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ORIGINAL RESEARCH

Secukinumab Persistence in Patients with Psoriatic Arthritis: An Adalimumab-Matched Retrospective Cohort Database Study (FLYWAY)

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ABSTRACT

Introduction: Long-term treatment of psoriatic arthritis (PsA) is required to prevent progression. However, persistence with current treatments is challenging due to tolerability and acceptability issues. The objective of this study was to estimate 1-year persistence with secukinumab in patients with PsA treated with secukinumab, to compare persistence rates between secukinumab and adalimumab, to estimate usefulness rates, and to document adverse events.

Methods: This retrospective study used data from the Japanese Medical Data Vision database. A total of 182 patients with PsA initiating secukinumab were identified between February 1, 2015 and September 30, 2020. Of these, 171 could be matched to 171 patients initiating adalimumab over the same period using a propensity score. Patients were followed until death, treatment discontinuation, or until the end of the study period. Persistence rates were analyzed using Kaplan–Meier survival analysis. Usefulness was evaluated using a published algorithm. Selected adverse events were documented.

Results: Twelve-month persistence with secukinumab was 68.3%. The median persistence duration was significantly higher ($p=0.002$) for secukinumab (27.8 months) than for adalimumab (12.5 months). After 12 months, the treatment was found to be useful in 47.0% of the secukinumab cohort and 22.2% of the adalimumab cohort ($p<0.001$). Fourteen patients (7.7%) in the unmatched secukinumab cohort and 32 (9.1%) in the unmatched adalimumab cohort presented an adverse event of interest.

Conclusions: Patients with PsA showed higher persistence with secukinumab than with adalimumab. Since PsA is a chronic disease that requires long-term treatment, long-term persistence and usefulness should be considered for the treatment choice.

Infographic available for this article.

Prior Publication: A poster presenting some of the data from this study was presented at the EULAR European Congress of Rheumatology, 12–15 June 2024. Vienna, Austria.

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Infographic:

SECUKINUMAB PERSISTENCE IN PATIENTS WITH PSORIATIC ARTHRITIS:
AN ADALIMUMAB-MATCHED RETROSPECTIVE COHORT DATABASE STUDY
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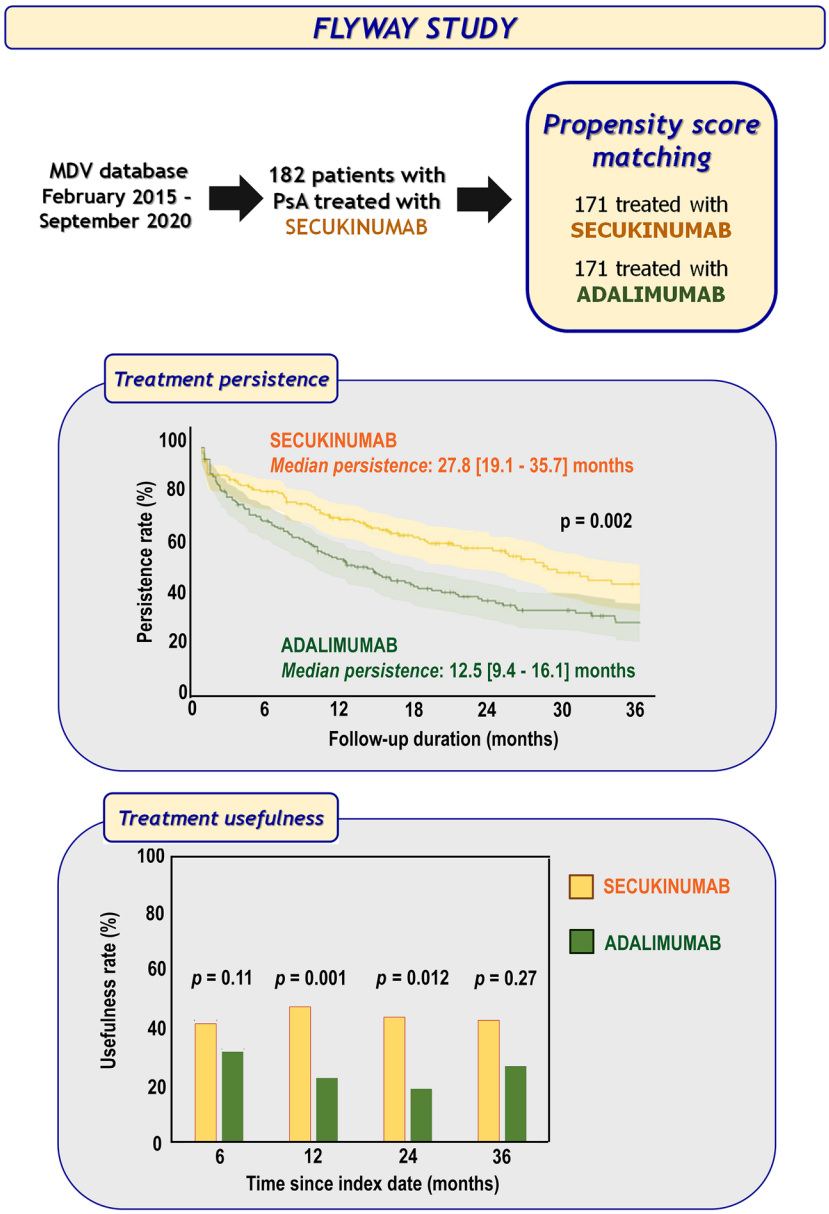

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PEER-REVIEWED FEATURE

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PLAIN LANGUAGE SUMMARY

Patients with psoriatic arthritis need to take medications that slow down the progression of their disease in order to control their symptoms. Secukinumab is an example of such a drug. These treatments need to be taken regularly to remain effective. However, many patients stop taking their medications because they are inconvenient or cause side effects. This study was conducted in order to estimate persistence with treatment with secukinumab in a sample of Japanese patients with psoriatic arthritis identified through their health insurance records. We found that 68.3% of these patients took secukinumab regularly for at least 1 year. This proportion is higher than the corresponding proportion for adalimumab, which is a previous-generation disease-modifying treatment for psoriatic arthritis. We also found secukinumab to be useful in more patients than was the case for adalimumab. The proportion of patients experiencing side effects was low (less than 10%) for both drugs.

Keywords: Secukinumab; Adalimumab; bDMARD; Persistence; Psoriatic arthritis

Key Summary Points

Why carry out this study?
Treatment persistence with disease-modifying treatments for psoriatic arthritis (PsA) is important to maintain long-term disease control.
However, in routine clinical practice, persistence is often sub-optimal.
We performed a study in a Japanese healthcare insurance database to estimate persistence with secukinumab in the real-world setting, and compare persistence between secukinumab and adalimumab.
What has been learned from the study?
Persistence with secukinumab in patients with PsA at 1 year was 68.3%. In addition, median persistence was longer in patients with PsA treated with secukinumab (27.8 months) than in those treated with adalimumab (12.5 months; $p=0.002$).
The treatment usefulness rate at 1 year was also higher in patients treated with secukinumab (47.0%) than in those treated with adalimumab (22.2%; $p<0.001$).
Adverse event rates were similar in the two groups (secukinumab: 7.7%; adalimumab: 9.1%).

