Figure 1: Treatments prescribed at diagnosis and currently in CEE and US

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THU0393

INFLAMMATORY BOWEL DISEASES AMONG SECUKINUMAB-TREATED PATIENTS: 24 CASES FROM THE MISSIL REGISTRY

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Background: An alert regarding about the tolerance of Interleukin 17 (IL-17) inhibitors has been issued from data of randomized controlled trials showing cases of de novo inflammatory bowel diseases (IBD). In a recent analysis of pooled data from 21 clinical trials, cases of IBD events (including Crohn's disease (CD), ulcerative colitis (UC) and inflammatory bowel disease unclassified (IBDU)) were uncommon (1). Yet, real-world data are lacking.

Objectives: To describe real-world data about patients treated by IL-17 inhibitors developing new onset IBD (CD or UC).

Methods: A French national registry called MISSIL was started in February 2018 to collect the cases of patients treated by IL-17 inhibitors developing new onset IBD. This registry is conducted by rheumatologist, dermatologist and gastroenterologist learned societies specialized on immune-mediated inflammatory diseases. In France, secukinumab (SEC) has been granted market authorization since June 2016 and ixekizumab since April 2018.

Results: 24 cases under SEC were reported between February 2018 and January 2020: 3 patients with psoriasis and 21 patients with spondyloarthritis. There were 20 patients with new onset CD and 4 with UC. Mean age was 51.7 ± 15.7 years old and 12/24 were female; 10 presented an axial spondyloarthritis, 5 a peripheral spondyloarthritis and 6 both, 13/17 were HLA-B27 positive, 7/19 had a radiographic sacroiliitis and 11/17 a MRI sacroiliitis. Only 2 were biological Disease-modifying antirheumatic drug (bDMARD)-naïve. Crohn's disease was mainly located at the ileum, colon and rectum. The median time to onset of

symptoms was 2 (1-6) months. The main symptoms were diarrhea, nausea and vomiting and loss of weight. Median CRP at the onset of symptoms was 68 mg/L (41-140.5); 21 patients underwent biopsies, 12 were in favor of CD. IL-17 inhibitors were consistently stopped. Patients were treated by corticosteroids (16/24), mesalazine (7/24), methotrexate (3/24), thiopurines (2/24), infliximab (9/243), adalimumab (3/24), golimumab (2/24), ustekinumab (5/24). The evolution was favorable under treatment with complete resolution (4/24), improvement (11/24) or stabilization (5/24). 3 patients worsened under treatment and 1 died (massive myocardial infarction).

Conclusion: IBD flare in patients treated with IL-17 inhibitor drugs. Further cases are needed to better characterize this complication. A case-control study will be conducted to identify patients at risk to develop IBD under IL-17 inhibitor.

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THU0394

COMPARISON OF TREATMENT RETENTION OF SECUKINUMAB AND TNF-INHIBITORS IN PSORIATIC ARTHRITIS. OBSERVATIONAL DATA FROM A NORDIC COLLABORATION.

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Background: A head-to-head trial (EXCEED) has indicated similar effectiveness of secukinumab (SEC) and the tumor necrosis factor inhibitor (TNFi) adalimumab (ADA) in psoriatic arthritis (PsA). In the clinical setting, treatment retention serves as a combined measure of overall effectiveness and tolerability.

Objectives: To explore baseline patient characteristics, and compare treatment retention rates for SEC and each of etanercept (ETN), infliximab (IFX), golimumab (GOL), certolizumab (CZP) and ADA in PsA.

Methods: Patients starting SEC or any TNFi in 2015-2018, in the 5 Nordic countries, were identified in clinical rheumatology registers. Data were pooled for analysis and stratified by 1st, 2nd and ≥3rd line of treatment. One year treatment retention was compared by crude Kaplan-Meier curves and a proportional hazard model for risk of discontinuation, censored at 1 year and adjusted for sex, age, country and baseline CRP, patient global and use of csDMARD, with ADA as reference.

Results: In total, 6062 patients with PsA were included, contributing 8172 treatment starts (table 1). SEC was mainly used as 2nd or ≥3rd line treatment. The survival curves and 1-year treatment retention rates, stratified by line of treatment, were similar for SEC compared to the TNFi, with some differences between the different TNFi (fig 1, table 2). Adjusted hazard ratios (HR) also indicated similar risk of SEC withdrawal compared to ADA (table 2).

