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A Retrospective Review of Patients' Response to Biologic Therapy for Psoriasis

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ABSTRACT

Background: Biologic treatments have taken the forefront in treating moderate-to-severe psoriasis. Although numerous randomized, controlled trials have demonstrated the efficacy of these agents, there is limited data suggesting that clinical trial outcomes are reproducible in real-world patients.

Objective: Obtain real-world evidence for the use of biologics that target different segments of the immune system in patients with moderate-to-severe psoriasis.

Methods: A retrospective chart review was conducted for 100 patients who initiated biologic therapy and had a follow-up visit within a 4- to 12-month period. Efficacy assessments included body surface area (BSA), Physician's Global Assessment (PGA) scores, composite BSA×PGA scores, and the National Psoriasis Foundation (NPF) Treat to Target (TTT) goal of ≤1% BSA.

Results: Biologic treatment led to notable reductions in BSA, PGA, and BSA×PGA relative to baseline, with the majority (67.0%) of the population achieving NPF TTT goals at follow-up. Disease improvements were observed in all patients, regardless of baseline body weight, prior experience with biologics, or the specific immune target of the prescribed biologic.

Conclusion: Long-term biologic therapy demonstrated effectiveness in treating patients with moderate-to-severe psoriasis.

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INTRODUCTION

Psoriasis is a lifelong, relapsing, immune-mediated disease that primarily affects the skin and joints.[1-3] It is estimated to affect more than 7 million people in the Unites States and approximately 125 million people worldwide.[2-4]

Plaque psoriasis is the most common form of the disease, affecting 80% to 90% of patients and manifesting as sharply demarcated, scaling, and erythematous lesions that vary in shape and size.[1,5,6] Multiple comorbidities, including cardiovascular disease, diabetes, metabolic syndrome, and renal disease, increase the disease burden beyond the realm of the skin, particularly with more severe disease.[2,3,6,7]

The majority of patients seen in clinical practice have mild psoriasis, and only about 20% to 25% have moderate-to-severe disease.[3,8] The Psoriasis Area and Severity Index (PASI) is among the most commonly used tools for monitoring response to treatment in clinical trials.[9,10] However, it is rarely used by dermatologists to guide disease management because it can be impractical to implement in clinical practice.[9-11] Measures such as the Physician's Global Assessment (PGA), the percent of body surface area (BSA) involvement, and composite BSA×PGA scores are other commonly used assessment tools,[6,10,12] with BSA being the most preferred instrument for evaluating patient responses.[13]

Because there is no cure for psoriasis, treatment strategies aim to clear active disease sites and prolong symptom-free periods.[8] Topical medications or phototherapy are sufficient therapeutic interventions for the majority of patients with limited disease.[8,9,14] However, more extensive disease often requires the use of systemic therapies, such as retinoids, methotrexate, cyclosporine, or acitretin, or biologic immune-modifying agents.[3,8,9,15] In recent years, newer therapies for moderate-to-severe psoriasis have become available, primarily through the development of biologics targeting tumor necrosis factor (TNF), interleukin (IL)-12/23, IL-23, and IL-17.[3] Because of their specificity, biologic treatments for psoriasis are considered safer than some of the traditional systemics,[16] and this has pushed them to the forefront in treating moderate-to-severe psoriasis.[8,9]

Despite their availability and overall success in treating psoriasis, there are many unanswered questions regarding how to appropriately match specific biologics to individual patients. Numerous randomized, controlled trials have demonstrated the efficacy of the different biologics against placebo, but the relative benefit of individual biologics remains unclear due to the limited number of head-to-head trials; comparative data in a real-world setting are even more sparse. Additionally, relevant practical information on chronic disease management with biologics is lacking.

Several other issues further complicate the selection and use of biologics. For example, it is possible for a given biologic to lose efficacy over time in a patient who initially responds favorably.[9] Further, there is a small percentage of patients who fail to recapture their initial level of response when their biologic therapy is resumed after a period of discontinuation, and switching biologics entirely may not always result in improved efficacy.[9] More evidence is needed to determine the relative efficacy of biologics in patients with psoriasis who have previously received biologic therapy ("bio-experienced") vs those who are initiating biologic therapy for the first time ("bio-naïve"), particularly in a real-world setting.

