Clinical, Cosmetic and Investigational Dermatology

Dovepress

open access to scientific and medical research

Open Access Full Text Article

RESEARCH LETTER

Real-World Experience of Bimekizumab in an Elderly Patients Cohort with Plaque-Type Psoriasis: A 24-Week Retrospective Study

Zeno Fratton[1], Vincenzo Maione[2], Stefano Bighetti[2], Luca Bettolini[2], Mariachiara Arisi[2], Giuseppe Stinco[1], Enzo Errichetti[1]

[1]Department of Medicine, Institute of Dermatology, University of Udine, Udine, Italy; [2]Dermatology Department, University of Brescia, ASST Spedali Civili di Brescia, Brescia, Italy

Correspondence: Enzo Errichetti, Institute of Dermatology, Department of Medicine, University of Udine, Piazzale Santa Maria della Misericordia, 15, Udine, 33100, Italy, Tel +39 0432559822, Email enzo.errichetti@uniud.it

Psoriasis significantly impacts the quality of life, particularly in elderly patients who may have additional comorbidities.[1] Conventional treatments often pose challenges due to the increased risk of adverse events (AEs) in this population. Bimekizumab (BKZ), a monoclonal antibody targeting both interleukin (IL)-17A and IL-17F, has shown promising results in clinical trials.[2] However, real-world data concerning its use in elderly patients, remains limited.

This 24-week retrospective study involving two Italian dermatological centers (Udine and Brescia) aims to bridge this knowledge gap by evaluating the efficacy and safety of BKZ in elderly patients with moderate-to-severe [Psoriasis Area and Severity Index (PASI) >10] plaque psoriasis. Consecutive psoriatic patients aged ≥65 year-old and treated with BKZ (standard dosing regimen)[2] were considered; we excluded patients lacking 24-week follow-up or taking concomitant anti-psoriatic therapies (systemic/topical). Demographic/medical information was collected (gender, age, BMI, date of diagnosis of psoriasis, comorbidities and previous/current systemic treatments). Treatment efficacy was evaluated using PASI score at baseline (week 0), Week-4, Week-16 and Week-24; percentage improvement of 75%, 90% and 100% compared to baseline (respectively PASI75, 90 and 100) was also considered at each time point. Safety profile was assessed by monitoring AEs.

A total of 15 elderly patients were enrolled in the analysis (M/F: 10/5; mean age: 71.3 ± 4.3 years (min. 66 years; max 81 years); and mean BMI: 26.0 ± 2.9); mean psoriasis duration was 16.1 ± 8.8 years. Fourteen patients (93.3%) had previously been treated with at least one conventional therapy, while eight (53.3%) and five (33.3%) patients were failure to one and three or more biologics, respectively. The most frequent comorbidity was arterial hypertension, followed by diabetes and chronic kidney disease. At baseline, the mean PASI was 15.3 ± 10.0, eight patients (53.3%) had involvement of one or more difficult-to-treat cutaneous domain (ie, genitalia, scalp, and palms/soles), and four patients (28.6%) had nail psoriasis. Table 1 summarizes all baseline demographic/clinical characteristics.

During the follow-up (Figure 1), mean PASI decreased from 15.3 ± 10.0 (baseline) to 3.7 ± 3.4 at Week 4 and to 0.8 ±1.2 at Week-16, whereas a slight increase (1.5 ± 4.0) was observed at Week-24. In terms of percentage improvement, at Week-4 we found PASI75 and PASI100 in 80.0% and 20.0% of patients, respectively, while at Week 16, 92.9%, 78.6% and 57.1% of patients respectively reached PASI75, PASI90 and PASI100, with this positive trend continuing at week 24 (PASI75, PASI90, PASI100 observed in 92.9%, 78.6% and 64.3% of patients, respectively). BKZ was overall well tolerated, with two patients (13.3%) discontinuing treatment due to acute urticaria and oral candidiasis at Week-8 and 24, respectively (both healed after BKZ withdrawal and specific treatment); no other AEs were reported.

