ankylosing spondylitis (AS) and non-radiographic (nr-) axSpA based on the presence or absence of definite structural changes in conventional radiographs (CR).

Objectives: Aim of this study was to determine whether comorbidities and gender could lead to a different response rate to TNF-inhibitors (TNFi) in ESa patients.

Methods: ESa patients treated with TNFi (adalimumab (ADA) or infliximab (IFX)) were retrospectively evaluated between November 2018 and October 2020 and divided in two cohort according to gender. In addition, TNFi treatments line/s, effectiveness and reasons of discontinuations, as inefficacy, intolerance, acute adverse reaction, development of infections and other causes, were evaluated at baseline (T0), at 6 (T6), 12 (T12), and 24 (T24) months of therapy. Patients who were failure to at least two TNFi were considered as "multifailure". Statistical analyses were performed using chi square/Fisher tests and variance analysis (SPSS software).

Results: 120 ESa patients (M 40.52%; F 40.18%) treated with TNFi were evaluated. Clinical and laboratory baseline (T0) characteristics are summarized in Table 1. AS subtype was more common in men (39.5%) than in woman (14.3%) ($p=0.03$). Concerning comorbidities, hypertension and anemia were more prevalent in men than women (25% vs 9%, $p=0.01$; 11.6% vs 1.3%, $p=0.02$, respectively), while thyroopathy and psychiatric disorders were more common in female than male (11.7% vs 0%, $p=0.02$; 16.9% vs 4.6%, $p=0.04$, respectively). No difference was observed between genders in distribution of BMI, smokers, disease duration, HLAB27 positivity and presence of extra-articular manifestations. 202 TNFi treatments (50.9% ADA and 24.3% IFX) were evaluated in 120 patients [74 treatments (36.6%) in 43 men; 128 treatments (63.4%) in 77 women]. Considering treatment effectiveness, higher prevalence of failure was observed in woman than in men (67.2% vs 39.2%, $p=0.0005$). Moreover, women with psychiatric disorders undergone more lines treatment than men (16.8% vs 4.6%, $p=0.01$, OR=4). On the other hand, men with hypertension, were more multifailure compared with women (25.6% vs 16.3%, $p=0.001$, OR=3). No other differences according to gender were found.

At T6, 7.5% of patients ($n=9$) had acute adverse reaction ($n=1$ with ADA; $n=8$ with IFX); at T12, 14.2% of patients ($n=17$) had IBD inefficacy. At T24, secondary inefficacy on IBD and/or SpA was the main cause of TNFi discontinuation compared with other causes (58.4% vs 41.6%; $p=0.04$), mostly in female cohort (40% vs 20% in woman; $p=0.04$). Analyzing TNFi effectiveness, CRP and HAQ improvement was noted at T6 ($p=0.024$ and 0.036 , respectively), as ASDAS-CRP and BASDAI ($p=0.02$ and $p=0.013$, respectively) and maintained in the following evaluations at T12 and T24. At T24, men shown higher PCR and BASDAI improvement compared with women ($p=0.036$ and $p=0.04$, respectively).

Conclusion: Data suggest that gender and comorbidities could influenced TNFi response in ESa patients, advising differences among woman and men. Knowledge of these variable represents a major challenge for a personalized treatment management.

Table 1. Clinical and laboratory baseline (T0) characteristics of ESa patients treated with TNFi.

