



ORIGINAL ARTICLE

Real-world experience of secukinumab in moderate to severe psoriasis patients in Thailand: Characteristics, effectiveness, and safety

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Abstract

Secukinumab demonstrated high efficacy and favorable safety profile in patients with moderate-to-severe plaque psoriasis (PsO) in clinical trials. However, understanding of patient characteristics and clinical outcomes in real world in Thailand is still limited. To describe patient characteristics, effectiveness and safety of secukinumab in Thai PsO patients. This retrospective study analyzed data from medical records of adult PsO patients who initiated secukinumab at 7 dermatology centers from September 2017 to April 2021. Study outcomes included patient characteristics and changes in Psoriasis Area and Severity Index (PASI) score from baseline at weeks 4 and 16 after secukinumab initiation. Adverse events were recorded. Subgroup analyses by adherence rate and completeness of loading dose were performed. Of 163 patients, the mean (SD) age was 44.0 (14.0) years. Most patients (84.7%) were previously treated with topical therapy while 62.0% and 21.5% of patients had received systemic and biologic therapy, respectively. The mean baseline PASI score was 15.4 (9.3). Overall, the mean PASI score improved by 58.0% at week 4 and 78.4% at week 16. Statistically significant differences in PASI improvement were revealed among subgroups of patients with different loading dose and adherence rate. Adverse effects were reported in 8.0% of patients. The characteristics of patients in this study were slightly different from clinical trials in terms of demographic and clinical characteristics, as well as PsO treatment. Secukinumab was effective and safe in Thai patients with PsO, especially among those with complete loading dose and a higher adherence rate.

KEYWORDS

biologics, IL-17, psoriasis, real world, secukinumab

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1 | INTRODUCTION

Psoriasis is a chronic systemic immune-mediated inflammatory disease with prominent skin manifestations. Its physical burdens substantially impact psychosocial well-being and socioeconomic status of affected individuals and their caregivers.^{1–6} The prevalence of psoriasis varies across different ethnics and geographic regions, ranging from 0.09% to 8%.^{7,8} The prevalence of psoriasis in Thailand is 0.13%, less than those in western countries but is similar to other east Asian countries.⁹

Psoriasis is a multifactorial disease dominated by the interplay between multiple genetic and environmental factors resulting in an abnormal exaggerated immune response and associated with several comorbidities. Recent insights into psoriasis immunopathogenesis reshaped the facet of therapeutic approaches to novel, highly selective biologic therapies aiming to achieve better outcomes and minimize adverse effects.^{8,10,11}

Secukinumab, a fully human IgG1 monoclonal antibody against interleukin (IL)-17A, has been approved by the US Food and Drug Administration (FDA) for adult plaque psoriasis since 2015. Secukinumab neutralizes IL-17A, a highly potent effector cytokine of IL-23/Th-17 pathway, leading to diminished psoriatic inflammatory response.^{12–15} The efficacy and tolerability of secukinumab for moderate-to-severe plaque psoriasis have been proven in multiple randomized controlled trials. Since its launch, the use of secukinumab continues to expand globally due to its favorable effectiveness and safety.

Despite the number of real-world evidences of secukinumab,¹⁶ only few studies focused on patient characteristics and clinical outcomes of secukinumab in Thai patients. As 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 describe patient characteristics, effectiveness, and safety of secukinumab in Thai real-world practice.

2 | METHODS

2.1 | Study designs and settings

This was a 16-week non-interventional, multi-center, retrospective medical record review study conducted in 7 dermatology centers in Thailand.

This study was approved by the Central Research Ethics Committee (CREC: COA-CREC092/2020) and the local Institutional Review Board (IRB) of each participating institution. This study was conducted in accordance with the Declaration of Helsinki and adhered to Good Clinical Practice guidelines. Due to retrospective nature of the study, informed consent was exempted by the IRB.

2.2 | Study population

This study included all patients aged at least 18 years who were diagnosed with moderate-to-severe plaque psoriasis with available

baseline Psoriasis Area and Severity Index (PASI) at index date (date 0 to date –7 prior to index date) and initiated secukinumab treatment for psoriasis from September 2017 to April 2021. The first documented secukinumab injection in the medical record was defined as the index date.

2.3 | Data collection

Medical records of eligible patients were reviewed to obtain data from the date of first psoriasis diagnosis to the most recent dose of secukinumab as of April 2021.

