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Predictive factors for early super response to bimekizumab in 341 patients with psoriasis—a 24-week short-term multicenter real-life experience

Tubanur Çetinarslan[a], Muhammed Ali Mergen[a], Aylin Türel Ermertcan[a], Emel Bülbül Başkan[b], Serkan Yazıcı[b], İsa An[c], Gülhan Gürel[d], Esra Adışen[e], Abdullah Demirbaş[f], Recep Dursun[g], Bahadır Aslancan[c], Zeynep Topkarcı[h], Mustafa Esen[i], Zafer Türkoğlu[j], Dilek Canat[j], Selim Kandiş[j], Arzu Kılıç[k], İlgen Ertam Sağduyu[l], Elif Irmak Yazıcı[m], Ece Gökyayla[n], Neslihan Demirel Öğüt[o], Özge Sevil Karstarlı Bakay[p], Selami Aykut Temiz[g], Vefa Aslı Erdemir[q], Fatma Aslı Hapa[r], Ömer Aydin[r], Pelin Hızlı[k], Berna Solak[s], Melike Bütüner[p], Sema Aytekin[t], Hülya Albayrak[t], Munise Daye[g], Ümit Türsen[u], Ayşe Nur Sarıbaş Yıldırım[u] and Beyhan Cengiz Özyurt[v]

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ABSTRACT

Purpose/Aim of the study: The efficacy of bimekizumab was shown in moderate to severe plaque psoriasis. The aim of this study was to investigate the early super responder (ESR) profile (at week 4) to bimekizumab.

Materials and Methods: We performed a multicenter retrospective study in 20 Dermatology outpatient clinics in Turkey. Adult patients with moderate-to-severe psoriasis who were under bimekizumab for at least 12 weeks were enrolled.

Results: A total of 341 adult patients were included. 136 had nail psoriasis (39.9%), 148 had psoriatic arthritis (PsA) (43.4%), 223 (65.4%) had at least one difficult-to-treat area involvement, 155 (45.5%) were bio-naïve, 110 (32.5%) had ≥ 2 biologics history. At week 4, PASI75 was achieved in 144 patients (49.8%), PASI90 was achieved in 88 patients (30.4%), PASI100 was achieved in 51 patients (17.6%). Family history ($p=0.041$), palmoplantar involvement ($p=0.008$), PsA ($p=0.097$), and bio-experienced status ($p=0.060$) were associated with lower odds of being an ESR, whereas each 1-point increase in baseline PASI was associated with significantly lower odds of ESR ($p<0.001$). Gender, age, disease duration, history of conventional systemic treatment, and presence of any comorbidity were not significantly associated with the likelihood of being an ESR (all $p>0.05$).

Conclusion: Bimekizumab is the effective treatment in both bio-naïve and bio-experienced patients; however, it may have a more rapid onset of action in bionaive patients. Further studies are needed on the long-term efficacy and safety data of bimekizumab.

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KEYWORDS
Psoriasis; bimekizumab; super responder; biologics; candidiasis

Introduction

Psoriasis is chronic, inflammatory skin disease characterized by well-bordered erythematous papules and plaques covered with silvery-white scales (1). Patients with psoriasis are at increased risk for comorbidities including psoriatic arthritis (PsA), inflammatory bowel disease, metabolic syndrome, hypertension, and depression, all of which significantly reduce the quality of life of patients (2).

Biologics are effective way to treat psoriasis when topical agents and systemic conventionals fail to respond and/or in case of contra-indication or not tolerated. The efficacy and safety of bimekizumab, which shows dual inhibition of IL-17A and IL-17F, have been shown in several clinical trials (3–6), however, there is still limited data on the characteristics of super responders (SR) to bimekizumab. The aim of this study is to describe the factors affecting the clinical response and early SR (ESR) profile (at week 4) to bimekizumab.

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Materials and method

Study design and patient eligibility criteria

A retrospective multicenter study was conducted between May 2025 and July 2025, in 20 Dermatology outpatient clinics in Turkey. To ensure consistency across the 20 centers, a standardized electronic case report form with predefined variable definitions was used. Investigators were provided with detailed guidance for data entry, and the coordinating center performed regular data checks to detect inconsistencies. In cases where clarification was required, local investigators were contacted to confirm or correct the information. While these procedures minimized heterogeneity and strengthened data reliability.

Patients aged ≥ 18 years, with moderate-to-severe psoriasis who were under bimekizumab for at least 12 weeks were enrolled. Patients who had not reached 12 weeks of follow-up were excluded.

The study protocol was approved by Medical Sciences Ethics Committee of Manisa Celal Bayar University (approval date 25/06/2025/20.478.486/3245). Informed consent was taken from all the participants to the use of medical records for research purposes.

Settings

Two subcutaneous injections of 160 mg bimekizumab, for a total of 320 mg, were administered at week 0, 4, 8, 12, 16 and every 8 weeks thereafter.

Patient demographics

Patients' age, gender, body mass index (BMI), duration of psoriasis, family history of psoriasis, clinical type of psoriasis, presence of specific area involvement, presence of nail psoriasis, presence of PsA, presence of comorbid diseases, and previous treatments, were recorded.

