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SECUKINUMAB IN PSORIASIS: RESULTS FROM A SINGLE-CENTER DATABASE

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ABSTRACT

Introduction: Due to the blanket immune damp down of conventional psoriasis therapies, secukinumab; a targeted IL-17 receptor inhibitor was introduced to manage moderate to severe psoriasis. This study aimed to ascertain the efficacy and safety of secukinumab either alone or in combination with topical agents, for managing psoriasis. **Methods:** A retrospective observational study was conducted at Zhongnan Hospital of Wuhan University from October 2021 to January 2023. Secukinumab therapy was analyzed in 91 moderate to severe psoriasis patients. Data was analyzes in SPSS using independent sample t-test and Parsons's Chi-square of Fischer's exact test. **Results:** A total of 91 psoriasis patients were analyzed; 69 (75.8%) males, and a mean (±SD) age of 45.8±15.7 years. Mean (±SD) baseline PASI score was 13.12±6.6. At 48 week, response to treatment as measured by PASI 50, 75, and 90 response rates were 28.6%, 7.1% and 3.6% for secukinumab monotherapy and 44.4%, 6.7% and 6.3% for secukinumab & topical combination therapy respectively. Only PASI 50 was statistically significant between the two groups. This finding suggest that combination of secukinumab & topical therapy was more effective than monotherapy. At 48 weeks, the PASI 50, 75, and 90 response rates were 13.1%, 4.7%, and 2.4% in biologics naïve patients versus 14.3%, 0%, and 0% in non-biologics naïve ones respectively, suggesting better response in biologics naïve patients. **Conclusion:** Combination of secukinumab & topical agent was safe and more effective than secukinumab monotherapy. Biologics naïve patients respond better to secukinumab than those pre-exposed to biologics.

KEYWORDS: Secukinumab, psoriasis, biologic treatment, efficacy, safety.

INTRODUCTION

Psoriasis is a chronic, immune-mediated inflammatory skin disease that is difficult to treat and affects about 2-3% of the population.[1] Due to the blanket immune damp down of the conventional topical and systemic therapies, secukinumab; a targeted IL-17 receptor inhibitor was introduced for treating moderate to severe psoriasis. Though the efficacy and safety of secukinumab in managing psoriasis was demonstrated in randomized clinical trials, trial results still differ from those of daily clinical practice. Because psoriasis is a chronic inflammatory disease.[2,4] affected patients experience several comorbidities (i.e., respiratory.[5,6] cardiovascular.[5,7] or gastrointestinal ones.[8,9] that all contribute to therapy failures.[10-12] It is therefore vital that well throughout therapeutic strategies are employed to limit its progression and detrimental effects on the quality of life.

Secukinumab is the first monoclonal antibody approved for treating psoriasis. It targets interleukin-17A, and has shown rapid and long-lasting efficacy in the management of moderate-to-severe psoriasis. However, difficult-to-treat cases in which even dose-escalation or multi-biologics have failed to provide a clinical response still exist.[13] In such a case, combining secukinumab with a conventional systemic or topical agent may be a rational approach. Since different patients have different biological fingerprints.[14,16] and there is generally no validated biomarkers or prediction algorithms to monitor prognosis, dermatologists rely on clinical experience and the few existing epidemiological data to choose their treatments.[17,18]

Given the scarcity of data on combination therapies in psoriatic patients.[19,20] we sought to retrospectively analyze the data of patients treated with secukinumab, either as a monotherapy or in combination with topical agents and other systemic agents at our hospital. We aimed at ascertaining the efficacy and safety of secukinumab either alone or in combination with topical agents, in the patients managed for psoriasis.