The study endpoints were patient characteristics, including baseline demographics, co-morbidities and treatment history, and the proportion of patients achieving at least 75%, 90%, and 100% improvement in PASI score from baseline (PASI 75, PASI 90, and PASI 100, respectively) at week 4 and week 16 after secukinumab initiation. 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), that is, 10 injections for week 4 and 16 injections for week 16.

2.4 | Statistical analysis

All analyses were performed using the SAS 9 platform. Categorical variables were reported as counts (*N*) and proportions (percentage), whereas continuous variables were summarized with either mean and standard deviation (SD) or median and interquartile range (IQR), depending on data distribution. If applicable, confidence intervals (CI) were derived. Subgroup analyses were performed in patients receiving secukinumab as the first biologic agent for treating plaque psoriasis and those with different adherence rate (100%, 75%–99%, 50%–74%, and <50%), using either Chi-square or Fisher's exact test. *p*-values of <0.05 were considered statistically significant.

3 | RESULTS

A total of 163 patients were enrolled and included in patient characteristic analyses. PASI score was available in 94 (57.7%) and 62 (38.0%) patients at week 4 and week 16, respectively.

Patient demographics and baseline characteristics are summarized in Table 1. Their median (IQR) duration from the first symptom of psoriasis was 11.0 (14.3) years while the duration of moderate to severe PsO diagnosis was 6.1 (10.9) years. Nearly half of patients were covered by private insurance or self-payment. Metabolic syndrome and psoriatic arthritis were the most common comorbidities.

Regarding previous therapy for psoriasis, topical steroids and methotrexate were the most commonly used topical and systemic therapy, respectively (94.9% and 87.1%). Only 21.5% of patients were biologic experienced (Table 2).

TABLE 1 Demographics and baseline clinical characteristics

Characteristics	N	n (%) unless otherwise stated
Sex		
Male		80 (49.1)
Female		83 (50.9)
Age (year), mean ± SD	163	44.0 ± 14.0
Weight (kg), mean ± SD	130	73.2 ± 18.9
Height (cm), mean ± SD	99	164.3 ± 8.9
BMI (kg/m ²), mean ± SD	98	26.7 ± 5.6
Health 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 disease		24 (14.7%)
Diabetes mellitus		21 (12.9%)
Psoriatic arthritis		20 (12.3%)
Latent tuberculosis		7 (4.3%)
Chronic kidney disease		6 (3.7%)
Hepatitis B virus infection		5 (3.1%)
Hepatitis C virus infection		2 (1.2%)
Others		67 (41.1%)

Abbreviations: BMI, body mass index; cm, centimeter; kg, kilogram; m², square meter; SD, standard deviation.

3.1 | Effectiveness of secukinumab in real-world practice

Overall, the mean PASI score improvement was reported as 58.0% at week 4 and 78.4% at week 16 (Table 3). A similar trend was reported in BSA. However, worsening PASI scores were observed in five patients during this study.

At baseline, the most common concomitant therapies with secukinumab were topical therapy (69.2%), systemic therapy (31.9%) and phototherapy (16.0%). Almost 40% of patients received more than one concomitant therapy. However, concomitant therapy use was gradually withdrawn at week 4 and week 16, respectively (Table 4).

3.1.1 | Achievement in PASI score

The proportions of patients achieving PASI 75, PASI 90, and PASI 100 significantly increased from week 4 to week 16 as shown in Figure 1.

TABLE 2 Treatment history for psoriasis

Treatment history	N	n (%) unless otherwise stated
Topical therapy		
Number of topical therapy use		
1 topical therapy		12 (7.4%)
>1 topical therapies		126 (77.3%)
None/No data		25 (15.3%)
Duration of topical therapy use (month), median (IQR)	56	73.4 (118.8)
Previously used topical therapy		
Topical corticosteroid		131 (94.9%)
Coal tar		114 (82.6%)
Vitamin D analogues		82 (59.4%)
Salicylic acid		33 (23.9%)
Mineral oil		18 (13.0%)
Calcineurin inhibitors		14 (10.1%)
Anthralin		4 (2.9%)
Olive oil		3 (2.2%)
Systemic therapy		
Number of systemic therapy use		
1 systemic therapy		39 (23.9%)
2 systemic therapies		38 (23.3%)
3 systemic therapies		24 (14.7%)
None/No data		62 (38.0%)
Duration of systemic therapy use (month), median (IQR)	55	60.0 (132.7)
Previously used systemic therapy		
Methotrexate		88 (87.1%)
Acitretin		54 (53.5%)
Cyclosporine		42 (41.6%)
Sulfasalazine		3 (3.0%)
Biologic therapy		
Number of systemic therapy use		
1 biologic therapy		29 (17.8%)
2 biologic therapies		5 (3.1%)
3 biologic therapies		1 (0.7%)
None/No data		128 (78.5%)
Duration of biologic therapy use (month), median (IQR)	25	9.3 (28.2)
Previously used biologic therapy		
Etanercept		10 (28.6%)
Ixekizumab		10 (28.6%)
Infliximab		8 (22.9%)
Secukinumab		6 (17.1%)
Ustekinumab		6 (17.1%)
Brodalumab		1 (2.9%)
Golimumab		1 (2.9%)