At baseline, the laboratory tests including QuantiFERON or tuberculin skin test (PPD), HIV, hepatitis B and C, were investigated.

Treatment effectiveness outcomes

Effectiveness outcomes, including Psoriasis Area and Severity Index (PASI) and Physician Global Assessment (PGA), were used.

PGA, PASI75, PASI90 and PASI100 responses were evaluated (at baseline, at week 4, 8, 12, 16 and 24), and adverse events (AEs), if any, were also investigated.

Primary failure was defined as failure to reach PASI50 at 8/12 weeks and secondary failure was defined as the loss of PASI50 response that reached by the 8th/12th weeks.

Results

Descriptive clinical characteristics

A total of 341 patients (189 males, 152 females) were included. Baseline demographics and clinical characteristics are summarized in Table 1. Most patients (317; 93%) presented with plaque psoriasis. Difficult-to-treat areas were observed in 223 patients (65.4%), including scalp (164; 48.1%), genital (81; 23.8%), palmoplantar (74; 21.7%), and face (31; 9.1%). Four patients had malignancy history (CIN1, colon cancer, papillary thyroid carcinoma in 2).

Prior to bimekizumab, 316 patients (92.7%) had received conventional systemic agents (methotrexate 292, acitretin 93, cyclosporine 83, phototherapy 58). Overall, 155 (45.5%) were bio-naïve and 186 (54.5%) bio-experienced (anti-TNFα 95; anti-IL-12/23 45; anti-IL-17 131; anti-IL-23 60); 110 of 186 had ≥2 biologics exposure. One patient tested positive for hepatitis B and two for HIV; appropriate treatments were initiated after Infectious disease consultation.

The QuantiFERON test was positive in 48 patients (20.6%). PPD was performed in 78 (22.9%). None with positive QuantiFERON or PPD showed radiological evidence of active tuberculosis; all received three-month isoniazid prophylaxis after Pulmonology consultation before bimekizumab.

Efficacy of bimekizumab

Mean baseline PASI was 15.03 ± 7.47 (14.33 ± 7.47 in females; 15.59 ± 7.43 in males). Moderate-to-severe disease (PASI ≥ 10) was present in 273 patients (80.1%). PASI improvements are shown in Figures 1 and 2, and Table 2. At baseline, PGA scores were: 0 in 14 patients (5.5%); 1 in 17 (6.6%); 2 in 41 (16%); 3 in 102 (39.8%); and 4 in 82 (32%) (Figure 3).

Table 1. Baseline demographics and clinical characteristics of patients with psoriasis under bimekizumab treatment.

Characteristic	*N* = 341 *n* (%)/mean ± SD
Male	189 (55.4)
Age (years)	45.26 ± 13.28
Geriatric patients	30 (8.8)
Disease duration (years)	14.55 ± 9.98
BMI (kg/m^2)	27.4 ± 4.73
Family history	91 (30.3)
Nail involvement	136 (39.9)
≥1 Difficult-to-treat areas	223 (65.4)
Psoriatic arthritis	148 (43.4)
Bio-experienced	186 (54.5)
≥2 Previous biologics	110 (32.3)
Previous anti-TNF	95 (27.9)
Previous anti-IL-12/23	45 (13.2)
Previous anti-IL-17	131 (38.4)
Previous anti-IL-23	60 (17.6)
Previous apremilast	12 (3.5)
Obese	76 (25.6)
Diabetes	60 (17.6)
Hypertension	68 (19.9)
Hyperlipidemia	33 (9.7)
Thyroid disease	10 (2.9)
Oncological disease	4 (1.2)
Cardiovascular disease	17 (4.9)
Other comorbidities	62 (18.1)
PASI at baseline	15.03 ± 7.47
NAPSI at baseline	19.83 ± 18.55
DLQI at baseline	16.27 ± 7.46

BMI: Body Mass Index; PASI: Psoriasis Area and Severity Index; NAPSI: Nail Psoriasis Severity Index; DLQI: Dermatology Life Quality Index.

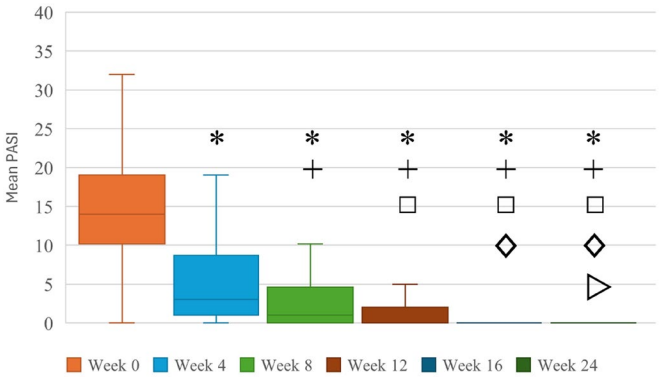

Figure 1. The reduction of mean PASI scores during bimekizumab treatment. The reduction of mean PASI scores. *$p < 0.01$ versus values of week 0; +$p < 0.01$ versus values of week 4; □$p < 0.01$ versus values of week 8; ◊$p < 0.01$ versus values of week 12; ▷$p < 0.01$ versus values of week 16, assessed by Wilcoxon Signed Ranks Test. PASI: Psoriasis Area and Severity Index.

