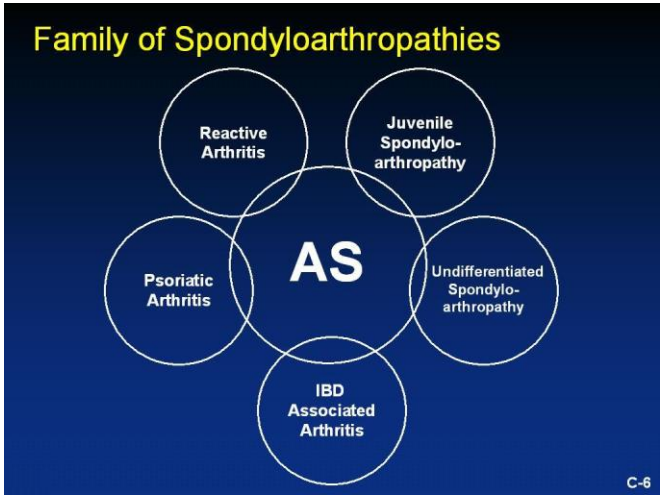
Οι ανάγκες και η αντιμετώπιση γυναικών με χρόνια φλεγμονώδη νοσήματα

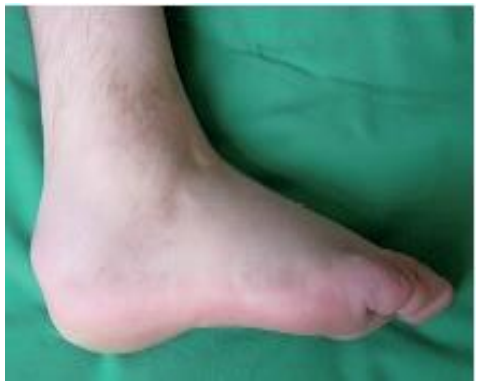
Μη ακτινολογική αξονική σπονδυλαρθρίτιδα

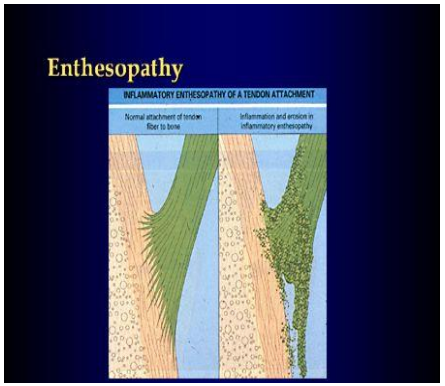
11ο Συνεδριο ΕΠΕΜΥ
Κερκυρα Απριλιος 2019

Δαούσης Δημήτρης
Αναπλ. καθηγητής Παθολογίας/Ρευματολογίας
Ιατρική Σχολή Πανεπιστημίου Πατρών

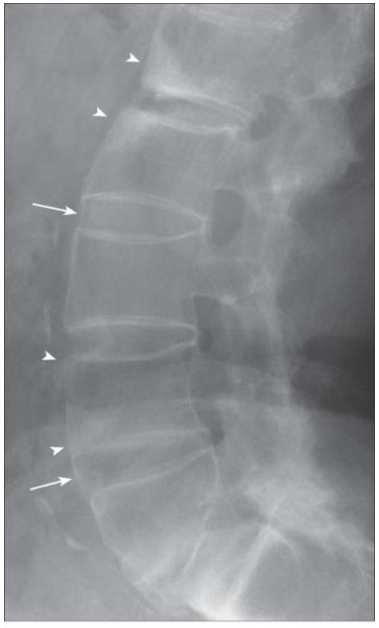
Σπονδυλαρθροπάθειες

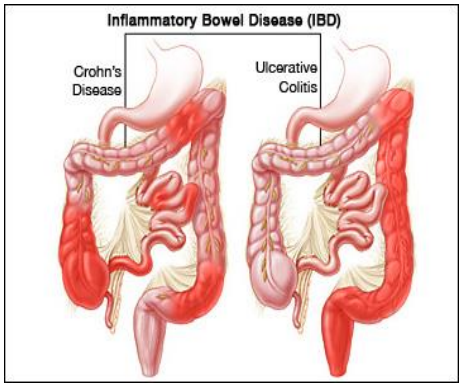






- Προσβολή αξονικού σκελετού- Οστεοπαραγωγή
- Ισχυρό γενετικό υπόβαθρο
- Φλεγμονή σε σημεία που δέχονται stress (μηχανικό ή μικροβιακό





The Spectrum of Spondyloarthritides

- Spondyloarthritides (SpA) are a group of chronic, inflammatory diseases of autoimmune nature.[1]
  - SpA encompasses a range of diseases, including those affecting:[1,2]
    - Involvement of the axial skeleton
    - Peripheral joints
    - Extra-articular manifestations

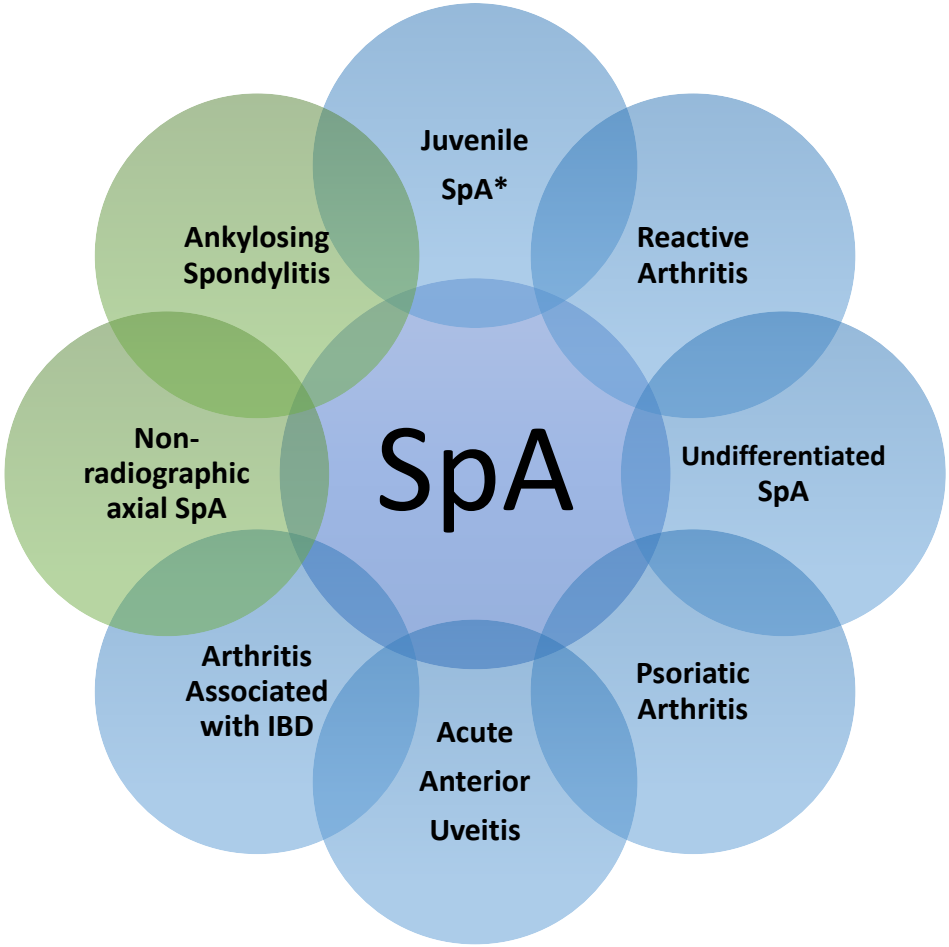
Patients with SpA typically present a range of symptoms that are either:

Predominantly Peripheral

-or-

Predominantly Axial

The Spectrum of SpA Diseases[1,2]



- IBD: Inflammatory Bowel Disease
- * Juvenile SpA commonly manifests as peripheral arthritis and enthesitis affecting the lower extremities. Spinal or sacroiliac joint involvement is infrequent at disease onset, but can develop during the disease course.[3]

[1] Rudwaleit et al. Ann Rheum Dis 2011;70:25–31
[2] Helmick et al. Arthritis Rheum. 2008;58(1):15–25
3 Tse and Laxar. Nat Rev Rhem. 2012;8(5):269–279

What is Axial Spondyloarthritis?

- Axial SpA (axSpA) is a chronic inflammatory disease that predominantly affects the sacroiliac (SI) joints and spine.[1]
  - Patients with axSpA have a range of disease burden, stemming from pain and stiffness of the SI joints and spine.[1]
  - X-ray changes of the spine *may* or *may not* be present.[1]
  - Prevalence of axSpA in the US is ~1%.[2]
- Patients with axSpA that have clearly defined structural changes of the SI joint on X-ray are classified as having Ankylosing Spondylitis (AS), as defined by the modified New York (mNY) criteria.[3]
  - Prevalence of AS in the US is ~0.5%.[4]

The Elements of Patient Burden in axSpA[1]

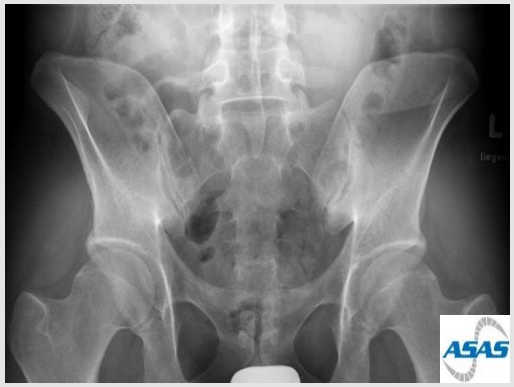
[1] Sieper and van der Heijde. Arthritis Rheum 2013;65:543–551
[2] Reveille et al. Arthr Care Res. 2012;64(6):905–910
[3] van der Linden et al. Arthritis Rheum. 1984;27:361–368
[4] Helmick et al. Arthritis Rheum. 2008;58(1):15–25

What is axSpA Without Radiographic Signs of AS?

