THU0373 USE OF CORTICOSTEROID HIP JOINT INJECTIONS IN SPONDYLOARTHRITIS PATIENTS UNDER TNF ALPHA INHIBITORS

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Background: The hip disease is a serious complication of spondyloarthritis (SpA), engaging the functional prognosis of patients. TNF alpha inhibitors are a breakthrough for the treatment of SpA and the management of this complication.

Objectives: To assess the efficacy of TNF alpha inhibitors on hip involvement in SpA by evaluating the use of intra-articular corticosteroid infiltrations.

Methods: Observational cohort study that included 94 SpA patients with hip disease (ASAS2009). Two groups were studied. Group 1 (G1): patients under anti-TNF alpha therapy and Group 2 (G2): TNF alpha inhibitors naive patients. Clinical (BASDAI, BASFI, hip (pain/mobility), index of severity for osteoarthritis for the hip (ISH)), biological (CRP) data were assessed and the use of corticosteroid hip joint infiltration was compared. Evaluations were performed and compared between the 2 groups at baseline (T0), two years (T2) and Tn (greater than or equal to 3 years). The correlation study was made by Pearson test. A correlation was considered statistically significant if $p < 0.05$.

Results: Group 1 and 2 included 48 and 46 patients respectively. The socio demographic and clinical characteristics of the disease were comparable between the two groups. Biological and radiological assessments of the two groups were comparable at T0. Group 1 had however a more active disease and a greater functional impairment. NSAIDs were prescribed in 40% of patients in G1 and 86% in G2 ($p < 0.0001$). DMARDs were prescribed in 20 patients in G1 and in 22 patients in G2 ($p = 0.6$). In G1 patients received infliximab, adalimumab and etanercept in 48%, 15% and 37% of cases respectively. Four patients of G1 and three of G2 patients received intra-articular corticosteroid infiltration in the year prior to the initial assessment ($p = 0.7$). Assessment at T2 showed a greater improvement in clinical and biological parameters of the disease in group 1 than in group 2 with Δ (T2-T0) significantly lower in group 1 for the BASDAI ($p < 0.0001$), the BASFI ($p < 0.0001$) and the ISH ($p = 0.017$). The number of painful hip was significantly lower in group 1 ($p < 0.0001$). The evaluation at Tn showed a sustained clinical and biological efficacy of TNF alpha inhibitors in Group 1. The use of corticosteroid injections was significantly higher in group 2. Table 1 summarizes the assessment of different parameters at T2 and Tn.

Conclusions: Hip involvement is a marker of severity of spondyloarthritis. Anti-TNF alpha treatment is effective on hip disease. It reduces the use of intra articular injections of corticosteroids.

Disclosure of Interest: None declared

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THU0374 LONG-TERM EFFECTS OF TNF-ALPHA INHIBITORS ON BONE MINERAL DENSITY AND THE INCIDENCE OF VERTEBRAL FRACTURES IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Ankylosing Spondylitis (AS) is not only characterized by pathological bone formation leading to ankylosis, but also by bone loss which may lead to vertebral fractures (VFX). TNF-alpha inhibitors (TNFi) have proven to be effective in blocking the inflammation process. A few studies also showed an increase of Bone Mineral Density (BMD) in AS patients treated with TNFi ¹⁻³ but the incidence of VFX after two years of treatment was increased. ³⁻⁴

Objectives: To evaluate the long-term effect of TNFi on BMD and the incidence of VFX in patients with AS.

Methods: Consecutive TNFi naive patients diagnosed with AS according to the Modified New York criteria were included. Patients were recruited from the VUmc and the Amsterdam Outpatient clinic Reade and were treated with TNFi for 4 years. BMD at hip and lumbar spine (LS) were measured at baseline, after 2 and 4 years. T-scores were categorized as "normal BMD", "osteopenia" and "osteoporosis", based on the WHO osteoporosis criteria. ⁵ The incidence of VFX was determined by two observers using the Genant method. ⁶

Results: In total, 70 AS patients with complete datasets (67.1% male) were included. The mean age was 41.6 years and the disease duration (time since diagnosis) was 9.8 years. At baseline 42% of the patients had a decreased BMD

of the hip and 34% of the spine, of whom 19 patients (27%) had both a decreased hip BMD as well as a decreased lumbar BMD. The BMD of spine and hip improved after 2 and 4 years of TNFi treatment (Table 1). In 7 patients (10%), 8 VFX were observed both at baseline and after 2 years. After 4 years of TNFi-treatment 11 VFX were observed in 9 patients.