Abbreviation: IQR, interquartile range.

	Week 0 (N = 163)	Week 4 (N = 94)	Week 16 (N = 62)
PASI score			
N	163	94	62
Mean (SD)	15.4 (9.3)	6.3 (5.8)	1.8 (4.0)
% Change, mean (SD)		58.0 (35.2)	78.4 (44.9)
BSA involvement, %			
N	82	60	58
Mean (SD)	37.2 (28.6)	18.0 (20.1)	3.4 (9.6)
% Change, mean (SD)		34.3 (49.4) ^a	76.3 (51.0) ^b
DLQI score			
N	30	3	4
Mean (SD)	12.4 (7.2)	6.0 (4.6)	4.5 (7.1)
% Change, mean (SD)		66.7 (23.7) ^a	25.0 (75.0) ^b

TABLE 3 Clinical improvement from baseline at week 4 and week 16 after secukinumab therapy initiation

Abbreviations: BSA, body surface area; DLQI, dermatology life quality index; IQR, interquartile range; PASI, Psoriasis Area and Severity Index.

^a53 and 3 Patients with BSA/DLQI score at both baseline and week 4, respectively.

^b39 and 3 Patients with BSA/DLQI score at both baseline and week 16, respectively.

TABLE 4 Concomitant therapy

Concomitant therapy	Week 0 (N = 163)	Week 4 (N = 94)	Week 16 (N = 62)
Topical therapy			
Topical corticosteroid	98 (60.1%)	53 (56.4%)	26 (42.0%)
Coal tar	53 (32.5%)	26 (27.7%)	14 (22.6%)
Vitamin D analogues	46 (28.2%)	18 (19.2%)	6 (9.7%)
Salicylic acid	13 (8.0%)	8 (8.5%)	1 (1.6%)
Mineral oil	7 (4.3%)	5 (5.3%)	2 (3.2%)
Calcineurin inhibitors	5 (3.1%)	2 (2.1%)	0 (0.0%)
Anthralin	2 (1.2%)	0 (0.0%)	0 (0.0%)
Phototherapy			
Yes	26 (16.0%)	6 (6.4%)	3 (4.9%)
Systemic therapy			
Methotrexate	27 (16.6%)	11 (11.7%)	6 (9.7%)
Acitretin	16 (9.9%)	9 (9.6%)	3 (4.8%)
Cyclosporine	14 (8.6%)	4 (4.3%)	2 (3.2%)
Sulfasalazine	3 (1.8%)	2 (2.1%)	1 (1.6%)
Leflunomide	2 (1.2%)	1 (1.1%)	0 (0.0%)
Combination therapy			
Topical therapy + Systemic therapy	39 (24.0%)	17 (18.1%)	10 (16.1%)
Topical therapy + Phototherapy	16 (9.8%)	4 (4.3%)	1 (1.6%)
Topical therapy + Phototherapy + Systemic therapy	6 (3.7%)	2 (2.1%)	0 (0.0%)

Note: Value is presented as n (%).

3.1.2 | Subgroup analyses for patients who received secukinumab as the first biologic agent

As shown in Figure 2, a numerically higher proportion of patients achieving PASI 75 and PASI 90 was observed in biologic-naïve patients at week 4 and week 16.

3.1.3 | Subgroup analyses for patients who received secukinumab with different adherence rates

According to adherence rate, 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 (Table 5).

Moreover, significant difference in PASI score improvement was observed between patients with complete and incomplete loading dose of secukinumab (Table 6). At both weeks 4 and 16, the proportions of patients achieving PASI 75, PASI 90, and PASI 100 were higher in patients with complete loading dose.

3.2 | Safety

Adverse events (AEs) possibly relevant to secukinumab therapy were reported in 13 (8.0%) patients. Seven adverse events were of mild severity, and the reported AEs led to secukinumab discontinuation in four patients (Table 7). A patient developed pancytopenia, which was

considered of moderate severity. Nevertheless, the condition spontaneously improved after discontinuing secukinumab.

