REAL-WORLD CLINICAL OUTCOMES OF *SECUKINUMAB*

IN THAI PATIENTS WITH PSORIASIS: SUBGROUP ANALYSES BY ADHERENCE RATE AND COMPLETENESS OF LOADING DOSE

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INTRODUCTION

- Little was known about real-world outcomes of secukinumab in Thai moderate-to-severe psoriasis (PsO) patients.
- The treatment outcomes in patients treated with various treatment patterns in the real world may differ from those observed in clinical trials.
- This study aimed to assess real-world clinical outcomes of secukinumab in Thai PsO patients, with subgroup analyses by adherence rate and completeness of loading dose.

METHODS

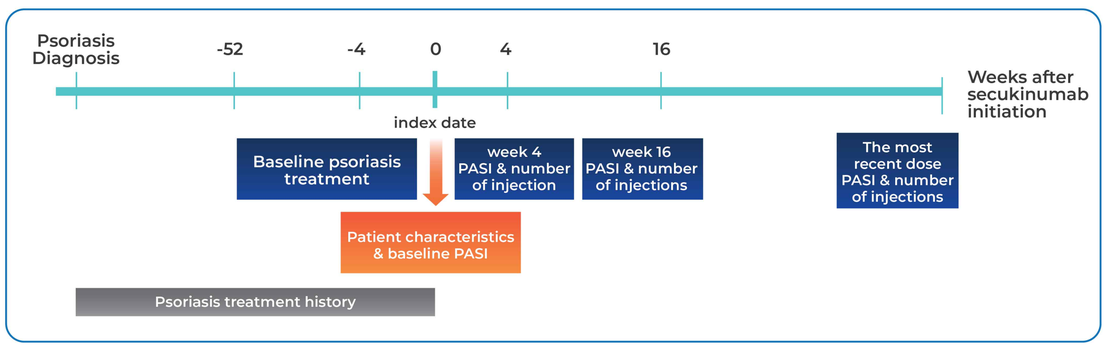
Study design

This was a 16-week non-interventional, multi-center, retrospective medical record review study conducted in 7 dermatology centers in Thailand. Adult patients with moderate-to-severe plaque PsO who initiated secukinumab treatment at all dosages from September 2017 to April 2021 were included.

Improvement in the Psoriasis Area and Severity Index (PASI) scores from baseline to weeks 4 and 16 after secukinumab initiation was assessed (Figure 1).

The adherence rate was calculated based on recommended total number of injections. Subgroup comparisons were performed with Chi-square or Fisher's exact test, and the significance level was set at 0.05.

Figure 1. Study design



Study Objective

To assess clinical outcomes and safety of secukinumab in real-world setting in Thai population at week 4 and week 16. Clinical outcomes were evaluated in terms of:

- Proportion of patients achieving 75%, 90%, and 100% improvement in PASI
- Subgroup analyses for patients who received secukinumab with different adherence rate* (100%, 75-99%, 50-74%, and <50% adherence)
- Subgroup analyses for patients who received secukinumab with complete or incomplete loading dose

*Adherence rate was denoted as the completeness of dosing by measuring the total number of injections at each time point regarding the standard dose of secukinumab (300 mg of secukinumab = 2 injections).

RESULTS

- A total of 163 patients were included in the analyses.
- There were 94 (57.7%) and 62 (38.0%) patients who had PASI scores at weeks 4 and 16, respectively.
- Patient demographics and baseline clinical characteristics were summarized in Table 1.
- The median PASI score improved from baseline by 60% at week 4 and 100% at week 16.
- There were 11.7%, 21.5%, 27.6%, and 39.3% of patients with 100%, 75-99%, 50-74%, and <50% adherence, respectively.
- The percentage of patients who achieved clear/almost clear skin was higher in the group with 100% adherence rate (Figure 2).
- PASI75 and PASI90 achievements at week 4 were significantly higher in a complete loading dose group (P=0.004 and P=0.006). At week 16, all PASI groups were significantly greater in patients with complete loading dose (Figure 3).
- Secukinumab was well tolerated, with 8.0% of patients reported adverse events, most of which were of mild severity, as shown in Table 2.

Table 1. Demographics and Baseline Characteristics

Characteristics	n (%) unless otherwise stated
Sex	
Male	80 (49.1)
Female	83 (50.9)
Age (year), mean ± SD (n=163)	44.0 ± 14.0
Weight (kg), mean ± SD (n=130)	73.2 ± 18.9
Height (cm), mean ± SD (n=99)	164.3 ± 8.9
BMI (kg/m^2), mean ± SD (n=98)	26.7 ± 5.6
Heath insurance scheme	
Universal Coverage Scheme	21 (13.0%)
Social Security Scheme	30 (18.5%)
Civil Servant Medical Benefits Scheme	33 (20.4%)
Private Insurance or Self-Pay	78 (48.2%)
Comorbidity	
None	60 (36.8%)
Hypertension	46 (28.2%)
Dyslipidemia	40 (24.5%)
Hepatic desease	24 (14.7%)
Diabetes Mellitus	21 (12.9%)
Psoriatic arthritis	20 (12.3%)
Latent tuberculosis	7 (4.3%)
Chronic kidney disease	6 (3.7%)
Hepatits B virus infection	5 (3.1%)
Hepatitis C virus infection	2 (1.2%)

Figure 2. Proportion of patients achieving PASI75, PASI90, and PASI100 at week 4 and week 16 after secukinumab initiation categorized by adherence rate

