



Secukinumab in psoriasis: A single-center experience

Psoriaziste sekukinumab: Tek merkez deneyimi

● Esra Ağaoğlu, ● Hilal Kaya Erdoğan*, ● Ersoy Acer*, ● Zeynep Nurhan Saraçoğlu*,
● Muzaffer Bilgin**

Kars Harakani State Hospital, Clinic of Dermatology, Kars, Turkey

*Eskişehir Osmangazi University Faculty of Medicine, Department of Dermatology; **Department of Biostatistics, Eskişehir, Turkey

Abstract

Background and Design: Several randomized clinical trials demonstrated the safety and efficacy of secukinumab in the systemic treatment of moderate-severe psoriasis; however, real-life data is limited. Thus, this study aimed to assess the efficacy and safety of secukinumab in patients with psoriasis.

Materials and Methods: In this study, 32 patients treated with secukinumab were retrospectively reviewed. The efficacy of secukinumab was evaluated as psoriasis area and severity index (PASI) 50, 75, and 90 response rates at 16., 24., and 36. weeks, respectively. Side effects of secukinumab treatment were recorded.

Results: The mean PASI of 32 patients before treatment was 12.38±6.49, which decreased to 1.96, 1.85, and 3.01, after 16, 24, and 36 weeks, respectively. At 16 weeks of treatment, 83.3% of patients reached PASI 50, 70.0% had PASI 75, and 50.0% had PASI 90 response rates. At 16, 24, and 36 weeks, PASI 50, 75, and 90 responses were generally higher in patients naive to biologic than the non-naive; however, differences were not statistically significant ($p>0.05$). Secukinumab was discontinued in 7 (21.9%) patients during the treatment. Of the 7 patients, 5 (15.6%) patients failed to respond to secukinumab and 2 (6.2%) developed various side effects. Oral candidiasis was observed in 4 (12.5%) patients, which was the most common side effect of secukinumab treatment.

Conclusion: Secukinumab is an effective and safe treatment option in patients with psoriasis. The secukinumab efficacy in clinical practice is higher in patients naive to biologic.

Keywords: Secukinumab, psoriasis, biologic treatment, efficacy, safety

Öz

Amaç: Birçok randomize klinik çalışma, orta-şiddetli psoriazisin sistemik tedavisinde sekukinumabın etkinliği ve güvenilirliğini ortaya koyarken, gerçek yaşam verileri sınırlıdır. Çalışmamızın amacı psoriaziste sekukinumabın etkinliği ve güvenilirliğini değerlendirmektir.

Gereç ve Yöntem: Çalışmada sekukinumab tedavisi alan 32 hasta retrospektif olarak incelendi. Sekukinumabın etkinliği tedavinin 16., 24. ve 36. haftalarında psoriazis alan şiddet indeksi (PAŞİ) 50, 75, 90 yanıt oranları ile değerlendirildi. Sekukinumab tedavisinin yan etkileri kaydedildi.

Bulgular: Otuz iki hastanın sekukinumab tedavisi öncesi PAŞİ ortalaması 12,38±6,49 olup tedavinin 16., 24. ve 36. haftalarında sırasıyla; 1,96, 1,85 ve 3,1'e geriledi. Tedavinin 16. haftasında hastaların %83,3'ü PAŞİ 50'ye ulaşırken %70'inde PAŞİ 75 ve %50'sinde PAŞİ 90 yanıt oranları elde edildi. Tedavinin 16., 24. ve 36. haftalarında, PAŞİ 50, 75 ve 90 yanıtları, biyolojik-naif hastalarda, biyolojik-naif olmayanlara göre daha yüksekti, ancak istatistiksel olarak anlamlı bir fark saptanamadı ($p>0,05$). Beş (%15,6) hastada yetersiz klinik yanıt, 2 (%6,2) hastada ise tedaviye bağlı yan etkiler nedeniyle toplam 7 (%21,9) hastada tedavi kesildi. Dört (%12,5) hastada görülen oral kandidiyazis sekukinumaba bağlı en sık yan etki olarak kaydedildi.

Address for Correspondence/Yazışma Adresi: Esra Ağaoğlu MD, Kars Harakani State Hospital, Clinic of Dermatology, Kars, Turkey
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ORCID: orcid.org/0000-0001-8985-6224

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Sonuç: Sekukinumab, orta-şiddetli psoriasis hastalarında etkili ve güvenli bir tedavi seçeneğidir. Sekukinumabın gerçek yaşam verisi olarak etkinliği biyolojik-naif hastalarda daha yüksek olabilir.

