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ORIGINAL RESEARCH

Novel Approach for Evaluating the Effectiveness of Biological Drugs in Patients with Plaque Psoriasis: Real-World Experience of a Single-Centre Study in Poland

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Introduction: Biologic therapies have revolutionized psoriasis treatment, offering targeted interventions that significantly improve outcomes for patients with moderate to severe forms of the disease. In Poland, biologic treatment for psoriasis is funded through the National Health Service's B.47 program, available since 2013.

Aim: This study aimed to perform a retrospective analysis of the effectiveness of biologic treatments during the first year of therapy in patients with plaque psoriasis, treated with biologic agents under the B.47 program at a single center in Poland.

Methods: Medical records of patients with plaque psoriasis who were enrolled in the National Health Service's B.47 drug program at the dermatology department between January 1, 2013, and August 2, 2024, were reviewed. This retrospective chart review utilized secondary data from these records. Ultimately, 159 patients totaling 300 drug-periods were enrolled to the study.

Results: Six distinct patterns of treatment response emerged within the first year. Anti-IL-17AF therapy achieved complete remission (PASI-100) in the shortest time (53.8 days vs 101.7 days for a total population, $p<0.05$). While treatment effectiveness did not differ between bio-naive and non-bio-naive patients overall, repeated exposures to anti-TNF and anti-IL-12/23 therapies were associated with a diminished clinical response.

Conclusion: The study highlights the critical importance of strategic selection of the treatment to optimize long-term outcomes.

Keywords: plaque psoriasis, biological drugs, effectiveness, psoriasis severity, PASI

Introduction

Biologic therapies have transformed the treatment landscape for psoriasis (PsO), offering targeted interventions that significantly improve outcomes for patients with moderate to severe forms of the disease. These advanced therapies, which modulate specific components of the immune system involved in psoriasis, are rapidly evolving, with new agents and approaches emerging regularly. However, because biologics are relatively new, many aspects of their long-term efficacy, safety, and optimal use are still under investigation.

Funding and access to biologic therapies differ widely across countries, reflecting varying healthcare policies and budgetary considerations. In Poland, biologic treatment for psoriasis is funded through a nationally sponsored initiative known as the Polish Drug Program B.47 "Treatment of Moderate to Severe Plaque Psoriasis (ICD-10 L40.0)", which has been available to eligible patients since January 1, 2013.[1,2] This program represents a structured approach to providing biologic therapy, with specific eligibility criteria, monitoring protocols, and administrative oversight to the patients who have not achieved sufficient results with at least two standard systemic therapies, such as PUVA-therapy, methotrexate, cyclosporine A, or acitretin. Eligibility requirements and the biologics available in the program have changed over time. Currently, patients with moderate to severe psoriasis, defined as having a DLQI, BSA, and PASI of more than 10, or

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involvement of specific areas (hands and feet, nails, face, anogenital area, or scalp), may be enrolled. Under the B.47 in Poland 11 biological drugs are available (adalimumab, etanercept, infliximab, certolizumab pegol, ixekizumab, secukinumab, ustekinumab, risankizumab, guselkumab, tildrakizumab, and bimekizumab).[1,2]

Moreover, treatment duration regulations under B.47 have undergone significant changes. Until 2018, the duration varied by drug and were terminated after 24, 48 or 96 weeks. From 2018 to 2023, all biologic treatments were standardized to a maximum of 96 weeks to simplify management. After the administrative termination of the treatment, the patient could be re-enrolled in the program if the DLQI, BSA, and PASI scores had increased by at least 50% compared to their values at the time of treatment cessation. If no contraindications were present, the patient was re-enrolled for the same drug that had been used previously. However, since 2023, the program has adopted an in-definite treatment model, allowing patients to continue biologic therapy as long as it remains effective and safe, removing prior time constraints and supporting sustained, individualized care for eligible psoriasis patients.[2] The administrative limits on treatment duration are unique compared to other countries and present an opportunity to explore how treatment efficacy may change with repeated exposures to the same drug in individual patients.

Material and Methods

Our study included patients enrolled in the Polish Drug Program B.47 "Treatment of Moderate to Severe Plaque Psoriasis (ICD-10 L40.0)" in accordance with the program's requirements, between January 1, 2013, and August 2, 2024, at the Dermatology Department. Ultimately, we reviewed the medical records of 159 patients treated within this period, and extracted secondary data, including demographic information, history of previous exposures to biologic drugs, DLQI, BSA, PASI scores and laboratory markers (baseline C-reactive protein, alanine aminotransferase, aspartate aminotransferase, creatinine levels, as well as white blood cell, neutrophil, lymphocyte, and platelet counts).

