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ORIGINAL RESEARCH

Long-Term Effectiveness and Drug Survival of Secukinumab in Vietnamese Patients with Psoriasis: Results from a Retrospective ENHANCE Study

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ABSTRACT

Introduction: Psoriasis (PsO), an immune-mediated inflammatory skin disorder, has substantial negative impact on patients' quality of life. Secukinumab, an approved treatment for moderate-to-severe plaque PsO, has an established long-term efficacy and safety profile. This study aims to provide real-world evidence of long-term effectiveness and retention rate of secukinumab in Vietnamese patients with PsO.
Methods: This retrospective, observational study collected medical records of adult patients with moderate-to-severe PsO receiving secukinumab treatment from Ho Chi Minh City Hospital of Dermato-Venereology. The primary objective was to evaluate secukinumab effectiveness in PsO as measured by 75% improvement in psoriasis area and severity index (PASI 75) at month 12. Secondary objectives were PASI 90/100, absolute PASI ≤ 3 and ≤ 5, Dermatology Life Quality Index (DLQI), and retention rate over 48 months.
Results: In total, 232 patients with moderate-to-severe PsO met inclusion criteria; 68.1% were male, with median age and age of onset of 39 and 27.5 years, respectively. Median time from onset of PsO to secukinumab treatment was 120 months, 95.3% were prior biologics/disease-modifying antirheumatic drugs naive and 41.4% received concomitant therapies for PsO; 82.3% had national insurance coverage. At month 12, 93.9% of patients achieved PASI 75 (primary endpoint); 80.2/56.9% achieved PASI 90/100; 91.4 and 84.8% patients achieved absolute PASI ≤ 5 and ≤ 3, respectively. The response was sustained over 48 months, with 91.9%/78.0%/52.0% of patients achieving PASI 75/90/100, 89.5% and 82.1% patients achieving absolute PASI ≤ 5 and ≤ 3, respectively. At month 12, 61.4% of patients achieved DLQI 0/1 which was sustained up to month 48 (69.2%). Secukinumab adherence rate of 84.9% at month 12 dropped to 34.2% at month 48. Patients receiving concomitant therapy and national insurance showed higher adherence rate.
Conclusion: Secukinumab demonstrated long-term effectiveness in real-world Vietnamese patients with moderate-to-severe PsO, with treatment adherence being higher in patients having concomitant therapies and national insurance.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s13555-022-00867-y.

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Keywords: Biologics; Secukinumab; Psoriasis; Real-world; Effectiveness

Key summary points

Why carry out this study?

Secukinumab has demonstrated rapid, significant and sustained long-term improvements across various manifestations of psoriasis in several clinical trials.

However, in real-world clinical practice, various factors are considered by the clinician before prescribing secukinumab and these include patients' benefit–risk profile, ongoing concomitant therapies, insurance coverage and local regulation, which may directly impact the treatment outcomes.

The real-world data on secukinumab efficacy and safety in lower-to-middle income countries such as Vietnam are scarce.

ENHANCE, a single-centre, retrospective, observational, non-interventional study, evaluated the long-term effectiveness and retention rate of secukinumab in Vietnamese patients with moderate-to-severe plaque psoriasis in real-world setting

What was learned from this study?

The findings from this study suggest that secukinumab is prescribed in Vietnamese patients with moderate-to-severe psoriasis who have pre-existing comorbidities (such as hypertension, obesity and psoriatic arthritis) and are undergoing concomitant psoriasis treatment.

The ENHANCE study results confirm the long-term effectiveness of secukinumab in Vietnamese patients with psoriasis, which is in line with the outcomes reported in clinical trials. Patients having insurance coverage and receiving concomitant therapy show higher adherence to secukinumab treatment

INTRODUCTION

Psoriasis (PsO) is an immune-mediated inflammatory disorder that presents different clinical manifestations affecting the skin or joints or both [1, 2]. Chronic plaque PsO accounts for almost 90% [1] of cases and is characterised by demarcated, erythematous plaques and scaly skin that most commonly occur on elbow, knees, scalp and lower back. This disease is considered stigmatising and can have substantial negative impact on patients' quality of life (QoL); hence, long-term management is critical to control signs and symptoms of the disease [3, 4]. Psoriasis is unequally distributed across geographical regions, and its prevalence is known in only 19% of countries worldwide, ranging from 0.1% in East Asia to 1.5% in Western Europe and is highest in high-income countries [3].

