Associations Between Clinical Characteristics and Screening Magnetic Resonance Imaging (MRI) Findings: Exploratory Analysis of the Ongoing Phase 4, Multicenter, Randomized, Controlled STAR Study of Biologic-naïve Patients with Psoriatic Arthritis with MRI-confirmed Axial Involvement



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Background

psoriatic arthritis (PsA) can develop axial inflammation in the sacroiliac joints (SIJ) and/or spine

Although validated classification criteria exist for axial spondyloarthritis, established criteria for classifying axial PsA are lacking

STAR (NCT04929210):

A Phase 4, multicenter, randomized, controlled trial of biologic-naïve PsA pts with magnetic resonance imaging (MRI)-confirmed axial inflammation

Prospectively evaluating the efficacy of guselkumab (GUS), a human IL-23p19-subunit inhibitor, on axial symptoms and objective measures (MRI) of axial inflammation¹

Objective

This exploratory analysis of available screening MRI data from STAR compared clinical characteristics between pts meeting or not meeting STAR MRI eligibility criteria

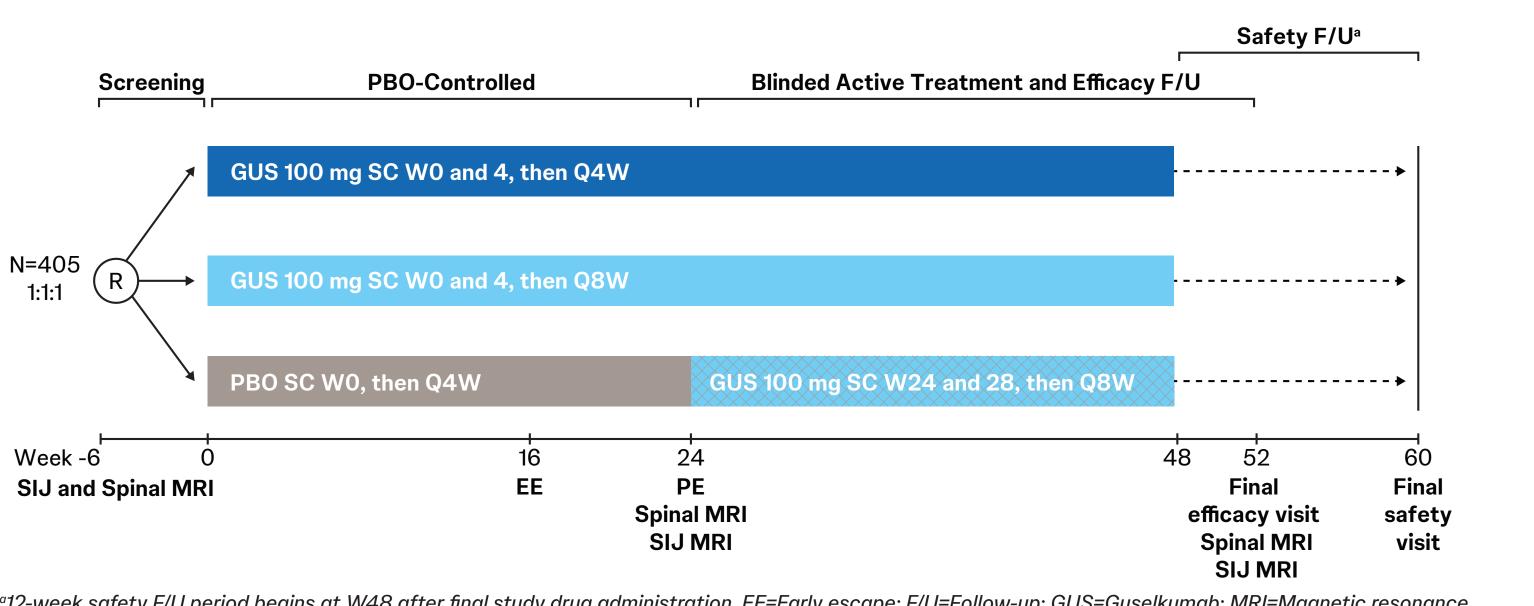
Methods

Analyses STAR: Key Study Eligibility Criteria Pt clinical characteristics and medical history documented at screening were compared Age ≥18 years between MRI-positive (+) and MRI-negative (-) cohorts to determine those associated History of, or current, plaque psoriasis