DIGITAL FEATURES

This article is published with digital features, including an infographic, to facilitate understanding of the article. To view digital features for this article, go to https://doi.org/10.6084/m9.figshare.28286825.

INTRODUCTION

Psoriatic arthritis (PsA) is an inflammatory, immune-mediated, chronic disease affecting various domains including skin and joints [1]. The disease is characterized by a progressive destructive pathology frequently resulting in irreversible disabling arthritis [2], overlain by episodic flares of symptom aggravation associated with increased inflammatory activity [3]. In Japan, PsA affects around ten percent of patients with psoriasis [4].

In 2005, the introduction of biological disease-modifying antirheumatic drugs (bDMARDs) targeting cytokines involved in the inflammatory process opened a new era in the treatment of PsA [5]. Current bDMARDs available in Japan include a range of inhibitors of tumor necrosis factor-α (TNF-α), anti-interleukin (IL)-23 monoclonal antibodies (mAbs), a bispecific anti-IL23 and anti-IL12 mAb, anti-IL17A mAbs,

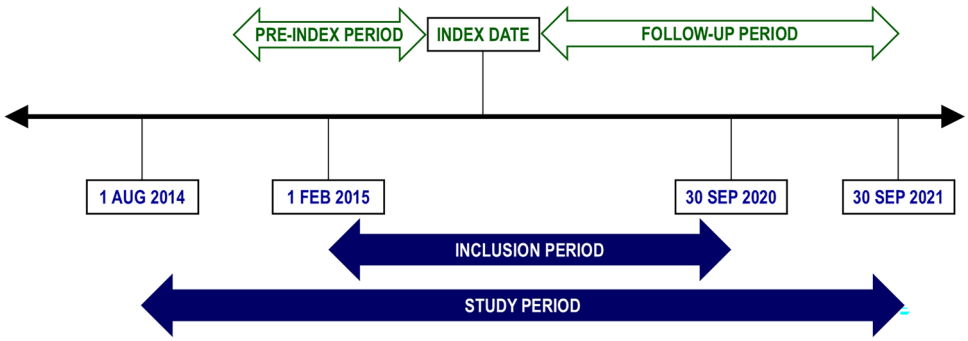

Fig. 1 Study design

an anti-IL17A and F mAb and a mAb directed against the IL17 receptor A. The most widely used bDMARDs for the treatment of PsA in Japan are the anti-TNF-α mAb adalimumab and the anti-IL17A mAb secukinumab [6].

Given the chronic nature of the disease, long-term treatment is required to preserve joint integrity and prevent progression [5]. However, persistence with treatment remains challenging due to tolerability and acceptability issues with available DMARDs [7, 8]. It has been reported that interruption of DMARD treatment results in rapid flares in the majority of patients [9, 10]. In addition, switching to another bDMARD, except in cases of treatment failure, should be performed with caution, as it may result in loss of efficacy and poorer treatment retention, as well as potential gaps in bDMARD exposure due to the need for dose titration [11, 12]. Treatment persistence is thus a crucial determinant of optimal therapy outcomes. Nonetheless, many studies have shown that persistence to bDMARDs in the real-world setting is poor, with a median treatment duration generally not exceeding 2 years [7, 13–15].

Understanding treatment persistence is essential for ensuring a long-term clinical response. However, the majority of available persistence studies have been performed with TNF-α inhibitors or with ustekinumab. In addition, there are limited data available from the real-world treatment setting, particularly regarding secukinumab [14, 16, 17]. A notable exception is the SERENA study, conducted in patients with PsA in sixteen countries in Europe, which has reported high persistence with secukinumab (85.2% at 1 year) [18]. For this reason, we have undertaken a large health insurance claims database study to evaluate persistence with the two most widely prescribed bDMARDs in Japan, secukinumab and adalimumab. The primary objective of this study was to estimate 1-year—persistence with secukinumab. Other objectives were to compare persistence rates between matched cohorts of patients treated with secukinumab and with adalimumab, to compare the characteristics of patients treated with secukinumab and adalimumab, to evaluate persistence rates in subgroups of patients defined by baseline characteristics, to estimate usefulness rates and to investigate the occurrence of adverse events (AEs) during treatment with secukinumab or adalimumab.

METHODS

Study Design

This study was a retrospective, longitudinal observational cohort study performed in Japan using the Medical Data Vision (MDV) health insurance claims database. The total study period covered the period from August 1, 2014 to September 30, 2021. Information was extracted from the database for all patients with a confirmed diagnosis of PsA during the total study period. The index date was defined as the date of the first prescription of secukinumab or adalimumab within an inclusion period between 1st February 2015 (following the launch of

secukinumab for PsA in Japan) and 30th September 2020. Patients were followed from the index date until death, discontinuation of treatments of interest or the end of the study period, whichever occurred first. A 6-month historical period immediately prior to the index date was also defined to document any diagnosis of PsA before the index date and to document comorbidities and prior DMARD use. The study design is illustrated in Fig. 1.

Data Source

Data were retrieved from the MDV database provided by the Medical Data Vision Co., Ltd. (Tokyo, Japan). This database, established in 2003, covers over 400 acute-care hospitals using the Japanese Diagnosis Procedure Combination fixed-payment reimbursement system [19], with information on over 42 million individual patients. The database contains standardized records on all care provision in MDV-affiliated hospitals.

Patients

The study population consisted of all adult patients (≥ 18 years old) with a confirmed diagnosis of PsA (ICD-10: L405) documented during the pre-index period or at the index date and at least one prescription of secukinumab or adalimumab at their approved dose in Japan, during the inclusion period, and present in the database for ≥ 6 months prior to the index date. Patients with a prescription record for secukinumab (for patients in the secukinumab cohort) or adalimumab (for patients in the adalimumab cohort) during the 6-month historical period were excluded.

Study Variables

Demographics

Age at the index date and gender were documented. The measure of height and weight closest to the index date was documented, and body mass index (BMI) was calculated therefrom. The facility department where the patient consulted on the index date was identified.

Exposure and Persistence

Exposure was considered to start on the index date. An individual prescription was considered to last from the date of the prescription plus the number of days covered by the bDMARD according to the prescribing information (secukinumab: 150 or 300 mg weekly up to week 4 and monthly thereafter; adalimumab: 40 mg every other week with a possibility of escalation to 80 mg if the clinical response is unsatisfactory). If a gap longer than 120 days between the estimated end of each individual prescription and the beginning of the following one (or the end of follow-up), the patient was considered to have discontinued, with the date of discontinuation defined as the date of the end of the period covered by the last prescription. A patient was considered as persistent from the index date until the date of discontinuation.

Medical History

The time interval between the first documented PsA-related claim and the index date was determined. It should be noted that the first documented date may not correspond to the actual date of diagnosis, since initial diagnosis may have been made elsewhere than a hospital participating in the MDV database and thus will not have been captured. Comorbidities of interest were documented at the index date or during the 6-month historical period using the diagnosis codes in Supplementary Table S1.

