Real-world clinical experience of secukinumab in Chinese patients with psoriasis in real-world practice: a 36-week single-center study of 24 patients

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To the Editor: Psoriasis is a chronic autoimmune inflammatory disease that has a significant negative impact on quality of life. Interleukin (IL)-17A, a key molecule in the T helper 17 pathway, is important in the pathogenesis of psoriasis. Secukinumab, a fully human immunoglobulin G1 kappa monoclonal antibody that targets IL-17A, was the first anti-IL-17A antibody approved by the US Food and Drug Administration in 2015. In China, it was approved in March 2019 for the treatment of moderate to severe psoriasis vulgaris (PsV), whereas in Japan, it is not only used for PsV but also psoriatic arthritis and generalized pustular psoriasis (GPP). The safety and efficacy of secukinumab have been assessed in four randomized controlled trials (RCTs) (ERASURE, FEATURE, JUNCTURE, and FIXTURE), which showed the superiority of secukinumab compared with placebo, etanercept, and ustekinumab, with long-term persistence of the clearance rate. However, the real-world setting of clinical practice is different from the strictly regulated setting of RCTs, which are conducted in only selected patients that fulfill strict inclusion and exclusion criteria to maximize internal validity. To date, there have been no official English reports of real-world studies published in China.

For this descriptive, retrospective study, data on 24 consecutive patients, who received secukinumab between July 2019 and July 2020 at the Department of Dermatology in the First Affiliated Hospital of Fujian Medical University, Fujian Province, China, were collected. All patients were followed up for 36 weeks. Patient demographic and treatment characteristics, duration of treatment, Psoriasis Area and Severity Index (PASI) scores, Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) scores, and Dermatology Life Quality Index (DLQI) scores were assessed. Adverse events were also recorded. Data are presented as mean ± standard deviation (continuous variables) or as number and proportion of patients (categorical variables). Groups were compared using the unpaired Student’s t-test or Mann–Whitney U-test for quantitative variables. The linear regression equation was used to compare the correlation between PASI improvement and DLQI improvement. P < 0.05 was considered statistically significant. All statistical analyses were performed using GraphPad Prism 4.0 (GraphPad Software Inc., La Jolla, CA, USA) and the SPSS 22.0 statistical package for Mac (IBM, Armonk, NY, USA).

During the past few decades, targeted biologic therapies have had a profound effect on the clinical management of individuals with PsV (moderate and severe disease), although their use in GPP has been limited. In our study, six patients were diagnosed with GPP, whereas 18 had PsV. The mean age of onset of GPP was significantly lower than that of PsV (GPP: 19.00 ± 13.25 years, PsV: 37.06 ± 14.99 years, P = 0.016). This does not seem to be consistent with the results of a previous study,[1] in which GPP was observed most frequently in middle-aged adults; however, the observation in the present study may have been obtained because GPP can also occur in children and most parents in China pay more attention to the timely treatment of their children. As the sample size in this study was relatively small, the analysis of age, body mass index, and comorbidities may have been biased (for more demographic data, see Supplementary Materials Table 1, http://links.lww.com/CM9/A405).

In this study, not only PASI-75 but also the more stringent PASI-90 and PASI-100 responses showed a favorable
Figure 1: Proportion of patients with clinical responses through week (W)-36 in psoriasis vulgaris (PsV) population (A, B, C). (A) Area of scalp accessed by the psoriasis scalp severity index (PSSI) response up to week 36. (B) Psoriasis Area and Severity Index (PASI)-50, -75, -90 and -100 responses in the overall 18 PsV population in whole body areas. (C) Area of palmoplantar region accessed by the palmoplantar Psoriasis Area and Severity Index (ppPASI). (D) Impact of difficult-to-treat areas (scalp and palmoplantar regions) and whole body scores on secukinumab therapy. Comparison of mean PASI improvement between three different regions. \( P < 0.05, \quad \star P < 0.01, \quad \star\star P < 0.001 \) for comparison between three different regions. PASI: Psoriasis Area and Severity Index. (E) Generalized Pustular Psoriasis Area and Severity Index (GPPASI) response in generalized pustular psoriasis (GPP) patients. At week 4, 100% achieved GPPASI-75. Of the patients, 83.0% achieved GPPASI-90 and 50.0% achieved PASI-100 at week 12. All patients achieved GPPASI-100 at the end of week 36. (F) Absolute value percentage of GPPASI mean change from baseline through week 36. Data are shown as observed through week 36. Secukinumab 150 mg was noninferior to secukinumab 300 mg at every week point \( P = 0.13 \). (G) Mean percent Psoriasis Area Severity Index (PASI) reduction vs. mean reduction in Dermatology Life Quality Index (DLQI) Score. (H) Mean percent Generalized Pustular Psoriasis Area and Severity Index (GPPASI) reduction vs. mean reduction in Dermatology Life Quality Index (DLQI) Score.
In the GPP group, the mean GPPASI score of GPP decreased from 35.78 ± 19.24 at the baseline to 1.20 ± 0.08 in week 36. All patients reached GPPASI-90 at 24 weeks and 83% of patients reached GPPASI-100. These observations are consistent with those of a phase III open-label multicenter Japanese study, which revealed that the area of erythema with pustules clears immediately after the start of secukinumab as early as week 1 to week 3 in most patients and improvements are sustained through 52 weeks.\(^\text{[2]}\) Case reports in India, the US, and other countries have shown that many patients achieve PASI-90 after just 1 week.\(^\text{[3,4]}\) Combined with our data, we hypothesized that secukinumab has a peculiar effect in the control of erythema-pustular lesions and can be considered as a first-line drug for the treatment of GPP.

The stigmatization and psychological distress associated with psoriasis were evident; more than 50% of patients with moderate-to-severe disease reported depression. The DLQI scores of all patients (n = 24) decreased from the baseline of 13.17 to 4.16 and 1.21 in weeks 24 and 36, respectively. In week 36, 75.0% (18/24) of patients achieved a DLQI of 0/1. The percentages of PASI and GPPASI improvement from the baseline did not correlate to PASI, and PASI and GPPASI improvement from the baseline did not correlate to DLQI changes (\(r^2 = 0.9995\) [Figure 1G] and \(r^2 = 0.9165\) [Figure 1H], respectively, from the baseline to 36 weeks). Several studies have demonstrated that a reduction in PASI predicts a reduction in DLQI. Thus, secukinumab may improve the quality of life of patients with psoriasis by clearing skin lesions. Overall, secukinumab induced a sustained clinical response and had an acceptable safety profile for 36 weeks in Chinese patients with psoriasis.

### Conflicts of interest

None.

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