RMD Open
Rheumatic & Musculoskeletal Diseases

SHORT REPORT

Impact of the time of initiation and line of biologic therapy on the retention rate of secukinumab in axial spondyloarthritis (axSpA): data from the French multicentre retrospective FORSYA study

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To cite: Dougados M, Lardy-Cléaud A, Desfleurs E, *et al*. Impact of the time of initiation and line of biologic therapy on the retention rate of secukinumab in axial spondyloarthritis (axSpA): data from the French multicentre retrospective FORSYA study. *RMD Open* 2024;**10**:e003942. doi:10.1136/rmdopen-2023-003942

Received 24 November 2023
Accepted 5 February 2024

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ABSTRACT

Objective To compare the 1-year retention rate of secukinumab in axial spondyloarthritis (axSpA) and its predisposing factors with regard to its time of initiation (eg, right after or remotely from its launch).

Methods Study design: Retrospective multicentre French study of patients with axSpA. Study periods: Two cohorts were evaluated regarding the time of initiation of secukinumab: cohort 1 (C1)—between 16 August 2016 and 31 August 2018—and cohort 2 (C2)—between 1 September 2018 and 13 November 2020. Statistical analysis: The 1-year retention rate of secukinumab was estimated using the Kaplan-Meier method, and the log-rank test was used to compare the retention curves of the two cohorts. Preselected factors (eg, disease characterristics, line and time of secukinumab initiation) of secukinumab retention at 1 year were analysed by univariate and multivariate Cox model regression.

Results In total, 906 patients in C1 and 758 in C2 from 50 centres were included in the analysis. The 1-year retention rate was better in C2 (64% (61%–68%)) vs C1 (59% (55%–62%)) (HR=1.19 (1.02–1.39); p=0.0297). In the multivariate analysis, the line of biologic therapy was the single predictive factor of the 1-year retention rate of secukinumab picked up in both cohorts, with a better retention rate when prescribed as first-line biologic therapy.

Conclusion The better secukinumab retention rate remotely from its launch is explained by its use at an earlier stage of the disease, suggesting a change in the behaviour of prescribing physicians. Our results emphasise the relevance of iterative evaluations of routine care treatments.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Secukinumab, a fully human monoclonal antibody to interleukin-17A, is approved for the treatment of axial spondyloarthritis (axSpA); however, there is a lack of real-world data.

⇒ Real-world evidence is recognised as of great value to better evaluate the effectiveness of a drug in daily practice.

WHAT DOES THIS STUDY ADDS

⇒ In a real-world setting, the secukinumab retention rate after 1 year of treatment in French patients with axSpA was better when administered as the first-line or second-line of therapy than as a third or more line of therapy.

⇒ The percentage of patients receiving secukinumab as first-line or second-line of therapy increased when this analysis was performed remotely from the secukinumab launch time.

HOW MIGHT THIS STUDY AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The evaluation of a new drug in a real-world setting should consider the time of this evaluation regarding the time of its launch.

INTRODUCTION

In addition to clinical trials conducted during drug development, real-world data (RWD) collected postmarket authorisation plays a crucial role in evaluating the safety and effectiveness of treatments. Real-world evidence (RWE), defined by the FDA as clinical evidence derived from analysis of RWD, provides valuable insights that may differ from randomised controlled trials owing to factors such as larger patient populations, longer drug exposure and variations in patient characteristics across different countries.[1] In the field of biologics for chronic inflammatory rheumatic diseases and in particular axial

spondyloarthritis (axSpA), randomised controlled trials predominantly focus on patients naive to biologics or those who have limited exposure to biologics.[2–4] Utilisation of RWD to generate evidence necessitates high-quality data. Data availability is a pivotal component of data quality when assessing drug efficacy in axSpA. It is tempting to refer to tools recommended by international and national scientific societies.[5 6] Composite indices such as assessment in ankylosing spondylitis (ASAS) response criteria[7] and ASAS-endorsed disease activity score[8] are among these recommended tools. However, these composite indices are often not collected or reported in routine clinical practice.[9 10] On the other hand, a single outcome measure that evaluates both efficacy and safety (eg, efficiency) may be more relevant than tools focusing solely on efficacy. In chronic inflammatory rheumatic diseases, a disease-modifying antirheumatic drug (DMARD), particularly biologic DMARD (bDMARD), is continued over time as long as it maintains an acceptable efficacy and safety profile. This is why, in RWD studies, the percentage of patients still on treatment over time, known as the drug retention rate, has been proposed as a surrogate measure of drug efficiency.[11–13] Studies conducted by pharmaceutical companies after drug approval are referred to as postmarketing surveillance studies.[13] These studies are often based on RWD and are typically conducted shortly after the drug becomes available in a specific country (launch time), particularly when mandated by health authorities. Previous RWD on the use of secukinumab in axSpA in France revealed that it was primarily prescribed as a third-line or even later biologic therapy, likely due to patients who had not responded to multiple antitumour necrosis factor (TNF) therapy seeking a new treatment option.[14] This aforementioned analysis was conducted on patients receiving secukinumab right after its launch in France.