Treatments

Concomitant prescription of treatments for PsA was documented during the index month, including oral or intra-articular glucocorticoids, conventional synthetic DMARDs (csDMARDs) and bDMARDs (Supplementary Table S2). Patients were considered as bDMARD-naïve if no prescription records for any bDMARD indicated

for psoriasis or PsA were retrieved during the 6-month historical period.

Usefulness

Treatment was considered useful if all the following criteria were met throughout the period that the patient was exposed to treatment [20]: (i) a medication possession ratio (MPR) [21] for secukinumab/adalimumab > 80%; (ii) no switch to another PsA therapy; (iii) no dose escalation; (iv) no addition of a csDMARD; (v) no increase in use of systemic glucocorticoids and (vi) ≤ 1 intra-articular glucocorticoid injection after the index date + 90 days.

Adverse Events

Adverse events of interest were documented from ICD-10 codes during the follow-up period (Supplementary Table S1). These adverse events were inflammatory bowel disease, anaphylactic reactions, neutropenia, and erythroderma (exfoliative dermatitis). In addition, confirmed serious infections were documented during the periods of exposure to secukinumab or adalimumab. Serious infections were defined as those leading to hospitalization (as the main diagnosis or disease behind the hospitalization) or which incurred the highest cost of all healthcare resource consumption during the hospitalization. If the patient died in the hospital where the patient was treated for PsA, the date of death was recorded.

Statistical Considerations

Descriptive Statistics

Continuous variables are presented as mean values ± standard deviation (SD) or median values with interquartile range [IQR] and compared with one-way analysis of variance. Categorical variables are presented as frequency counts and percentages and compared with the χ^2 test or Fisher's exact test as appropriate. A probability threshold of 0.05 was taken as statistically significant. All analyses were performed using SAS version 9.4.

Persistence

Persistence rates were analyzed using Kaplan–Meier survival analysis at 6 months, 1, 1.5, 2, 2.5 and 3 years, and median persistence times estimated, together with their 95% confidence intervals (CI). Persistence was compared between the secukinumab and adalimumab cohorts using the log-rank test.

Propensity Score Matching

In order to reduce inclusion bias and to minimize confounding by covariates, propensity score matching was performed to compare persistence rates between the secukinumab and adalimumab cohorts [22–24]. A propensity score was calculated using logistic regression analysis of the following baseline variables: age at the index date, gender, time from PsA diagnosis, comorbidities, concomitant treatment and previous bDMARD experience. The resulting propensity score was then determined individually for each patient enrolled. For each patient in the secukinumab cohort, a patient in the adalimumab cohort was selected with a matching propensity score, identified on a nearest neighbor basis using a pre-defined caliper, initially set at 0.2 times the standard deviation of the logit-transformed propensity score. Propensity score matching was used for the analysis of persistence and usefulness, but not for the analysis of adverse events.

Subgroup Analysis

Persistence rates were estimated in predefined subgroups of patients defined by gender, treatment history (bDMARD-naïve or bDMARD experienced), time since the first PsA-related claim and the hospital department where the patient consulted.

Ethics

The study complied with all relevant international and Japanese national legislation on medical research and data privacy. In particular, it complied with the Declaration of Helsinki and with the Japanese Act on the Protection of

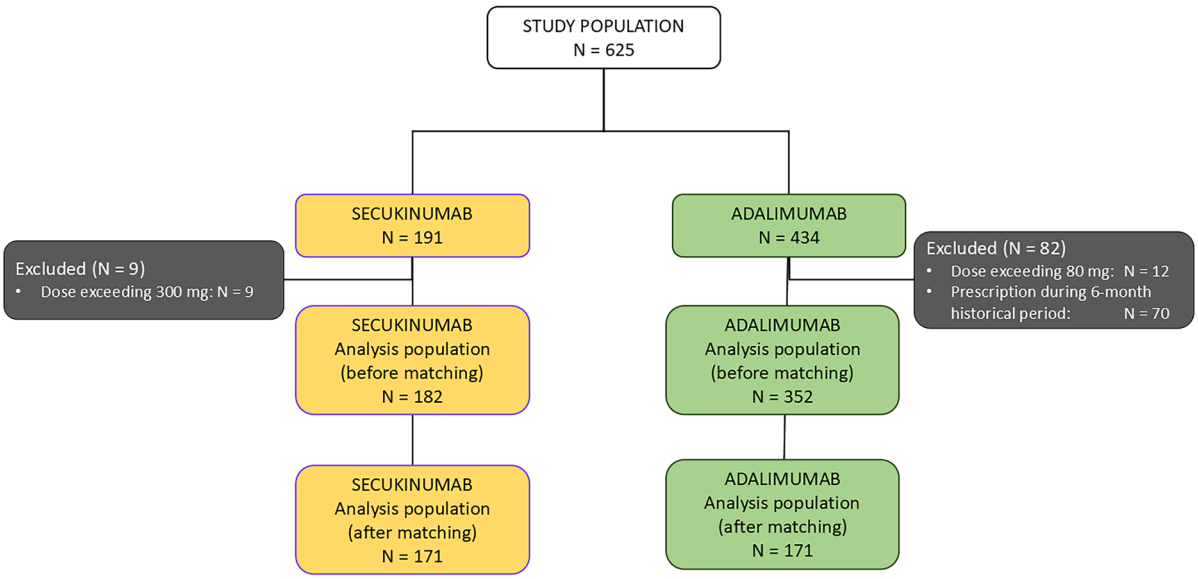

Fig. 2 Patient flow diagram

Personal Information. The requirement for ethics approval and informed consent is regulated by the Japanese Pharmaceuticals and Medical Devices Agency guidelines for conducting pharmaco-epidemiological research using medical databases. In accordance with these guidelines, the study was not subject to an ethics review as anonymized processed information has already been created by the data provider (as stipulated in Article 2, Paragraph 6 of the Personal Information Protection Act). Collecting patient consent to participate is not relevant to this study since the data came from an administrative healthcare insurance database in which all patient data is anonymized and the individual patients whose data is used cannot be identified.

RESULTS

Study Population

Overall, 625 patients with a confirmed diagnosis of PsA and treated with secukinumab or adalimumab were identified during the inclusion period, of whom 534 (85.4%) were eligible and made up the analysis population before matching (182 patients treated with secukinumab and 352 treated with adalimumab). Of these, 171 patients initiating secukinumab could be matched to 171 patients initiating adalimumab. A patient flow diagram is provided in Fig. 2.

Patient characteristics in the analysis population at the index date before and after matching are presented in Table 1. After matching, the two groups were comparable (standardized difference <0.1) for most variables, apart from certain comorbidities and concomitant treatments (Table 1). The groups were slightly unbalanced with respect to BMI, but this variable was not included in the propensity score due to substantial missing data. The mean time since the first PsA-related claim was 4.1 ± 2.5 months, around two-thirds were bDMARD-naïve and around one-fifth were also prescribed methotrexate. Data on C-reactive peptide (CRP) levels at the index date were available for <10 patients in each cohort (after matching). Seventy patients, 38 in the secukinumab group (22.2%) and 32 in the adalimumab group (18.7%), were prescribed methotrexate at the index date or during the same calendar month.

