Psoriasis: Targets and Therapy

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ORIGINAL RESEARCH

Real-World Experience of Bimekizumab in a Cohort of 109 Patients Over 48 Weeks and Identification of Predictive Factors for an Early Super Response and Risk of Adverse Events

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Introduction: Psoriasis is a chronic inflammatory skin disease significantly impairing quality of life. The introduction of biologic therapies, such as bimekizumab—a monoclonal antibody targeting IL-17A and IL-17F—has revolutionized treatment outcomes. This study investigates the effectiveness of bimekizumab in a real-world setting, focusing on the predictors of Early Super Response (ESR), defined as achieving PASI 100 by week 4, and evaluates the safety profile over a 48-week follow-up period.

Methods: A retrospective study was conducted on 109 psoriasis patients treated with bimekizumab at two Italian dermatology centers. Of these, 61 patients completed a 48-weeks follow-up. Baseline clinical and demographic data, PASI scores at multiple time points, and adverse events were collected. ESR predictors were analyzed using univariate and multivariate logistic regression models. Safety was assessed using Cox proportional hazards models to find predictive factors associated with the risk of adverse events (AEs).

Results: At week 4, 28.4% of patients achieved PASI 100. Baseline PASI (OR: 0.93, p = 0.029), absence of nail involvement (OR: 0.12, p = 0.003), and fewer biologic failures (OR: 0.14, p = 0.038) were independently associated with ESR status. Safety analysis revealed that 15.6% of patients experienced adverse events, with asthma/allergic rhinitis significantly associated with a higher risk (HR: 6.43, p = 0.012). Candidiasis (7.3%) and eczema (4.6%) were the most common adverse events.

Conclusion: Bimekizumab demonstrated significant effectiveness and an acceptable safety profile in a real-world setting. Baseline PASI, nail involvement, and prior biologic failures influenced early treatment response. Identifying predictors of ESR and adverse events can guide personalized therapeutic approaches, optimizing outcomes for psoriasis patients.

Keywords: bimekizumab, safety, efficacy, super responder, asthma, nails

Introduction

Psoriasis is a chronic inflammatory skin disease affecting approximately 2–3% of the global population,[1] significantly impacting patients' quality of life.

Over time several biological therapies have emerged as promising treatment options, targeting those cytokines reputed to be key in the immunopathogenesis of psoriasis, namely Tumor Necrosis Factor alpha (TNF-a), Interleukin (IL)-23, IL-17A and IL-17F.

Bimekizumab, a selective monoclonal antibody targeting both IL-17A and IL-17F, has demonstrated promising results both in clinical trials[2] and in several real-world experiences,[3,4] with shares of patients reaching rapid complete clearance (Psoriasis Area Severity Index (PASI)-100 as soon as week 4) ranging between 32.4% and 43.3% according to some studies.[3–6]

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The constant and continuous improvements of biologics in achieving psoriasis clearance (in terms of PASI and percentages of involved Body Surface Area (BSA)) has led to the quest to identify a "super responder" (SR) profile that enables dermatologists to select those patients who will respond better to a specific biological therapy.

While there is currently no consensus on the definition of SR in psoriasis,[7] several studies have attempted to define a SR profile in several ways. While some studies have posed their focus on the achievement of a PASI100 or PASI90 response at week 12,[8] other studies have considered super responders those who achieved complete skin clearance by week 20[9] or by week 52.[10] Super response was defined as the achievement of PASI 100 at week 16 and its maintenance at week 28 in Mastorino et al.[11]

Hagino et al[12] evaluated super response to bimekizumab in a cohort of 56 patients defined as the share of patients achieving PASI100 response at week 16 (short-term SR) and at week 52 (long-term), finding that patients with lower baseline values of neutrophil-to-lymphocyte ratio (NLR), monocyte-to-lymphocyte ratio (MLR), systemic inflammatory response index (SIRI) might have better treatment responses to bimekizumab at week 16, while patients with lower baseline values of MLR and younger age might achieve better responses at week 52.

Some studies have demonstrated how the achievement of an early rapid improvement as soon as at week 4 can help identify those patients who will achieve a super response.[13,14] To the best of our knowledge no study has to date investigated the baseline characteristics of patients treated with bimekizumab achieving a complete clearance as soon as week 4, a response that we will define as "Early Super Response" (ESR).

This study aims to evaluate the effectiveness of bimekizumab in a cohort of 109 psoriatic patients followed up for 48 weeks and identify baseline clinical and demographic characteristics associated with ESR. We will also evaluate the safety by assessing adverse events (AEs) and analyze those clinical characteristics associated with a higher risk for adverse events.

Patients and Methods

This real-world retrospective study involved two dermatology outpatient clinics at affiliated university hospitals (Dermatology Clinic of the University Hospital of Udine and the Dermatology Department of the University Hospital of Brescia) in the period from April 2024 to December 2024.

