Dermatology Practical & Conceptual

Impact of Disease Activity-Guided Dose Reduction on IL-17 and IL-23 Inhibitors in Psoriasis: A Real-World Assessment of Efficacy, Safety, and Economic Benefits

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ABSTRACT

Introduction: Psoriasis is a chronic inflammatory multisystem disease for which IL-17 and IL-23 inhibitors have transformed treatment. However, high costs and the possibility of overtreatment in patients with excellent and sustained responses have driven interest in dose reduction (DR) to lower expenses without compromising efficacy.

Materials & Methods: We conducted a multicenter observational trial assessing the efficacy and safety of DRs for secukinumab, brodalumab, guselkumab, and risankizumab in adults with stable plaque psoriasis. Eligible participants were adults with low disease activity (PASI ≤ 3, DLQI ≤ 3 for at least 9 months). DR involved lengthening intervals to approximately 67% of the authorized standard dose. From the 361 enrolled (March 2023–January 2025), we analyzed data on 156 participants with ≥12 months of follow-up or early discontinuation due to DR failure.

Results: Seventy of these patients (44.87%) received IL-17 inhibitors, and 86 (55.13%) received IL-23 inhibitors. After 52 weeks, the overall dose-reduction survival was 0.75 (95% CI: 0.69–0.82). For IL-23 inhibitor and IL-17 inhibitor cohorts, the dose-reduction survival was 0.83 (95% CI: 0.75–0.91) and 0.66 (95% CI: 0.55–0.78), respectively. Moreover, Kaplan-Meier curves suggested significant (p-value log-rank test=0.018) higher dose reduction survival for IL-23 inhibitors compared to IL-17.

Discussion: Our preliminary findings suggest that extended dosing intervals for IL-17 and IL-23 inhibitors can effectively maintain disease control in stable plaque psoriasis. Larger randomized trials are needed to confirm these results, identify predictive markers of DR success, and optimize patient selection for safe and cost-effective management of psoriasis.

Introduction

Psoriasis is a chronic immune-mediated inflammatory multisystem disease primarily characterized by cutaneous manifestations, with chronic plaque psoriasis accounting for approximately 90% of cases. Beyond skin lesions, psoriasis is often associated with-comorbidities such as cardiometabolic disease and psoriatic arthritis [1,2]. Over the past decade, the advent of biologic therapies for chronic plaque psoriasis and psoriatic arthritis have represented a groundbreaking advancement in treatment. Recently, new therapeutic options for moderate-to-severe psoriasis have emerged, including IL-17 inhibitors (IL-17i) (secukinumab, ixekizumab, brodalumab, and bimekizumab) and IL-23 inhibitors (IL-23i) (guselkumab, risankizumab, and tildrakizumab), which have demonstrated remarkable efficacy [1,2]. However, their high cost imposes a significant burden on the national health care system, necessitating the exploration of strategies to reduce economic strain without compromising treatment outcomes.

Currently, the main guidelines for the management of psoriasis [1,2] do not include a flexible therapeutic window based on patients' clinical response, and biologic therapies are typically prescribed in fixed doses, but "long-term responder" patients, achieving excellent and sustained responses, may not require the standard regimen, which could lead to overtreatment. This underscores the importance of studies focusing on dose reduction (DR) to ensure cost-efficiency while maintaining high effectiveness. Previous research has demonstrated the effectiveness and safety of a reduced dose compared to the standard dose (StD) in psoriasis treatment, with a slightly increased Psoriasis Area and Severity Index (PASI) while maintaining a stable Dermatology Life and Quality Index (DLQI) [3-7]. Consequently, dose reduction (DR), also referred to as dose tapering, appears to be a promising strategy. However, extending the therapeutic window should be guided by patient profiling and tailored therapeutic choices to ensure optimal outcomes. In this regard, these inhibitors have demonstrated significant efficacy in reducing disease severity; however, their pharmacodynamics differ, making one drug class potentially more suitable than the other for dose spacing. IL-23i provide longer-lasting effects by targeting the root of the inflammatory cascade, whereas IL-17i act more immediately on downstream inflammation [8]. The aims of this study were to contribute to the understanding of the DR outcomes in real-life settings and to investigate whether disease activity-guided DR of Il-17i and IL-23i could be a suitable option for selected psoriasis patients. The secondary aim was to analyse potential differences in effectiveness and safety between IL-17i and IL-23i during DR.