Table 1 Patient characteristics at the index date

	Before matching			After matching		
	Secukinumab (*N* = 182)	Adalimumab (*N* = 352)	(d)	Secukinumab (*N* = 171)	Adalimumab (*N* = 171)	(d)
Age at index date (years)						
Mean ± SD	55.4 ± 14.1	56.7 ± 14.2	0.10	55.8 ± 14.1	56.0 ± 14.7	0.01
18–19 years	0 (0.0%)	2 (0.6%)	0.11	0 (0.0%)	1 (0.6%)	0.11
20–29 years	4 (2.2%)	8 (2.3%)	0.01	3 (1.8%)	7 (4.1%)	0.14
30–39 years	17 (9.3%)	31 (8.8%)	0.02	16 (9.4%)	15 (8.8%)	0.02
40–49 years	48 (26.4%)	66 (18.8%)	0.18	43 (25.1%)	30 (17.5%)	0.19
50–59 years	45 (24.7%)	91 (25.9%)	0.03	44 (25.7%)	50 (29.2%)	0.08
60–69 years	33 (18.1%)	79 (22.4%)	0.11	30 (17.5%)	34 (19.9%)	0.06
70–79 years	26 (14.3%)	64 (18.2%)	0.11	26 (15.2%)	26 (15.2%)	0.00
80–89 years	9 (4.9%)	10 (2.8%)	0.11	9 (5.3%)	8 (4.7%)	0.03
90–99 years	0 (0.0%)	1 (0.3%)	0.08	0 (0.0%)	0 (0.0%)	–
Gender						
Male	88 (48.4%)	187 (53.1%)	0.10	83 (48.5%)	78 (45.6%)	0.06
Treatment history						
bDMARD-naïve	119 (65.4%)	261 (74.1%)	0.19	114 (66.7%)	106 (62.0%)	0.10
bDMARD-experienced	63 (34.6%)	91 (25.9%)	0.19	57 (33.3%)	65 (38.0%)	0.10
Time from PsA diagnosis to index date (months)						
Mean ± SD	4.1 ± 2.5	4.1 ± 2.5	0.01	4.1 ± 2.5	4.1 ± 2.5	0.00
Comorbidities of interest[a]						
Psoriasis	128 (70.3%)	211 (59.9%)	0.22	120 (70.2%)	116 (67.8%)	0.05
Inflammatory bowel disease	2 (1.1%)	3 (0.9%)	0.08	2 (1.2%)	2 (1.2%)	0.00
Uveitis	3 (1.6%)	5 (1.4%)	0.03	2 (1.2%)	3 (1.8%)	0.07
Ankylosing spondylitis	9 (4.9%)	11 (3.1%)	0.17	8 (4.7%)	8 (4.7%)	0.00
Hypertension	41 (22.5%)	79 (22.4%)	0.01	39 (22.8%)	43 (25.1%)	0.49
Hyperlipidemia	52 (28.6%)	77 (21.9%)	0.56	46 (26.9%)	48 (28.1%)	0.08
Type 2 diabetes	54 (29.7%)	98 (27.8%)	0.10	50 (29.2%)	50 (29.2%)	0.00
Hyperuricemia/gout	30 (16.5%)	23 (6.5%)	3.71	25 (14.6%)	21 (12.3%)	0.74
Depression/anxiety	8 (4.4%)	21 (6.0%)	0.26	8 (4.7%)	12 (7.0%)	0.38
Fibromyalgia	2 (1.1%)	6 (1.7%)	0.16	2 (1.2%)	1 (0.6%)	0.20

Table 1 continued

	Before matching			After matching		
	Secukinumab ($N=182$)	Adalimumab ($N=352$)	(d)	Secukinumab ($N=171$)	Adalimumab ($N=171$)	(d)
Concomitant treatments[b]						
Glucocorticoids (intra-articular)	5 (2.7%)	7 (2.0%)	0.05	5 (2.9%)	5 (2.9%)	0.00
Non-steroidal anti-inflammatory drugs	66 (36.3%)	167 (47.4%)	0.64	61 (35.7%)	66 (38.6%)	0.13
Methotrexate (oral)	40 (22.0%)	141 (40.1%)	1.12	38 (22.2%)	32 (18.7%)	0.22
Glucocorticoids (oral)	28 (15.4%)	55 (15.6%)	0.02	28 (16.4%)	21 (12.3%)	0.34
Ciclosporin (oral)	11 (6.0%)	7 (2.0%)	0.52	9 (5.3%)	6 (3.5%)	0.21
Apremilast	3 (1.6%)	9 (2.6%)	0.16	3 (1.8%)	3 (1.8%)	0.00
Etretinate	6 (3.3%)	9 (2.6%)	0.13	6 (3.5%)	6 (3.5%)	0.00
Body mass index (kg/m^2)[c]	$N=79$	$N=170$		$N=74$	$N=87$	
Mean ± SD	24.7 ± 4.9	23.2 ± 4.7	0.04	24.6 ± 5.0	23.7 ± 5.1	0.11
< 18.5 kg/m^2 (underweight)	8 (10.1%)	21 (12.4%)	0.07	8 (10.8%)	11 (12.6%)	0.08
18.5–25 kg/m^2 (normal)	34 (43.0%)	101 (59.4%)	0.24	33 (44.6%)	43 (49.4%)	0.14
25–30 kg/m^2 (overweight)	28 (35.4%)	36 (21.2%)	0.15	24 (32.4%)	24 (27.6%)	0.00
≥ 30 kg/m^2 (obese)	9 (11.4%)	12 (7.1%)	0.08	9 (12.2%)	9 (10.3%)	0.00
Facility department[c]						
Dermatology	107 (58.8%)	152 (43.2%)		99 (57.9%)	85 (49.7%)	
Rheumatology	21 (11.5%)	48 (13.6%)		21 (12.3%)	17 (9.9%)	
Orthopedics	18 (9.9%)	53 (15.1%)		17 (9.9%)	28 (16.4%)	
Internal medicine	32 (17.6%)	100 (28.4%)		32 (18.7%)	40 (23.4%)	
Others	25 (13.7%)	65 (18.5%)		22 (12.9%)	30 (17.5%)	

bDMARD biological disease-modifying antirheumatic drug, *(d)* standardized differences, *PsA* psoriatic arthritis, *SD* standard deviation

[a]At the index date or during the 6-month historical period

[b]During the month around the index date

[c]This variable was not used in the propensity score matching as the number of patients with the information registered was not sufficient

Treatment Persistence

Before matching, the persistence rate for secukinumab in the analysis population was 68.3% [95% CI: 60.8–74.6%] at 12 months (Fig. 3). After matching, the persistence rate was 67.4% [59.6–74.0%] at 12 months and 41.2% [31.5–50.5%] at 36 months for secukinumab and 51.3% [43.5–58.6%] and 25.5% [18.1–33.6%] respectively for adalimumab (Fig. 4). Persistence was significantly higher in the matched secukinumab cohort than in the