Another consideration in the use of biologics relates to body weight. Patients with psoriasis, particularly those requiring systemic treatment, tend to be above normal weight, and it is now recognized that obesity is a risk factor for the incidence and severity of psoriasis.[17-20] Excess body weight may interfere with therapeutic efficacy, with high interference identified for fixed-dose biologics that do not account for differences in body weight.[17,18,20] In fact, body weight reduction in obese patients on biologics may increase the efficacy of the drug, especially for agents that are administered at fixed doses.[19-21] Studying clinical outcomes in patients who vary in body weight in a real-world setting will help guide treatment approaches.

In the present study, we performed a retrospective chart review to address some of these issues and determine if they contribute to biologic efficacy in daily dermatology practice. Clinical outcomes involving 9 different biologic agents were assessed up to 1 year after the biologics were prescribed to bio-naïve or bio-experienced patients who had a wide range of body weights.

MATERIALS AND METHODS

Study Design

This was a single-center, observational study of 100 patients to assess the efficacy of biologic therapy in a real-world setting in a psoriasis population consisting mostly of patients with moderate-to-severe psoriasis, per baseline BSA assessments. A retrospective chart review was conducted for patients who were evaluated at the center between August 1, 2015, and November 1, 2019. Patients who had initiated biologic therapy within 6 months of the baseline visit and who had a follow-up visit within a 12-month period were selected for analysis. Eligible patients included male and nonpregnant female adults ≥18 years of age with moderate-to-severe chronic plaque psoriasis.

Patients who were undergoing therapy with a conventional systemic treatment for psoriasis discontinued their regimen at the time of biologic prescription; systemic treatments could be added later at the discretion of the study investigator. Concomitant use of topical medications was permitted throughout the study duration. Treatment was guided by each patient's clinical response and insurance coverage, with biologic prescriptions being switched, titrated, or discontinued as needed. Modifications to a patient's biologic regimen was allowed at the follow-up visit, or any time prior. Additional psoriatic treatments, including traditional systemic therapies, were prescribed in combination with biologic therapy as needed.

This study was conducted in accordance with the principles of the Declaration of Helsinki and with Good Clinical Practice guidelines.

Study Outcomes

Efficacy and safety assessments were performed at baseline and follow-up visits. Disease severity outcome measures included the percent of affected BSA, score on the 5-point PGA in which 0=clear, 1=almost clear, 2=mild, 3=moderate, and 4=severe, and the BSA×PGA composite score. Additional efficacy assessments included the overall disease improvement at follow-up, which was calculated as $(BSA{\times}PGA_{follow\text{-}up} - BSA{\times}PGA_{baseline})/BSA{\times}PGA_{baseline}$, and the percent of patients achieving the National Psoriasis Foundation (NPF) Treat to Target (TTT) goal of BSA ≤1% at follow-up.[13] Adverse events (AEs) were captured as observations from the investigator or events reported by the patients, regardless of severity, seriousness, or causality.

Statistical Analysis

All analyses were performed by the investigator. No comparator statistical testing was performed for the efficacy or safety data. Continuous variables were summarized using descriptive statistics. For categorical variables, frequencies and percentages were presented. Data were summarized for the overall population and for subgroups of patients that were stratified by baseline body weight, prior experience with biologics, and the class of biologic that was initiated at baseline.

RESULTS

Baseline Demographics and Disease Characteristics

A total of 100 patients were included in the study (Table 1). Patients had had a diagnosis of psoriasis for an average of 16.4 years; the majority (66.0%) were bio-naive. Overall, patients had significant disease activity at baseline: the mean affected BSA was 13.3%, and the mean assigned PGA score was 3.0. Based on the American Academy of Dermatology's definition of disease severity in which mild, moderate, and severe psoriasis correspond with <5%, ≥5% to <10%, and ≥10% BSA involvement, respectively,[8] the majority of the population consisted of patients with severe psoriasis at baseline (69.0%), with the remaining patients having either moderate (21.0%) or mild (10.0%) disease.

