- Initiated ixekizumab within 7 days of screening
- Device with access to the internet

Assessments

- Web-based questionnaires administered at baseline, Weeks 2, 4, 8, 12, and 24
  - **PREPI:** single question for estimating BSA involvement where palm of patient's hand equaled BSA 1%
  - **Itch NRS:** Scale from 0=no itch to 10=worst itch imaginable in the past 24 hours. Minimum clinically important difference: ≥4 points[2]
  - **Skin Pain NRS:** Scale from 0=no pain to 10=worst pain imaginable in the past 24 hours
  - **DLQI:** Scale of 0-30, with 0 to 1=no effect on patient's life over the past week
  - **PROMIS SF v1.0 Sleep-Related Impairment SF 4a:** Scale 4-20, with 1=not at all to 5=very much over the past 7 days
  - **PatGA:** Patients were asked to rank the severity of PsO over the previous day, on a scale of 0-5, with 0=clear and 5=severe
- Patients were divided into mild (BSA <3%), moderate (BSA 3-10%), or severe (BSA>10%)[3]

Statistical Analyses

- PROs were assessed through Week 24
  - Evaluated percentage of patients with 0 or 1 scores at baseline and at Week 24 for the DLQI, PatGA, Itch NRS, and Skin Pain NRS
- Descriptive analyses with observed data
- No data imputation was performed
- Data are reported for the overall study population and by bio-naïve and bio-experienced and by psoriatic arthritis subgroups
- Changes from baseline were evaluated with a mixed effects model
- P-values are for within-group comparisons of responses at baseline and at Week 24

Patient Demographics and Baseline Characteristics

	Psoriasis Severity		
	Mild (N=180)	Moderate (N= 223)	Severe (N=120)
Age, mean ± SD	49.4 ± 12.0	47.0 ± 12.0	45.7 ± 11.8
Women, n (%)	122 (68%)	139 (62%)	71 (59%)
White, n (%)	150 (83%)	197 (88%)	104 (87%)
BMI, kg/m², mean ± SD	30.7 ± 6.7	32.1 ± 8.0	34.0 ± 8.6
Duration from onset of psoriasis, months, mean ± SD	190.1 ± 172.2	185.3 ± 151.8	229.4 ± 184.1
Psoriasis locations, n (%)			
Scalp psoriasis	93 (52%)	135 (61%)	97 (81%)
Genital psoriasis	20 (11%)	50 (22%)	45 (38%)
Nail psoriasis	44 (24%)	57 (26%)	39 (33%)
Psoriatic arthritis, n (%)	120 (67%)	109 (49%)	58 (48%)
Bio-experienced (previous 2 years), n (%)	110 (61%)	97 (44%)	47 (39%)

ABBREVIATIONS

BMI=body mass index; BSA=body surface area; CSP=Customer Support Program; DLQI=Dermatology Life Quality Index; IXE=ixekizumab; NRS=numeric rating scale; PatGA=Patient's Global Assessment; PREPI=Patient-Reported Extent of Psoriasis Involvement; PROs=patient-reported outcomes; PROMIS=Patient-Reported Outcomes Measurement Information System; PsA=psoriatic arthritis; PsO=psoriasis; SD=standard deviation

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2. Kimball, et al. Br J Dermatol. 2016; 157-162
3. Armstrong, et al. JAMA Dermatol. 2013;149(10):1180–1185

DISCLOSURES

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