- Sex and age, HLA-B27 antigen, swollen joint count, tender joint count, BASDAI, spinal
- Medical history of inflammatory back pain, dactylitis, enthesitis, uveitis, nail psoriasis, scalp psoriasis, inverse psoriasis, genital psoriasis, and palmoplantar psoriasis
- MRI reading for SIJ and spine^a - 2 central readers and an adjudicator, requiring agreement by 2 readers to confirm
- a + or MRI result - Required only 1 confirmed +MRI result (SIJ or spine) for study entry

with MRI-detected inflammation of the SIJ and/or spine

Disease Activity Index; CRP=C-reactive protein; HLA=Human leukocyte antigen; MRI=Magnetic resonance imaging; Pt=Patient;



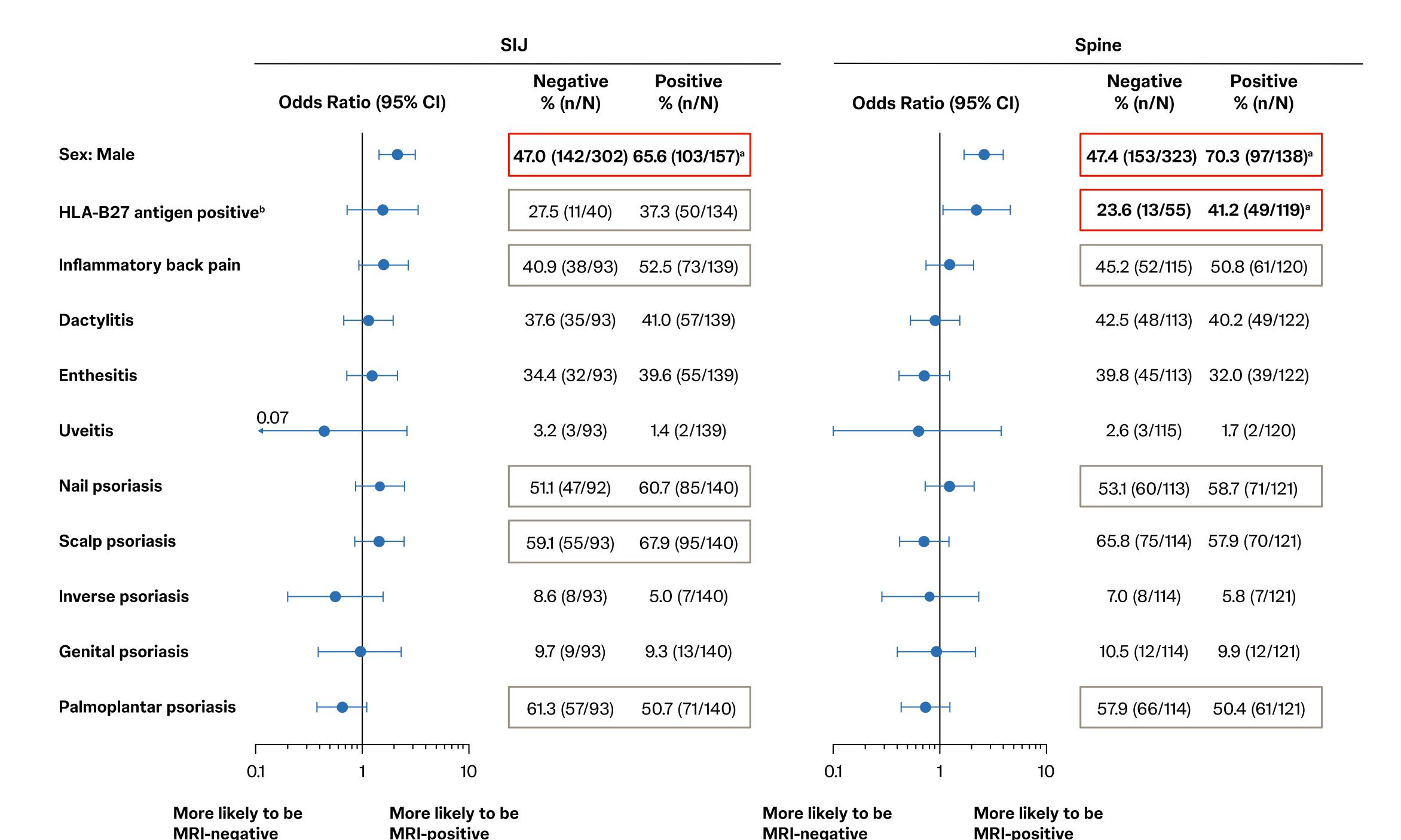
BASDAI ≥4 Spinal pain^a (VAS ≥4) Screening MRI-confirmed axial involvement (positive spine and/or SIJ MRI defined by blinded, centrally-read SPARCC score ≥3) Naïve to biologic agents and Janus kinase inhibitors Criteria for Psoriatic Arthritis; CRP=C-reactive protein; MRI=Magnetic resonance imaging; PsA=Psoriatic arthritis; SIJ=Sacroiliac joints; SPARCC=Spondyloarthritis Research Consortium of Canada; VAS=Visual analog scale.

