

3^ο Θερινό Σχολείο Ακτινολογίας Μυοσκελετικού “Η Ρευματολογία συναντά την Ορθοπαιδική”

**Νεότερες εξελίξεις στις
Σπονδυλοαρθρίτιδες**

ΝΙΚΟΛΑΟΣ ΚΟΥΓΚΑΣ

ΕΠΙΚ. ΕΠΙΜΕΛΗΤΗΣ Β΄

ΡΕΥΜΑΤΟΛΟΓΙΚΗ ΚΛΙΝΙΚΗ ΠΑΓΝΗ



Περίγραμμα

- Επικαιροποίηση συστάσεων της EULAR για τη διαχείριση της Ψωριασικής Αρθρίτιδας
- Νεότερα φαρμακευτικά μόρια
- Επιλογή θεραπείας μετά από αστοχία σε Anti-TNF
- Κλινικές εκδηλώσεις
 - ΑΣ και μη ακτινολογικής Αξονικής Σπονδυλοαρθρίτιδας
 - Η επίδραση της ψωρίασης στο φορτίο νόσου της Αξονικής και Περιφερικής Σπονδυλοαρθρίτιδας
- Ακτινολογικά ευρήματα ενδεικτικά Σπονδυλοαρθρίτιδας στο γενικό πληθυσμό



EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update

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Συστάσεις EULAR

- Επικαιροποίηση των συστάσεων του 2015 για τη διαχείριση της ΨΑ
- Αρκετές τροποποιήσεις και κάποιες νέες οδηγίες
- Νέα φαρμακευτικά μορια (JAK inhibitors)
- Ειδικές εκδηλώσεις της νόσου (δακτυλίτιδα, αξονική προσβολή, σοβαρή ψωρίαση)
- Αποκλιμάκωση θεραπείας

Table 2 Comparison of the 2015 and 2019 recommendations

2019 (current) version	Changes performed	2015 version
Overarching principles		
A Psoriatic arthritis is a heterogeneous and potentially severe disease, which may require multidisciplinary treatment.	Unchanged	Psoriatic arthritis is a heterogeneous and potentially severe disease, which may require multidisciplinary treatment.
B Treatment of psoriatic arthritis patients should aim at the best care and must be based on a shared decision between the patient and the rheumatologist, considering efficacy, safety and costs.	Unchanged	Treatment of psoriatic arthritis patients should aim at the best care and must be based on a shared decision between the patient and the rheumatologist, considering efficacy, safety and costs.
C Rheumatologists are the specialists who should primarily care for the musculoskeletal manifestations of patients with psoriatic arthritis; in the presence of clinically significant skin involvement, a rheumatologist and a dermatologist should collaborate in diagnosis and management.	Unchanged	Rheumatologists are the specialists who should primarily care for the musculoskeletal manifestations of patients with psoriatic arthritis; in the presence of clinically significant skin involvement, a rheumatologist and a dermatologist should collaborate in diagnosis and management.
D The primary goal of treating patients with psoriatic arthritis is to maximise health-related quality of life, through control of symptoms, prevention of structural damage, normalisation of function and social participation; abrogation of inflammation is an important component to achieve these goals.	Unchanged	The primary goal of treating patients with psoriatic arthritis is to maximise health-related quality of life, through control of symptoms, prevention of structural damage, normalisation of function and social participation; abrogation of inflammation is an important component to achieve these goals.
E In managing patients with psoriatic arthritis, consideration should be given to each musculoskeletal manifestation and treatment decisions made accordingly.	New	Not applicable
F When managing patients with psoriatic arthritis, non-musculoskeletal manifestations (skin, eye and gastrointestinal tract) should be taken into account; comorbidities such as metabolic syndrome, cardiovascular disease or depression should also be considered.	Rephrased	When managing patients with psoriatic arthritis, extra-articular manifestations, metabolic syndrome, cardiovascular disease and other comorbidities should be taken into account.

Recommendations

1	Treatment should be aimed at reaching the target of remission or, alternatively, low disease activity, by regular disease activity assessment and appropriate adjustment of therapy.	Rephrased	Treatment should be aimed at reaching the target of remission or, alternatively, minimal/low disease activity, by regular monitoring and appropriate adjustment of therapy.
2	Non-steroidal anti-inflammatory drugs may be used to relieve musculoskeletal signs and symptoms.	Rephrased	In patients with psoriatic arthritis, non-steroidal anti-inflammatory drugs may be used to relieve musculoskeletal signs and symptoms.
3	Local injections of glucocorticoids should be considered as adjunctive therapy in psoriatic arthritis; systemic glucocorticoids may be used with caution at the lowest effective dose.	Renumbered	Local injections of glucocorticoids should be considered as adjunctive therapy in psoriatic arthritis; systemic glucocorticoids may be used with caution at the lowest effective dose.
4	In patients with polyarthritis, a csDMARD should be initiated rapidly, with methotrexate preferred in those with relevant skin involvement.	Modified	In patients with peripheral arthritis, particularly in those with many swollen joints, structural damage in the presence of inflammation, high ESR/CRP and/or clinically relevant extra-articular manifestations, csDMARDs should be considered at an early stage, with methotrexate preferred in those with relevant skin involvement.
5	In patients with monoarthritis or oligoarthritis, particularly with poor prognostic factors such as structural damage, high erythrocyte sedimentation rate/C reactive protein, dactylitis or nail involvement, a csDMARD should be considered.	New	Not applicable but partly covered in the recommendation above.
6	In patients with peripheral arthritis and an inadequate response to at least one csDMARD, therapy with a bDMARD should be commenced; when there is relevant skin involvement, an IL-17 inhibitor or IL-12/23 inhibitor may be preferred.	Modified and merged	In patients with peripheral arthritis and an inadequate response to at least one csDMARD, therapy with a bDMARD, usually a TNF inhibitor, should be commenced. In patients with peripheral arthritis and an inadequate response to at least one csDMARD, in whom TNF inhibitors are not appropriate, bDMARDs targeting IL-12/23 or IL-17 pathways may be considered.
7	In patients with peripheral arthritis and an inadequate response to at least one csDMARD and at least one bDMARD, or when a bDMARD is not appropriate, a JAK inhibitor may be considered.	New	Not applicable.
8	In patients with mild disease and an inadequate response to at least one csDMARD, in whom neither a bDMARD nor a JAK inhibitor is appropriate, a PDE4 inhibitor may be considered.	Modified	In patients with peripheral arthritis and an inadequate response to at least one csDMARD, in whom bDMARDs are not appropriate, a targeted synthetic DMARD such as a PDE4 inhibitor may be considered.
9	In patients with unequivocal enthesitis and insufficient response to NSAIDs or local glucocorticoid injections, therapy with a bDMARD should be considered.	Modified	In patients with active enthesitis and/or dactylitis and insufficient response to NSAIDs or local glucocorticoid injections, therapy with a bDMARD should be considered, which according to current practice is a TNF inhibitor.
10	In patients with predominantly axial disease which is active and has insufficient response to NSAIDs, therapy with a bDMARD should be considered, which according to current practice is a TNF inhibitor; when there is relevant skin involvement, IL-17 inhibitor may be preferred.	Modified	In patients with predominantly axial disease that is active and has insufficient response to NSAIDs, therapy with a bDMARD should be considered, which according to current practice is a TNF inhibitor.
11	In patients who fail to respond adequately to, or are intolerant of a bDMARD, switching to another bDMARD or tsDMARD should be considered*, including one switch within a class†.	Modified	In patients who fail to respond adequately to a bDMARD, switching to another bDMARD should be considered, including switching between TNF inhibitors.
12	In patients in sustained remission, cautious tapering of DMARDs may be considered.	New	Not applicable.