Methods and Data Extraction from Patient Database

Eligible patients were adults (≥18 years old) with chronic plaque psoriasis who were commenced on treatment with bimekizumab between December 2022 and November 2024 in accordance with the Italian guidelines:[15] at baseline, they had either a psoriasis area and severity index (PASI) ≥10 or a PASI < 10 with the involvement of sensitive areas (including face, nails, palms/soles or genitals). Patients who had used concomitant systemic therapy for the treatment of psoriasis were excluded from the study.

The characteristics of all patients, including age, comorbidities, disease duration, previous treatments and PASI scores at each visit, were obtained from electronic medical records. At weeks 4, 16, 24, 36 and 48, the proportions of patients reaching a reduction of 75%, 90%, and 100% in PASI compared with baseline (PASI 75, PASI 90 and PASI 100, respectively) were recorded. We also analyzed the percentages of patients who achieved an absolute PASI of 2 or less at each visit. During each dermatological examination, patients were questioned about the onset of any adverse event (AE), including AEs leading to the discontinuation of bimekizumab.

Given the retrospective design of our study, not all visits were completed by all patients. Therefore, all data for follow-up visits they had yet to attend were deemed missing.

The study was conducted in accordance with the ethical standards established by the 1964 Declaration of Helsinki. Ethical approval was obtained from local Ethics Committee (Comitato Etico Territoriale Lombardia 6, protocol 4710). Written informed consent was obtained from all individual participants included in the study. All the participants gave their consent to the use of medical records for research purposes.

Definition of Early Super Responder and Non-Early-Super-Responders

There is no consensus on the definition of Early Super Responder (ESR) in psoriasis,[7] therefore, based on the relevant literature and our real-life experience, we define ESR as patients who achieved PASI 100 response at week 4. Non-Early Super Responder (N-ESR) is defined as all patients included in the study except for ESR.

Outcome Measures

Effectiveness was measured by assessing the share of patients reaching improvement of 75%, 90%, and 100% in PASI compared with baseline score (PASI75, PASI90, and PASI100, respectively) and reaching an absolute PASI < 2. Safety was measured assessing Adverse Events (AEs), including their type, week of onset and whether they led to therapy discontinuation.

Statistical Analysis

Continuous variables were reported using mean and standard deviation (SD), while categorical variables were presented as absolute numbers and frequencies. The effectiveness of bimekizumab in terms of achievement of PASI100 at week 4 (ESR status) was evaluated according to different variables, including age, body mass index (BMI), comorbidities, involvement of difficult to treat areas (scalp, palms/soles, genitals, nails) and previous exposure to biological treatments. Chi-square test and exact Fisher's test were used to analyze categorical variables, while Student's *t*-test and Mann–Whitney *U*-test were used for continuous data. The normality of the data was checked using the Shapiro–Wilk test. To investigate which variables were independent predictive of ESR status, multifactorial logistic regression analysis was performed on all variables with $p < 0.2$ in the univariate analysis. Odds ratios (ORs) and 95% confidence intervals (CIs) were reported. Model fit was assessed using residual deviance and Akaike Information Criterion (AIC).

Cox proportional hazards models were employed to determine the predictors of adverse events (AEs). Explanatory variables included gender, age, disease duration, psoriasis family history, age at diagnosis, involvement of difficult to treat areas, (scalp, genitals, palms/soles) BMI, presence of any comorbidity, number and type of comorbidities (hypertension, diabetes, obesity, chronic kidney disease, psychiatric disorders, asthma and/or allergic rhinitis, cardiac diseases, Gastroesophageal Reflux Disease (GERD) and/or chronic gastritis, thyroid diseases and dyslipidemia/hypercholesterolemia). Results were reported as Hazard Ratios (HRs) with 95% confidence intervals (95% CIs).

First, a Cox regression model was constructed from univariate analyses and then only those variables presenting $p<0.20$ and/or biologically plausible were included in two progressive multivariable regression (Table 1).

The proportional hazards assumption was tested using Schoenfeld residuals. Statistical significance was set at $p<0.05$. The discriminatory ability of the model was evaluated using the concordance index (C-index), while the overall fit of the model was assessed with the Likelihood Ratio Test.

Table 1 Multivariate Cox Regression Model Assessing Associations with Adverse Events (AEs)

Variable	Univariate Analysis		Adjusted Model 1*		Adjusted Model 2**	
	HR (95% C.I.)	P value	HR (95% C.I.)	P value	HR (95% C.I.)	P value
Gender (M)	1.08 (0.40–2.93)	0.873			0.75 (0.23–2.41)	0.626
BMI	0.98 (0.89–1.08)	0.752				
Age at diagnosis	1.00 (0.97–1.03)	0.804				
Age	1.01 (0.98–1.04)	0.533			1.01 (0.97–1.06)	0.629
Disease duration	1.04 (1.0–1.1)	0.078	1.01 (0.96–1.07)	0.694	1.01 (0.96–1.07)	0.703
Psoriasis family history	0.19 (0.04–0.83)	**0.028**	0.23 (0.05–1.09)	0.064	0.22 (0.05–1.10)	0.065
Psoriatic Arthritis	1.81 (0.69–4.76)	0.228				

(*Continued*)

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Table 1 (Continued).