This 24-week real-life study suggests that BKZ is an effective treatment for moderate-to-severe plaque psoriasis in elderly patients, even in multi-failure cases. Complete (PASI100) or nearly complete (PASI90) responses after 6 months were greater than Secukinumab[3,4] and slightly lower than Ixekizumab[5,6] in the same subset of patients in real life, yet

Received: 20 July 2024
Accepted: 28 September 2024
Published: 30 September 2024

Table 1 Demographic and Clinical Data of Study Population

Study population	
Patients, *n*	15
Age, *years*	71.3 ± 4.3
Sex, *male*	10 (66.7%)
Psoriasis duration, *years*	16.1 ± 8.8
Psoriatic Arthritis, n (%)	3 (20.0%)
Psoriatic Arthritis duration, *years*	16.3 ± 6.8
Involvement of difficult to treat areas, n *(%)* Scalp Genitals Palms and soles	8 (53.3%) 2 (13.3%) 6 (40.0%) 1 (6.7%)
Nail involvement, n (%)	4 (26.7%)
PASI Baseline W4 W16 W24	 15.3 ± 10.0 3.7 ± 3.4 0.8 ± 1.2 1.5 ± 4.0
BMI	26.0 ± 2.9
Comorbidities or associated disease, n *(%)*: Hypertension Diabetes Chronic Kidney Disease Hypercholesterolemia Hyperuricemia Heart failure	12 (80%) 10 (66.7%) 2 (13.3%) 2 (13.3%) 2 (13.3%) 2 (13.3%) 1 (6.7%)
Psoriasis Family history	6 (40.0%)
Previous conventional treatments, n *(%)*: Phototherapy Cyclosporine Methotrexate Acitretin Fumarates	14 (93.3%) 8 (53.3%) 6 (40.0%) 5 (33.3%) 4 (26.7%) 4 (26.7%)
Biologics: Naive Adalimumab Ixekizumab Secukinumab Ustekinumab Etanercept Guselkumab Infliximab	8 (53.3%) 7 (46.7%) 8 (53.3%) 5 (33.3%) 3 (20.0%) 3 (20.0%) 2 (13.3%) 1 (6.7%) 1 (6.7%)

(*Continued*)

Table 1 (Continued).

Study population	
Biologics failure, n *(%)*:	8 (53.3%)
1 failure	2 (13.3%)
2 failures	1 (6.7%)
3+ failures	5 (33.3%)
Adverse Events, n *(%)*:	2 (13.3%)
Oral Candidiasis	1 (6.7%)
Acute Urticaria	1 (6.7%)

Abbreviations: PASI, Psoriasis Area and Severity Index; BMI, Body Mass Index.

more than half of our instances were resistant to such agents. In another study evaluating biologic therapies in the elderly[7] Brodalumab achieved slightly superior PASI75 and PASI90 responses than PASI75 and PASI90 responses in our study at week 24. However, this result must be taken with caution since patients' characteristics of the group under Brodalumab treatment were not reported, preventing us from making any comparison between the frequencies of patients' features in the two groups that might impair treatment responses. Furthermore, PASI100 responses were not reported.

Considering anti-IL-23 therapies, patients treated with BKZ in our study achieved PASI90 and PASI100 responses in higher proportions than patients from a study evaluating the safety and efficacy of Tildrakizumab[8] and from another study evaluating the safety and efficacy of the three currently approved IL-23p19-inhibitors.[9] Interestingly, we also found slightly lower responses after 24 weeks compared to another real-life analysis not considering specifically the elderly,[10] consistently with other studies evaluating the impact of aging on clinical responses to anti-psoriatic biologics.[11] This finding might result from a lower number and decreased activity of regulatory T cells in elderly patients that make their psoriasis more resistant to treatments.[12]

Other studies have evaluated the efficacy of BKZ in a real-world setting. Rimke et al[13] and Rompoti et al[14] reported similar PASI75, 90 and 100 responses to what was observed in our study, while Hagino et al[15] reported lower proportions of patients achieving PASI75, 90 and 100, even though we focused on an older population. An explanation to these