Efficacy and safety of upadacitinib in patients with active ankylosing spondylitis (SELECT-AXIS 1): a multicentre, randomised, double-blind, placebo-controlled, phase 2/3 trial

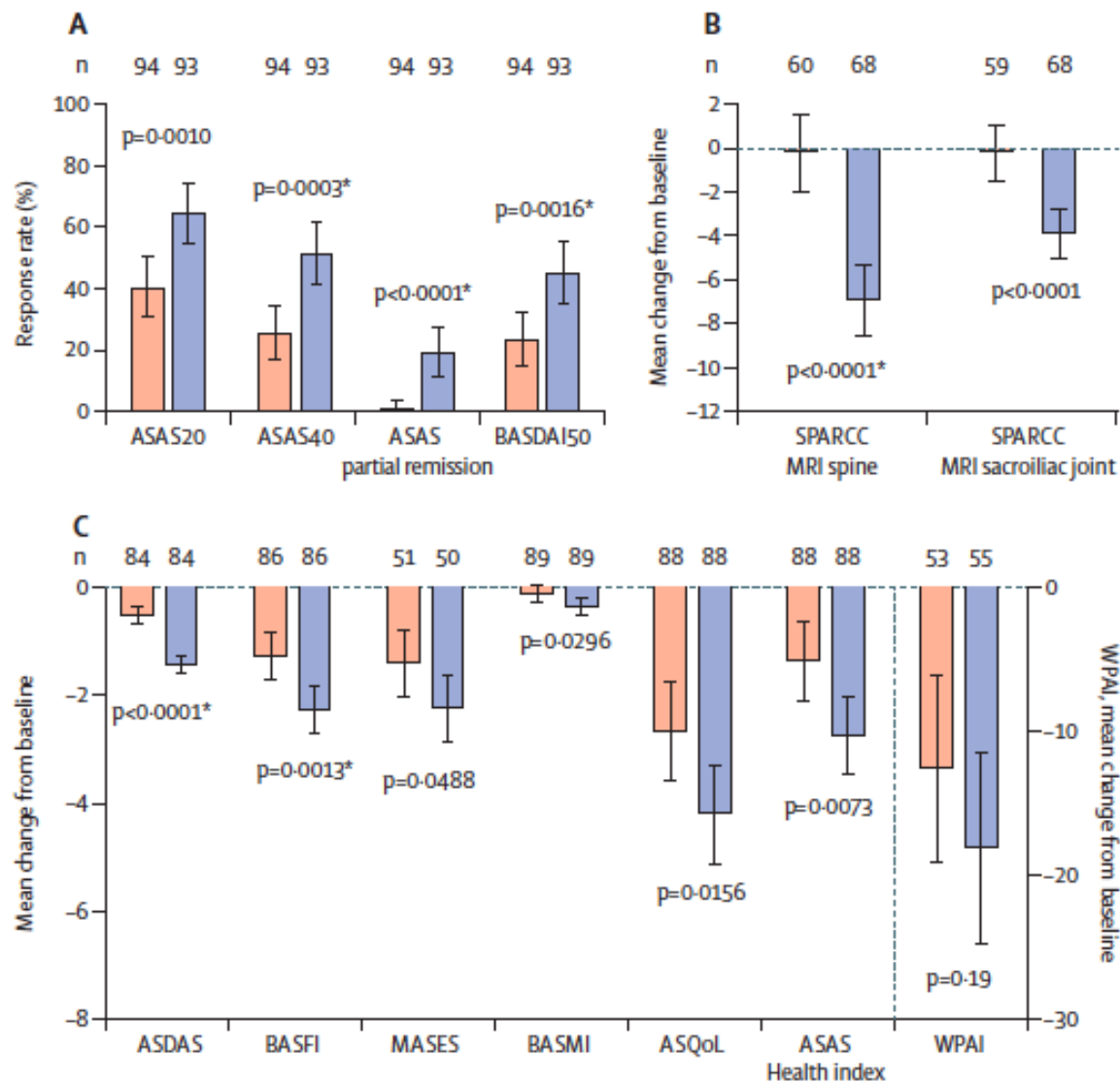


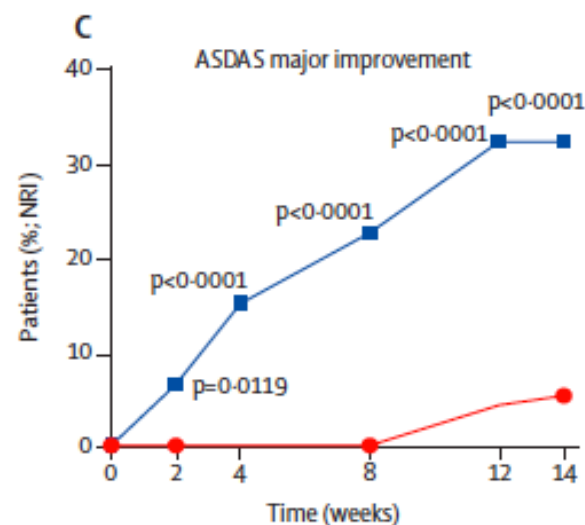
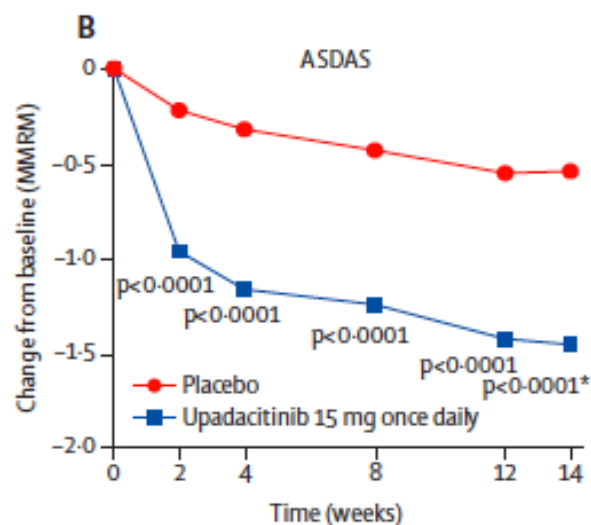
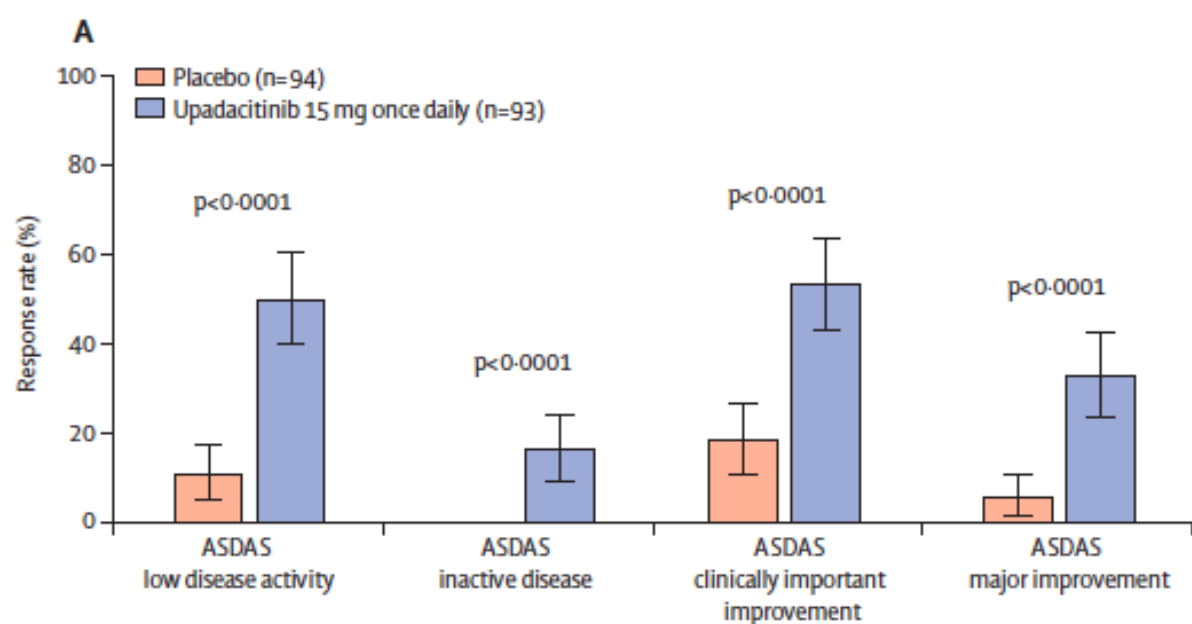
Désirée van der Heijde, In-Ho Song, Aileen L Pangan, Atul Deodhar, Filip van den Bosch, Walter P Maksymowych, Tae-Hwan Kim, Mitsumasa Kishimoto, Andrea Everding, Yunxia Sui, Xin Wang, Alvina D Chu, Joachim Sieper

Objectives-Methods

- To assess the efficacy and safety of upadacitinib, a selective JAK1 inhibitor, in patients with AS
- Multicentre, randomised, double-blind, placebo-controlled, two-period, parallel-group, phase 2/3 study
- AS patients (N.Y. criteria), 2 NSAIDS failure or intolerance
- Oral upadacitinib 15 mg once daily or oral placebo for the 14-week period 1 (1:1 randomization)
- Primary endpoint: ASAS 40 week 14

Placebo Upadacitinib 15 mg once daily





Conclusion