	Women N=77	Men N=43
Age (years)	44.5±14.5	42.9±11.9
Duration of ESa (months)	81±75.13	85.46±77.09
IBD duration (months)	187.35±112.9	219.35±123.5
Diagnostic delay of ESa (months)	43±65.4	75.71±122
Peripheral ESa	42/54.5	17/39.5
Axial ESa	35/45.5	26/60.5
CD (n / %)	48/62.3	33/76.4
UC (n / %)	29/37.7	10/23.6
Family history (n%)	17/22	7/16.3
Appendectomy (n%)	25/32.5	10/23.3
Smokers (n%)	19/24.7	12/27.9
BMI	23.7±3.9	24.8±3.7
HLAB27 positivity (n%)	8/10.4	4/9.3
Extra-articular manifestations (n%)	34/44.2	17/39.5
Comorbidities (n%)	32/41.6	21/48.8
TNFi treatments:		
biologic-naïve	50/64.9 *	16/37.2
ADA treatments:		
biologic-naïve	68/83.1	35/47.3
second/third line	32/74.1	17/48.6
IFX treatments:		
biologic-naïve	25/36.9	18/51.4
second line	46/59.9	32/43.2
ESR (mm/h)	35/76.1	26/21.3
second line	11/23.9	6/18.7
ESR (mm/h)	26.3±25.1	28.1±23.1
CRP (mg/dL)	0.7±1.1	1.12±1.4
VAS pain (0-10)	5±2.53	4±3
(PG)-VAS (0-10)	5±2.4	4.6±2.4
ASDAS-CRP	2.6±0.9	3.7±0.5
BASDAI	5.28±2.2	3.85±2.34
BASFI	3.8±0.5	1.9±2.1
HAQ-S	1.9±0.2	0.5±0.5

Data are expressed as mean ± SD. * Women versus men ESa: Enteropathic Spondylarthritides; IBD: inflammatory bowel disease; CD: Crohn's disease; UC: Ulcerative colitis; BMI: body mass index; TNFi: tumor necrosis factor inhibitor; ADA: Adalimumab; IFX: infliximab; CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; VAS: Visual Analog Scale; PG: patient global; ASDAS: ankylosing spondylitis disease activity score; BASDAI: bath ankylosing spondylitis disease activity index; BASFI: bath ankylosing spondylitis functional index; HAQ-S: health assessment questionnaire for SpA.

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POS0232

CLINICAL EFFECTIVENESS OF ADALIMUMAB VERSUS NON-BIOLOGIC THERAPY IN THE MANAGEMENT OF EXTRA-ARTICULAR MANIFESTATIONS IN ANKYLOSING SPONDYLITIS PATIENTS OVER 24 MONTHS – RESULTS OF THE COMPLETE-AS CANADIAN OBSERVATIONAL STUDY

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Background: COMPLETE-AS was a Canadian observational study among biologic-naïve adults with active ankylosing spondylitis (AS) initiated on either adalimumab (ADA) or subsequent non-biologic disease-modifying anti-rheumatic drugs and/or non-steroidal anti-inflammatory drugs (nbDMARD/NSAID) after a switch from initial treatment due to inadequate response or intolerance, as per the judgement of the treating physician.

Objectives: The aim of this analysis was to assess the 24-month effectiveness of ADA compared to nbDMARD/NSAID in the management of heel enthesitis and extra-articular manifestations (EAMs).

Methods: Patients were enrolled between July 2011 and December 2017, and followed for up to 24 months. Patients were treated as per routine care and all analyses were performed using the intent-to-treat (ITT) approach. The disease outcomes assessed in this study included enthesitis (of the heel) and EAMs [inflammatory bowel disease (IBD), uveitis, and psoriasis (PsO)]. The rate ratio (RR) for first occurrence or flare-up/exacerbation of disease outcomes was ascertained with multivariate models. The time to first occurrence of EAMs and enthesitis was ascertained with Cox proportional hazard models, generating a hazard ratio (HR).

Results: A total of 452 patients treated with ADA and 187 patients receiving a subsequent nbDMARD/NSAID were enrolled in the study. Baseline characteristics were overall comparable between treatment groups: patients had a mean (SD) age of 42.7 (13.4) years, 55.6% were male, and 85.8% were Caucasian. The mean (SD) duration of AS since diagnosis was 5.6 (9.3) years. A total of 17.7%, 12.4%, 18.5%, and 16.3% of patients had experienced enthesitis, IBD, uveitis, and PsO, respectively at baseline. Disease severity (mean [SD] BASDAI) was however higher among ADA- vs. nbDMARD/NSAID-treated patients (6.4 [1.8] vs. 5.0 [1.8]; $p<0.001$).