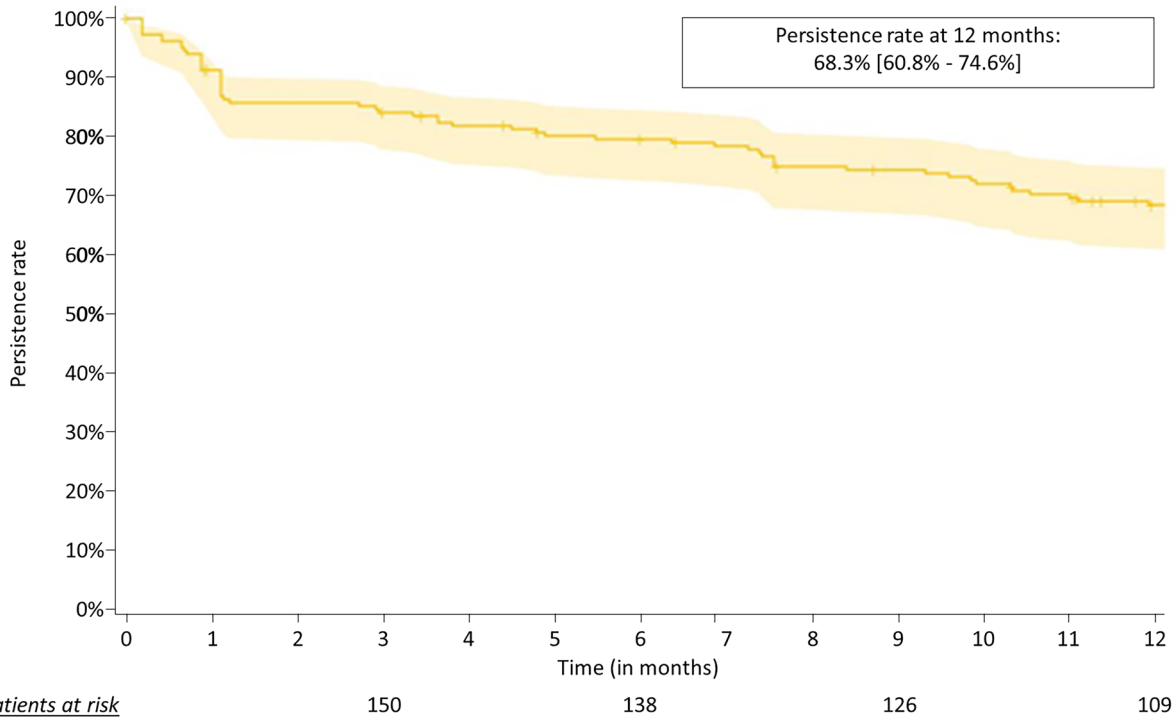

Fig. 3 Persistence with secukinumab at 1 year (before matching). Data are presented as a Kaplan–Meier survival curve, with the *shaded band* representing the 95% confidence interval of the estimate

matched adalimumab cohort ($p=0.002$; log-rank test). The comparison between the unmatched secukinumab cohort and the unmatched adalimumab cohort is provided in Supplementary Figure S1. This analysis yielded very similar results to that in the matched population, with a lower persistence rate in the adalimumab cohort (51.3% [45.8–56.5%]) than in the secukinumab cohort (68.3% [60.8–74.6]) at 12 months.

Persistence in Patient Subgroups

Persistence rates and median persistence rates were estimated for a number of subgroups (Fig. 5). Patient numbers were low in several of these subgroups. For the majority of subgroups, the median persistence duration for both secukinumab and adalimumab fell within the 95% confidence intervals of the estimate for the full analysis population after matching. Persistence was higher in bDMARD-naïve patients than in bDMARD-experienced patients. In all patient subgroups, persistence was higher in the secukinumab group than in the adalimumab group, although between-group differences were not always significant. Significant differences in persistence between the two groups ($p<0.05$; log-rank test) were observed for women, bDMARD-naïve patients, bDMARD-naïve patients with their first PsA-related claim < 12 months prior to the index date, and patients consulting in dermatology or rheumatology departments. It should be noted that no bDMARD-naïve patients had their first PsA-related claim > 12 months prior to the index date. Kaplan–Meier survival curves for persistence in certain of these subgroups are provided in Supplementary Figures S2–S4.

Usefulness

The proportion of patients for whom the definition of usefulness (see Methods) was fulfilled ranged across study visits from 41.1 to 47.0% in the secukinumab group and from 18.4 to 31.3% in the adalimumab group, with no

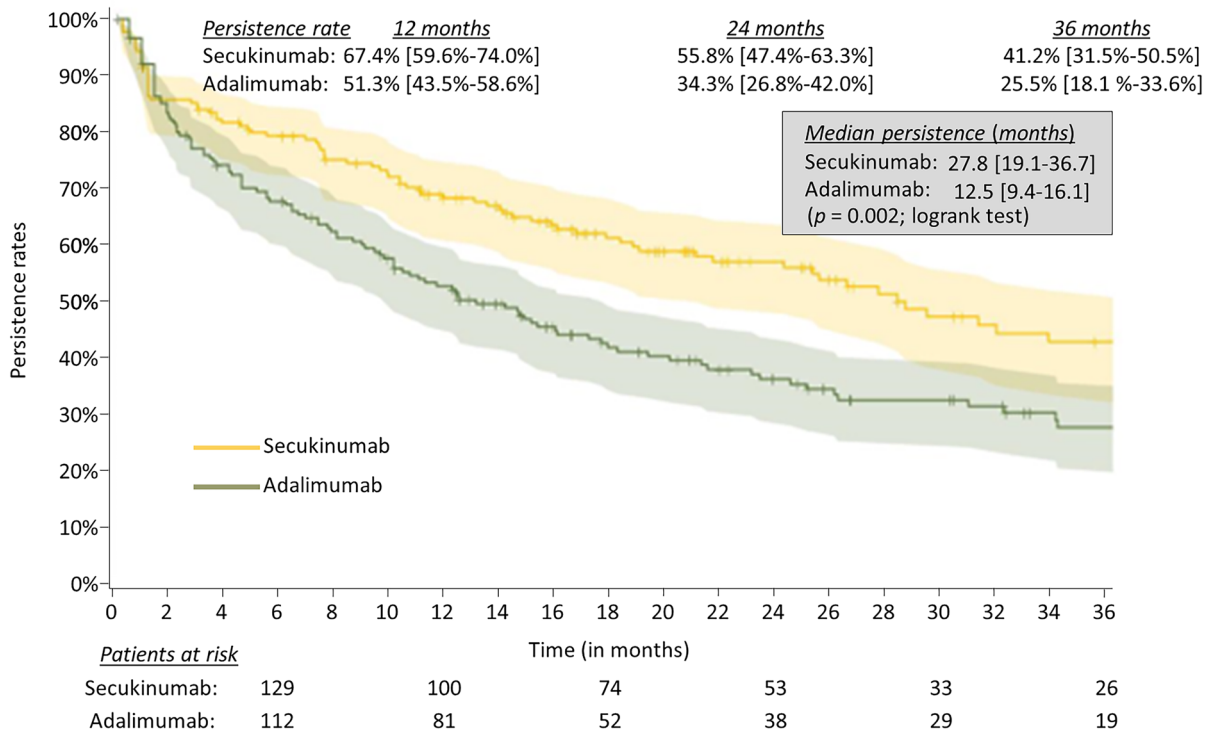

Fig. 4 Persistence with secukinumab and adalimumab up to 3 years (after matching). Data are presented as Kaplan–Meier survival curves, with the *shaded bands* representing the 95% confidence intervals of the estimates. Median persistence estimates are provided with their 95% confidence intervals

