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AB0698

REAL CLINICAL PRACTICE IN THE CONTROL OF REPORTED OUTCOMES BY THE PATIENT (PROS) DIAGNOSED WITH PSORIATIC ARTHRITIS AND/OR ANKYLOSING SPONDYLITIS WHO BEGIN TREATMENT WITH SECUKINUMAB. A PROSPECTIVE MULTICENTRIC STUDY.

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Background:

Objectives: Analyse the effect of secukinumab in terms of the patient's own variables, specifically: fatigue, sleep, pain and quality of life in patients with psoriatic arthritis or spondyloarthritis.

Methods: A multicentric longitudinal observational prospective study was carried out at 6 months in patients who begin treatment with secukinumab. At the start and after 6 months the following data was collected on the outcome: pain through an visual analogue scale (VAS), fatigue using the FACIT-fatigue scale, sleeping problems using the insomnia severity index (ISI) and quality of life with the EuroQol-3L-5D and the PsAQoL.

The sample can be described in terms of the distribution of the variables through measures of central tendency. It was analysed if the change after 6 months was statistically relevant using Student's t-test for paired data in the case of FACIT, VAS, PsAQoL and ISI and chi-squared for the dimensions of the EQ-5D. The size of the effect of each of the measurements taken was calculated using Cohen's D. the results are given grouped by disease and globally. The analysis was carried out using Stata v12 (College Station Tx, USA)

Results: In table 1, the changes in the scales of normal distribution can be seen. Apart from general VAS, all the scales experience significant relevant changes. The PROs preferred by the patient with the best therapeutic response is the quality of sleep. The adjustment of the regression models does not produce changes in the results, apart from small adjustments to the confidence intervals (final column table 1). The subdomain in which the most significant change in the EQ-5D is produced is in that of pain and discomfort.

Scale	Basal*	6 months*	change (adjusted)*+
VAS general (0-100, from worst to best)	56.9 [4.6 a 64.2]	50.9 [42.4 a 59.4]	-6.0 [-12.7 a 0.7]
FACIT-fatigue (better when)	25.3 [21.6 a 29.0]	32.5 [28.0 a 37.0]	7.2 [5.1 a 9.3]
ISI (0to28, best to)	16.0 [14.0 a 1.0]	10.6 [8.4 a 12.8]	-5.4 [-6.8 a -
PsAQoL (0 to 20, best to worst)	12.5 [1.8 a 14.1]	9.0 [7.0 a 11.0]	-5.4 [-6.8 a -
EQ-5D (0-100 from worst to best)	42.3 [35.7 a 48.8]	60.6 [52.0 a 69.3]	18.4 [13.9 a 22.8]

Conclusion: After 6 months patients who begin treatment with secukinumab, present with improvements in all sizes of the effects of the treatment in the various studied scales. The improvement achieves global and generalised statistical significance after 6 months of study. The greatest effect is on sleep, quality of life and fatigue.

The measurements of the outcomes reported by the patients are a clinical value added to our objective evaluations of the health and activity of the disease, and allow us, in a more integrated and comprehensive manner, to undertake a more exact and close evaluation of their state of health and wellbeing.

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AB0699

RESIDUAL DISEASE BURDEN PRESENT IN AXIAL SPONDYLOARTHRITIS AND PSORIATIC ARTHRITIS PATIENTS ACHIEVING LOW DISEASE ACTIVITY STATES

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Background: Despite achieving Low Disease Activity (LDA) states, patients with SpondyloArthritis (SpA) may have considerable residual disease. Sparse data is currently available from Asia.

Objectives: We aimed to evaluate the burden of residual disease in patients with axial SpondyloArthritis (axSpA) or Psoriatic Arthritis (PsA) who achieved LDA.

Methods: We used data from a registry of SpA from an outpatient setting in a tertiary hospital in Singapore. For axSpA, LDA was defined as Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) <4/10. For PsA, LDA was defined by achieving 5/7 cutoffs in the Minimal Disease Activity (MDA) or clinical Disease Activity index for Psoriatic Arthritis (cDAPSA) ≤13.

Results: From 262 cases of axSpA (21% women; mean ± standard deviation (SD) age 42 ± 14 years), 58% of patients achieved LDA states. While from 142 cases of PsA (49% women; mean ± SD age 51 ± 14 years), 38% and 63% achieved MDA and cDAPSA LDA, respectively. Both axSpA and PsA patients with LDA had pain scores range from 17.2 to 25.7/100 and fatigue scores from 3.3 to 3.5/10. (Table 1). Substantial burden in physical disability and mental well-being were seen as a low physical and mental component summary of SF-36. cDAPSA classified nearly twice as many PsA patients into LDA than MDA. Compared to PsA patients in MDA, PsA patients in cDAPSA LDA had higher pain scores, Patient Global Assessment (PtGA), dactylitis, and enthesitis. axSpA patients in LDA classified by BASDAI had the highest pain and fatigue scores, and PtGA.

