Dermatology Practical & Conceptual

Evaluating the Efficacy of Bimekizumab across the Different Sensitive Areas in Moderate-to-Severe Psoriasis: A 52-week Italian Multicenter Real-Life Lazio Experience

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ABSTRACT

Introduction: Psoriasis significantly impacts a patient's quality of life (QoL). Bimekizumab targets IL-17A and IL-17F, offering a broader blockade of the IL-17 pathway compared to other IL-17 inhibitors.

Objectives: This study evaluated the clinical efficacy of bimekizumab in bio-naive and bio-experienced patients with moderate-to-severe psoriasis over a 52-week period, with a focus on improvements across different body areas and QoL.

Methods: A retrospective analysis of real-world data was conducted on 132 patients from eight medical centers. Efficacy was assessed using PASI scores, at baseline and at weeks 4, 16, 24, and 52, and DLQI scores. Patients were categorized based on prior biologic treatment experience.

Results: The mean PASI score decreased for all patients, from 14.41 at baseline to 0.18 at week 52, indicating substantial improvement. Area-specific PASI subscores showed significant reductions: head (3.24 to 0.13), upper limb (8.49 to 0), trunk (8.35 to 0.03), and lower limb (8.61 to 0.12). Complete skin clearance was achieved by week 16 in the majority of patients: 85% achieved complete skin clearance on the head, 90% on upper limbs, and 94% on both trunk and lower limbs. DLQI scores significantly improved, from 13.57 at baseline to 0.86 at week 16, highlighting the early positive impact of bimekizumab in improving QoL. When comparing PASI scores between bio-naive and bio-experienced patients, no significant difference was found.

Conclusions: Bimekizumab demonstrates significant efficacy in reducing psoriasis severity across different body areas and improving QoL over a 52-week period. These findings support this robust treatment option for moderate-to-severe psoriasis.

Introduction

Psoriasis (PsO) is a chronic, immune-mediated skin disorder that causes the rapid proliferation of keratinocytes, leading to thick, scaly plaques. It affects 2%–3% of the global population, with prevalence varying across regions. For example, it reaches 2.5% in Western Europe but only 0.17% in East Asia [1-3]. PsO is more than a skin condition; it is a persistent inflammatory disease that significantly impacts quality of life (QoL). The red, scaly plaques, along with associated comorbidities, underscore the systemic nature of the disorder [4]. Treatments include topical therapies, phototherapy, and systemic agents such as methotrexate, cyclosporine, and biologics. Biologic therapies target key immune pathways, including tumor necrosis factor-alpha (TNF-α), interleukin-12/23 (IL-12/23), and interleukin-17 (IL-17), to modulate the immune system and reduce inflammation [1,2].

The pathogenesis of psoriasis involves genetic, environmental, and immune factors. A key driver is the overactivation of T-helper 17 (Th17) cells, which release pro-inflammatory cytokines like IL-17A and IL-17F. These cytokines induce keratinocyte proliferation and inflammation, creating the characteristic plaques of psoriasis. Targeting the IL-17 pathway, therefore, is central to treatment strategies [5,6].

Bimekizumab is a novel monoclonal antibody that uniquely targets both IL-17A and IL-17F, cytokines that are crucial in the pathogenesis of psoriasis. By inhibiting these two cytokines, bimekizumab offers a broader blockade of the IL-17 pathway than other IL-17 inhibitors that target only IL-17A. This dual inhibition is hypothesized to provide superior efficacy in reducing the inflammatory burden and clinical symptoms of psoriasis. Clinical trials have demonstrated that bimekizumab significantly improves psoriasis symptoms, achieving higher rates of skin clearance compared to placebo and active comparators such as secukinumab, adalimumab, and ustekinumab. For example, in the BE READY, BE SURE, and BE VIVID phase 3 trials, bimekizumab showed superior clinical efficacy, with many patients achieving complete skin clearance (PASI 100) by week 16 of treatment [7].

Objectives

The aim of this study was to evaluate the clinical efficacy and safety of bimekizumab in patients with moderate-to-severe psoriasis over a follow-up period of 52 weeks.

Methods

Study Design

A retrospective analysis of real-world data was conducted on 132 patients, drawing on the clinical expertise of healthcare facilities in the Lazio region, Italy. Data collection took place across eight medical centers, detailed in Table 1.

Outcome Measures

The primary endpoint consisted in assessing the efficacy of bimekizumab over time and according to different body areas by evaluating the improvement in psoriasis symptoms using

Table 1. Centers Involved in the Study.

Center
UOC of Dermatology, Policlinico Umberto I, Sapienza University of Rome
UOC of Dermatology Polo Pontino, Sapienza University of Rome
UOC of Dermatology, A.O. Sant'Andrea, Sapienza University of Rome
UOSD of Dermatology, University of Rome Tor Vergata
UOC of Dermatology, Policlinico Agostino Gemelli
Dermopatic Institute of Immaculate (IDI) IRCCS, Rome
Ospedale Viterbo
UOS of Dermatology Campus Bio-medico of Rome

Table 2. Patients' Baseline Characteristics.