- Patients with the typical manifestations of axSpA without X-ray evidence of sacroiliitis are classified as having non-radiographic axSpA (nr-axSpA).[1]
  - With the advent of Magnetic Resonance Imaging (MRI), it is now possible to visualise acute inflammatory lesions that can be highly suggestive of axSpA.[1]
    - Inflammation is often seen in axSpA patients before the formation of structural damage.[1,2]
  - The major difference between patients with AS and nr-axSpA is the presence, or lack of structural damage to the SI joints as evidenced upon X-ray.[1,2]

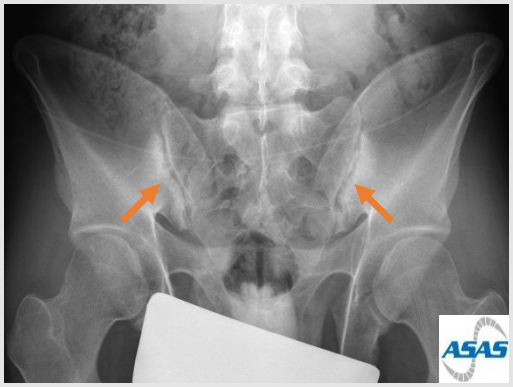
X-RAY: STRUCTURAL DAMAGE

nr-axSpA[3]



No definite radiographic sacroiliitis (grade 0 on the right side and grade 1 [possible subchondral sclerosis] on the left side).

AS[3]



Definite radiographic sacroiliitis (grade 2 bilaterally) fulfilling radiographic criterion of mNY.

MRI: INFLAMMATION

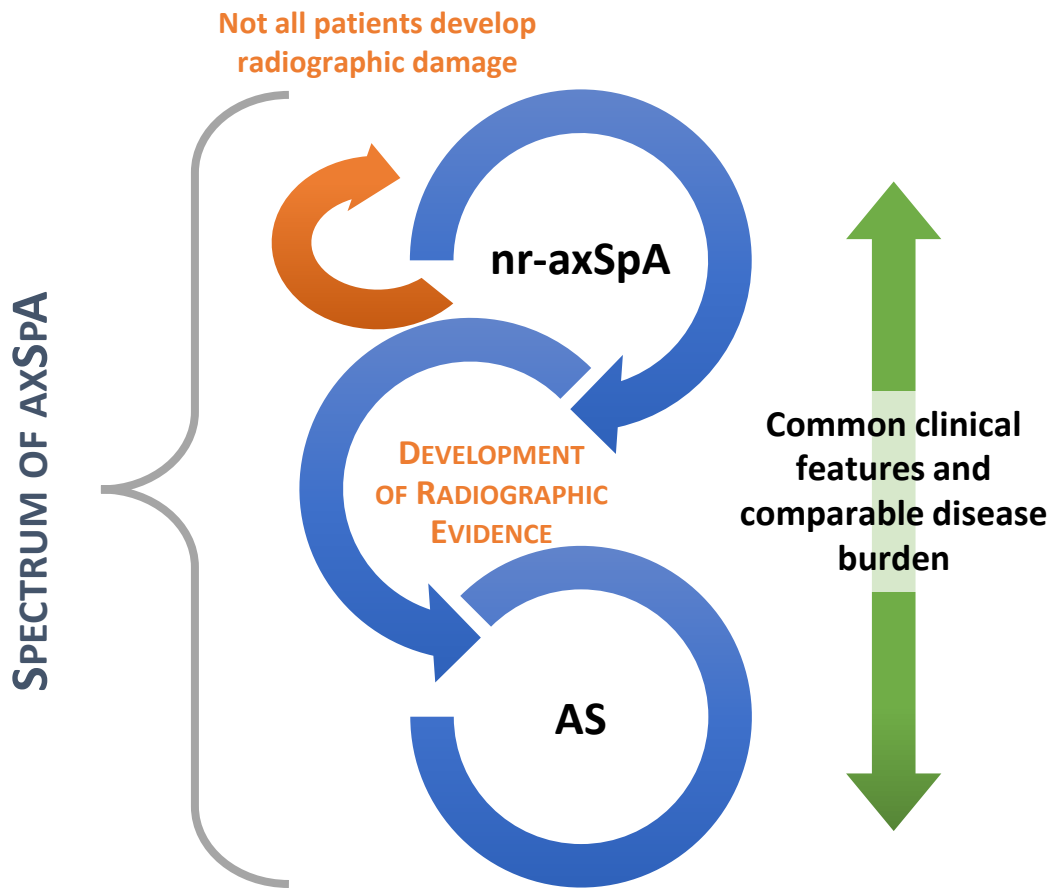
SI-Inflammation[3]

Subchondral periarticular bone marrow oedema.
Acute sacroiliitis, predominantly on the left side.

[1] Sieper and van der Heijde. Arthritis Rheum 2013;65:543–551
[2] Rudwaleit et al. Ann Rheum Dis. 2009;68:777–783
[3] Images adapted from ASAS Educational Slide Kits. 2013. Available online at: http://www.asas-group.org/education.php?id=04. Accessed 8th April 2014

axSpA is a Spectrum that Includes AS and nr-axSpA

- **axSpA encompasses a spectrum of diseases that includes both AS and nr-axSpA.[1,2]**
  - Patients with AS and nr-axSpA share common clinical features:[1,2]
    - Inflammation
    - Back pain
    - Arthritis
    - Other SpA features
  - Patients with AS and nr-axSpA have comparable disease burden:[1,2,3]
    - Pain
    - Physical functional ability
    - Health-related quality of life



[1] Rudwaleit et al. Ann Rheum Dis. 2009;68:777–783
[2] Sieper and van der Heijde. Arthritis Rheum 2013;65:543–551
[3] Kiltz et al. Arthritis Care Res. 2012;64(9):1415–1422

The ASAS Classification Criteria

- **The finalized ASAS criteria for axSpA are intended to be applied to patients with chronic back pain for ≥3 months with age of onset <45 years.**

**Sacroiliitis on imaging*
plus
≥1 SpA feature#**

OR

**HLA-B27
plus
≥ 2 other SpA features#**

#SpA features:

- Inflammatory back pain
- Arthritis
- Enthesitis (heel)
- Uveitis
- Dactylitis
- Psoriasis
- Crohn's/colitis
- Good response to NSAIDs
- Family history for SpA
- HLA-B27
- Elevated CRP

*Sacroiliitis on imaging

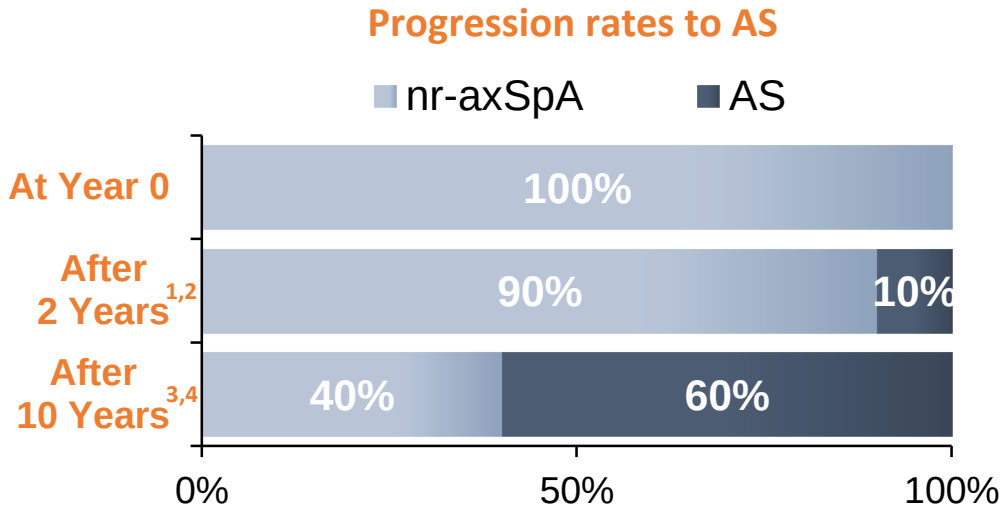
- Active (acute) inflammation on MRI highly suggestive of sacroiliitis associated with SpA
- Definite radiographic sacroiliitis according to mNY criteria

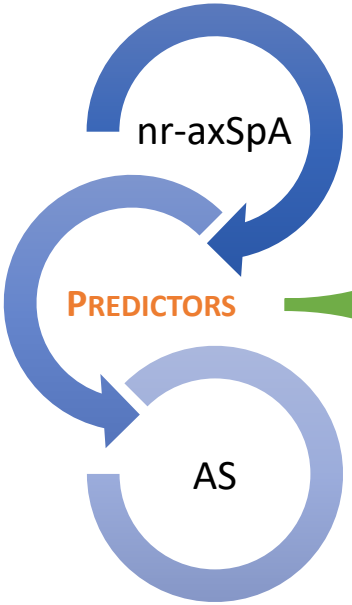
n=649 patients with back pain
Sensitivity: 82.9%, Specificity: 84.4%
Imaging alone: Sensitivity: 66.2%, Specificity: 97.3%

Adapted from Rudwaleit et al. Ann Rheum Dis. 2009;68:777–783

Progression from nr-axSpA to AS

- Several national and international referral programs estimate that 25−70% of all axSpA patients have nr-axSpA.[1,2]
- Rate of progression from nr-axSpA to AS (the development of definite radiographic sacroiliitis) is up to 60% after 10 years.[3,4]
- Given this, it is clear that not all axSpA patients will develop definite radiographic sacroiliitis.





There is currently no way to definitely predict whether an individual patient will develop radiographic changes.

Studies examining progression rates to AS in patients with nr-axSpA have identified various risk markers for disease progression:

- **SI Inflammation on MRI**: predictor of radiographic damage within 8 years[5]
- **Elevated CRP:** 25% of those with nr-axSpA develop AS within 4 years[3]
- **HLA-B27 positivity**: significant predictor for AS within 5 years[6]

[1] Rudwaleit and Seiper. Nat Rev Rheumatol 2012;8:262–268 [2] Poddubnyy et al. Ann Rheum Dis 2012;71:1998–2001
[3] Poddubnyy et al. Ann Rheum Dis 2011;70:1369–1374 [4] Mau et al. Clin Rheumatol 1987;6 Suppl 2:60–6
[5] Bennett et al. Arthritis Rheum 2008;58:3413–3418 [6] Sampaio-Barros et al. J Rheumatol 2010;37:1195–1199

Comparison of nr-axSpA and AS

- Comparison of Patient Demographics

Registry Data	GESPIC[1] (Germany)			Herne Cohort[1,2] (Germany)		DESIR[1] (France)	
	All AS <10 Years)	AS <5 years	nr-axSpA	AS	nr-axSpA	AS	nr-axSpA*
Number of patients	238	119	226	56	44	181	475
Age, mean years	35.6	36.1	36.1	41.2	39.1	33.3	33
Symptom duration, mean years	5.2	3.0	2.8	12.8	9.4	1.6	1.6
% Female	36.0	34.5	57.1	23.2	68.2	41.4	49.7

Randomised Controlled Trial Data	ATLAS[3]		ABILITY-1[4]		RAPID^{TM}-axSpA[5]	
	AS		nr-axSpA		AS	nr-axSpA
Number of patients	315		185		178	147
Age, mean years	42.3		38.0		41.5	37.4
Symptom duration, mean years	10.9		10.1		9.1	5.5
% Female	25.1		54.6		27.5	51.7

