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SAT0386

PREVALENCE OF SUBCLINICAL CARDIOVASCULAR DISEASE IN PSORIATIC ARTHRITIS: A MULTICENTRIC STUDY

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Background: There are scarce data regarding subclinical vascular disease in psoriatic arthritis (PsA)(1). Similarly to rheumatoid arthritis, the real CVR could also be underestimated by clinical risk charts (2).

Objectives: To study the prevalence of subclinical vascular atheromatosis in patients with PsA; to analyze the association of carotid plaques with PsA characteristics; to identify which patients with intermediate or high clinical risk would be worthwhile to undergo carotid ultrasound to detect plaque.

Methods: Descriptive, transversal and multicentric study, of patients with clinical diagnose of PsA followed in 4 Spanish hospitals. Demographic data, classic CVR factors and clinical characteristics were recorded. The probability of a 10 years fatal cardiovascular event was calculated by SCORE charts adapted for Spain (3), and afterwards a systematic bilateral common carotid ultrasound (4) was conducted. The intima-media thickness of the carotid wall and the presence of atheroma plaque were registered. Patient's characteristics were described using descriptive analysis techniques. For univariate comparisons we used Chi2 and Anova. Multivariate analyses were conducted by logistic regression. The probability of plaque according to the age and the presence of CVR factors was calculated for patients with clinical intermediate or high risk by means of logistic regression. The study was approved by the Hospital General Universitario de Elda Ethic Committee (RCV-PS-MC/26/02/2016).

Results: 309 patients were included. The characteristics of the sample and the prevalence of CVR factors are depicted in Table 1. Patients were stratified by SCORE as follows: low risk 41 patients (13.3%), intermediate 182 (58.9%), high 75 (24.3%) and very high 11 (3.6%)

Table 1.. Clinical characteristics

Sex	Women 149 (48.2%), Men 160 (51.8%)
Age	54.8 (SD 12.5), median 55
Type of PsA	Axial: 94 (30.4%) Only axial: 18 (5.8%) Peripheral: 290 (93.9%) Only peripheral: 215 (69.6%) Axial and peripheral: 76 (24.6%)
Treatment	NSAIDs 31 (10%) cDIMARDs 124 (40.1%) bDIMARDs 151 (48.8%) Others (Aza, cyclosporin) 2 (0.6%)
PsA duration	125.1 months (SD 110.5)
Hypertension	89 (28.8%)
DM	45 (14.6%)
Dyslipidaemia	82 (26.5%)
Previous CV events	12 (3.9%)
BMI ≥30	110 (35.6%)
Tobacco	73 (23.6%)
Hyperuricemia	50 (16.2%)
Presence of CVR factors	
0 factors	107 (34.6%)
1 factor	108 (35%)
2 factors	60 (19.4%)
≥3 factors	34 (11%)

patients. Plaque criteria by ultrasound was found in 95 patients (30.7%), who were reclassified as very high risk. Final distribution after carotid ultrasound showed a decrease in all groups (12%, 43.7% and 14.2% in low, intermediate and high risk, respectively) with a consequent increase in the very high risk group (30.1%). In the univariate study, plaque was associated with age ($p<0.001$), diabetes ($p=0.004$), hypertension ($p=0.001$), hyperuricemia ($p=0.01$) and dyslipidaemia ($p<0.001$); any association with PsA characteristics wasn't found. In the multivariate analyses, plaque was associated with age >55 years (OR 2.84; IC 1.54-5.55), and with the number of classical CVR factors (OR 1.49; IC 1.13-1.97). In the presence of 3 or more risk factors, the probability of having plaque was 57.2% in patients with clinical intermediate risk and 61.8% in patients with high risk, and raised with increasing presence of CVR factors (Table 2).

Conclusion: Subclinical vascular disease is present in almost a third of the patients with PsA. SCORE tables may prove inaccurate for estimating the real CVR, and carotid ultrasound would be advisable in patients with intermediate or high risk who present any classical CVR factor.

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SAT0387

CONSISTENT EFFICACY IN PATIENT SUBGROUPS ACROSS BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS: RESULTS FROM A PHASE 2 STUDY OF GUSELKUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

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Background: Guselkumab (GUS) is a monoclonal antibody targeting interleukin-23 that has demonstrated efficacy in a phase 2 trial of psoriatic arthritis (PsA).¹

Objectives: Here subgroup analyses were conducted to evaluate the consistency of efficacy on the primary endpoint, ACR20 response.