In terms of the rates of first occurrence or flare-up/exacerbation of enthesitis and EAMs, statistically significant between-group differences were found, whereby ADA-treated patients had a 60% reduced rate of both uveitis [RR (95% CI): 0.4 (0.2-0.6)] and enthesitis [0.4 (0.3-0.7)] compared to nbDMARD/NSAID-treated patients. The rates of first occurrence or flare-up/exacerbation for IBD [1.1 (0.7-1.7)] and PsO [3.3 (0.9-12.7)] were statistically comparable between treatment groups.

The time to first occurrence of both enthesitis and uveitis was also statistically significant ($p<0.05$) between groups. ADA-treated patients had a 50% lower risk of enthesitis as a first occurrence compared to nbDMARD/NSAID-treated patients [HR (95% CI): 0.5 (0.3-0.9)], and an 80% lower risk of uveitis [0.2 (0.0-0.8)]. The time to first occurrence of IBD [0.7 (0.2-2.1)] and PsO [1.9 (0.8-4.6)], were statistically comparable between treatment groups.

Conclusion: Despite a comparable proportion of patients reporting baseline EAMs and enthesitis, patients treated with ADA were less likely to experience a first occurrence or flare-up/exacerbation, of both enthesitis and uveitis compared to patients treated with nbDMARD/NSAID. The results of this real-world Canadian study suggest that treatment with ADA among AS patients is more effective at preventing the first occurrence / exacerbation of select EAMs and heel enthesitis.

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POS0233

THE EFFICIENCY OF TREATMENT OF COXITIS IN AXIAL SPONDYLOARTHRITIS: EXPERIENCE OF REAL CLINICAL PRACTICE

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Background: Standard therapy for axial spondyloarthritis (axSpA) is effective in inflammatory lesions of the axial skeleton and peripheral arthritis, but its effect on coxitis has not been studied.

Objectives: To assess the effectiveness of anti-TNF therapy for coxitis in patients with axSpA.

Methods: An open observational study was conducted. There were 56 patients with axSpA and coxitis for 2 years who received NSAIDs or NSAIDs+anti-TNF therapy in real clinical practice. The study included only those patients who completed a 2-year follow-up period. All patients regardless of complaints underwent X-ray examination of the pelvis, ultrasound and magnetic resonance imaging (MRI) of the hip joints. An increase in the cervical-capsular distance (CCD) of more than 7 mm and the presence of asymmetry between the joints of more than 1.5 mm were taken for coxitis on ultrasound of the hip joint. The presence of synovitis and/or osteitis was taken for coxitis on MRI. The average age was 31.1±7.0 years, with an average duration of the disease 74.5±100.1 months. HLA-B27 positive were 52 (92%) patients.

Results: A comparative analysis of clinical, laboratory and other parameters of the disease was carried out against the background of 2-year follow-up of patients who were constantly taking only NSAIDs or their combination with anti-TNF therapies (Table 1).

Table 1.

Parameters	Group NSAIDs+ anti-TNF n=27 baseline	Group NSAIDs+ anti-TNF n=27 after 2 y	p	Group NSAIDs n=29 baseline	Group NSAIDs n=29 after 2 y	p
BASRI hip ≥2; n %	10 (37%)	18 (67%)	>0,05	6 (21%)	14 (48%)	<0,05
MRI coxitis; n %	27 (100%)	19 (70%)	<0,05	28 (97%)	24 (83%)	>0,05
CCDmm; Me, [25 %; 75%]	7,9 [7,0;8,2]	7,2 [6,1;8,3]	<0,05	7,2 [6,2;7,8]	6,2[5,6;7,8]	>0,05
CRP,mg/L; Me, [25 %; 75%]	23,7[8,4;56]	6,0 [1,0;17,3]	<0,05	10,3 [2,9;18,6]	8,4[2,9;18,5]	>0,05
ESR; Me, [25 %; 75%]	25 [15;38]	15,0 [5;35,2]	<0,05	13 [7,8;25,5]	13 [6;26,3]	>0,05
ASDAS CRP; Me, [25 %; 75%]	3,5 [2,4;4,7]	2,0 [1,0;2,4]	<0,05	2,6 [1,3;3,6]	2,0[1,1;2,3]	>0,05
BASDAI; Me, [25%; 75%]	4,7[4,2;6,9]	2,2 [2,0;3,7]	<0,05	4,2 [2,4;5,8]	2,2[1,4;4,2]	>0,05
BASFI; Me,[25%;75%]	4,0 [2,0;6,5]	1,9 [0,9;2,9]	<0,05	1,2 [0,3;2,5]	0,9[0,4;2,8]	>0,05

Conclusion:

1. Anti-TNF+NSAIDs therapy with 2 years of use effectively controls the activity of axSpA.

2. Two-year therapy with NSAIDs in combination with anti-TNF, reduces the inflammation of hip joints in some patients according to ultrasound and MRI data.