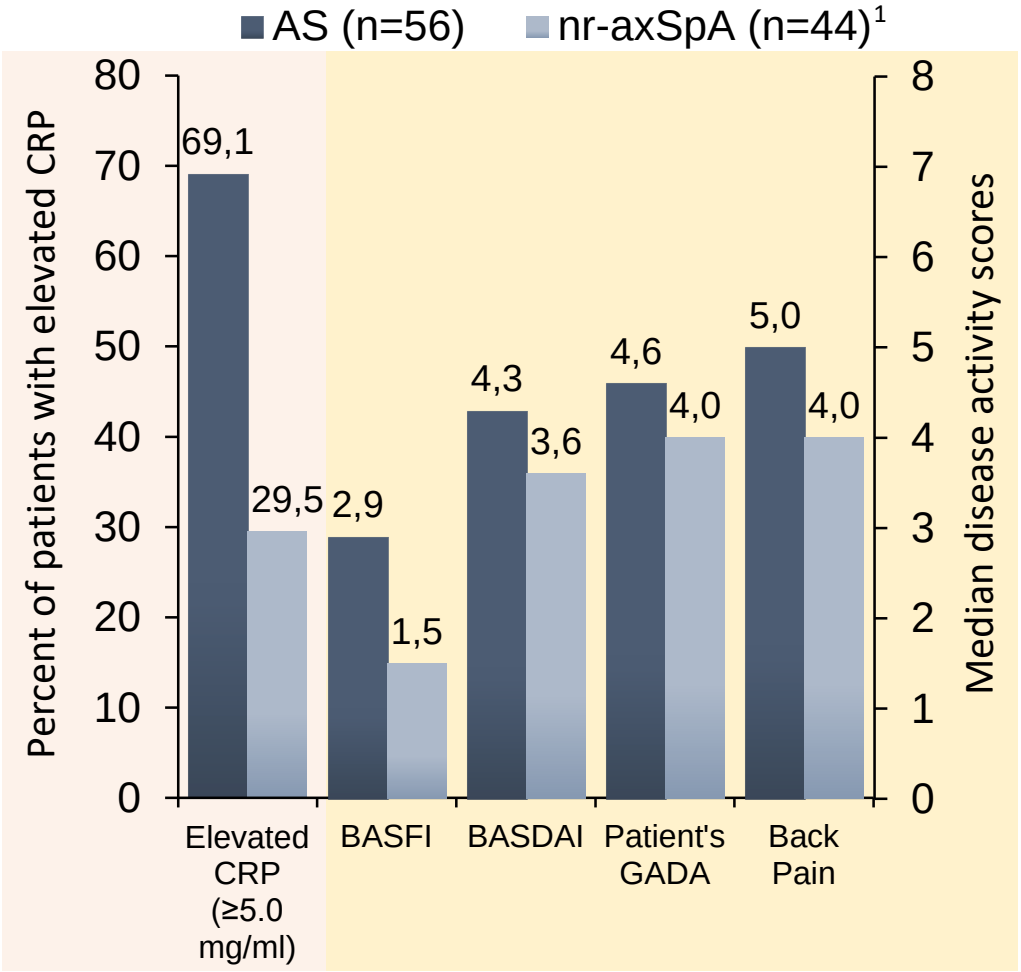
- GESPIC (German Spondyloarthropathy Inception Cohort);
- DESIR (Devenir des Spondyloarthropathies Indifférenciées Récentes);
- *In the DESIR study, nr-axSpA group was overall axSpA population and included both nr-axSpA and AS

[1] Sieper and van der Heijde. Arth Rheum. 2013;65(3):543–551
[2] Kiltz et al. Arthritis Care Res. 2012;64(9):1415–1422
[3] van der Heijde et al. Arth Rheum. 2006;54(7):2136–2146
[4] Sieper et al. Ann Rheum Dis. 2013;72:815–822 [5] Landewe et al. Ann Rheum Dis. 2014;73(1):39–47

Burden of nr-axSpA and AS

Registry Data
Herne Cohort

- Comparison of Disease Activity



- Elevated CRP:
  - A marker of inflammation taken from a blood sample.
- Bath Ankylosing Spondylitis Functional Index:[2,3]
  - A questionnaire used to determine a patient's physical functional abilities.
- Bath Ankylosing Spondylitis Disease Activity Index:[2]
  - A questionnaire used to determine disease activity in patients.
- Global Assessment of Disease Activity:[4]
  - Self-completed scale (0–10) measuring disease activity.
- Back Pain:[2,5]
  - Numerical rating scale to determine the level of pain experienced by the patient.

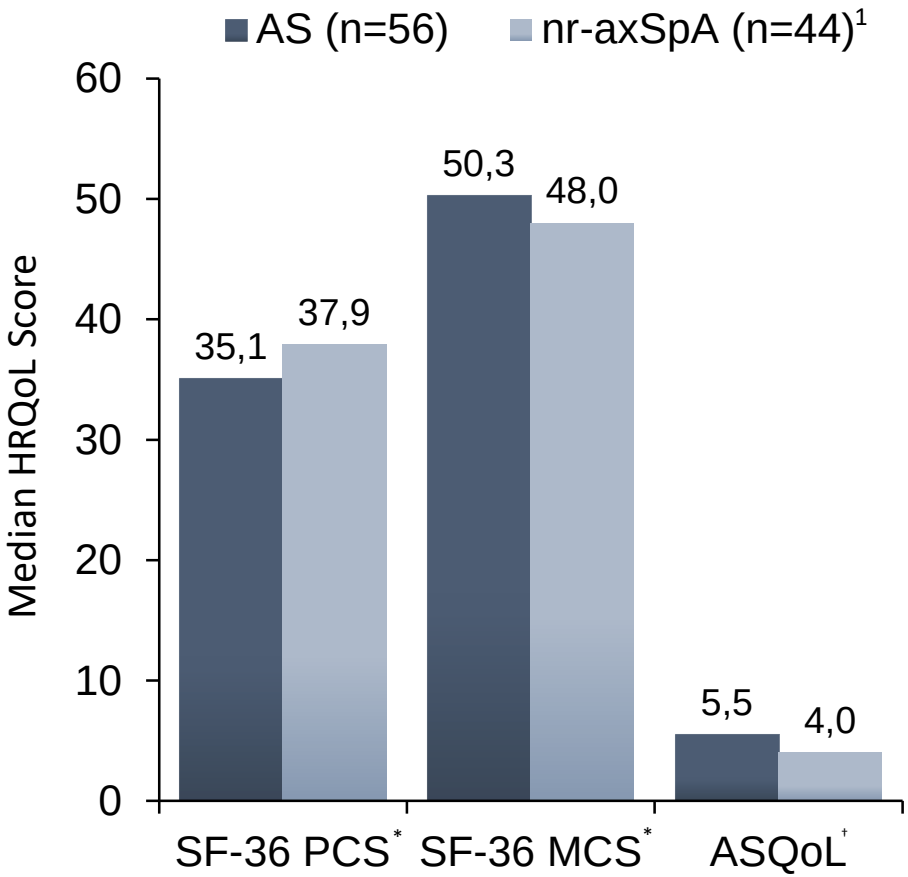
- High scores indicative of worse disease activity.
- GADA: Global assessment of disease activity.

[1] Kiltz et al. Arthritis Care Res. 2012;64(9):1415–1422 [2] Sieper et al. Ann Rheum Dis. 2009;68(suppl II):ii1–ii44
[3] Calin et al. J Rheumatol 1994;21(12):2281–2285
[4] UCB. Data on File. (AS001 Wk24 Clinical Study Report p58)
[5] Haibel et al. Arthritis Rheum. 2008;58(7):1981–1991

Burden of nr-axSpA and AS

Registry Data
Herne Cohort

- Comparison of Health-Related Quality of Life



- Short-Form 36:
  - The SF-36 is a multi-purpose, self-administered survey designed to assess health-related quality of life.[2]
  - Both physical (PCS) and mental (MCS) component summaries are evaluated.[2]
- Ankylosing Spondylitis Quality of Life:
  - The ASQoL is an instrument, originally designed to assess AS-specific health-related quality of life, that has been validated to also evaluate axSpA patients.[3,4]

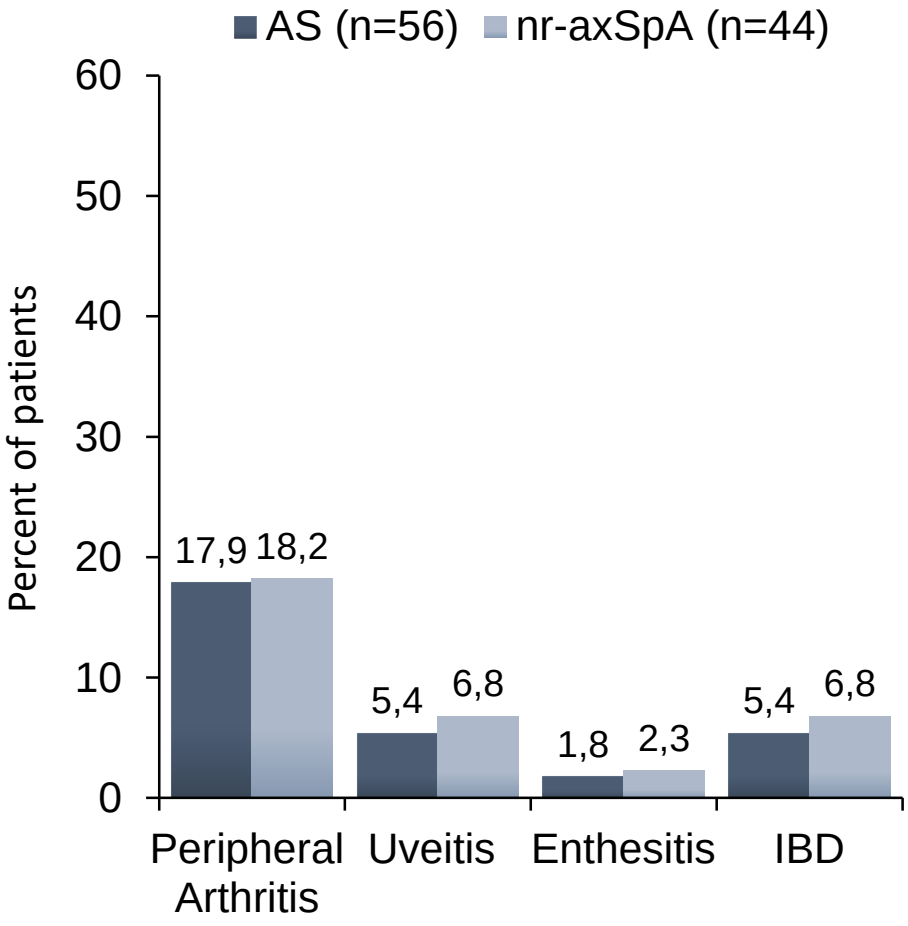
- * Low scores indicative of worse health-related quality of life.
- † High scores indicative of worse health-related quality of life.