In line with the B.47 program guidelines, treatment effectiveness evaluations were conducted two months (± 30 days) and four months (± 30 days) after the administration of biological drug, and thereafter at least once every six months (± 30 days). An adequate response to treatment was defined as either a reduction in the PASI score of at least 75%, or a reduction in the PASI score of at least 50%, combined with an improvement in quality of life as assessed by the DLQI (or CDLQI) scale of at least 5 points. Primary failure was classified as the lack of an adequate response to the administered active substance after four months (± 30 days). Secondary failure was defined as a loss of adequate response observed during two consecutive visits. The termination of a treatment period due to B.47 program duration regulations, was considered an administrative conclusion to therapy.

Data on psoriasis severity, assessed using the Dermatology Life Quality Index (DLQI), Body Surface Area (BSA), and Psoriasis Area and Severity Index (PASI), during the first year of therapy were extracted for analysis. The study design with specific time points used in the analysis are detailed in Figure 1.

The biological drugs were grouped into 5 groups, according to the molecule they are interacting with: anti-TNF (adalimumab, infliximab), anti-IL-12/23 (ustekinumab), anti-IL-17 (ixekizumab, secukinumab), anti-IL-23 (guselkumab, risankizumab, tildrakizumab), and anti-IL-17AF (bimekizumab).

Statistical analyses were performed using Statistica 13.3 (TIBCO Software Inc). Descriptive statistics were used to summarize patient demographics, disease characteristics and treatment regimens. Variables were derived from the secondary data extracted from patients' medical records. Categorical variables were presented as counts and percentages, while continuous variables were expressed as means with ranges or medians along with IQRs depending on the distribution of the variables (normal and non-normal, respectively). Statistical analysis used Friedman's ANOVA to assess the variability of multi-variate repeated parameters, Wilcoxon analysis for bivariate repeated parameters and Mann–Whitney ANOVA in comparisons of variability of independent characteristics. Logistic regression analysis was used to test the effect of selected demographic and clinical variables on the dependent variables. The significance level was set at $p \leq 0.05$.

The study was exempted from the requirement for bioethics committee approval and informed consent from the subjects due to its retrospective design, as it involved the analysis of previously collected, anonymized patient data, in accordance with applicable ethical standards and regulations (the Bioethics Committee of the Medical University of Lodz decision nr RNN/196/24/KE from September, 10 2024). The study was performed in accordance with the Helsinki

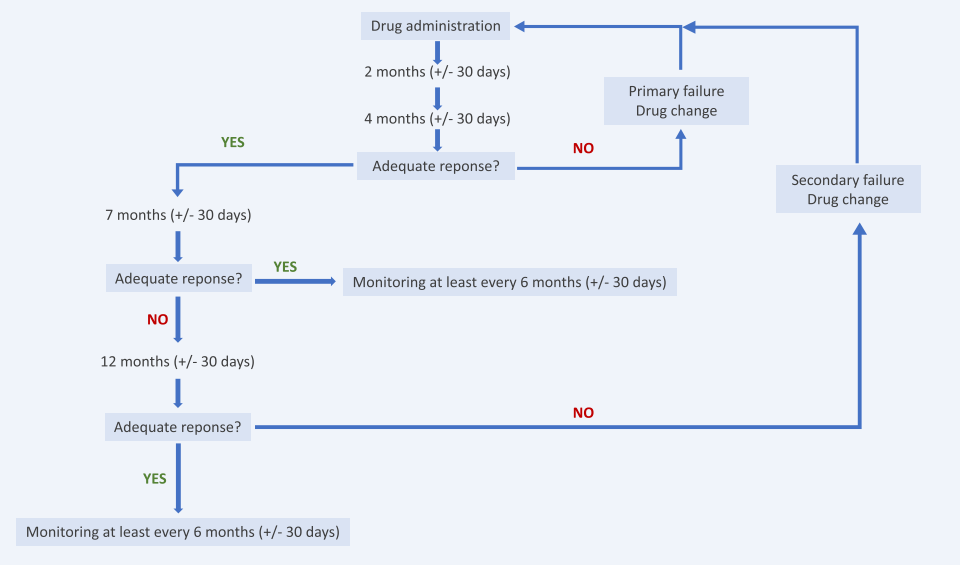

Figure 1 Study design.

Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

Results

Patient Characteristics

Our study group consisted of 159 patients enrolled in the B.47 drug program, associated with a total of 300 drug-periods and 131,251 persondays. All patients were Caucasians. 69 patients were females, while 90 were males. Mean age of onset of psoriasis was 25.73 ± 13.57 years, mean disease duration prior biological treatment was 18.61 ± 12.96 years. 130 patients were bio-naïve, and 29 patients (18.24%) had a prior exposure to the biological drugs. The additional demographic data (eg comorbidities, family history of psoriasis) were incomplete for 13 patients, and for the remaining 146 patients, the data is summarized in the Table 1. Unfortunately, not all patients were screened for psoriatic arthritis, thus in the variables the authors included joint pain reported by a patient.

During the program, 63% of patients received only one biologic treatment, 18% received two treatment periods, 4% received three treatment periods, 6% received four treatment periods, and 8% received five or more treatment periods. Over the course of the study, patients underwent 110 treatments with anti-IL-23 agents (33 with guselkumab, 69 with risankizumab, 8 with tildrakizumab), 77 treatments with anti-TNF agents (68 with adalimumab, 9 with infliximab), 55

Table 1 Patient Demographics (N=146)

Variable	Value
Total number of patients, n	146
Family history of psoriasis, n (%)	66 (45.21)
BMI (kg/m2, mean ± SD)	28.9 ±5.86
Overweight, n (%)	55 (37.67)
Obesity, n (%)	57 (39)
Dyslipidemia, n (%)	40 (24.40)
Arterial hypertension, n (%)	54 (37)
Current or former smoking, n (%)	27 (18.49)
Diabetes mellitus type 2, n (%)	23 (15.75)
Joint pain, n (%)	50 (34.25)

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Table 2 Number of Drug Periods for Each Biological Drug During the First year of Treatment and Reasons for Treatment Discontinuation (N=300)

	Primary Failure	Secondary Failure	Administrative End	Side Effects	Other	Continuation	Total	Duration
anti-TNF	6	13	46	4	2	6	77	429.06 ± 366.55
anti-IL-12/23	0	6	28	0	1	3	38	428.26 ± 250.33
anti-IL-17	2	7	4	5	2	35	55	462.30 ± 287.39
anti-IL-23	6	13	2	5	3	81	110	491.04 ± 356.84
anti-IL-17AF	0	0	0	0	0	20	20	217.44 ± 136.91
total	14	39	80	14	8	145	300	444.92 ± 332.08

treatments with anti-IL-17 agents (22 with ixekizumab, 33 with secukinumab), 38 treatments with ustekinumab, and 20 treatments with bimekizumab.

The mean duration of drug periods and the reasons for treatment discontinuation are summarized in Table 2. Notably, the observation period for bimekizumab is the shortest, as the drug was introduced to the B.47 program in March 2023. This should be taken into account when interpreting the results. Primary failure was most commonly noted in patients receiving anti-TNF agents (7.79%) and was not observed in patients treated with ustekinumab or bimekizumab. Secondary failure was observed across all drugs, except for bimekizumab, with the highest rates occurring in patients treated with anti-TNF (16.88%) and anti-IL-12/23 agents (15.79%). Side effects were reported in only 14 patients.

Treatment Effectiveness

Baseline mean psoriasis severity in the analyzed group was: DLQI 19.38 ± 6.06, BSA 23.08 ± 15.2, PASI 17.39 ± 8.24. The charts presenting in details the changes in psoriasis severity are provided in Figure 2.

In the analyzed group, within the first year of treatment, patient responses followed one of six patterns, with remission defined as a 75% reduction in the PASI score. The patterns are described below and summarized in the Figure 3.

1. Lack of effectiveness – patient does not reach PASI-75 within 16 weeks (± 30 days).
2. Minimal effectiveness – single PASI-75 achievement, followed by loss of effectiveness.
3. Low effectiveness – alternating remissions and relapses, with loss of effectiveness at the one-year mark.
4. Average effectiveness – alternating remissions and relapses, followed by a remission lasting at least one year.
5. High effectiveness – remission observed at the 4-month (± 30 days) visit and sustained for at least one year.
6. Complete effectiveness – remission observed at the 2-month (± 30 days) visit and sustained for at least one year.

