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ORIGINAL RESEARCH

Predictors of Successful Secukinumab Dose Tapering in Moderate-to-Severe Psoriasis: A Retrospective Study

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Background: Psoriasis (PsO) is a prevalent chronic disease affecting millions, with biologic therapies like secukinumab showing efficacy. With the extensive and prolonged use of secukinumab, identifying strategies for successful dose tapering has emerged as a recent challenge.

Objective: This retrospective study aims to identify predictors of successful secukinumab dose tapering in patients with moderate-to-severe plaque psoriasis.

Methods: This retrospective study included patients who received secukinumab 300 mg weekly for 5 weeks, then every 4 weeks, achieving and maintaining Psoriasis Area and Severity Index (PASI) 90 for ≥6 months. Statistical analyses included the Mann–Whitney *U*-test, Friedman M test, and logistic regression ($P<0.05$).

Results: Among the 75 secukinumab-treated patients, 40 (53.33%) successfully tapered their dosage. BMI, dose tapering timing, and pre-tapering treatment duration were significant predictors of tapering success. Seasonal effects were observed, with autumn and winter attempts having an increased risk of failure. PASI 75 and PASI 90 rates dropped from week 6 to 12, with no serious adverse events.

Conclusion: Lower BMI, dose tapering initiation in spring and summer, and rapid PASI 90 achievements are associated with successful secukinumab dose tapering. These findings suggest that, under appropriate clinical conditions, dose tapering may be a feasible strategy to maintain disease control while potentially reducing treatment-related costs and minimizing the risk of adverse effects.

Plain Language Summary:

- Psoriasis is a chronic condition impacting many people, and biologicals like secukinumab demonstrate therapeutic benefits. As its use grows, developing effective tapering regimens becomes a challenge.
- Our study found that dose tapering is feasible in people living with psoriasis who are treated with secukinumab. Lower BMI, tapering in spring-summer, and a rapid PASI 90 response predict success.

Keywords: psoriasis, dose tapering, secukinumab, predictive factors, efficacy

Introduction

Psoriasis (PsO) is a chronic immune-mediated inflammatory disease affecting over 60 million people worldwide and impairing patients' quality of life.[1] Biologic therapies have shown significant efficacy and safety in the long-term treatment of moderate-to-severe plaque psoriasis. Agents such as tumor necrosis factor-α (TNF-α) inhibitors and

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antibodies targeting interleukin (IL)-12/23, IL-17A, the IL-17 receptor, and IL-23p19 are approved for the treatment of moderate-to-severe PsO.[2]

Secukinumab is a fully human monoclonal antibody that selectively binds to and neutralizes IL-17A, a key cytokine involved in the development of PsO, and has demonstrated long-lasting efficacy and safety in moderate-to-severe plaque psoriasis.[3] The standard regimen is a 300 mg loading dose administered weekly at weeks 0, 1, 2, 3, and 4, followed by 300 mg maintenance dosing every 4 weeks. Clinical trial evidence and real-world experience have substantiated the long-term safety and effectiveness of secukinumab in PsO management. The safety and long-term effectiveness of secukinumab in PsO treatment have been confirmed by pre-marketing studies and real-world experience.[3–6]

Despite its effectiveness, secukinumab also has disadvantages, such as high costs and potential adverse events. As PsO is a chronic disease with a significant impact on patients' quality of life, lifelong treatment is often required for long-term disease control. However, lifelong fixed-dose treatment may not be necessary for patients with good responses, as some may be overtreated.[7] Therefore, it is imperative to explore strategies for biologic dose tapering and identify populations suitable for this approach in order to manage the disease effectively over the long term while minimizing these drawbacks.

The current e-Delphi consensus has synthesized standardized dose reduction protocols for biologics targeting moderate-to-severe psoriasis, including TNF-α inhibitors (adalimumab, etanercept) and IL-12/23 inhibitors (ustekinumab), for use in clinical practice.[8] Conversely, evidence on dose tapering of IL-17A inhibitors, particularly secukinumab, remains limited to randomized controlled trials with no real-world experience reported. [9] Given the expanding use of secukinumab, determining appropriate tapering timing constitutes a pivotal clinical decision point in psoriasis.