[1] Kiltz et al. Arthritis Care Res. 2012;64(9):1415–1422
[2] Ware and Gandek. J Clin Epidemiol. 1998;51(11):903–912
[3] Haibel et al. Arthritis Rheum. 2008;58(7):1981–1991
[4] Barkham et al. Arthritis Rheum. 2009;60(4):946–954

Comparison of nr-axSpA and AS

Registry Data
Herne Cohort

- Comparison of SpA Features

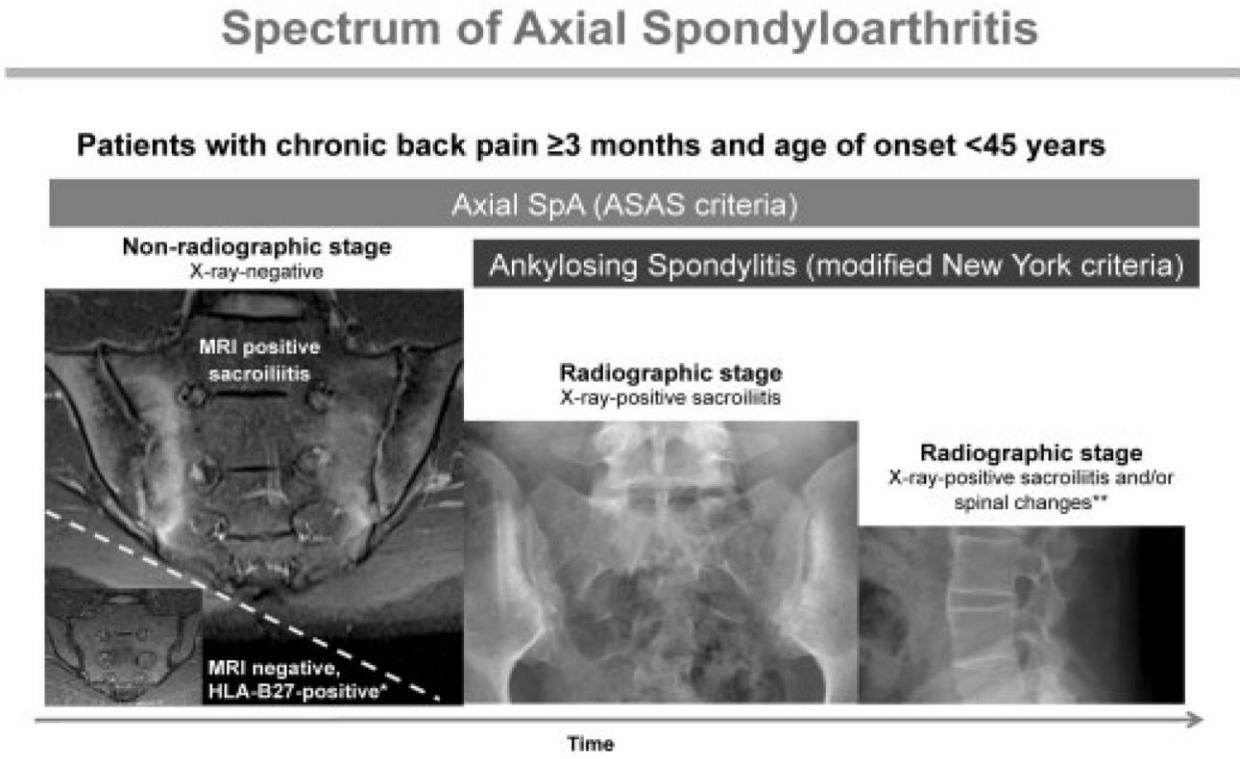


- Kiltz et al. 2012
  - Recruited 100 anti-TNF naïve patients with axSpA.
  - Systematically compared AS and nr-axSpA patients using standardised clinical tools.
  - Determined differences and similarities in clinical manifestations, SpA features, disease activity and health-related quality of life between these patient subpopulations.

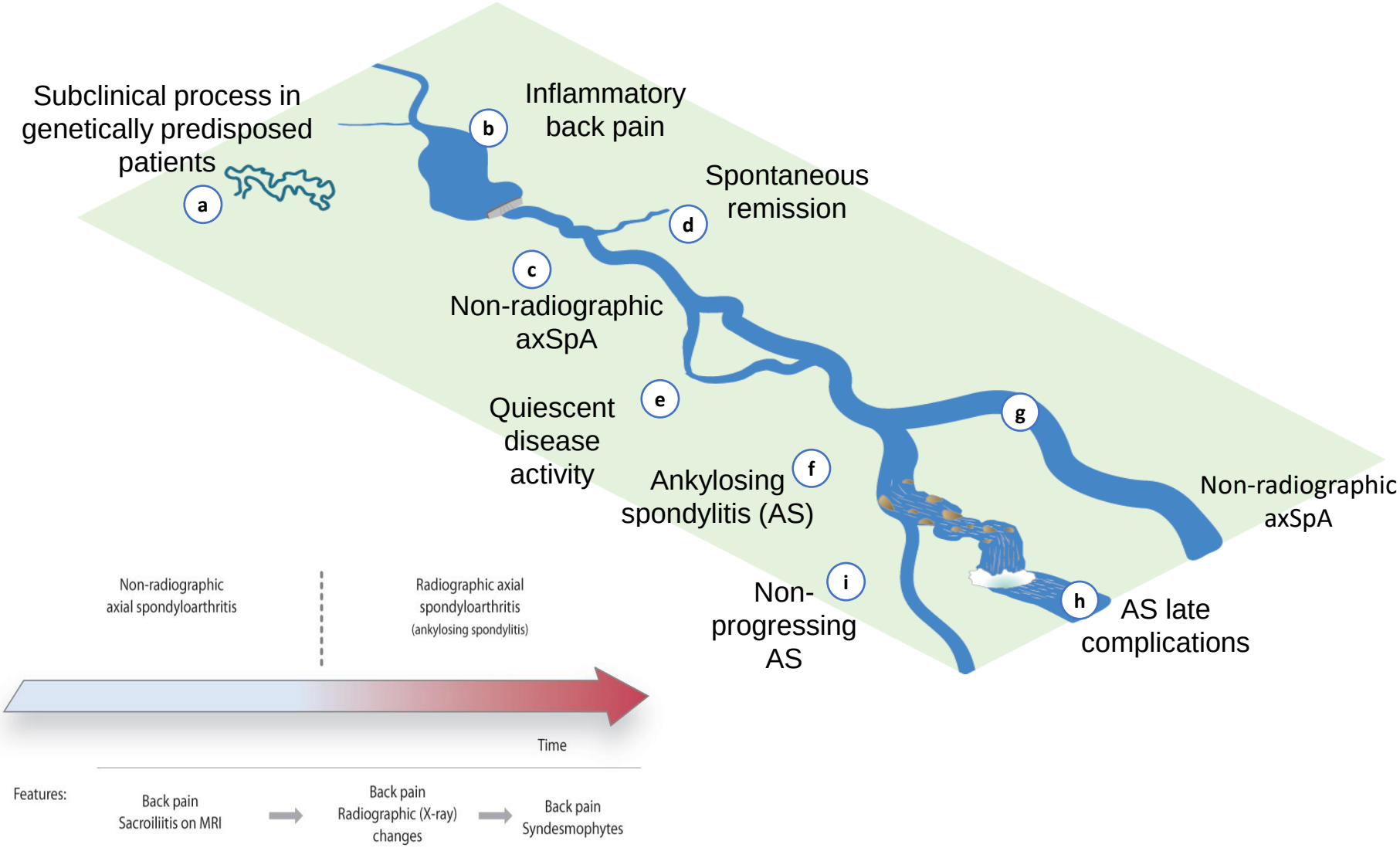
Kiltz et al. Arthritis Care Res. 2012;64(9):1415–1422

Ερωτήματα σχετικά με την nr-AxSpA

- **Είναι απλά πρώιμη ΑΣ??**
- Και ναι και όχι. Σε κάποιους ασθενείς είναι απλά ΑΣ πρώιμη. Στους περισσότερους ασθενείς όμως φαινεται να είναι μια ειδική υποκατηγορία με χαμηλότερη πιθανότητα ακτινολογικής εξέλιξης



The Natural History of Axial Spondyloarthritis



Είναι μια καινούργια νόσος?

- Οχι
- Απλά παλαιότερα καλυπτόταν απο την ομπρέλα «αδιαφοροποίητη ΣΠΑ»

REVIEW

Nonradiographic Axial Spondyloarthritis

New Definition of an Old Disease?

Joachim Sieper[1] and Désirée van der Heijde[2]

Μήπως καταλήγουμε να κάνουμε υπερδιάγνωση?
Μήπως θεραπεύουμε και ασθενείς με ινομυαλγία?

- Μόνο 2% ασθενών με ινομυαλγία πληρούν κριτήρια AxSpA
- Το αντίθετο είναι συχνό...

RHEUMATOLOGY

Rheumatology 2018;57:1541–1547
doi:10.1093/rheumatology/kex318
Advance Access publication 6 September 2017

Original article

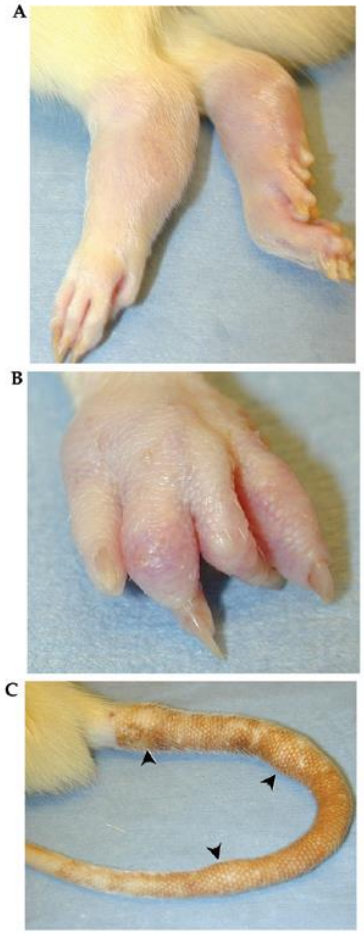
Patients with fibromyalgia rarely fulfil classification criteria for axial spondyloarthritis

Xenofon Baraliakos[1], Andrea Regel[1], Uta Kiltz[1], Hans-Jürgen Menne[2], Friedrich Dybowski[3], Manfred Igelmann[4], Ludwig Kalthoff[5], Dietmar Krause[6], Ertan Saracbasi-Zender[7], Elmar Schmitz-Bortz[8] and Jürgen Braun[1]

Γιατί δεν υπερέχουν άνδρες σε αυτήν την κατηγορία?