Prescribed Treatments

A total of 9 different biologic agents were prescribed throughout the study (Table 3). These biologics fell within 3 categories based on their shared immune targets (Table 4).

TABLE 1.

Baseline Demographics and Disease Characteristics	
Baseline Characteristic	**Biologic Treatment (N=100)**
Age (years), mean (SD)	47.2 (14.8)
Sex, n (%)	
Male	54 (54.0)
Female	46 (46.0)
Race, n (%)	
White	83 (83.0)
Nonwhite	14 (14.0)
Not reported	3 (3.0)
Weight (lb), mean (SD)	191.8 (50.0)
≤200 lb, n (%)	64 (64.0)
>200 lb, n (%)	36 (36.0)
Psoriasis duration (years), mean (SD)	16.4 (11.8)
Prior biologic treatment, n (%)	
Bio-naïve	66 (66.0)
Bio-experienced	34 (34.0)
BSA, mean (SD)	
Overall	13.3 (9.8)
≤200 lb	13.0 (10.2)
>200 lb	13.8 (9.2)
Bio-naïve	14.6 (10.2)
Bio-experienced	10.8 (8.6)
PGA, mean (SD)	
Overall	3.0 (0.7)
≤200 lb	3.0 (0.6)
>200 lb	3.1 (0.7)
Bio-naive	3.0 (0.6)
Bio-experienced	3.0 (0.7)
BSA×PGA, mean (SD)	
Overall	41.5 (34.5)
≤200 lb	39.9 (33.7)
>200 lb	44.4 (36.2)
Bio-naive	44.7 (34.2)
Bio-experienced	35.4 (34.9)

Bio, biologic; *BSA*, body surface area; *BSA×PGA*, composite BSA and PGA score; *PGA*, Physician's Global Assessment; SD, standard deviation.

TABLE 2.

Summary of Adverse Events	
Adverse Event	**Cases, n (%[a])**
Bronchitis	4 (4.0)
Upper respiratory infection	4 (4.0)
Influenza	2 (2.0)
Kidney stones	2 (2.0)
Cardiac arrhythmia	1 (1.0)
Common cold	1 (1.0)
Ear infection	1 (1.0)
Folliculitis	1 (1.0)
Gastroenteritis	1 (1.0)
Paroxysmal atrial fibrillation	1 (1.0)
Prostatitis	1 (1.0)
Right lung mass	1 (1.0)
Sinusitis	1 (1.0)
Sore throat	1 (1.0)
Tennis elbow	1 (1.0)
Torn meniscus	1 (1.0)
Trigger finger	1 (1.0)

[a]Percentages are calculated based on total number of patients (N=100).

TABLE 3.

Prescribed Biologic Treatment		
Biologic	**Patients Receiving Biologic Treatment, n (%)**	
	At Baseline (N=100)	**At Follow-up (N=100)**
Ustekinumab (Stelara®)	24 (24.0)	24 (24.0)
Guselkumab (Tremfya®)	20 (20.0)	22 (22.0)
Ixekizumab (Taltz®)	17 (17.0)	16 (16.0)
Adalimumab (Humira®)	13 (13.0)	10 (10.0)
Secukinumab (Cosentyx®)	13 (13.0)	12 (12.0)
Risankizumab (Skyrizi®)	8 (8.0)	9 (9.0)
Etanercept (Enbrel®)	3 (3.0)	3 (3.0)
Brodalumab (Siliq®)	1 (1.0)	1 (1.0)
Certolizumab (Cimzia®)	1 (1.0)	1 (1.0)
None[a]	0 (0.0)	2 (2.0)

[a]Patients who discontinued biologic therapy.
Specific biologic regimens were permitted to have been switched, titrated, or discontinued prior to follow-up. The time interval between baseline and follow-up visits ranged between 4 and 12 months across all patients, with a mean of 6.7 months.

