Real-World Use of Bimekizumab Therapy in Patients with Difficult-to-Treat Plaque Psoriasis: A Retrospective Analysis from a Large Academic Center

Editor's Pick

While clinical trials support the efficacy of bimekizumab, real-world data in difficult-to-treat cases is not as evident. This study provides insight into its use in patients who have cycled through multiple systemic therapies, offering a practical perspective beyond randomized controlled trials. By addressing a critical gap, this research enhances understanding of bimekizumab's effectiveness in real clinical settings.

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Abstract

Bimekizumab is a humanized monoclonal IgG1 antibody that selectively inhibits IL-17A and IL-17F, two cytokines that play a critical role in psoriasis vulgaris pathogenesis. Randomized clinical trials demonstrating the superiority of bimekizumab compared to placebo and other injectable biologics led to its approval by the United States FDA for moderate-to-severe plaque psoriasis. Due to the often-strict inclusion/exclusion criteria of randomized clinical trials, patient characteristics in real practice may drastically differ. Thus, the authors sought to investigate the use of this medication among real-world patients at their large academic center.

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Charts of patients prescribed bimekizumab between October 2023–April 2024 with a diagnosis of moderate-to-severe plaque psoriasis and follow-up within 6 months of medication initiation were included. Results showed that of the 24 patients prescribed bimekizumab, 83.3% (n=20) had concurrent diagnoses of psoriasis and psoriatic arthritis. At bimekizumab initiation, all patients had a baseline body surface area (BSA) affected by psoriasis of ≥10%, with mean BSA being 13.4%. After a mean of 163.5 days of therapy, BSA decreased to 3.8%. Overall, 83.3% of patients experienced a decrease in BSA after initiating bimekizumab, with 37.5% of patients obtaining a BSA of 0% (skin clear). Aligning with clinical trials, this study reinforces bimekizumab as a useful therapeutic option for moderate-to-severe plaque psoriasis. Future real-world research investigating bimekizumab would benefit from increased size and longer follow-up. Despite limitations, this study supports bimekizumab as an appropriate option for treatment of moderate-to-severe plaque psoriasis among patients in real clinical practice.

Key Points

1. Psoriasis affects 2–3% of the population worldwide, with about 30% of these patients developing psoriatic arthritis.
2. This retrospective review presents 24 patients with difficult-to-treat psoriasis who had failed prior systemic therapies and were initiated on bimekizumab with positive effects.
3. Bimekizumab can be considered as a next-step therapy for bio-experienced patients, even for patients who have failed another IL-17 inhibitor.

INTRODUCTION

Bimekizumab is a humanized monoclonal IgG1 antibody that selectively inhibits IL-17A and IL-17F, two cytokines that play a critical role in psoriasis vulgaris pathogenesis.[1] Randomized clinical trials (RCT) demonstrating the superiority of bimekizumab compared to placebo and other injectable biologics and its clinical safety led to its approval by the United States FDA for moderate-to-severe plaque psoriasis.[2] Presently, few studies have investigated the effectiveness of bimekizumab in real clinical practice.[3] Due to the often strict inclusion/exclusion criteria of RCTs, patient characteristics in real practice may drastically differ, making real-world studies imperative.[4] Herein, the authors describe the use of bimekizumab among 24 patients with difficult-to-treat plaque psoriasis, the majority of whom had previously cycled through multiple systemic therapies.

METHODS

Charts of patients prescribed bimekizumab for psoriasis between October 2023 (time of United States FDA approval) to April 2024 at a large academic center in the United States were retrospectively retrieved and reviewed. For inclusion, a diagnosis of moderate-to-severe plaque psoriasis and follow-up within 6 months of bimekizumab initiation was necessary. The authors defined "difficult-to-treat plaque psoriasis" as that which was refractory to at least two prior systemic therapies.