Variable	Univariate Analysis		Adjusted Model 1*		Adjusted Model 2**	
	HR (95% C.I.)	P value	HR (95% C.I.)	P value	HR (95% C.I.)	P value
PsA duration	0.92 (0.75–1.12)	0.393				
Scalp involvement	1.34 (0.51–3.48)	0.544				
Genital involvement	0.28 (0.08–0.97)	**0.045**	0.37 (0.09–1.51)	0.166	0.41 (0.10–1.73)	0.222
Palmoplantar involvement	1.94 (0.68–5.53)	0.211				
Nail involvement	1.38 (0.53–3.57)	0.509				
Any comorbidity	0.55 (0.18–1.74)	0.313				
Number of comorbidities per patient	1.22 (0.87–1.73)	0.253			0.97 (0.62–1.51)	0.880
Hypertension	0.79 (0.28–2.25)	0.659				
Obesity	0.79 (0.28–2.25)	0.660				
Diabetes	0.66 (0.15–2.90)	0.586				
Chronic Kidney Disease	2.16 (0.62–7.53)	0.226			1.83 (0.35–9.55)	0.474
Any psychiatric disorder	2.76 (0.9–8.49)	0.076	4.46 (1.32–15.06)	**0.016**	3.53 (0.95–13.13)	0.060
Asthma and/or allergic rhinitis	3.77 (1.23–11.57)	**0.021**	4.63 (1.42–15.08)	**0.011**	6.43 (1.50–27.51)	**0.012**
Any cardiac disease	2.14 (0.49–9.36)	0.313				
GERD and/or chronic gastritis	0.71 (0.09–5.39)	0.744				
Any thyroid disease	2.10 (0.28–15.82)	0.473				
Dyslipidemia/ Hypercholesterolemia	0.38 (0.05–2.90)	0.353				

Notes: *Adjusted for variables with p<0.2 in the univariate analysis: Disease duration, Psoriasis family history, genital involvement, any psychiatric disorder, asthma/allergic rhinitis. **Adjusted for variables with p<0.2 in the univariate analysis and variables with known clinical significance: Disease duration, Psoriasis family history, genital involvement, any psychiatric disorder, asthma/allergic rhinitis, age, gender, chronic kidney disease, number of comorbidities. P-values in bold denote statistical significance ($p < 0.05$).
Abbreviations: C.I, Confidence Interval; HR, Hazard Ratio; BMI, Body Mass Index; GERD, Gastro Esophageal Reflux Disease.

Microsoft Excel was used for data collection, while GraphPad Prism version 10.0.0 for Mac OS (GraphPad Software, Boston, Massachusetts USA) was used to generate graphs. All analyses were performed using R Statistical Software (v4.1.2; R Core Team 2021).

Results

Clinical and Demographic Characteristics of the General Population

One hundred and nine patients were included in this study. Of these, 101 patients completed 16 weeks of treatment, while 95, 69 and 61 of them respectively reached 24, 36 and 48 weeks of follow up. Sixty-seven patients were male (61.5%), the mean age was 49.2 years, with a standard deviation (SD) of 14.4. Mean psoriasis duration was 13.9 years (SD 9.7). Mean BMI was 27.3 (SD 5.2) and 29.4% of our patients were obese (BMI $\geq$ 30). A concomitant diagnosis of Psoriatic Arthritis (PsA) was observed in 26.6% of patients, and 78% of all the patients were affected by at least one comorbidity, with 8.3% of patients being affected by four or more comorbidities. The most represented comorbidity was hypertension (30.3%), followed by obesity (29.4%) and diabetes mellitus (13.8%). More than one third of patients had never received a biologic therapy before starting bimekizumab (35.8%), while the most prescribed biologics in bio-experienced patients were adalimumab (46.8%) followed by secukinumab (17.4%), ixekizumab (13.8%) and guselkumab (11%). Forty patients (36.7%) had failed one biologic, while 20 (18.3%) had failed three or more biologics, with an average of 1.9

(SD 1.2) failures per patient. Eighty-two patients (75.2%) had involvement of one or more sensitive areas (scalp, genitals, palms and soles), while 43 (39.4%) suffered from nail psoriasis.

Additional data regarding the characteristics of our populations are summarized in Table 2.