Diagnosis of PsA for ≥6 months prior to enrollment and met CASPAR criteria at screening

Active PsA: ≥3 swollen joints, ≥3 tender joints, CRP ≥0.3 mg/dL

Males comprised a significantly higher proportion of pts in both the SIJ+ vs SIJ- and Spine+ vs Spine- cohorts

- The Spine+ cohort comprised a significantly higher proportion of pts positive for the human leukocyte antigen (HLA)-B27 antigen than the Spinecohort; a numerically higher proportion of pts had a history of inflammatory back pain and nail psoriasis in the Spine+ vs Spine- cohort • The SIJ+ cohort comprised a numerically higher proportion of pts with a history of inflammatory back pain, nail psoriasis, and scalp psoriasis than the SIJ- cohort
- Pts with a history of palmoplantar psoriasis appeared numerically less likely to exhibit MRI-detected axial inflammation in the SIJ or spine



^a95% CI excluding 1 indicates statistically significant difference. ^bHLA-B27 antigen marker was only captured in MRI-eligible pts, thus no comparison exists between the SIJ+/Spine+ and SIJ-/Spine- cohorts. CI=Confidence interval; HLA=Human leukocyte antigen; MRI=Magnetic resonance imaging; Pts=Patients; SIJ=Sacroiliac joints.

Key Takeaways

SIJ-/Spine-cohorts

axial inflammation:

inflammation

• The SIJ+/Spine+ cohort comprised a numerically higher proportion of pts with a history of inflammatory back pain

Preliminary findings from the ongoing STAR study, evaluating biologic-naïve PsA pts with MRI-confirmed