After 4 years, 2 out of 9 patients with ≥ 1 VFX had a decreased BMD at hip and lumbar spine whereas the other 7 patients had a normal BMD. The majority of VFX was localized in the mid or lower thoracic spine.

Table 1, BMD measurement in spine and hip of 70 AS patients treated with TNFi

	Baseline	After 2 years of TNFi	After 4 years of TNFi
Osteopenia LS*	23 (32.9)	19 (27.1)	21 (30.0)
Osteoporosis LS	6 (8.6)	3 (4.3)	2 (2.9)
Abnormal BMD LS	29 (41.5)	21 (31.4)	23 (32.9)
Osteopenia total hip	22 (31.4)	19 (27.1)	16 (22.9)
Osteoporosis total hip	2 (2.9)	2 (2.9)	3 (4.3)
Abnormal BMD total hip**	24 (34.3)	21 (30.0)	19 (27.2)
Patients with VFX	7 (10.0)	7 (10.0)	9 (12.9)
Total number of VFX	8	8	11

*Lumbar Spine; **N=68, because 2 patients had a total hip replacement. Abnormal BMD = osteopenia and/or osteoporosis according to WHO guideline⁶. Vertebral fractures (VFX) are presented in number of patients with a VFX and the actual prevalence of VFX. Outcomes are presented in n (%).

Conclusions: The percentage of relatively young AS patients with a decreased BMD at baseline of the hip and lumbar spine was high (34–41%). After 4 years of TNFi-treatment the BMD of the lumbar spine improved in 8.6% of the patients and of the hip in 7.2% of the patients. At baseline, several vertebral fractures were found and a few additional vertebral fractures were observed after 4 years of treatment.

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THU0375 CHARACTERISTICS ASSOCIATED WITH IMPROVEMENTS IN SPARCC SIJ AND ASDAS SCORES IN PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS TREATED WITH ETANERCEPT

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Background: The EMBARK trial of etanercept (ETN) (NCT01258738)¹ has demonstrated the long-term efficacy of ETN in patients with non-radiographic axial spondyloarthritis (nr-axSpA) and shown correlations between decreased inflammation and clinical outcomes. ²

Objectives: To determine which baseline (BL) characteristics are associated with clinical improvements after 48 weeks of treatment with ETN in patients with nr-axSpA.

Methods: This post hoc analysis was performed on data from patients with nr-axSpA enrolled in the 92-week open-label phase of the EMBARK trial. The primary analysis population was the EMBARK modified intent-to-treat (mITT) population (patients who had ≥ 1 dose of ETN, had ≥ 1 on-therapy evaluation, and met the Assessment in Ankylosing Spondylitis classification criteria for axSpA). Patients' SpondyloArthritis Research Consortium of Canada (SPARCC) sacroiliac joint (SIJ) scores and Ankylosing Spondylitis Disease Activity Scores (ASDAS) were recorded, and patients were divided into 4 quadrants (Q1–4) based on the minimally important change (MIC) for each instrument (SPARCC SIJ score, change from BL [cfb] of ≥ 2.5 ; ASDAS, cfb ≥ 1.1). Patients in Q1 achieved MIC in SPARCC SIJ but did not achieve MIC in ASDAS. Q2 did not achieve MIC in SPARCC SIJ and did not achieve MIC in ASDAS. Q3 did not achieve MIC in SPARCC SIJ but achieved MIC in ASDAS. Q4 achieved MIC in SPARCC SIJ and achieved MIC in ASDAS. Missing data were imputed using last observation carried forward. P-values were obtained using the Chi-squared test (categorical variables) and the Kruskal-Wallis test (continuous variables) in order to compare BL characteristics across improvement status. Multivariable

Abstract THU0373 – Table 1. Comparison of Clinical and biological variations between the 2 groups at T2 and Tn

	T2/T0			Tn/T0		
	G1	G2	p	G1	G2	p
ΔISH	-7.7 [-19, 2]	-1.6 [-19, 8]	0,01	-9.3 [-20, 2]	0.1 [-4, 4]	0,005
ΔBASFI	-2.7 [-9, 7]	1.1 [-1, 4]	<0,0001	-3.2 [-9, 1]	0.2 [-3, 6]	<0,0001
ΔBASDAI	-3 [-8, 3]	0.4 [-3, 5]	<0,0001	-3.4 [-9, 2]	-0.9 [-6, 4]	0,001
Hip pain (%)	35	75	<0,0001	20	67	<0,0001
Limitation of hip mobility (%)	71	83	0,2	50	86	<0,0001
ΔCRP (mg/l)	-33.6 [-132, 69]	-6.1 [-72, 18]	0,3	-25.5 [-89, 6]	-1 [-99, 58]	0,04
Corticosteroids hip joint injections (n)	1	3	0,2	0	4	0,04

multinomial logistic regression modelling was used to calculate which BL characteristics were associated with clinical improvements when adjusted for all other BL characteristics.

