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POS0927

EFFECTIVENESS AND SAFETY OF SECUKINUMAB IN NAÏVE OR TNF-INHIBITORS FAILURE AXIAL SPONDYLOARTHRITIS PATIENTS IN REAL LIFE: A 24-MONTHS PROSPECTIVE MULTICENTRIC STUDY

M. Lorenzin¹, A. Ortolan¹, M. S. Chimenti², A. Marchesoni³, E. Lubrano⁴, L. Santo⁵, A. Semeraro⁶, C. Salvarani⁷, N. Girolimetto⁸, E. Praino⁹, G. L. Fonti², R. Foti¹⁰, A. Carletto¹¹, A. Doria¹², R. Ramonda¹² On behalf of Italian Society of Rheumatology (SIR) "Spondyloarthritis and Psoriatic Arthritis Study Group—A. Spadaro". ¹University of Padova, Rheumatology Unit, Department of Medicine DIMED, Padova, Italy; ²University of Rome "Tor Vergata", Rheumatology, Allergology and Clinical Immunology Department of "Medicina dei Sistemi", Roma, Italy; ³ASST Gaetano Pini-CTO, Milan, Department of Rheumatology, Milano, Italy; ⁴University of Molise, Campobasso, Academic Rheumatology Unit, Dipartimento di Medicina e Scienze per la Salute "Vincenzo Tiberio", Campobasso, Italy; ⁵ASL BT Andria – DSS4 Barletta, Italy, Barletta-Andria-Trani, Rheumatology Unit, Barletta-Andria-Trani, Italy; ⁶Martina Franca-ASL Taranto, Rheumatology Unit, Taranto, Italy; ⁷University of Modena and Reggio Emilia, Rheumatology Unit, Reggio Emilia, Italy; ⁸Azienda USL-IRCCS, Istituto di Ricovero e Cura a Carattere Scientifico, Rheumatology Unit, Department of Internal Medicine, Reggio Emilia, Italy; ⁹ASL BT Andria – DSS4 Barletta, Italy, Barletta-Andria-Trani, Rheumatology Unit, Barletta-Andria-Trani, Italy; ¹⁰A.O.U. Policlinico S. Marco, Catania, Italy, Rheumatology Unit, Catania, Italy; ¹¹AOUI University of Verona, Rheumatology Unit, Department of Medicine, Verona, Italy; ¹²University of Padova, Rheumatology Unit, Department of Medicine DIMED, Padova, Italy

Background: Axial Spondyloarthritis (axSpA) can be distinguished in radiographic axSpA (r-axSpA) and non-radiographic (nr-axSpA). Secukinumab (SEC) is a novel treatment for axSpA, but data from real-life are still missing.

Objectives: 1) to evaluate the effectiveness and safety of a wide cohort of axSpA patients on SEC followed in 8 Italian Rheumatologic centers for 24-months; 2) to compare the features and disease-activity indices of SEC-treated axSpA patients subdivided in naïve biological drugs (**group A**) and in TNF-inhibitors failure patients (**group B**).

Methods: Consecutive patients with active axSpA (diagnosis according Assessment of SpondyloArthritis International Society ASAS criteria), who started SEC treatment, were evaluated prospectively. Data on disease characteristics, previous/ongoing treatments and imaging were collected. Disease-activity/functional/clinical scores and biochemical values were recorded at baseline (T0), at 6 (T6), 12 (T12), and 24 (T24) months. Effectiveness was evaluated over-time with descriptive statistics. Anova (Kruskal Wallis) and generalized linear models were used to compare variables over-time. Infections, adverse events were collected.