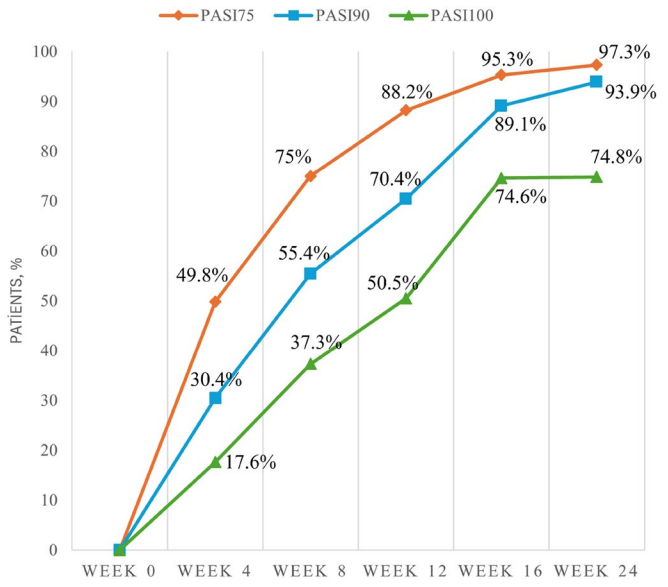

Figure 2. PASI improvements during bimekizumab treatment. PASI: Psoriasis Area and Severity Index.

Table 2. PASI improvements during bimekizumab treatment.

	Mean PASI ± SD	PASI75, %	PASI90, %	PASI100, %
Week 0 (n = 341)	15.03 ± 7.47	NA	NA	NA
Week 4 (n = 289)	5.14 ± 5.28	49.8%	30.4%	17.6%
Week 8 (n = 276)	2.63 ± 3.76	75%	55.4%	37.3%
Week 12 (n = 272)	1.34 ± 2.36	88.2%	72.4%	50.5%
Week 16 (n = 211)	0.47 ± 1.54	95.3%	89.1%	74.6%
Week 24 (n = 147)	0.23 ± 0.57	97.3%	93.9%	74.8%

PASI: Psoriasis Area and Severity Index.

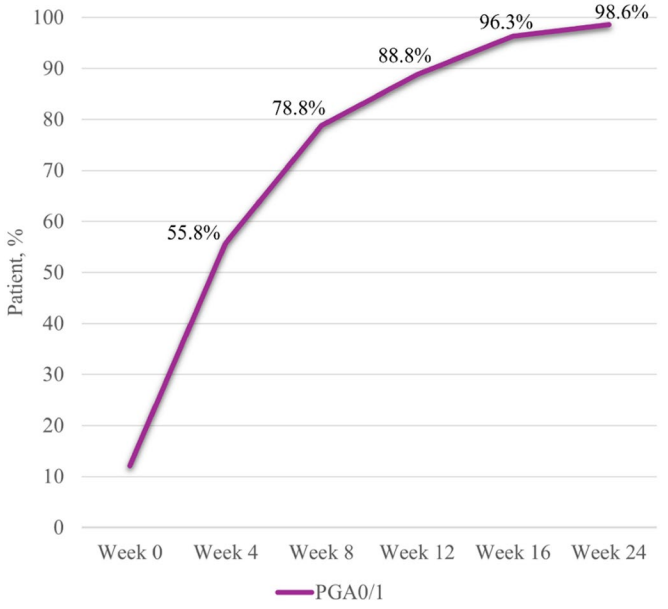

Figure 3. PGA 0/1 responses during bimekizumab treatment. PGA: Physician Global Assessment.

Seven patients did not achieve PASI50 at week 12; 4 of 12 patients continued treatment. One reached PASI50 at week 16 (scalp/nail involvement + PsA) and another PASI100 at week 24 (palmoplantar involvement, ≥2 prior biologic history). Two patients with PsA achieved PGA 0/1 despite not reaching PASI50 and were not considered primary failure. Treatment was discontinued in three patients due to primary failure.

Predictors of early super response (PASI100 response at week 4)

Univariate logistic regression compared baseline characteristics of ESR and non-ESR patients (Table 3). Higher baseline PASI ($p = 0 < 001$), female gender ($p = 0.422$), family history ($p = 0.014$), ≥1 difficult-to-treat areas involvement ($p = 0.158$), palmoplantar involvement ($p = 0.052$), PsA ($p = 0.152$), bio-experienced status ($p = 0.066$), ≥2 previous biologic failures ($p = 0.002$), anti-TNFα ($p = 0.015$), anti-IL-17 ($p = 0.005$) and anti-IL-23 failures ($p = 0.09$) were associated with reduced probability of being an ESR.