Table 2 Summary of Demographic and Clinical Characteristics of Included Patients

Study Population	
Patients, n	109
Age, years	49.2 (± 14.4)
Sex, male	67 (61.5%)
Body Mass Index, kg/m^2	27.3 (± 5.2)
Psoriasis duration, years	13.9 (± 9.7)
Psoriasis family history, n (%)	40 (36.7%)
Psoriatic Arthritis, n (%)	29 (26.6%)
Psoriatic Arthritis duration, years	6.4 (± 5.4)
Involvement of difficult to treat areas, n (%) Scalp Genitals Palms and soles	82 (75.2%) 44 (40.4%) 40 (36.7%) 24 (22.0%)
Nail involvement, n (%)	43 (39.4%)
Patients with one or more comorbidities, n (%): Hypertension Obesity Diabetes Any Psychiatric Disorder* Dyslipidemia/Hypercholesterolemia Chronic Kidney Disease Asthma and/or allergic Rhinitis Any cardiac disease** GERD and/or chronic gastritis Thyroid disease***	85 (78%) 33 (30.3%) 32 (29.4%) 15 (13.8%) 14 (12.8%) 12 (11.0%) 9 (8.3%) 9 (8.3%) 7 (6.4%) 7 (6.4%) 4 (3.7%)
Patients with one comorbidity, n (%) Patients with two comorbidities, n (%) Patients with three comorbidities, n (%) Patients with 4 or more comorbidities, n (%) Comorbidities per patient, n (%)	41 (37.6%) 16 (14.7%) 19 (17.4%) 9 (8.3%) 1.6 ± 1.4
Previous systemic non-biologic treatments, n (%): Cyclosporin Methotrexate Phototherapy Acitretin Dimethyl fumarate Apremilast Leflunomide	 46 (42.2%) 38 (34.9%) 33 (30.3%) 17 (15.6%) 9 (8.3%) 3 (2.8%) 2 (1.8%)

(*Continued*)

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Table 2 (Continued).

Study Population	
Biologics:	
Naive	39 (35.8%)
Adalimumab	51 (46.8%)
Secukinumab	19 (17.4%)
Ixekizumab	15 (13.8%)
Guselkumab	12 (11.0%)
Ustekinumab	9 (8.3%)
Certolizumab	9 (8.3%)
Etanercept	5 (4.6%)
Risankizumab	3 (2.8%)
Brodalumab	2 (1.8%)
Upadacitinib	2 (1.8%)
Golimumab	1 (0.9%)
Infliximab	1 (0.9%)
Tildrakizumab	1 (0.9%)
Biologics failure, n (%):	
1 failure	40 (36.7%)
2 failures	9 (8.3%)
3+ failures	20 (18.3%)
Failures per patient, n ± SD:	1.9 (± 1.2)

Notes: *Including bipolar disorder, ADHD, anxious-depressive syndrome. **Including ischemic heart disease, atrial fibrillation, atrial flutter, heart failure. ***Including Hashimoto hypothyroidism and multinodular goiter.
Abbreviations: GERD, Gastro Esophageal Reflux Disease, SD, Standard Deviation.

Effectiveness of Bimekizumab

At baseline, the mean PASI was 14.3 (SD 9.5). During the treatment with bimekizumab, it decreased to 2.9 (SD 3.4) at week 4, 1.1 (SD 2.1) at week 16 and 0.7 (SD 1.6) after 24 weeks of treatment. Mean PASI was similar after 36 and 48 weeks of therapy, being 0.5 (SD 1.0) and 0.6 (SD 1.0) respectively. At week 4, 72.5% of the patients reached PASI 75, 40.4% PASI 90, 28.4% PASI 100 and 42.2% PASI ≤2. The effectiveness of bimekizumab was maintained throughout the study period, with 76.2%, 85.3%, 85.5% and 85.2% of patients reaching PASI 90 after 16, 24, 36 and 48 weeks of treatment, respectively. In the same time intervals 61.4%, 72.6%, 72.5% and 72.1% of patients reached PASI100. Additional data on the effectiveness of bimekizumab at each time point in terms of mean PASI, PASI 75/90/100 and PASI ≤2 are shown in Table 3 and Figure 1.

Table 3 PASI Improvements During the Treatment Period

	Mean PASI ± SD	PASI75, %	PASI90, %	PASI100, %	PASI<2, %
Baseline (n=109)	14.3 (± 9.5)	NA	NA	NA	NA
Week 4 (n=109)	2.9 (± 3.4)	72.5%	40.4%	28.4%	42.2%
Week 16 (n=101)	1.1 (± 2.1)	87.1%	76.2%	61.4%	77.2%
Week 24 (n=95)	0.7 (± 1.6)	93.7%	85.3%	72.6%	84.2%
Week 36 (n=69)	0.5 (± 1.0)	98.6%	85.5%	72.5%	85.5%
Week 48 (n=61)	0.6 (± 1.0)	96.7%	85.2%	72.1%	82.0%