Anahtar Kelimeler: Sekukinumab, psoriasis, biyolojik tedavi, etkinlik, güvenilirlik

Introduction

Psoriasis is a chronic, immune-mediated inflammatory skin disease that affects approximately 2-3% of the population¹. As a T-cell-mediated inflammatory skin disease, many targeted immunological therapeutic options were recently tried in psoriasis. Interleukin-17 (IL-17) plays a substantial role in the immunopathogenesis of psoriasis. Secukinumab is an IL-17 receptor inhibitor that was applied for moderate and severe plaque psoriasis treatment in adult patients^{2,3}.

The efficacy and safety of secukinumab in patients with psoriasis were demonstrated in randomized clinical trials; however, results differ from those enrolled in daily practice. This study aimed to evaluate the efficacy and safety of secukinumab in patients with psoriasis in our tertiary hospital.

Materials and Methods

Patients with moderate to severe plaque psoriasis older than 18 years old, who received at least 16 weeks of secukinumab treatment in May 2018-March 2020 were retrospectively evaluated. No patient received any systemic conventional therapy concurrent with secukinumab. Topical treatments were allowed with secukinumab. Patients with erythrodermic, guttate, pustular, and palmoplantar psoriasis were excluded from the study. Sociodemographic features of patients, previous systemic and biologic treatments, presence of coexisting psoriatic arthritis (PsA), and nail involvement were recorded. Treatment response was assessed with the psoriasis area and severity index (PASI) score (at baseline, 16., 24., and 36. weeks). Treatment duration and side effects were recorded. The treatment efficacy was evaluated by PASI 50, 75, and 90 response rates. The study protocol was approved by Eskişehir Osmangazi University Ethics Committee (approval number: 31, date: 10.09.2019).

Statistical Analysis

Descriptive statistics are given as a number, percentage (%), mean, and standard deviation. Pearson chi-square and pearson exact chi-square were used in the cross table analysis. International Business Machines SPSS 21.0 (Armonk, NY: IBM Corp.) was used for the analysis. For statistical significance, $p < 0.05$ was accepted as the criterion.

Results

A total of 32 patients diagnosed with psoriasis were included in this study, wherein 22 (68.7%) were males and 10 (31.3%) were females. The median age of patients was 45.68 ± 14.09 years. PsA was present in 4 (12.5%) patients and 7 (21.9%) had nail involvement.

Previous treatment evaluation revealed all patients to receive methotrexate, 13 (40.6%) received narrow-band ultraviolet B, 18 (56.3%) received cyclosporine, 17 (53.1%) received acitretin, 12 (37.5%) received adalimumab, 8 (25.0%) received infliximab, 7 (21.9%) received ustekinumab, and 1 (3.1%) received certolizumab before

secukinumab at different times. Previous biological treatment was not received in 14 (43.8%) patients (Table 1).

Secukinumab response was evaluated at 16, 24, and 36 weeks of treatment. At 16 weeks of treatment, PASI 50, 75, and 90 response rates were reached in 83.3%, 70.0%, and 50.0% of patients, respectively. At 24 weeks of treatment, PASI 50, 75, and 90 responses were reached in 81.5%, 77.5%, and 51.9% of patients, respectively. At 36 weeks of treatment, PASI 50, 75, and 90 responses were reached in 76.0%, 72.0%, and 44.0% of patients, respectively. At 16, 24, and 36 weeks, PASI 50, 75, and 90 response rates were generally higher in patients naive to biologics than the non-naive; however, differences between these groups were not statistically significant (Table 2).

The mean duration of secukinumab treatment was 10.52 ± 4.49 months. Secukinumab was stopped during the treatment in 5 (15.6%) patients due to lack or loss of clinical response, and all of these patients were non-naive to biologics. At 16 weeks of treatment, 3 (60%) patients did not reach PASI 50 response rate, thus secukinumab was ceased, and 2 (40%) patients had an initially PASI 50 response (PASI >50% of initial value) rates; however, this response was lost in the following time of treatment, thus secukinumab was ceased.