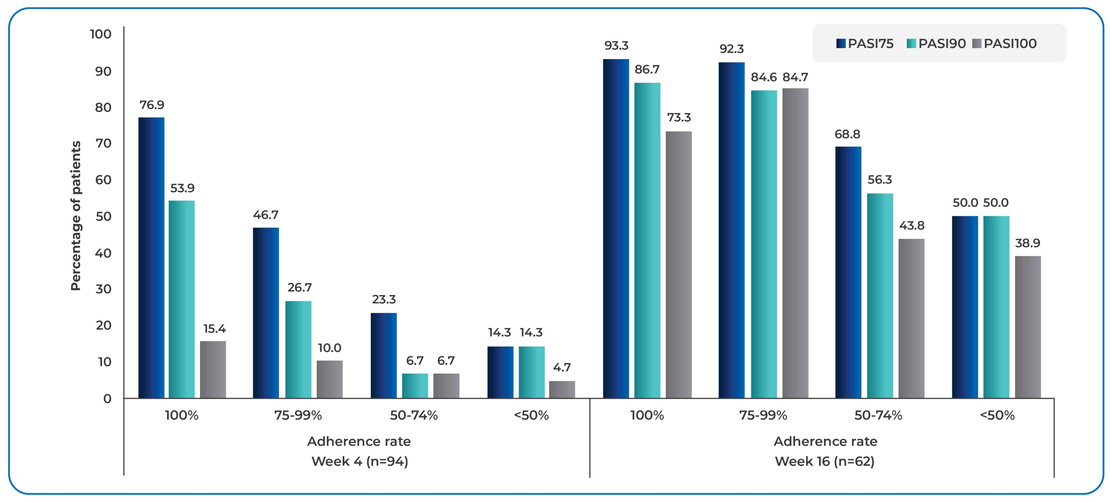


Figure 3. Proportion of patients achieving PASI75, PASI90, and PASI100 at week 4 and week 16 after secukinumab initiation categorized by completeness of loading dose

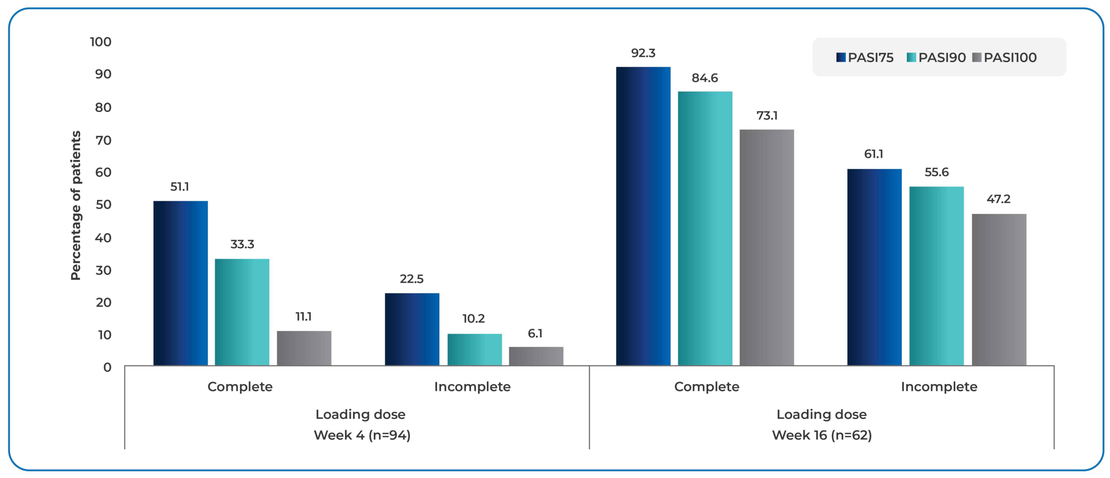


Table 2. Summary of specific adverse events (N=163)

Adverse events	n(%)	Treatment discontinuation n (%)
Eczema	2 (1.2%)	2 (1.2%)
Injection site reaction	1 (0.6%)	0 (0.0%)
Pancytopenia	1 (0.6%)	1 (0.6%)
Pruritus	1 (0.6%)	0 (0.0%)
Seborrheic dermatitis	1 (0.6%)	0 (0.0%)
Dermatophyte infection	1 (0.6%)	1 (0.6%)
Upper respiratory tract infection	1 (0.6%)	0 (0.0%)
Worsening PASI score	5 (3.1%)	-†

†No specified detail.

DISCUSSION

- In real practice, patients received secukinumab with various treatment patterns (66.7% with incomplete loading and 67.0% with <75% adherence rate), which differed from clinical trials. This finding could express the availability and accessibility of biologics in Thailand which possibly lead to compromised treatment outcomes.
- Despite suboptimal adherence rate and incomplete loading in real-world setting, a proportion of patients achieving PASI75, PASI90, and PASI100 at weeks 4 and 16 was proven evidence of secukinumab effectiveness. These achievements were comparable to the results of a meta-analysis of 7 phase 3 clinical trials and a meta-analysis of 43 real-world studies (Augustin et al., 2020; Ryoo et al., 2016).
- Our findings reaffirm the association between initial weekly loading dose and treatment effectiveness. Gisondi et al. reported significantly greater PASI75 and PASI90 response rates at week 12 in psoriatic patients who received the labelled loading dose versus those who did not. The absence of loading dose was also associated with a higher proportion of primary inefficiency.
- Secukinumab showed good tolerability in both short-term and long-term clinical trials and real-world studies (Armstrong et al., 2016; Augustin et al., 2020; Galluzzo et al., 2018; Langley et al., 2014).

CONCLUSION

Secukinumab demonstrated good real-world clinical outcomes in Thai moderate-to-severe plaque PsO patients. Higher PASI achievement was revealed among patients who received complete loading dose and those with high adherence rate.

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