- Άγνωστο
- Μηπως οι άνδρες εξελίσσονται πιο γρήγορα ακτινολογικά και περνούν συντομότερα στην φάση ΑΣ?

Πως γίνεται η έκτοπη οστεοποίηση
Ο ρόλος του μηχανικού stress..

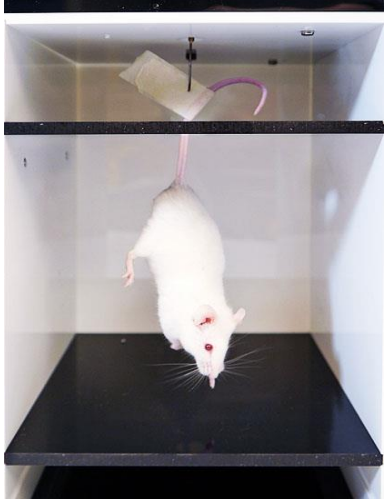


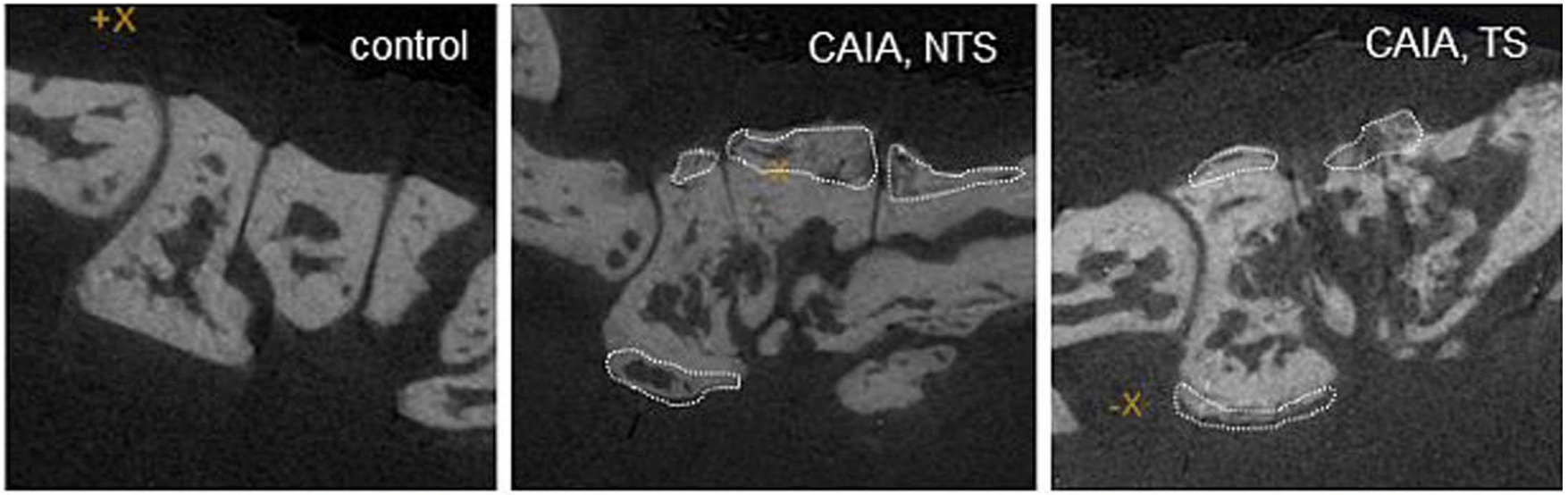
- Σε κανένα πειραματικό μοντέλο σπονδυλοαρθροπάθειας δεν αγκυλώνεται η σπονδυλική στήλη
- Γιατί?

EXTENDED REPORT

Proof of concept: enthesitis and new bone formation in spondyloarthritis are driven by mechanical strain and stromal cells

Peggy Jacques,[1] Stijn Lambrecht,[1] Eveline Verheugen,[1] Elin Pauwels,[2] George Kollias,[3] Maria Armaka,[3] Marleen Verhoye,[4] Annemie Van der Linden,[4] Rik Achten,[5] Rik J Lories,[6] Dirk Elewaut[1]





- Τα ποντίκια που δεν δέχονται μηχανικό stress δεν αγκυλώνονται (χωρίς να επηρεάζεται η φλεγμονή…)

Summary

- **AxSpA encompasses a disease spectrum, which includes both patients with AS and nr-axSpA.[1]**
  - Patients can suffer for years without a diagnosis.[1]
  - The major defining feature between patients with nr-axSpA or AS is radiographic evidence of structural damage at the sacroiliac joint or the spine.[2]
- **ASAS classification criteria represent an evolution in our understanding of the axSpA disease spectrum.[3]**
- **Patients with nr-axSpA and AS share similar clinical characteristics and comparable disease burden:[2,3,4]**
  - Clinical manifestations
  - Disease burden
  - SpA features
  - Health-related quality of life

[1] Rudwaleit et al. Arthritis Rheum 2005;52:1000–1008
[2] Sieper and van der Heijde. Arthritis Rheum 2013;65:543–551
[3] Rudwaleit et al. Ann Rheum Dis. 2009;68:777–783
[4] Kiltz et al. Arthritis Care Res. 2012;64(9):1415–1422

Efficacy and Safety Outcomes in Patients with Non-Radiographic Axial Spondyloarthritis Treated with Certolizumab Pegol: Results from the First 52-Week Randomized Placebo-Controlled Study

A. Deodhar,[1] L. S. Gensler,[2] J. Kay,[3] W.P. Maksymowych,[4] N. Haroon,[5] R. Landewé,[6] M. Rudwaleit,[7] S. Hall,[8] L. Bauer,[9] B. Hoepken,[9] N. de Peyrecave,[10] B. Kilgallen,[11] D. van der Heijde[12]

[1]Oregon Health & Science University, Portland, OR, USA; [2]University of California, San Francisco, CA, USA; [3]Division of Rheumatology, Department of Medicine, UMass Memorial Medical Center and University of Massachusetts Medical School, Worcester, MA, USA; [4]Department of Medicine, University of Alberta, Edmonton, Canada; [5]University Health Network, Krembil Research Institute, and University of Toronto, Toronto, Ontario, Canada; [6]Academic Medical Center and Zuyderland Medical Center, Heerlen, Netherlands; [7]Department of Internal Medicine and Rheumatology, Klinikum Bielefeld, Bielefeld, Germany; [8]Cabrini Medical Centre, Monash University and Emeritus Research, Melbourne, Australia; [9]UCB Pharma, Monheim am Rhein, Germany; [10]UCB Pharma, Slough, UK; [11]UCB Pharma, Raleigh, NC, USA; [12]Department of Rheumatology, Leiden University Medical Center, Leiden, Netherlands

Monday 22 October 2018

Presentation Number: 1868

Key Features of the C-axSpAnd Trial

OBJECTIVE: To investigate the effects of CZP vs 'standard care' therapy in patients with non-radiographic axSpA and objective signs of inflammation

52-week placebo-controlled period to evaluate natural history

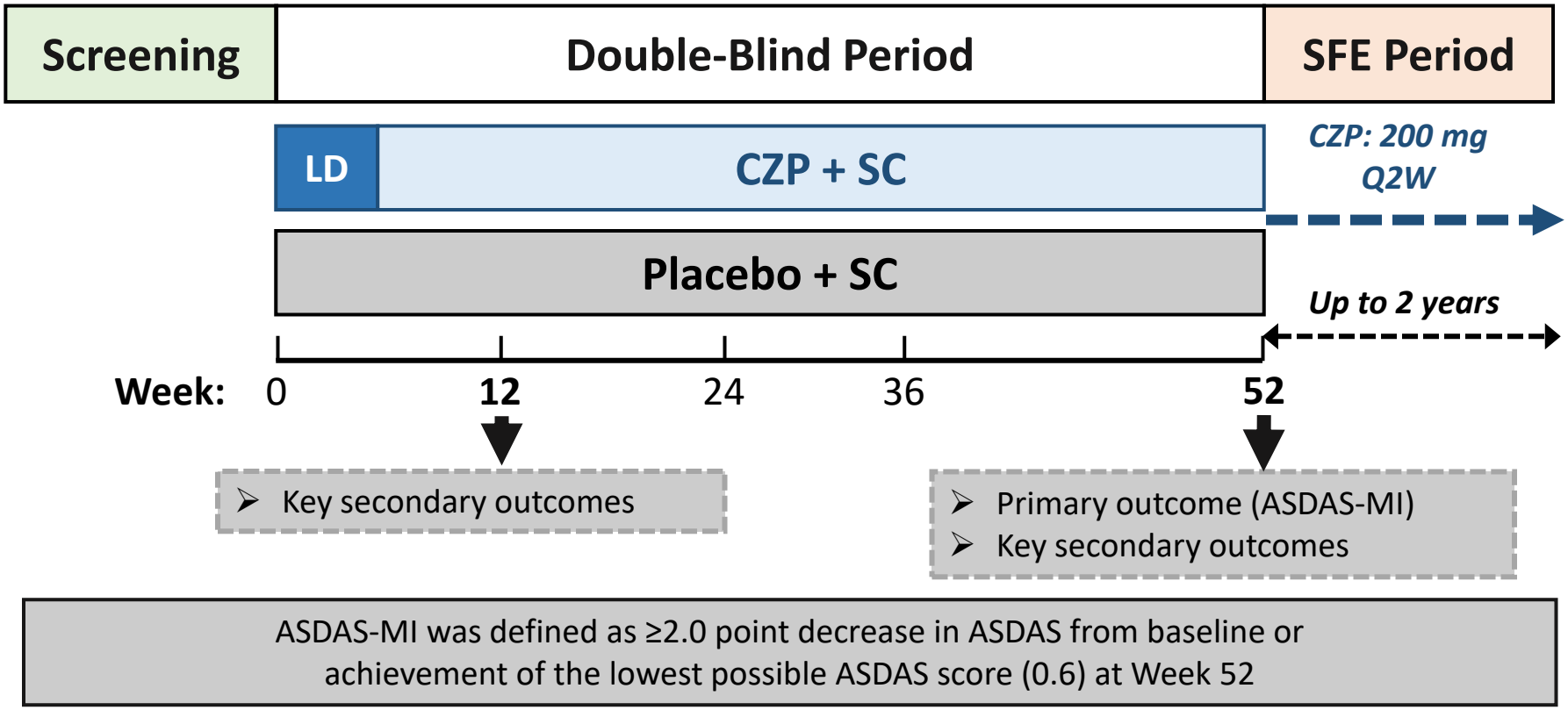
Changes in background medication permitted at any point*

Shift to open-label treatment permitted at any point*

Deodhar A et al. ACR 2018. Oral Presentation 1868.

