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Real-World Effectiveness of Biologic Treatments for Moderate-to-Severe Plaque Psoriasis in Poland In comparison with Efficacy Report in clinical Trials

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BACKGROUND

Psoriasis is a chronic autoimmune skin disease characterized by the development of flaky, inflamed patches on the skin, with plaque psoriasis being the most common form.[1] It is the most prevalent dermatological condition in Poland, affecting an estimated 1 million people, which represents a substantial disease burden.[2]

To address moderate-to-severe cases of plaque psoriasis, Poland offers treatment through the drug program B.47, titled "Treatment of Moderate-to-Severe Plaque Psoriasis (ICD-10: L40.0)." Through this program, patients have access to 11 different biologic therapies.[3] Although these agents are approved for use, it is crucial to evaluate whether their effectiveness in real-world settings aligns with the outcomes observed in clinical trials. This study bridged that gap by systematically comparing the performance of these biologic treatments using data from clinical trials.

OBJECTIVE

This study aimed to evaluate the real-world effectiveness of biologic treatments in patients with moderate-to-severe plaque psoriasis in Poland, comparing these outcomes with efficacy data from pivotal clinical trials of the analyzed biologic agents.

METHODS

This retrospective, observational study analyzed real-world data from approximately 5,000 patients enrolled in the Polish national drug program B.47 between 2013 and 2023. Data were sourced from the National Health Fund and included patient demographics, treatment history, program qualification dates, counseling visit records, prescribed biologics, and clinical indices. The psoriasis-specific measures used to determine disease severity and selected as comparable indicators between clinical trials and the program in the study were shown in Table 1. To evaluate effectiveness of biologic agents, PASI75 and DLQI 0/1 were assessed between weeks 12 and 16, as well as between weeks 36 and 40 of treatment.

Table 1. Psoriasis-specific measures of disease severity

Psoriasis Area and Severity Index (PASI)	Dermatology Life Quality Index (DLQI)
A scale from 0 to 72 assessing disease severity and affected body area.[4] PASI75 refers to the percentage of patients with ≥75% reduction from baseline.	Dermatology-specific quality of life (QoL) questionnaire, score ranging 0 to 30 with 0 meaning no negative impact of disease[5]. **DLQI 0/1** assesses the percentage of patients who attained DLQI score of 0 or 1.

Real-world outcomes were compared with Phase III randomized controlled trials (RCTs)—one per drug—selected based on European Medicines Agency (EMA) references, preference for Phase III trial phase, sample size, and follow-up duration (Table 2). Nine trials were included in the comparison. Bimekizumab and Etanercept were excluded due to limited clinical trial data.

Table 2. Clinical trials selected to compare treatment effectiveness

Drugs	Trial	N (Patients)	Publication
Bimekizumab	BE VIVID	567	Reich, 2021[6]
Certolizumab pegol	CIMPASI	461	Gottlieb, 2018[7]
Ixekizumab	UNCOVER-3	1346	Griffiths, 2015[8]
Risankizumab	IMMHANCE	507	Blauvelt, 2020[9]
Tildrakizumab	reSURFACE-2	1090	Reich, 2017[10]
Adalimumab	–	1212	Menter, 2008[11]
Guselkumab	VOYAGE-2	992	Reich, 2017[12]
Secukinumab	FIXTURE	1306	Langley, 2014[13]
Ustekinumab	PHOENIX-1	766	Leonardi, 2008[14]
Infliximab	EXPRESS	378	Reich, 2005[15]
Etanercept	–	672	Leonardi, 2003[16]

RESULTS

The initial characteristics of participants of the drug program and the clinical trials were presented in the Table 3. On average, the patients enrolled in the drug program were younger than those included in the clinical trials. Average baseline PASI and BSA scores were similar, but program patients had higher DLQI scores, indicating poorer quality of life. At weeks 12–16, secukinumab, ixekizumab, risankizumab, certolizumab pegol, and guselkumab had the highest efficacy in the drug program. At weeks 36–40, tyldrakizumab was most effective, with certolizumab pegol, guselkumab, risankizumab, and ixekizumab above 90% (Figure 1). In the analyzed clinical trials, at weeks 12–16, the highest proportions of patients achieving PASI75 were reported for risankizumab and ixekizumab.