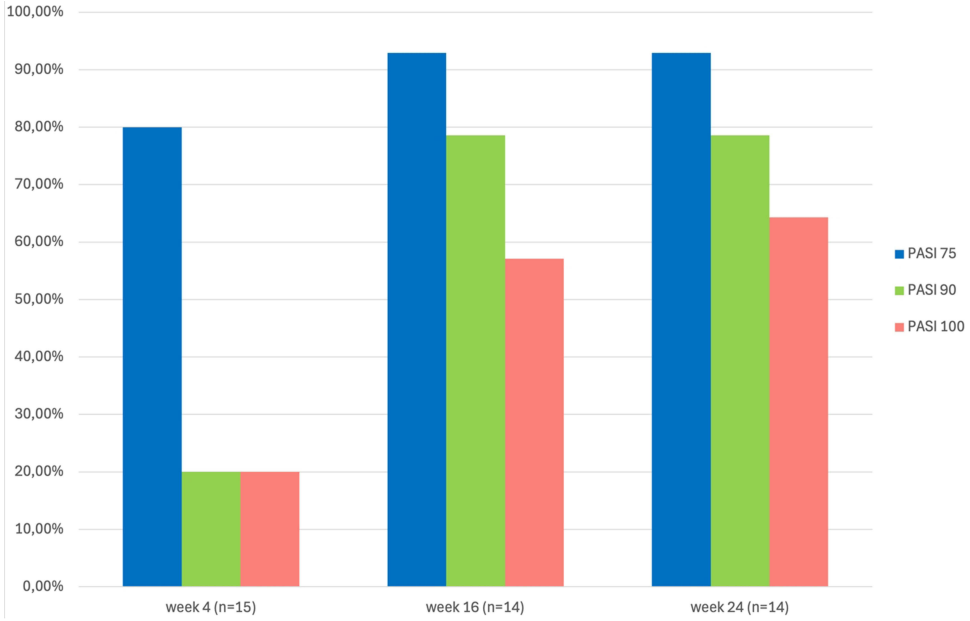

Figure 1 PASI responses at follow-up visits. Psoriasis Area Severity Index (PASI) 75, 90 and 100 responses after 4, 16, and 24 weeks of Bimekizumab treatment.

results might be found in the baseline characteristics of patients included in each study. For instance, while 13.3%, 6.7% and 26.7% of our patients presented respectively scalp, palmoplantar and nail involvement, these same characteristics were present respectively in 41.0%, 18% and 36.1% of patients in Rompoti et al, while scalp and nail involvement were present in 91.7% and 66.7% of patients respectively in Hagino et al. These factors might represent a predictor of worse response regardless of age.

Finally, despite the complex health profiles typical of elderly populations, BKZ demonstrated a favorable safety profile, with only two patients discontinuing treatment due to minor AEs, with a rate lower than what observed in a real-life analysis including both elderly and non-elderly.[10] Limitations to our study are the small sample size and the relatively short observation period. Furthermore, we did not collect patients' non-dermatological medication use, which might have played a role in the development of adverse events. Future analyses with larger cohorts and longer follow-up are needed to validate our findings and to possibly identify patients' characteristics that may better predict treatment responses and the likelihood of adverse events' occurrence.

Data Sharing Statement

All the data of the study is included in the present manuscript.

Compliance with Ethics Guidelines

The patients in this manuscript provided informed consent for the publication of case details, and institutional approval was not required, as the study was based on data retrospectively collected in a routine clinical setting (AIFA Determination, March 20, 2008). This study complies with the Declaration of Helsinki and no ethical approval was required as it results from clinical routinary activity.

Author Contributions

All authors made a significant contribution to the work reported (ie, conception, study design, execution, acquisition of data, analysis, and interpretation); took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

No funding or sponsorship was received for this study or publication of this article.

Disclosure

The authors report no conflicts of interest in this work.