Results: At screening, male patients had significantly higher median SPARCC SIJ scores compared with female patients [4.83 [range 0.0–48.0] vs 1.5 [0.0–32.0], $P<0.0001$]. At wk48, 69.1% of 194 patients achieved MIC in either SPARCC SIJ scores, ASDAS or both (Q1/3/4, Figure). There was a statistically significant difference in the number of male versus female patients who achieved MIC in both scores (Q4), compared with patients who achieved MIC in only one or neither (Q1–3, Figure) ($P<0.0001$). However, multinomial logistic regression modelling showed that age ($P=0.0358$), BL ASDAS ($P<0.0001$), and screening SPARCC Spine ($P=0.0358$) and SPARCC SIJ ($P<0.0001$) scores, not gender, were significantly associated with achievement of MIC in both SPARCC SIJ and ASDAS at wk48 for the total population (after adjustment for the effects of other variables).

Conclusions: Although BL summaries showed a significant difference in gender across quadrants, the BL SPARCC SIJ score was strongly correlated with gender (male patients had more inflammation). When both were included in a multivariable model, gender was non-significant. Only age, BL ASDAS, and screening SPARCC SIJ and Spine scores were associated with MIC after 48 weeks of etanercept treatment.

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- Disclosure of Interest:** K. de Vlam Consultant for: Abbott, Celgene, Janssen, Pfizer, and UCB, Speakers bureau: Abbott, Celgene, Janssen, Pfizer, and UCB, A. Burden Employee of: Quanticate, M. A. Dilleen Shareholder of: Pfizer, Employee of: Pfizer, C. Boone Shareholder of: Pfizer, Employee of: Pfizer
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THU0376 REAL-WORLD USE OF SECUKINUMAB WITH AND WITHOUT A LOADING REGIMEN AMONG PATIENTS WITH ANKYLOSING SPONDYLITIS IN THE UNITED STATES: PATIENT PROFILE AND DOSING

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Background: Secukinumab is a fully human anti-interleukin-17 monoclonal antibody approved for the treatment of patients with moderate to severe plaque psoriasis, psoriatic arthritis and ankylosing spondylitis (AS), and may be administered with or without a loading regimen of 150 mg at weeks 0, 1, 2, 3 and 4 followed by maintenance dosing every 4 weeks. The dosing pattern of secukinumab in a real-world setting of patients with AS has not been evaluated since its approval in the United States on January 15, 2016.

Objectives: To describe the demographic, clinical and treatment characteristics (loading, dose) of patients with AS who were treated with secukinumab in routine clinical practice in the United States.

Methods: Retrospective data from the Symphony Health Solutions Lx commercial claims database were used to identify AS patients who had ≥ 1 secukinumab treatment between January 15, 2016 and June 30, 2016. Patients eligible for inclusion were ≥ 18 years of age who had the diagnosis of AS and ≥ 1 pharmacy or medical claim in the 12 months prior to their first secukinumab treatment (index date). Patient demographics and secukinumab dosage were examined at the index date. Clinical characteristics, comorbidities and treatment history in the 12 months prior to the index date were identified and presented by use versus no use of a loading regimen of secukinumab.

Results: A total of 152 patients who initiated secukinumab were included in

this study; the mean (SD) age of included patients was 45.3 (11.1) years and 53.9% were female. Of the 152 patients, 119 patients (78.3%) received a loading regimen and 33 (21.7%) did not. Patient demographics, clinical characteristics and treatment history were not significantly different between the two cohorts (Table 1). The majority of patients (65.5%) with loading initiated secukinumab with the 150-mg dose, whereas the majority of patients (60.6%) without loading initiated with the 300-mg dose. More than half of the patients in each cohort received a biologic therapy during the 12-month baseline period (loading, 65.5%; no loading, 51.5%). Other prior treatments included oral corticosteroids (30.3% for both), conventional synthetic disease-modifying antirheumatic drugs (DMARDs) (loading, 31.9%; no loading, 21.2%) and targeted synthetic DMARDs (loading, 4.2%; no loading, 12.1%). The prevalence of comorbidities was similar between the two cohorts, with the most prevalent comorbidities being hypertension (19.1%), rheumatoid arthritis (19.1%) and other skin diseases (18.4%).