RESULTS

Of the 24 patients prescribed bimekizumab, 83.3% (n=20) had concurrent diagnoses of psoriasis and psoriatic arthritis; the remaining 16.7% (n=4) of patients had psoriasis only (Table 1). At bimekizumab initiation, all patients had a baseline body surface area (BSA) affected by psoriasis of ≥10%, with

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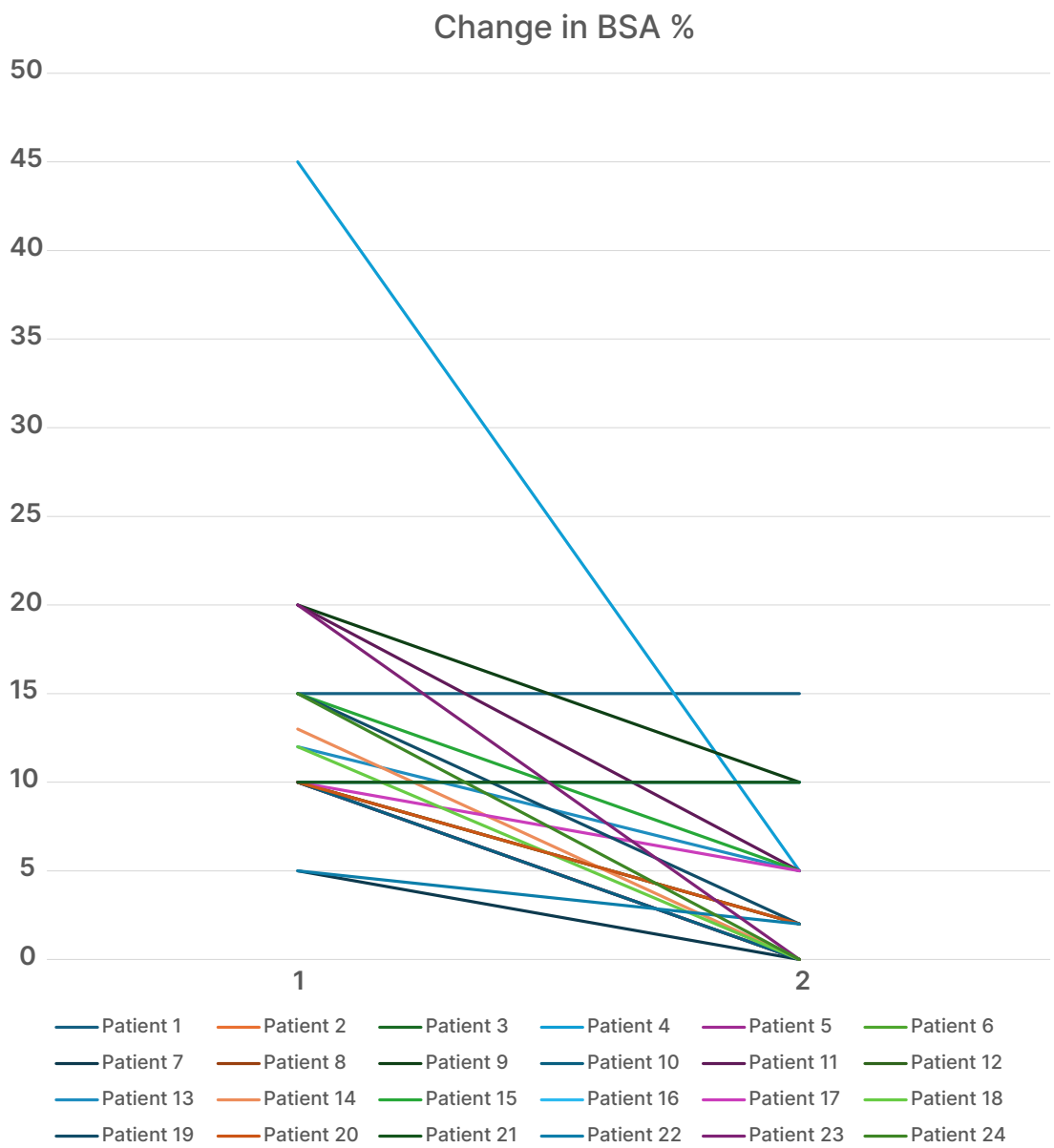
mean BSA being 13.4±7.8 (Figure 1). At the start of treatment, the mean age and number of failed systemic therapies was 54.6 years and 4.5 therapies, respectively. All patients (except one) were bio-experienced, and 87.5% of patients had previously cycled through at least two systemic options, with either an inadequate response or secondary loss of efficacy to each.

Immediately prior to bimekizumab switch, 66.7% of patients were on an IL-17A or IL-17RA inhibitor, 20.8% of patients were on an IL-23 inhibitor, 8.33% of patients were on a TYK2 inhibitor, and one patient was on a TNF-α inhibitor. After a median of 184 days of therapy, BSA decreased to 3.8%. Overall, 83.3% of patients experienced a decrease in BSA after initiating bimekizumab, with 37.5%

Figure 1: Change in body surface area (%) from initial follow-up visit.