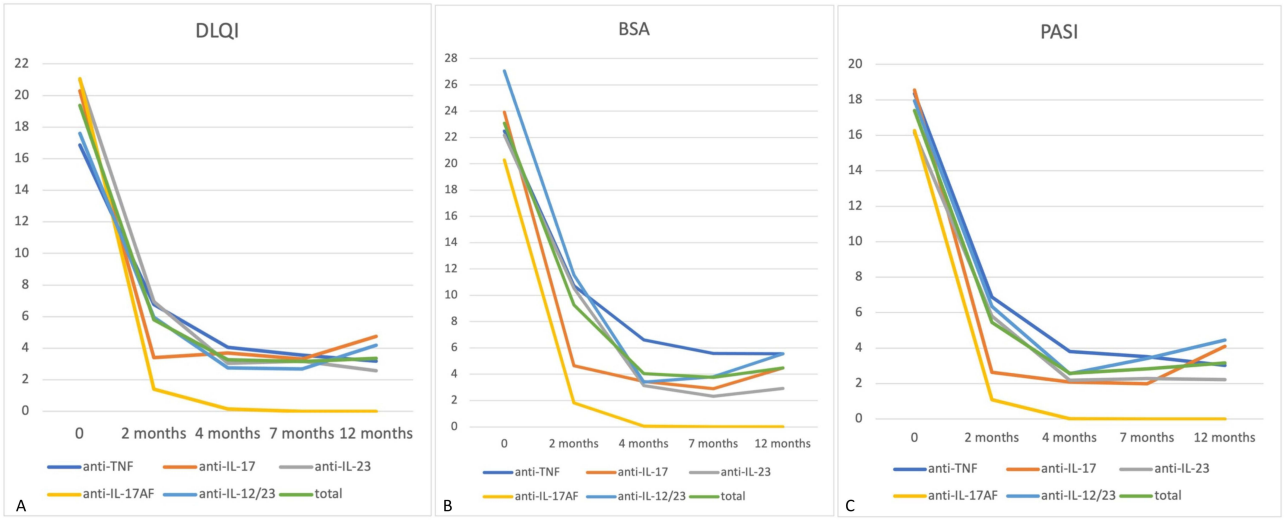

Figure 2 Changes in psoriasis severity during the first year of treatment, assessed using: (**A**) DLQI, (**B**) BSA, and (**C**) PASI scales. Measurements were taken at the following time points: baseline (treatment initiation), 2 months (±30 days), 4 months (±30 days), 7 months (±30 days), and 12 months (±30 days).

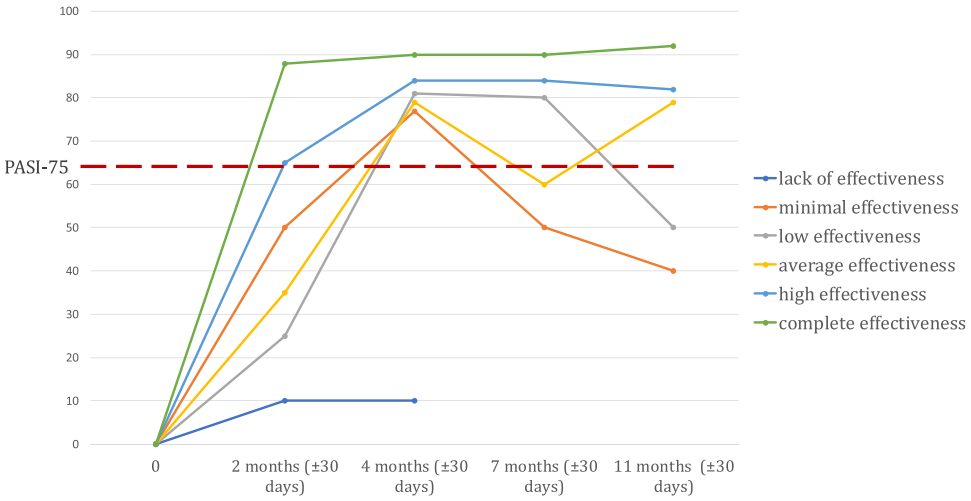

Figure 3 Six patterns of drug effectiveness in the first year of therapy, using PASI-75 as the threshold for defining treatment success.

High and complete effectiveness was observed in all the patients treated with bimekizumab, about 70% of the patients treated with anti-IL-23 or anti-IL-17, slightly over half of the patients treated with adalimumab or infliximab, and 38% of patients treated with ustekinumab. Lack of effectiveness was observed in about 15% of patients treated with anti-TNF and anti-IL-23 drugs, about 8% of ustekinumab cases and 4% of anti-IL-17 patients (Figure 4). Overall, anti-IL-23 drugs had higher effectiveness than anti-IL-12/23 (p=0.0187) and anti-IL-17 (p=0.0245). Statistical analysis comparing the effectiveness did not include anti-IL-17AF, as the number of treatment periods for this drug was significantly lower compared to other substances.