Materials and Methods

Study Design

The PSORED study (study number CE 102/2023) was conducted by the University of Eastern Piedmont and included the primary prescribing centers for biological drugs in Piedmont. This prospective observational open-label study was conducted from March 2023 to December 2024 to investigate the efficacy and safety of reduced-dose (RD), an off-label treatment strategy for secukinumab, brodalumab,

Table 1. Secukinumab, Brodalumab, Risankizumab, and Guselkumab Authorized Interval of Drug Administration at Maintenance Compared with Dose Spacing for the Same Drugs.

Biologic therapy	Authorized interval of drug administration at maintenance	Dose spacing
Secukinumab	300 mg Q4W	300 mg Q6W
Brodalumab	210 mg Q2W	210 mg Q3W
Risankizumab	150 mg Q12W	150 mg Q18W
Guselkumab	100 mg Q8W	100 mg Q12W

guselkumab, and risankizumab in patients with plaque psoriasis; these drugs were chosen because of the evidence of their efficacy reported in previous studies with RD [9-15]. Adult patients with plaque psoriasis treated with these biologics were eligible for inclusion in the study when they had stable, low disease activity on the authorized StD; an absolute PASI ≤ 3 and absolute DLQI ≤ 3 for at least nine months was considered as a criterion of treatment success and stability of response. DR was achieved by dose spacing (DS), i.e., increasing the interval of drug administration; the time interval between the maintenance dose injections was prolonged by 1.5 times, resulting in administration of 67% of the full authorized dose (Table 1).

Exclusion criteria included individuals under age 18 years, patients with psoriatic arthritis not adequately controlled by therapy, and those requiring multiple immunomodulatory therapies to manage their disease.

At baseline, patient and treatment characteristics were recorded, including age, sex, weight, height, body mass index (BMI), Psoriasis Area Severity Index (PASI), concomitant psoriatic arthritis (PsA), Dermatology Life Quality Index (DLQI), treatment history, comorbidities, and disease duration. Follow-up assessments were conducted at 26 weeks ± 2, at 52 weeks ± 2, at 78 weeks ± 2, and then at 104 weeks ± 2; PASI and DLQI were calculated and registered at each visit.

In cases of disease flare (i.e., PASI and/or DLQI score >5), patients were advised to return to their previous effective original dose. Supplementary study visits were implemented in cases of worsening of the disease; PASI and DLQI score were recorded in these additional visits.

The study was approved by the Institutional Ethics Committee (Comitato Etico Interaziendale AOU Maggiore della Carità, ASL Bi, ASL NO, ASL VCO) and conducted according to the Declaration of Helsinki principles, with all patients providing informed consent.

Study Population

The PSORED study recruited patients through cooperation with dermatologists specialized in the treatment of psoriasis using biologics. Each participant received detailed oral and written information from the local investigator, who also obtained written informed consent. The dosing schedule was tailored to the specific biologic therapy used by each patient. Patients were free to withdraw from the study at any time without repercussions, while investigators retained the authority to withdraw patients for urgent medical reasons. Preliminary data from the first 52 weeks of the study were analyzed for this paper. Additional study visits were scheduled as needed in response to disease flares occurring outside the planned follow-up appointments.

Statistical Analysis

Descriptive statistics of the subjects included are reported overall and separately for treatment type (IL-17i and IL-23i). Categorical variables are summarized using absolute and relative frequencies, while for numerical ones, mean and standard deviation (SD) or median and interquartile range are reported, as appropriate. Differences at baseline between groups were evaluated using chi-squared/Fisher test or t-test/alternative non-parametric tests, as appropriate.