Secukinumab selectively blocks interleukin (IL)-17A, a key effector cytokine in the pathogenesis of PsO, and is approved for the treatment of PsO on the basis of results from pivotal studies [5]. Several randomised controlled trials (RCTs) have demonstrated promising efficacy and a favourable safety profile of secukinumab in the treatment of moderate-to-severe plaque PsO. However, real-world populations differ from those enrolled in RCTs. As per the analysis reported by BIOBADADERM, a Spanish registry, about 30% of real-world populations receiving

systemic therapies are ineligible for RCTs [6]. Factors such as presence of existing comorbidities, ongoing concomitant therapies and challenges with access to medicines which directly impact the treatment choice and outcomes differentiate patients in real-world clinical practice from those enrolled in RCTs [7]. Furthermore, the treatment regimens prescribed by clinicians may differ from the label or current treatment recommendations based on clinicians' judgement on the benefit–risk profile of secukinumab for individual patients in a real-world setting and the characteristics of local health systems [8]. Thus, it is essential to evaluate the real-world effectiveness and understand the impact of treatment patterns of secukinumab in everyday clinical practice.

Currently, limited data exist on the long-term effectiveness of secukinumab and drug survival in a real-world setting in Asian populations [9]. The PROSPECT study, as well as studies in high-income countries such as Japan and Taiwan have demonstrated the effectiveness and safety of secukinumab in a real-world setting. However, the data from these studies may not be applicable to a lower-middle-income country such as Vietnam [10]. As per epidemiology data, the prevalence of PsO is found to be higher in Vietnam as compared with Taiwan and Japan [10–12]. Secukinumab was approved for use in Vietnam in 2016; however, it is only partially reimbursed since 2019.

To date, real-world data on the long-term effectiveness and safety of secukinumab in lower-middle-income countries such as Vietnam are scarce. A recently published observational, non-interventional retrospective study reported that secukinumab treatment for 16 weeks was effective in Vietnamese patients with PsO irrespective of obesity, comorbidities and concomitant psoriatic arthritis (PsA) status [10]. The ENHANCE study aims to assess long-term effectiveness of secukinumab and its treatment retention in Vietnamese patients with PsO.

METHODS

Study Design

This was a retrospective observational study that used secondary data collected from the medical records of patients with PsO. Patients treated with secukinumab in Ho Chi Minh City Hospital of Dermato-Venereology (HHDV) from 1 November 2016 to 31 October 2021 (60 months; Fig. 1) were included.

This study has been reviewed and approved by the Institutional Review Board/Independent Ethics Committee of the HHDV (approval number 1460/CN-BVDL 25 November 2021) and performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Informed consent was waived due to the retrospective nature of the study.

Study Population

Adult male and female patients aged $\geq$ 18 years with a confirmed diagnosis of moderate-to-severe plaque PsO, who initiated treatment with secukinumab during the identification period, and had a follow-up visit after the index date (date of start of secukinumab treatment) at day 1 and week 16, receiving at least six doses of secukinumab 300 mg over 12 months were included. Patients with incomplete information in their medical records and those reported as pregnant at the index date were excluded.

Study Objectives

The primary objective was to evaluate the long-term effectiveness of secukinumab in patients with moderate-to-severe plaque PsO. The primary endpoint was the percentage of patients achieving a 75% reduction of psoriasis area and severity index (PASI) at month 12.

The secondary objectives were: (1) To evaluate the effectiveness of secukinumab in patients with moderate-to-severe plaque PsO with respect to: (a) percentage of patients achieving PASI 75 at months 24, 36 and 48; (b) percentage of patients achieving PASI 90/100 at months 12, 24, 36 and 48; (c) percentage of patients