Moreover, a multivariate logistic regression analysis was conducted to explore the potential effects of demographic and clinical variables on the effectiveness of individual drugs. Independent variables included patient age, disease duration, age at PsO diagnosis, and a set of clinical parameters (baseline C-reactive protein, alanine aminotransferase, aspartate aminotransferase, creatinine levels, as well as white blood cell, neutrophil, lymphocyte, and platelet counts). The dependent variable was defined as achieving either a complete or high response. The analysis did not identify any significant correlations (p>0,05).

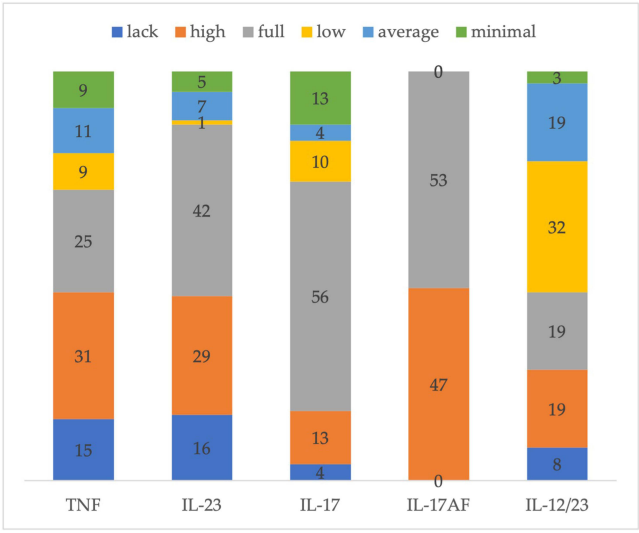

Figure 4 Comparison of drug effectiveness in the studied group in % (N=300).

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Time to Achieve PASI-100

For this part of analysis, the authors included only the patients who had at least a 24 ± 8 weeks observation in the study. This timepoint was chosen based on the earliest administrative termination of the drug-period, at 24 weeks. Thus, patients with shorter treatment duration at the end of the study, or the patients with side effects terminating the treatment prior 24 ± 8 weeks, were not included. In total, we analyzed 270 drug-cycles.

Across this population, PASI-100 was achieved at some point during the treatment in a total of 122 drug periods (45.19%), with 42.62% of these cycles occurring in women. In PASI-100 group, the mean age of onset of psoriasis was 25.70 ± 13.65 years, the mean disease duration prior biological treatment was 19.99 ± 13.23 years, and the mean age at the introduction of biological therapy was 45.69 ± 14.03 years. For the group not achieving PASI-100 the mean age of onset of psoriasis was 28.05 ± 15.10 years, the mean disease duration prior biological treatment was 22.84 ± 14.11 years, and the mean age at the introduction of biological therapy was 50.89 ± 15.10 years. The mean weight in this group was 85.76 ± 16.27 kg, compared to the mean weight of 87.30 ± 21.08 kg in the group not achieving PASI-100. Psoriasis severity was comparable between the PASI-100 and non-PASI-100 groups (BSA 23.25 ± 13.75 vs 21.96 ± 14.14, PASI 17.91 ± 7.97 vs 17.15 ± 7.93, respectively). As for DLQI, in PASI-100 it was on average 20.21 ± 6.06, while in non-PASI-100 group 18.57 ± 6.16. 54.10% of PASI-100 responses occurred in patients previously exposed to biologics, compared to 64.19% of patients with failure to reach a complete remission.

In U Mann–Whitney test, a significant difference between these groups was identified only for the age at the onset of biological therapy (p=0.0032), and initial DLQI (p=0.0321). For other variables, the differences did not reach statistical significance (p>0.05). These results should be interpreted with caution, as the sample size was relatively small, which may have affected the ability to achieve statistical significance. Additionally, due to the limited number of patients treated with each drug, the analysis of variables was not conducted separately for each active substance.