- *Although changes before Week 12 were discouraged. Background medication included non-steroidal anti-inflammatory drugs (NSAIDs, including COX-2 inhibitors), analgesics, slow-acting anti-rheumatic drugs (SAARDs), corticosteroids. CZP: certolizumab pegol

Study Design



ASDAS-MI was defined as ≥2.0 point decrease in ASDAS from baseline or achievement of the lowest possible ASDAS score (0.6) at Week 52

Deodhar A et al. ACR 2018. Oral Presentation 1868.

- Patients were permitted to withdraw from the study drug at any timepoint. SFE: safety follow-up extension; CZP: certolizumab pegol; SC: standard care; LD: loading dose; OL: open-label; Q2W: every 2 weeks; ASDAS-MI: Ankylosing Spondylitis Disease Activity Score – Major Improvement

C-axSpAnd – Patient Population

Randomized set (n=317)	Placebo + SC (n=158)	CZP + SC (n=159)
Baseline Characteristics		
Age, years, mean (SD)	37.4 (10.8)	37.3 (10.5)
Female, n (%)	82 (51.9)	81 (50.9)
HLA-B27 positive, n (%)	132 (83.5)	128 (80.5)
Caucasian, n (%)	148 (93.7)	152 (95.6)
Disease Characteristics		
Symptom duration, years, mean (SD)	8.0 (7.5)	7.8 (7.7)
ASDAS, mean (SD)	3.8 (0.9)	3.8 (0.8)
BASDAI total score, mean (SD), [scale: 0–10]	6.8 (1.3)	6.9 (1.4)
BASFI, mean (SD), [scale: 0–10]	5.4 (2.2)	5.4 (2.1)
Elevated CRP at baseline (CRP>10.0 mg/L), n (%)	83 (52.5)	89 (56.0)
Sacroiliac joint MRI SPARCC score, mean (SD)	8.5 (12.3)	7.8 (10.8)
Nocturnal spinal pain, mean (SD), [scale: 0–10]	6.6 (2.1)	6.6 (2.3)

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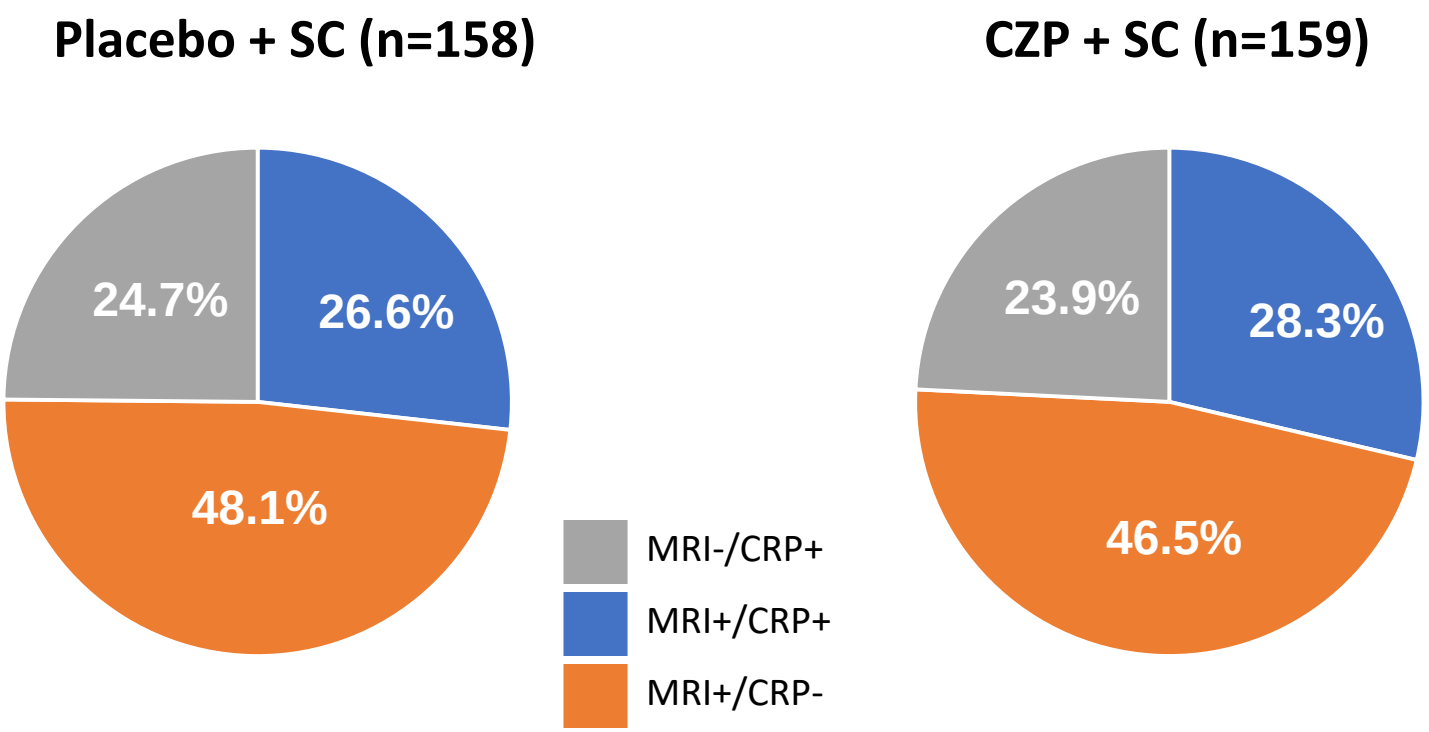
SC: standard care; CRP: C-reactive protein; CZP: certolizumab pegol; ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; SPARCC: Spondyloarthritis Research Consortium of Canada

MRI/CRP Stratification



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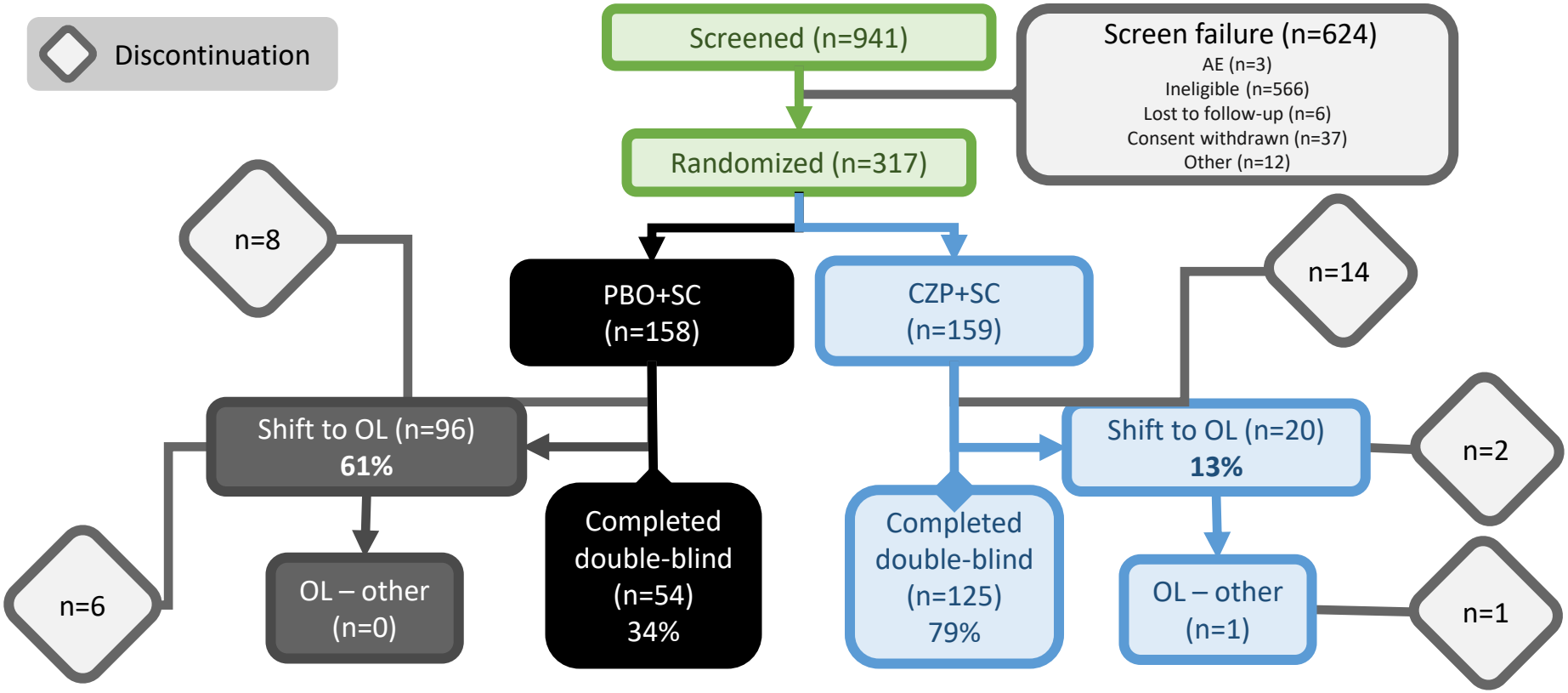
CZP: certolizumab pegol; SC: standard care; CRP: C-reactive protein; MRI: magnetic resonance imaging