Table 1. Residual disease burden in patients with axSpA and PsA who have achieved LDA

	axSpA	PsA	
	LDA (n=153)	LDA by MDA (n=54)	LDA by cDAPSA (n=90)
Age, years*	42.2 (14.0)	52.5 (13.2)	52.5 (13.2)
Female, n (%)	26 (17.0)	30 (55.6)	45 (50.0)
TJC*	0.1 (0.3)	0.8 (1.0)	1.0 (1.4)
SJC*	0.1 (0.3)	0.7 (1.3)	0.9 (1.3)
VAS-pain (0-100)*	25.7 (19.0)	17.2 (17.8)	20.8 (16.7)
BASDAI (0-10)*	2.3 (1.0)	2.4 (1.6)	2.7 (1.7)
BASDAI fatigue (0-10)*	3.5 (2.2)	3.3 (2.3)	3.4 (2.3)
PtGA (0-100)*	27.8 (19.5)	20.9 (17.9)	23.5 (17.6)
Dactylitis (0-20)*	—	0.3 (0.5)	0.5 (0.9)
LEI (0-6)*	—	0.1 (0.4)	0.2 (0.5)
HAQ (0-3)*	0.1 (0.1)	0.1 (0.2)	0.2 (0.4)
HAQ < 0.5, n (%)	149 (97.4)	52 (96.3)	77 (85.6)
SF-36 PCS*	46.8 (9.9)	45.8 (11.5)	45.1 (11.7)
SF-36 MCS*	46.4 (11.2)	46.1 (11.3)	45.6 (10.6)

axSpA, axial Spondyloarthritis; PsA, Psoriatic Arthritis; LDA, Low Disease Activity; MDA, Minimal Disease Activity; cDAPSA, clinical Disease Activity index for Psoriatic Arthritis; TJC, tender joint count; SJC, swollen joint count; VAS, Visual Analog Scale; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; PtGA, patient's global assessment; LEI, Leeds Enthesitis Index; HAQ, Health Assessment Questionnaire; SF-36, Short-Form 36; SF-36 PCS, norm-based Physical Component Summary (mean=50, SD=10); SF-36 MCS, norm-based Mental Component Summary (mean=50, SD=10)

*mean (SD)

Conclusion: Despite being in LDA, axSpA and PsA patients experienced substantial pain, fatigue and poorer functional health and mental well-being.

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AB0700

RADIOGRAPHIC PROGRESSION IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS UNDER TREATMENT WITH TNF INHIBITORS. DATA FROM REGISPONSERBIO (SPANISH REGISTER OF BIOLOGICAL THERAPY IN SPONDYLOARTHRITIDES)

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Background: Clinical efficacy of TNF inhibitors (TNFi) in axial spondyloarthritis (axSpA) has been widely probed in randomized control trials. In clinical practice, some studies suggested that long-term (more than 4 years) treatment with TNFi could slow down radiographic progression in axSpA; however, whether this treatment inhibits structural damage remains unclear.

Objectives: To evaluate radiographic progression in axSpA patients receiving long-term TNFi (over 4 years) in comparison with patients starting TNFi.

Methods: A total of 204 patients with axSpA were included in the Spanish Register of Biological Therapy in Spondyloarthritis (REGISPONSERBIO). Out of these, 80 patients (31 starting TNFi and 49 under long-term TNFi) were included in this study based on the availability of spinal radiographs (cervical and lumbar lateral views), at two time points. Radiographs in patients starting TNFi were available: i) at baseline (before TNFi) and ii) after 3 to 5 years of TNFi therapy (mean follow-up 3.7±0.8), while in long-term TNFi patients, these were available: i) at one follow-up visit at least 4 years later since TNFi was started and ii) after 3 to 5 years of this visit (mean follow-up 3.5±1.1). Two trained readers, not blinded for chronological order, independently scored lateral cervical and lumbar spine images according to the mSASSS system (0-72). Following definitions for progression were used: change of the absolute scores, change of ≥2 units, development of new syndesmophytes, and development of new syndesmophytes or growth of the existing syndesmophytes.

Results: Reliability of both readers was excellent with intraclass correlation coefficients (ICCs) of 0.98 (0.98-0.99) at inclusion and 0.98 (0.97-0.99) at follow-up. Most patients (82.5%) were classified as radiographic axSpA. Mean BASDAI at first visit (i) was of 5.0±2.4 for starting TNFi patients and of 3.2±1.9 for long-term TNFi patients. The table depicted the results for radiographic scores and progression. Mean mSASSS score at first visit (i) was 15.8±21.5 and 15.1±18.4 units for starting TNFi and long-term TNFi patients, respectively. The change score between both visits was 2.3±4.2 and 2.3±4.1, respectively. Similarly, no differences were found for change of ≥2 points (32.3% in starting TNFi and 35% in long-term TNFi patients). However, development of new syndesmophytes or growth of the existing syndesmophytes were found to be more frequently (but not significant) in starting TNFi patients compare to long-term TNFi patients.

Conclusion: In patients with axSpA treated with TNFi in clinical practice radiographic progression is observed, independently of the time under this therapy. Nevertheless, the development and growth of syndesmophytes seem to be lower in long-term treated patients.

Table.

	Starting TNFi patients	Long-term TNFi patients*	p-value
Presence of syndesmophytes at first visit, % (n)	45.2% (14)	53.1% (26)	NS
Presence of syndesmophytes at follow up, %	51.6% (16)	55.1% (27)	NS
Mean change score, mean ± SD	2.32 ± 4.19	2.26 ± 4.09	NS
Change of ≥ 2 units in the score % (n)	32.3% (10)	34.7% (17)	NS
Development of new syndesmophytes, % (n)	29% (9)	18.4% (9)	0.3
Progression or development of new syndesmophytes % (n)	29% (9)	22.4% (11)	0.5

* Patients with more than 4 years under TNFi treatment

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