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of patients obtaining a BSA of 0% (skin clear). In contrast, after an average of 119.25 days of therapy, 16.7% of patients experienced no change in disease severity. No patients clinically worsened while prescribed bimekizumab. Four patients experienced adverse events, with two of these resulting in bimekizumab discontinuation (gastrointestinal symptoms, injection site reaction [ISR]).

DISCUSSION

To the authors' knowledge, this study is the first analysis of bimekizumab use in clinical practice in the United States. Aligning with clinical trials, this study reinforces bimekizumab as a useful therapeutic option for moderate-to-severe plaque psoriasis.[1,2,5] In the Phase III bimekizumab randomized clinical trials (BE READY, BE RADIANT, BE VIVID, BE SURE),[1,5-7] patients were excluded if they had experienced a primary failure to an IL-17 inhibitor or had failed more than one biologic other than an IL-17 inhibitor. Further, in each of the four trials, less than half of the patients were bio-experienced.[1,5-7] In contrast, 21 out of the 24 patients included in this study had attempted multiple biologics or systemic medications to treat their plaque psoriasis prior to attempting treatment with bimekizumab. Twenty-two patients had attempted an IL-17 inhibitor, with 15 trialing secukinumab, 12 trialing ixekizumab, and eight trialing brodalumab (Table 1). Additionally, patients with certain comorbidities were excluded from the bimekizumab trials, for example those with hepatitis C infection. Although only one of the patients included in this study reported chronic hepatitis C infection, this patient had an improvement in affected BSA after starting therapy with no adverse events noted. Regarding special site involvement, nine patients had scalp psoriasis, with four achieving clearance, three achieving mild improvement, and two showing no improvement. Two patients had facial psoriasis that cleared after bimekizumab initiation, and three patients had palm/sole psoriasis with mild improvement. No patients presented with genital psoriasis.

Interestingly, oral candidiasis was a frequently reported adverse event in the bimekizumab clinical trials but was observed in only one patient in this study. This may be due to limited follow-up and small sample size.

Table 1: Real-world use of bimekizumab in 24 patients with difficult-to-treat plaque psoriasis.

Pt	Age (y) / sex	BMI (kg/m²)	Comorbidities	Diagnosis	Previous systemic therapies	BSA (%) at week 0*	BSA (%) at 2–6 months*	Change in BSA (%)	Duration of BIM (days)†	AEs
1	46/F	22.9	PCOS	PSO/PsA	BROD, SEC, ETAN, ADA, IXE, MTX, UPA	15	15	(0)	131	NO
2	56/M	29.5	Allergic rhinitis, HCL, HLD	PSO/PsA	ADA, GUS, RIS, IXE	10	0	(-10)	186	NO
3	54/F	36.3	n/a	PSO/PsA	ADA, USTE, IXE, ETAN	10	0	(-10)	113	NO
4	47/M	36.1	n/a	PSO/PsA	ADA, GUS, SEC, ETAN, IXE, APREM, MTX	45	5	(-40)	172	TC,‡ OC‡
5	65/F	25.2	T2DM, HTN	PSO/PsA	SEC, GUS, BROD, RIS, APREM	10	0	(-10)	56	NO

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Table 1: Continued.