		Patients
Age (yrs)	N	132
	Mean (SD)	49.73 (14.63)
Weight (kg)	N	123
	Mean (SD)	74.02 (15.63)
BMI	N	120
	Mean (SD)	25.57 (4.43)
Age at PsO diagnosis (yrs)	N	129
	Mean (SD)	29.16 (17.90)
Time from PsO diagnosis to bkz (yrs)	N	124
	Mean (SD)	21.78 (16.53)

Abbreviations: Bkz: bimekizumab; BMI: body mass index; PsO: psoriasis; SD: standard deviation.

the Psoriasis Area and Severity Index (PASI) scores. This included evaluating the mean PASI scores at different time-points (baseline, week 4, week 16, week 24, and week 52) and according to different body areas (PASI subscore: head, lower limb, upper limb, trunk) and the percentage of patients achieving significant reductions in PASI scores (e.g., PASI 90 and PASI 100).

Secondary endpoints aimed to evaluate the impact of bimekizumab on the patients' quality of life using the Dermatology Life Quality Index (DLQI) and the drug's effectiveness in bio-naive vs bio-experienced patients.

Statistical Analysis

Continuous variables are described using mean, median and standard deviation, while absolute and relative frequencies are provided for discrete variables. A Venn diagram shows the logical relation between locations involved. Paired T-test was used to compare changes in PASI subscores at each time-point vs baseline. All p-values were considered nominal, and a value <0.05 was considered statistically significant.

A multivariate logistic regression model was used to evaluate determinant factors to PASI subscores equal to 0 at week 16, considering as factors bio-treatment (bio-naive vs bio-experienced), sex, age at first bimekizumab treatment, time from PsO diagnosis to bimekizumab initiation, and BM/ (<25 vs >=25).

An ANOVA model for repeated measures and an ANCOVA model were used to evaluate the PASI reduction in bio-naive and bio-experienced patients.

Results

Patients Baseline Characteristics

The study included 132 patients with a mean age of 49.73 years (SD 14.63). The demographic and clinical characteristics of the study participants are summarized in Table 2.

PsO Involvement

Psoriasis involvement was recorded in 110 patients for the head and neck, and in 132 patients for the upper limbs, trunk, and lower limbs (Figure S1 A-B). The distribution of affected areas showed seven patients with involvement in one area, 17 in two areas, 49 in three areas, and 38 in all four areas (Figure S1 C). Among 102 patients analyzed for palmoplantar involvement, nine were involved, while 93 did not (Figure S1 D).

Biologic Therapy Before Bimekizumab

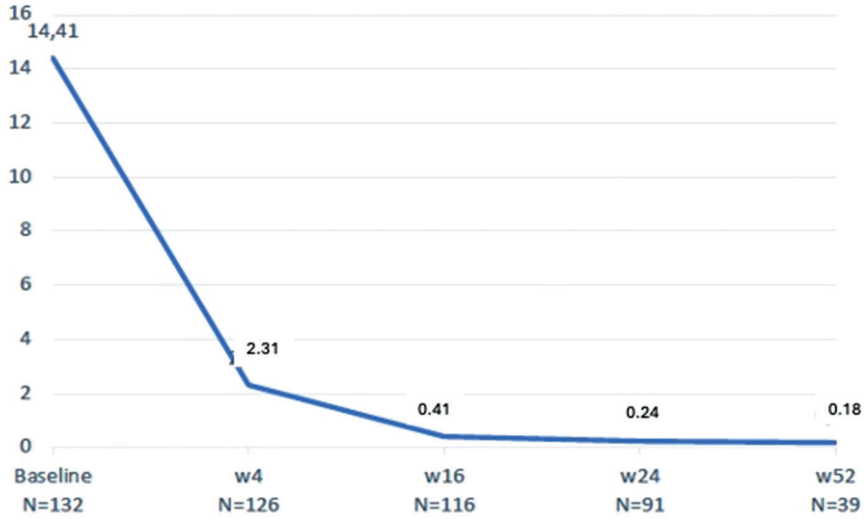
Among the 132 enrolled patients, 66 were biologic-experienced, and 66 were biologic-naive. Furthermore, the number of biologic treatments received before starting bimekizumab shows that among all enrolled patients, 85% had received one prior biologic therapy, 7% had received two, and 8% had received more than two (Figure S2 A-B).

Efficacy of Bimekizumab Over Time

PASI score: For all enrolled patients (N=132), the mean PASI score decreased from 14.41 at baseline to 2.31 at week 4 (N=126), 0.41 at week 16 (N=116), 0.24 at week 24 (N=91), and 0.18 at week 52 (N=39), indicating a significant reduction in psoriasis severity over time (Figure 1).