Table 1. Patient characteristics at treatment start

	1 st line		2 nd line		≥3 rd line	
	SEC N=164	TNFi N=3808	SEC N=273	TNFi N=1767	SEC N=767	TNFi N=1393
Females	48%	47%	44%	42%	36%	39%
Age, years	52 (13)	49 (13)	50 (12)	50 (13)	52 (12)	51 (12)
Disease duration, years	12 (10)	10 (10)	13 (10)	13 (10)	16 (10)	16 (10)
Swollen joint count 28	3 (4)	2 (3)	2 (3)	2 (3)	3 (4)	2 (3)
CRP, mg/L	10 (18)	10 (17)	7 (11)	9 (17)	13 (22)	11 (20)
Patient global score	57 (24)	58 (24)	60 (25)	59 (26)	68 (23)	65 (24)
Concomitant therapy						
csDMARD	30%	60%	41%	57%	49%	53%
Methotrexate	24%	49%	31%	48%	40%	44%
Sulphasalazine	2%	9%	5%	5%	4%	6%

Numbers are mean (SD) unless noted otherwise

Table 2. One year treatment retention and hazard of discontinuation for SEC and TNFi

Line of treatment	Drug	N	1 year treatment retention % (95% CI)	Adjusted HR (95% CI) for discontinuation
1 st line	ADA	569	73 (69-76)	Ref
	CZP	273	66 (60-72)	1.2 (0.9-1.6)
	ETN	1747	73 (71-75)	0.9 (0.7-1.1)
	GOL	212	67 (60-73)	1.2 (0.9-1.7)
	IFX	1007	62 (59-65)	1.4 (1.1-1.7)
2 nd line	SEC	164	72 (63-78)	1.0 (0.7-1.4)
	ADA	415	69 (63-73)	Ref
	CZP	176	51 (43-58)	1.6 (1.2-2.2)
	ETN	701	63 (59-66)	1.2 (0.9-1.5)
	GOL	151	69 (61-76)	0.9 (0.6-1.2)
≥3 rd line	IFX	324	65 (59-70)	1.0 (0.8-1.4)
	SEC	273	69 (62-74)	0.9 (0.7-1.2)
	ADA	346	67 (62-72)	Ref
	CZP	221	49 (42-56)	1.5 (1.2-2.0)
	ETN	372	62 (57-67)	1.1 (0.9-1.5)
	GOL	206	56 (49-63)	1.3 (1.0-1.8)
	IFX	248	57 (50-63)	1.3 (1.0-1.8)
	SEC	767	63 (59-67)	1.0 (0.8-1.3)

Conclusion: In this large study of bDMARD treatment of PsA in clinical practice, SEC was most often used as 2nd or ≥3rd line treatment, and the treatment retention of SEC was comparable with that of TNFi. Further analyses, taking into account other comorbidities, channeling and effectiveness will be presented.

Figure 1. Treatment retention for secukinumab and TNFi, stratified by 1st, 2nd and ≥3rd line of treatment.

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THU0395 EFFICACY OF IXEKIZUMAB ON DISEASE ACTIVITY AND QUALITY OF LIFE IN PATIENTS WITH ACTIVE NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS AND OBJECTIVE SIGNS OF INFLAMMATION, STRATIFIED BY BASELINE CRP/SACROILIAC JOINT MRI STATUS

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Background: Ixekizumab (IXE), a high-affinity anti-interleukin-17A monoclonal antibody, is effective in patients (pts) with active non-radiographic axial spondyloarthritis (nr-axSpA), who had elevated C-reactive protein (CRP) and/or active sacroiliitis on magnetic resonance imaging (MRI).¹

Objectives: To determine if disease activity and patient-reported outcomes at Week 16 were similar between groups after stratifying pts by CRP/sacroiliac joint (SIJ) MRI status at baseline.

Methods: COAST-X (NCT02757352) included pts with active nr-axSpA and objective signs of inflammation, i.e. presence of sacroiliitis on MRI (Assessment of Spondyloarthritis International Society [ASAS]/ Outcome Measures in Rheumatology criteria) or elevation of serum CRP (>5.0 mg/L). Pts were randomized 1:1:1 to receive subcutaneous 80 mg IXE every 4 weeks (Q4W) or Q2W, or placebo (PBO). Depending on the baseline values of CRP and MRI SIJ (Spondyloarthritis Research Consortium of Canada [SPARCC] score), pts in the intent-to-treat population (N=239) were divided into 3 subgroups (CRP >5 and MRI ≥2; CRP ≤5 and MRI ≥2; CRP >5 and MRI <2). Logistic regression analysis with treatment, subgroup, and treatment-by-subgroup interaction was used to detect treatment group differences in ASAS40, Ankylosing Spondylitis Disease Activity Score (ASDAS) <2.1 (low disease activity), and Bath Ankylosing Spondylitis Disease Activity Index 50 (BASDAI50) responses at Week 16. Analysis of covariance model with baseline value, treatment, subgroup, and treatment-by-subgroup interaction was used to detect the treatment group difference in change from baseline in Short Form-36 physical component score (SF-36 PCS).

Results: The proportion of pts achieving ASAS40 (primary endpoint), ASDAS <2.1, and BASDAI50 (secondary endpoints) was higher in IXE treatment groups compared to PBO at Week 16 (Figure 1). The response rates in IXE-treated subjects were higher in all subgroups (CRP >5 and MRI ≥2; CRP ≤5 and MRI ≥2; CRP >5 and MRI <2) without consistent differences in efficacy between the subgroups. Similarly, pts in the IXE groups showed improvement in SF-36 PCS scores (secondary endpoint) versus pts on PBO at Week 16 (Figure 2).