Pt	Age (y) / sex	BMI (kg/m²)	Comorbidities	Diagnosis	Previous systemic therapies	BSA (%) at week 0*	BSA (%) at 2–6 months*	Change in BSA (%)	Duration of BIM (days)†	AEs
6	69/F	25.8	Chronic rhinitis	PSO/PsA	UPA, BROD, ADA, SEC, INFLIX, GOL, USTE, APREM, IXE	10	10	(0)	105	NO
7	69/F	28.3	HTN, chronic HepC, fatty liver	PSO/PsA	GUS, SEC, ETAN	5	0	(-5)	216	NO
8	71/F	25.1	MIS, HCL, HTN, GERD	PSO/PsA	BROD, UPA, ETAN, SEC, APREM	10	2	(-8)	222	NO
9	79/M	26.0	PVD, HCL, CAD, NMSX	PSO/PsA	BROD, UPA, ACI	20	10	(-10)	232	NO
10	44/M	n/a	n/a	PSO/PsA	n/a	10	0	(-10)	79	NO
11	52/F	n/a	T2DM	PSO/PsA	IXE, DEUC, CsA, APREM	20	5	(-15)	150	NO
12	30/M	36.5	n/a	PSO/PsA	ADA, IXE, SEC, GUS, RIS, USTE, BROD, TIL, APREM	10	2	(-8)	194	NO
13	78/F	25.3	GERD, HLD, OA	PSO/PsA	IXE, SEC, ADA, RIS, TIL, DEUC	12	5	(-7)	190	GI sx‡
14	39/F	27.1	n/a	PSO/PsA	BROD, ETAN, ADA, SEC	13	0	(-13)	197	NO
15	56/F	28.3	n/a	PSO	RIS, IXE, GUS	15	5	(-10)	190	ISR‡
16	40/F	22.4	n/a	PSO/PsA	SEC, CERT, GUS, CsA	10	10	(0)	47	ISR§
17	73/M	34.7	HTN, CAD, T2DM, GERD	PSO/PsA	SEC, ETAN, ADA, IXE, MTX	10	5	(-5)	166	NO
18	86/M	27.3	HTN, HLD, CAD, CVA, NMSC, Afib	PSO/PsA	RIS	12	0	(-12)	194	NO
19	52/M	32.9	HLD, CAD, T2DM, HTN	PSO/PsA	RIS, IXE, SEC, ETAN, BROD	15	2	(-13)	217	NO
20	30/F	20.6	n/a	PSO/PsA	IXE	10	2	(-8)	120	NO
21	53/M	26.8	n/a	PSO	SEC, RIS, BROD	10	10	(0)	194	NO
22	33/M	32.8	n/a	PSO	RIS, SEC, MTX, DEUC	5	2	(-3)	182	NO

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Table 1: Continued.

Pt	Age (y) / sex	BMI (kg/m²)	Comorbidities	Diagnosis	Previous systemic therapies	BSA (%) at week 0*	BSA (%) at 2–6 months*	Change in BSA (%)	Duration of BIM (days)†	AEs
23	39/M	25.2	n/a	PSO	SPE, CERT, ETAN, ADA, USTE, IXE, APREM	20	0	(-20)	175	NO
24	50/M	25.1	n/a	PSO/PsA	IXE, ETAN, SEC, USTE, GUS	15	0	(-15)	195	NO
Avg.	54.6	28.2	-	-	4.5	13.4	3.8	-9.6	163.5	-

*Because this was a retrospective study, data for patients were recorded when patients returned for visits, BSA was used as a proxy for disease severity as PASI scores were not consistently reported.

†Duration of bimekizumab was calculated from the date of initiation of bimekizumab to the date of most recently known follow-up.

‡Required discontinuation.

§Did not require discontinuation.

ACI: acitretin; ADA: adalimumab; AE: adverse event; Afib: atrial fibrillation; APREM: apremilast; Avg: average; BIM: bimekizumab; BROD: brodalumab; BSA: body surface area; CAD: coronary artery disease; CERT: certrolizumab pegol; CsA: cyclosporine; CVA: cerebral vascular accident; DEUC: deucravacitinib; ETAN: etanercept; GERD: gastroesophageal reflux disorder; GI: gastrointestinal; GOL: golimumab; GUS: guselkumab; HCL: hypercholesterolemia; HDL: hyperlipidemia; HepC: hepatitis C; HTN: hypertension; INFLIX: infliximab; ISR: injection site reaction;IXE: ixekizumab; MIS: melanoma *in situ*; MTX: methotrexate; NMSC: non-melanoma skin cancer; OA: osteoarthritis; OC: oral candidiasis; PCOS: polycystic ovarian syndrome; PsA: psoriatic arthritis; PSO: psoriasis; Pt: patient; PVD: peripheral vascular disease; RIS: risankizumab; SEC: secukinumab; SPE: spesolimab; T2DM: Type 2 diabetes; TC: tinea cruris; TIL: tildrakizumab; UPA: upadacitinib; USTE: Ustekinumab; y: years.

Also of note, ISR was reported in a small percentage in each of the four clinical trials; however, in this study, it was reported by two patients, with one patient requiring bimekizumab discontinuation due to ISR. As bimekizumab was only recently approved by the FDA, the duration of treatment with bimekizumab is limited by this constraint, as evident in this study.

CONCLUSION

Future real-world research investigating bimekizumab would benefit from increased size and longer follow-up. Despite limitations, this study supports bimekizumab as an appropriate option for treatment of moderate-to-severe plaque psoriasis among patients in real clinical practice, even those who previously failed multiple systemics and/or biologic therapies. Bimekizumab may be considered as a next-choice biologic therapy in biologic experienced patients who might have failed a prior biologic for psoriasis.

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