Table 3. Comparison of the baseline characteristics of participants in the drug program and clinical trials.

	Age	Men [%]	Body weight [kg]	Systemic therapy [%]	Biological therapy [%]	PASI	BSA	DLQI
Drug program	32.4 (12.2)	69	86.4 (21.2)	100	14	19.4 (8.0)	28.6 (18.1)	20.8 (5.4)
Clinical trials (aggregated data)	45.3 (10.1)	69	90 (22.8)	65	28	20.5 (7.3)	28.1 (15.2)	12.8 (6.1)

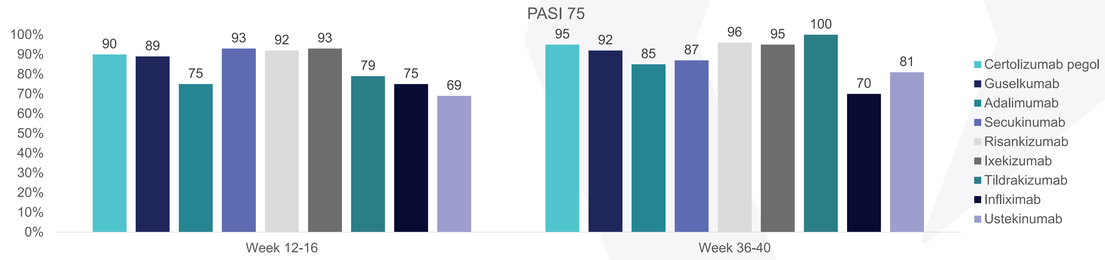

Figure 1. PASI75 Comparison of Treatment Effectiveness in the B.47 Drug Program

Data at weeks 36–40 were available for certolizumab pegol, ustekinumab, and secukinumab. For the remaining drugs, the proportion of patients achieving PASI75 at the last available measurement point was used. Data for etanercept were not available from clinical trials, and data for ustekinumab* were only available at weeks 36–40, but not at weeks 12–16. The highest proportions of patients achieving PASI75 were reported for risankizumab and guselkumab (Figure 2).

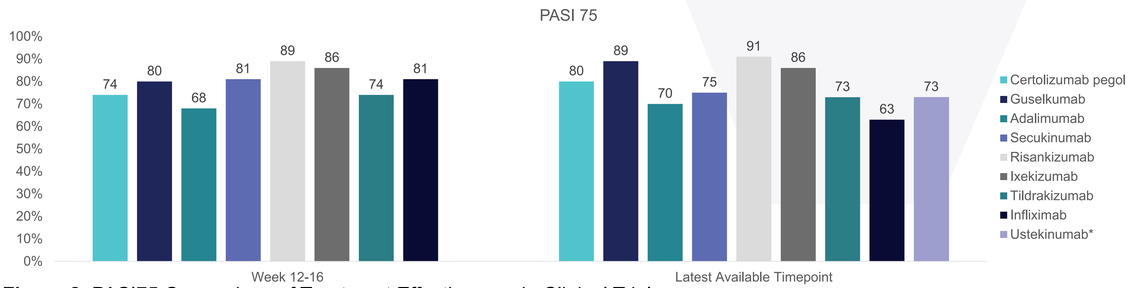

Figure 2. PASI75 Comparison of Treatment Effectiveness in Clinical Trials

Table 3. Results of the DLQI 0/1 Comparison

Drugs	Timepoints (weeks)	DLQI 0/1 Program	DLQI 0/1 Trials
Certolizumab pegol	44-48	100	46
Lxekizumab	12-16	66	64
Risankizumab	12-16	68	65
Tildrakizumab	24-28	49	59.5
Adalimumab	24-28	38.3	-
Guselkumab	24-28	30	58
Secukinumab	48-52	68	63
Ustekinumab	28-32	55	64
Infliximab	48-52	63.3	-

In a naïve comparison, proportions of patients reaching DLQI 0/1 were similar (Table 3) between the program and clinical trials.

CONCLUSION

In the real world, the effectiveness of biologics for patients with moderate-to-severe plaque psoriasis in the Polish setting was similar to that observed in clinical trials, though several drugs showed faster effectiveness in B.47 program patients compared to trial participants.

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