Results: One-hundred-seven patients [49.53% men; median age 49years; median treatment duration 18.5years] were enrolled; 53(49.53%) had HLA-B27, 47.66% were r-axSpA and 52.34% nr-axSpA. Signs of sacroiliitis were present on MRI in 97 (90.65%) and X-rays in 51 (47.66%). SEC was prescribed as first line biologic treatment in 32 (29.9%) patients and as second or more line biological treatment in 75 (70.1%) patients (Figure 1). In all population significant decrease was achieved in: Visual Analogue Scale of pain and general-health; Leeds Enthesitis Index; Health Assessment Questionnaire modified for spondyloarthritis (HAQ-s); Bath Ankylosing Spondylitis Functional Index (BASFI); C-reactive protein. Bath Ankylosing Spondylitis Metrology Index and Erythrocyte-sedimentation-rate not significantly decreased. Effectiveness was associated to an improvement in Ankylosing Spondylitis disease activity score (ASDAS) [T0=3.4 (2.9-3.9) vs T24=1.9 (1.2-2.7); p=0.02] and in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [T0=6.6 (5.0-7.8) vs T24=3.2 (2.0-5.0); p=0.03]. At T0 **group B** had a longer disease duration (p=0.04), a greater prevalence of peripheral arthritis (p=0.02), enthesitis (p=0.04) and psoriasis (p=0.05) and was mostly male (p=0.05), while no significant difference was observed for functional and disease-activity indices and signs of sacroiliitis on MRI/X-rays. At T24 **group A** showed better physical functioning and lower disease activity compared to **group B** [HAQs A vs. B=0.1(0.0-0.5) vs 0.3(0.1-0.8); BASFI A vs B=1.6(0.8-4.8) vs 4.0(2.5-4.6); BASDAI A vs B=2.2(1.0-3.8) vs 3.9(2.7-5.0); ASDAS A vs B=1.3(1.0-2.2) vs 2.1(1.6-2.9)]. After T24 of treatment 70.2% of **Group A** and 68.4% of **Group B** had a low disease activity, accordingly to ASDAS <2.1. Twenty-three patients (21.5%) stopped the treatment during the follow-up mainly because of primary (7) or secondary loss of

efficacy (9). Only 7 patients suspended SEC because of adverse events. A low number of episodes of mild infections (19) occurred; SEC was instead permanently discontinued in 4 cases for: oral refractory mucositis (2); recurrent aphthosis (1); recurrent broncopneumoniae (1). The retention rate at T24 was good in the whole population (73%). Survival curves for **Group A** and **B** were similar (log-rank test=0.81; p=0.69).

Conclusion: In a real-life clinical setting, SEC was safe and effective in axSpA, as shown by a significant decrease of BASDAI and ASDAS over a 24-months follow-up.

Baseline characteristics of 107 axSpA patients treated with secukinumab in the period January 2017- December 2020.