Approximately half of the patients (52.0%) were prescribed a biologic that inhibits IL-12/23 and IL23 at baseline, and the other half were prescribed a biologic that inhibits either IL-17 (31.0%) or TNFα (17.0%) (Table 4). Ten patients switched biologics, with 4 of those patients switching prior to the follow-up study visit. The biologic dosing frequency was reduced to every 24 weeks at follow-up for 1 patient; 2 patients discontinued biologic treatment entirely (1 prior to follow-up, and the other at follow-up). Concomitant psoriatic treatments including apremilast, acitretin, and narrowband ultraviolet B (UVB) phototherapy were prescribed to 5 patients either before or at follow-up. One patient discontinued use of acitretin prior to follow-up but maintained their biologic regimen throughout the study. The time interval between baseline and follow-up visits ranged between 4 and 12 months across all patients, with a mean of 6.7 months.

TABLE 4.

Prescribed Biologics Grouped by Shared Immune Targets		
Biologic by Target, n (%)	Biologic Treatment at Baseline (N=100)	Biologic Treatment at Follow-up (N=100)
IL-12/23 and IL23 inhibitor[a]	52 (52.0)	55 (55.0)
IL-17 inhibitor[b]	31 (31.0)	29 (29.0)
TNFα inhibitor[c]	17 (17.0)	14 (14.0)
None[d]	0 (0.0)	2 (2.0)

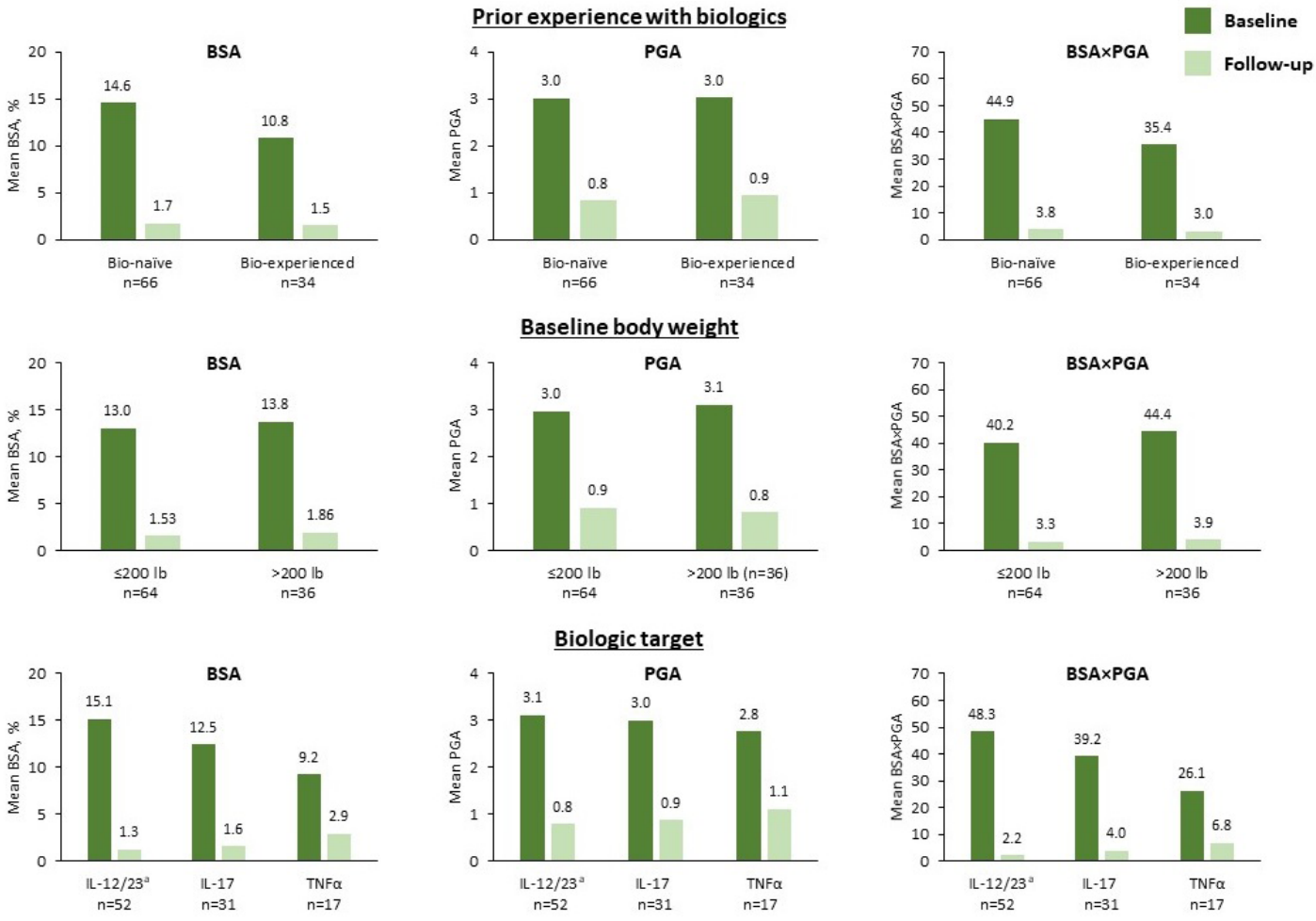
IL, interleukin; *TNFα*, tumor necrosis factor alpha.
[a]Guselkumab, risankizumab, ustekinumab.
[b]Brodalumab, ixekizumab, secukinumab.
[c]Adalimumab, certolizumab, etanercept.
[d]Patients who discontinued biologic treatment entirely.
The 9 biologic agents that were prescribed throughout the study fell within 3 categories based on their shared immune targets: (1) risankizumab and guselkumab, which target the p19 subunit of IL-23, and ustekinumab, which targets the p40 subunit of both IL-12 and IL-23[22-24]; (2) secukinumab, brodalumab, and ixekizumab, which target an IL-17 pathway;[25-27] and (3) etanercept, adalimumab, and certolizumab, which target a TNFα pathway.[28-30]