Recognized positive association between serum

- Several clinical characteristics, including male sex,

spinal pain score, and fewer tender joints, were

Fewer tender joints in the pts with MRI-detected

The associations between clinical features and

SIJ/spine +/- MRI screening results will require

The STAR study (NCT04929210) is actively enrolling¹

confirmation in the overall study population

younger age, presence of HLA-B27 antigen, higher

associated with the presence of MRI-detected axial

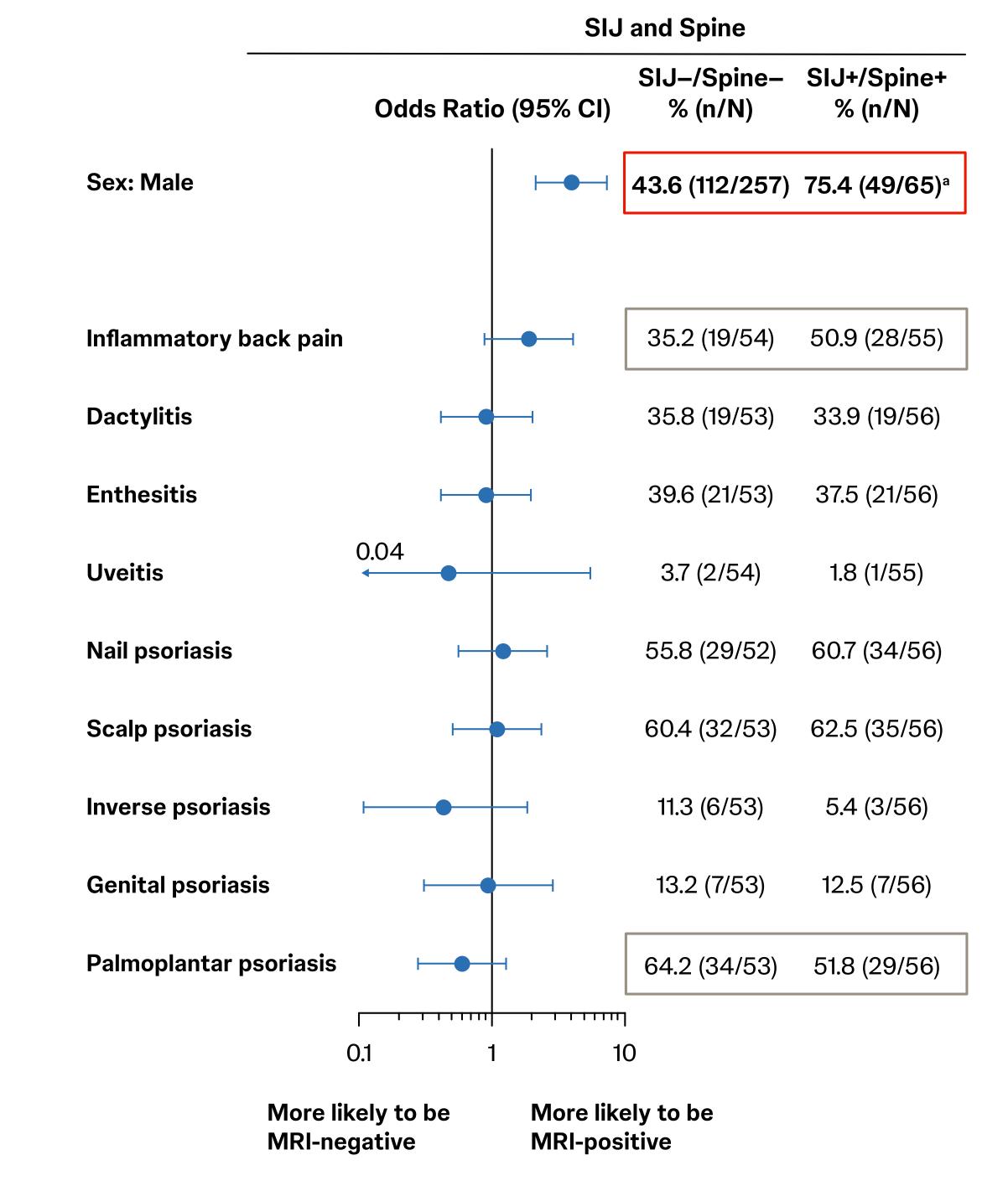
axial inflammation may reflect the moderate-to-high

levels of peripheral joint involvement seen across all

CRP levels and axial involvement in PsA^{2,3}

• Pts with a history of palmoplantar psoriasis appeared numerically less likely to exhibit MRI-detected axial inflammation in the SIJ and spine

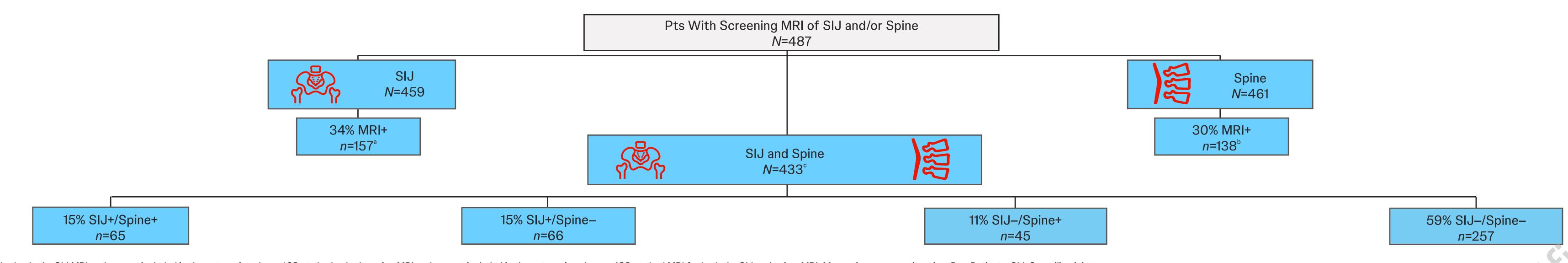
Males also comprised a significantly higher proportion of pts in the SIJ+/Spine+ vs