Multivariate logistic regression included variables with $p < 0.20$ after collinearity checks. The final model showed good fit (Nagelkerke $R^2 = 0.274$; −2LL = 213.545; Hosmer–Lemeshow $\chi^2(8) = 6.045$, $p = 0.642$). Family history (OR = 0.41, 95% CI 0.17–0.97, $p = 0.041$), palmoplantar involvement (OR = 0.29, 95% CI 0.12–0.72, $p = 0.008$), PsA (OR = 0.55, $p = 0.097$) and bio-experienced status (OR = 0.51, $p = 0.060$) were linked to lower odds of ESR. Each 1-point PASI increase significantly reduced ESR likelihood (OR = 0.86, 95% CI 0.81–0.91, $p < 0.001$).

Factors affecting PASI75-90-100 responses at week 4 and 24

At week 4, bio-naïve patients achieved higher PASI75 and PASI90 than bio-experienced (61.8% vs 39.2%, $p < 0.001$; 37.5% vs 24.2%, $p = 0.014$), while PASI100 difference was not significant (22% vs 13.7%, $p = 0.064$). At week 24, no statistical difference was found in PASI75-90-100 responses between bio-naïve and bio-experienced patients.

At week 4, patients with multiple biologic failures had significantly lower PASI 75/90/100 response rates (27.8% vs 60.9% for PASI75; $p < 0.001$; 11.3% vs 40.1% for PASI90, $p < 0.001$; 7.2% vs 22.9% for PASI100, $p < 0.001$). At week 24, rates remained lower but not significant (36.1% vs 61.2%, $p = 0.598$; 34% vs 59.9%, $p = 0.246$; 27.2% vs 47.6%, $p = 0.65$).

At week 4, patients with anti-IL17 failure had lower PASI75/90/100 response rates (41.2% vs 55.4%, $p = 0.018$; 22.8% vs 35.4%, $p = 0.023$; 9.6% vs 22.8%, $p = 0.004$). At week 24, responses remained lower (38.8% vs 58.5%; 38.1% vs 55.8%; 29.9% vs 44.9%) but not significant ($p = 0.158$, $p = 0.819$, $p = 0.728$).

At week 4, patients with anti-IL23i failure showed lower PASI75/90/100 response rates (22.6% vs 55.9%, $p < 0.001$; 11.3% vs 34.7%, $p = 0.001$; 1.7% vs 15.9%, $p = 0.083$). At week 24, rates remained lower (23.8% vs 73.5%; 23.1% vs 70.7%; 19% vs 55.8%) but not significant ($p = 0.053$; $p = 0.237$; $p = 0.85$).

At week 4, patients with anti-TNFα showed lower PASI75/90/100 response rates (28.4% vs 58.2%, $p < 0.001$; 13.6% vs 37%, $p < 0.001$; 2.4% vs 15.2%, $p = 0.012$). At week 24, rates remained lower (29.3% vs 68%; 27.2% vs 66.7%; 20.4% vs 54.4%) but not significant ($p = 0.827$; $p = 0.452$; $p = 0.225$).

At week 4, patients with palmoplantar involvement had lower PASI75/90/100 response rates (8.7% vs 41.1%, $p = 0.003$; 4.2% vs 26.1%, $p = 0.004$; 2.4% vs 15%, $p = 0.047$). At week 24, rates remained lower (25.5% vs 71.7%, $p = 0.064$; 23.4% vs 71%, $p = 0.006$; 20.7% vs 54.5%, $p = 0.976$).

At week 4, patients with PsA had lower PASI75/90/100 response rates (21.5% vs 28.4%, $p = 0.261$; 11.4% vs 19%, $p = 0.045$; 6.6% vs 11.1%, $p = 0.150$). At week 24, rates remained lower (46.3% vs 51%, $p = 0.353$; 44.2% vs 49.7%, $p = 0.315$; 32% vs 42.9%, $p = 0.02$).

Table 3. Comparison of baseline demographic and clinical characteristics of ESR and non-ESR.