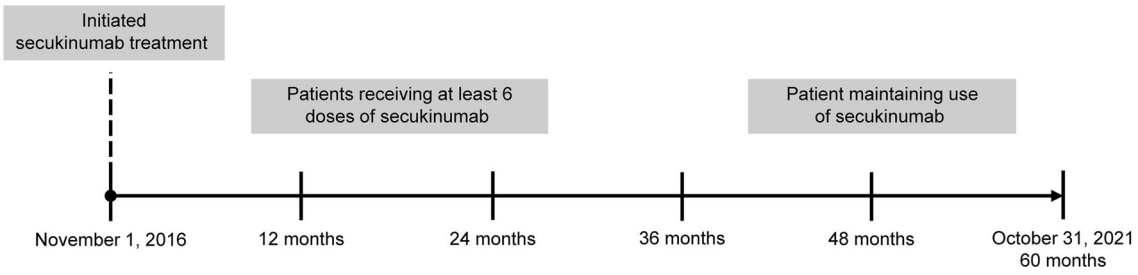

Fig. 1 Study design

Table 1 Patient demographics and baseline characteristics

Characteristics	Study population (N = 232)
Age (years), median (IQR)	39.0 (30.0; 52.3)
Male, *n* (%)	158 (68.1)
BMI (kg/m^2), median (IQR)	23.5 (21.4; 25.9)
Age of onset (years), median (IQR)	27.5 (19.0; 38.3)
Time from onset to secukinumab therapy (months), median (IQR)	120.0 (60.0; 216.0)
Comorbidity, *n* (%)	65 (28.0)
Hypertension, *n* (%)	18 (7.8)
Diabetes, *n* (%)	12 (5.2)
Obese, *n* (%)	15 (6.5)
Psoriatic arthritis, *n* (%)	30 (12.9)
Other comorbidities*, *n* (%)	7 (3.0)
History of PsO treatment	
Biologic-naive, *n* (%)	221 (95.3)
DMARD-naive, *n* (%)	221 (95.3)
Concomitant PsO treatment, *n* (%)	96 (41.4)
Topical, *n* (%)	91 (39.2)
Systemic, *n* (%)	9 (3.9)
Insurance coverage, *n* (%)	191 (82.3)
Baseline PASI score, median (IQR)	22.0 (16.2; 29.4)

BMI body mass index, *DMARD* disease-modifying antirheumatic drug, *IQR* interquartile range, *PASI* psoriasis area and severity index, *PsO* psoriasis

*Other comorbidities consisted of anxiety and depression (n = 1), cardiovascular disease (n = 2), inflammatory bower disease (n = 2), axial arthritis (n = 1) and rheumatoid arthritis (n = 1)

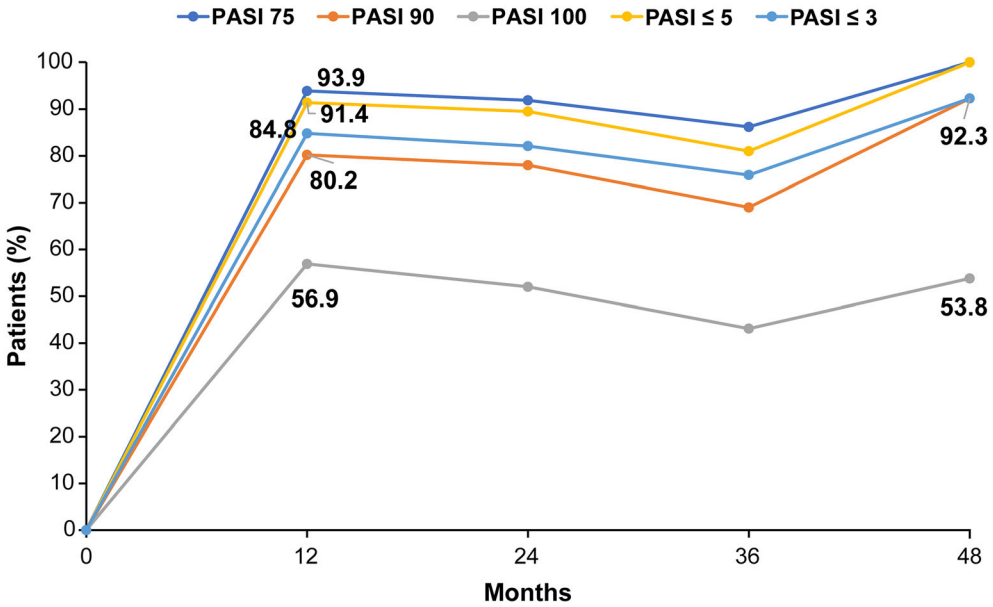

Fig. 2 Proportion of patients achieving PASI 75, PASI 90, PASI 100, PASI $\leq$ 5 and PASI $\leq$ 3. *PASI* psoriasis area and severity index