- **Upadacitinib 15 mg once daily significantly improved disease activity, function, and MRI-detected axial inflammation in patients with active ankylosing spondylitis after 14 weeks of treatment**
- **The incidence of adverse events was similar with upadacitinib and placebo**
- **No new safety signals were observed compared with previous studies in rheumatoid arthritis**

Κλινική σημασία

- Σημαντικός ο ρόλος των JAK αναστολέων στη θεραπεία της ΑΣ
- Μια ακόμα, διαφορετικής τάξης, αγωγή για τις σπονδυλοαρθρίτιδες

CLINICAL SCIENCE

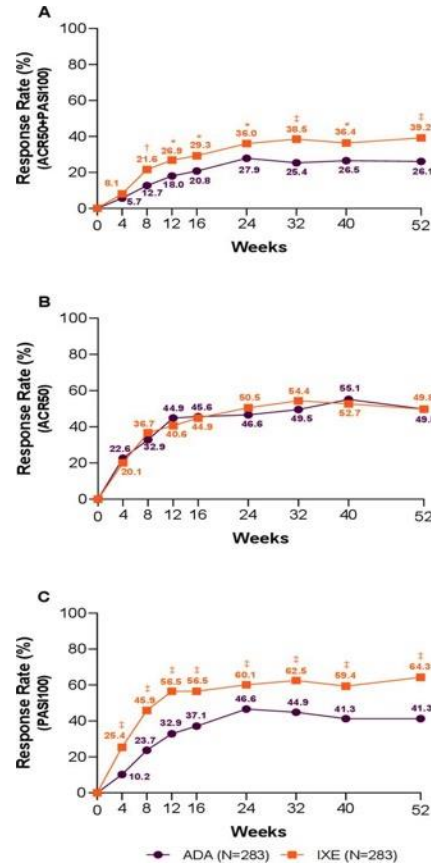
Multicentre, randomised, open-label, parallel-group study evaluating the efficacy and safety of ixekizumab versus adalimumab in patients with psoriatic arthritis naïve to biological disease-modifying antirheumatic drug: final results by week 52

Josef S Smolen,¹ Philip Mease,^{2,3} Hasan Tahir,⁴ Hendrik Schulze-Koops ⁵,
Inmaculada de la Torre,⁶ Lingnan Li,⁶ Maja Hojnik,⁶ Christophe Sapin,⁶
Masato Okada,⁷ Roberto Caporali,⁸ Jordi Gratacós,⁹ Philippe Goupille,¹⁰
Soyi Liu Leage,⁶ Sreekumar Pillai,⁶ Peter Nash ¹¹