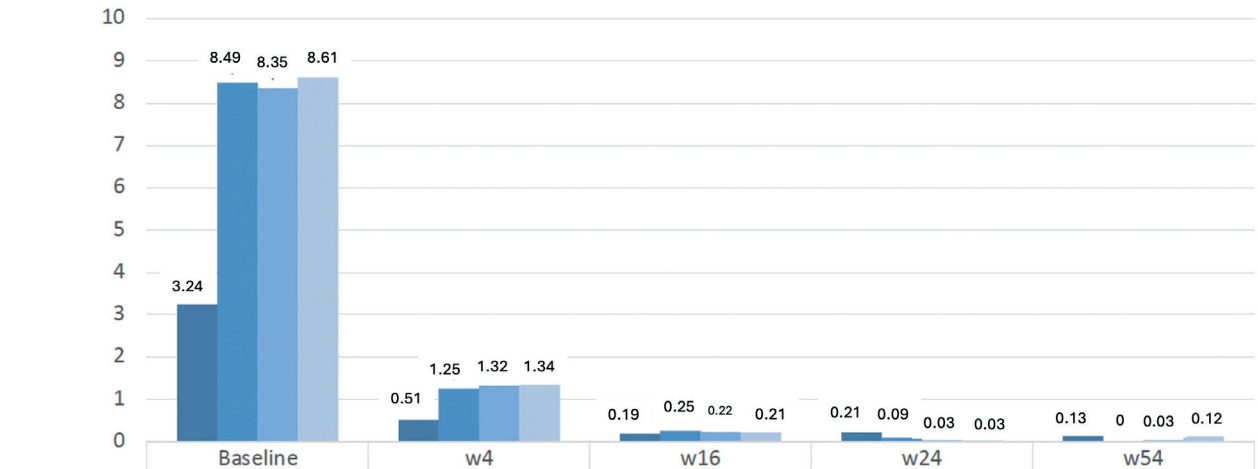
Baseline PASI scores by area were: head (3.24), upper limb (8.49), trunk (8.35), and lower limb (8.61). By week 24, these scores decreased to 0.21, 0.09, 0.03, and 0.03, respectively. By week 54, the scores further decreased to 0.13 (head), 0 (upper limb), 0.03 (trunk), and 0.12 (lower limb) (Figure 2).

By week 4, 67% of patients achieved PASI 0 for the head, 53% for the upper limbs, 52% for the trunk, and 53% for the lower limbs. These increased to 85-94% across all areas by week 16 and maintained similar levels through week 54 (Figure 3).



Variable	N	Mean	Std Dev	Median	Minimum	Maximum
pasi_b	132	14.41	8.68	12.00	0.00	54.00
pasi_w4	126	2.31	2.95	2.00	0.00	15.00
pasi_w16	116	0.41	1.56	0.00	0.00	15.00
pasi_w24	91	0.24	0.78	0.00	0.00	6.00
pasi_w54	39	0.18	0.51	0.00	0.00	2.00

Figure 1. Mean PASI score over time for all enrolled patients. (N=132). The mean PASI scores are presented at baseline, week 4 (N=126), week 16 (N=116), week 24 (N=91), and week 52 (N=39). The scores show a significant reduction from a mean value of 14.41 at baseline to 0.18 at week 52, indicating a substantial improvement in psoriasis severity.



	Baseline N=49; 109; 110; 104	w4 N=49;106; 108; 100	w16 N=48; 99; 101; 92	w24 N=42; 75; 77; 69	w54 N=24; 28; 32; 26
Head	3.24	0.51	0.19	0.21	0.13
Upper Limb	8.49	1.25	0.25	0.09	0
Trunk	8.35	1.32	0.22	0.03	0.03
Lower Limb	8.61	1.34	0.21	0.03	0.12

Figure 2. PASI subscores by body area over time. Mean PASI subscores by body area (head, upper limb, trunk, lower limb) over time for all enrolled patients. The PASI subscores were recorded at baseline, week 4 (W4), week 16 (W16), week 24 (W24), and week 52 (W52).

PASI score based on previous therapy: The PASI score trend between bio-naive and biopsy patients revealed no significant differences between the two groups, although differences across timepoints were observed.