Patient Disposition at Week 52



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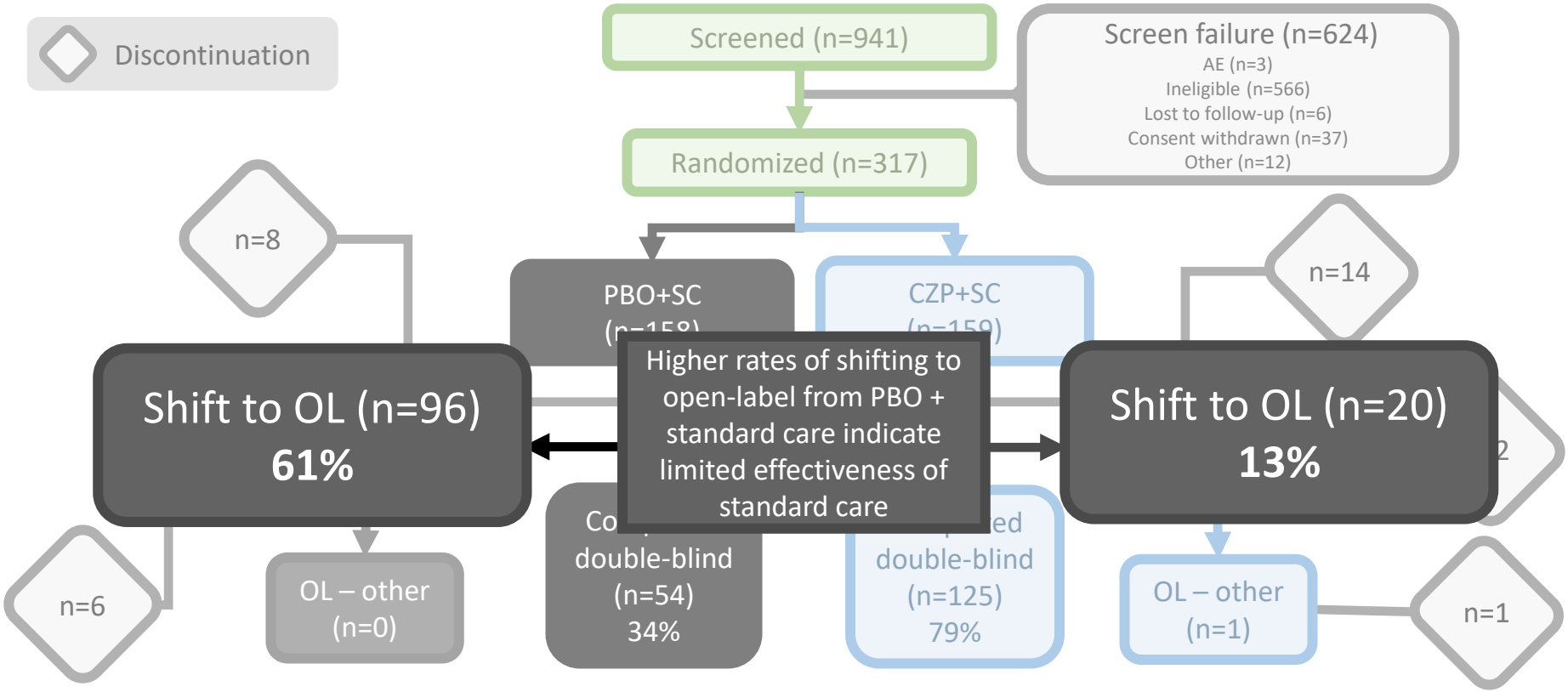
- AE: adverse event; CZP+SC: certolizumab pegol + standard care; PBO+SC: placebo + standard care; OL: open-label

Patient Disposition at Week 52



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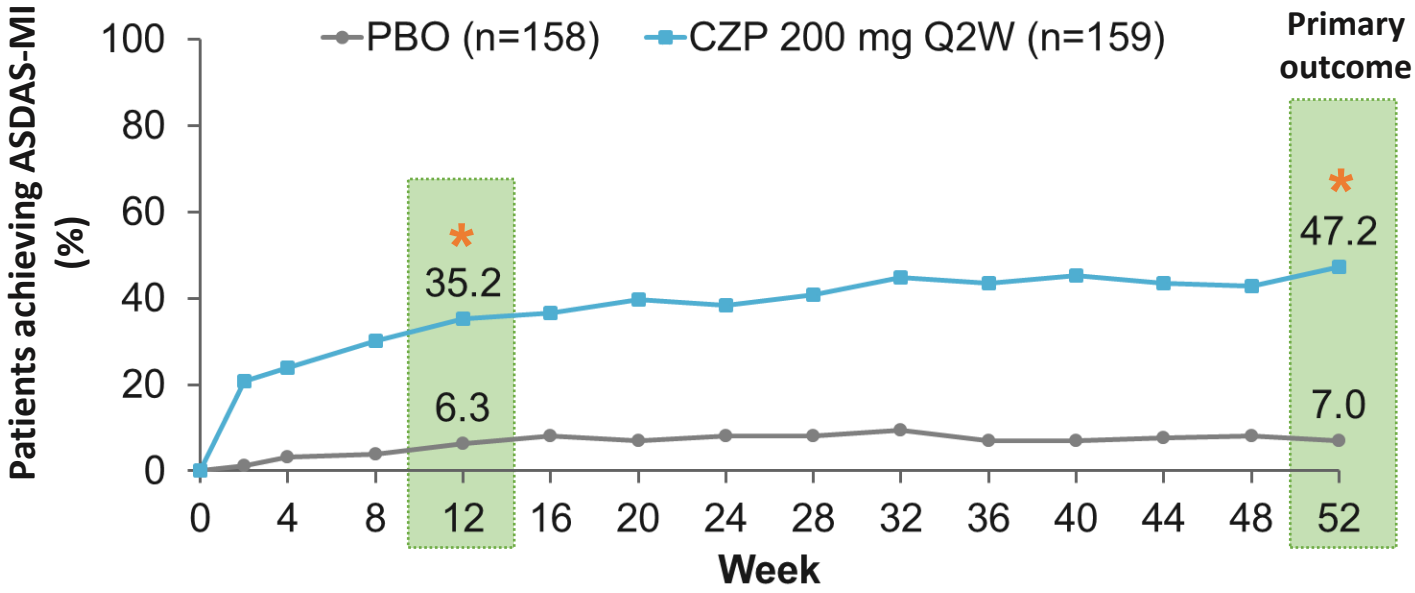
- AE: adverse event; CZP+SC: certolizumab pegol + standard care; PBO+SC: placebo + standard care; OL: open-label

Primary Outcome: ASDAS-MI at Week 52



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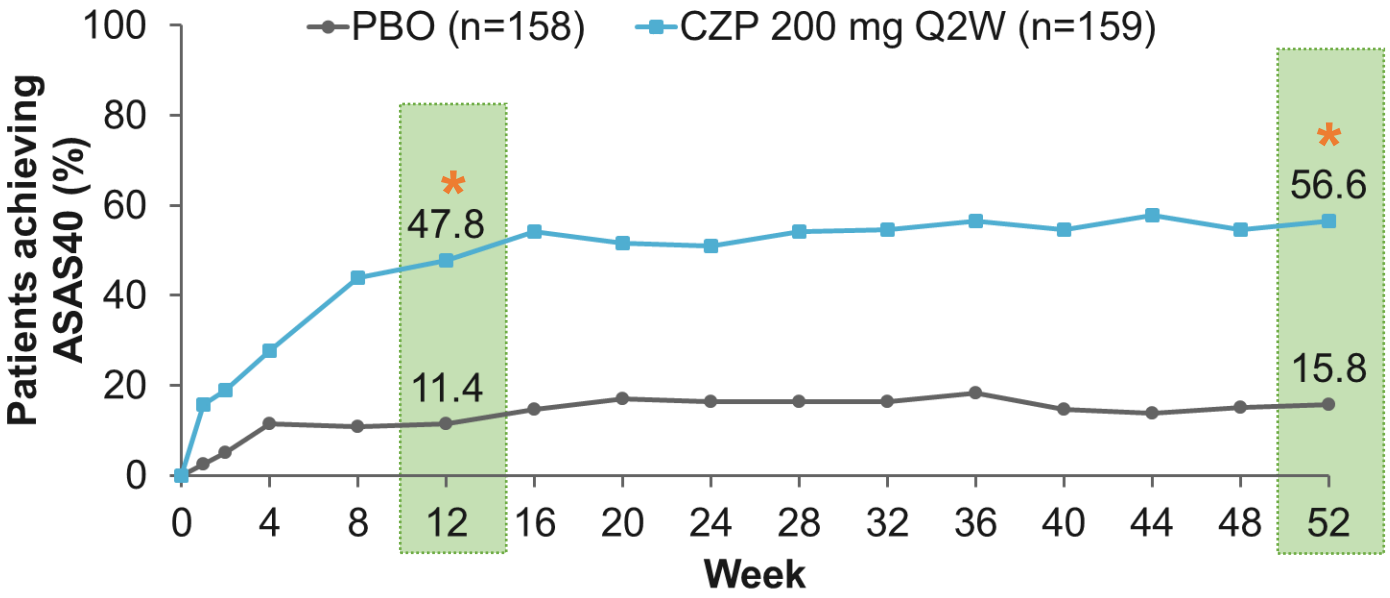
- *p<0.001 CZP vs PBO. Full Analysis Set. ASDAS-MI: Ankylosing Spondylitis Disease Activity Score – Major Improvement; FAS: full analysis set; NRI: non-responder imputation; PBO: placebo; CZP: certolizumab pegol; SC: standard care

ASAS40 to Week 52



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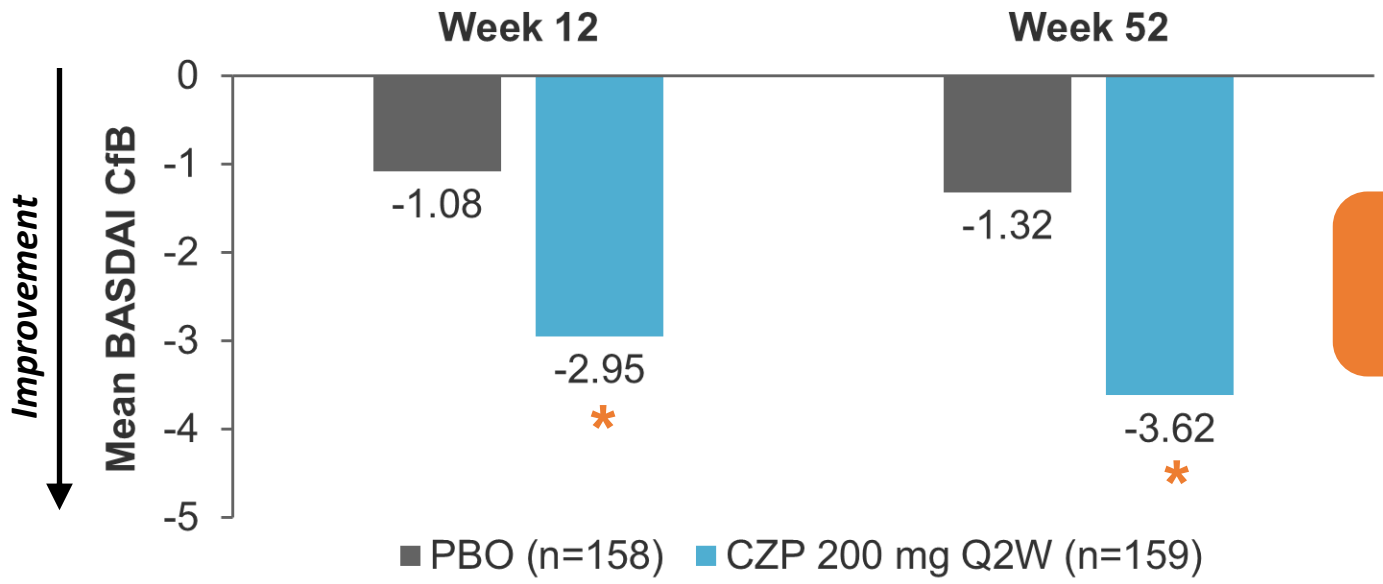
*p<0.001 CZP vs PBO. Full Analysis Set. ASAS40: Assessment in SpondyloArthritis international Society change from baseline of ≥40%; NRI: non-responder imputation; PBO: placebo; CZP: certolizumab pegol; Q2W: every two weeks; SC: standard care