The primary objective of this retrospective study was to assess the efficacy and safety of dose tapering achieved through gradual increases in dosing intervals with secukinumab. The secondary objective was to identify significant predictors of successful dose tapering in these patients. This study will contribute to a safer and more effective long-term treatment strategy for individuals with PsO receiving secukinumab. Furthermore, reducing drug exposure while maintaining clinical efficacy may lower treatment costs, offer greater economic benefits to patients, and potentially improve treatment adherence.

Methods

Study Population

This is a retrospective study of patients with moderate-to-severe plaque psoriasis, conducted with ethical approval and in accordance with the Declaration of Helsinki. We collected data from patients who were admitted to the Department of Dermatology at the First Affiliated Hospital of Fujian Medical University for PsO between December 2020 and August 2023. All patients received secukinumab treatment with an initial dose of 300 mg subcutaneously every week for 5 weeks, followed by a standard dose (300 mg) administered every 4 weeks. Inclusion criteria were: (i) longstanding moderate-to-severe PsO treated with secukinumab administered at a standard dose of 300mg q4w; (ii) achieving PASI 90 and maintaining it for at least six months; (iii) meeting taper conditions and extending the dosing interval to 300mg subcutaneously every 6 weeks. Exclusion criteria were: (i) failure to achieve PASI 90; (ii) achieving PASI 90 but not maintaining it for six months; (iii) incomplete clinical records.

Study Design

After maintaining PASI 90 for half a year, the dosing intervals were progressively extended to every 6 weeks. Patients were evaluated for a minimum period of 9 months and up to 3.2 years. Efficacy was assessed using PASI, Physician's Global Assessment (PGA), and Dermatology Life Quality Index (DLQI) scores at baseline, before dose tapering, and 3 months after dose tapering. Adverse events were recorded at each follow-up visit. Demographic data, clinical PsO information, and personal comorbidities were also documented. Successful dose tapering was defined as maintaining PASI $\leq$ 5 and/or PGA 0–2, and DLQI $\leq$ 5 after 3 months of dose reduction, otherwise it was considered a failure.

Statistical Analysis

Deviations from the Gaussian distribution was assessed using the Kolmogorov–Smirnov test. Statistical analysis was performed using the Mann–Whitney test to compare non-normally distributed continuous variables. Repeated measurements from multiple groups of non-normally distributed variables were analyzed using the Friedman M test. Categorical data were analyzed using the $\chi 2$ test or Fisher's exact test. Continuous variables were summarized as means with standard errors (SE), while categorical variables were presented as proportions. Non-normally distributed data were reported as the median [first quartile (Q1), third quartile (Q3)] and the range (minimum, maximum). Three regression models were developed to estimate the association between several risk factors and the odds ratio (OR) (95% CI) for successful dose tapering in patients with PsO: Model 1 (unadjusted); Model 2 was adjusted for gender, age, and marital status; and Model 3 was adjusted for gender, age, marital status, hypertension, diabetes, smoking history, and alcohol use. All analyses were performed using GraphPad Prism (version 9.0; GraphPad Software), R statistical software (version 3.4.3) and Empower software (version 2.0). The level of statistical significance was set at $P < 0.05$.

Results

Characteristics of Participants

A total of 75 participants treated with secukinumab had their pretreatment biologic naïve status confirmed through medical record verification. Of these, 51 (68%) were male and 24 (32%) were female, with a mean age of 43.72 ± 12.70 years. The baseline PASI, PGA and DLQI scores for these patients were 9.80 (7.30–12.30), 3.00 (3.00–3.00), and 11.00 (9.00–14.00), respectively. All patients had prior topical corticosteroid exposure, with non-topical therapy use including phototherapy (6 patients, 8.0%), acitretin (6 patients, 8.0%), traditional Chinese medicine (5 patients, 6.7%), and methotrexate (3 patients, 4.0%). Based on reduction outcomes, statistically significant differences were observed in BMI, smoking, alcohol use, diabetes, history of hypertension, treatment duration before dose tapering, timing of dose tapering (all $P < 0.05$). Baseline characteristics of the study population according to dose tapering are shown in Table 1.