^a95% CI excluding 1 indicates statistically significant difference. CI=Confidence interval; MRI=Magnetic resonance imaging; SIJ=Sacroiliac joints.

Results

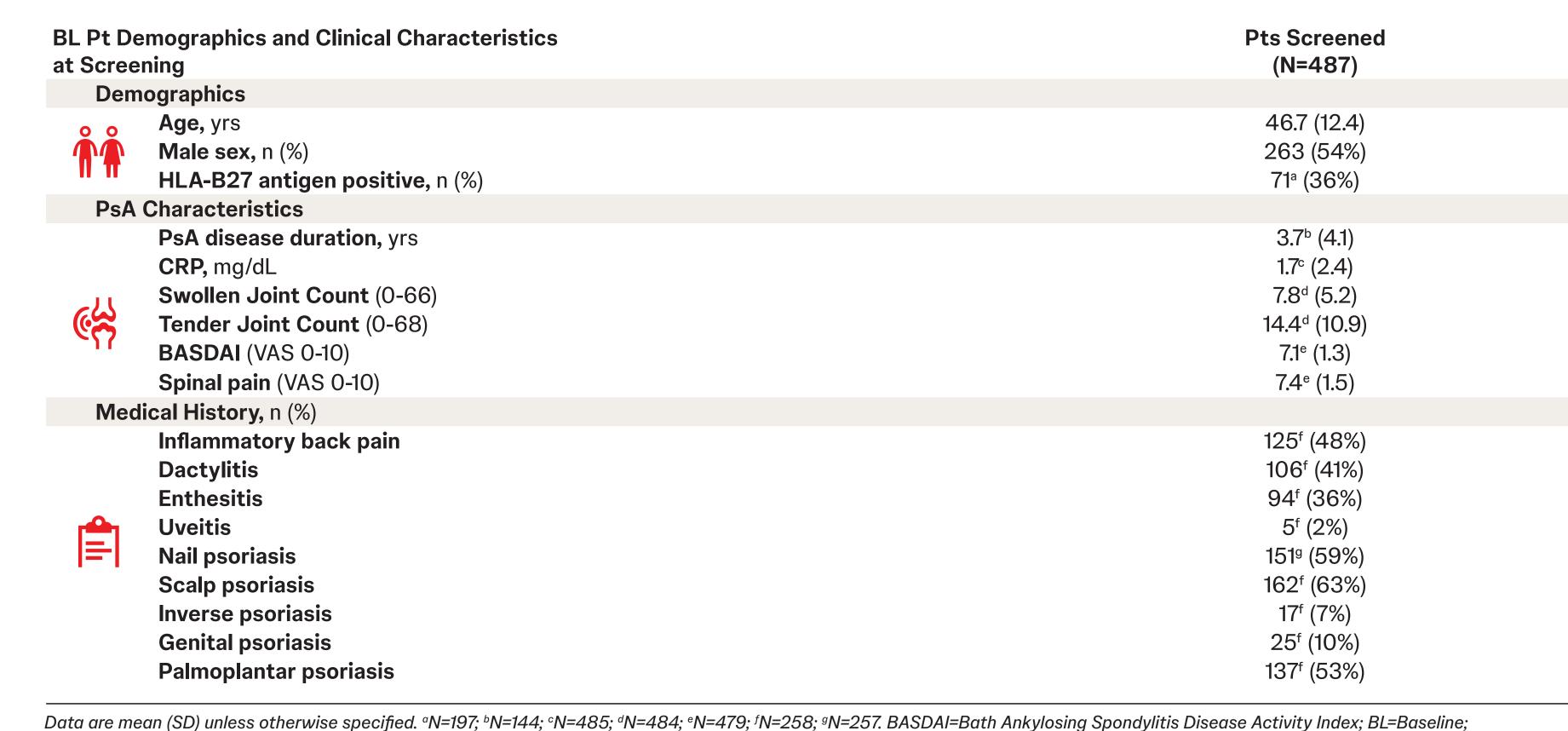
Among 487 pts screened at the time of this analysis, those with available SIJ and/or spine MRI were included