Full clearance of skin lesions was observed in 9 cycles with ustekinumab (25%), 25 cycles with anti-TNF therapy (33.33%), 24 cycles with anti-IL-17 drugs (50%), 54 cycles with anti-IL-23 therapy (55.67%), and 10 cycles with bimekizumab (71.43%). In the vast majority of cases with PASI-100, the treatment effectiveness was 'high' or 'complete'. However, two cycles with ustekinumab and two cycles with anti-IL-17 showed only "low" effectiveness, while "average" effectiveness was observed in one cycle with anti-IL-17, two cycles with anti-TNF, and six cycles with anti-IL-23 drugs. The mean time to reach PASI-100 was 101.7 days and the minimum time required to achieve PASI-100 was similar across all drugs, at approximately 28 days. However, the mean time varied significantly between treatments. For most drugs, the mean time was around 100 days (95.6 days for ustekinumab, 103.4 days for anti-IL-17 drugs, 106 days for anti-TNF drugs, and 108.8 days for anti-IL-23 drugs). In contrast, bimekizumab showed a faster response comparing to other substances, with a mean time to PASI-100 of 53.8 days (p=0.0078; anti-IL-17AF vs anti-TNF p=0.0038, anti-IL-17AF vs anti-IL-23 p=0.0053, anti-IL-17AF vs anti-IL-17 p=0.04, anti-IL-17AF vs anti-IL12/23 p=0,0963) (Figure 5).

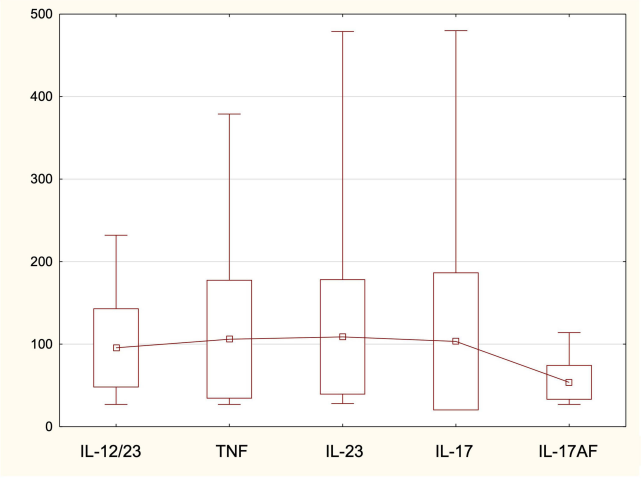

Figure 5 Time to achieve PASI-100 (in days) for the analyzed drugs.

How Does Prior Exposure to Biologic Drugs Affect Treatment Effectiveness?

In the analyzed group, the number of previous exposures to the biologics did not affect the overall effectiveness of the treatment (p=0.0501). However, treatment with other biologic drugs in previous cycles, rather than the one currently administered, increased the chances of achieving complete or high response by more than 2.5 times (OR=2.568, 95% CI= [1.314–5.015], p=0.006).

In subsequent cycles of the same drugs, treatment effectiveness varied among patients. Among those receiving additional treatments with anti-TNF, 60% (12 patients) showed a decreased response, 4 had varying responses across cycles, and 4 maintained the same level of effectiveness. For IL-12/23, subsequent exposures resulted in either a reduced or variable response. For IL-17, 4 patients experienced a decreased response, 2 had the same response, and 1 showed an improvement. Patients receiving an additional cycle of IL-23 generally had the same or improved response, with the exception of one patient.

Discussion

Our study offers a detailed analysis of the outcomes of biologic therapies in patients with plaque psoriasis treated under Poland's National Health Service B.47 program, focusing specifically on treatment effectiveness during the first year. We analyzed 159 patients who underwent 300 treatment cycles with biological drugs. Unfortunately, the drug groups were not evenly distributed, making it challenging to analyze the results. Demographically, our group was not significantly different from other populations of psoriatic patients.[2–4]

The results highlight significant variability in patient responses, revealing six distinct response trajectories. These trajectories were characterized by the time to achieve PASI-75 and the ability to maintain it, and were classified as lack, minimal, low, average, high, and complete effectiveness.

A high or complete response, defined as achieving PASI-75 within 16 weeks (±30 days) and maintaining it for at least one year, represents a full therapeutic success. Notably, bimekizumab achieved the highest rates of high and complete responses across all patients. Similarly, anti-IL-23 and anti-IL-17 therapies demonstrated strong effectiveness, with the majority of patients achieving sustained responses. While anti-IL-23 drugs had a relatively high rate of primary failures (16%), their effectiveness was excellent among patients who did not experience initial treatment failure. By contrast, ustekinumab exhibited a lower rate of primary failures (8%) but sustained one-year effectiveness (complete, high, and average responses) in only 57% of patients.