achieving absolute PASI $\leq$ 3 and $\leq$ 5 at months 12, 24, 36 and 48; (d) proportion of patients with Dermatology Life Quality Index (DLQI) score 0/1 and its change from baseline at months 12, 24, 36 and 48. (2) Long-term retention rate with respect to the proportion of patients that received secukinumab at months 12, 24, 36 and 48. (3) Factors that were independently associated with secukinumab drug survival with respect to: (a) proportion of patients achieving treatment retention (i.e. receiving treatment continuously without an interruption > 90 days) for overall population and by subgroup (age, sex, biologic status, use of concomitant therapy and insurance type); (b) proportion of patients who discontinued treatment and the reason(s) for discontinuation assessed at months 12, 24, 36 and 48.

Data Collection

For this study, the data of all patients were collected from the index date to month 60 and were retrieved from the HHDV database. Data collected included patient demographics, baseline characteristics and information regarding patient treatment utilisation (including biologics treatment duration and conventional systemic therapies prior to baseline, use of concomitant medication and discontinuation from secukinumab treatment during the study period, or patients with treatment gaps > 90 days during the study period).

Statistical Analysis

The data analysis was descriptive. No inferential analysis and statistical hypothesis testing were planned for this study. A sample size of 205 patients was planned to be enrolled to estimate the PASI75 response of 67% at month 12 using an exact test for one proportion considering 0.80 power and 0.05 alpha. Only the full analysis set (FAS) was utilised in this study, which included all patients who received one or more dose of study treatment and had at least a baseline and any post-baseline assessment on treatment.