4 | DISCUSSION

Our study reports patient and disease characteristics and asserts real-world effectiveness and safety of secukinumab in Thai psoriasis patients. At baseline, the patient demographics and disease characteristics were comparable to phase 3 randomized controlled trial populations (ERASURE, FIXTURE, and CLEAR) in terms of age, but of lower proportion of males, lower BMI, shorter duration of psoriasis diagnosis, and lower proportion of concomitant psoriatic arthritis. Gender ratio.^{17,18} The high proportion of patients with metabolic comorbidities was congruent with previous real-world studies in other countries.^{19,20}

The majority of patients in this study were biologic naïve and covered by private insurance or self-payment. Most of them had been treated with topical and systemic therapies for at least 6 years before receiving biologics. In addition, almost half of patients still had nail and scalp psoriasis at baseline. These treatment patterns may indicate the patients' psoriasis severity and long cycling of conventional therapies for psoriasis. This study also revealed that, in the 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 the compromised treatment outcomes.

Our patients' baseline PASI score (15.4) was comparable to those of previous real-world studies in Asia-Pacific and Middle-east regions, Japan, China, and Italy.²¹⁻²⁴ In addition to baseline PASI score, several

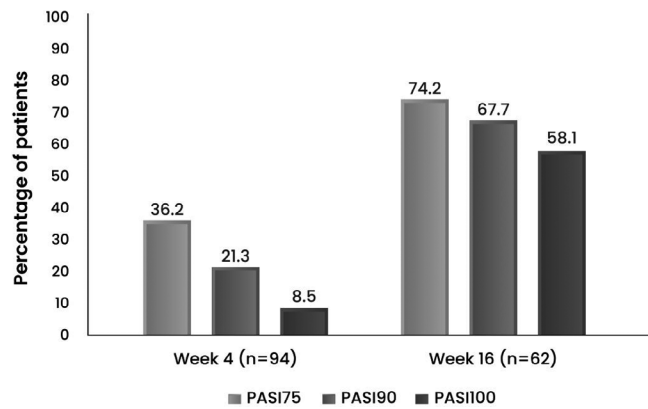


FIGURE 1 Percentage of patients achieving PASI 75, PASI 90, and PASI 100 at week 4 and week 16 after secukinumab initiation

