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

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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
Familial history 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. 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 anti-inflammatory drugs; csDMARDs, conventional synthetic disease-modifying antirheumatic drugs. ns=not statistical significant. NA=not applicable

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

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