Retention rate and predictors of discontinuation for secukinumab treatment: real-life data in a cohort of patients with spondyloarthritis

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Abstract

Objective

This study evaluated the real-world retention rate and predictors of discontinuation for secukinumab therapy in patients with spondyloarthritis (SpA).

Methods

This observational, retrospective cohort study included SpA patients treated with secukinumab at a referral centre. Baseline demographic and clinical data were recorded, covering comorbidities, prior biologic/targeted synthetic therapies, and disease duration. Secukinumab retention rates were analysed at 12 months and at the end of the study (last observation or discontinuation). Drug retention rate (DRR) was assessed using time-to-discontinuation, with log-rank testing for comparisons. Cox proportional hazards regression models identified baseline predictors of discontinuation.

Results

A total of 178 patients (64.6% female) were included. The overall DRR for secukinumab was 64%, with the highest retention rate of 78% at 1 year. Discontinuation reasons included secondary inefficacy (57.8%), primary inefficacy (25%), and adverse events (17.2%), with infections being the most common adverse event. Higher body mass index (BMI) (HR 1.07, 95% CI: 1.02–1.12, p=0.010) and previous treatments (HR 1.34, 95% CI: 1.03–1.73, p=0.030) predicted long-term discontinuation. For 12-month discontinuation, peripheral phenotype (HR 4.28, 95% CI: 1.26–14.48, p=0.019) and prior biologic/targeted synthetic therapies (HR 1.76, 95% CI: 1.24–2.51, p=0.002) were predictors, while axial involvement was protective (HR 0.37, 95% CI: 0.17–0.83, p=0.016).

Conclusion

Secukinumab demonstrates sustained effectiveness in SpA patients, with a significant proportion maintaining therapy over time. Retention is influenced by BMI, prior treatments, and disease phenotype, suggesting that outcomes may be optimised through tailored patient selection and early intervention.

Key words

spondyloarthritis, secukinumab, real-world data, drug discontinuation, treatment outcomes, predictors

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Introduction

Spondyloarthritis (SpA) encompasses a group of chronic inflammatory diseases that include inflammatory back pain, peripheral arthritis, enthesitis, uveitis, psoriasis (PsO), and inflammatory bowel disease (IBD) (1-3). SpA affects 2–3% of the population and accounts for about 5% of chronic lower back pain (4).

SpA is classified into axial (axSpA) and peripheral forms; axSpA includes non-radiographic (nr-axSpA) and radiographic types, with the latter also known as ankylosing spondylitis (AS) (1, 5). Symptoms such as chronic back pain and stiffness often begin in early adulthood, affecting quality of life (1, 6). AS, the more severe form of axSpA, leads to chronic inflammation and osteoproliferation in the spine, causing structural damage (7). Comorbidities, including cardiovascular diseases, metabolic disorders, and depression, complicate disease management (8).

The advent of biologics, such as TNF inhibitors and interleukin 17A (IL-17A) antagonists, has revolutionised SpA treatment (5). Secukinumab, an IL-17A inhibitor, has shown promising results in managing PsO, psoriatic arthritis (PsA), and AS. Phase III trials have demonstrated significant symptom reduction in AS patients (7), and secukinumab was subsequently approved for AS and nr-axSpA in 2015 and 2020, respectively (8).

Besides clinical trials confirming the clinical efficacy of secukinumab (9-12), real-world studies have provided further evidence of its long-term effectiveness. Notably, drug retention rate (DRR) and factors influencing drug persistence have been investigated (13-15), revealing differences across SpA phenotypes and associated comorbidities.

This study aims to further evaluate the real-world impact of secukinumab by assessing its DRR and identifying key factors influencing treatment discontinuation in patients with SpA. Our research seeks to provide a deeper understanding of how patient characteristics, such as comorbidities and prior treatments, affect long-term therapy outcomes, contributing to the growing body of evidence supporting the sustained efficacy of secukinumab in patients with SpA.

Patients and methods

Study design and population

This is a real-world, observational, retrospective cohort study conducted at the Academic Rheumatology Center of Mauriziano Hospital in Turin – Department of Clinical and Biological Sciences, University of Turin. Patients with AS, PsA, or nr-axSPA who began secukinumab treatment by February 2023 were included in the study.