obvious change in usefulness over time (Fig. 6). A significant between-group difference was observed at 1 year and 2 years after the index date. Information for each of the individual usefulness criteria is provided in Table 2. No patient switched to another PsA therapy. In the secukinumab group, < 5% of patients (< 10% in the adalimumab group) increased their use of systemic glucocorticoids over baseline at any time-point, with no increase compared to baseline after 3 years. At each time-point, at least one-third of patients treated with adalimumab increased the dose from 40 to 80 mg. Ten patients (5.8%) in the secukinumab group and 17 (9.9%) in the adalimumab group added methotrexate during follow-up.

Adverse Events

Fourteen patients in the secukinumab group (7.7%) and 32 in the adalimumab group (9.1%) experienced an adverse event of interest (unmatched cohorts), most frequently a serious infection (Table 3). The only serious infections reported in more than a single patient were Gram-negative *Bacillus* sepsis (two patients in the adalimumab group), bacterial pneumonia (one patient in each group), acute pneumonia (two patients in the adalimumab group) and pneumonia (three patients in the adalimumab group). A full list of all infections encountered is provided in Supplementary Table S3. When the pathogen was documented, these infections were principally bacterial, although there was one case of herpes zoster. Adverse events frequently occurred in the 6 months following treatment initiation (in 9/14 patients in the secukinumab cohort and in 12/32 patients in the adalimumab cohort). The adverse events also included nine in-hospital deaths of undocumented causes in the adalimumab group.

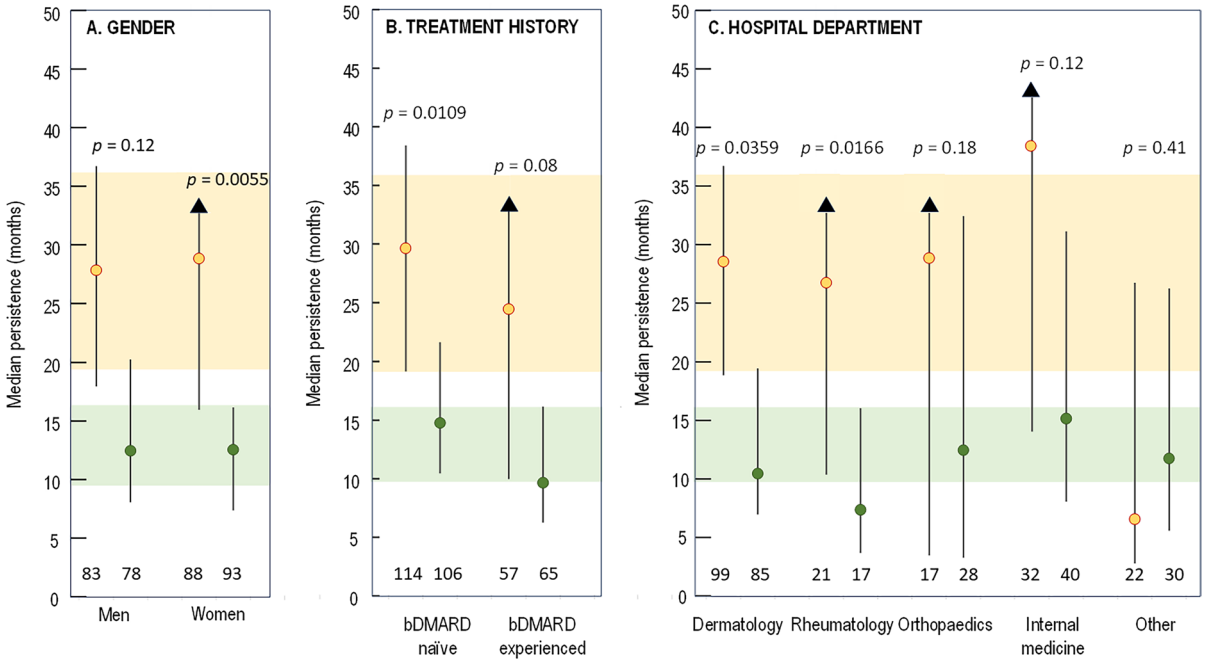

Fig. 5 Median persistence duration in patient subgroups. Median persistence durations are presented with their 95% confidence intervals. *Yellow symbols*: secukinumab; *green symbols*: adalimumab. The *black arrowheads* on certain confidence intervals indicate that the upper bound of the confidence interval could not be calculated. The *pale yellow band* represents the 95% confidence interval of the estimate of median persistence for secukinumab in the total analysis population after matching. The *pale green band* represents the 95% confidence interval of the estimate of median persistence for adalimumab in the total analysis population after matching. The *numbers below the points* indicate the number of patients in each subgroup. *bDMARD* biological disease-modifying antirheumatic drug

DISCUSSION

This health insurance claims database study performed in patients with PsA in Japan estimated the 12-month persistence rate for secukinumab at 68.3% [60.8–74.6%]. Persistence was higher in patients treated with secukinumab than in those treated with adalimumab ($p=0.002$; log-rank test). In addition, the usefulness rate was higher in patients treated with secukinumab than in those treated with adalimumab.

The strengths of the study include the relatively large number of patients prescribed secukinumab and adalimumab, and the range of outcomes (persistence, usefulness, and safety) documented in the same population. The follow-up period (3 years) was relatively long compared to previous studies, and covered the period throughout which both treatments of interest were available to prescribers. Finally, propensity score matching was used to generate two comparable treatment cohorts, and thus minimize inclusion bias from confounding by covariates when comparing the two cohorts.

The demographic profile and treatment history of included patients are typical of patients with PsA. Over half of the patients were followed in dermatology departments, which is the medical specialty that is typically responsible for the diagnosis and management of patients with PsA in Japan.