Methods: In this randomized, double-blind, placebo-controlled, Phase-2 trial, pts with active PsA (≥ 3 tender, ≥ 3 swollen joints, C-reactive protein ≥ 3 mg/L, $\geq 3\%$ body surface area [BSA] of plaque psoriasis) despite current or previous treatment with standard-of-care therapies were randomized 2:1 to subcutaneous GUS 100 mg (n=100) or placebo (PBO, n=49) at Wk0, Wk4, and every 8 wks (q8w) through Wk44. At Wk16, pts with $<5\%$ improvement in both swollen and tender joints could escape early to open-label ustekinumab. Pts continuing PBO crossed-over to receive GUS 100mg at Wk 24, 28 then q8w through Wk44. The primary analysis was performed in a modified Intent-to-Treat (mITT) population which include all randomized subjects who received at least 1 administration of study agent based on their assigned treatment regardless actual treatment received. Pts who met treatment failure criteria, escaped early, or had missing data at Wk24 were considered non-responders for ACR20 at Wk24. Pre-planned subgroup analyses by demographic and disease characteristics at baseline and PsA medication use were performed, using the same data handling rules as in the primary analysis.

Results: At Wk24, 58/100 (58.0%) of pts in the GUS vs 9/49 (18.4%) in the PBO group achieved an ACR20 response ($p<0.001$). Efficacy was consistently observed in subgroups defined by demographics (gender, age, weight, region), disease characteristics at baseline (disease duration, PsA subtypes, tender/swollen joint counts, HAQ-DI, CRP, presence of dactylitis or enthesitis, PASI, and BSA) or PsA medication use (prior use of DMARDs or anti-TNFs, concomitant use of MTX, oral corticosteroids, or NSAIDs) (Table). The treatment effect was statistically significant in the majority of subgroups with the lower bound of the 95% confidence interval of the difference between GUS and PBO exceeding 0 in favor of GUS. There are a few exceptions where small sample sizes of the subgroups limited the interpretation. All enrolled subjects were white; therefore, the effect of guselkumab in other racial groups could not be assessed. Among GUS-treated pts, pts with enthesitis, dactylitis, PASI ≥ 12 , BSA $>10\%$, tender joint count ≤ 10 or swollen joint count ≤ 10 appeared to have numerically higher ACR20 response rate than those corresponding subgroups defined otherwise, although the sample size is small and the data should be interpreted with caution.