Inclusion and exclusion criteria

Patients were included if they were aged 18 or older, met classification criteria for AS (based on the modified New York criteria) (16, 17), PsA (CASPAR criteria) (18) or nr-axSpA (ASAS criteria) (19), and were treated with secukinumab. Patients received secukinumab 150 mg or 300 mg (at week 0, 1, 2, 3, 4 then every 4 weeks) according to the judgement of the treating physician in accordance with the manufacturer's instructions (20).

Patients were excluded if there was insufficient data on their treatment adherence or if information on their comorbidities was lacking.

Data collection and variables

Patient demographic and clinical data were collected from medical records, including age, sex, body mass index (BMI), and smoking history (current/former). Disease-related variables included type and duration of SpA diagnosis, clinical manifestations (peripheral arthritis, PsO, enthesitis, uveitis), and comorbidities (*e.g.* cardiovascular diseases, hepatic steatosis, diabetes, malignancies). Prior treatments with conventional synthetic disease-modifying anti-rheumatic drugs (DMARDs) and biologic/targeted synthetic DMARDs were recorded, as well as the number and types of biologic therapies used before secukinumab initiation.

Outcome measures

The primary outcome was secukinumab DRR, defined as the time to drug discontinuation. Secondary outcomes included predictors of discontinuation,

such as BMI, the number of prior biologic therapies, and the presence of peripheral involvement. Safety outcomes were assessed by recording adverse events (AEs) during treatment, including infections, gastrointestinal complications, cardiovascular events, and malignancies.

Statistical analysis

Descriptive statistics were used to summarise baseline demographic and clinical characteristics. Depending on the data distribution, continuous variables were reported as means and standard deviations or medians and interquartile ranges (IQRs). Categorical variables were presented as frequencies and percentages. DRR was assessed as the time to drug discontinuation using the log-rank test for comparison. Cox proportional hazards regression was employed to identify predictors of secukinumab discontinuation. Hazard ratios (HRs) and 95% confidence intervals (CIs) were reported for each predictor variable. Both univariable and multivariable analyses were performed. In the multivariable analysis, we adjusted for clinical baseline confounders and tested variables with potential clinical relevance (21). Stepwise regression was used to assess the variables that retained significance in the multivariable analysis. A significance threshold of α=0.05 was set. Statistical analyses were performed using IBM SPSS Statistics v. 29.0.1.

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki and received approval from the Institutional Ethics Committee of the Interagency Territorial Ethics Committee A.O.U. Città della Salute e della Scienza, protocol code no. 277/2023, approved on 09/13/2023.

Results

Demographic and clinical characteristics of patients

The study population consisted of 178 patients diagnosed with SpA, including AS, PsA, and nr-axSpA. All patients were treated with secukinumab and followed up for a median duration of 20 months (IQR 9–39). The cohort included 64.6% women, with a median age at diagnosis of 48 years (IQR 42–56) and a median BMI of 26.9 kg/m^2 (IQR 23.8–31.2). Smoking history was reported in 29.2% of patients. The median disease duration at the start of secukinumab treatment was 2 years (IQR 1–7). PsA was the most common diagnosis (79.2%), followed by AS (14.0%) and nr-axSpA (6.7%). Regarding clinical manifestations, 69.7% of the cohort had peripheral arthritis, 61.2% had PsO, 52.3% had axial involvement, and 40.4% had enthesitis involvement. All these data are summarised in Table I.

As shown in Table II, 64% of patients remained on secukinumab at the last observation point. Overall, 52 (29%) of patients underwent an increase in the monthly dosage from 150 mg to 300 mg. Patients experiencing a dose escalation remained on secukinumab throughout follow-up in 75% *versus* 60% of patients not escalating the dosage (p=0.059).

A total of 78 (43.8%) patients experienced failure with one prior biologic/targeted synthetic DMARDs, 28 (15.7%) with two biologics/targeted synthetic DMARDs and 16 (9.0%) with three or more. Additionally, 56 (31.5%) patients were biologic-naive.