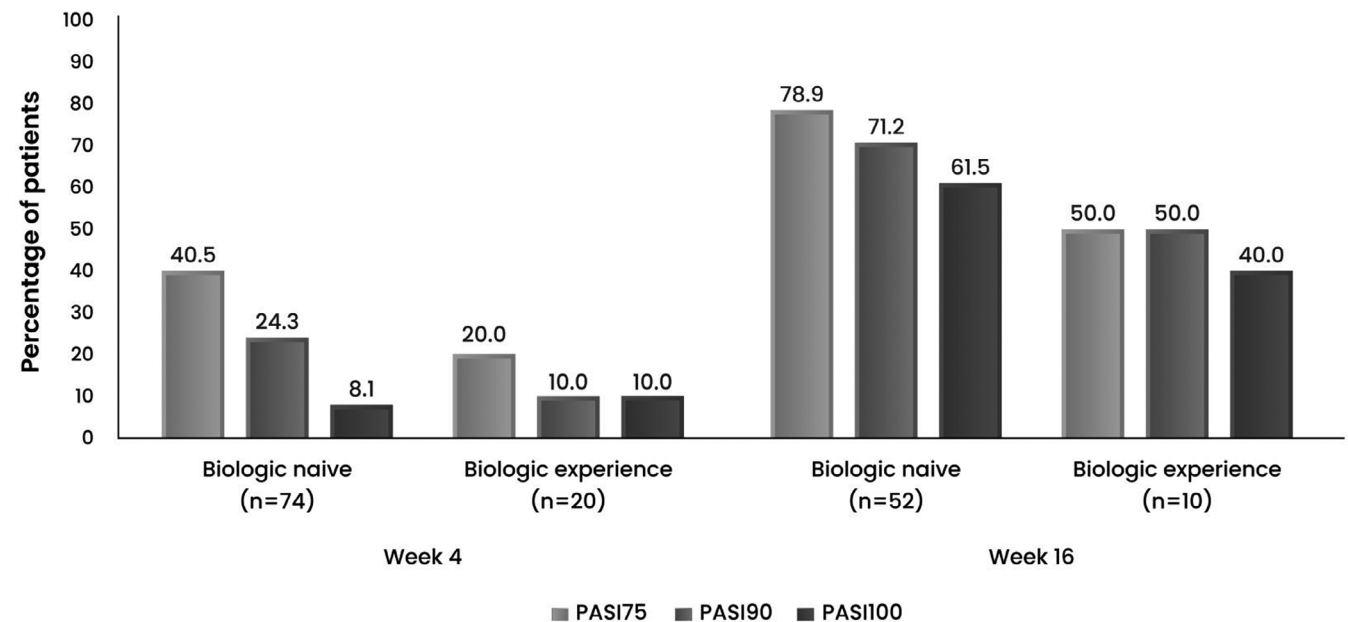


FIGURE 2 Percentage of patients achieving PASI 75, PASI 90, and PASI 100 at week 4 and week 16 after secukinumab initiation in biologic-naïve and biologic-experienced patients

TABLE 5 Proportion of patients achieving PASI 75, PASI 90, and PASI 100 at week 4 and week 16 after secukinumab initiation categorized by adherence rate

PASI improvement (%)	Adherence rate				p-value
	100%	75%–99%	50%–74%	<50%	
	n (%) (95% CI)	n (%) (95% CI)	n (%) (95% CI)	n (%) (95% CI)	
Week 4					
N	13	30	30	21	
PASI 75	10 (76.9%) (54.0–99.8)	14 (46.7%) (28.8–64.5)	7 (23.3%) (8.2–38.5)	3 (14.3%) (0.0–29.3)	0.001 ^{†*}
PASI 90	7 (53.9%) (26.8–81.0)	8 (26.7%) (10.8–42.5)	2 (6.7%) (0.0–15.6)	3 (14.3%) (0.0–29.3)	0.005 ^{†*}
PASI 100	2 (15.4%) (0.0–35.0)	3 (10.0%) (0.0–20.7)	2 (6.7%) (0.0–15.6)	1 (4.7%) (0.0–13.9)	0.726 [‡]
Week 16					
N	15	13	16	18	
PASI 75	14 (93.3%) (80.7–100.0)	12 (92.3%) (77.8–100.0)	11 (68.8%) (46.1–91.5)	9 (50.0%) (26.9–73.1)	0.014 ^{†*}
PASI 90	13 (86.7%) (69.5–100.0)	11 (84.6%) (65.0–100.0)	9 (56.3%) (31.9–80.6)	9 (50.0%) (26.9–73.1)	0.054 [‡]
PASI 100	11 (73.3%) (51.0–95.7)	11 (84.7%) (65.0–100.0)	7 (43.8%) (19.4–68.1)	7 (38.9%) (16.4–61.4)	0.026 ^{†*}

*p-value <0.05, indicating a statistically significant difference. [†]Overall p-value (2-sided) based on Chi-square test.

[‡]Overall p-value (2-sided) based on Fisher's exact test.

TABLE 6 Proportion of patients achieving PASI 75, PASI 90, and PASI 100 at week 4 and week 16 after secukinumab initiation for patients with complete and incomplete loading dose of secukinumab

PASI improvement (%)	Week 4 (N = 94)			Week 16 (N = 62)		
	Loading dose of secukinumab		p-value	Loading dose of secukinumab		p-value
	Complete (N = 45)	Incomplete (N = 49)		Complete (N = 26)	Incomplete (N = 36)	
	n (%) (95% CI)	n (%) (95% CI)		n (%) (95% CI)	n (%) (95% CI)	
PASI 75	23 (51.1%) (36.5–65.7)	11 (22.5%) (10.8–34.1)	0.004 ^{†*}	24 (92.3%) (82.1–100.0)	22 (61.1%) (45.2–77.0)	0.006 ^{†*}
PASI 90	15 (33.3%) (19.6–47.1)	5 (10.2%) (1.7–18.7)	0.006 ^{†*}	22 (84.6%) (70.8–98.5)	20 (55.6%) (39.3–71.8)	0.016 ^{†*}
PASI 100	5 (11.1%) (1.9–20.3)	3 (6.1%) (0.0–12.8)	0.473 [‡]	19 (73.1%) (56.0–90.1)	17 (47.2%) (30.9–63.5)	0.042 ^{†*}

*p-value <0.05, indicating a statistically significant difference. [†]Overall p-value (2-sided) based on Chi-square test.