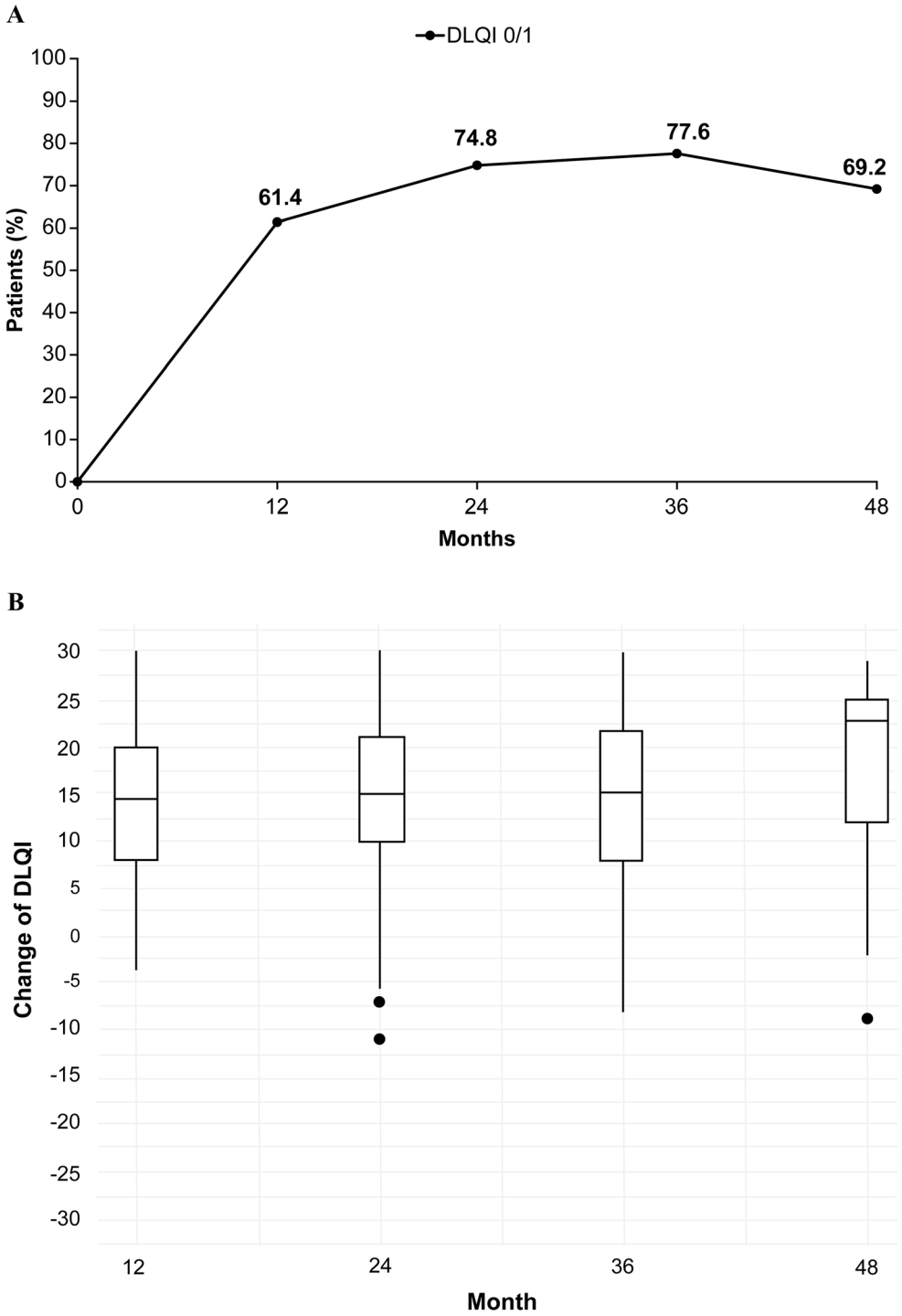

Fig. 3 **A** Rate of achieving DLQI 0/1 over 48 months of secukinumab treatment. **B** Change in DLQI over 48 months of secukinumab treatment. *DLQI* dermatology life quality index

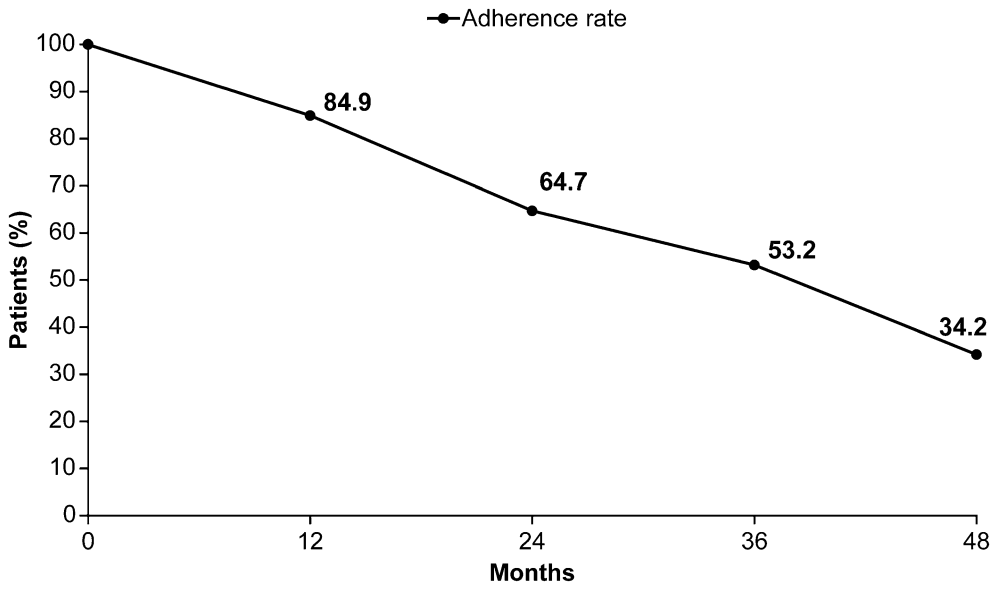

Fig. 4 Adherence rate to secukinumab treatment over 48 months

The primary endpoint along with 95% confidential interval (CI) were provided using the Clopper–Pearson exact method. Categorical data were presented as frequency and percentage. A summary of continuous data had mean, standard deviation (SD), 25th percentile, median, 75th percentile, minimum and maximum. The analysis of study treatment data was based on the FAS as there was no safety analysis planned for this study.

A subgroup analysis was performed to explore possible effect modification due to patient characteristics such as PsA, body mass index (BMI), treatment experience (naive/prior biologics treatment), comorbidities and transition period prior to biologic at baseline.