ANOVA for repeated measures and ANCOVA analyses were conducted. Using the baseline PASI score as a covariate, the p-value at week 4 was less than 0.0001, indicating a significant difference from baseline. At week 16, the

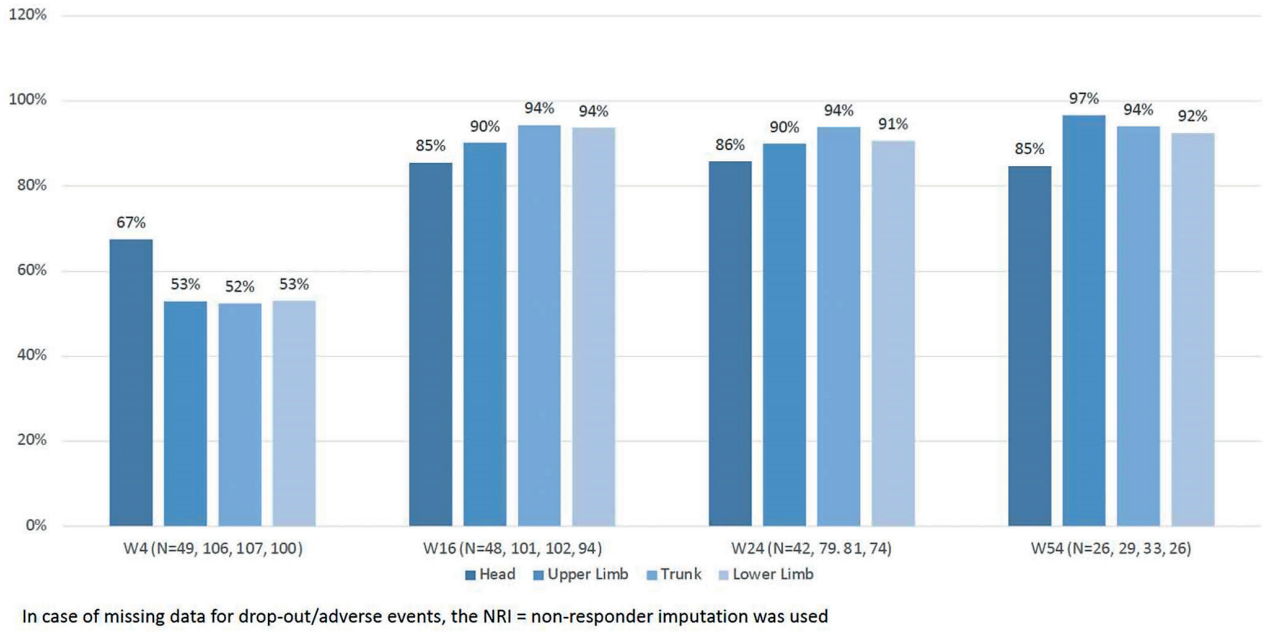


Figure 3. Percentage of patients with PASI subscore of 0 over time. Patients achieving a PASI subscore of 0 (indicating no psoriasis) in different body areas (head, upper limb, trunk, lower limb) over time for all enrolled patients. The percentages were recorded at week 4 (W4), week 16 (W16), week 24 (W24), and week 52 (W52).

p-value was 0.0012, also indicating significance. However, at week 24, the p-value was 0.1590, showing no significant change, while at week 54, the p-value was 0.0041, indicating a significant difference from baseline.

When comparing bio-naive and bio-experienced patients, the p-values were as follows: 0.4230 at week 4, 0.1285 at week 16, 0.5384 at week 24, and 0.2781 at week 54, indicating no significant differences between the groups at any timepoint.

PASI subscores according to different body areas*:* For all enrolled patients, the mean PASI subscores for the head were 3.24 at baseline (N=49), decreasing to 0.51 at week 4 (N=49), 0.19 at week 16 (N=48), 0.21 at week 24 (N=42), and 0.13 at week 54 (N=24). The percentage of patients achieving PASI 100 (complete skin clearance) for the head improved over time: 67% at week 4, 85% at week 16, 86% at week 24, and 85% at week 54 (Figure 4).

For the upper limbs, mean PASI subscores were 8.49 at baseline (N=109), decreasing to 1.25 at week 4 (N=106), 0.25 at week 16 (N=99), 0.09 at week 24 (N=75), and 0 at week 54 (N=28). The percentage of patients achieving PASI 100 for the upper limbs steadily increased: 53% at week 4, 90% at week 16, 90% at week 24, and 97% at week 54. These changes were statistically significant at all timepoints, with p-values less than 0.0001 (Figure 5).

For the trunk, mean PASI subscores were 8.35 at baseline (N=110), decreasing to 1.32 at week 4 (N=108), 0.22 at week 16 (N=101), and 0.03 at both weeks 24 (N=77) and 54 (N=32). The percentage of patients achieving PASI 100 for the trunk increased from 52% at week 4 to 94% at weeks 16, 24, and 54. These changes were also statistically significant at each timepoint (p-values less than 0.0001) (Figure 6).

For the lower limbs, mean PASI subscores were 8.61 at baseline (N=104), decreasing to 1.34 at week 4 (N=100), 0.21 at week 16 (N=92), 0.03 at week 24 (N=69), and slightly increasing to 0.12 at week 54 (N=26). PASI 100 achievement rates for the lower limbs were 53% at week 4, 94% at week 16, 91% at week 24, and 92% at week 54. These changes were statistically significant at each timepoint (p-values less than 0.0001) (Figure 7).

