emergent AEs with an IR of 65.2. Serious AEs (≥ 1) were reported for 51 (8.0%) patients with an IR of 6.8. Discontinuations due to AEs were reported for 38 (5.9%) patients with an IR of 5.1. One death was reported, a suicide, in a patient with a documented prior history of depression and judged by the blinded principal investigator to be unrelated to the investigational product. The overall infection IR was 39.4, with both serious and opportunistic infections reported with an IR of 1.7. Among opportunistic infections, no *Tuberculosis* infections or reactivations were reported and the *Candida* infection IR was 1.2. No infections were associated with grade 3 or 4 neutropenia. The confirmed major adverse cardiovascular events IR was 0.1. The malignancy IR was 0.4 with acute promyelocytic leukemia, bladder cancer, and ovarian cancer reported. The depression IR was 0.8. The adjudicated inflammatory bowel disease (IBD) IR was 1.5 with 4 of 11 patients having prior history of IBD. The Anterior uveitis (AU) IR was 3.9 with 24 of 29 patients having prior history of AU. The injection site reaction IR was 11.3.

Table 1. Integrated Safety Outcomes

	n (%)	IR (CI)
Treatment Emergent AEs	489 (76.3%)	65.2 (59.7, 71.3)
Serious AEs	51 (8.0%)	6.8 (5.2, 9.0)
Discontinuation due to AEs	38 (5.9%)	5.1 (3.7, 7.0)
Death	1 (0.2%)	0.1 (0.0, 0.9)
Infections*	295 (46.0%)	39.4 (35.1, 44.1)
Serious Infections	13 (2.0%)	1.7 (1.0, 3.0)
Opportunistic Infections	13 (2.0%)	1.7 (1.0, 3.0)
<i>Candida</i>	9 (1.4%)	1.2 (0.6, 2.3)
<i>Tuberculosis</i>	0	0
Confirmed MACE	1 (0.2%)	0.1 (0.0, 0.9)
Malignancies	3 (0.5%)	0.4 (0.1, 1.2)
Depression	6 (0.9%)	0.8 (0.4, 1.8)
Adjudicated IBD	11 (1.7%)	1.5 (0.8, 2.6)
Anterior Uveitis	29 (4.5%)	3.9 (2.7, 5.6)
Injection Site Reactions	85 (13.3%)	11.3 (9.2, 14.0)

*Infections reported with frequencies $\geq 5\%$ included nasopharyngitis (12.2%), upper respiratory tract infection (10.9%), pharyngitis (4.2%), bronchitis (3.6%), urinary tract infection (2.7%), and gastroenteritis (2.5%).

MACE, major adverse cardiovascular events; IBD, inflammatory bowel disease; AE, adverse event; n, number of patients; IR, incidence rate; CI, 95% confidence interval

Conclusion: The reported safety profile for IXE in r-axSpA is consistent with the profile reported for other indications. During the extension period, the overall safety profile of ixekizumab remained consistent with that observed during the double-blind period of COAST-V and COAST-W.^{1,2}

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FRI0401

EFFECT OF LONG-TERM TREATMENT WITH SECUKINUMAB ON LIPID PROFILE IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS AND PSORIATIC ARTHRITIS: POOLED 4 YEAR ANALYSIS

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Background: Systemic inflammation may adversely affect the lipid profile in AS and PsA patients (pts)¹. Treatment with some TNF and JAK inhibitors have reported increased total cholesterol (TC) and triglycerides (TG) despite reduction in inflammation²⁻³. Secukinumab (SEC), a fully human monoclonal antibody that directly inhibits IL-17A, has demonstrated a sustained efficacy and consistent safety profile in pts with AS and PsA⁴

Objectives: To evaluate the long-term effect of SEC on key lipid parameters in AS and PsA pts from pooled phase 3 clinical trials, through 208 weeks (wks)