Comorbidities were common, with the most prevalent conditions being arterial hypertension (34.8%), hepatic steatosis (22.5%), hyperlipidaemia (22.0%), and diabetes (11.8%). Cardiovascular issues affected 18.5% of patients. Additionally, 6.2% had nephropathy, further

Table I. Demographic and disease characteristics.

	n (%) or median (IQR 25th–75th)
Total patients	178 (100%)
Sex	
Females	115 (64.6%)
Males	63 (35.4%)
Weight (kg)	78 (67.2–87.2)
Height (cm)	168 (161–175)
BMI (kg/m^2)	26.90 (23.8–31.2)
Age at diagnosis (years)	55 (48–61)
Disease duration from diagnosis to secukinumab prescription (years)	2 (1–7)
Dosage	
300 mg	94 (52.8%)
150 mg	84 (47.2%)
Therapy duration at discontinuation or last follow-up (months)	20 (9–39)
Smoking history (current or past)	52 (29.2%)
Diagnosis	
PsA	141 (79.2%)
AS	25 (14.0%)
Non-radiographic SpA	12 (6.7%)
Clinical characteristics	
Peripheral involvement	124 (69.7%)
Psoriasis	109 (61.2%)
Axial involvement	93 (52.3%)
Enthesis involvement	72 (40.4%)

BMI: body mass index; PsA: psoriatic arthritis; AS: ankylosing spondylitis

Table II. Secukinumab therapy and previous therapies.

Therapy	n (%)
Secukinumab	
Secukinumab ongoing at the last observation	114 (64.0)
Previous therapy	
Failure of 1 bDMARD/tsDMARD n (%)	78 (43.8)
Failure of 2 bDMARDs/tsDMARDs n (%)	28 (15.7)
Failure of 3 or more bDMARDs/tsDMARDs n (%)	16 (9.0)
Biologic-naive	56 (31.5)

bDMARD/tsDMARD: biologic disease-modifying anti-rheumatic drug/targeted synthetic disease-modifying anti-rheumatic drug.

complicating their clinical management. Of particular concern, 10.7% had a personal history of neoplasia with a mean time of 9.8±7.3 years since diagnosis, and 7.9% had a family history of malignancies. The data are summarised in Table III.

Table III. Comorbidities in SpA patients.

	n (%)
Hypertension	62 (34.8%)
Hepatic steatosis	40 (22.5%)
Hyperlipidaemia	41 (22.0%)
Cardiovascular issues	33 (18.5%)
Diabetes	21 (11.8%)
Personal history of neoplasia	19 (10.7%)
Family history of malignancies	14 (7.9%)
Nephropathy	11 (6.2%)
Family history of cardiovascular diseases	8 (4.5%)
Chronic inflammatory bowel disease	1 (0.6)

Predictors of secukinumab discontinuation over the follow-up period

Among the 64 patients (36%) who discontinued secukinumab during the follow-up period, the primary reasons were secondary inefficacy (37 patients), primary inefficacy (16 patients), and AEs (11 patients) (Supplementary Table S1). The median time to discontinuation in the whole cohort was 20 months (IQR 9–39); patients incrementing secukinumab dosage to 300 mg monthly tended to persist longer on drug before withdrawal (time to discontinuation (months): 27 (14.5–39.0) *vs*. 15 (7-37), p=0.076).

There was no significant difference in discontinuation rates based on whether secukinumab was used as a first-, second-, or third-line treatment. However, a trend toward higher discontinuation was observed when used beyond the third line (p=0.094). Cox regression analysis revealed that higher BMI and number of previous treatments independently predicted discontinuation (Table IV); while peripheral involvement showed a trend toward higher discontinuation rates, this was not statistically significant (Table IV). The characteristics of patients who discontinued secukinumab are summarised in Supplementary Table S2.

Table IV. Baseline predictors of discontinuation

	Univariable		Multivariable	
	HR (95% CI)	p-value	HR (95% CI)	p-value
BMI	1.06 (1.0–1.1)	0.017	1.07 (1.0–1.1)	0.010
PsA	1.57 (0.7–3.3)	0.232	–	
PsO	1.14 (0.7–1.9)	0.627	–	
Nr-axSpA	0.21 (0.0–1.5)	0.124	–	
Peripheral involvement	1.69 (0.9–3.1)	0.089	1.80 (0.9–3.5)	0.085
Axial involvement	0.65 (0.4–1.1)	0.083	0.76 (0.4–1.3)	0.333
bDMARD (6 months prior)	1.59 (1.0–2.6)	0.064	–	
Infliximab	2.14 (0.9–5.0)	0.076	0.80 (0.2–2.7)	0.719
Use over third line	1.88 (0.9–4.0)	0.094	–	
Number of treatments before secukinumab	1.40 (1.1–1.8)	0.006	1.34 (1.0–1.7)	0.030.