We hypothesised that the observed data might differ if the analysis had been conducted at a different time, especially further from the initial launch of secukinumab in France.

Building on these findings, we conducted a study to evaluate the retention rate of secukinumab and any changes in its ranking order of administration, further from its initial launch in France.

METHODS

Study design

A retrospective multicentre French study of patients with axSpA (1) having initiated and received at least one dose of secukinumab and (2) with at least a 1-year follow-up.

Table 1 Population characteristics according to cohort

Population characteristics	Cohort 1* (n=906)	Cohort 2 (n=758)
Age (years), mean (SD); n	46.2 (11.7); n=906	47.0 (12.2); n=758
Male, n/N (%)	382/906 (42.2)	330/758 (43.5)
Body mass index (kg/m^2), mean (SD); n	27.0 (5.5); n=533	26.9 (5.3); n=571
Current smoker, n/N (%)	231/715 (32.3)	182/663 (27.5)
Disease duration, years, mean±SD	9.3 (9.1); n=807	9.0 (9.7); n=683
Human leucocyte antigen-B27+, n/N (%)	527/825 (63.9)	430/710 (60.6)
Sacroillitis (MRI) or sSIJ structural damage (X-ray); n/N (%)	665/854 (77.9)	538/696 (77.3)
Past or present arthritis or synovitis, n/N (%)	258/803 (32.1)	233/696 (33.5)
Past or present enthesitis, n/N (%)	314/756 (41.5)	271/668 (40.6)
Past or present extrarheumatological manifestations, n/N (%)	467/690 (37.2)	240/689 (34.8)
► Inflammatory bowel disease, n/N (%)	22/878 (2.5)	19/709 (2.7)
► Psoriasis, n/N (%)	199/791 (25.2)	167/636 (26.3)
► Uveitis, n/N (%)	131/859 (15.3)	91/708 (12.9)
≥1 objective sign of inflammation, n/N (%)†	617/715 (86.3)	519/636 (81.6)
Number of biologic therapies received before secukinumab, mean±SD; n	2.7 (1.7); n=899	2.0 (1.5); n=748
Concomitant treatments at secukinumab initiation		
Non-steroidal anti-infllammatory drugs, n/N (%)	367/755 (48.6)	291/610 (47.7)
Conventional synthetic disease-modifying antirheumatic drugs, n/N (%)	128/906 (14.1)	86/758 (11.3)

Obective sign of inflammation, C reactive protein ≥5 mg/L and/or MRI inflammation at the sacroiliac or spine level.
*Cohort 1=patients who initiated secukinumab right after its launch in France. Cohort 2=patients who initiated secukinumab remotely from its launch in France.
† Presence of a) inflammation at the Sacrolliac Joint or spine level at MRI or b) CRP> 5mg/l.
SiJ, sacroiliac joint.

Study periods

Two cohorts were evaluated with respect to the time of initiation of secukinumab: cohort (C1)—between 11 August 2016 (the time of the launch of secukinumab in France) and 31 August 2018—and cohort 2 (C2)—between 1 September 2018 and 13 November 2020, further from the launch. The detailed description and results of C1 have been reported previously.[14] The methodology for C2, including the selection of the centres, patient inclusion criteria and data collection procedure, was identical to those in C1.

Statistical analysis

The 1-year retention rate of secukinumab was estimated using the Kaplan-Meier method, and the log-rank test was used to compare the retention curves of the two cohorts. Preselected factors potentially affecting secukinumab retention at 1 year (≥1 objective sign of inflammation (C reactive protein (CRP) >5 mg/L, MRI inflammation at the sacroiliac or spine level), age, sex, body mass index, smoking, human leucocyte antigen (HLA)-B27, non-radiographic versus radiographic axSpA, past or present uveitis, inflammatory bowel disease (IBD), psoriasis, arthritis, synovitis, diagnostic delay (time lag between the date of the first symptoms and the date of the diagnosis), disease duration, secukinumab line of biologic therapy, secukinumab maintenance dose, concomitant csDMARD, oral corticosteroids, proton pump inhibitor at secukinumab initiation, history of depression or fibromyalgia (based on the opinion of the treating physician) were analysed using multivariate Cox model regression. Only variables with less than 20% missing data were included in the model after multiple imputations and stepwise selection (significance level for entering variables=20% and for removing variables=10%). Two multivariate analyses have been conducted (one for C1 and one for C2) to identify predictive factors for 1-year retention.