DR survival was defined as the time from the dose reduction start to failure of DR for any patient; time was censored to 52 weeks. Median DR survival time and median follow up were estimated using the Kaplan-Meier (KM) methods. KM curves were estimated, and the log rank test was calculated to evaluate differences between treatment groups. Moreover, dose reduction survival at 52 weeks was reported with 95% confidence intervals (95% CI). Then, the relationship between DR survival and treatment type was considered in unadjusted and adjusted Cox models, and hazard ratios (HRs) with 95% CI were estimated. Particularly, the adjustment for clinical covariates (age, sex, baseline BMI, psoriasis type, comorbidity, previous biological treatment, therapy time before DR) was performed calculating the linear predictors for each subject obtained by logistic model with all the covariates included. Missing values in the covariates were imputed using a simple approach: the mean or median was used for continuous variables, and the mode was used for categorical variables.

All the analyses were performed using SAS 9.4 and R, and the significance threshold was set to 0.05 (two-tailed).

Results

Patient Characteristics

A total of 361 patients, from 10 participating hospitals in the Piedmont region, provided informed consent and were

enrolled in the study between March 2023 and January 2025. In this preliminary analysis, only patients with at least 52 weeks of follow-up or patients who exited the study for DR failure were considered. Particularly, we excluded 109 patients with only baseline information and 96 with 26 weeks of follow-up. Among the 156 patients included, 70 (44.87%) received IL-17i and 86 (55.13%) IL-23i. Regarding treatment distribution, the most prescribed dose spacing regimen was secukinumab (50, 32.05%), followed by guselkumab (49, 31.41%), risankizumab (37, 23.72%), and brodalumab (20, 12.82%).

The mean age (SD) at diagnosis was 53.68 (15.83) years (range: 18–85), with a predominance of males (n=101, 68.24%). The mean BMI score was 25.92 (SD 6.38). Patient and treatment characteristics were summarized in Table 2.

Baseline characteristics and preliminary dose spacing results, grouped and subcohort analysis.

Patient' PASI and DLQI records were analyzed at baseline, considered as start of treatment, at the initiation of DR, and during the follow-up visits at 26 ± 2 weeks and 52 ± 2 weeks. At baseline, the mean (SD) PASI was 15.12 (7.14), without significant differences between the two groups (*P*=0.7619); conversely, the mean (SD) DLQI was 12.84 (6.08), with a significant difference between IL-17i and IL-23i groups (*P*=0.0009). The majority of patients achieved and maintained good disease management, both for PASI and DLQI, during the 52 weeks of follow-up; these results are summarized in Table 3.

Flare-Ups, Treatment Adjustments, and Dose Reduction Survival

Thirty-nine patients interrupted the DR: four before first follow-up visit, 27 during the first visit, one between the first and second follow-up visit, and seven during the second follow-up visit. Disease flare-ups, and subsequent reversion to the StD, were observed in 24 patients with IL-17 and 15 with IL-23.

Kaplan-Meier DR survival curves–overall and differentiated–are reported in Figure 1. Overall DR survival at 52 weeks was 0.75 (95% CI: 0.69–0.82). Moreover,

Table 2. Patient and Treatment Characteristics, Overall and by Treatment Drug. Absolute and Relative Frequencies are Reported for Categorical Variables and Means (standard deviation) or Median [Q1; Q3] for Numerical Ones. P-values are also reported.