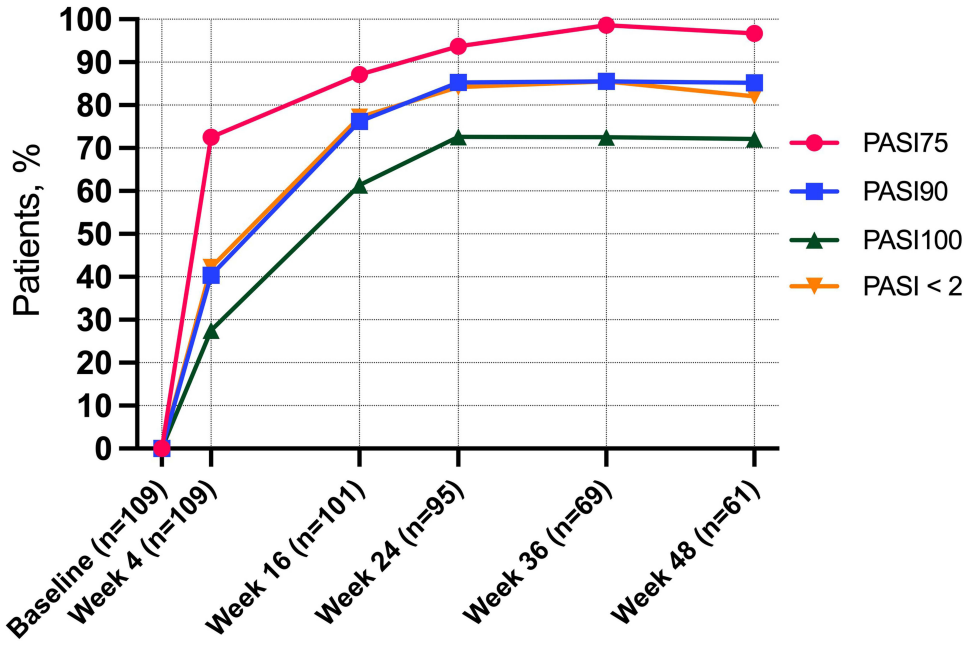

Figure 1 Percentage of patients achieving PASI75, PASI90, PASI100, and PASI <2 responses over time.
Note: The numbers in parentheses indicate the number of patients evaluated at each time point.
Abbreviation: PASI, Psoriasis Area and Severity Index.

Predictors of Early Super Response (PASI100 at week 4 of Treatment)

Univariate Analysis

The demographic and clinical characteristics at baseline of psoriasis cohort, classified according to their response to bimekizumab, are given in Table 4. Early Super Responders displayed lower baseline PASI (11.1 ± 8.0 vs 15.6 ± 8.2), a lower proportion of male patients (51.6% vs 65.4%), multifailures (6.5% vs 23.1%), mean biologic failures (1.4 ± 1.0 vs 2.1 ± 1.3), personal history of cardiac diseases (0% vs 9%), patients with scalp involvement (25.8% vs 46.2%), palmoplantar involvement (12.9% vs 25.6%) and nail involvement (16.1% vs 48.7%), although statistical significance could only be found in differences in baseline PASI (p=0.013) and nail involvement (p=0.003).

Table 4 Comparison of Baseline Characteristics of Early Super Responders and Not Early Super Responders and Multivariate Logistic Regression of Baseline Characteristics Associated with Early Super Responder Status

Variable	Univariate Analysis			Multivariate Analysis	
	Early Super Responder (n = 31)	Non-Early Super Responder (n = 78)	p	OR (95% C.I.)	p
Gender (M)	16 (51.6%)	51 (65.4%)	0.265		
BMI	27.1 ± 5.2	27.4 ± 5.2	0.747		
Age at diagnosis	34.7 ± 17.0	35.4 ± 15.3	0.842		
Age	48.6 ± 14.6	49.5 ± 14.4	0.778		
Disease duration	13.2 ± 9.8	14.2 ± 9.7	0.604		
Psoriasis family history	35.5%	37.2%	1		
Psoriatic Arthritis	19.4%	29.5%	0.401		
PsA duration	6.8 ± 5.3	6.3 ± 5.5	0.825		

(*Continued*)

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Table 4 (Continued).