RESULTS

Patient Demographics and Baseline Characteristics

In total, 232 patients met the study's inclusion criteria and were included in the retrospective study. The majority of patients (68.1%) were male, with median age and age of onset of 39 years and 27.5 years, respectively. Since only patients with moderate-to-severe PsO were included, the median PASI was 22.0. Nearly one-third of patients (28.0%) had at least one comorbidity, the most common were hypertension (7.8%), obesity (6.5%) and PsA (12.9%). Overall, 95.3% never received prior biologics or disease-modifying anti-rheumatic drugs (DMARDs), and the median time from onset of PsO to secukinumab initiation was 120 months. More than 40% of patients received concomitant PsO therapy which included systemic and topical therapies, and > 80% were covered with a national insurance policy. Patient demographics and baseline characteristics are summarised in Table 1.

Secukinumab Effectiveness

In this study, 93.9% (95% CI 89.6–96.8%) of patients with PsO achieved PASI 75 at month 12 (primary endpoint; Fig. 2). Improvement with regard to the secondary endpoints was reflected with 80.2% (95% CI 73.9–85.5%) and 56.9% (95% CI 49.6–63.9%) of patients achieving PASI 90 and PASI 100 at month 12, respectively (Fig. 2). Absolute PASI $\leq$ 5 and PASI $\leq$ 3 was

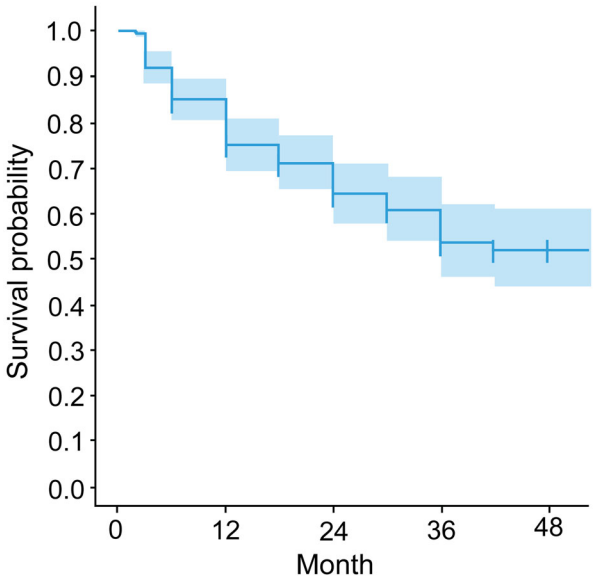

Fig. 5 Kaplan–Meier secukinumab drug survival curve

achieved by 91.4% (95% CI 86.5–94.9%), and 84.8% (95% CI 79.0–89.5%) of patients with PsO at month 12, respectively (Fig. 2).

Overall, the median duration (interquartile range) of secukinumab therapy was 24.0 (12.0, 31.5) months, and 141 (60.8%) patients showed adherence to secukinumab treatment. The response rates were sustained after 24 months of secukinumab treatment as 91.9% of the 190 evaluable patients with PsO achieved PASI 75; and 78.0% and 52.0% of patients achieved PASI 90 and 100, respectively. Similarly, absolute PASI $\leq$ 5 and PASI $\leq$ 3 was achieved by 89.5% and 82.1% of patients, respectively (Fig. 2). The response rates for PASI 75 and PASI 90/100 dropped by 5.7% and 9.0%, respectively, from month 24 to 36. The PASI 75/90 response rates at month 48 were, however, higher than those at month 12, which may be due to decreased patient adherence to secukinumab treatment.

With regard to QoL, 61.4%, 74.8%, 77.6% and 69.2% of patients achieved DLQI 0/1 at months 12, 24, 36 and 48, respectively (Fig. 3).

A rise in dropout rates was observed with 15.1% at month 12 to 35.6% at month 24 and toward steady rates of 27.1% and 32.0% at months 36 and 48, respectively. The majority of dropout (57.1%) observed at month 12 was due to unknown reasons/loss to follow-up; 14.3% were due to financial issues, and 11.4% either switched to other treatment or continued in other facility. The dropout rate due to loss of efficacy and pregnancy planning was 12.5% at month 48 (Supplementary Table 1).