	Univariate analysis			Multivariate analysis	
Characteristics	ESR ($n=51$)	Non-ESR ($n=238$)	p	OR (95% CI)	p
Male	31 (60.7%)	130 (54.6%)	0.422		
Age (years)	44.6 ± 13,1	44.7 ± 13.3	0.942		
Geriatric patients	3 (5.9%)	22 (9.2%)	0.442		
Disease duration (years)	13.7 ± 10.4	14.7 ± 9.9	0.514		
Age at diagnosis (years)	29.4 ± 15	29.8 ± 14	0,857		
Family history	8 (15.6%)	80 (33.6%)	**0.014**	0.408 (0.173–0.964)	**0.041**
Nail involvement	22 (43.1%)	96 (40.3%)	0.712		
Palmoplantar involvement	7 (13.7%)	65 (27.3%)	0.052	0.289 (0.115–0.724)	**0.008**
≥1 Difficult-to-treat areas	32 (62.7%)	173 (72.6%)	0.158		
Psoriatic arthritis	19 (37.2%)	115 (48.3%)	0.152	0.550 (0.272–1.115)	0.097
Systemic conventional history	48 (94.1%)	226 (95%)	0.806		
Bio-experienced	21 (41.1%)	132 (55.4%)	0.066	0.512 (0.254–1.030)	0.060
≥2 Previous biologics	7 (13.7%)	90 (37.8%)	**0.002**		
Previous anti-TNF	7 (13.7%)	74 (31%)	**0.015**		
Previous anti-IL 12/23	4 (7.8%)	28 (11.7%)	0.421		
Previous anti-IL 17	11 (21.5%)	103 (43.2%)	**0.005**		
Previous anti-IL 23	5 (9.8%)	48 (20.1%)	0.090		
Previous apremilast	1 (1.9%)	10 (4.2%)	0.459		
Any comorbidity	25 (49%)	108 (45.3%)	0.636		
Diabetes	12 (23.5%)	38 (15.9%)	0.298		
Hypertension	9 (17.6%)	48 (20.1%)	0.682		
Hyperlipidemia	7 (13.7%)	25 (10.5%)	0.507		
Cardiovascular disease	1 (1.96%)	13 (5.46%)	0.312		
PASI at baseline	9.9 ± 6.8	16.1 ± 7.6	**0.000**	0.860 (0.812–0.912)	**0.000**

P values in bold are statistically significant. ESR: Early Super Responder; PASI: Psoriasis Area and Severity Index; OR: Odds Ratio; CI: Confidence Interval.

At week 4, geriatric patients had PASI75/90/100 response rates of 56%, 36%, and 12% vs 49.2%, 29.9%, and 18.1% in non-geriatric patients, without significance ($p=0.518$; $p=0.528$; $p=0.588$). At week 24, responses remained similar (100% vs 96.9%, $p=1.000$; 92.8% vs 93.9%, $p=1.000$; 71.4% vs 75.1%, $p=0.751$).

At week 4, male patients had PASI75/90/100 response rates of 54.6%, 32.9%, and 19.2% vs 43.7%, 27.3%, and 15.6% in females, with no significance ($p=0.065$; $p=0.306$; $p=0.421$). At week 24, responses were similar (97.4% vs 97.1%, $p=1.000$; 92.2% vs 95.7%, $p=0.499$; 74% vs 75.7%, $p=0.814$).

At week 4, obese patients had PASI75/90/100 response rates of 49.7%, 32%, and 18.2% vs 46.7%, 21.7%, and 10.8% in non-obese, with no significance ($p=0.641$; $p=0.075$; $p=0.114$). At week 24, responses were similar (96.7% vs 97.9%, $p=1.000$; 92.3% vs 95.8%, $p=0.719$; 76.9% vs 81.2%, $p=0.666$).

At week 4 and week 24, other demographic and clinical subgroups showed no differences in PASI75/90/100 response rates (all $p>0.05$).

Safety of bimekizumab

The safety profile of bimekizumab is summarized in Table 4. No new safety concerns and no serious AEs were identified. Most common AEs were candidiasis (47; 13.7%), headache (5; 1.46%), injection site reaction (4; 1.17%) and upper respiratory tract infection (4 patients; 1.17%). All AEs were mild in severity. Most cases of oral candidiasis were managed successfully with topical antifungal agents; however, four patients required systemic antifungal therapy, all of whom responded well without recurrence. Other adverse events, such as headache, upper respiratory tract infection, and injection-site reaction, were managed with symptomatic treatment and resolved without complications. One patient (0.29%) developed bloody diarrhea at week 1; after Gastroenterology evaluation and treatment, symptoms resolved without recurrence, and bimekizumab was continued. No patient discontinued due to AEs.

Table 4. Treatment-emergent adverse events until week 24 of bimekizumab treatment ($n=341$).

TEAE	Patients, n(%)	Week of onset, mean ± SD
All TEAEs	70 (20.5%)	6.5 ± 4.5
Serious AE	0	
AE leading to discontinuation of bimekizumab	0	
AE leading to death	0	
Individual AEs	70 (20.5%)	6.5 ± 4.5
Candidiasis	47 (13.7%)	8 ± 4.2
Oral	42 (12.3%)	
Other	5 (1.46%)	
Injection site reaction	4 (1.17%)	5 ± 2.7
Headache	5 (1.46%)	3.2 ± 2.7
Acne	1 (0.29%)	NA
Upper respiratory tract infection	4 (1.17%)	8 ± 6.9
Herpes simplex	1 (0.29%)	8
Nausea/Vomiting	3 (0.87%)	6 ± 2
Burning tongue	2 (0.58%)	2.5 ± 2.1
Neutropenia	2 (0.58%)	16
Bloody diarrhea	1 (0.29%)	1

P values in bold are statistically significant. TEAE: Treatment-emergent adverse event; AE: Adverse event.