To further evaluate the impact of secukinumab time of initiation on the 1-year retention rate, an ancillary analysis was performed where the groups of patients were defined by the calendar year of its initiation: group I: patients initiating secukinumab between 11 August 2016 and 31 August 2017; group II: between 1 September 2017 and 31 August 2018; group III: between 1 September 2018 and 31 August 2019 and group IV: after 1 September 2019. Thereafter, the 1-year retention rate of secukinumab was estimated in these four groups (Kaplan-Meier technique) and compared using the log-rank test. Finally, univariate and multivariate analyses were performed on the whole population of the study in order to pick up associated or predisposing factors of this retention rate; for this purpose, all the covariates of interest were included, especially the aforementioned four groups and also the line of biologic therapy.

Ethics

The study was registered with the Health Data Hub and conducted in accordance with the Guidelines for Good Pharmacoepidemiology Practices of the International Society for Pharmacoepidemiology. All patients were individually informed of this study and had the opportunity to refuse the extraction of the data contained in their medical files.

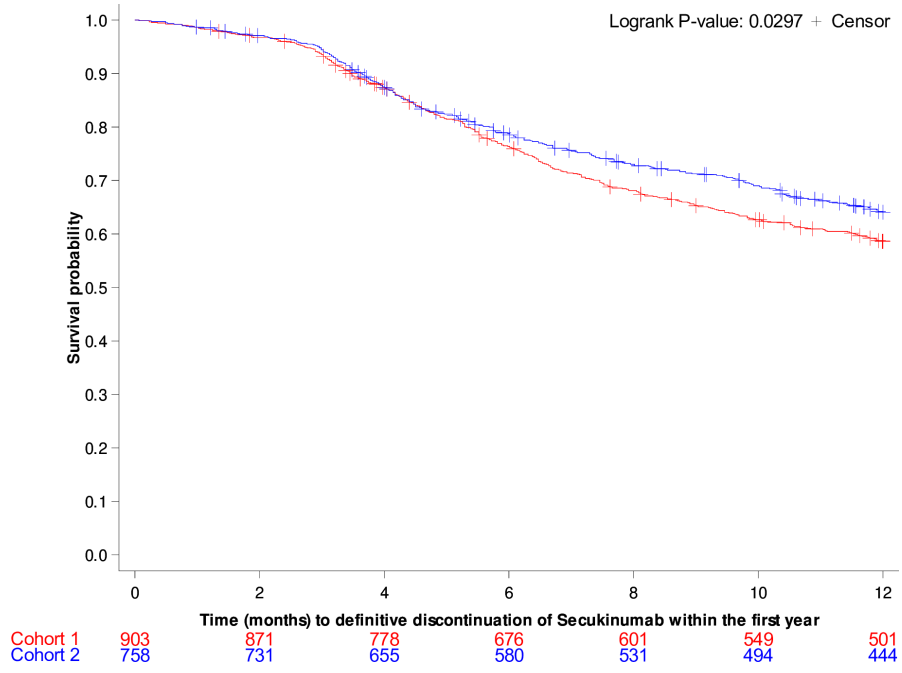

Figure 1 Retention until 1 year of secukinumab according to the cohort.

Table 2 Impact of secukinumab line of biologic therapy on secukinumab retention rate at 1 year with regard of its time of initiation (cohort 1 vs cohort 2*)

Secukinumab line (L) (* reference)	Survival probability at 1 year (95% CI)†	Adjusted HR (95% CI)‡	P vs ref	P type III
Cohort 1				
► First L (n=68, 8%)*	70% (59% to 81%)			0.084
► Second L (n=132, 15%)	62% (54% to 70%)	1.53 (0.91 to 2.57)	0.107	
► ≥Third L (n=676, 77%)	57% (53% to 61%)	1.67 (1.06 to 2.62)	0.028	
Cohort 2				
► First L (n=93, 13%)*	78% (69% to 86%)			0.007
► Second L (n=192, 27%)	63% (56% to 70%)	1.92 (1.18 to 3.13)	0.009	
► ≥Third L (n=437, 60%)	62% (57% to 66%)	2.11 (1.32 to 3.35)	0.002	

*Cohort1=patients who initiated secukinumab right after its launch in France. Cohort 2=patients who initiated secukinumab remotely from its launch in France.
†Estimated % with its 95%CI (Kaplan Meier Technic).
‡Adjustment on: cohort 1 (objective sign of inflammation, Inflammatory bowel disease, history of depression or anti-depressive concomitant treatment). Cohort 2 (objective sign of inflammation, History of depression or antidepressive concomitant treatment, disease duration and corticosteroids).