The adherence rate to secukinumab treatment decreased from 84.9% at month 12 to 64.7%, 53.2% and 34.2% at months 24, 36 and 48, respectively (Fig. 4). No correlation was observed between adherence to secukinumab treatment and patient characteristics such as age group, biologic-naive state or DMARDs-naive state ($p > 0.05$; Supplementary Table 2). Male patients were found to have 1.18 times higher adherence as compared with female patients at month 12 ($p = 0.007$), but no differences were observed at months 24, 36 and 48. Adherence to secukinumab increased from 1.14 at month 12 to 1.43 at month 36 in patients receiving concomitant therapy, but not at month 48. Adherence to secukinumab also increased from 1.41 at month 12 to 5.01 at month 36 in patients with medical insurance coverage (Supplementary Table 2).

The median drug survival using survival analysis was not achieved in this study. Median time to discontinue secukinumab treatment was 30 months, and 39.2% (91/232) of patients withdrew secukinumab treatment at the end of the study (Fig. 5). The drug survival rate for secukinumab was 74.8%, 64.0%, 53.1% and 51.6% at months 12, 24, 36 and 48, respectively. On subgroup analysis, male patients were found to have longer time on secukinumab treatment as compared with female patients. A similar trend was observed in patients with PsO receiving other concomitant topical/systemic medications and in patients covered by medical insurance. On the other hand, factors such as age, biologic-naive status and DMARD-naive status did not affect secukinumab drug survival (Supplementary Figure).

DISCUSSION

The present analysis is a single-centre retrospective study that evaluated the effectiveness and retention rate of secukinumab treatment in Vietnamese patients with moderate-to-severe

PsO over 48 months in a real-world setting. This study confirms the long-term effectiveness of secukinumab treatment in Vietnamese patients with moderate-to-severe PsO, which is comparable to that observed in the real-world studies of the global population [13, 14].

The proportions of patients who achieved PASI 75/90 in this study are consistent with those reported earlier, albeit the duration of the studies reported were diverse, ranging from 40 to 104 weeks[15–17]. Moreover, the PASI 75/90 response rates in our study were higher than those reported in the pivotal phase 3 secukinumab studies ERASURE and FIXTURE in patients receiving secukinumab 300 mg [5]. The high efficacy of secukinumab in the study can be attributed to the high number of patients naive to biological and/or conventional DMARDs treatments as well as to the median BMI of patients at baseline, both of which have been shown to partially influence the secukinumab response in several real-world studies and clinical trials [15, 18]. Additionally, the results of this study were found to be higher than other real-world evidence studies in European and Asian population with respect to the rate of PASI 75/90/100 and absolute PASI ≤ 3 [18–21]. The PASI response rates in this study were comparatively higher than REALIA, a real-world study in Asia–Pacific and Middle Eastern patients, who received 12-month secukinumab treatment [8]. The PASI response rates were sustained after 24 months of secukinumab treatment in this study and were comparable to those reported in the 104-week real-world study by Rompoti et al. which included patients with moderate-to-severe chronic plaque psoriasis [16].

The PASI response rates in this study decrease at months 36 and 48, which may be due to the decrease in patient adherence to treatment. The proportion of patients achieving DLQI 0/1 at month 12 in our study was similar to a meta-analysis of 43 real-world evidence studies with similar observation periods, confirming the effectiveness of secukinumab in improving patients' QoL in clinical practice [22]. Likewise, the rate of achieving DLQI 0/1 at month 12 was comparable to the rate observed with secukinumab treatment in the REALIA real-world study. A decrease in adherence rate was observed from month 12 to month 48 in our study; however, the adherence rate at month 12 was higher than that reported by Galluzo et al. [23]. This might be due to differences in sample size and the severity of PsO in the population enrolled (baseline PASI was 17.7) in these studies.

This study showed no correlation between secukinumab adherence and age groups, biologic-naive state or DMARDs-naive state ($p > 0.05$). This was similar to the findings reported by Ferrieres et al. which showed no difference in adherence due to age, prior exposure to biologics or DMARDs [24]. However, in the current study, male patients showed higher adherence than female patients at month 12, differing from the findings of Ferrieras et al. which showed no difference in adherence due to gender.