MATERIALS AND METHODS

This study was conducted at the Dermatology clinic of Zhongnan Hospital of Wuhan University, China. 91 patients with moderate to severe psoriasis who underwent secukinumab therapy from October 2021 to

January 2023 were recruited. Permission to conduct the study was obtained from the Zhongnan Hospital of Wuhan University Research Ethics committee, and patient consent was waived by the committee since the data were retrospectively obtained. Patients included in the study were based on the following criteria: Aged 18 years and above, had undergone 24 to 48 weeks of Secukinumab therapy, and did not have tuberculosis or hepatitis B virus infection. Those who didn't meet these criteria were excluded. No patient received any systemic conventional therapy concurrent with secukinumab, but some received topical therapy concurrent with secukinumab. Information on patient sociodemographic features, topical therapy, previous systemic and biologic treatments, presence of coexisting comorbidities, body distribution of psoriasis, dosage of secukinumab and adverse effects were retrieved from the electronic medical database. Secukinumab was administered subcutaneously at a dosage of 300mg at weeks 0, 1, 2, 3, and 4, then followed by monthly maintenance dose of 30mg from week 8 to week 48. Treatment response was assessed using psoriasis area and severity index (PASI) score (at baseline, and at the end of treatment, 48 weeks), and efficacy of treatment was evaluated using PASI 50, 75, and 90 response rates.

Statistical Analysis

Collected data were entered into Microsoft excel and analyzed using Statistical Package for Social Science, SPSS (version 25.0). Categorical variables were grouped using counts and percentages, while continuous variables were summarized in terms of mean and standard deviation (SD). Independent sample t test was used to evaluate differences between lone secukinumab therapy versus secukinumab and topical agent combination therapy, while Pearson chi-square test was used for categorical variables. For statistical significance, $p<0.05$ was considered significant.

RESULTS

Overall patient characteristics

A total of 91 patients diagnosed with psoriasis were included in this study; 69 (75.8%) and 22 (24.2%) females, with a mean (±SD) age of 45.8±15.7 years. The patients had a mean (±SD) baseline PASI score of 13.12±6.6, and psoriasis body distribution as summarized in **Figure 1.** Benvitimod cream 61.9% was the most used topical agent concurrent with secukinumab, while Adalimumab; 60.6%, and methotrexate; 57.1% were the most previously used biologic and non-biologic systemic therapies respectively. 32.9% of the patients did not previously receive any systemic treatment, with 92.3% having not received any biologics before, (biologics naïve). Adverse events were noted in 25 (27.5%) of the patients. Detailed patient information is presented in **Table 1.**

Characteristics of patients who received secukinumab or secukinumab & a topical agent

Among the patients recruited, 28 received secukinumab monotherapy, while 63 were treated with combination of secukinumab and a topical agent. Mean age difference between the two groups of patients, family history of psoriasis, presence of comorbidities, and body mass index (BMI) were not statistically significant (all $p > 0.05$), while gender difference, and smoking were significant (all $p < 0.05$). **Table 2.**

Response to secukinumab therapy

Efficacy of secukinumab therapy was evaluated at the end of treatment (48 weeks). Treatment efficacy was compared in patients who received secukinumab monotherapy versus those who received concurrent secukinumab and topical therapy. At the 48th week, treatment response measured by PASI 50, 75, and 90 response rates were 28.6%, 7.1% and 3.6% for secukinumab monotherapy and 44.4%, 6.7% and 6.3% for secukinumab & topical combination therapy respectively. PASI 50 was statistically significant between the two groups, while PASI 75 and 90 were not significant, **Table 3.** After 48 weeks of treatment, 17 (60.7%) of the secukinumab monotherapy patients did not reach PASI 50 response rate, while 28 (44.4%) of the secukinumab & topical combination therapy did not reach PASI 50 response rate. Secukinumab monotherapy was discontinued in 1 patient after 1 week of therapy due to adverse events.

Secukinumab efficacy was further evaluated in patients who were biologics naïve versus those who had previously used biologics therapy. At 48 weeks, the PASI 50, 75, and 90 response rates were 13.1%, 4.7%, and 2.4% in naïve patients and 14.3%, 0%, and 0% in patients who had used biologics therapy before respectively, suggesting that those who were biologics naïve responded better to secukinumab therapy. **Table 4.**

DISCUSSION

This study evaluated the use of secukinumab for the management of psoriasis at our hospital. Secukinumab is a new systemic immunoglobulin that was approved by the US FDA in 2015 for the management of moderate to severe plaque psoriasis.[21] It is an anti-IL-17A recombinant human immunoglobulin G monoclonal antibody that specifically targets IL-17A. Its use was approved in response to recent studies that have demonstrated that higher levels of IL17A were present in psoriatic lesion compared to unaffected skin of patients with psoriasis.[22,23] Further randomized placebo-controlled clinical trials indicated that using secukinumab to treat psoriasis resulted into higher number of patients with PASI 75, 90, and 100 response rates compared to placebo at 12 weeks,[24,26] and this has since been replicated several times in various clinical studies.[27-29]