Quality of Life

For all enrolled patients, the mean DLQI score at baseline was 13.57 (N=96), which significantly decreased to 0.86 at week 16 (N=87) (Figure S3).

Discussion

Psoriasis is a chronic, immune-mediated inflammatory skin disease affecting around 2% of people in Europe and North America [8]. Stress significantly contributes to its onset and exacerbation, highlighting the importance of addressing both the clinical and psychosocial aspects of the condition [9]. Effective management is essential, especially with advancements in treatment options like biologics that target specific cytokines, which have improved psoriasis management over the past decade [10]. Bimekizumab is one such promising treatment for moderate-to-severe psoriasis, offering high efficacy and safety [7,11–13], though real-world evidence is still limited [7].

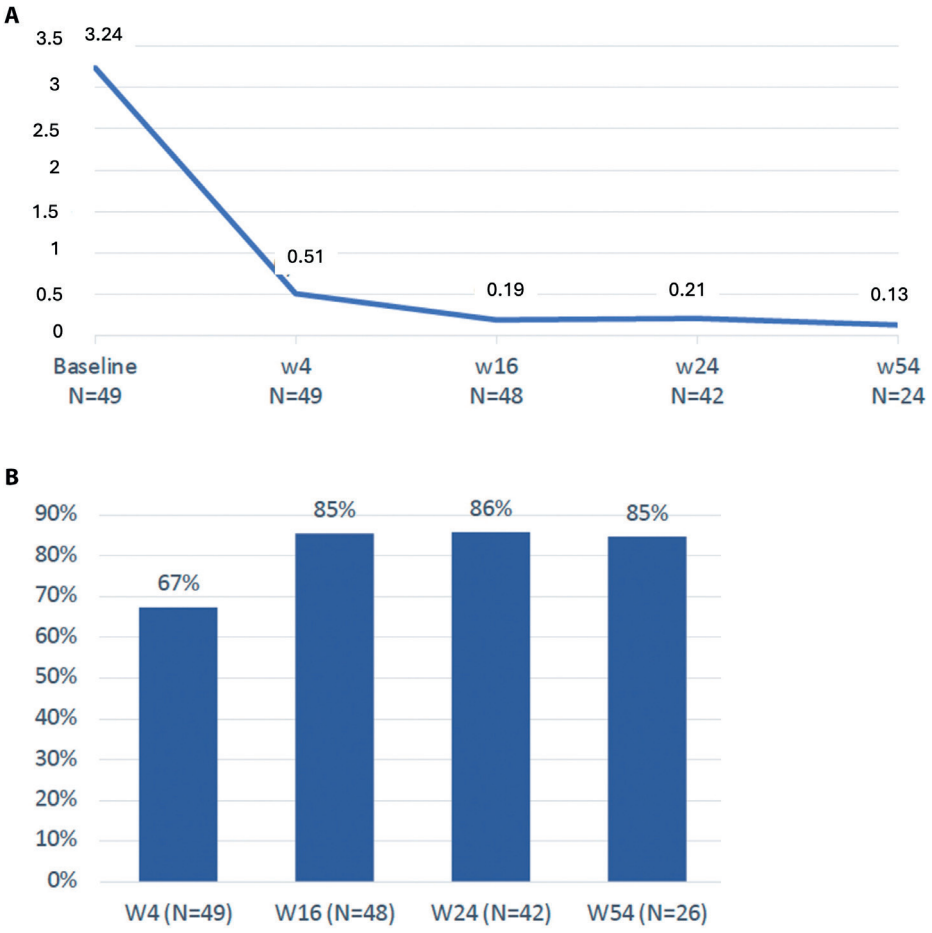


Figure 4. (A) Mean PASI head subscore over time. Mean PASI subscore for the head region over time for all enrolled patients. The PASI subscores were recorded at baseline, week 4 (W4), week 16 (W16), week 24 (W24), and week 52 (W52). (B) Percentage of patients achieving PASI 100 subscore for the head region over time. Patients achieving a PASI 100 subscore (complete clearance of psoriasis) for the head region over time for all enrolled patients. The percentages are recorded at W4, W16, W24, and W52.