axSpA Features	Total patients	GROUP A	vs.	GROUP B	p
Male sex (N, %)	53 (49.53%)	23 (71.88%)		30 (40%)	0.05
Age (years), median (IQR)	49 (40.5-58)	44 (35.75-58)		52 (42-58.5)	0.04
Age of diagnosis (years), median (IQR)	43 (32.5-51)	39.5 (30.5-50)		43 (33.5-53)	ns
Age of disease onset (years), median (IQR)	39 (29.5-49)	36.5 (22.75-46)		40 (30.5-49)	ns
Disease duration (years), median (IQR)	9 (4-13.5)	7 (2-14.25)		10 (6-13)	0.04
axSpA (n, %)	107	32 (29.91%)		75 (70.09%)	NA
r-axSpA	51 (47.66%)	15 (46.88%)		36 (48%)	ns
nr-axSpA	56 (52.34%)	17 (53.13%)		39 (52%)	ns
HLA-B27 positive, N (%)	53 (49.53%)	16 (50%)		37 (49.33%)	ns
SII-MRI positive, N (%)	97 (90.65%)	28 (87.5%)		69 (92%)	ns
SII-X-rays positive, N (%)	51 (47.66%)	15 (46.9%)		36 (48%)	ns
Peripheral arthritis, N (%)	62 (57.94%)	15 (46.9%)		47 (62.67%)	0.02
Enthesitis, N (%)	66 (61.68%)	17 (53.13%)		49 (65.33%)	0.04
Dactylitis, N (%)	14 (13.08%)	5 (15.63%)		9 (12%)	ns
Psoriasis, N (%)	50 (46.73%)	13 (40.63%)		37 (49.33%)	0.05
Onicopathy, N (%)	22 (20.56%)	6 (18.75%)		16 (21.33%)	ns
IBD, N (%)	4 (3.74%)	2 (6.25%)		2 (2.67%)	ns
Uveitis, N (%)	5 (4.67%)	0 (0%)		5 (6.67%)	ns
Familiality with psoriasis or SpA	36 (33.64%)	12 (37.5%)		24 (32%)	ns
Smoking, N (%)	26 (24.30%)	8 (25%)		18 (24%)	ns
Weight (kg), median (IQR)	70 (60.5-82)	70.5 (64.5-82.25)		70 (60-81.5)	ns
Height (cm), median (IQR)	169 (161-177)	174 (165-178)		168 (160-175.5)	ns
BMI, median (IQR)	24.69 (21.95-28.05)	23.97 (22.65-26.20)		24.9 (21.79-28.24)	ns
BASMI [0-10], median (IQR)	3 (1-6)	2 (0-4)		4 (1-7)	0.03
LEI [0-6], median (IQR)	1 (0-2)	0 (0-1.5)		1 (0-2)	ns
ESR [0-25] (mm/h), median (IQR)	16 (9-28)	13.5 (5-27.25)		18.5 (10-28)	ns
CRP [0-6] (mg/L), median (IQR)	5 (2.9-11)	3.45 (2.4-15.3)		5 (2.9-11)	0.04
VAS-pain [0-10], median (IQR)	7 (6-8)	6.65 (6-7.45)		7 (6-8)	ns
VAS-gf [0-10], median (IQR)	5.6 (4-7)	5.0 (4.25-7.0)		6 (4-7.1)	ns
HAQ-s [0-8], median (IQR)	1 (0.5-1.5)	0.75 (0.2-1.0)		1 (0.75-1.50)	0.05
BASFI [0-10], median (IQR)	6 (4.95-7.03)	5.5 (3.63-7.05)		6 (5.1-7.0)	ns
BASDAI [0-10], median (IQR)	6.6 (5-7.8)	6 (3.7-6.95)		7 (5.25-8.2)	ns
ASDAS [0-6], median (IQR)	3.35 (2.85-3.86)	3.33 (2.67-3.68)		3.35 (2.90-3.86)	ns
Mean treatment duration (months), median (IQR)	18.5 (12-32.5)	18.10 (12-30)		18.93 (12-32.5)	ns
Dosage 300 mg/injection (N, %)	33 (30.84%)	6 (18.75%)		27 (36%)	0.04
Dosage 150 mg/injection (N, %)	74 (69.16%)	26 (81.25%)		48 (64%)	0.04
1 st line (N, %)	32 (29.91%)	32 (100%)		0 (0%)	NA
Failure biological drugs (N, %)	75 (70.10%)	0 (0%)		75 (100%)	NA
2 nd line (N, %)	33 (30.84%)	0 (0%)		33 (44%)	NA
3 rd line (N, %)	23 (21.50%)	0 (0%)		23 (30.67%)	NA
4 th line (N, %)	13 (12.15%)	0 (0%)		13 (17.33%)	NA
>5 th line (N, %)	6 (5.61%)	0 (0%)		6 (8%)	NA
Concomitant NSAIDs, N (%)	68 (63.55%)	21 (65.63%)		47 (62.67%)	ns
Concomitant glucocorticosteroid, N (%)	22 (20.56%)	6 (18.75%)		16 (21.33%)	ns
Concomitant csDMARDs, N (%)	23 (21.50%)	6 (18.75%)		17 (22.67%)	ns

Legend: Data are expressed as median (interquartile range) unless otherwise specified; range of possible values are indicated in square brackets. p < 0.05. Anova (Kruskal Wallis) a to p < 0.05. GROUP A= naïve to anti-TNFα inhibitors; GROUP B= TNFα failure inhibitors; SpA, Spondyloarthritis; axSpA, axial Spondyloarthritis; r-axSpA, radiographic axial Spondyloarthritis; nr-axSpA, non-radiographic axial Spondyloarthritis; IBD, Inflammatory bowel disease; HLA-B27, Human leukocyte antigen (HLA) B27; SII, Sacroiliac Joints; MRI, Magnetic Resonance Imaging; X-rays, Conventional Radiography; Kg, kilogram; cm, centimeter; BMI, body mass index; BASMI, Bath Ankylosing Spondylitis Metrology Index; LEI, Leeds Enthesitis Index; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein; VAS, Visual Analogue Scale; gf, Global Health; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; ASDAS, Ankylosing Spondylitis disease activity score; HAQ-s, Health Assessment Questionnaire modified for spondyloarthritis; NSAIDs, non-steroidal inflammatory drugs; csDMARDs, conventional synthetic disease-modifying antirheumatic drugs. ns=not statistical significant. NA=not applicable