Predictors of adverse events

The predictors of AEs were assessed using univariate and multivariate Cox regression (HR, 95% CI; Table 5). Two multivariate models were tested: Model 1 included covariates with $p<0.20$ in univariate analyses, while Model 2 additionally forced in atopic diseases and genital involvement based on prior evidence. Binary variables were coded as presence vs absence, continuous per unit increase. The event was time to first AE, with censoring at last follow-up. Proportional hazards assumptions were met for all covariates. Overall model fit was significant (Model 1: $\chi^2(12)=34.79$, $p=0.001$; Model 2: $\chi^2(14)=36.23$, $p=0.001$).

In univariate Cox analyses (Table 5), longer disease duration (HR = 1.046; 95% CI 1.022–1.072; $p=0.001$), PsA (HR = 2.726;

Table 5. Assessment of predictors of adverse events with multivariate COX regression analysis.

	Univariate Analysis		Model 1		Model 2	
Characteristics	HR (95% CI)	*p*	HR (95% CI)	*p*	HR (95% CI)	*p*
Male	0.614 (0.335–1.128)	0.115	0.647 (0.342–1.224)	0.181	0.648 (0.344–1.221)	0.180
Age (years)	1.012 (0.989–1.035)	0.299				
Geriatric patients	1.093 (0.390–3.063)	0.867				
Disease duration (per 1 year)	1.046 (1.022–1.072)	**0.001**	1.032 (0.998–1.067)	0.067	0.635 (0.332–1.215)	0.051
Age at diagnosis (per 1 year)	0.985 (0.963–1.007)	0.166	1.007 (0.980–1.034)	0.635	1.006 (0.979–1.034)	0.664
BMI (per 1 kg/m^2)	1.021 (0.961–1.085)	0.511				
Family history	1.758 (0.949–3.256)	0.080	1.547 (0.808–2.964)	0.188	1.575 (0.823–3.012)	0.170
Nail involvement	1.147 (0.622–2.113)	0.662				
Genital involvement	1.033 (0.508–2.101)	0.929			0.689 (0.332–1.428)	0.316
≥1 Difficult-to-treat areas	1.352 (0.692–2.641)	0.367				
Psoriatic arthritis	2.726 (1.435–5.178)	**0.001**	1.985 (1.003–3.929)	**0.049**	2.023 (1.010–4.052)	**0.047**
Systemic conventional history	3.589 (0.494–26.090)	0.116	1.474 (0.197–11.041)	0.706	1.590 (0.209–12.079)	0.654
Bio-experienced	2.279 (1.167–4.452)	**0.011**	0.746 (0.222–2.510)	0.636	0.781 (0.230–2.645)	0.691
≥2 Previous biologics	2.830 (1.541–5.198)	**0.001**	1.889 (0.563–6.345)	0.303	1.980 (0.591–6.637)	0.268
Previous anti-TNF	2.135 (1.159–3.935)	**0.018**	0.947 (0.354–2.536)	0.914	0.901 (0.338–2.398)	0.834
Previous anti-IL 17	2.598 (1.403–4.811)	**0.002**	1.706 (0.625–4.655)	0.297	1.630 (0.591–4.498)	0.346
Previous anti-IL 23	2.029 (1.039–3.963)	**0.038**	1.254 (0.569–2.765)	0.574	1.303 (0.584–2.908)	0.517
Any comorbidity	1.310 (0.716–2.400)	0.382				
Obese	1.066 (0.554–2.051)	0.847				
Diabetes	1.314 (0.642–2.803)	0.448				
Hypertension	1.530 (0.769–3.044)	0.242				
Hyperlipidemia	1.570 (0.661–3.726)	0.333				
Cardiovascular disease	2.575 (0.796–8.333)	0.166	3.548 (1.010–12.461)	**0.048**	3.757 (1.074–13.142)	**0.038**
Atopic diseases	1.136 (0.156–8.256)	0.902			2.644 (0.332–21.088)	0.359

Model 1 was set for variables with $p < 0.2$ in the univariate analyses: Gender, disease duration, age at diagnosis, family history, psoriatic arthritis, systemic conventional history, biologic status, multiple biologic failure history, anti-TNF failure history, anti-IL-17 failure history, anti-IL-23 failure history and cardiovascular disease.
Model 2 was set for variables with $p < 0.2$ in the univariate analyses and variables that have been shown to be significant (genital involvement and atopic disease).
CI: Confidence Interval; HR: Hazard Ratio; BMI: Body Mass Index.

1.435–5.178; $p=0.001$), bio-experienced status (HR = 2.279; 1.167–4.452; $p=0.011$), ≥2 prior biologic failure (HR = 2.830; 1.541–5.198; $p=0.001$), and prior failure to anti-TNF (HR = 2.135; 1.159–3.935; $p=0.018$), anti-IL-17 (HR = 2.598; 1.403–4.811; $p=0.002$), and anti-IL-23 (HR = 2.029; 1.039–3.963; $p=0.038$) were associated with higher AE risk.

In multivariate Cox analyses, PsA and cardiovascular disease remained independent predictors: Model 1—HR = 1.985 (95% CI 1.003–3.929), $p=0.049$ and HR = 3.548 (95% CI 1.010–12.461), $p=0.048$; Model 2—HR = 2.023 (95% CI 1.010–4.052), $p=0.047$ and HR = 3.757 (95% CI 1.074–13.142), $p=0.038$, respectively.