A real-world study by Gargiulo et al. included 237 patients to assess bimekizumab's efficacy and safety over 16 weeks. At 16 weeks, 75.4% of patients achieved complete skin clearance (PASI 100), 89.5% achieved PASI 90, and 94.7% had a PASI score of ≤2 [7]. Our cohort of 132 patients showed a similar reduction in disease severity. The mean PASI score decreased from 14.41 at baseline to 2.31 at week 4, 0.41 at week 16, 0.24 at week 24, and 0.18 at week 52. A subgroup of 94 patients followed for 24 weeks showed a baseline mean PASI of 14.76, decreasing to 2.24 at week 4, 0.43 at week 16, and 0.24 at week 24. These results underscore bimekizumab's efficacy in reducing psoriasis severity across different cohorts and timepoints, improving patient quality of life. These findings are consistent with prior studies showing that rapid and sustained reductions in PASI scores are indicative of effective psoriasis management [14,15]. Moreover, a multicenter study by Gargiulo et al. demonstrated that 75.4% of patients achieved PASI 100 by week 16, with 89.5% reaching PASI 90 and 94.7% achieving PASI 75, further highlighting bimekizumab's robust efficacy in a real-world setting [7]. Recently, a real-world, multicenter retrospective study conducted by Orsini et al. evaluated the efficacy and safety of bimekizumab in 98 elderly patients (≥65 years) with moderate-to-severe plaque psoriasis treated across 33 Italian dermatology clinics. Over 36 weeks, bimekizumab significantly reduced mean PASI scores, from 16.6 ± 9.4 at baseline to 4.3 ± 5.2 at week 4 and 1.1 ± 1.7 at weeks 16 and 36 (P< 0.001). By week 16, 87.8%, 72.4%, and 53.1% of patients achieved PASI 75, PASI 90, and PASI 100, respectively, with sustained results through week 36. Clearance of difficult-to-treat areas, including scalp, genital, palmoplantar, and nail psoriasis, was high, with 99% achieving genital clearance by week 36. The treatment was well tolerated, with only mild adverse events (5.1%), including eczema and oral candidiasis, managed without discontinuation [16].

Moreover, the data's consistency across different follow-up periods reinforces the reliability of bimekizumab

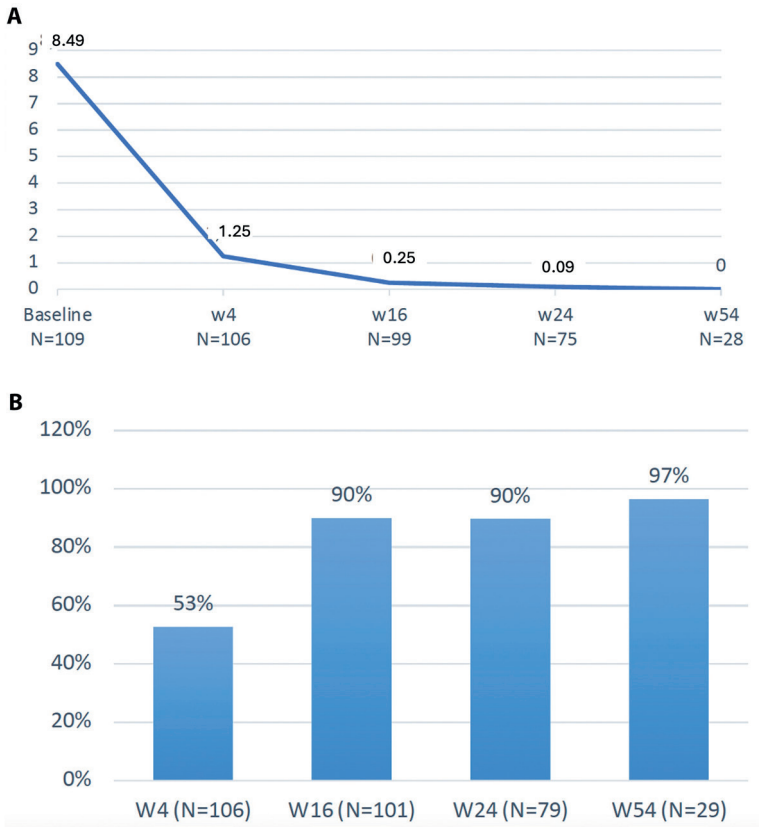


Figure 5. (A) Mean PASI subscore for upper limb over time for all enrolled patients. The scores were recorded at baseline, week 4 (W4), week 16 (W16), week 24 (W24), and week 52 (W52). (B) Percentage of patients achieving PASI 100 subscore for upper limb over time. Patients achieving a PASI 100 subscore (complete clearance of psoriasis) for the upper limb over time. The percentages were recorded at W4, W16, W24, and W52.

as a therapeutic agent. The continued improvement observed up to week 52 in a subset of patients suggests that bimekizumab not only provides immediate benefits but also maintains its efficacy over longer treatment durations.

This study shows significant enhancements in PASI scores across different body parts in patients who received bimekizumab. Baseline PASI scores for specific body sites were 3.24 for the head, 8.49 for upper limbs, 8.35 for the trunk, and 8.61 for lower limbs, which dropped significantly by week 24. By week 54, the scores further decreased. These findings align well with other real-world studies evaluating the effectiveness of bimekizumab.