Objectives-Methods

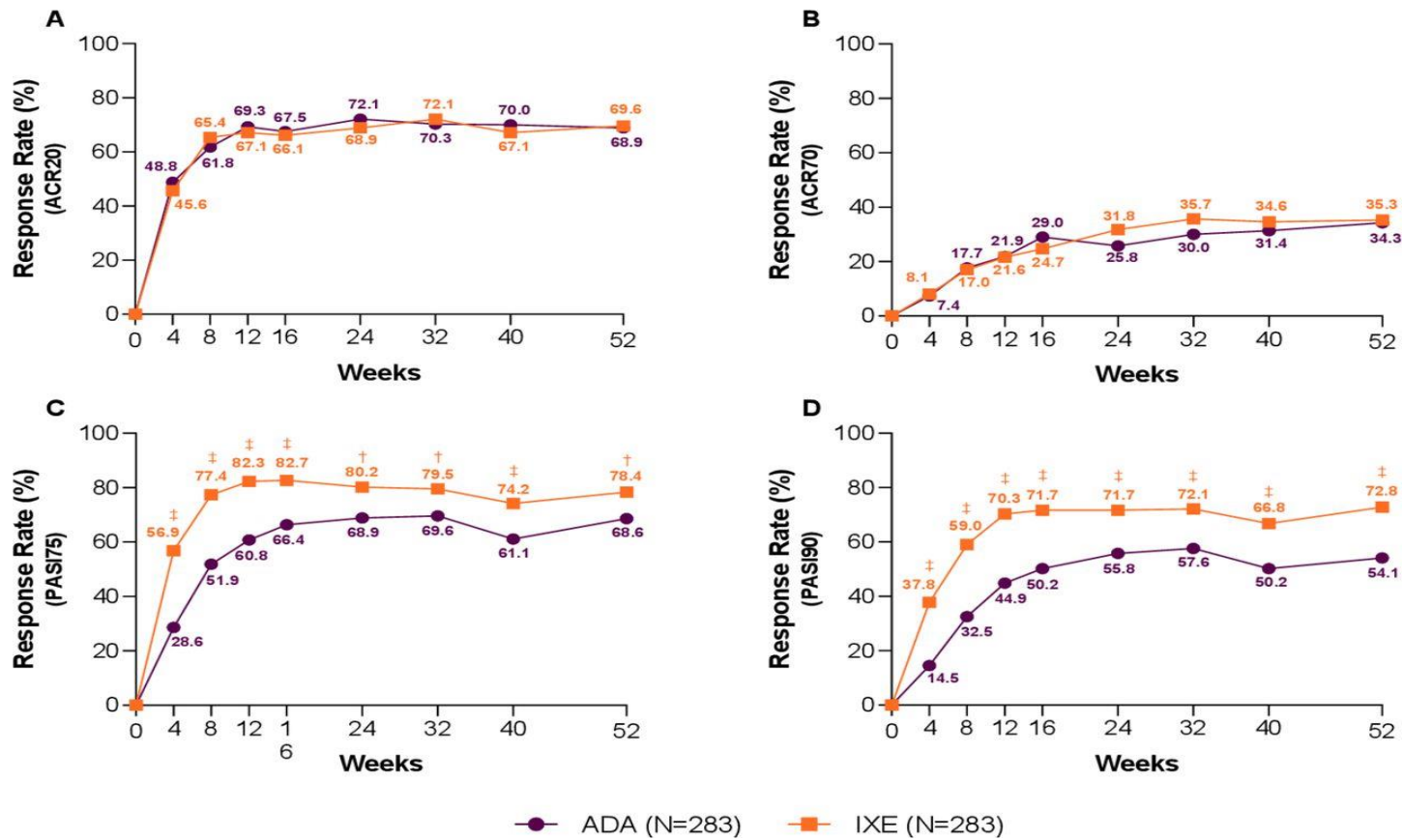
- To evaluate the efficacy and safety of Ixekizimab (IXE) versus Adalimumab (ADA) after 52wk of treatment
- Subgroup analysis of concomitant csDMARD use
- Multicentre, open-label ,blinded-assessor study
- Bionäive patients with PsA
- Patients were randomised 1:1 to IXE or ADA with stratification by concomitant csDMARD use and presence of moderate-to-severe plaque psoriasis

Key clinical response rates through week 52 (non-responder imputation).



Josef S Smolen et al. Ann Rheum Dis 2020;79:1310-1319

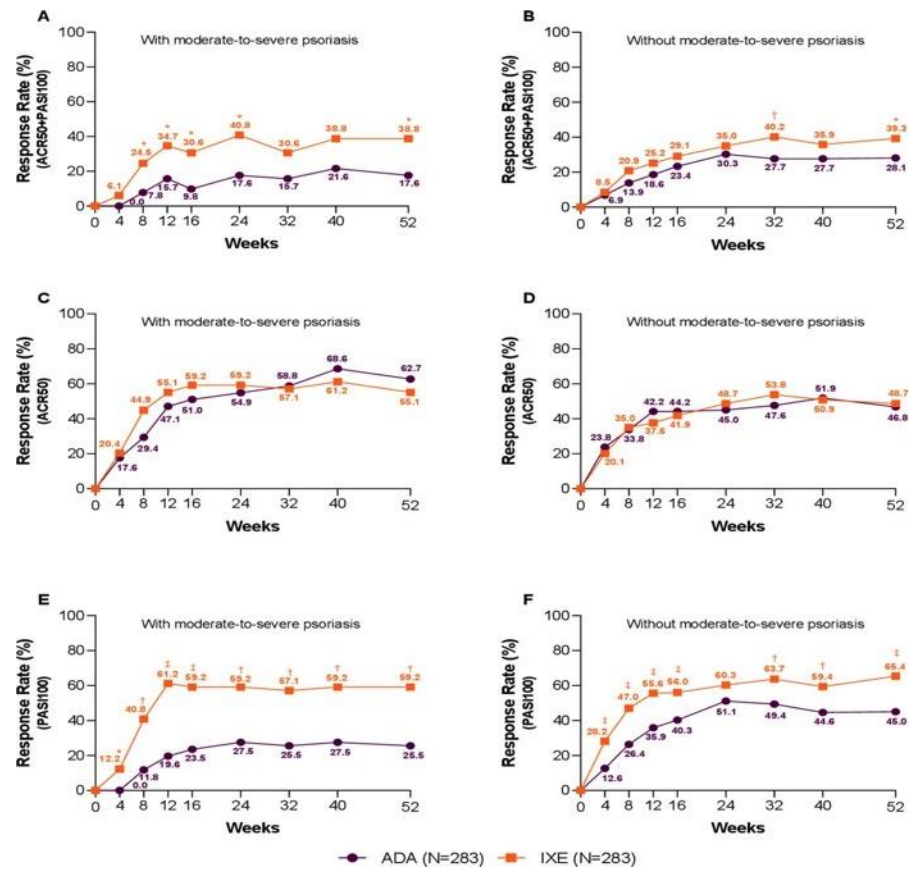
Additional efficacy outcomes—American College of Rheumatology (ACR) and Psoriasis Area and Severity Index (PASI).