3. The present study did not conclusively confirm that 2-year anti-TNF therapy with NSAIDs effectively prevents the progression of X-ray bursitis in axSpA.

4. Further studies are needed to improve the effectiveness of treatment of coxitis in axSpA.

Disclosure of Interests: None declared.

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POS0234

SECUKINUMAB RETENTION AND SAFETY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS OR ANKYLOSING SPONDYLITIS: 2 YEAR INTERIM RESULTS OF THE OBSERVATIONAL SERENA STUDY

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Background: SERENA is an ongoing, prospective, non-interventional study evaluating retention, effectiveness, safety/tolerability and quality of life in more than 2900 patients (pts) with moderate to severe plaque psoriasis, active psoriatic arthritis (PsA) or active ankylosing spondylitis (AS) treated with secukinumab (SEC) at 438 sites across Europe for a period of up to 5 years¹.

Objectives: We present interim results reporting SEC treatment retention and safety data through 2 years in the PsA and AS pts enrolled in the study.

Methods: This interim analysis presents data from 534 PsA and 470 AS pts who were enrolled (target population fulfilling all eligibility criteria) in the study and were followed up for at least 2 years. Pts (aged ≥18 years) with active PsA or AS should have received at least 16 weeks SEC treatment before enrolment in the study¹. Retention rate was defined as the percentage of pts who have not discontinued SEC treatment. A treatment break was defined as interruption of therapy for at least 3 months after last injection.

Results: The mean treatment duration prior to enrolment in the study was 1.0 year and 0.91 year for PsA and AS, respectively. The retention rates for SEC after 1 year since enrolment and since initiation of treatment were: PsA, 85.2% [n=519, CI: 82.01–88.32] and 96.8% [n=528, CI: 95.18–98.38]; AS, 85.8% [n=452, CI: 82.52–89.17] and 94.2% [n=464, CI: 91.94–96.42], respectively. After 2 years since enrolment and since initiation of treatment, the retention rates were: PsA, 74.9% [n=498, CI: 70.99–78.81] and 87.0% [n=515, CI: 83.99–89.99]; AS, 78.9% [n=437, CI: 75.01–82.88] and 84.8% [n=454, CI: 81.39–88.21], respectively. Survival probabilities for individual indications are presented in Figure 1. At baseline, the majority of PsA (79.5%; n/N=423/532) pts were receiving SEC 300 mg, while 97.0% (n/N=456/470) of AS pts were receiving SEC 150 mg. The majority of pts continued their initial SEC dose; "no dose change" in SEC treatment was reported after 1 and 2 years in the study (Year 1: PsA, 93.4% [n=499] and AS, 92.6% [n=435]; Year 2: PsA, 89.7% [n=479] and AS, 87.9% [n=413]). SEC treatment break was recorded for 31 PsA pts [median (min, max) treatment break duration in days: 125.0 (61, 461)] and for 42 AS [118.0 (61, 813)] pts mainly due to adverse events reported in 58.1% (n=18) and 45.2% (n=19) of pts, respectively. The retreatment started with monthly dosing in most of the cases: PsA, 80.6% (n/N=25/31) and AS, 76.2% (n/N=32/42). No new or unexpected safety signals were reported (Table 1).

Conclusion: Secukinumab retention rates in a real world setting after more than 2 years since initiation of treatment and after 2 years since enrolment in the study indicate high persistence rates. Safety data collected prospectively for up to 2 years confirm the favorable safety profile of secukinumab.

Figure: Time to treatment discontinuation of secukinumab by individual indications

REFERENCES:

[1] Kiltz, U et al. Adv Ther 2020; 37:2865–83.