Table 1 Characteristics of Study Population According to Dose Tapering

Dose Reduction	Failed Dose Tapering	Successful Dose Tapering	P-value
N	35	40	
Age (years)			0.136
≤60	29 (82.86%)	38 (95.00%)	
>60	6 (17.14%)	2 (5.00%)	
Gender			0.112
Male	27 (77.14)	24 (60.00)	
Female	8 (22.86%)	16 (40.00%)	
Marital status			0.050
Married	31 (88.57%)	28 (70.00%)	
Unmarried	4 (11.43%)	12 (30.00%)	
BMI (kg/m^2)			0.005
Normal weight	16 (45.71%)	32 (80.00%)	
Overweight	14 (40.00%)	7 (17.50%)	
Obese	5 (14.29%)	1 (2.50%)	
Smoking history			0.030
Smoke	14 (40.00%)	7 (17.50%)	
Non-Smoke	21 (60.00%)	33 (82.50%)	
Alcohol use	13 (37.14%)	3 (7.50%)	0.002

(*Continued*)

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Table 1 (Continued).

Dose Reduction	Failed Dose Tapering	Successful Dose Tapering	P-value
Diabetes	7 (20.00%)	0 (0.00%)	0.003
Hypertension	9 (25.71%)	1 (2.50%)	0.003
Disease period	7.00 (4.50–10.00)	5.00 (3.00–7.00)	0.067
Time to target before DT			<0.001
≤12 weeks	3 (8.57%)	35 (87.50%)	
>12 weeks	32 (91.43%)	5 (12.50%)	
Timing of reduction			<0.006
Fall/Winter	25 (71.43%)	16 (40.00%)	
Spring/Summer	10 (28.57%)	24 (60.00%)	
TG	4.68 (4.33–5.09)	4.78 (4.08–5.54)	0.868
LDL	3.25 (2.79–3.59)	3.21 (2.71–4.04)	0.982

Abbreviations: BMI, body mass index; DT, dose tapering; TG, triglyceride; LDL, Low Density Lipoprotein Cholesterol.

Dose Tapering Evaluation

Predictors of Outcomes in Dose Tapering

During the follow-up, 40 (50.33%) successful tapering events occurred. We designed 3 logistic regression models to investigate several risk factors related to tapering outcomes. After multivariate adjustment, BMI, timing of dose tapering, and treatment duration before dose tapering were all positively associated with successful dose tapering, with statistical significance. These associations remained stable across all three models (Table 2). When successful dose tapering was considered a positive outcome, in Model 3, overweight and obese patients were less likely to achieve successful tapering. The OR value and 95% CIs for normal weight, overweight, and obese patients were 1.00 (reference), 0.18 (0.04,0.83), and 0.04 (0.00,0.48), respectively. Among them, compared with spring and summer [1.00 (reference)], patients who tapered in autumn and winter were 82% more likely to experience failed dose tapering [OR: 0.21 (0.06,0.73), $P = 0.0141$]. In addition, patients who reached the reduction point after more than 12 weeks were also more likely to fail, suggesting that those who achieved PASI 90 in a shorter period were more likely to succeed in subsequent dose reductions.

Table 2 Three Logistic Regression Models to Investigate Several Risk Factors Related to Tapering Outcomes

Successful Dose Tapering			
	Model 1[a]	**Model 2[b]**	**Model 3[c] ‡**
BMI (kg/m2)[d]			
Normal weight	Reference	Reference	Reference
Overweight	0.25 (0.08, 0.74) 0.0125	0.22 (0.06, 0.82) 0.0238	0.18 (0.04, 0.83) 0.0273
Obese	0.10 (0.01, 0.93) 0.0429	0.04 (0.00*, 0.49) 0.0120	0.04 (0.00*, 0.48) 0.0114
Timing of reduction			
Spring/Summer	Reference	Reference	Reference
Fall/Winter	0.27 (0.10, 0.70) 0.0075	0.17 (0.05, 0.57) 0.0036	0.21 (0.06, 0.73) 0.0141
Time to target before DT[e]			
≤ 12 weeks	Reference	Reference	Reference
>12 weeks	0.01 (0.00*, 0.06) <0.0001	0.01 (0.00, 0.07) <0.0001	0.00* (0.00, 0.04) <0.0001