In our study, we evaluated the efficacy of secukinumab monotherapy compared to secukinumab & topical combination therapy in the management of moderate to severe psoriasis, and found that secukinumab & topical combination therapy had a better outcome than

secukinumab monotherapy after 48 weeks of treatment. (PASI 50; 8 (28.6) vs 28 (44.4) respectively; $p = 0.019$). A comprehensive literature review by Bagel et al.[30] summarized various studies that demonstrated that combination use of topical agents with conventional systemic drugs or biologics including secukinumab was more efficacious in the management of moderate to severe psoriasis. Indeed Damiani et al.[31] demonstrated that the loss of efficacy of secukinumab can be prevented by using combination therapy, enabling secukinumab to remain effective after a potential secondary failure. Although combination of therapy may increase the potential for adverse events, in our study we did not observe that.

Results from different studies suggest that previous use of biologic treatment affects the efficacy of secukinumab (20,28), and that patients who are biologics naïve have better PASI response rates. For instance, Galluzo et al.[32] conducted a multicenter study where 51.4% of the patients had previously used biologics, and reported that biologics naïve patients reached PASI 75 much faster at 4 weeks than those with history of biologics use. In our study, 84 (92.3%) of the patients were biologics naïve, and our results showed much improved PASI 50, 75 and 90 response rates in them than in those with previous use of biologics. This is also consistent with the results by Ger et al.[33] who showed that prior biologics use were associated with decrease response rate of secukinumab treatment.

Adverse events were reported in 27.5% of the patients studied. These included pharyngitis, diarrhea, and upper respiratory infections, and oral candida infection. Secukinumab acts by targeting IL-17A which is a key mediator of adaptive and innate immune systems, resulting into the rise in opportunistic infections such as candida[34] Similar adverse effects have been observed by Özçelik et al.[29] and Silfvast-Kaiser et al.[22] One patient who was on secukinumab monotherapy had his treatment discontinued due to adverse effects. While secukinumab had been associated with weight gain in previous studies.[35,36] we did not notice any significant weight gains in our study.

This study had a few noticeable limitations: First, the sample size was small and this could have affected the statistical power of the study. Second, the data were all retrospectively collected, bringing in biases associated with retrospective studies. Third, this was a single center study, and so the results may not be generalized for other populations.

Table 1: Overall patient characteristics.

Characteristics	**Total patients on Secukinumab (n = 91)**
Age, years, mean (SD)	45.8±15.7
Gender, n (%)	
Male	69 (75.8)
Female	22 (24.2)
BMI, n, (%)	
<18.5	2 (2.2)
18.5 – 24.9	72 (79.1)
25 – 29.9	17 (18.7)
>30	0 (0)
Baseline PASI score, mean, SD	9.12±6.6
Smoking, yes, n (%)	4 (4.4)
Family history, yes, n (%)	12 (13.2)
Comorbidity, yes, n (%)	6 (6.6)
Concurrent topical therapy, n (%)	
Benvitimod cream	39 (61.9)
Halometasone cream	13 (20.6)
Calcipotriol cream	11 (17.5)
Previous biologics therapy, n (%)	
Adalimumab	4 (57.1)
Ustekinumab	1 (14.3)
Infliximab	2 (28.6)
Previous non-biologics systemic therapy, n (%)	
Phototherapy	7 (25.0)
Methotrexate	16 (57.1)
Cyclosporine	4 (14.3)
Acitretin	1 (3.6)
Previous systemic therapy naïve, n (%)	30 (32.9)
Adverse events, n (%)	25 (27.5)

BMI: Body mass index. SD: Standard deviation. PASI: Psoriasis area and severity index

Table 2: Characteristics of secukinumab monotherapy and secukinumab & topical combination therapy patients.