Methods: This *post hoc* analysis included pooled data from MEASURE 1-4 (SEC 150 mg) in AS (N = 892) and FUTURE 2-5 studies (SEC 150/300 mg) in PsA (N = 2049), from pts treated with SEC or placebo (PBO). Serum TC, TG, LDL- and HDL-cholesterol and TC/HDL-C levels were assessed at baseline (BL), Wks 16, 104 and 208 in overall population and in sub-groups by prior anti-TNF therapy, concomitant methotrexate (MTX) and BL statin usage. Shift of common terminology criteria for adverse events (CTCAE) grade from BL through Wk 208 were also analysed

Results: BL characteristics were comparable across SEC and PBO groups. Lipid levels were stable in SEC treated AS and PsA pts through Wk 208 (Table) with mean change (mmol/L) from BL in AS: TC = ± 0.1 , TG = $0.1-0.2$, LDL-C = ± 0.1 , HDL-C = ± 0.04 and TC/HDL-C = ± 0.2 and PsA: TC = ± 0.2 , TG = $0.001-0.2$, LDL-C = ± 0.2 , HDL-C = ± 0.06 and TC/HDL-C = ± 0.2 . Stable lipid values were also seen across key sub-groups by prior anti-TNF therapy, concomitant MTX and BL statin usage, which remained stable through Wk 208. No Change in CTCAE lipid grades was observed in >90% of SEC-treated pts through Wk 208

Conclusion: SEC did not adversely affect the lipid profile and TC/HDL-C ratio in pts with AS and PsA, over 4 years. The lipid profile remained stable with SEC treatment and was sustained irrespective of prior anti-TNF status, concomitant MTX and BL statin usage

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Lipid levels in AS and PsA pts through Wk 208

Parameters (Normal level ^b)	Wk	AS		PsA	
		SEC 150 mg (N=504)	PBO (N=388)	SEC 300 mg (N=461)	SEC 150 mg (N=907)
TC (<5.2) ^a	BL	4.92 (502)	4.90 (387)	4.99 (459)	5.07 (905)
	16	5.03 (486)	4.87 (362)	5.08 (448)	5.14 (879)
	104	4.91 (390)		5.02 (199)	5.13 (350)
	208	4.91 (135)		4.88 (74)	5.06 (72)
TG fasting (<1.7) ^a	BL	1.29 (502)	1.31 (387)	1.48 (460)	1.53 (905)
	16	1.40 (486)	1.31 (362)	1.62 (448)	1.64 (879)
	104	1.42 (390)		1.61 (199)	1.60 (350)
	208	1.44 (135)		1.66 (74)	1.67 (72)
LDL-C (<2.6) ^a	BL	3.09 (502)	3.08 (387)	3.11 (460)	3.18 (905)
	16	3.12 (486)	3.02 (362)	3.16 (448)	3.20 (879)
	104	3.08 (390)		3.15 (199)	3.24 (350)
	208	3.08 (135)		3.03 (74)	3.24 (72)
HDL-C (>1.5) ^a	BL	1.44 (502)	1.43 (387)	1.43 (460)	1.44 (905)
	16	1.46 (486)	1.43 (362)	1.43 (448)	1.45 (879)
	104	1.47 (390)		1.40 (199)	1.49 (350)
	208	1.41 (135)		1.42 (74)	1.38 (72)
TC/HDL-C ratio	BL	3.67 (502)	3.68 (387)	3.72 (459)	3.79 (905)
	16	3.72 (486)	3.61 (362)	3.81 (448)	3.88 (879)
	104	3.58 (390)		3.82 (199)	3.76 (350)
	208	3.72 (135)		3.69 (74)	3.94 (72)

n, number of pts with data at both BL and at that time point; N, total number of pts
^ammol/L (n). ^b<https://optimalhealthsolutions.ca/cholesterol-ratio/>

FRI0402 SECUKINUMAB FOR AXIAL SPONDYLOARTHRITIS: DRUG SURVIVAL IN REAL-WORLD SETTING AND RESPONSE FACTORS

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Background: IL-17 inhibition has been proved effective in patients with ankylosing spondylitis (AS) in clinical trials and it has been added to the most recent national and international treatment guidelines. However, real-world data of its use is still scarce.