Josef S Smolen et al. Ann Rheum Dis 2020;79:1310-1319



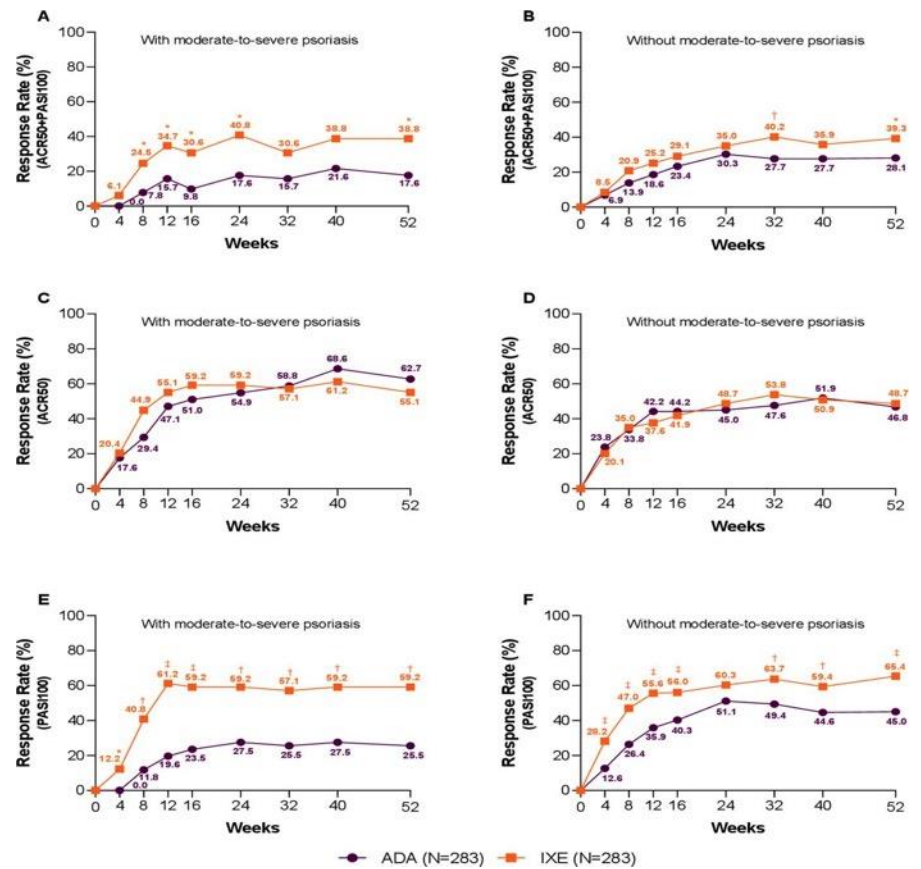
Subgroup analysis based on presence/absence of moderate-to-severe psoriasis—clinical response rates for the key outcomes.



Josef S Smolen et al. Ann Rheum Dis 2020;79:1310-1319



Subgroup analysis based on presence/absence of moderate-to-severe psoriasis—clinical response rates for the key outcomes.



Josef S Smolen et al. Ann Rheum Dis 2020;79:1310-1319



Conclusion

- **IXE showed better efficacy on psoriasis and performed at least as well as ADA on musculoskeletal manifestations**
- **IXE efficacy was consistent irrespective of concomitant csDMARD use**

Κλινική σημασία

- Επιβεβαίωση της ανωτερότητας των αναστολέων της IL-17 στην αντιμετώπιση της ψωρίασης
- Ανεξάρτητο θεραπευτικό αποτέλεσμα από τη χρήση DMARD

CLINICAL SCIENCE

Effectiveness of secukinumab versus an alternative TNF inhibitor in patients with axial spondyloarthritis previously exposed to TNF inhibitors in the Swiss Clinical Quality Management cohort

Raphael Micheroli,¹ Christoph Tellenbach ,^{1,2} Almut Scherer,² Kristina Bürki,¹ Karin Niederman,³ Michael J Nissen,⁴ Pascal Zufferey,⁵ Pascale Exer,⁶ Burkhard Möller ,⁷ Diego Kyburz,⁸ Adrian Ciurea ¹

Objectives-Methods

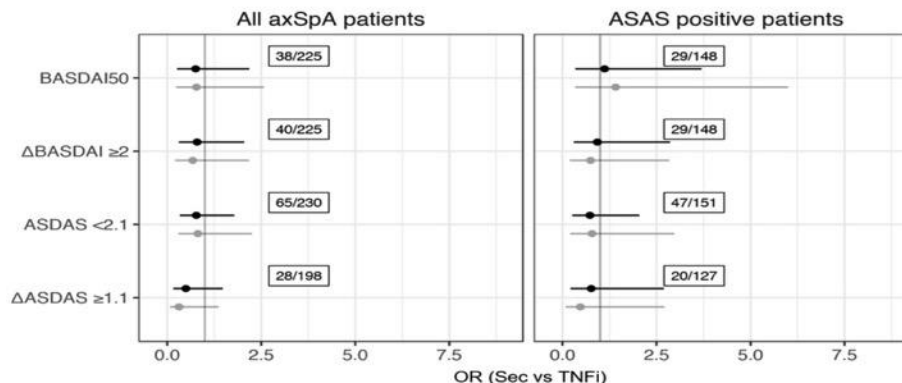
- To compare effectiveness of treatment with secukinumab (SEC) with that of alternative tumour necrosis factor inhibitors (TNFis) in patients with axial spondyloarthritis (axSpa) after withdrawal from one or more TNFis
- Patients with axSpa in the SCQM registry who initiated SEC (n=106) or an alternative TNFi (n=284) after experiencing TNFi failure
- Drug retention was investigated with matching weights propensity score (PS) analyses and multiple adjusted Cox proportional hazards models
- Matching weights PS-based analyses and multiple-adjusted logistic regression analyses were used to assess the proportion of patients reaching BASDAI 50 at 1 year