Patients (overall)	All (N=156)	Il-17 (N=70)	Il-23 (N=86)	p-value
Age, years				
Mean (SD)	53.68 (15.83)	55.67 (14.41)	52.13 (16.77)	0.1702
Sex				
Male	101 (68.24%)	49 (74.24)	52 (63.41)	0.1596
Physical characteristics				
Height, m mean (SD)	1.71 (0.09)	1.71 (0.09)	1.71 (0.09)	0.8385
Weight, kg mean (SD)	76.48 (16.86)	74.90 (13.53)	77.76 (19.14)	0.3069
BMI, kg/m^2 mean (SD)	25.92 (6.38)	25.02 (4.76)	26.66 (7.39)	0.1195
Smoking history				
Never	62 (44.29)	23 (37.70)	39 (49.37)	0.0286
Ex (>1 year)	39 (27.86)	14 (22.95)	25 (31.65)	
Current	39 (27.86)	24 (39.34)	15 (18.99)	
Level of education*				
Low	68 (48.92)	34 (54.84)	34 (44.16)	0.3091
Medium	60 (43.17)	25 (40.32)	35 (45.45)	
High	11 (7.91)	3 (4.84)	8 (10.39)	
Psoriasis type				
Vulgaris	139 (91.45)	62 (89.86)	77 (92.77)	0.5222
Arthropathy				
Yes	20 (14.08)	15 (22.73)	5 (6.58)	0.0058
Comorbidity				
Yes	63 (40.38)	29 (41.43)	34 (39.53)	0.8105
Previous biological treatment				
Yes	27 (18.12)	13 (19.40)	14 (17.07)	0.7134
Therapy time before DR				
Median [Q1; Q3]	2.80 [1.60; 4.20]	4.10 [3.00; 5.30]	1.80 [1.00; 3.00]	<.0001

*low=middle school or less, medium=high school, high= college degree or more.

Table 3. PASI and DLQI Values, Overall and by Treatment. Mean and Standard Deviation Scores were Calculated at Treatment Start, at Dose Reduction, and at Different Follow-up Appointments.

Variables	All		Il-17i		Il-23i	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
PASI						
Treatment start	156	15.12 (7.14)	70	14.93 (7.19)	86	15.28 (7.14)
Dose reduction	156	0.15 (0.38)	70	0.16 (0.4)	86	0.15 (0.36)
26 ± 2 weeks	152	0.8 (1.59)	68	0.91 (1.65)	84	0.71 (1.55)
52 ± 2 weeks	124	0.4 (0.99)	51	0.55 (1.05)	73	0.3 (0.94)
DLQI						
Treatment start	156	12.84 (6.08)	70	14.71 (7.44)	86	11.31 (4.14)
Dose reduction	156	0.04 (0.21)	70	0.06 (0.23)	86	0.03 (0.18)
26 ± 2 weeks	152	0.72 (1.94)	68	0.93 (2.19)	84	0.56 (1.71)
52 ± 2 weeks	124	0.35 (1.55)	51	0.69 (2.28)	73	0.12 (0.58)