The persistence rates for secukinumab observed in this study can be compared with 12-month persistence rates reported in other studies [17, 18, 25–30]. These range from 63.2% in Israel [25] and Japan [17] to 85.2% in the multinational prospective SERENA cohort [18]. In

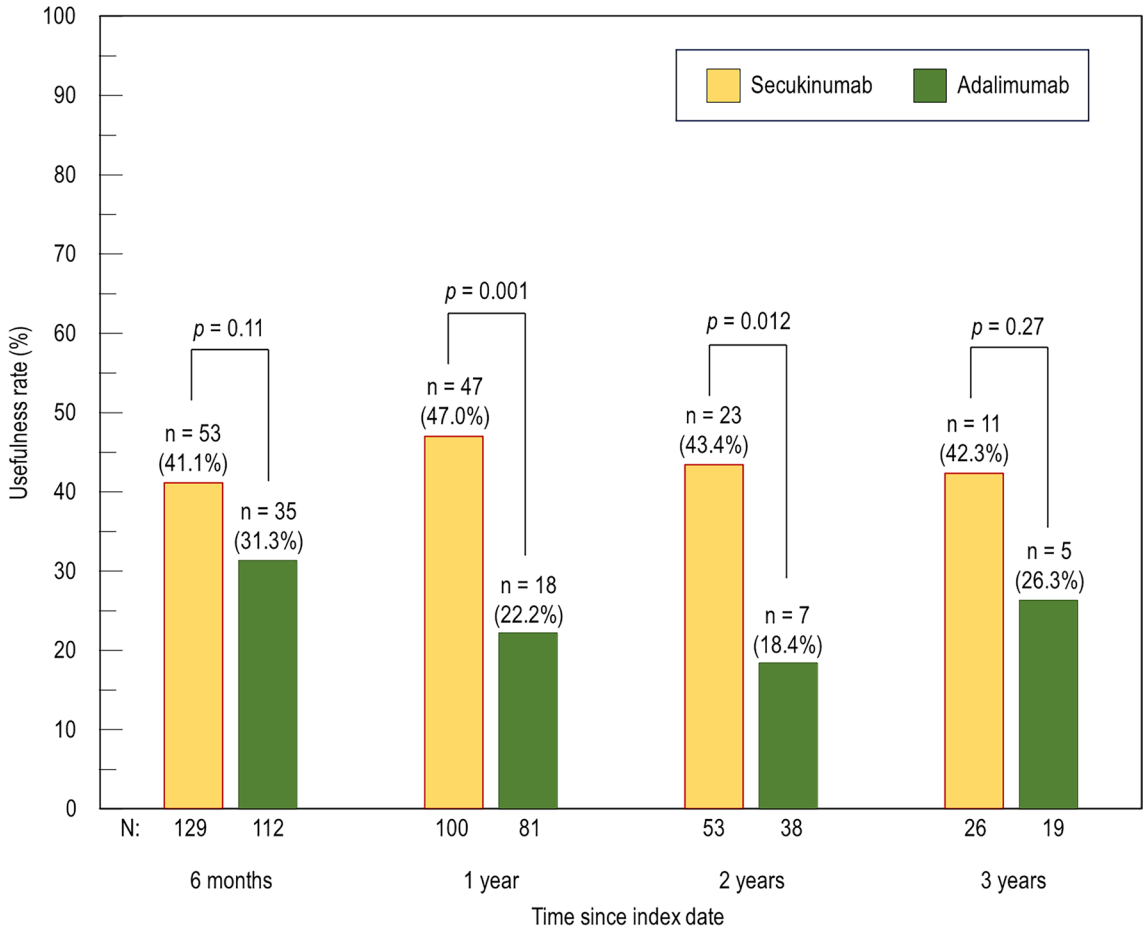

Fig. 6 Usefulness of secukinumab and adalimumab up to 3 years (after matching). See Methods for the definition of usefulness

spite of differences in study design and definitions of persistence, these data from different countries are rather consistent. Taken together, the findings of all these studies underscore the efficacy of secukinumab in a wide geographic context, and emphasize the pertinence of secukinumab in managing PsA worldwide. In addition, persistence rates with secukinumab are similar to those reported in a previous multicentre cohort study (RAILWAY) performed in 123 patients with psoriasis in Japan (78.0% [95% CI: 69.6–84.4] at 1 year) [31].

Superior persistence rates were observed for secukinumab than for adalimumab. This is consistent with the findings of several previous studies in PsA [25, 29, 32, 33], as well as in psoriasis in general [32–34], where these two bDMARDs have been compared. In addition, the EXCEED randomized clinical trial comparing secukinumab to adalimumab also reported superior persistence with secukinumab (86% versus 76%) [35]. However, it should be noted that not all studies have reported a difference in persistence between secukinumab and adalimumab [14, 28, 36, 37].

Only certain adverse events of interest, previously characterized for bDMARDs, were evaluated. The incidence of these adverse events was relatively low (< 10%) in both treatment groups, consistent with the findings of the EXCEED study [35]. However, nine in-hospital deaths were observed in the adalimumab group

Table 2 Usefulness criteria over the follow-up period (after matching)

	Secukinumab (*N* = 171)		**Adalimumab (*N* = 171)**	
	N	***n* (%)**	***N***	***n* (%)**
Overall usefulness rate				
At 6 months	129	53 (41.1%)	112	35 (31.3%)
At 1 year	100	47 (47.0%)	81	18 (22.2%)
At 2 years	53	23 (43.4%)	38	7 (18.4%)
At 3 years	26	11 (42.3%)	19	5 (26.3%)
High adherence				
At 6 months	129	105 (81.4%)	112	91 (81.3%)
At 1 year	100	94 (94.0%)	81	68 (84.0%)
At 2 years	53	49 (92.5%)	38	29 (76.3%)
At 3 years	26	24 (92.3%)	19	16 (84.2%)
No switch to another PsA therapy				
At 6 months	129	129 (100.0%)	112	112 (100.0%)
At 1 year	100	100 (100.0%)	81	81 (100.0%)
At 2 years	53	53 (100.0%)	38	38 (100.0%)
At 3 years	26	26 (100.0%)	19	19 (100.0%)
No dose escalation over time				
At 6 months	129	100 (77.5%)	112	73 (65.2%)
At 1 year	100	76 (76.0%)	81	50 (61.7%)
At 2 years	53	40 (75.5%)	38	16 (42.1%)
At 3 years	26	18 (69.2%)	19	10 (52.6%)
No addition of csDMARD				
At 6 months	129	102 (79.1%)	112	77 (68.8%)
At 1 year	100	78 (78.0%)	81	53 (65.4%)
At 2 years	53	41 (77.4%)	38	28 (73.7%)
At 3 years	26	22 (84.6%)	19	13 (68.4%)
No increase in use of systemic glucocorticoids				
At 6 months	129	124 (96.1%)	112	106 (94.6%)
At 1 year	100	99 (99.0%)	81	74 (91.4%)
At 2 years	53	51 (96.2%)	38	35 (92.1%)
At 3 years	26	26 (100.0%)	19	19 (100.0%)

Table 2 continued

	Secukinumab ($N = 171$)		Adalimumab ($N = 171$)	
	N	*n* (%)	*N*	*n* (%)
≤ 1 intra-articular glucocorticoid injection				
At 6 months	129	102 (79.1%)	112	91 (81.3%)
At 1 year	100	83 (83.0%)	81	68 (84.0%)
At 2 years	53	43 (81.1%)	38	36 (94.7%)
At 3 years	26	21 (80.8%)	19	18 (94.7%)

csDMARD conventional synthetic disease-modifying antirheumatic drugs, *PsA* psoriatic arthritis