Hagino et al. reported significant improvements in PASI scores in a cohort of 36 Japanese patients, with median PASI reductions of 79.8% at week 4 and 96.4% achieving PASI ≤2 by week 16 [16]. The PASI assessment on the trunk and upper and/or lower extremities promptly and significantly decreased at week 4 by a median 86.7%, 80.0%, or 66.7% from baseline, respectively, and then stabilized. The PASI on the scalp and neck seemed to diminish at the end of the fourth week by a median 73.2% from the initial level. These results further support the effectiveness of bimekizumab across different patient populations and geographical regions [17]. Moreover, Orsini et al. reported comparable findings in their study focused on genital psoriasis. Their 16-week multicenter real-world study found that 98.4% of patients achieved a clear sPGA-G score, with significant improvements in PASI scores and Dermatology Life Quality Index (DLQI) scores, reinforcing the treatment's effectiveness in challenging-to-treat areas [18].

This study shows significant improvements in PASI subscores across different body areas with bimekizumab treatment. Detailed outcomes indicate bimekizumab effectiveness in attaining and sustaining skin clearance. Mean PASI subscores for the head area reduced from 3.24 at baseline to 0.13 at week 54, with increasing percentage of patients achieving PASI 100 over time. Patients with 24-week follow-up showed a decrease in mean PASI subscores for the head and improved percentage of achieving PASI 100. A shorter time from diagnosis to bimekizumab treatment initiation and older age were linked to higher chances of complete response in head PASI subscore by week 16.

The mean PASI subscores for upper limbs decreased over time, with the percentage of patients achieving PASI

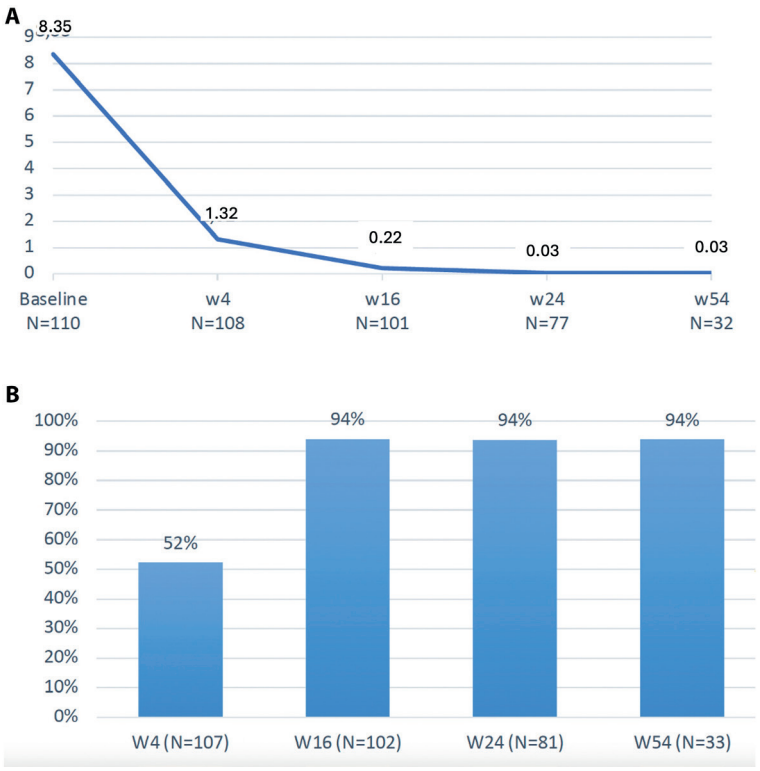


Figure 6. (A) Mean PASI subscore for trunk over time for all enrolled patients. The scores were recorded at baseline, week 4 (W4), week 16 (W16), week 24 (W24), and week 52 (W52). (B) Percentage of patients achieving PASI 100 subscore for trunk over time. Patients achieving a PASI 100 subscore (complete clearance of psoriasis) for the trunk region over time. The percentages were recorded at W4, W16, W24, and W52.

100 increasing. The mean PASI subscores for patients with 24-week follow-up also decreased, with an increasing percentage of achieving PASI 100. These changes from baseline were statistically significant. Similarly, for trunk area, mean PASI subscores decreased, with an increasing percentage of patients achieving PASI 100. Patients with 24-week follow-up showed similar trends in mean PASI subscores and achievement of PASI 100. Changes from baseline were statistically significant.

The mean PASI subscores for lower limbs decreased significantly over time in enrolled patients. Patients achieved PASI 100 at varying rates throughout the study. For patients with a 24-week follow-up, PASI subscores decreased significantly as well. The percentage of these patients achieving PASI 100 also increased over time. Statistical analysis showed significant changes in PASI subscores from baseline at each timepoint.

These results are consistent with other studies on bimekizumab, such as that by Merola et al., which reported high rates of complete clearance in high-impact areas like the scalp, nails, and palms over two years of treatment. Warren et al. and Strober et al. also highlighted the long-term efficacy and sustained response of bimekizumab, demonstrating that high levels of clinical response are maintained through three years of treatment [19–21].