Efficacy Assessments

Overall, the mean affected BSA decreased from 13.3% to 1.1% (Figure 4A), and the mean PGA decreased from 3.0 to 0.9 (Figure 4B), demonstrating that up to 12 months of biologic therapy improved psoriasis severity on average from "moderate" to "almost clear" in the pooled population. Similarly, there was a pronounced improvement in the overall mean composite BSA×PGA score (Figure 4C).

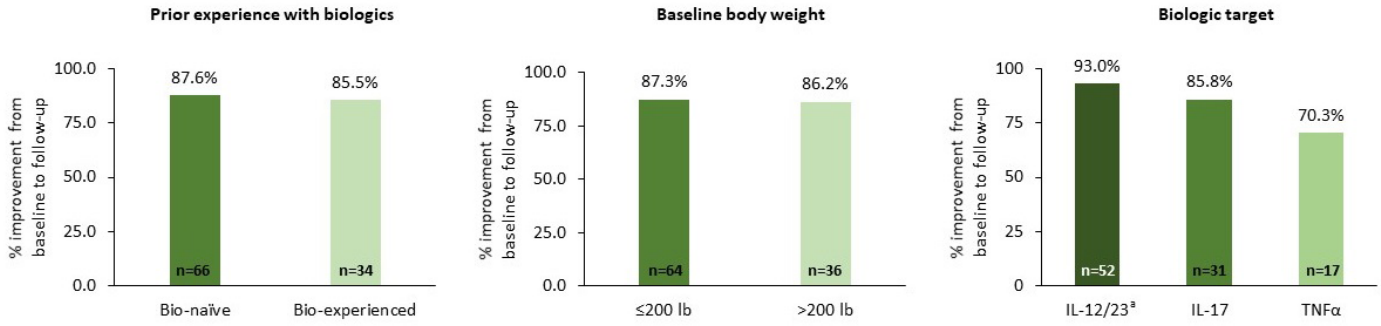
Improvements in disease severity outcomes were also observed in all subgroup analyses (Figure 1). Bio-naïve and bio-experienced patients showed comparable improvements in psoriasis severity (Figure 1, top); both subgroups exhibited robust decreases in their mean BSA, PGA, and composite BSA×PGA scores from baseline to follow-up.