^a26 pts had only the SIJ MRI and are not included in the categories above; ^b28 pts had only the spine MRI and are not included in the categories above; categories above;

Approximately half of the overall screened population had inflammatory back pain with moderate-to-high levels of peripheral and spinal disease activity

- A majority of screened pts had a history of nail, scalp, and palmoplantar psoriasis
- Mean joint counts/visual analog scale (VAS) scores indicated moderate-to-high levels of disease activity/spinal pain



C-reactive protein (CRP), age, spinal pain score, and tender joint counts were associated with the presence or absence of MRI-detected axial inflammation

- CRP levels were significantly higher in both SIJ+ vs SIJ- and Spine+ vs Spine- cohorts
- The SIJ+ cohort was characterized by younger age, a higher spinal pain score, and fewer tender joints vs the SIJ- cohort
- Differences between the SIJ+/Spine+ (N=65) and SIJ-/Spine- (N=257) cohorts were generally consistent with those of the SIJ and spine cohorts

		SIJ MRI		Spine MRI		SIJ and Spine MRI	
Pt Clinical Characteristics by Screening MRI Status		Negative (N=302)	Positive (N=157)	Negative (N=323)	Positive (N=138)	Both Negative (N=257)	Both Positive (N=65)
De	emographics						
	Age, yrs	47.4 (12.7)	44.7 (11.8)*	46.2 (12.9)	47.9 (11.0)	46.6 (12.9)	44.2 (10.4)
Ps	A Characteristics	<u>'</u>					
	CRP, mg/dL	1.5 (2.3) ^a	2.0 (2.7)*	1.5 (2.2) ^b	1.9 (2.8)*	1.4 (2.1)°	2.5 (3.1)*
	SJC (0-66)	8.0 (5.4) ^d	7.5 (5.0)	8.1 (5.7) ^b	7.1 (4.4)	8.1 (5.5)°	6.6 (4.0)*
	TJC (0-68)	15.5 (11.9) ^d	12.6 (8.8)*	15.1 (11.9) ^b	12.6 (8.4)	15.6 (12.3)°	11.1 (6.8)*
	BASDAI (VAS 0-10)	7.1 (1.3) ^e	7.2 (1.2) ^f	7.1 (1.3) ^g	6.9 (1.3) ^h	7.1 (1.3) ⁱ	7.1 (1.3)
	Spinal pain (VAS 0-10)	7.3 (1.6)°	7.7 (1.4)*f	7.4 (1.6) ^g	7.6 (1.4) ^h	7.3 (1.6) ⁱ	7.8 (1.4)*

Data are mean (SD) unless otherwise specified. aN=300: bN=321: cN=255: dN=299: eN=295: fN=156: gN=316: hN=137: fN=251. *Nominal p<0.05: ANOVA. Van der Waerden rank test. Note: Duration of PsA was documented in a small subset of pts during screening and showed no difference between pt cohorts. ANOVA=Analysis of variance; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; CRP=C-reactive protein; MRI=Magnetic resonance imaging; PsA=Psoriatic arthritis; Pt=Patient; SD=Standard deviation; SIJ=Sacroiliac joints; SJC=Swollen joint count; TJC=Tender joint count; VAS=Visual analog scale; yrs=Years.

CRP=C-reactive protein; HLA=Human leukocyte antigen; PsA=Psoriatic arthritis; Pt=Patient; SD=Standard deviation; VAS=Visual analog scale; yrs=Years.

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