BMI: body mass index; PSO: psoriasis; PSA: psoriatic arthritis; Nr-axSpA: non radiographic axial spondyloarthritis; bDMARD: biologic disease modifying anti-rheumatic drug.
Cox regression model assessing independent predictors of secukinumab discontinuation (HR: hazard ratio; CI: confidence interval). The model was adjusted for baseline confounders including age, sex, baseline secukinumab dosage and disease duration at the start of secukinumab treatment. Variables included in the multivariable model: BMI, peripheral involvement, axial involvement, infliximab use, and the number of treatments prior to secukinumab initiation.

DRR and predictors of secukinumab discontinuation at 1 year

The DRR in the long-term follow-up was 64%, reaching 77.8% at 12 months, while 22.2% of patients discontinued secukinumab therapy within the first year. Predictors of discontinuation at 1 year included a peripheral phenotype (HR: 4.3; 95% CI: 1.3–14.5; p=0.019) and the number of treatments before secukinumab therapy (HR: 1.8; 95% CI: 1.2–2.5; p=0.002). An axial phenotype was associated with a lower discontinuation rate at 1 year (HR: 0.4; 95% CI: 0.2–0.8; p=0.016) (Fig. 1).

Safety outcomes

Safety outcomes were assessed by recording AEs during treatment. Respiratory infections, including COVID-19, were the most common AEs, affecting 20.2% of patients. Other infections included urinary tract infections (2.8%), diverticulitis (0.6%), and candidiasis (1.1%). There was one case of sepsis due to *E. coli*.

Rare AEs included skin reactions (1.1%) and neoplastic events (1.1%), comprising prostate cancer and non-melanoma skin cancer. Among the two patients who experienced neoplastic events, only one had a prior history of cancer unrelated to the current diagnosis. In patients with a history of cancer, no recurrences related to their previous neoplasia were observed during follow-up. Cardiovascular events, such as myocardial infarction and deep venous thrombosis, were observed in 0.6% of patients each. Additionally, there were two new cases of Crohn's disease and one severe relapse of ulcerative colitis, which led to bowel perforation and ischemic colitis. Gastrointestinal symptoms unrelated to IBD or infections were reported in 5.1% of patients. The data are summarised in Table V.

Discussion

This study provides a comprehensive real-world evaluation of the persistence and safety of secukinumab in patients with SpA, including AS and PsA. We documented a DRR of over 64% in the long-term follow-up, reaching 78% at 12 months, and observed that DRR was influenced by disease phenotype. Our findings align with other real-world studies emphasising the effectiveness and retention of secukinumab in SpA patients. For example, the SERENA study demonstrated a 79% DRR at 2 years in patients with AS and PsA (22),