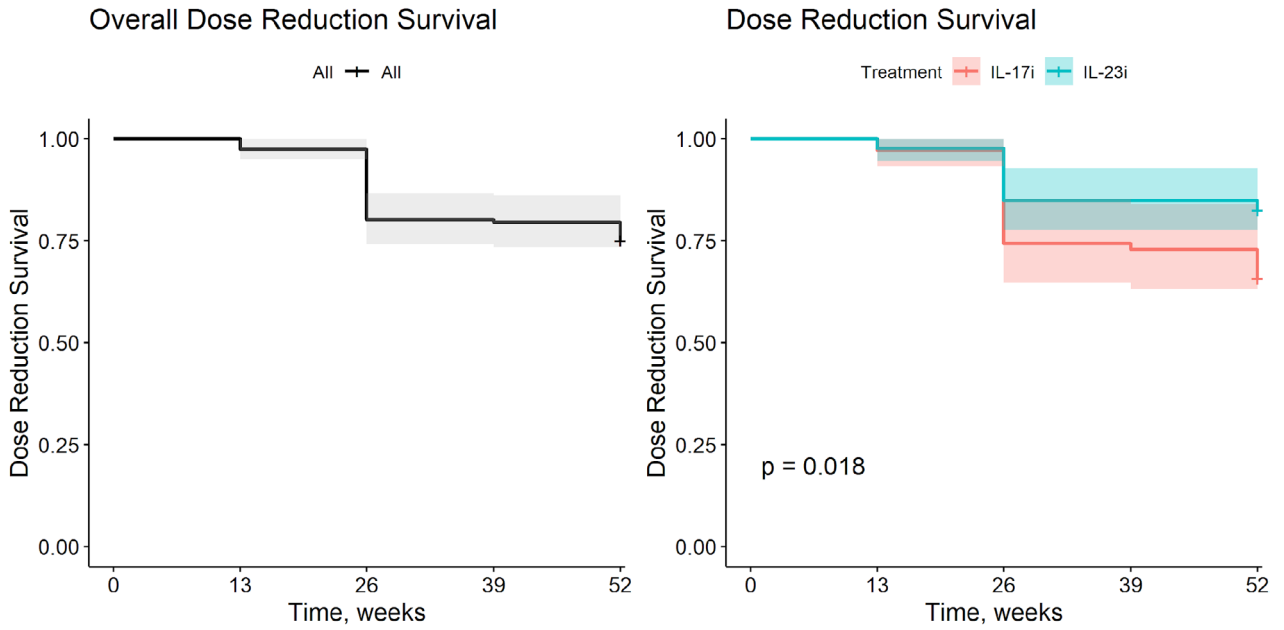

Figure 1. Dose reduction survival overall (left panel) and separately by class of treatment (right panel). P-value iSs the result of log-rank test.

IL-23i had higher dose-reduction survival at 52 weeks than did IL-17i: 0.83 (95% CI: 0.75–0.91) and 0.66 (95% CI: 0.55–0.78], respectively. This difference was statistically significant (*P*=0.0181) based on log-rank test. Moreover, unadjusted and adjusted estimates of Cox models indicate that patients treated with IL-23i had a significant (*P*=0.0309, *P*=0.0244, respectively) lower risk of DR discontinuation compared with IL-17i, with a hazard ratio of 0.49 (95% CI: 0.26–0.94] and 0.48 (95% CI: 0.25–0.91), respectively. Kaplan-Meier curves are also reported for different treatments (Figure 2). Il-23i had the highest dose-reduction survival rate; in particular, at 52 weeks, DR survival for guselkumab was 0.84 (95% CI: 0.74–0.95), followed closely by risankizumab with 0.81 (95% CI: 0.69–0.95). Otherwise, the DR survival observed for IL-17i was 0.68 (95% CI: 0.56–0.82] for secukinumab and 0.60 (95% CI: 0.42–0.86] for brodalumab. No statistically significant difference between different treatments was observed (*P*=0.0849).

Among the 39 patients who experienced a disease flare-up and reverted to the StD; 97.44% of patients (n=38/39) achieved an adequate disease response resuming the StD; only one patient (2.56%) required a therapy change (secukinumab switching to risankizumab) in order to regain good control of the disease. Adverse events (AEs) were experienced by five (3.21%) patients: 4/70 (5.71%) in IL-17i group and 1/86 (1.16%) in IL-23i group. The adverse events, apart from disease flare-up, included sacroiliitis, arthralgia, enthesitis, and pruritus; all adverse events resolved after