Table 3 Adverse events of interest occurring throughout the follow-up (before matching)

Adverse event	Secukinumab ($N = 182$)	Adalimumab ($N = 352$)
Any adverse event of interest	14 (7.7%)	32 (9.1%)
Inflammatory bowel diseases	2 (1.1%)	5 (1.4%)
Anaphylactic reactions	1 (0.5%)	3 (0.9%)
Neutropenia	0 (0.0%)	1 (0.3%)
Erythroderma (exfoliative dermatitis)	0 (0.0%)	0 (0.0%)
Serious infections	11 (6.0%)	18 (5.1%)
In-hospital death	0 (0.0%)	9 (2.6%)

Data represent the number of patients (%) presenting the adverse event over the course of the study

Individual patients could experience more than one adverse event (or experience an adverse event and die). For this reason, the individual events listed are not mutually exclusive

(none in the secukinumab group). It is possible that the lower mortality and incidence of adverse events with secukinumab observed in the present study indicated better tolerability, which may have contributed to the higher persistence. Given the low absolute numbers, this difference is nonetheless difficult to interpret. However, tolerability cannot be the only explanation for the difference in persistence since, in the EXCEED trial, the safety profiles of the two bDMARDs were very similar. Alternatively, the risk of attenuation of the treatment effect due to development of neutralizing antibodies may not be the same for the two antibodies due to differences in immunogenicity [38].

In most patient subgroups analyzed, persistence was similar to that observed in the total population, and persistence with secukinumab was superior to persistence with adalimumab. However, between-group differences were not always significant, which may be explained by low patient numbers and limited statistical power. Persistence appeared better in bDMARD-naïve patients than in bDMARD-experienced patients, a finding which has been reported elsewhere with secukinumab and other bDMARDs [13, 17, 36, 39]. We did not observe any difference in persistence between men and women, in contrast to a number of previous studies [33, 36, 39–41]. We observed much lower persistence

for patients consulting in hospital departments other than those which typically manage patients with PsA in Japan (dermatology, rheumatology, orthopedics, or internal medicine). A recent cross-sectional questionnaire survey involving physicians for the clarification of the diagnosis of PsA in Japan suggested some differences in daily clinical practice between clinical departments [42]. Therefore, this unanticipated finding may reflect less information provided about the risks of not treating PsA and the importance of persistence than would be expected in departments where PsA care is generally managed in Japan [43].

The usefulness of treatment was also higher in the secukinumab group than in the adalimumab group. Usefulness is a composite measure of indices of adherence and of treatment intensification [20], so it can be taken as a proxy marker for effectiveness and acceptability, which are otherwise difficult to determine in database studies. In Japan, physicians are allowed to increase the dose of adalimumab from 40 to 80 mg in case of inadequate efficacy. At 3 years, such a dose increase had been made in 47.4% of patients. For secukinumab, the Japanese prescribing information recommends the full dose of 300 mg in all patients except in underweight patients who may use a lower dose of 150 mg.

A major limitation intrinsic to such database studies is the limited clinical information available in the MDV database. In particular, there is no information on disease severity or activity which would enable computation of standard composite measures, such as the Disease Activity Index for Psoriatic Arthritis (DAPSA) or minimal disease activity (MDA) status. The availability of such indices would have been useful firstly for inclusion in the propensity score to ensure that the secukinumab and adalimumab groups were adequately matched for disease activity, and secondly to estimate how many patients actually achieved remission or low disease activity on each treatment. In addition, the reasons for bDMARD discontinuation are not documented. In previous studies, lack of efficacy has been the principal reason for discontinuation of bDMARDs [7, 13, 16] but this cannot be evaluated in the present study. Mortality is probably underestimated as only deaths in MDV-participating hospitals are documented. Adverse events may also be underestimated if they were managed in another hospital; for example, patients experiencing anaphylactic shock are likely to be treated in the nearest hospital, which may not be the one where they are managed for PsA. On the contrary, if a patient is managed in two different hospitals there is a risk that they will be included in the study twice, or that the date of initial PsA diagnosis is not attributed correctly. Finally, the size of the study population is insufficient to explore persistence in certain patient subgroups (for example, patients with concomitant methotrexate) and certain determinants of bDMARD persistence (including disease severity [44]) are not documented in the MDV database.

CONCLUSIONS

In conclusion, this study demonstrated that 12-month persistence with secukinumab in the real-world treatment setting in Japan was 68.3% with a median persistence of 27.8 months. After performing propensity score matching, it was observed that the percentage of patients remaining on secukinumab was twice as high as those remaining on adalimumab. However, since PsA is a long-term chronic and progressive disease, physicians should take the necessary steps to encourage their patients to continue with their original prescribed medication for as long as it is of benefit. Nonetheless, they should ensure that alternative treatment options are available and can be initiated quickly in case a patient needs to interrupt treatment with secukinumab.

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Data Availability. The data that support the findings of this study are available from MDV but restrictions apply to their availability, which were used under license for the current study, and so are not publicly available. Reasonable requests for access to the data can be addressed to the authors who will put the applicant in contact with the database managers.

Declarations

Conflict of Interest. Hideto Kameda has received speaker's fees from AbbVie, Asahi Kasei, AstraZeneca, Boehringer, Bristol Myers Squibb, Eisai, Eli Lilly, Johnson & Johnson Innovative Medicine, Mitsubishi-Tanabe, Novartis, Pfizer and UCB, consultancy fees from AbbVie and Sanofi, and research grants from Asahi Kasei, Boehringer, Chugai, Eisai, Mitsubishi-Tanabe, Pfizer and Taisho. Kentaro Ishii, Junna Kiriyama, Toshiaki Mikami are employees of Novartis, who manufactures and co-markets secukinumab in Japan. Hideya Uratsuji is an employee of Maruho, who co-markets secukinumab in Japan. Akimichi Morita has received research grants, consultancy fees or speaker's fees from AbbVie, Amgen, Boehringer-Ingelheim, Bristol Myers Squibb, Eisai, Eli Lilly, Johnson & Johnson Innovative Medicine, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB Japan, and Ushio.

Ethical Approval. The study complied with all relevant international and Japanese national legislation on medical research and data privacy. In particular, it complied with the Declaration of Helsinki and with the Japanese Act on the Protection of Personal Information. The requirement for ethics approval and informed consent is regulated by the Japanese Pharmaceuticals and Medical Devices Agency guidelines for conducting pharmaco-epidemiological research using medical databases. In accordance with these guidelines, the study was not subject to an ethics review as anonymized processed information has already been created by the data provider (as stipulated in Article 2, Paragraph 6 of the Personal Information Protection Act). Collecting patient consent to participate is not relevant to this study since the data came from an administrative healthcare insurance database in which all patient data is anonymized and the individual patients whose data is used cannot be identified.

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