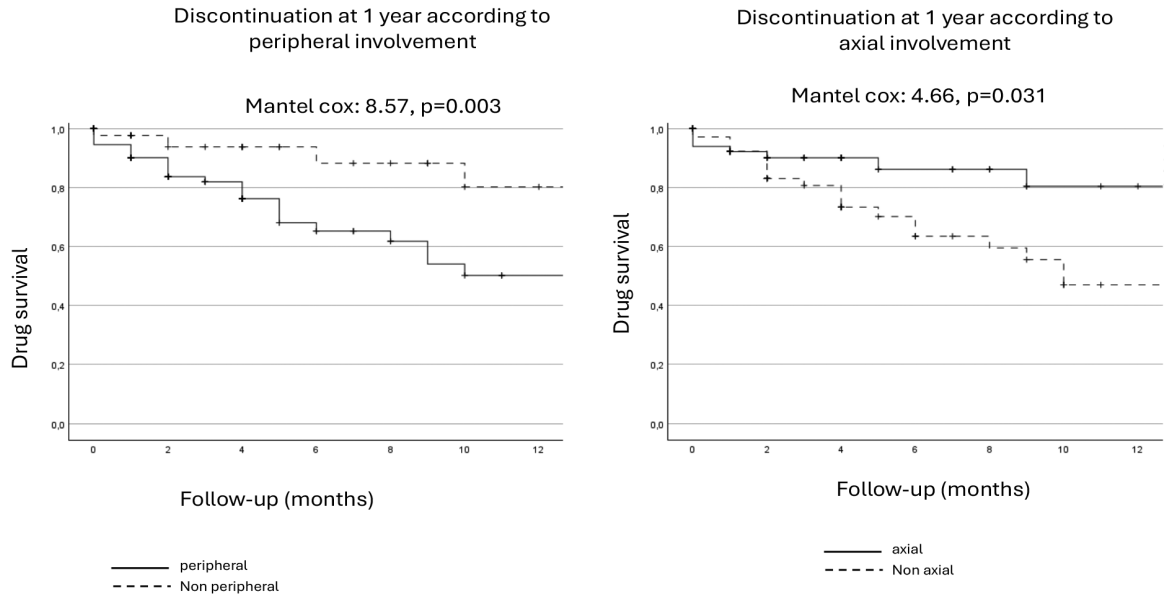

Fig. 1. Secukinumab discontinuation at 1 year based on peripheral and axial involvement.

Table V. Adverse events after secukinumab treatment.

	n (%)
Infections	
Total COVID-19 infection	27 (15.2)
Severe COVID-19 infection	3 (1.7)
Total respiratory infections (including COVID-19 infections)	36 (20.2)
Candidiasis	3 (1.7)
Zoster infection	2 (1.1)
Recurrent HSV infections	2 (1.1)
Urinary infections	7 (3.9)
Diverticulitis	5 (2.8)
Sepsis due to *E.coli* infection	1 (0.6)
Skin reaction	2 (1.1)
Neoplastic disease	
Total	2 (1.1)
Prostate cancer	1 (0.6)
Non-melanoma skin cancer	1 (0.6)
Cardiovascular events	
Myocardial infarction	1 (0.6)
Atrial fibrillation	1 (0.6)
Deep venous thrombosis	1 (0.6)
New onset of IBD	
Crohn's disease	2 (1.1)
IBD relapse	
Severe relapse of ulcerative colitis with bowel perforation and ischemic colitis	1 (0.6)
New onset of chronic kidney disease	1 (0.6)
Gastrointestinal symptoms (excluding IBD and infections)	9 (5.1)

HSV: virus herpes simplex; IBD: inflammatory bowel disease.

while DRR at 12 months ranged from 60% to over 80% across different cohorts (23,24). These observations indicate that secukinumab is effective overall. However, the decline in retention over time, especially among patients with multiple prior treatments, highlights the challenges of maintaining long-term therapy.

Discontinuation due to inefficacy or loss of effectiveness remains a concern in complex cases (24, 25). Previous studies report that 16.7% of patients discontinue secukinumab due to lack of effectiveness (24), aligning with our data. However, in our cohort, secondary inefficacy (*i.e.* loss of effectiveness) accounted for a greater subset of discontinuations (26), representing 57.8% of cases. This finding may advocate for close monitoring and potential combination therapies, particularly in patients with more resistant disease phenotypes (25).

Previous treatments, either biologics or small molecules, predicted discontinuation at any time point in our cohort, consistent with recently published data from other research groups. Ramonda *et al*. demonstrated a 67.4% DRR at 48 months in a large Italian cohort of SpA patients, with biologic-naïve individuals showing improved disease control (15). Similarly, Dougados *et al*. identified prior biologic exposure and the presence of objective signs of inflammation as predictors of 1-year discontinuation (14). These real-world data highlight the need for prompt treatment strategies, potentially introducing anti-IL-17 therapy early in the disease course, particularly in patients with complex comorbidities or extensive treatment histories (27). Notably, a higher proportion of patients increasing the dosage to 300 mg monthly tended to persist on treatment for a longer time span, suggesting that dosage optimisation should be taken into account.

The pattern of articular involvement has been inconsistently associated with DRR. In our cohort, peripheral involvement predicted discontinuation at 1 year, while axial involvement protected against it. Other authors have reported a similar DRR regardless of disease pattern (26), possibly because of follow-up

duration. Indeed, the long-term DRR was not significantly impacted by disease phenotype in our cohort, despite peripheral involvement showing a trend toward discontinuation. This suggests that axial patients with a shorter disease history may maximise the benefits of secukinumab treatment. At the same time, long-standing refractoriness may overshadow the original disease expression pattern in the longer term.