Adverse events were experienced in 7 (21.9%) patients during the treatment course. The most common adverse event was oral candidiasis, which developed in 4 (12.5%) patients, whereas nasopharyngitis and

Table 1. Baseline demographic and disease characteristics of patients

Characteristic	Number (%) of patients	
Gender, n (%)	Male	22 (68.3%)
	Female	10 (31.3%)
Age (years), mean \pm SD	45.68 \pm 14.09	
Psoriatic arthritis, n (%)	4 (12.5%)	
Nail psoriasis, n (%)	7 (21.9%)	
PASI baseline, mean \pm SD	12.38 \pm 6.49	
Previous conventional systemic therapy, n (%)		
Methotrexate	32 (100.0%)	
Cyclosporine	18 (56.3%)	
Acitretin	17 (53.1%)	
Phototherapy	13 (40.6%)	
Previous biologic treatment, n (%)		
Adalimumab	12 (37.5%)	
Ustekinumab	7 (21.9%)	
Infliximab	8 (25.0%)	
Certolizumab	1 (3.1%)	
Mean duration of secukinumab (month), mean \pm SD	10.52 \pm 4.49	
SD: Standard deviation, PASI: Psoriasis area and severity index		

Table 2. Results of PASI responses of patient groups according to weeks

	Total	Naive	Non-naive	p
Total patients, n (%)	32 (100%)	14 (43.8%)	18 (56.3%)	-
Number of patients at week 16	30	13	17	-
PASI 50, n (%)	25 (83.3%)	13 (100%)	12 (70.6%)	0.09
PASI 75, n (%)	21 (70.0%)	13 (100%)	8 (47.1%)	0.006
PASI 90, n (%)	15 (50.0%)	9 (69.2%)	6 (35.3%)	0.14
Number of patients at week 24	27	10	17	-
PASI 50, n (%)	22 (81.5%)	10 (100%)	12 (70.6%)	0.16
PASI 75, n (%)	21 (77.8%)	10 (100%)	11 (64.7%)	0.09
PASI 90, n (%)	14 (51.9%)	8 (80.0%)	6 (35.3%)	0.06
Number of patients at week 36	25	8	17	-
PASI 50, n (%)	19 (76.0%)	8 (100%)	11 (64.7%)	0.15
PASI 75, n (%)	18 (72.0%)	8 (100%)	10 (58.8%)	0.09
PASI 90, n (%)	11 (44.0%)	6 (75%)	5 (29.4%)	0.08

PASI: Psoriasis area and severity index

external otitis were observed in 1 (3.1%) patient. Secukinumab was discontinued in 2 (6.2%) patients due to adverse events, wherein 1 patient was due to erectile dysfunction and another patient for weight gain problems.

Discussion

Psoriasis is a papulosquamous skin disorder that occurs with complex interactions between the immune system, hereditary, and environmental factors. The precise pathogenesis of psoriasis is not fully understood; however, it is considered a T-cell mediated inflammatory disease⁴. Recently, the key role of T helper-17 (Th-17) cells, which produce cytokines, such as IL-17A, IL-17F, IL-22, and IL-26, was documented in the disease inflammatory response. Higher cytokines were observed in the psoriatic lesion and non-affected skin of patients with psoriasis^{3,5}. Secukinumab is a recombinant human immunoglobulin G1 monoclonal antibody that specifically binds to IL-17A. The treatment of moderate to severe plaque psoriasis was approved in 2015 and PsA in 2016⁶. The randomized placebo-controlled clinical trials revealed that secukinumab has higher PASI 75, 90, and 100 response rates compared to placebo at 12 weeks⁷⁻⁹.

Looking into real-world data, several studies demonstrated a promising efficacy of secukinumab in clinical practice¹⁰⁻¹⁵. However, in our study, PASI 75 and 90 clinical response rates were lower than previous real-life studies^{10,11,13,16,17} but similar to the study of Notario et al.¹⁸ at 16 weeks. At 24 weeks of secukinumab treatment, previous studies^{19,21} reported similar PASI 75 response rates with our study, whereas lower PASI 90 responses compared to other studies^{19,20}. A study conducted by Chiricozzi et al.²¹ reported similar PASI 75 and 90 response rates with our study at 24 weeks. In addition, the rate of their patients naive to biologics was similar to our results. Recently, Galuzzo et al.¹¹ retrospectively evaluated the efficacy of secukinumab in a real-world setting and reported higher PASI 75 and 90 response rates at 24 weeks compared to our study. The number of patients naive to biologics in their study was higher than that of our study.

Several studies revealed that previous biologic treatments affect secukinumab response and patients naive to biologics reached higher PASI response rates^{10,11,18}. A retrospective study in which 51.4% of patients previously received biological treatment revealed that patients naive to biologics achieved PASI 75 faster than non-naive at 4 weeks¹⁹. Similarly, Ger et al.²² suggested that several prior biologic failures were significantly associated with a decrease response rate of secukinumab treatment.