Other research groups had also attempted to identify response trajectories after biologics introduction in psoriasis patients. For example, Geifman et al analyzed British population from the BADBIR database and distinguished four response patterns to psoriasis treatment defined by their time to response, the magnitude of effect and time to relapse.[5] Two of those patterns demonstrated a moderate and sustained reduction in disease severity over time (class 1 and 3), while the other two demonstrated an increase in disease severity following an initial improvement (class 2 and 4). Different clinical characteristics (including psoriasis lesions distribution, PASI and BMI), as well as certain genetic markers were associated with these response patterns. For instance, higher number of HLA-C*06:02 allele was associated with class 3 response. Moreover, higher BMI in Class 1 patients was linked to a reduced magnitude of PASI improvement in response to biologic treatment.[5]

Several factors have previously been identified as significant influencers of treatment outcomes in psoriasis. These include BMI, baseline disease severity and psoriasis subtype, comorbidities, and genetic and inflammatory profiles.[5–9] For example, increased body weight has been shown to be positively associated with greater psoriasis severity and a poorer response to biological therapy. BMI is emerging as the strongest predictive biomarker for biological treatment response.[6,10–12] Among biologics, anti-IL-17 inhibitors appear to have the least negative impact on drug-related body weight increase and may also be effective in obese patients. Additionally, secukinumab offers a more intensive dosing regimen for patients weighing 90 kg or more, if the standard dose proves ineffective, potentially further optimizing treatment outcomes.[11,13] For some drugs, eg guselkumab, a delayed onset of clinical response might be observed in obese patients.[7,9,14] Studies have also suggested that older age, female sex, and prior exposure to biologics may diminish

treatment response.[7,9] Although our research did not replicate these findings, they underscore the importance of considering individual patient profiles to optimize outcomes in psoriasis management.

With advancements in treatment strategies, the treatment goals for psoriasis have evolved over time, progressing from PASI-75 to PASI-90 and ultimately to PASI-100. Today, achieving complete skin clearance is not the only focus; the time required to achieve full clearance is equally important. Different therapies vary in their response times, with IL-17 inhibitors acting faster than IL-23 inhibitors, as well as other biologics and conventional treatments.[15] The rapid action of IL-17 inhibitors is due to their direct impact on the psoriasis inflammatory cascade, as IL-17 is most directly responsible for keratinocyte-driven inflammation and proliferation and plays a crucial role in the effector phase of the pathway. By targeting this cytokine, IL-17 inhibitors deliver quicker results. In contrast, IL-23 inhibitors modulate immune cell signaling rather than directly affect keratinocytes, resulting in a slower onset of clinical improvements.[16] Supporting this, a recent study published in the Journal of the American Academy of Dermatology compared the performance of IL-17 inhibitors, IL-23 inhibitors, and the IL-12/23 inhibitor ustekinumab, using metrics such as $PASI100_{25}$ and $PASI100_{50}$ (time required for at least 25% and 50% of patients to achieve PASI100, respectively). Patients treated with IL-17 inhibitors generally reached faster clearance compared to those treated with IL-23 inhibitors, except for risankizumab, which showed similar clearance times to secukinumab and ixekizumab.[17]

In our research, we decided to extract anti-IL-17AF (bimekizumab) from IL-17 inhibitors group, since it differs by offering a dual inhibition mechanism. This provides broader suppression of the inflammatory pathways associated with psoriasis and leads to faster skin clearance compared to other drugs.[18] In our study, the mean time to achieve PASI-100 was much shorter for bimekizumab at 7.7 weeks than for other drugs. The analysis by Pfau et al also highlights bimekizumab as the fastest drug to achieve complete skin clearance. It required just 5.5 weeks to achieve $PASI100_{25}$, followed by brodalumab at 7 weeks, and ixekizumab at 8.5 weeks. For PASI10050, bimekizumab again led with 9.5 weeks, compared to 16 weeks for secukinumab, 21 weeks for risankizumab and 25 weeks for ixekizumab. Ustekinumab failed to achieve $PASI100_{25}$ and $PASI100_{50}$.[17] These findings underscore the superiority of IL-17 inhibitors, particularly bimekizumab, in achieving rapid skin clearance.