Variable	Univariate Analysis			Multivariate Analysis	
	Early Super Responder (n = 31)	Non-Early Super Responder (n = 78)	p	OR (95% C.I.)	p
Baseline PASI	11.1 ± 8.0	15.6 ± 8.2	**0.013**	0.93 (0.863–0.987)	**0.029**
Bio-naïve	10 (32.3%)	29 (37.2%)	0.793		
Multifailure (3+ failed biologics)	2 (6.5%)	18 (23.1%)	0.080	0.14 (0.016–0.779)	**0.038**
Number of failed biologics per patient	1.4 ± 1.0	2.1 ± 1.3	0.210		
Scalp involvement	25.8%	46.2%	0.082	0.36 (0.092–1.255)	0.118
Genital involvement	41.9%	34.6%	0.621		
Palmoplantar involvement	12.9%	25.6%	0.233		
Nail involvement	16.1%	48.7%	**0.003**	0.12 (0.024–0.448)	**0.003**
Previous secukinumab	4 (12.9%)	15 (19.2%)	0.613		
Previous ixekizumab	2 (6.5%)	13 (16.7%)	0.224		
Previous brodalumab	0 (0%)	2 (2.6%)	1		
Previous failure to any IL-17 inhibitor	6 (19.4%)	21 (26.9%)	0.478		
Previous guselkumab	2 (6.5%)	10 (12.8%)	0.503		
Previous risankizumab	0 (0%)	3 (3.8%)	0.557		
Previous tildrakizumab	0 (0%)	1 (1.3%)	1		
Previous failure to any IL-23p19 inhibitor	2 (6.5%)	12 (15.4%)	0.342		
Any comorbidity	23 (74.2%)	61 (78.2%)	0.844		
Number of comorbidities per patient	1.4 ± 1.3	1.6 ± 1.4	0.361		
Hypertension	8 (25.8%)	25 (32.1%)	0.683		
Obesity	10 (32.2%)	22 (28.2%)	0.852		
Diabetes	5 (16.1%)	10 (12.8%)	0.759		
Chronic Kidney Disease	2 (6.5%)	7 (9.0%)	1		
Any psychiatric disorder*	2 (6.5%)	12 (15,4%)	0.342		
Asthma and/or allergic rhinitis	2 (6.5%)	7 (9.0%)	1		
Any cardiac disease**	0 (0.0%)	7 (9.0%)	0.188	NA (NA–6.51 × 10^{72})	0.993
GERD and/or chronic gastritis	2 (6.5%)	3 (3.8%)	1		
Any thyroid disease***	1 (0.9%)	3 (3.8%)	1		
Dyslipidemia/ Hypercholesterolemia	5 (16.1%)	7 (9.0%)	0.316		

Notes: *Including bipolar disorder, **Including ischemic heart disease, atrial fibrillation, atrial flutter, heart failure. ***Including Hashimoto hypothyroidism and multinodular goiter. P-values in bold denote statistical significance ($p < 0.05$).
Abbreviations: OR, Odds Ratio; BMI, Body Mass Index; GERD, Gastro Esophageal Reflux Disease; ADHD, anxious-depressive syndrome.

Multivariate Analysis

Multivariate logistic regression analysis was performed to identify baseline factors independently associated with being an Early Super Responder. Variables with $p<0.2$ in the univariate analysis were included in the multivariate analysis. The final model showed good fit, adequately capturing the data structure as reflected by a residual deviance of 70.28 on 69 degrees of freedom and an AIC of 82.28. All results are shown in Table 4.

Nail involvement (OR: 0.12, 95% CI: 0.024–0.448, p = 0.003), multifailure (OR: 0.14, 95% CI: 0.016–0.779, p = 0.038), and baseline PASI score (OR: 0.93 per unit increase, 95% CI: 0.863–0.987, p = 0.029) were significantly associated with a reduced probability of being an Early Super Responder. Scalp involvement (OR: 0.36, 95% CI: 0.092–1.255, p = 0.118) and cardiac disease (OR: 6.99×10^{-8}, 95% CI: NA–6.51×10^{72}, p = 0.993) did not show significant associations in the adjusted model.

Safety of Bimekizumab and Causes of Treatment Discontinuation

A total of 17 patients (15.6%) experienced an AE. Of these, the most frequent AE was Candida infection (8 patients, 7.3%) followed by onset of eczematous lesions (5 patients, 4.6%), diarrhea (2 patients, 1.8%) and urinary tract infection (2 patients, 1.8%). One of the latter patients had a history of recurrent urinary tract infections before starting bimekizumab and was hospitalized at week 13 of treatment due to the development of sepsis. Another patient experienced an episode of pneumonia evolving in sepsis 40 weeks after starting bimekizumab, which was suspended and then resumed after resolution of the infection. Both patients recovered with appropriate medical therapy.

Adverse Events presented on average at week 18 of treatment, with Candida infections manifesting on average at week 20 and eczemas presenting on average at week 18.

Treatment was discontinued in 12 patients (11.0%). Four patients discontinued bimekizumab due to primary inefficacy on skin (3 patients) or on psoriatic arthritis (1 patient). Eight patients discontinued bimekizumab after the onset of candida infection (2 patients), eczematous lesions (2 patients), acute urticaria (1 patient), liver enzymes elevation (1 patient), diarrhea (1 patient) and urosepsis (1 patient). In the latter case, treatment was discontinued as a precautionary measure due to the personal history of recurrent UTIs. Additional data regarding the observed AEs and causes of discontinuation are summarized in Table 5.

Table 5 Adverse Events Observed During the Treatment Period

Adverse Events, n (%):	**Total: 17 (15.6%)**	**Week of onset, mean: 18.4 ± 11.8**
Candidiasis Oral Axillary	8 (7.3%) 7 (6.4%) 1 (0.9%)	20.6 ± 11.7
Eczema	5 (4.6%)	18.0 ± 7.6
Diarrhea	2 (1.8%)	7 ± 8.5
Urinary Tract Infection Complicated with Sepsis No Sepsis	2 (1.8%) 1 (0.9%) 1 (0.9%)	12.5 ± 0.7
Pneumonia with evolution to sepsis	1 (0.9%)	40
Urticaria	1 (0.9%)	4
Recurrent aphthosis	1 (0.9%)	16
Liver enzymes elevation	1 (0.9%)	27

(*Continued*)

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Table 5 (Continued).