Cardiovascular and metabolic comorbidities significantly impacted drug persistence and efficacy in PsA and AS populations (28). Although comorbidities did not emerge as independent predictors of discontinuation in our cohort, conditions such as hypertension, hepatic steatosis, and hyperlipidaemia were common, highlighting the complex management of SpA. The influence of comorbidities on the DRR of secukinumab remains a topic of interest. While our study did not identify comorbidities as independent predictors of discontinuation, prior research suggests a more nuanced relationship. For instance, Ruscitti *et al*. evaluated the DRR of secukinumab in a real-life cohort of PsA patients and found that generic comorbidities did not negatively impact retention rates. Interestingly, they observed a trend toward improved DRR in patients with cardiometabolic multimorbidities, including hypertension, dyslipidaemia, and type 2 diabetes (29). These findings align with emerging evidence on the role of IL-17A in contributing to both chronic inflammation and metabolic dysfunction, which may explain the observed benefit in these patients. Given the overlapping inflammatory pathways in SpA and cardiometabolic diseases, future studies should explore how personalised treatment approaches could improve long-term outcomes in patients with complex disease profiles.The role of ethnicity and regional differences in drug retention rates is increasingly recognised. For example, Kim *et al*. reported that biologic drug retention in Korean patients with ankylosing spondylitis was influenced by age and disease onset. Similarly, Moskal *et al*. demonstrated that in Central-Eastern Europe, administrative barriers and healthcare system disparities played a role in drug survival. Additionally, Rosenberg *et al*. highlighted differences in drug survival across geographical regions, emphasising the impact of healthcare policies on patient adherence. These findings suggest that drug retention may vary significantly across populations, necessitating further studies to explore ethnicity-related differences in treatment outcomes (30-32). In our study, the potential influence of ethnicity on DRR was not analysed due to the predominance of Caucasian participants in the sample. As a result, the lack of diversity limited our ability to explore ethnic differences in DRR outcomes.

Comorbidities not only increase the disease burden but also influence treatment outcomes. Fattorini *et al*. emphasised that systemic inflammation in SpA patients contributes to an increased risk of cardiovascular events, including atrial fibrillation and major adverse cardiac events (33). These findings underline the importance of considering comorbidities when evaluating long-term treatment persistence and optimising patient management strategies.

In our cohort, 10.7% of patients had a previous history of neoplasia that was in remission at the time of secukinumab prescription. Importantly, no disease recurrences related to their prior neoplastic conditions were observed during the study period. These findings are consistent with previous research suggesting that secukinumab is a safe therapeutic option for patients with a history of neoplasia. (34, 35).

The most common AEs in our cohort were infections, particularly respiratory infections, including COVID-19. While secukinumab was generally well-tolerated, the risk of serious infection and new-onset or flare of IBD, although rare, emphasises the need for careful patient selection and monitoring.

These results reinforce the role of secukinumab as an effective treatment option in real-world settings while underscoring the challenges of maintaining long-term therapy, particularly in patients with complex disease profiles and prior treatment failures.

Limitations of our study include its retrospective design, which is associated with a certain amount of missing data. However, we identified early and late discontinuation predictors in a large real-world cohort of SpA patients, shedding light on the importance of early treatment and patient phenotyping to optimise drug effectiveness. Additionally, the absence of a control group represents a significant limitation, particularly when evaluating treatment efficacy and adverse event profiles. Future prospective studies with control groups are necessary to validate our findings and better understand the long-term impact of secukinumab on both efficacy and safety outcomes.

Conclusion

This real-world study supports the efficacy of secukinumab in managing SpA, demonstrating a remarkable DRR in our cohort. The axial phenotype appears to protect against treatment discontinuation at 1 year. In contrast, peripheral involvement, the number of previous treatments and higher BMI are associated with a higher likelihood of discontinuation throughout follow-up. The occurrence of AEs and secondary inefficacy should be carefully monitored in patients with complex disease profiles and multiple prior treatment failures. Our real-world data contribute to the growing body of evidence on the role of secukinumab in SpA management and emphasise the importance of timely and personalised therapeutic approaches to improve outcomes in refractory patient populations. Further research is needed to optimise treatment strategies and address the unmet needs of these patients.

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