Notes: [a]Model 1: no covariates were adjusted. [b]Model 2: adjusted for gender, age, and marital status. [c]Model 3: adjusted for gender, age, marital status, hypertension, diabetes, smoking history, and alcohol use. [d]BMI: body mass index. [e]DT: dose tapering. ‡Model 3 Fit Statistics for BMI: Nagelkerke R2 = 0.532, Cox & Snell R2 = 0.399; Hosmer-Lemeshow test: p = 0.567. Timing of reduction: Nagelkerke R2 = 0.481, Cox & Snell R2 = 0.360; Hosmer-Lemeshow test: p = 0.959. Time to target before DT: Nagelkerke R2 = 0.844, Cox & Snell R2 = 0.632, Hosmer-Lemeshow test: p = 0.291. *0.00: keep two decimals.
Abbreviations: BMI, body mass index; DT, dose tapering.

Efficacy and Safety During Dose Tapering

Changes in PASI, PGA and DLQI scores before and after dose tapering were recorded at each follow-up time point (Figures 1–3). At week 6, 53 patients (70.67%) maintained PASI 75, and 45 patients (60%) maintained PASI 90. At week 12, 40 patients (53.33%) maintained PASI 75, and 34 patients (45.33%) maintained PASI 90. Additionally, 40 patients met the criteria for successful dose tapering. No unexpected safety signals were observed during the follow-up period. No serious adverse events or deaths were reported.

Discussion

At present, biologics have become one of the first-line treatments for moderate-to-severe PsO. With the long-term use of biologics, determining whether and how to reduce the dosage is a problem that needs to be addressed. The standards and predictors for dose tapering of different biologics are not fully unified.[7–9] Secukinumab, one of the most commonly used biologics for the treatment of moderate-to-severe PsO, effectively controls the disease by targeting and inhibiting IL-

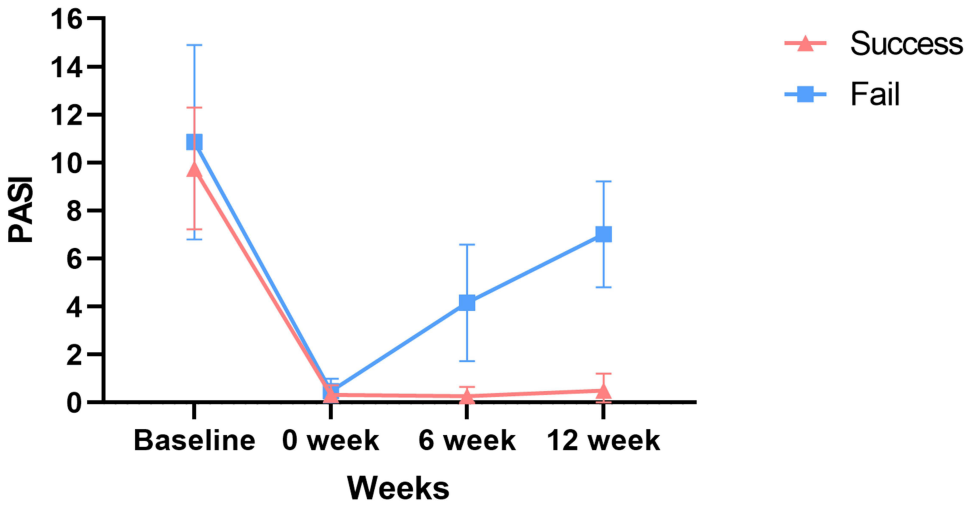

Figure 1 "Changes of PSO patients' PASI scores before and after dose tapering".