FIGURE 1. Psoriasis severity assessments for subgroups separated by prior biologic experience, baseline body weight, and immune target of prescribed biologic.



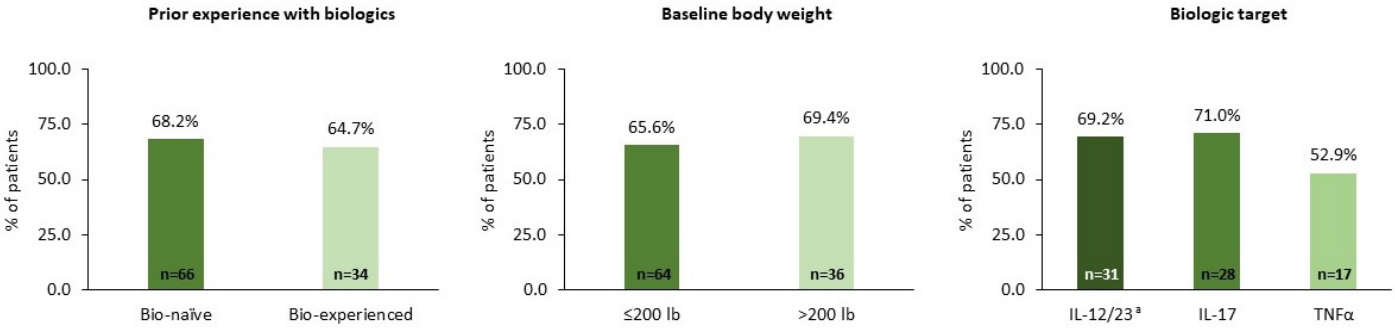
Bio, biologic; *BSA*, body surface area; *BSA×PGA*, composite BSA and PGA score; *IL*, interleukin; *PGA*, Physician's Global Assessment; *TNFα*, tumor necrosis factor alpha.
[a]Note that this group of biologics targeted either IL-23 alone or both IL-12 and IL-23.

FIGURE 2. Disease improvement as % change in BSA×PGA at follow-up in subgroups separated by prior biologic experience, baseline body weight, and immune target of prescribed biologic.



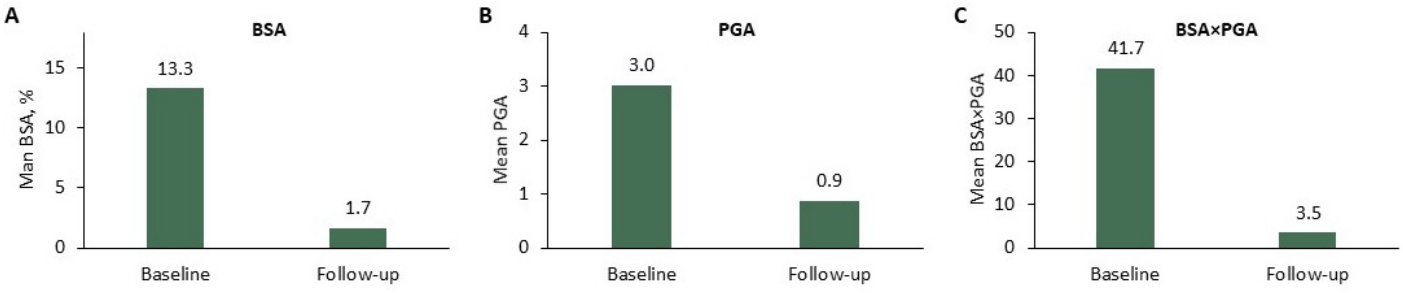
Bio, biologic; *BSA*, body surface area; *BSA×PGA*, composite BSA and PGA score; *IL*, interleukin; *PGA*, Physician's Global Assessment; *TNFα*, tumor necrosis factor alpha.
[a]Note that this group of biologics targeted either IL-23 alone or both IL-12 and IL-23.