Adverse Events, n (%):	**Total: 17 (15.6%)**	**Week of onset, mean: 18.4 ± 11.8**
Causes of discontinuation, n (%):	12 (11.0%)	
Primary Inefficacy:	4 (3.7%)	
Cutaneous	3 (2.8%)	
Articular	1 (0.9%)	
Adverse Events:	8 (7.3%)	
Candidiasis	2 (1.8%)	
Eczema	2 (1.8%)	
Urticaria	1 (0.9%)	
Liver Enzymes Elevation	1 (0.9%)	
Diarrhea	1 (0.9%)	
Urosepsis	1 (0.9%)	

Predictors of AEs During Bimekizumab Treatment

The univariable Cox regression analyses (Table 1) showed that the only baseline variable significantly associated with a higher risk of incident AEs during bimekizumab treatment was asthma and/or allergic rhinitis (HR 3.77, 95% CI 1.23–11.57), while psoriasis family history (HR 0.19, 95% CI 0.04–0.83) and genital involvement (HR 0.28, 95% CI 0.08–0.97) were significantly associated with a lower risk of incident AEs.

The aforementioned significant variables were included in two progressive multivariable Cox regression models, as shown in Table 1.

Asthma and/or allergic rhinitis remained significantly associated with a higher risk of AEs after adjustment for disease duration, psoriasis family history, genital involvement, personal history of psychiatric disorders (HR 4.63, 95% CI 1.42–15.08) and even after additional adjustment for age, gender, number of comorbidities and chronic kidney disease (HR 6.43, 95% CI 1.50–27.51). Personal history of psychiatric disorders was significantly associated with a higher risk of AEs in model 1 (p=0.016) but not in model 2 (p=0.06). A detailed comparison of the clinical and demographic characteristics between subjects who experienced adverse events (AEs) and those who did not is provided in the Supplementary Material.

Discussion

Effectiveness and Safety Comparison with Other Real-Life Studies

While several real-world experiences on bimekizumab use in the short term have been published,[3,6,16] long term real-life data on bimekizumab treatment are currently limited. Compared with PASI responses reported by Rompoti et al[6] and Rimke et al[17] we observed similar results at week 4 and week 16, while we observed slightly inferior results in the same time points in comparison with what was reported by Gargiulo et al.[3] In the latter study, however, a higher share of patients were bio-naïve (56.5%), and a lower share of patients had involvement of difficult to treat areas (61.6%). In the long term, our results at week 48 were almost identical to PASI 75, PASI 90 and PASI 100 responses at week 52 reported by Sood et al,[4] Hagino et al[12] and Potestio et al.[18]

Hagino et al[19] also reported data about the effectiveness of bimekizumab on nails, scalp and genital psoriasis, showing that 74.3%, 96.7% and 97.1% of patients reached a Physician Global Assessment (PGA) of 0/1 respectively on the nail, genital and scalp domains. Similar results were observed by Bettolini et al[20] and Campione et al.[21]

Regarding safety, we observed a total of 17 patients (15.6%) experiencing AEs, in line with what was reported by Sood et al[4] and Potestio et al[18] over an observation period of 52 weeks.

In the aforementioned studies, candidiasis was observed respectively in 5.7% and 9.3% patients, similarly to what we reported, while eczema occurred in a higher proportion of patients, namely 10.7% and 7% respectively. In the same observation period Hagino et al[12] reported higher rates of treatment-emergent adverse events (62.5%) and specifically of

candidiasis and eczema (10.7% in both cases). The heterogeneity in the baseline clinical characteristics of the patients analyzed in these studies might explain part of the differences observed in the AEs rates.

Early Super Response

We assessed which baseline clinical and demographic characteristics might affect the achievement of PASI 100 response at week 4 during treatment with bimekizumab. Using a univariate logistic regression to analyze the characteristics considered to be the most clinically relevant, we showed that nail involvement and a higher baseline PASI were significantly associated with lower odds of achieving complete clearance by week 4, while scalp involvement and having failed three or more biologics showed a tendency towards association with the Non-Early Super Response, without reaching statistical significance ($p > 0.05$). After multivariate logistic regression three independent variables emerged as significantly associated with lower odds of achieving complete clearance by week 4: higher baseline PASI, nail involvement and having failed three or more biologics. To the best of our knowledge, no study to date has analyzed which baseline characteristics influence treatment response at week 4 to any biological therapy, thus a direct comparison with other studies assessing factors associated with the super responder status to other IL-inhibitors cannot be performed. However, baseline PASI and multifailure status (patients who have failed 3 or more biologics) had already emerged as factors influencing treatment response in other studies.[22–24]

Furthermore, while other studies on other biologics reported significant differences in treatment responses between patients exposed to different IL-inhibitors,[25] this finding was not confirmed in our experience, since differences in failures to the aforementioned drug class did not show any statistical significance.