Factors affecting candidiasis

The most common AE was candidiasis (13.7%), reported at mean of week 8. It was more frequent in females (19% vs. 9.5%, $p=0.011$), patients with family history of psoriasis (23% vs. 11.9%, $p=0.014$), bio-experienced (17.2% vs. 9.6%, $p=0.045$), ≥2 biologic failures (22.7% vs. 9.5%, $p=0.001$) and cardiovascular disease (40% vs. 12.6%, $p=0.009$). Candidiasis was also associated with lack of PASI75/90/100 responses at week 4 ($p=0.011$, $p=0.002$, $p=0.003$), 8 ($p=0.011$, $p=0.009$, $p=0.003$), or 12 ($p=0.721$, $p=0.016$, $p=0.012$), longer disease duration (18.8±11.2 vs. 13.8±9.5, $p=0.002$), and younger age at onset (26.2±13.2 vs. 30.8±14.4, $p=0.044$). No significant difference was observed with PASI responses at week 16 ($p=1.000$ $p=0.252$, $p=0.132$) and week 24 ($p=585$, $p=0.689$, $p=0.272$).

Discussion

The definition of SR has varied across studies (7,8). In clinical trials, bimekizumab demonstrated a rapid onset of action (3–6). Reich et al. defined SR as achieving complete skin clearance (PASI100) by week 20 (8), whereas Fratton et al. considered achieving PASI100 at week 4 as an "Early Super Response," with lower baseline PASI, absence of nail involvement, and fewer biologic failures being independent predictors (9). In our own clinical practice, we have experienced that the effectiveness of bimekizumab begins quite rapidly in some patients between the 2nd and 4th weeks of the treatment, and we preferred to evaluate the 4th week as the basis for defining ESR. Reported PASI100 rates also differ among trials: Gordon et al. observed responses in 18.9% at week 4 and 68.2% at week 16 (3); Hagino et al. reported 40% and 70% at weeks 4 and 16, respectively (10); Warren et al. showed 15.4% and 60.8% (6); while the BE VIVID and BE RADIANT trials reported similar findings, with week-4 responses around 13–15% and week-16 responses around 59–62% (4,5). In the present multicenter retrospective study, PASI100 was achieved in 17.6% of patients at week 4, 74.6% at week 16, and 74.8% at week 24. Unlike some previous reports, PASI75, PASI90, and PASI100 responses were not significantly influenced by bio-naïve status at 16 and 24 weeks. However, lower baseline PASI, absence of family history of psoriasis ($p=0.041$), absence of palmoplantar involvement ($p=0.008$), absence of PsA ($p=0.097$), and no prior biologic failure ($p=0.060$) were associated with ESR (Table 3).

Bimekizumab is an effective treatment in both bio-naïve and bio-experienced patients (11–14).

In our study, baseline PASI scores were slightly higher in bio-naïve patients compared to bio-experienced patients (15.22±7.38 vs. 14.86±7.56, $p=0.552$). However, bio-experienced patients had significantly higher mean PASI scores at weeks 4 and 8 (both $p=0.02$). Although this trend persisted, no significant differences were observed at weeks 12 ($p=0.061$), 16 ($p=0.743$), or 24 ($p=0.095$) (Figure 4). These findings suggest that bimekizumab may have a faster onset of action in bio-naïve patients, whereas long-term outcomes appear similar between groups. Consistent with this, Potestio et al. (15) and Megna et al. (16) reported no significant long-term differences according to bio-naïve status after 52 weeks of treatment. In our study, while PASI75 and PASI90 responses at week 4 were significantly higher in bio-naïve patients, by week 24 these differences were no longer significant.

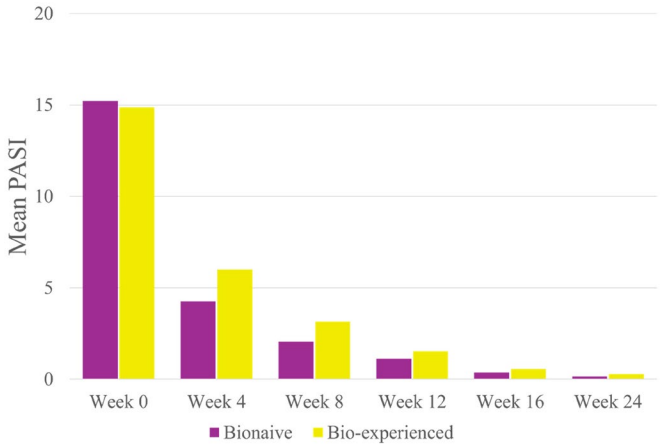

Figure 4. The reduction of mean PASI score in bionaïve and bio-experienced patients at baseline and during bimekizumab treatment. Inter-week comparison of reduction in mean PASI scores was assessed by Wilcoxon Signed Ranks Test while Mann–Whitney Test was assessed for inter-category comparisons. PASI: Psoriasis Area and Severity Index.