FIGURE 3. Percent of patients achieving TTT at follow-up in subgroups separated by prior biologic experience, baseline body weight, and immune target of prescribed biologic.



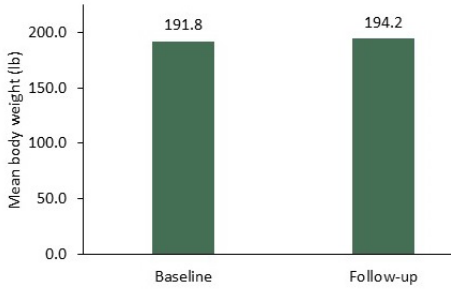
Bio, biologic; *BSA*, body surface area; *BSA×PGA*, composite BSA and PGA score; *IL*, interleukin; *PGA*, Physician's Global Assessment; *TNFα*, tumor necrosis factor alpha; *TTT*, Treat to Target.
[a]Note that this group of biologics targeted either IL-23 alone or both IL-12 and IL-23.

FIGURE 4. Psoriasis severity assessments at baseline and follow-up for the overall population.



BSA, body surface area; *BSA×PGA*, composite BSA and PGA score; *PGA*, Physician's Global Assessment.

FIGURE 5. Body weight at baseline and follow-up in the overall population.



In terms of body-weight subgroups, the decrease from baseline to follow-up in mean BSA, PGA, and composite BSA×PGA scores was approximately equivalent between patients who were ≤200 lb vs >200 lb at baseline (Figure 1, middle). Overall, body weight remained relatively stable from baseline to follow-up (Figure 5), eliminating the possibility of long-term weight changes as a confounding factor in this analysis.

Improvements in disease severity assessments were observed regardless of the target pathway of the biologic that was prescribed (Figure 1, bottom). Biologics that targeted IL-12/23, IL-17, or TNFα pathways were all successful in reducing the mean BSA, PGA, and composite BSA×PGA scores. TNF inhibitors were slightly less efficacious in all categories evaluated.

The efficacy of biologic treatment resulted in an 86.9% improvement in psoriasis disease activity in the overall population, with comparable rates of improvement being observed in each of the subgroups (Figure 2). The mean affected BSA at baseline of 13.3% was substantially higher than the NPF TTT goal of ≤1%. However, at follow-up, 67.0% of the entire population had achieved the TTT goal for BSA, and the ability of the biologic therapy to help patients achieve the TTT goal was relatively consistent across all subgroups (Figure 3).

Safety Assessments

Few AEs were reported (Table 2). There were 25 AEs in 19 (19.0%) patients. The most frequently reported AEs were bronchitis (4.0%) and upper respiratory infection (4.0%).

DISCUSSION

This retrospective study examined the clinical benefits of biologic therapy for psoriasis in a real-world setting in a population consisting mostly (90%) of individuals with moderate-to-severe disease. As would be expected in a real-world setting, the study population was heterogeneous and included subgroups of patients with and without prior experience using biologics, patients varying in body weight, and a wide range of biologics prescribed (9 different ones) at the beginning of the study. The mixed characteristics of this population provided a unique opportunity to assess the long-term effectiveness of biologics in treating moderate-to-severe psoriasis while accounting for several known factors that might influence the choice (and results) of therapeutic interventions in actual dermatology practice.

Overall, the results from this chart review demonstrated that biologic therapy was safe and effective. Biologic therapy resulted in improvements in all assessed disease severity measures when evaluated 4 to 12 months after initiating treatment. There were notable reductions in BSA, PGA scores, and composite BSA×PGA scores, which, in the aggregate, corresponded with a >85% improvement in the extent and severity of psoriatic lesions in the pooled population. The success of biologic intervention within this population was further evident from the observation that the majority (67%) of patients achieved the NPF TTT goal of ≤1% affected BSA. These results are consistent with findings from numerous randomized, controlled trials that have compared the efficacy of these biologics individually against placebo and provide further support for their use in clinical practice.