In our study, PASI 75 and 90 response rates were lower compared to other studies^{19,22} at 36 weeks due to the lower rate of patients naive to biologics. However, no statistically significant difference was found between patients with naive and non-naive to biologics in our study. Variation of PASI responses in clinical practice comparing randomized controlled trials is explained by differences in baseline characteristics of the study population¹⁸. A retrospective study reported that patients aged 55 years and older were less responsive to secukinumab treatment, wherein 50.0% of patients reached PASI 75 at 12 weeks²³. However, at 16 weeks of the treatment period, 62.5% (5/8) of our patients aged 55 years and older achieved PASI 75 and 90 response rates. Megna et al.²⁴ evaluated the efficacy of secukinumab in patients with psoriasis aged ≥ 65 years. In this study, the mean PASI score was 11.4 at baseline and reduced to 2.1 at 24 weeks. Our results confirmed the high effectiveness of secukinumab in patients aged ≥ 65 years, with a mean PASI score at baseline of 12.7 and reduced to 1.08 at 24 weeks. Rompoti et al.¹² reported that patients with accompanying PsA showed lower clinical responses to secukinumab. Similarly, Chiricozzi et al.²¹ suggested that the higher rate of patients with PsA decreases the clinical response in terms of absolute PASI scores. In our study, fewer patients had PsA compared to reported studies^{12,21}, wherein 75% (3/4) of patients reached PASI 90 responses at the 16, 24, and 36 weeks of secukinumab treatment.

Secukinumab was stopped in 5 (15.6%) patients due to a lack of clinical response in our study. In recent studies^{10,21} with 52-week treatment duration, the rate of patients naive to biologics was higher, whereas lower discontinuation rates were reported than our patients. Moreover, Notario et al.¹⁸ reported that 26.5% of patients discontinued

secukinumab due to lack of efficacy at 52 weeks, which was higher than our study. In this study, previous biological treatment was not received in 28% of patients. These results confirm that prior biologic treatments affect the continuation rates of secukinumab.

The most frequently reported adverse events of secukinumab are pharyngitis, diarrhea, and upper respiratory infections³. Blockage of the mediators of adaptive and innate immune systems induced by biologic therapies predispose to opportunistic infections. In addition, IL-17A is known to have a substantial role in immune defense against mucocutaneous infections, such as *Candida albicans*²⁵. Georgakopoulos et al.²³ evaluated the safety of secukinumab and found that *Candida* infections were observed in 9 (4.2%) of 47 patients. In a study conducted by Özçelik et al.¹³, oral candidiasis was detected in only 1 (3.8%) patient who received secukinumab. In our study, oral candidiasis developed in 4 (12.5%) patients, which were higher than that of the previous studies^{13,23,16}; however, all patients responded to oral and topical antifungal therapies without secukinumab treatment discontinuation.

In our study, secukinumab was discontinued in 2 (6.2%) patients due to adverse events. Significant weight gain was experienced in 1 (3.1%) patient, who refused to continue the treatment. Several studies assessed the body weight changes in patients with psoriasis treated with anti-tumor necrosis factor (TNF) agents, and significant weight gain was observed with adalimumab and infliximab treatments²⁶⁻²⁸. Takamura et al.²⁹ retrospectively reviewed the impact of infliximab, ustekinumab, and secukinumab treatments on body weight, and significant weight gain was reported only with infliximab after 7 months of treatment; however, no gain was reported in patients who received ustekinumab and secukinumab. Moreover, a recent study conducted by Topaloğlu et al.¹⁵ revealed that weight gain was more common in patients treated with ustekinumab and secukinumab than anti-TNF agents.

Erectile dysfunction developed in 1 (3.1%) of our patients after the 10th secukinumab injection. Dastoli et al.³⁰ reported the first case of the secukinumab-induced erectile dysfunction, which developed 60 days after treatment initiation and disappeared with substituting secukinumab with ixekizumab. To our best knowledge, our patient is the second case of secukinumab-induced erectile dysfunction, thus treatment was discontinued.

Study Limitations

This is a retrospective study with a small number of patients who had completed the 16, 24, and 36 weeks of secukinumab treatment.

Conclusion

Secukinumab is considered an effective and safe biologic treatment option in patients with moderate to severe psoriasis; however, wider scale studies are required to assess its safety and efficacy in real clinical practice.

Ethics

Ethics Committee Approval: The treatment efficacy was evaluated by PASI 50, 75, and 90 response rates. The study protocol was approved by Eskişehir Osmangazi University Ethics Committee (approval number: 31, date: 10.09.2019).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: E.A., H.K.E., M.B., Concept: E.A., H.K.E., E.Ac., Design: E.A., H.K.E., E.Ac., Data Collection or Processing: E.A., H.K.E., E.Ac., M.B., Analysis or Interpretation: E.A., H.K.E., E.Ac., Z.N.S., M.B., Literature Search: E.A., H.K.E., Writing: E.A., H.K.E., E.Ac.,

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