The study showed that bimekizumab led to significant improvements in DLQI scores for psoriasis patients. The mean DLQI score decreased from 13.57 to 0.86 by week 16 for all patients. In the subgroup with a 24-week follow-up, the mean DLQI score decreased similarly. By week 16, 74% of these patients achieved a DLQI score of 0 or 1, indicating no impact on their quality of life; 24% did not achieve this score, and 2% had missing data. These findings are consistent with previous studies evaluating the efficacy of bimekizumab in the treatment of moderate-to-severe plaque psoriasis. Strober et al. reported that among patients achieving a PASI 100 response at week 16, 76.3% also achieved a DLQI 0/1 response, which increased to 89.0% by the end of year 3 of continuous bimekizumab treatment [21]. This sustained improvement in quality of life underscores the long-term benefits of bimekizumab beyond mere clinical skin clearance.

Comparative studies have shown that bimekizumab offers superior efficacy over other biologics. In the BE VIVID trial, bimekizumab demonstrated a significantly higher rate of PASI 90 response compared to ustekinumab and placebo at week 16, with corresponding improvements in DLQI

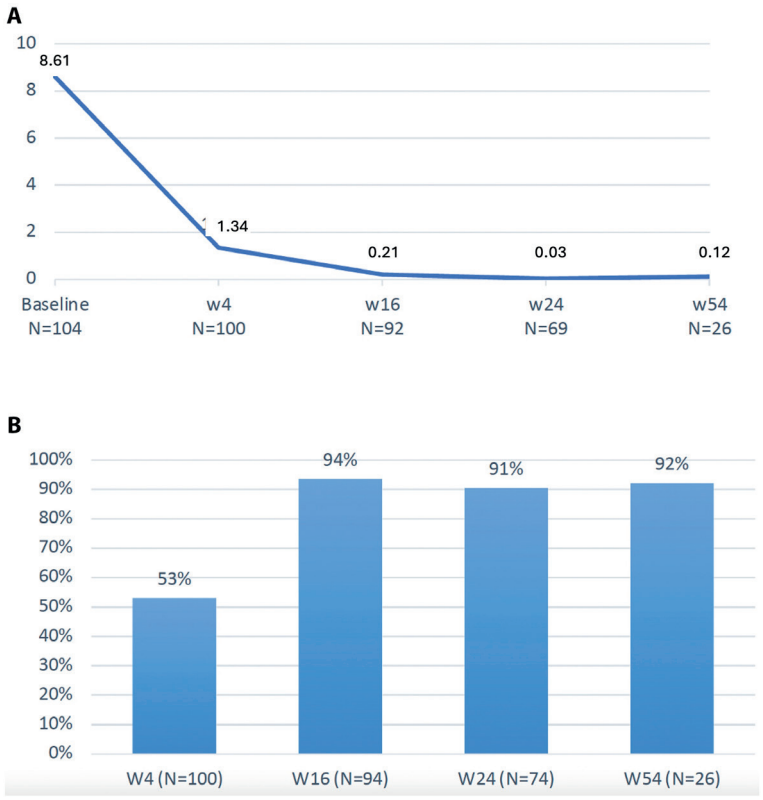


Figure 7. (A) Mean PASI subscore for lower limb over time. PASI subscore for the lower limb over time for all enrolled patients. The scores were recorded at baseline, week 4 (W4), week 16 (W16), week 24 (W24), and week 52 (W52). (B) Percentage of patients achieving PASI 100 subscore for lower limb over time. Patients achieving a PASI 100 subscore (complete clearance of psoriasis) for the lower limb over time. The percentages were recorded at W4, W16, W24, and W52.

scores [22] . Similarly, Ruggiero et al. reported that bimekizumab treatment resulted in a 91% PASI 90 response rate at week 16, with significant improvements in DLQI scores [13]. The data from Sharma et al. corroborate these findings, showing that patients treated with bimekizumab experienced substantial improvements in both PASI scores and quality of life measures, which were sustained over long-term treatment periods [23].

Limitations

While the findings provide compelling evidence of the efficacy of bimekizumab in treating moderate-to-severe psoriasis, there are some limitations related to this study. The limited sample size and absence of a control group restrict the generalizability and causal inferences of the results. Also, the focus on one geographic area limits applicability to other populations. Additionally, the follow-up duration, while informative, would benefit from extension to better understand the long-term efficacy and safety of bimekizumab. Future research will focus on larger cohorts with different characteristics and longer follow-up periods to confirm these findings and further elucidate the long-term benefits associated with bimekizumab.

Conclusion

The current study adds valuable real-world evidence to the growing body of literature supporting the use of bimekizumab in psoriasis management. These results offer promising implications for clinical practice, suggesting that bimekizumab can significantly enhance the quality of life of patients with moderate-to-severe psoriasis by providing rapid and sustained improvements in skin clearance and overall well-being.

Author's Contribution: AD, GP, AGR, NB conceptualized the work, AD, GP, AGR, NB, drafted the work, AD, GP, AGR, NB, and all authors critically revised and approved the final version.

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