In our study, the group of patients achieving complete clearance of psoriatic lesions was younger and with higher initial DLQI values. This group did not significantly differ from the remaining population in terms of sex, age of psoriasis onset, disease duration, weight, previous exposure to biologics, and severity of psoriatic lesions assessed with BSA and PASI scales. However, in the literature, patients who achieve long-term high effectiveness are referred to as "super-responders" (SRs), and some identifying characteristics have been reported. Conversely, patients with refractory psoriasis are termed "super nonresponders" (SNRs) and their characteristic features were identified as well. According to the Danish analysis of the DERMBIO database, which included 3,280 psoriatic patients, superresponders tend to have fewer comorbidities and a higher socioeconomic status, while SNRs are more likely to have a higher BMI.[19] Similarly, the analysis of 13721 patients' chart collected in BADBIR database, found that female sex, higher DLQI, and a greater number of comorbidities reduced the change of complete clearance of PsO lesions.[9] Additionally, a recent retrospective chart review from a Korean hospital compared patients who achieved nearly complete skin clearance (PASI-90) with those who attained complete clearance (PASI-100). The researchers identified smoking and the presence of psoriatic lesions on the anterior lower legs as risk factors for not reaching PASI-100.[6] Further research on patients with an exceptional response to biologics is needed to identify factors that increase the likelihood of achieving PASI-100, as complete clearance of psoriatic lesions is expected to become a key treatment goal in the future.

It is proven that biologic-naïve patients generally demonstrate better responses to biologic treatments compared to biologic-experienced patients. This may be attributed to the theory that prior exposure to similar therapies can result in altered immune profiles or the development of anti-drug antibodies. In contrast, biologic-naïve patients typically have a more intact immunological baseline, enabling faster and more robust treatment outcomes.[20] In our group, no correlation was observed between prior exposure to biologic treatments and treatment effectiveness ($p = 0.05010$). However, it is important to consider that the relatively small sample size may have limited our ability to achieve statistical significance. It is possible that similar research conducted on a larger cohort could yield significant results, providing clearer insights into this relationship.

Nevertheless, we identified varying responses to the exposure of the same drugs.

Until 2023, the treatment in the B.47 drug program was terminated after determined period and patients had to wait for the in-between exacerbation of psoriasis to be reenrolled and be given biological drugs for another treatment cycle. As a default, the patients were given the same drug that was effective in the previous cycle. This provides a unique insight into the effectiveness to repeated exposures to the same substances. According to the literature, switching to the same class of biologic agents may be still effective, but with moderate improvement, and had been proven for IL-17 and TNF inhibitors.[21–23] In our study group, repeated exposures to IL-12/23, IL-17, or TNF inhibitors were not beneficial and often resulted in diminished PASI-75 responses. Conversely, IL-23 inhibitors demonstrated the ability to achieve similar or even improved responses with multiple exposures. This finding is particularly relevant for clinicians managing patients who experience secondary failure with anti-IL-23 therapies. In such cases, switching to another IL-23 inhibitor represents a viable and effective option. For other classes of biologics, a switch to a different therapeutic target should be considered.

Several limitations should be acknowledged when interpreting the findings of our study. First, the relatively small sample size limits the generalizability of the results, making it harder to detect subtle differences in treatment patterns or outcomes, which was particularly evident in the near-statistically significant correlation between previous exposure to biologics and treatment effectiveness (p=0.0501). Moreover, the retrospective nature of the study introduces the potential for incomplete or inaccurate data collection, and it also restricts the ability to gather additional data. Finally, the study was conducted at a single center in Poland, thus the findings may not fully reflect the broader population of patients with plaque psoriasis.

Conclusions

The study highlights the varied response trajectories to biologic treatments for plaque psoriasis within the B.47 drug program in Poland, providing insight into the first-year effectiveness of these therapies. Anti-IL-23, anti-IL-17, and anti-IL-17AF therapies demonstrated the best effectiveness, with the majority of patients achieving and sustaining PASI-75 responses throughout the one-year observation. Anti-IL-17AF therapy was notably the most effective in achieving rapid complete remission (PASI-100). When evaluating the time to onset of action among available therapies for plaque psoriasis, clinicians can identify bimekizumab as the drug with the fastest time to achieve clearance of skin lesions. While overall effectiveness was comparable between bio-naive and non-bio-naive patients, repeated exposures to certain biologics, specifically anti-TNF and anti-IL-12/23 agents, were associated with reduced effectiveness, underscoring the importance of strategic initial treatment selection. These findings suggest that treatment personalization based on patient history with biologics could optimize clinical outcomes.

Data Sharing Statement

The data presented in this study are available on request from the corresponding author.

Institutional Review Board Statement and Informed Consent

The study was exempted from the requirement for bioethics committee approval and informed consent from the subjects due to its retrospective design, as it involved the analysis of previously collected, anonymized patient data, in accordance with applicable ethical standards and regulations (the Bioethics Committee of the Medical University of Lodz decision nr RNN/196/24/KE from September, 10 2024). The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

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Disclosure

The authors report no conflicts of interest in this work.

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