Concomitant therapies and medical insurance correlated with higher adherence to secukinumab treatment, as these factors may have helped patients to experience rapid improvements and lower the overall cost of treatment per month. Median drug survival was not attained in this study. Median time to discontinue secukinumab treatment was 30 months, and 39.2% of patients withdrew the treatment at the end of the study. The drug survival rate of our study was consistent with that previously reported in a 12-month pooled analysis of 16 studies, which included another real-world study in a Greek population [20, 22]. However, secukinumab survival at 24 months was lower compared with the real-world study by Rompoti et al., which included patients treated with secukinumab over 2 years. This might be because there were more biologic-naive patients in the study by Rompoti et al. [16]. As per PSOLAR and BADBIR registries, discontinuation of prior biologic therapy was predictive of lower drug survival with subsequent biologics [25, 26]. Similar findings were reported in a retrospective study of patients treated with secukinumab in clinical practice, which included > 50% biologic-experienced patients who showed lower drug survival compared with the biologic-naive patients at months 12 and 18 [13].

The dropout rates in this study were comparable to those reported by a single-centre real-world study from Japan at month 12 [21]. This study showed higher drop-out rates as compared with a 2-year observational study of France, which may be attributable to the disparities in economic circumstances and study population of both countries [24]. The proportion of patients that discontinued secukinumab treatment due to lack of efficacy in this study at month 48 was higher compared with that reported by a meta-analysis with a similar observation period and in a 21-month multicentre, real-life retrospective Italian study [7, 22]. This decrease in adherence could be attributed to the fact that a high number of the patients achieved their desired efficacy, as well as the high cost incurred to biologic treatment. The national health insurance in Vietnam covers only 40% of the cost of biological agents such as secukinumab. The discontinuation rate due to adverse effects was otherwise found to be low in our study, which was consistent with that reported in previous real-world studies [7, 8, 19]. Secukinumab withdrawal rates due to pregnancy planning in our study were comparable to a real-life, retrospective, French study [7, 24]. A considerable proportion of patients in this study (14.3–37.5%) withdrew from the treatment due to financial reasons. Almost none of the previous studies have reported this finding. The longer secukinumab survival rate in patients covered by national medical insurance in our study suggests that secukinumab therapy is costly for Vietnamese patients with PsO who have lower-to-middle income.

To the best of our knowledge, this is one of the first real-world studies to evaluate secukinumab effectiveness and treatment adherence over a longer observation period of 48 months in a Vietnamese population with PsO. In addition, the current study validated the drug survival rate stratified on the basis of age, gender, comorbidities, concomitant therapies and insurance coverage, thus mirroring the challenges faced in real-world clinical practice and providing a greater understanding of the influence of these factors on treatment adherence.

Due to the inherent non-interventional nature of the study, there were foreseen limitations, including selection bias, lack of internal validity, incomplete or missing data, and difficulties in interpreting or verifying documented information. The study was single-centre and, hence, had a relatively small sample size. The study was not planned to assess the safety profile of the patients.

CONCLUSIONS

In Vietnamese patients with moderate-to-severe PsO, the long-term effectiveness of secukinumab was demonstrated. Secukinumab treatment adherence was higher in patients who had concomitant therapies and national medical insurance. The findings of this study will add to the mounting evidence of the long-term effectiveness of secukinumab in improving the QoL of patients with PsO in a real-world setting.

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Author contributions. All authors contributed to the manuscript concept and design. Study conception and Design: HTN; data collection: NTUP, TNAT, NNP, TTPV; data analysis and interpretation: HTN, NTUP, TNAT, NNP, YTB, TTPV; manuscript drafting and revision: HTN, NTUP, TNAT, NNP, YTB, TTPV. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility

for the integrity of the work, and have given their approval for this version to be published.

Disclosures. Hao T. Nguyen has served as an advisory board member and speaker for Novartis, Janssen, and Menarini. Nhi T. U. Pham, Tu N. A. Tran, and Thao T. P. Vu have served as a speaker for Novartis, Janssen, and Menarini. Yen T. Bui is an employee of Novartis Vietnam Co., Ltd. Nguyen N. Pham has nothing to disclose.

Ethical approval. This study has been reviewed and approved by the Institutional Review Board/Independent Ethics Committee of the HHDV (Approval Number: 1460/CN-BVDL 25 November 2021) and performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Informed consent was waived due to the retrospective nature of the study.

Data availability. The datasets generated during and/or analysed during the current study are available on reasonable request from the corresponding author.

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