Table 1. Demographics, clinical characteristics and treatment history of patients with AS treated with secukinumab with or without a loading dose of 150 mg

	Overall (n = 152)	Loading (n = 119)	No Loading (n = 33)
Age, mean (SD), years	45.3 (11.1)	46.0 (10.8)	42.6 (11.9)
Female, n (%)	82 (53.9)	67 (56.3)	15 (45.5)
Region, n (%)			
South	46 (30.3)	37 (31.1)	9 (27.3)
Northeast	37 (24.3)	29 (24.4)	8 (24.2)
Midwest	36 (23.7)	25 (21.0)	11 (33.3)
West	33 (21.7)	28 (23.5)	5 (15.2)
Index dose, n (%)			
150 mg	91 (59.9)	78 (65.5)	13 (39.4)
300 mg	61 (40.1)	41 (34.5)	20 (60.6)
Physician specialty, n (%)			
Rheumatology	121 (79.6)	94 (79.0)	27 (81.8)
Internal medicine	8 (5.3)	5 (4.2)	3 (9.1)
Treatment history, n (%)			
NSAID	38 (25.0)	27 (22.7)	11 (33.3)
Oral corticosteroid	46 (30.3)	36 (30.3)	10 (30.3)
csDMARD	45 (29.6)	38 (31.9)	7 (21.2)
tsDMARD	9 (5.9)	5 (4.2)	4 (12.1)
Biologic	95 (62.5)	78 (65.5)	17 (51.5)
Etanercept	31 (20.4)	23 (19.3)	8 (24.2)
Adalimumab	30 (19.7)	27 (22.7)	3 (9.1)
Certolizumab	22 (14.5)	19 (16.0)	3 (9.1)
Golimumab	17 (11.2)	13 (10.9)	4 (12.1)
Infliximab	15 (9.9)	12 (10.1)	3 (9.1)
Ustekinumab	3 (2.0)	3 (2.0)	0 (0.0)
Comorbidities, n (%)			
Rheumatoid arthritis	29 (19.1)	21 (17.6)	8 (24.2)
Hypertension	29 (19.1)	24 (20.2)	5 (15.2)
Other skin diseases	28 (18.4)	23 (19.3)	5 (15.2)
Hyperlipidemia	25 (16.4)	19 (16.0)	6 (18.2)
Fatigue	19 (12.5)	13 (10.9)	6 (18.2)
Depression	18 (11.8)	13 (10.9)	5 (15.2)
Cancer	17 (11.2)	12 (10.1)	5 (15.2)
Psoriatic arthritis	17 (11.2)	13 (10.9)	4 (12.1)
Diabetes	10 (6.6)	9 (7.6)	1 (3.0)
Anxiety	8 (5.3)	6 (5.0)	2 (6.1)
Obesity	6 (3.9)	4 (3.4)	2 (6.1)

AS, ankylosing spondylitis; csDMARD, conventional synthetic disease-modifying antirheumatic drug; NSAID, nonsteroidal anti-inflammatory drug; tsDMARD, targeted synthetic disease-modifying antirheumatic drug.

Conclusions: In this retrospective, administrative claims-based study, the majority of patients with AS initiated secukinumab treatment with a loading regimen. Although only the 150-mg dose of secukinumab is approved for the treatment of AS, almost 40% of patients received the 300-mg dose, indicating a need to better understand patient and treatment characteristics for secukinumab in patients with AS. The results of this study provide early insights into real-world use of secukinumab with and without a loading regimen in patients with AS in the United States.

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THU0377 LOW DOSE IL-2 THERAPY CAN RECOVERY TH17/TREG CELL BALANCE IN PATIENTS WITH SPONDYLOARTHRITIS THROUGH INCREASING REGULATORY T CELLS NUMBERS

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Background: The imbalance in the number of Th17 and Treg cells is suggested to be associated with the pathogenesis of SpA. Recent studies have shown that interleukin-23 (IL-23) and Th17 play a crucial role in the pathogenesis of SpA. However the status of CD4+CD25+Foxp3+Treg cells which exert immunoregulatory functions remains to investigate.