Management of psoriasis in geriatric patients can be challenging due to polypharmacy, systemic AEs, and age-related metabolic changes (17). The number of studies investigating age-related treatment response to bimekizumab is limited (10,14,18).

Orsini et al. (14) reported that bimekizumab is both effective and well tolerated in elderly patients, whereas Hagino (10) and Esposito (11) described more favorable responses in younger populations. Li et al. (17) further demonstrated that serum IL-17 and IL-6 levels were lower in healthy young Chinese subjects compared with elderly subjects. In our study, we observed no significant differences in SR or PASI responses between geriatric and non-geriatric patients up to 24 weeks, indicating that bimekizumab efficacy is preserved in older patients. Notably, IL-17 levels may be influenced not only by age but also by ethnicity, disease severity, and disease duration (19).

Hagino et al. (10) reported that male sex was associated with PASI100 response at week 16. In contrast, Gioacchini et al. (20) and Potestio et al. (15) observed comparable outcomes between genders, suggesting that the therapeutic efficacy of bimekizumab provides a consistent clinical response regardless of sex. Similarly, in our study, no significant differences were detected between male and female patients in terms of treatment effectiveness up to week 24.

Several studies have reported comparable efficacy of bimekizumab in obese and normal-weight patients (13,15,21). Some evidence, however, suggests a trend toward better responses in patients with BMI <30, particularly for achieving PASI90 and PASI100 (13). In our study, no significant differences were observed between obese and normal-weight patients throughout the 24-week follow-up period.

The efficacy of bimekizumab in site-specific involvement, including genital, nail, and scalp psoriasis, has been demonstrated (22–25). Esposito et al. (11) reported that nail disease and palmoplantar involvement were negative predictors of complete response, whereas scalp and genital involvement were associated with more favorable outcomes. They also emphasized that 16 weeks of observation may be insufficient to capture significant improvement in nail and palmoplantar disease (11). In our study, genital, nail, and scalp involvement did not affect PASI75, PASI90, or PASI100 responses. However, patients with palmoplantar involvement had significantly lower PASI75 ($p=0.003$), PASI90 ($p=0.004$), and PASI100 ($p=0.047$) responses at week 4 compared with those without such involvement. By week 24, these differences were no longer significant (PASI75: 71.7% vs. 25.5%, $p=0.064$; PASI90: 71% vs. 23.4%, $p=0.006$; PASI100: 54.5% vs. 20.7%, $p=0.976$). This pattern may reflect the greater treatment resistance of palmoplantar plaques.

After 52 weeks of bimekizumab treatment, Potestio et al. (15) reported no significant impact of comorbidities or PsA on therapeutic outcomes. In contrast, Hagino et al. (10) found that the absence of comorbidities and PsA was associated with achieving PASI100 at week 16. In line with these findings, our study showed that patients without PsA achieved higher PASI75, PASI90, and PASI100 responses at both week 4 ($p=0.231$, $p=0.045$, $p=0.150$) and week 24 ($p=0.353$, $p=0.315$, $p=0.02$).

Previous studies have reported candidiasis as the most frequent adverse event (AE), ranging between 7.3% to 21% of patients (9,13). In phase III clinical trials, the most common AEs over a 3-year period were nasopharyngitis, oral candidiasis, and upper respiratory tract infection (26,27). In our study, the overall AE frequency was 20.5% ($n=70$). The most frequently observed AE was candidiasis (13.7%), followed by headache (1.46%, $n=5$), upper respiratory tract infection (1.17%, $n=4$), and injection-site reaction (1.17%, $n=4$).

The frequency of AEs with bimekizumab in elderly patients has been reported to be comparable to that in younger populations (28,29). Fratton et al. (9) observed that asthma and allergic rhinitis were significantly associated with a higher risk of AEs, whereas a family history of psoriasis and genital involvement were linked to a lower risk. Only a few studies have investigated predisposing factors for oral candidiasis under bimekizumab therapy (30). Yoneyama et al. (30) found that patients who developed oral candidiasis had a significantly longer disease duration than those who did not. Longer disease duration often implies prolonged exposure to immunosuppressive therapies, which may in turn increase susceptibility to candidiasis (30,31). In our study, the frequency of candidiasis was 13.7%, which falls within the previously reported range of 7.3%–21% (9,13). Similarly, in our study, candidiasis was more common in those with a longer disease duration and also associated with female gender, younger age at onset, family history of psoriasis, bio-experienced status, ≥2 biologic failures, lack of PASI75/90/100 responses at week 4, at week 8, and at week 12. All these factors may indicate that patients who develop candidiasis under bimekizumab treatment have more prolonged and resistant disease.

Conclusion

This multicenter study with a large patient population provides real-world insights into the ESR profile of bimekizumab. However, the retrospective design introduces potential risks of selection bias, missing data, and heterogeneity in clinical records, which may limit the robustness and generalizability of the conclusions. Although standardized data collection tools and quality checks were applied to minimize these issues, further prospective studies with longer follow-up are needed to confirm the long-term efficacy and safety of bimekizumab.

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Data availability statement

Data results are available upon reasonable request to the corresponding author.

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