References

1. Parisi R, Iskandar IYK, Kontopantelis E, Augustin M, Griffiths CEM, Ashcroft DM. National, regional, and worldwide epidemiology of psoriasis: systematic analysis and modelling study. *BMJ*. 2020;369. doi:10.1136/bmj.m1590
2. Gordon KB, Langley RG, Warren RB, et al. Bimekizumab safety in patients with moderate-to-severe plaque psoriasis: pooled data from up to 3 years of treatment in randomized phase III trials. *Br J Dermatol*. 2024;190(4):477–485. doi:10.1093/bjd/ljad429
3. Megna M, Camela E, Cinelli E, Fabbrocini G. Real-life efficacy and safety of secukinumab in elderly patients with psoriasis over a 2-year period. *Clin Exp Dermatol*. 2020;45(7):848–852. doi:10.1111/ced.14258
4. Talamonti M, Russo F, Malara G, et al. Efficacy and safety of secukinumab in elderly patients with moderate to severe plaque-type psoriasis: post-hoc analysis of the SUPREME study. *Clin Cosmet Invest Dermatol*. 2023;16:847–852. doi:10.2147/CCID.S400520
5. Megna M, Cinelli E, Balato A, Gallo L, Fabbrocini G. Efficacy and safety of ixekizumab in a group of 16 elderly patients with psoriasis over a 1-year period. *J Eur Acad Dermatol Venereol*. 2020;34(11). doi:10.1111/jdv.16063
6. Dattola A, Bernardini N, Caldarola G, et al. Effectiveness of ixekizumab in elderly patients for the treatment of moderate-to-severe psoriasis: results from a multicenter, retrospective real-life study in the Lazio region. *Dermatol Pract Concept*. 2024;14(3). doi:10.5826/dpc.1403a166
7. Bakirtzi K, Sotiriou E, Papadimitriou I, et al. Elderly patients with psoriasis: long-term efficacy and safety of modern treatments. *J Dermatol Treat*. 2022;33(3):1339–1342. doi:10.1080/09546634.2020.1809623
8. Orsini D, Caldarola G, Dattola A, et al. Efficacy and safety of tildrakizumab in elderly patients: real-world multicenter study (ESTER - study). *J Dermatol Treat*. 2024;35(1):2319304. doi:10.1080/09546634.2024.2319304

9. Ruggiero A, Fabbrocini G, Cinelli E, et al. Anti-interleukin-23 for psoriasis in elderly patients: guselkumab, risankizumab, and tildrakizumab in real-world practice. *Clin Exp Dermatol*. 2022;47(3):561–567. doi:10.1111/ced.14979
10. Gargiulo L, Narcisi A, Ibba L, et al. Effectiveness and safety of bimekizumab for the treatment of plaque psoriasis: a real-life multicenter study-IL PSO (Italian landscape psoriasis). *Front Med Lausanne*. 2023;10:1243843. doi:10.3389/fmed.2023.1243843
11. Rosset F, Mastorino L, Dapavo P, Ortoncelli M, Quaglino P, Ribero S. Aging impact in response to different classes of biological treatment in psoriatic patients: a real-life observational study. *J Clin Med*. 2023;12(23):7215. doi:10.3390/jcm12237215
12. Palatella M, Guillaume SM, Linterman MA, Huehn J. The dark side of Tregs during aging. *Front Immunol*. 2022;13:940705. doi:10.3389/fimmu.2022.940705
13. Rimke A, Sood S, Rankin BD, et al. Real-world experience of bimekizumab for adult patients with plaque psoriasis: a 16-week multicenter retrospective study. *J Am Acad Dermatol*. 2024;91(2):359–361. doi:10.1016/j.jaad.2024.04.027
14. Rompoti N, Stefanaki I, Panagakis P, et al. Bimekizumab in psoriasis: a monocentric study evaluating short- and mid-term effectiveness and safety profile in a real-world setting. *Arch Dermatol Res*. 2024;316(5):133. doi:10.1007/s00403-024-02868-7
15. Hagino T, Saeki H, Fujimoto E, Kanda N. Real-world effectiveness and safety of bimekizumab in Japanese patients with psoriasis: a single-center retrospective study. *J Dermatol*. 2024;51(5):649–658. doi:10.1111/1346-8138.17186