RESULTS

Patients' characteristics

A total of 901 patients in C1 and 758 in C2 from 50 centres were included in the analyses.

Their characteristics are summarised in table 1 and were similar in both cohorts except for the number of biologic therapies (eg, anti-TNF) received before secukinumab initiation (2.7±1.7 in C1 vs 2.0±1.5 in C2). Moreover, the percentage of patients receiving secukinumab as the first-line, second-line or ≥third-line therapy in C1 versus C2 was 8% vs 13%, 15% vs 27% and 77% vs 60%, respectively. In particular, the percentage of patients receiving secukinumab either as the first-line or second-line biotherapy increased from 23% in C1 to 40% in C2.

Secukinumab retention rate at 1 year

The 1-year retention rate of secukinumab was higher in C2 compared with C1 (64% (61%–66%) vs 59% (55%–62%), respectively, HR=1.19 (1.02–1.39), p=0.0297)) (see figure 1). In both cohorts, patients mainly discontinued secukinumab for inefficacy or intolerance: 74.4% or 20.5% in C1 and 78.1% or 16.4% in C2.

While dividing the patients by the calendar year of initiation of secukinumab (four groups), the estimated 1-year retention rate of secukinumab was 58% (54%–62%) vs 60% (54%–64%) vs 61% (58%–66%) vs 67% (62%–72%) in group I (n=538) vs group II (n=365) vs group III (n=401) vs group IV (n=357), respectively (log-rank p value=0.069)

Predictive factors of secukinumab retention at 1 year

The line of biologic therapy was the single predictive factor of a better 1-year retention of secukinumab picked up in the two multivariate analyses (one for each cohort) (see table 2). In C1, the secukinumab 1-year retention rate increased from 57% to 70% when secukinumab was initiated as the >third-line therapy and as the first-line therapy, respectively. The magnitude of this increase was similar in C2 (62%–78%).

In the analysis performed in the whole population of the study in order to pick up predisposing or associated factors of the 1-year retention rate of secukinumab, we observed that in the univariate analysis, there was a trend in favour of the year of initiation (eg, the above four groups) (p=0.070) with a higher risk of secukinumab discontinuation for groups I (HR=1.35 (1.08–1.69), p=0.009) and II (HR=1.28 (1.00–1.64), p=0.049) versus group IV; this trend disappeared in the multivariate analysis (p=0.242), while, in this analysis, the line of biologic therapy was the most important predisposing factor (p<0.001).

DISCUSSION

These data confirm that the retention rate of a DMARD (in particular, a bDMARD) in chronic inflammatory rheumatic diseases, such as axSpA, is highly influenced by its ranking order of administration as a biologic therapy. Additionally, these data suggest that this ranking order may vary over time due to different factors, including the confidence and experience that physicians have in this treatment.

This study has several strengths but also some weaknesses.

Our primary objective was to assess the drug retention rate rather than specific outcome measures such as composite indices for efficacy or a detailed description of side effects for safety. Retention rate as an outcome measure of drug efficiency has been criticised because non-medical factors have been reported to influence such outcome; for example, it has been previously reported that the country where secukinumab was used might have an impact on outcomes,[15] it has to be emphasised that our study aimed to compare the retention rate of secukinumab in two cohorts differing only by the time when the study was conducted (ie, immediately after the availability of secukinumab in France for C1 and remotely from this launch for C2). However, one can argue that the 2 years difference

between the two cohorts may not have been sufficient to draw firm conclusions. The results observed in the analysis evaluating the four groups of patients according to the calendar year of initiation of secukinumab showed also a trend in favour of a better retention rate when secukinumab has been initiated remotely from the launch (67% vs 58% when initiated after August 2019 vs between August 2016 and August 2017).