BASDAI Change from Baseline at Weeks 12 and 52



BL mean
PBO+SC: 6.79
CZP+SC: 6.88

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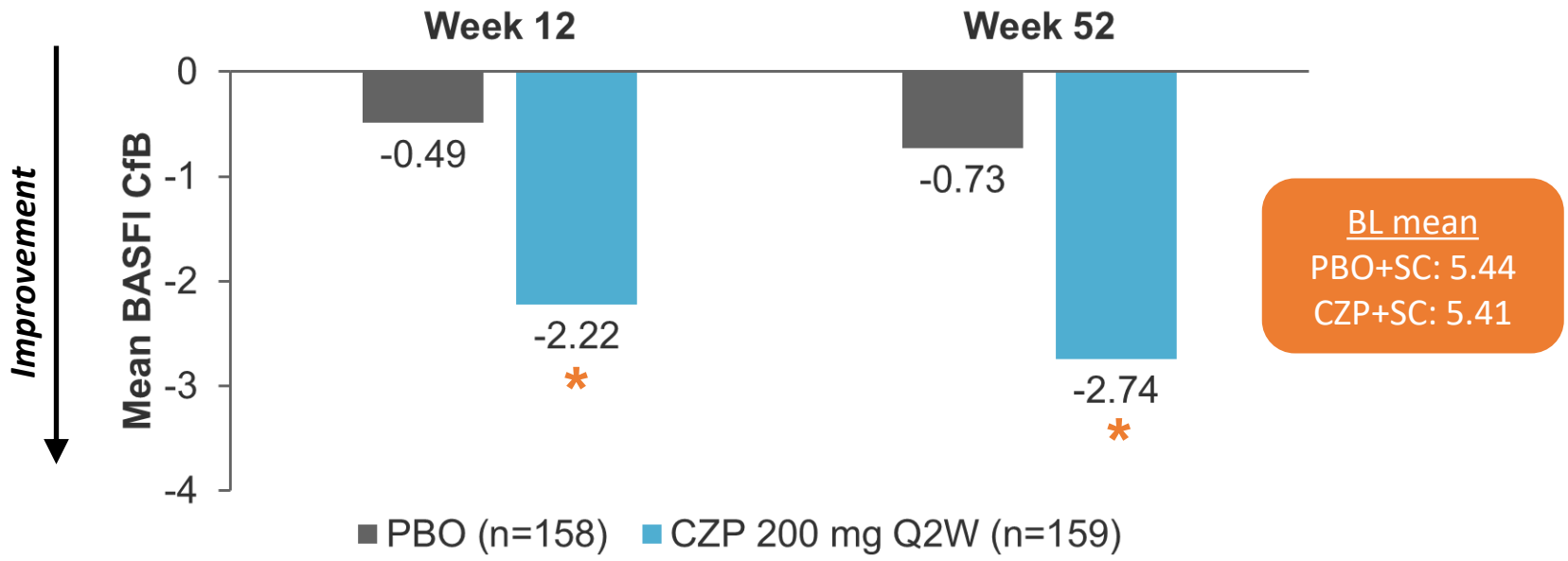
- *p<0.001 CZP vs PBO. Full Analysis Set. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; CfB: change from baseline; DB LOCF: double-blind last observation carried forward; BL: baseline; PBO: placebo; CZP: certolizumab pegol; Q2W: every two weeks; SC: standard care

BASFI Change from Baseline at Weeks 12 and 52



BL mean
PBO+SC: 5.44
CZP+SC: 5.41

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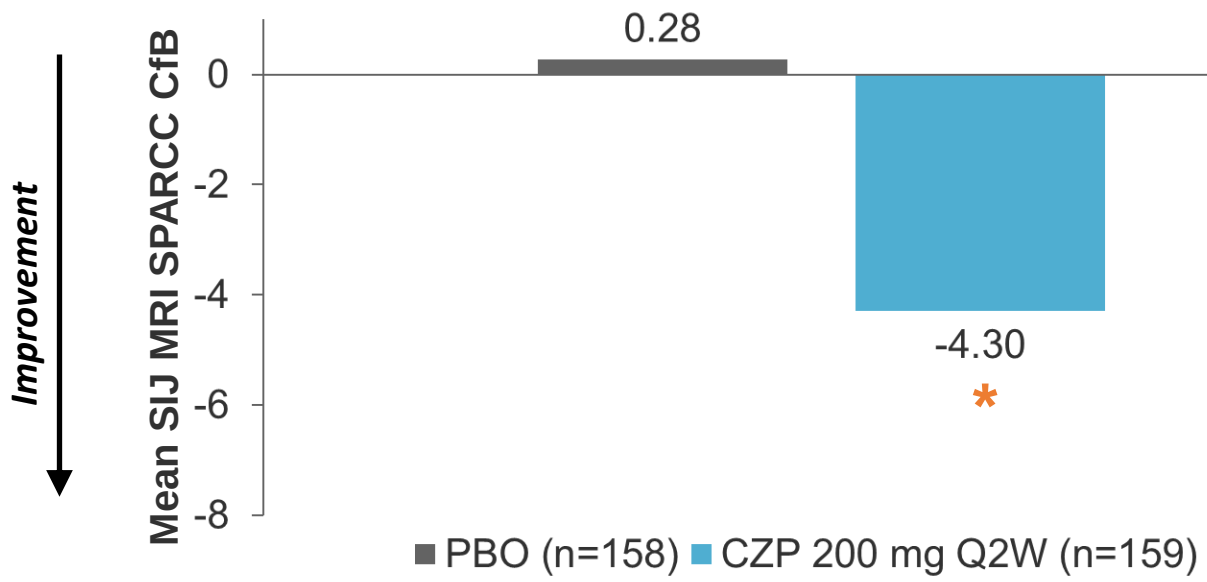
- *p<0.001 CZP vs PBO. Full analysis set. CfB: change from baseline; DB LOCF: double-blind last observation carried forward; BL: baseline; PBO: placebo; CZP: certolizumab pegol; Q2W: every two weeks; SC: standard care

Sacroiliac Joint MRI SPARCC Score CfB at Week 12



BL mean
PBO+SC: 8.46
CZP+SC: 7.79

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- *p<0.001 CZP vs PBO. Full analysis set. SIJ-SPARCC: sacroiliac joint Spondyloarthritis Research Consortium of Canada; CfB: change from baseline; R-B MI: reference-based multiple imputation; BL: baseline; PBO: placebo; CZP: certolizumab pegol; Q2W: every two weeks; SC: standard care

Safety Outcomes

Full analysis set (n=317), n (%)	**Placebo + SC (n=158)**	**CZP + SC (n=159)**
Patient exposure (patient years)	94.01	145.12
Any TEAE	101 (63.9)	120 (75.5)
Serious TEAEs	3 (1.9)	8 (5.0)
Drug-related TEAEs	23 (14.6)	48 (30.2)
Deaths	0	0
TEAEs of interest		
Opportunistic infections (including TB)	0	0
Serious infections	0	1 (0.6)
Malignant or unspecified tumors*	1 (0.6)	2 (1.3)
Serious cardiovascular events	0	0
Hematopoietic cytopenia	0	0
Serious bleeding events	0	0
Hepatic events	4 (2.5)	9 (5.7)
Hypersensitivity/anaphylactic reactions	0	0
Demyelinating disorders	0	0

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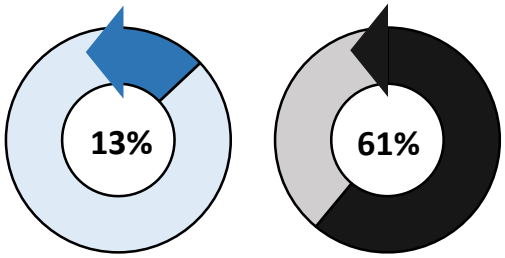
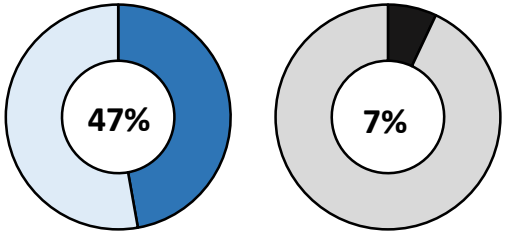
Conclusions

Treatment Switches



CZP + SC vs PBO + SC

Primary Outcome: ASDAS-MI



CZP + SC vs PBO + SC

Secondary Outcomes

Improvements in clinical efficacy and objective signs of inflammation to Week 52

- CZP + standard care was **superior** to placebo + standard care for treatment of nr-axSpA
- The 52-week placebo-controlled period suggests that active nr-axSpA is **not self-limiting**
- C-axSpAnd highlights **limitations of current standard care therapy** for this condition

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- ASDAS-MI: Ankylosing Spondylitis Disease Activity Score – Major Improvement; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; CZP: certolizumab pegol; SC: standard care

FDA News Release

FDA approves treatment for patients with a type of inflammatory arthritis

For Immediate Release March 28, 2019

Release

The U.S. Food and Drug Administration today approved Cimzia (certolizumab pegol) injection for treatment of adults with a certain type of inflammatory arthritis called non-radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation. This is the first time that the FDA has approved a treatment for nr-axSpA.

“Today’s approval of Cimzia fulfills an unmet need for patients suffering from non-radiographic axial spondyloarthritis as there has been no FDA-approved treatments until now,” said Nikolay Nikolov, M.D., associate director for rheumatology of the Division of Pulmonary, Allergy, and Rheumatology Products in the FDA’s Center for Drug Evaluation and Research.

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