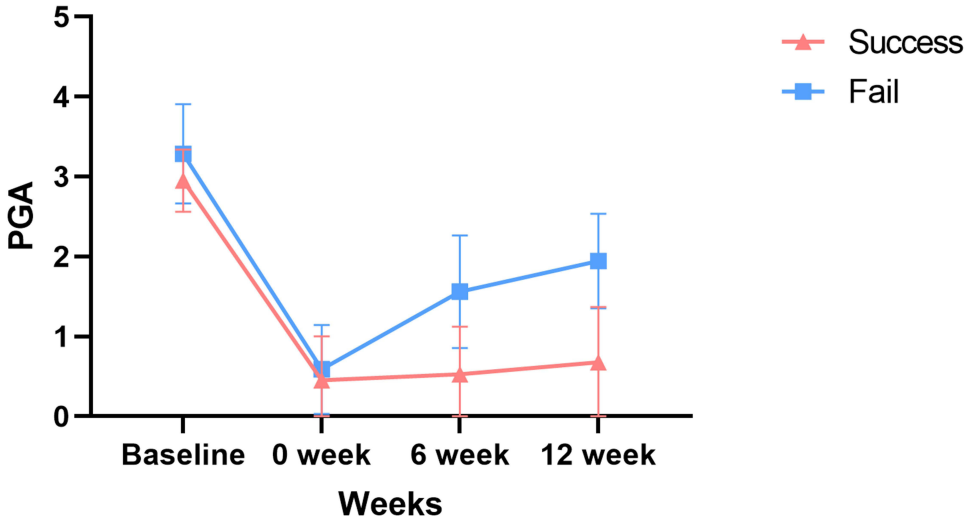

Figure 2 "Changes of PSO patients' PGA scores before and after dose tapering".

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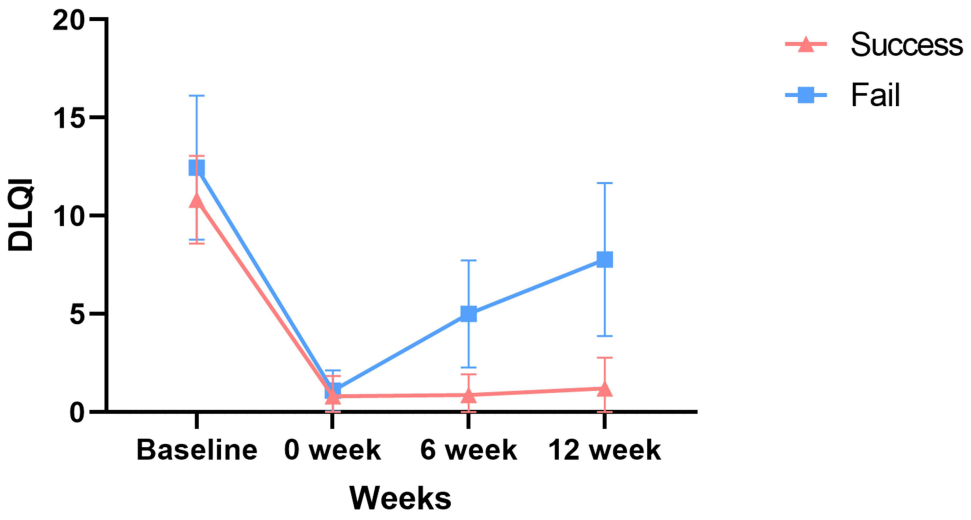

Figure 3 "Changes of PSO patients' DLQI before and after dose tapering".

17A.[10] Currently, its dose tapering in real-world settings also faces great challenges, but there is a lack of research on this topic.

This retrospective cohort comprised 75 individuals with moderate-to-severe psoriasis who maintained PASI 90 response for ≥6 months under standard secukinumab dosing. Clinically implemented tapering extended dosing intervals from every 4 weeks to every 6 weeks, a regimen analogous to the OPTIMISE trial strategy. This study demonstrates that reducing the dose by lengthening the dosing interval is feasible for patients receiving secukinumab who require tapering.[8] Referring to the reduction principles for other biologics,[11] we defined successful reduction as a disease assessment conducted 12 weeks after the reduction, with PASI≤5 and/or PGA 0–2, and DLQI≤5. Since dose tapering may offer advantages in terms of reducing long-term adverse events and improving cost-effectiveness, we emphasize the importance of identifying possible clinical predictors to determine which patients may benefit from dose reduction while maintaining adherence and quality of life.