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POS0928

NETAKIMAB EFFICACY IN ANTI-TNF-NAÏVE AND ANTI-TNF-EXPERIENCED PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS: RESULTS OF SUBANALYSIS OF PHASE 3 ASTERA TRIAL

S. Erdes¹, V. Mazurov², T. Dubinina³, I. Gaydukova^{2,4}, A. Kundzer⁵, N. Soroka⁶, A. Ereemeeva⁷. ¹Nasonova Research Institute of Rheumatology, Laboratory of Spondyloarthritis, Moscow, Russian Federation; ²Mechnikov North-Western State Medical University, Department of Therapy and Rheumatology

of Temporary Disability and Medical Care Quality Expertise, St-Petersburg, Russian Federation; ³Nasonova Research Institute of Rheumatology, Laboratory of Medical and Social Problems of Rheumatology, Moscow, Russian Federation; ⁴Clinical Rheumatology Hospital No 25, Consultative Outpatient Department, St-Petersburg, Russian Federation; ⁵Belarusian Medical Academy of Postgraduate Education, Department of Cardiology and Rheumatology, Minsk, Belarus; ⁶Belarusian State Medical University, Department of Internal Diseases №2, Minsk, Belarus; ⁷JSC BIOCAD, Clinical Development Department, St-Petersburg, Russian Federation

Background: According to previous studies, the effectiveness of interleukin-17 (IL-17) inhibitors was higher in anti-TNF-naïve patients with ankylosing spondylitis (AS) [1,2]. Netakimab (NTK) is a humanized anti-IL-17A antibody approved for the treatment of AS, psoriatic arthritis, moderate-to-severe plaque psoriasis in Russia and Belarus.

Objectives: To compare the efficacy of NTK in anti-TNF-naïve patients with anti-TNF-experienced patients with active AS at week 16 of therapy.

Methods: ASTERA (NCT03447704) is an ongoing phase 3 placebo (PBO)-controlled clinical study, aimed at evaluating NTK efficacy in AS [3]. 228 adult patients with active AS (BASDAI ≥ 4) were randomly assigned (1:1) to receive 120 mg NTK or PBO subcutaneously at week 0,1,2 and then q2w. This analysis includes 112 patients in NTK group. Efficacy endpoints included ASAS20/40, ASAS5/6 and ASAS partial remission (PR) at week 16 of therapy.

Results: 28 (25.0%) of 112 patients in NTK group had previous inadequate response/intolerance to anti-TNF (anti-TNF-IR): 24 (21.4%) – one anti-TNF, and 4 (3.6%) – two anti-TNF. 84 (75.0%) patients were TNF-naïve. Achievement of ASAS criteria response at week 16 was similar in both groups (Table 1).

Table 1. Efficacy of NTK at week 16

Parameter	TNF-naïve (n = 84)	anti-TNF-IR (n = 28)	p-value*
ASAS20, n (%)	52 (61.9%)	17 (60.7%)	0.91
ASAS40, n (%)	35 (41.7%)	11 (39.3%)	0.82
ASAS5/6, n (%)	39 (46.4%)	11 (39.3%)	0.51
ASAS(PR), n (%)	15 (17.9%)	4 (14.3%)	0.78

*. Fisher's exact test

Conclusion: NTK 120mg provided sustained improvements in signs and symptoms of AS in anti-TNF-naïve and anti-TNF-IR patients at 16 weeks of therapy.

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POS0929

FACTORS ASSOCIATED WITH THE DEVELOPMENT OF ANTI-DRUG ANTIBODIES TO TUMOUR NECROSIS FACTOR INHIBITORS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS: A TWO YEAR FOLLOW-UP STUDY

E. Durak Ediboglu¹, D. Solmaz¹, G. Kabadayi¹, M. Ozmen¹, M. Çınar², G. Sargin³, O. Karadag⁴, G. Kınıklı⁵, Ö. Gerçik⁶, A. Kalyoncu⁴, S. Yılmaz², A. Cefle⁷, G. Hatemi⁸, T. Senturk³, G. Keser⁹, B. Kıcak¹⁰, F. Yargucu⁹, L. Kozaci¹¹, S. Akar¹.
¹Izmir Katip Çelebi University, Rheumatology, Izmir, Turkey; ²University of Health Sciences, Gulhane Faculty of Medicine, Rheumatology, Ankara, Turkey; ³Adnan Menderes University, Rheumatology, Aydın, Turkey; ⁴Hacettepe University, Rheumatology, Ankara, Turkey; ⁵Ankara University, Rheumatology, Ankara, Turkey; ⁶Tepecik Education and Research Hospital, Rheumatology, Izmir, Turkey; ⁷Kocaeli University, Rheumatology, Kocaeli, Turkey; ⁸Istanbul University, Cerrahpaşa School of Medicine, Rheumatology, Istanbul, Turkey; ⁹Ege University, Rheumatology, Izmir, Turkey; ¹⁰Medical Park Hospital, Rheumatology, Gaziantep, Turkey; ¹¹Yıldırım Beyazıt University, Biochemistry, Ankara, Turkey