[‡]Overall p-value (2-sided) based on Fisher's exact test.

factors, that is, BSA, DLQI, area of involvement, course of disease, and so forth contribute to physician decision on biologic use.^{17,18} The assessment of PASI, BSA, and DLQI will provide comprehensive information on the impact of psoriasis on the patients' life, and suggest early treatment step-up. However, these assessments are not routinely assessed in real-world clinical practice in Thailand.

Despite suboptimal adherence rate in real-world setting, an impressive proportion of patients achieving PASI 75, PASI 90, and

PASI 100 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.^{16,25} Our study reported that 5 patients (3.07%) had worsening PASI score during secukinumab treatment, with 4 of them received secukinumab with <50% adherence rate.

Regarding subgroup analyses of patients who received secukinumab as the first biologic agent, previous real-world evidences revealed

TABLE 7 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%)	- ^a

^aNo specified detail.

variations across different regions, which may be attributed to a discrepancy in biologic access.^{26,27} Our findings revealed numerically higher proportions of patients achieving PASI improvement at weeks 4 and 16 in biologic-naïve than biologic-experienced groups. Compared to our finding, a higher proportion of biologic-experienced patients was reported in REALIA and studies by Fujita et al. and Caldarola et al. while a lower proportion was observed in the study of Zhao et al.²¹⁻²⁴ A similar trend of a greater efficacy toward biologic-naïve patients was observed in real-world studies in Japan and China.^{22,23}

Moreover, significant differences in the proportion of patients with improved PASI score were demonstrated among different adherence rates. Of which, the greater percentage was observed in patients with 100% adherence rate compared to those with <75% adherence rate, and in patients who received a complete loading dose. Our findings reaffirm the association between initial weekly loading dose and treatment effectiveness. Gisondi et al.²⁸ reported significantly greater PASI 75 and PASI 90 response rates at week 12 in psoriatic patients who received the labeled loading dose versus those who did not. The absence of loading dose was also associated with a higher proportion of primary inefficiency.

Overall safety profile of secukinumab in our study was consistent with previous secukinumab trials. The use of biologic agents potentially raises the risk of infection due to their function in the inhibition of IL-17, which plays an important role in innate and adaptive immune system.²⁹ A previous real-world study reported patients receiving secukinumab experienced a slightly increased risk of infection compared to other biologics (e.g., anti-TNF, anti-IL12/23, and anti-IL17A) (16.6% vs. 11.7%) which was, nevertheless, similar to that observed in clinical studies.^{21,30} In our study, infection was reported in only 1.2% of our patients. During therapy, one patient experienced pancytopenia, which improved shortly after secukinumab discontinuation. However, no previous report of pancytopenia in secukinumab studies was available. In addition, eczema occurred in 1.2% of our patients, which was comparable to a previous study (1.6%).³¹

We acknowledge a few limitations in this study. First, the retrospective design limited the access to some information that was not generally measured in real-life practice. Second, the missing data in various variables, including the PASI scores at weeks 4 and 16, limited

the number of patients included in our pre-specified subgroup analyses.

In conclusion, most secukinumab-treated patients were biologic-naïve and in private insurance or self-payment. Baseline patient demographics and disease characteristics were similarly reported in other real-world studies. According to the limited biologics access, patients were treated with various treatment patterns, and most of them received suboptimal dose of secukinumab. However, our results support good clinical outcomes and safety of secukinumab in Thai patients, especially among those with complete loading dose and a higher adherence rate.

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CONFLICT OF INTEREST

Dr. Asawanonda received honoraria for lecturing and research grant for Novartis, Zeullig Pharma, Kyowa Kirin, Janssen, and Leo Pharma. Dr. Pattamadilok received research grant and has served as a principal investigator, and an advisory board member for Novartis, Eli Lilly, Leo Pharma, and Boehringer Ingelheim. Dr. Chularojanamontri has served as paid speaker for Novartis, Janssen, and Zeullig Pharma. Dr. Chuamanochan received honoraria for lecturing for Novartis, Leo Pharma, and Janssen. Dr. Choonhakarn has served as paid speaker for Novartis, Janssen, Menarini, Beiersdorf, Galderma, Zuellig Pharma, Takeda, MSD, GSK, and BeRich. Dr. Chakkavittumrong has served as paid speaker, and received research grant for Novartis, Zuellig Pharma, Janssen, Galderma, and IQVIA. Dr. Rajatanavin has served as paid speaker, and principal investigator for Novartis, Sanofi, Eli Lilly, and Boehringer Ingelheim. Ms. Sangob is a medical lead in Novartis.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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