We performed subgroup analyses to determine if certain variables that are believed to affect treatment outcomes modulated the efficacy of biologic intervention in this population. Surprisingly, none of these variables seemed to affect the efficacy of biologic intervention within the assessed time frame.

Despite evidence suggesting that body weight can affect the efficacy of biologic treatment, we did not observe an effect of weight on any of the assessed measures. In this population, biologic efficacy was equivalent in patients with relatively high vs relatively low body weight. The consistency of body weight during the present study is all the more remarkable because some biologics are known to be associated with weight gain, which in turn can negatively impact disease progression and treatment outcomes.

Patients' prior experience with biologics can sometimes influence the response to subsequent treatment regimens that incorporate the same or different biologic regimens. In the present study, we did not observe a negative effect of prior experience with biologics on treatment outcomes. Additionally, very few patients switched or discontinued biologic treatment during the study period, suggesting that the patients and their dermatologists were satisfied with the management of their disease symptoms, regardless of their prior treatment experiences.

Several different classes of biologics were prescribed to the patients in this study. These biologics were categorized as targeting IL-12/23, IL-17, or TNFα pathways. Regardless of the class of biologic prescribed, substantial improvements in

disease activity were attained in all of the assessed clinical outcomes, with slightly lower clinical benefit in response to TNF inhibitors.

There were a few limitations to the study. This was single-center study involving a relatively small patient population, and therefore may not be representative of all patient types. Additionally, because this study was conducted in a clinical setting, all patients received some form of active treatment, and no statistical inference can be made on comparability due to the absence of a control group. As this study was not designed prospectively, the distribution of patients within each of the identified subgroups was not balanced. However, it is unlikely that increasing power in groups with relatively fewer patients (eg, 34 biologic-experienced patients vs 66 biologic-naïve patients) would strongly influence the interpretation of our results, as the efficacy outcomes in these groups did not differ appreciably from that in the larger group sizes. Lastly, patients were permitted to use concomitant medications throughout the study period and were able to discontinue or switch treatments at any time. Thus, while these data may not provide an accurate representation of the safety and efficacy of patients solely receiving a single-prescribed biologic, they are representative of what occurs in a real-world setting in which patients use concomitant medications and undergo varying adjustments to their individualized treatment plans.

CONCLUSION

Overall, biologic intervention in patients with moderate-to-severe psoriasis appeared to be safe and effective for the long-term management of psoriasis symptoms. Across the spectrum of real-world patients included in this study, commendable efficacy was achieved regardless of the class of biologic treatment, baseline patient body weight, or prior biologic experience. Taken together with data from clinical trials, the current results provide further evidence supporting the use of biologic therapy in dermatology practice.

DISCLOSURES

Dr. Bagel has received research funds payable to the Psoriasis Treatment Center of New Jersey from AbbVie, Amgen, Arcutis Biotherapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Celgene Corporation, Corrona LLC, Dermavant Sciences, LTD, Dermira/UCB, Eli Lilly and Company, Glenmark Pharmaceuticals Ltd, Janssen Biotech, Kadmon Corporation, LEO Pharma, Lycera Corp, Menlo Therapeutics, Novartis, Pfizer, Regeneron Pharmaceuticals, Sun Pharma, Taro Pharmaceutical Industries Ltd, and Valeant Pharmaceuticals; consultant fees from AbbVie, Amgen, Celgene Corporation, Eli Lilly and Company, Janssen Biotech, LEO Pharma, Novartis, Sun Pharmaceutical Industries Ltd, and Valeant Pharmaceuticals; and fees for speaking from AbbVie, Celgene Corporation, Eli Lilly, Janssen Biotech, and Novartis. Brianna Butler has no financial interests to declare. Elise Nelson has received consultant fees from Eli Lilly and Company and LEO Pharma. Alexa Hetzel has received fees for speaking from Sun Pharmaceutical Industries Ltd. and AbbVie.

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