Background: Axial spondyloarthritis (axSpA) is a chronic inflammatory rheumatic disease affecting sacroiliac joints and spine as well as peripheral joints and entheses. Tumour necrosis factor inhibitors (TNFi) are widely used in patients with

persistently high disease activity despite non-steroidal anti-inflammatory drugs. Some patients fail to respond or loose responsiveness during therapy with TNFi. The development of anti-drug antibodies (ADA) might play a role in non-response or some adverse events. However it has never been evaluated for 2-years period.

Objectives: Therefore, the aim of the present study was to evaluate the development of ADA against TNFi longitudinally during 2-years period in axSpA patients and factors associated with it.

Methods: In total 180 axSpA patients according to ASAS classification criteria with a new TNFi prescription in the last two weeks period were included in this observational study. Clinical data and serum samples were collected at baseline and at every 12 weeks. Serum drug levels and ADAs were measured on 12, 24, 52 and 104 weeks of treatment by ELISA in one center to avoid inter-assay variability. The development of ADA over time was investigated by using generalized estimating equations (GEE) which is a technique for longitudinal data analysis allowing the use of all available data even deviated from normality.

Results: 180 biologic naïve axSpA patients (116 male, median [IQR] 44.5 [14,5] years) who started anti-TNF agents (infliximab [20%], adalimumab [27.2%], etanercept [32.2%] and golimumab [20.6%]) were included in the analysis. In comparison to baseline values BASDAI, ASDAS-CRP and CRP values were significantly decreased in third months of follow-up (Figure 1). In total 172 patients had at 12 weeks, 154 at 24, 121 at 52, and 73 at 104 week serum samples available for ADA determination. In longitudinal analysis; baseline age and TNFi type, as well as longitudinal BASDAI, ASDAS, serum CRP levels and the development of adverse events and discontinuation of the drug were found to be associated with the development of ADA. In order to determine independent association/s with the development of ADA two longitudinal multivariable models were run; (a) with ASDAS as an activity measure, (b) with BASDAI and CRP levels and produced that all the variables were independently associated with longitudinally development of anti-drug antibodies (Table 1). Antibodies to adalimumab were related with lower serum drug levels.

Conclusion: The results of the present study with up to 2 years of follow-up, revealed that the development of ADA against TNFi therapy is associated with high disease activity, the development of adverse events and treatment discontinuation in patients with axSpA. And etanercept might be negatively associated with the development of ADA.

Table 1. Factors associated with the development of anti-drug antibodies

	Model 1			Model 2		
	B	95% CI	P	B	95% CI	P
Age years	-0.061	-0.109;-0.012	0.015	-0.058	-0.107;-0.010	0.018
TNFi Treatment						
ETN	-1.981	-4.369;-0.134	0.104	-2.475	-4.791;-0.076	0.036
ADA	1.438	-0.002;0.407	0.073	1.275	-0.119;-0.160	0.064
INF	1.550	3.010;3.102	0.050	1.255	2.666;2.629	0.073
GOL	0 ^a			0 ^a		
Presence of adverse event, no	-0.824	-1.451;-0.198	0.010	-0.835	-1.461;-0.208	0.009
TNF treatment discontinuation	1.289	0.043;2.534	0.043	1.248	-0.075;2.571	0.065
BASDAI	0.035	0.015;0.055	0.001			
CRP	0.020	-0.035;0.005	0.008			
ASDAS-CRP				0.852	0.466;1.238	0.000

0^a:set to zero because this parameter is redundant.

Figure 1. Mean change in disease activity and CRP levels during follow-up duration. (P values for 3rd months BASDAI<0.0001, CRP<0.001, ASDAS-CRP<0.001 respectively)

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