Objectives: This study aims to analyze drug survival of secukinumab for axial spondyloarthritis (AxSpA) in a real world setting and identify response factors.

Methods: Multicentric observational, retrospective, longitudinal study conducted in 4 tertiary hospitals of the Madrid region. Patients over 18 y.o. with clinical diagnosis of AxSpA and having received at least one dose of secukinumab between January 2016 and October 2018 were included. Medical records were reviewed to collect demographic and clinical data related to AxSpA, its features and treatment. Statistical analysis was performed including bivariate analysis (considering withdrawal of drug during study period or not) and survival analysis with Kaplan-Meier and Cox regression. Reasons for discontinuating therapy are described. To detect influential variables, demographic characteristics, HLA-B27 positivity, radiographic features, previous biologic therapies, comorbidities and extra-articular involvement were analyzed.

Results: Out of 143 patients included, 89 (62%) maintained secukinumab therapy at the end of the observation period (Dec 31, 2018), with an average drug survival time of 17 ± 8.2 months. 54 patients (38%)

withdrawn therapy, due to primary ineffectiveness (26), secondary ineffectiveness (14), adverse events (7) and other reasons (7). Median time to withdrawal was 6 months (0-21). No significative differences were found between groups, but a tendency to higher number of female patients (55% vs 41%, p 0.07), non radiographic AxSpA (35% vs 27%, p 0.053) and lower HLA-B27 positivity (50% vs 65%, p 0.052) was noted in the group withdrawing therapy. Previous exposure to biologic therapy did not differ (75% vs 71%, p 0.37). Number of bDMARDs before Secukinumab therapy was also similar in both groups; the proportion of patients with previous exposure to 2 or more bDMARDs were 17% vs 22% (p 0.373). Neither differences were found in all other variables studied (demographic, hip arthropathy, syndesmophytes, extra-articular involvement -uveitis, psoriasis, inflammatory bowel disease- nor in comorbidities (tobacco exposure, hypertension, diabetes mellitus, dyslipidemia, ischemic heart disease, malignancy)

Conclusion: This study assessing drug survival of secukinumab in real-world setting showed a trend to lower drug survival in comparison to clinical trial data. No differences were found in the treatment withdrawal group. Population in which secukinumab is prescribed in real-world setting differs from clinical trials, with higher previous exposure to bDMARDs and higher comorbidity.

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FRI0403 HIGH BASELINE PATIENT'S COMPARED WITH EVALUATOR'S GLOBAL ASSESSMENT IS ASSOCIATED WITH LOWER RETENTION AND REMISSION RATES OF FIRST TNF INHIBITOR IN AXSPA PATIENTS – DATA FROM THE EUROSPA COLLABORATION

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Background: Discordance between baseline patient's and evaluator's global assessment of disease activity is common.¹ However, the impact of such discordance on retention and remission rates of TNF inhibitor (TNFi) therapy in axial spondyloarthritis (axSpA) patients remains unexplored.

Objectives: To assess the impact of baseline discordance, defined as "patient's minus evaluator's global assessment of disease activity" (Δ PEG), on retention and remission rates of first TNFi in female and male axSpA patients across Europe.

Methods: AxSpA patients from 10 European registries participating in the European Spondyloarthritis Research Network Collaboration (EuroSpA) were included. Retention rates after 6/12/24 months' treatment with first TNFi were assessed with Kaplan-Meier analyses, with comparison between baseline Δ PEG quartiles with log rank test, stratified by gender. Proportions of patients in BASDAI remission (≤ 2) and ASDAS inactive disease (< 1.3) after 6/12/24 months for different Δ PEG quartiles were compared with Chi-square test, stratified by gender.

Results: A total of 9013 axSpA patients were included. Mean(SD) age for women(n=3639)/men(n=5374) were 42.7(12.0)/41.7(12.0) years, disease duration 5.1(7.4)/6.9(8.7) years, median(25-75 percentiles) baseline Δ PEG