Results

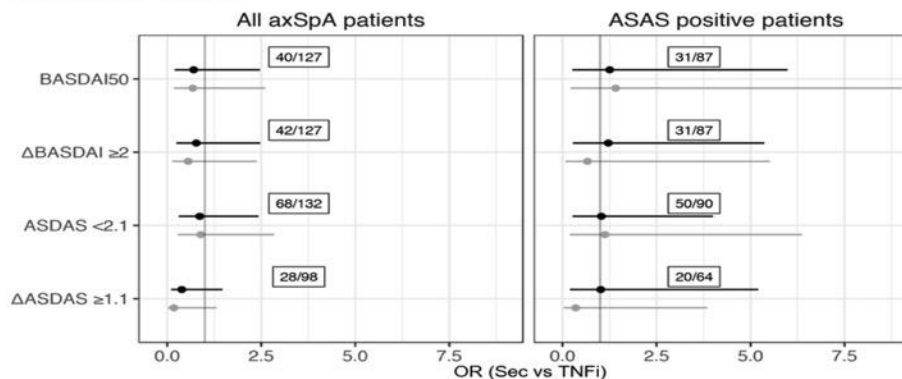
- SEC was more often used as 3rd -line or later-line biologic (76% vs 40% for TNFi)
- Patients starting SEC had higher BASDAI, BASFI, BASMI and CRP levels
- Comparable risk of drug discontinuation was found for SEC versus TNFi (HR 1.14, 95% CI 0.78 to 1.68 in the PS-based analysis and HR 1.16, 95% CI 0.79 to 1.71 in the multiple-adjusted analysis)
- No significant difference in BASDAI 50 responses at 1 year between the two modes of biological drug action, with CI of estimates being, however, wide (OR for SEC vs TNFi 0.76, 95% CI 0.26 to 2.18 and 0.78, 95% CI 0.24 to 2.48 in the PS-based and the covariate-adjusted model, respectively)

Comparison of response rates at 1 year of treatment with secukinumab (SEC) versus an alternative tumour necrosis factor inhibitor (TNFi) for different outcome measures, taking into account potential confounding by indication with two different methods.

A. Response/tolerance analysis



B. Completer analysis



Raphael Micheroli et al. Ann Rheum Dis 2020;79:1203-1209

Conclusion



- **These longitudinal data from a real life axSpA cohort suggest that after TNFi exposure, switching to SEC is comparably effective to switching to another TNFi.**

Κλινική σημασία

- Επιβεβαίωση των υπάρχοντων κατευθυντήριων οδηγιών
- Τυχαιοποιημένες συγκριτικές μελέτες είναι απαραίτητες για ασφαλέστερα συμπεράσματα και ταυτοποίηση συγκεκριμένων ασθενών στους οποίους η αλλαγή τάξης βιολογικού παράγοντα θα ήταν επωφελής

EPIDEMIOLOGICAL SCIENCE

Clinical manifestations, disease activity and disease burden of radiographic versus non-radiographic axial spondyloarthritis over 5 years of follow-up in the DESIR cohort

Clementina López-Medina ^{1,2,3} Anna Molto ^{1,2} Pascal Claudepierre,^{4,5}
Maxime Dougados^{1,2}