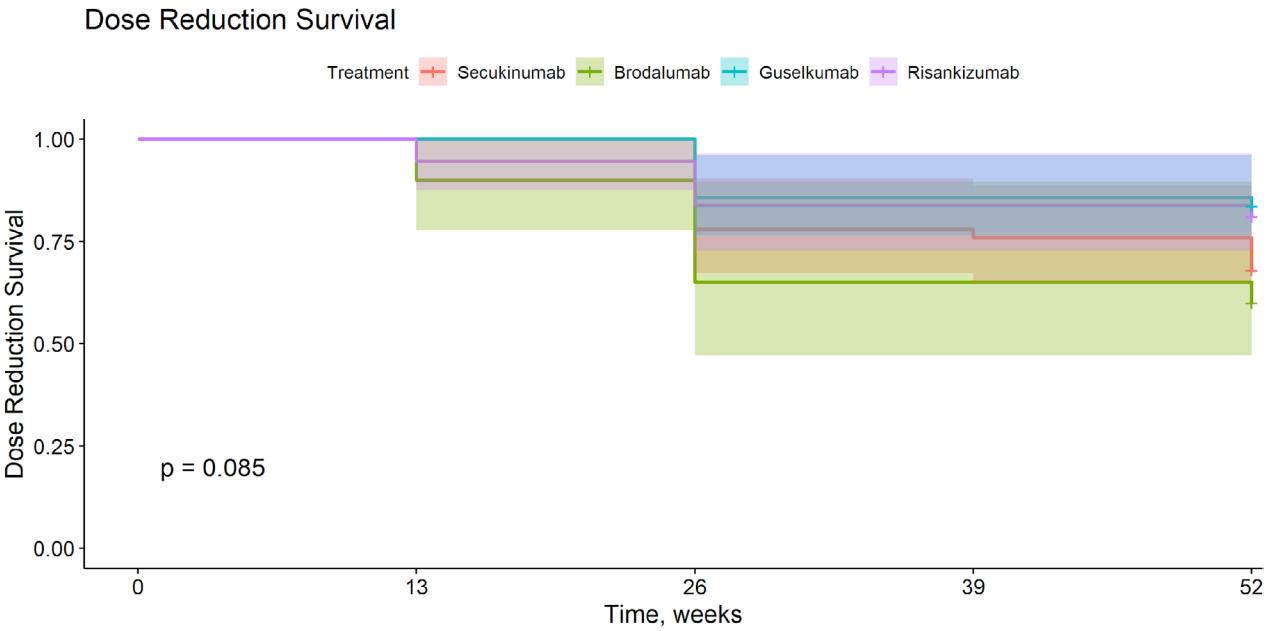

Figure 2. Discontinuation survival by different treatments. P-value is the result of log-rank test.

reintroducing the standard treatment dose. A single case of diplopia due to meningioma was observed in this patient cohort. This adverse event is not considered related to the DR protocol.

Discussion

Based on our experience, implementing DR through extended dosing intervals for IL-17 and IL-23 inhibitors appears to be an effective therapeutic strategy for many patients with stable plaque psoriasis. At both 26 and 52 weeks, most patients maintained disease control indicated by PASI and DLQI scores ≤ 3, while only a small percentage experienced flare-ups requiring a return to the standard dose (StD) or a change in therapy. The feasibility of administering reduced or spaced doses or DS was already explored with these therapies, with good results. Notably, the IL-23i risankizumab has shown the capacity to sustain clinical improvement for up to 66 weeks following a single intravenous administration [14]. Furthermore, an as-needed dosing approach has proven viable in maintaining response, as evidenced by a successive study of 64 patients that progressively extended dosing intervals to an average of over 38 weeks [11]. The GUIDE randomized clinical trial demonstrated noninferiority of treatment with guselkumab every 16 weeks vs 8-weeks in super-responder patients (those who achieved and maintained PASI 0 at both Week 20 and Week 28) [12]. In the OPTIMISE study [13], the IL-17 inhibitor secukinumab was prescribed every six weeks during the maintenance phase, although the final results favored the superiority of the standard four-week dosing schedule. In contrast, a recent study by Daudén et al. proposed a DR strategy for patients who had achieved prolonged remission with secukinumab [9]. Most patients in that study simply extended the interval between administrations—some also halved the dose—and 77.8% maintained therapeutic success without compromising safety. Meanwhile, the phase II OLE study evaluated the efficacy and safety of brodalumab in patients with moderate-severe plaque psoriasis, revealing that individuals weighing ≤ 100 Kg who received brodalumab 140 mg Q2W achieved comparable response to those receiving 210 mg [15].

A cohort of "long term responders" was selected to initiate the reduced dose in our study. To the best of our knowledge, this is the first multicenter study evaluating the effectiveness of DS in maintaining the clinical response achieved with IL-17/IL-23 inhibitors in patients affected by moderate/severe psoriasis. The rationale for the off-label use of spaced doses of IL-17/IL-23 inhibitors in treating moderate-to-severe psoriasis lies in identifying the minimal effective dose needed to sustain response, thereby preserving the treatment's safety profile while alleviating healthcare costs. This cost-saving objective is particularly pertinent given psoriasis's high prevalence and associated economic and social impact [16-18]. Consistent with prior research [6], our finding indicates potential cost savings of up to 30%, although further tailoring of individual dosing schedules may enhance the long-term sustainability of this approach; a more comprehensive and accurate pharmacoeconomic analysis has been planned for an upcoming dedicated article. Both IL-17i and IL-23i showed sustained efficacy after one year of follow-up; however, a comparison of the two cohorts revealed a