A few studies have investigated the impact of nail psoriasis on the achievement of efficacy outcomes during biologic therapy. In a cohort of patients treated either with adalimumab, etanercept, infliximab or ustekinumab Bardazzi et al[26] showed that patients with nail psoriasis reach PASI 75 more slowly than patients without nail involvement. Similar results were reported by Thaçi et al[27] who observed lower shares of patients with nail psoriasis achieving PASI 75 in the first 8 weeks of treatment with adalimumab, but no significant differences compared to patients without nail involvement after week 12. Conrad et al[28] observed different responses in two patients groups being treated with either ustekinumab or secukinumab depending on their nail status, finding slower treatment responses at week 16 and 52 among patients with nail psoriasis in the ustekinumab group, and only less pronounced differences in reaching PASI = 0 in the secukinumab group. However, no statistical analysis was performed in that study due to its exploratory nature. Finally, Rich et al[29] did not find any significant negative impact of nail psoriasis on treatment outcomes in patients treated with ixekizumab.

Providing a biological rationale for why nail involvement negatively affects PASI responses poses some challenges. Genetics might play a role, as nail psoriasis has been found to be less associated with the HLA-Cw*06:02 allele and more with HLA B27, HLA DR07.[30–32] Several studies have investigated the association of the HLA-Cw*06:02 allele to treatment responses to different biologics. Interestingly, presence of HLA-Cw*06:02 allele was found to be associated to better responses to Ustekinumab[33,34] and Secukinumab[35,36] compared to its absence, while negative HLA-Cw*06:02 status was associated to better responses to adalimumab,[33] suggesting differences in the signaling pathways downstream TNF-α among carriers and non-carriers of the allele.

Risk of AEs

The main clinical and demographic characteristic we found to be associated with the risk of developing AEs is a personal history of asthma and/or allergic rhinitis. This finding comes as no surprise when new onset eczemas are considered (three out of five eczema cases in our cohort had a reported personal history of asthma and/or allergic rhinitis), as this comorbidity had already been described as the main risk factor for the development of eczemas under IL-17 inhibitor therapies.[37] Finding an explanation to why such therapies induce eczemas is not straightforward. While a large body of literature has provided evidences on the mechanisms underlying the bilateral plasticity along the Th1/Th17 axis[38] and on the unilateral Th2-to-Th17 plasticity,[39] fewer proofs exist on the mechanisms that might drive the transition from the Th17 to the Th2 polarization.[40,41] The existence of a subset of Th17/Th2 cells capable of producing both IL-17A and IL-4[42,43] might in part explain this phenomenon.

The association of asthma with oral candidiasis can be easily explained with the use of inhalatory corticosteroids (ICS),[44] that can induce a local immunosuppression leading to the proliferation of *Candida spp*, especially in an individual undergoing IL-17A/F inhibition, two cytokines well known to be involved in anti-fungal responses.[45] Furthermore, the Th2 polarization typical of atopic subjects might potentially impair anti-fungal responses via down-regulation of Th17 axis by IL-4,[39] contributing to the proliferation of *Candida spp*. in patients with allergic asthma.

Interestingly, while another report found an incidence of 40% of AEs in a cohort of patients with chronic kidney disease,[46] this clinical characteristic did not emerge as an independent risk factor for the development of AEs (see Table 1).

The finding that a family history of psoriasis and genital involvement were protective factors against the development of adverse events in the univariate analysis was not confirmed in the multivariable models. While it could be speculated that patients with these characteristics exhibit a more stable Th1/Th17 polarization, which may prevent a shift towards a Th2-driven immune response or enable a more effective defense against *Candida* spp. infection even under IL-17A/F inhibition, these results should be interpreted with caution.

Limitations

The main limitations of the present study are inherent to its retrospective nature and the small sample size. Furthermore, non-dermatological medication history was not recorded in the data analyzed, which might have potentially played a role in treatment effectiveness and AEs onset.

Conclusions

Our study confirms the effectiveness and safety profile of bimekizumab in a real-world setting. Achieving complete clearance at week 4 was negatively influenced by nail involvement, higher baseline PASI, and prior failure of three or more biologics. Additionally, patients with a personal history of atopic diathesis exhibited a higher risk of developing adverse events during the treatment period. This study expands the current understanding of bimekizumab use in clinical practice by aiding clinicians in identifying patients likely to achieve faster PASI responses and mitigating the risk of adverse events through careful patient selection based on individual risk factors.

Data Sharing Statement

All the data are contained in the manuscript.

Consent Statement

Consent to Publication form has been signed by the patients included in this study.

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Disclosure

The authors report no conflicts of interest in this work.

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