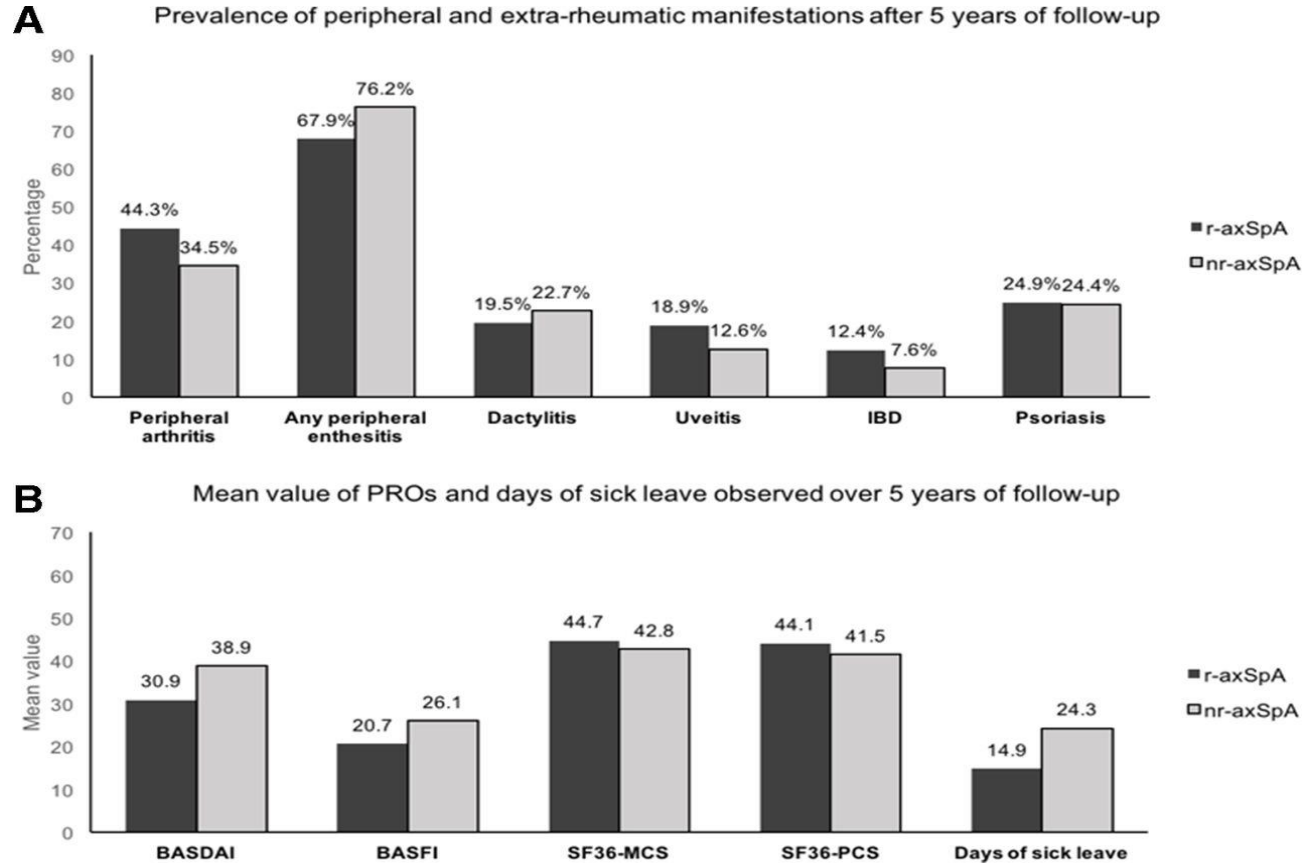
Objectives-Methods

- To compare the clinical manifestations, disease activity and disease burden between patients with radiographic (r-axSpa) and non-radiographic axial spondyloarthritis (nr-axSpa) over a 5-year follow-up period in the DESIR cohort
- The incidence of first episodes of peripheral and extra-rheumatic manifestations was compared between the two groups adjusted for sex, age and tumour necrosis factor blocker (TNFb) intake
- Mean values of patient reported outcomes (PROs) and days of sick leave over 5 years of follow-up were also compared

Results

- 669 patients were included
 - 185 (27.7%) were classified as r-axSpa
 - 484 (72.3%) were classified as nr-axSpa,
- At baseline, the r- axSpa patients showed a significantly higher prevalence of males
- After adjusting for age, sex and TNFb intake, cox regressions for peripheral and extra-rheumatic manifestations did not show any significant differences between groups
- Mixed models also showed similar mean levels in PROs and days of sick leave between groups over time

Main outcomes after 5 years of follow-up.



Clementina López-Medina et al. Ann Rheum Dis 2020;79:209-216

Conclusion

- **The incidence of peripheral and extra- rheumatic manifestations as well as the disease burden over time remained similar between r-axSpa and nr- axSpa groups after adjusting for intermediate variables**

Κλινική σημασία

- Η αξονική νόσος είναι μία οντότητα και ως τέτοια πρέπει να αντιμετωπίζεται
- Ο διαχωρισμός σε ακτινογραφική ή μη σπονδυλοαρθρίτιδα είναι χρήσιμος μόνο για κλινικές μελέτες

Original Article

Axial and peripheral spondyloarthritis: does psoriasis influence the clinical expression and disease burden? Data from REGISPONSER registry

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M. Carmen Castro-Villegas¹, Pilar Font-Ugalde¹, M. Ángeles Puche-Larrubia¹,
Ignacio Gómez-García¹, Iván Arias-de la Rosa¹, Nuria Barbarroja,
Ruxandra Schiotis^{3,*} and Eduardo Collantes-Estévez^{1,*}

Objectives-Methods

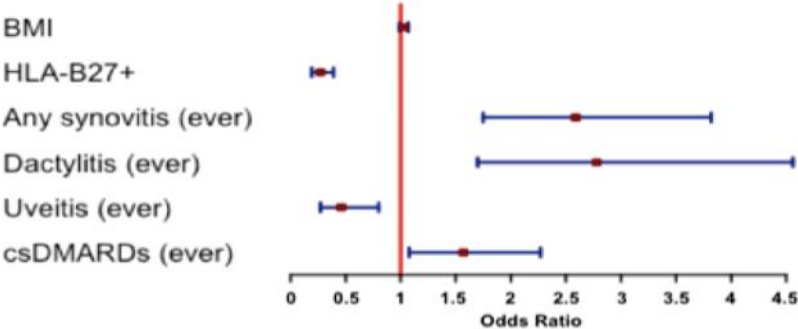
- To evaluate whether the presence of psoriasis influences the clinical expression, disease activity and disease burden in both axial and peripheral phenotypes of SpA
- Patients from the REGISPONSER registry classified as SpA according to the ESSG criteria
- Classification as psoriatic or non-psoriatic depending on the presence of cutaneous or nail psoriasis; thereafter, they were classified as having either axial [presence of radiographic sacroiliitis OR IBP] or peripheral phenotype (absence of radiographic sacroiliitis AND absence of IBP AND presence of peripheral involvement)
- Pair-wise univariate and multivariate analyses among the four groups (psoriatic/non-psoriatic axial phenotypes and psoriatic/non-psoriatic peripheral phenotypes) were performed with adjustment for treatment intake.

Results

- 2296 patients were included
- Among patients with axial phenotype, psoriasis was independently associated ($P < 0.05$) with **HLA-B27** [odds ratio (OR) 0.27], **uveitis** (OR 0.46), **synovitis** (ever) (OR 2.59), **dactylitis** (OR 2.78) and the **use of csDMARDs** (OR 1.47) in comparison with non-psoriatic patients
- Among patients with peripheral phenotype and adjusting for csDMARD intake, psoriasis was independently associated with **higher age at disease onset** (OR 1.05), **HLA-B27** (OR 0.14) and **heel enthesitis** (OR 0.22)
- Higher scores for patient-reported outcomes and greater use of treatment at the time of the study visit were observed in psoriatic patients with either axial or peripheral phenotype

Fig. 2 Comparison of axial phenotype patients with regard to the presence of psoriasis. Multivariate ...

A Clinical characteristics: psoriatic axial phenotype (ref) vs non-psoriatic axial phenotype



B Current status: psoriatic axial phenotype (ref) vs non-psoriatic axial phenotype