difference in therapeutic maintenance showed a trend favoring IL-23i. This difference may be linked to the superior drug survival of the IL-23i [19], to IL-23i's sustained suppression of CD8-positive tissue-resident memory T cells in lesional skin that play a crucial role in psoriasis recurrence [12], to the difference in patient selection (slightly higher DLQI), and/ or to the mechanism of action of treatments. In particular, brodalumab, by its unique mechanism - IL-17 receptor A blockade, provides fast onset of action but may also simultaneously correlate with a greater secondary loss of efficacy in dose spacing regime. Most patients who reverted to StD regained complete control of the disease, with only 2.56% (0.64% compared to the total of DR) requiring a therapy switch, indicating that DR is both a reversible and manageable strategy. However, interval prolongation might increase the production of anti-drug antibodies (ADA), thus reducing the drug's effectiveness [5]. Moreover, excessive prolongation between administrations, e.g., doubling the therapeutic window, could likely lead to a significant reduction in therapeutic response, as already highlighted in the study conducted by Blauvelt et al. [20]. Hence, careful patient selection is essential to optimizing outcomes. Factors such as biologic treatment history, speed of response to treatment, disease duration, baseline PASI/DLQI scores, BMI, or type of biologic agent used should be considered prior to initiating DR. Further studies are needed to identify potential predictive markers that can more accurately forecast successful outcomes.

The primary clinical implication of our study is represented by the potential benefits of DR in reducing the economic burden on healthcare systems without compromising treatment efficacy. In fact, DR could lead to more sustainable long-term management of psoriasis, especially in healthcare settings with limited resources, and aligns with the principles of personalized medicine. The future of biologic treatments for psoriasis is promising in this regard. Continuous therapy with the minimal effective dose, based on the clinical situation, has been considered for other psoriasis treatments, such as cyclosporin and acitretin, and could represent the future of biologic treatment [21]. To optimize drug efficacy and minimize toxicity, measuring drug concentrations in a patient's blood could be a possibility. Therapeutic drug monitoring (TDM) is a clinical practice that helps achieve this goal by ensuring appropriate dosing based on individual pharmacokinetics. Particularly valuable for medications with a narrow therapeutic index, TDM could also guide personalized treatment decisions in biologic treatment, enhancing patient safety and therapeutic outcomes.

Nevertheless, our study suffers from several limitations. The data are preliminary, the sample size is relatively small, and the observational design introduces potential biases, including selection bias from the inclusion criteria and a lack of randomization. These factors limit the generalizability of our findings, underscoring the need for additional research. Future research direction can be represented by larger randomized controlled trials to confirm the efficacy and safety of DR strategies and by longitudinal studies to assess the long-term outcomes and sustainability of DR. Moreover, biologic mechanisms underlying successful DR must be explored in depth to identify appropriate biomarkers useful for patient selection. Currently, prolonged remission is the main criterion for dose reduction eligibility [22], but the identification of more specific criteria could further improve the results obtained through this strategy.

Conclusions

The disease activity-guided DR of IL-17 and IL-23 inhibitors appears to be a feasible and effective strategy for selected patients with plaque psoriasis. It allows for the optimization of treatment regimens, improving patient quality of life and reducing healthcare costs. Based on our experience, we encourage clinicians to consider DR for patients who have maintained low disease activity over an extended period, while emphasizing the importance of regular monitoring for early detection of flare-ups. Future studies should include randomized controlled trials and long-term follow-up to confirm these results and assess their implications for clinical practice. Finally, clear communication and patient education are essential to ensuring that patients are actively involved in the decision-making process of a valuable yet off-label protocol and to knowing when to report any concerning symptoms.

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