Characteristics	Secukinumab alone (N = 28)	Secukinumab + topical (N = 63)	p-value
Age, years, mean (SD)	45.7 (15.6)	45.9 (15.8)	0.62
Gender, male (%)	17 (61)	52 (82.5)	< 0.001*
BMI, n, (%)			0.58
<18.5	1 (3.6)	1 (1.6)	
18.5 – 24.9	22 (78.6)	50 (79.3)	
25 – 29.9	5 (17.8)	12 (19.1)	
>30	0 (0)	0 (0)	
BSA score, median (IQR)	15 (11, 18)	15 (12, 18)	0.010*
IGA score, mean (SD)	3.18 (0.75)	3.15 (0.77)	0.126
Smoking, yes, n (%)	1 (3.6)	3 (4.8)	<0.01*
Family history, yes, n (%)	0 (0)	1 (1.6)	0.54
Comorbidity, yes, n (%)	0 (0)	1 (1.6)	0.63

BMI: Body mass index. SD: Standard deviation. BSA: Body surface area. IGA: Investigator's Global Assessment. IQR: Interquartile range. *Statistical significance

Table 3: Treatment efficacy.

Characteristics	Secukinumab alone (N = 28)	Secukinumab + topical (N = 63)	p-value
Number of patients at 48 weeks			
PASI 50, n (%)	8 (28.6)	28 (44.4)	0.019*
PASI 75, n (%)	2 (7.1)	3 (6.7)	0.436
PASI 90, n (%)	1 (3.6)	4 (6.3)	0.672

PASI: Psoriasis area and severity index. *statistically significant

Table 4: Biologics naïve patients, vs patients with history of biologics use.

Characteristics	Biologics Naïve (N = 84)	Previous history of biologics (N = 7)
Number of patients at 48 weeks		
PASI 50, n (%)	11 (13.1)	1 (14.3)
PASI 75, n (%)	4 (4.7)	0 (0)
PASI 90, n (%)	2 (2.4)	0 (0)

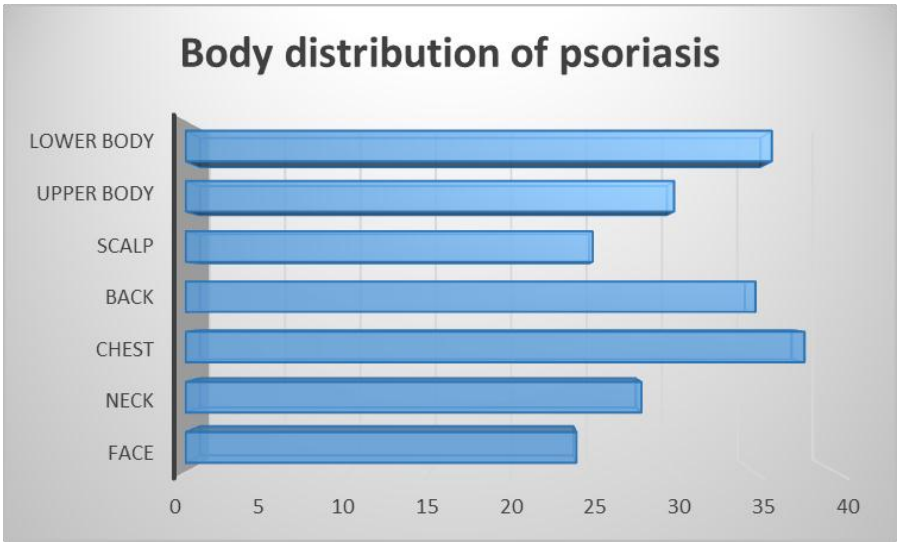

Figure 1: Body distribution of psoriasis.

CONCLUSION

In summary, this study showed that secukinumab is a safe and effective biologic treatment for patients with moderate to severe psoriasis in our setting. Its efficacy is further improved in combination with a topical agent, without necessarily increasing toxicity. Lastly, biologics treatment naïve patients generally responded better to secukinumab than those pre-exposed to biologics. To validate the results of this study, we recommend a larger scale well designed, probably multicenter prospective study.

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NA.

Author contribution
SAEV: Conceived the study, conducted data collection, data analysis and wrote the draft manuscript.

XJ: Reviewed the manuscript and supervised the study.

Conflict of interest
The authors declare no conflict of interest.

Ethical approval
Permission to conduct the study was obtained from the Zhongnan Hospital of Wuhan University Research Ethics Committee.

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