The ranking order of administration of a biologic is a critical parameter considered in the drug development programmes (eg, phase II and III trials). The limitation of these trials to biologic-naive patients or those who have only received one or two biologics is certainly explained by the negative impact of this parameter on the drug efficacy. This parameter is arguably the most important one when comparing patients participating in a clinical trial to those receiving the drug in daily practice. However, this parameter is sometimes overlooked when comparing the retention rate of different drugs.[16]

While investigating the predisposing factors of a retention rate, the ranking order of DMARD administration is consistently retained in multivariate analysis as statistically significant[13 14 17] with a better drug retention rate when the drug was initiated as the first or second biologic line therapy.

Our study confirms these previously reported findings with the line of therapy as the most important predisposing factor of the 1-year secukinumab retention rate in the multivariate analysis performed in the whole group of patients, but our findings also highlight that this ranking order of administration may change over time. As previously mentioned, one of the strengths of our study is that the single parameter that differed between the two cohorts was the timing of secukinumab initiation. Clearly, all other parameters (country, centres, data collection process, etc) were identical between the two cohorts.

The better retention rate in C2 in comparison to C1 can be attributed to the higher percentage of patients receiving secukinumab as a first-line or second-line biotherapy and likely reflects changes in the behaviour of prescribing physicians with increased confidence in this treatment.

Therefore, these data underscore the importance of ongoing evaluations of treatments, particularly bDMARDs in daily practice over time.

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Acknowledgements The authors thank the patients who participated in this study. The following abstract was presented at EULAR 2023. POS1123: Impact of the time of initiation and line of biologic therapy on the retention rate of secukinumab (SECU) in axial spondyloarthritis (AxSpa). data from the French multicenter retrospective FORSYA study.

Contributors All authors were involved in the drafting and critical review of the manuscript and approved the final version for submission. MD, PC, PG, ARW, AS, AT, DW and CL were involved in the acquisition of clinical data and participated as investigators in the clinical study. MD, ED, PC, PG, ARW, AS, AT, DW and CL were involved in the conception of the study. ALC was involved in the statistical analysis of the data. All authors were involved with the interpretation of the results. All authors agreed to be accountable for all aspects of the work and attest to the accuracy and integrity of the work.

Funding NOVARTIS France financially supported this study.

Competing interests MD: grant/research support from AbbVie, Eli Lilly, Merck, Novartis, Pfizer and UCB Pharma; consultant of AbbVie, Eli Lilly, Merck, Novartis, Pfizer and UCB Pharma; speakers bureau: AbbVie, Eli Lilly, Merck, Novartis, Pfizer and UCB Pharma. ALC: employee of RCTs, a CRO provider on behalf of Novartis Pharma. ED: employee of Novartis with stocks. PC: research grants, consultant and speaker fees from AbbVie, Bristol Myers Squibb, Janssen, Lilly, Merck Sharp & Dohme, Novartis, Pfizer and UCB. PG: research grants, consultation fees or speaker honoraria from AbbVie, Amgen, Biogen, BMS, Celgene, Chugai, Janssen, Lilly, Medac, MSD, Nordic Pharma, Novartis, Pfizer, Sanofi and UCB. ARW: consulting (Pfizer, AbbVie, Novartis, Lilly and Janssen); honoraria (AbbVie, Bristol-Myers Squibb, Galapagos, Fresenius-Kabi, Mylan-Viatris, MSD, Novartis, Lilly, UCB, Pfizer, Roche-Chugai and Sanofi) and support for attending meetings (Abbvie, Amgen and Fresenius-Kabi). AS: research grants, consultant fees and speaker fees from AbbVie, Bristol Myers Squibb, Lilly, MSD, Nordic, Novartis, Pfizer, Roche-Chugai and UCB. AT: research grants, consultant fees and speaker fees from AbbVie, Fresenius-Kabi, Janssen, Lilly, MSD, Novartis, Pfizer, Roche-Chugai and Sanofi. DW: financial interests: none; lasting or permanent links: none; occasional interventions: AbbVie, BMS, MSD, Pfizer, Roche Chugai, Amgen, Nordic Pharma, UCB, Novartis, Lilly, Sandoz and galapagos; and indirect interests: AbbVie, Pfizer, MSD, UCB, galapagos and Fresenius Kabi. CL: research grants, consultant fees and speaker fees from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Fresenius, Janssen, Lilly, MSD, Novartis, Pfizer, Roche Chugai and UCB.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval This study involves human participants. The study was registered with Health Data Hub and conducted in accordance with the Guidelines for Good Pharmacoepidemiology Practices of the International Society for Pharmacoepidemiology (2015).

Provenance and peer review Not commissioned; externally peer reviewed.

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