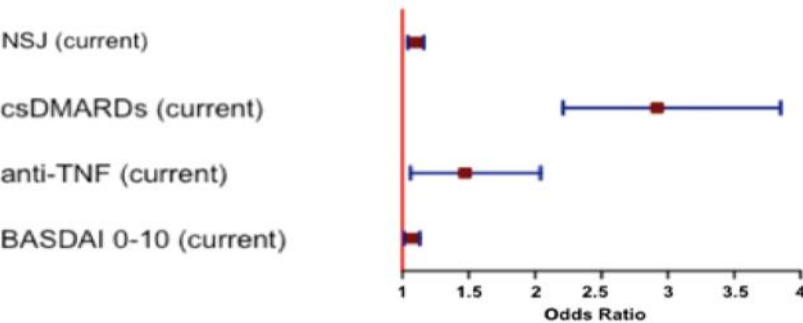
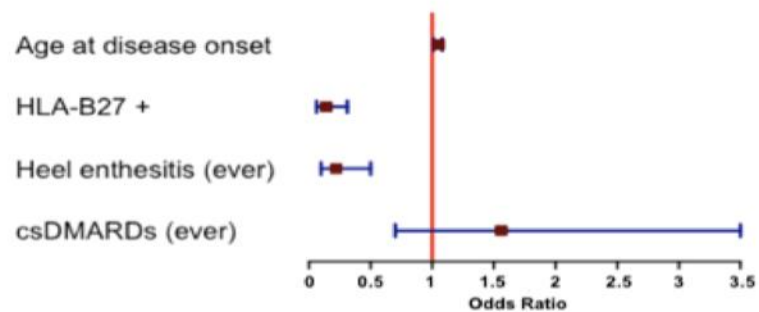
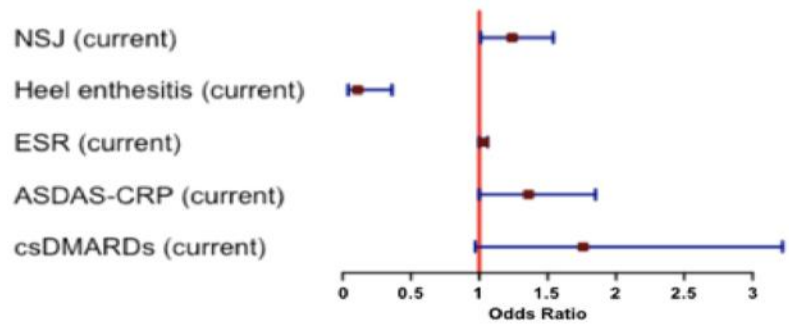


Fig. 3 Comparison of peripheral phenotype patients with regard to the presence of psoriasis. Multivariate ...

A Clinical characteristics: psoriatic peripheral phenotype (ref) vs non-psoriatic peripheral phenotype



B Current status: psoriatic peripheral phenotype (ref) vs non-psoriatic peripheral phenotype



Conclusion

- **This study suggests that, across the whole group of SpA, psoriasis is associated with differences in clinical disease expression, a greater disease burden and increased use of drugs**

Κλινική σημασία

- Ισχυρή συσχέτιση της ψωρίασης με περιφερική νόσο, ακόμα και στους ασθενείς με φαινότυπο αξονικής προσβολής
- Ανάγκη για πιο “επιθετική” αγωγή και στενότερη παρακολούθηση σε αυτήν τη περίπτωση

EPIDEMIOLOGICAL SCIENCE

Frequency of MRI changes suggestive of axial spondyloarthritis in the axial skeleton in a large population-based cohort of individuals aged <45 years

Xenofon Baraliakos ¹, Adrian Richter,^{2,3} Daniel Feldmann,¹ Anne Ott,¹ Robin Buelow,⁴ Carsten O Schmidt,² Juergen Braun¹

Objectives-Methods

- To investigate the frequency of bone marrow oedema (BME) and fatty lesions (FL) suggestive of axial spondyloarthritis (axSpA) on MRI of the spine and sacroiliac joints (SIJ) in a general population sample
- Volunteers underwent spinal (sagittal T1/T2) and SIJ (semicoronal STIR) MRI examinations

Results

Table 1 Occurrence rate of MRI lesions of the sacroiliac joints and in the spine according to subcategories from the number of participants ('n') with available information

Parameter (n patients with data available) and subcategory		n (%) patients in each subcategory	Sacroiliac joints	Spine	
			n (%) quadrants with BME on MRI	n (%) segments with BME on MRI	n (%) segments with FL on MRI
Age, years (n=793)	<30	114 (14.4%)	24 (2.63%)	19 (0.72%)	208 (7.93%)
	30–35	120 (15.1%)	20 (2.08%)	57 (2.07%)	288 (10.43%)
	35–40	198 (25.0%)	51 (3.22%)	104 (2.28%)	499 (10.96%)
	40–45	361 (45.5%)	92 (3.19%)	182 (2.19%)	1309 (15.77%)
Sex (n=793)	Male	392 (49.4%)	100 (3.19%)	158 (1.75%)	1284 (14.24%)
	Female	401 (50.6%)	87 (2.71%)	204 (2.21%)	1020 (11.06%)
hsCRP, mg/dL (n=761)	Normal	708 (93%)	169 (2.98%)	337 (2.07%)	2054 (12.61%)
	Increased	53 (7%)	15 (3.54%)	18 (1.48%)	165 (13.54%)
HLA-B27 (n=756)	Negative	689 (91.1%)	157 (2.85%)	307 (1.94%)	1995 (12.59%)
	Positive	67 (8.9%)	26 (4.85%)	38 (2.47%)	195 (12.65%)
BMI category, kg/m ² (n=793)	<25 (under-normal weight)	357 (45%)	60 (2.1%)	159 (1.94%)	803 (9.78%)
	25–30 (overweight)	287 (36.2%)	83 (3.61%)	146 (2.21%)	918 (13.91%)
	>30 (obese)	149 (18.8%)	44 (3.69%)	57 (1.66%)	583 (17.01%)
Ever smoked (n=792)	Yes	497 (62.8%)	126 (3.17%)	240 (2.1%)	1499 (13.11%)
	No	295 (37.2%)	61 (2.58%)	122 (1.8%)	800 (11.79%)
Back pain (n=793)	NRS=0	342 (43.1%)	63 (2.30%)	170 (2.16%)	985 (12.52%)
	NRS=1–3	223 (28.1%)	69 (3.87%)	99 (1.93%)	648 (12.63%)
	NRS≥4	228 (28.8%)	55 (3.02%)	93 (1.77%)	671 (12.8%)

Results

Table 2 Frequency of patients with 'positive' lesions based on different lesion cut-offs (≥ 1 to ≥ 5 lesions) for bone marrow oedema (BME) and fatty lesions (FL) in the sacroiliac joints (SIJ) and the spine

Site and lesion		Cut-off numbers of lesions				
		≥ 1	≥ 2	≥ 3	≥ 4	≥ 5
SIJ	BME	136	37	7	3	1
Spine	BME	218	86	38	13	6
	FL	645	500	351	270	185

Conclusion

- **High frequency of inflammatory and fatty MRI lesions suggestive of axSpA, especially in the spine, are found in general population**
- **This indicates a limited value of such MRI findings for diagnosis and classification of axSpA.**
- **The increasing frequency with age suggests that mechanical factors could play a role**

Κλινική σημασία

- Προσοχή στη διάγνωση βασιζόμενη σε «θετική MRI» ,ειδικά σε απουσία ισχυρών κλινικών ευρημάτων
- Πιθανή επικαιροποίηση του ορισμού της «θετικής MRI» ιερολαγονίων για την ταξινόμηση των ασθενών με αξονική σπονδυλοαρθρίτιδα