In our study, multivariate regression model analysis identified obesity, dose reduction in spring/summer, and maintaining PASI 90 for more than 12 weeks prior to reduction as clinical features that predicted the risk of relapse in patients undergoing dose reduction. Previous studies have reported that genetic polymorphisms in males are associated with the success of TNF-α inhibitor dose tapering, and that patients with a higher BMI and younger than 52 years of age are prone to relapse after reduction.[7,9,12,13] However, in our study, there was no significant difference in success between genders or across age groups. Psoriasis severity and therapeutic response to secukinumab have been proven to correlate with BMI.[14,15] Obesity is associated with an increase in visceral fat mass and adipose tissue inflammation. In the state of obesity, adipose tissue is infiltrated by various immune cells, including macrophages, T cells, and neutrophils, which contribute to the production of pro-inflammatory cytokines such as TNF-α, exerting systemic inflammatory effects.[16–18] Therefore, weight loss interventions have been proven to improve the treatment outcomes of individuals with PsO, which may also be one of the possible reasons why BMI can affect the outcomes of tapering. [19]

Furthermore, our study showed that dose reduction was more successful in patients who reached PASI 90 within less than 12 weeks of initial therapy, which is consistent with the treatment-to-target consensus for PsO.[20] At the clinical follow-up 12 weeks after the start of dose tapering, patients with successful dose reduction showed sustained clinical improvement, and the safety profile of secukinumab remained favorable in both the success and failure groups.

Interestingly, our results showed that patients who initiated dose tapering in the spring or summer were more successful than those who did so in the fall or winter ($P < 0.05$). The difference in dose tapering outcomes between seasons may be related to the seasonal pattern in PsO, with patients being more prone to flare-ups and aggravated conditions in autumn and winter.[21] The seasonal variation in psoriasis severity may be attributed to both differential gene expression across seasons and seasonally driven environmental changes. Substantial evidence indicates that the immune

system exhibits a markedly pro-inflammatory transcriptomic profile during the winter months, characterized by elevated levels of soluble IL-6 receptor and C-reactive protein, which may contribute to the exacerbation of PsO.[22] Moreover, environmental factors presenting seasonal patterns, such as solar radiation, ambient humidity, air pollution, and alterations in circadian rhythm, can affect genetic background and inflammatory drive within the skin. These environmental influences may exert their effects on psoriasis-associated genes via epigenetic modifications, thereby contributing to disease pathogenesis and seasonal fluctuation.[23]

However, this study has several limitations. The retrospective design may introduce recall bias and limit the ability to establish causal relationships. Further prospective investigations are needed to validate whether lower BMI, initiation of dose tapering during spring or summer, and a shorter time to achieve PASI 90 with the standard regimen are reliable predictors of successful secukinumab dose tapering. Additionally, the small sample size and single-center nature of the study may restrict the generalizability of the findings. Multicenter studies are warranted to enhance external validity and confirm the reproducibility of these results.

Conclusions

In this retrospective study, lower BMI, initiation of secukinumab dose tapering during spring or summer, and rapid achievement of PASI 90 response were significantly associated with successful tapering outcomes. These findings support the feasibility of individualized dose reduction strategies in individuals with moderate-to-severe psoriasis, thereby maintaining disease control and potentially reducing treatment costs and adverse effects. Validation through prospective multicenter studies is warranted to establish standardized tapering protocols in the future.

IRB Approval Status

This study was approved by the Ethics Committee of the First Affiliated Hospital of Fujian Medical University (IRB [2022]007).

Abbreviations

PsO, Psoriasis; PASI, Psoriasis Area and Severity Index; TNF-α, Tumor necrosis factor-α; PGA, Physician's Global Assessment; DLQI, Dermatology Life Quality Index; SE, standard errors; Q1, first quartile; Q3, third quartile; OR, odds ratio.

Data Sharing Statement

The data supporting the findings of this study are available upon request from the corresponding authors, Ting Gong and Chao Ji. The data are not publicly available due to privacy or ethical restrictions.

Informed Consent Statement

The studies involving human participants were reviewed and approved by the Medical Ethical Committee of the First Affiliated Hospital of Fujian Medical University (IRB [2022]007) and comply with the Declaration of Helsinki. The patients/participants provided written informed consent to participate in this study.

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Disclosure

The authors report no conflicts of interest in this work.

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