Table. Number of Patients Achieving ACR-20 Response at Week 24 by Treatment Group in Subgroups of Patients Defined by Baseline Demographic/Disease Characteristics and PsA Medication Use			
	Placebo n/N (%)	Guselkumab n/N (%)	Difference (95% CI)
All Patients	9/49 (18.4)	58/100 (58.0)	39.6 (25.2, 54.1)
Gender			
Male	5/24 (20.8)	29/52 (55.8)	33.8 (12.6, 54.9)
Female	4/25 (16.0)	29/48 (60.4)	43.2 (22.8, 63.7)
Age (yrs)			
<65	9/47 (19.1)	48/89 (53.9)	34.7 (19.6, 49.9)
≥65	0/2 (0)	10/11 (90.9)	90.9 (73.9, 100.0)
Weight (kg)			
≤90	8/31 (25.8)	38/67 (56.7)	31.2 (11.9, 50.5)
>90	1/18 (5.6)	20/33 (60.6)	55.2 (35.7, 74.7)
Geographic Region			
USA, Canada, Spain, or Germany	2/11 (18.2)	9/19 (47.4)	29.0 (0.0, 59.7)
Poland, Russia, or Romania	7/38 (18.4)	49/81 (60.5)	42.4 (26.2, 58.5)
PsA duration (yrs)			
<1	1/10 (10.0)	10/15 (66.7)	56.7 (26.4, 86.9)
1 to <3	5/10 (50.0)	16/25 (64.0)	16.7 (-19.6, 52.9)
≥3	3/29 (10.3)	32/60 (53.3)	43.0 (26.4, 59.6)
PsA Subtype			
Arthritis Mutans	0/3 (0)	0	
Asymmetric Peripheral Arthritis	2/14 (14.3)	18/26 (69.2)	52.3 (25.4, 79.2)
Dip Joint Involvement	3/7 (42.9)	8/17 (47.1)	-2.9 (-49.5, 43.6)
Polysynovial Arthritis with Absence of Rheumatoid Nodules	3/20 (15.0)	19/39 (48.7)	32.1 (9.1, 55.0)
Spondylitis with Peripheral Arthritis	1/5 (20.0)	13/18 (72.2)	48.8 (7.0, 90.5)
# Swollen joints			
<5	0/7 (0)	4/10 (40.0)	40.0 (9.6, 70.4)
5-10	5/25 (20.0)	28/44 (63.6)	43.1 (22.0, 64.2)
>10	4/17 (23.5)	26/46 (56.5)	32.1 (7.6, 56.6)
# Tender joints			
<5	0/1 (0)	1/2 (50.0)	50.0 (-19.3, 100.0)
5-10	0/11 (0)	13/20 (65.0)	66.6 (46.5, 86.8)
>10	9/37 (24.3)	44/78 (56.4)	32.1 (14.7, 49.6)
CRP			
<1	5/28 (17.9)	29/53 (54.7)	36.5 (16.9, 56.1)
≥1	4/21 (19.0)	29/47 (61.7)	41.9 (20.1, 63.6)
HAQ-DI			
<1	1/10 (10.0)	11/19 (57.9)	46.8 (16.5, 77.0)
≥1	8/39 (20.5)	47/81 (58.0)	37.5 (21.0, 53.9)
PASI Score			
<12	6/31 (19.4)	30/60 (50.0)	30.9 (12.2, 49.6)
12-20	0/9 (0)	12/17 (70.6)	72.4 (52.7, 92.2)
>20	2/8 (25.0)	15/21 (71.4)	43.4 (6.9, 80.0)
Psoriatic BSA (%)			
3-10	6/29 (20.7)	24/43 (55.8)	34.9 (14.0, 55.9)
10-20	1/6 (16.7)	17/30 (56.7)	40.5 (5.5, 75.5)
>20	2/14 (14.3)	17/27 (63.0)	48.1 (22.3, 73.9)
Enthesitis			
Yes	5/31 (16.1)	46/76 (60.5)	43.9 (27.1, 60.8)
No	4/18 (22.2)	12/24 (50.0)	26.7 (-0.2, 53.5)
Dactylitis			
Yes	6/23 (26.1)	36/58 (62.1)	35.8 (14.1, 57.5)
No	3/26 (11.5)	22/42 (52.4)	40.8 (21.5, 60.2)
Prior PsA Med use:			
Anti-TNF			
Yes	0/4 (0)	6/9 (66.7)	66.7 (35.9, 97.5)
No	9/45 (20.0)	52/91 (57.1)	37.1 (21.7, 52.6)
DMARD			
0	2/8 (25.0)	4/10 (40.0)	15.0 (-27.7, 57.7)
1	5/33 (15.2)	43/71 (60.6)	45.4 (28.8, 62.0)
≥2	2/8 (25.0)	11/19 (57.9)	30.6 (-7.2, 68.3)
Baseline PsA Med use:			
MTX			
Yes	5/19 (26.3)	27/47 (57.4)	30.0 (5.8, 54.2)
No	4/30 (13.3)	31/53 (58.5)	44.4 (26.5, 62.2)
Corticosteroid			
Yes	2/8 (25.0)	10/12 (83.3)	61.3 (27.3, 95.4)
(oral)			
No	7/41 (17.1)	48/88 (54.5)	37.5 (22.0, 52.9)
NSAID			
Yes	7/36 (19.4)	42/70 (60.0)	40.6 (23.5, 57.8)
No	2/13 (15.4)	16/30 (53.3)	38.3 (12.0, 64.6)

ACR-20 = 20% improvement in American College of Rheumatology criteria; BSA = Body Surface Area; CI = confidence interval; CRP = C-Reactive Protein; HAQ-DI = Health Assessment Questionnaire-Disability Index; MTX = methotrexate; Med=medication; NSAID = non-steroidal anti-inflammatory drug; PASI = Psoriasis Area and Severity Index; PsA = psoriatic arthritis; TNF = tumor necrosis factor. 95% CI's were calculated based on Wald statistics.

Conclusion: In this phase 2 trial of patients with PsA, GUS demonstrated efficacy consistently across subgroups of pts according to baseline demographics, disease characteristics, and PsA-medication use. The relationship between baseline characteristics and clinical outcome will be further explored in phase 3 studies with a larger PsA population.

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SAT0388

CHARACTERIZATION OF PATIENTS WITH PSORIATIC ARTHRITIS AND NAIL PSORIASIS: DATA FROM THE CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS (PSA/SPA) REGISTRY

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Background: Nail disease is an important feature of PsA and may even precede the disease by many years.¹ Nail psoriasis is considered one of the 6 disease domains of PsA²; however, there have been limited real-world studies that have examined characteristics of patients with PsA and nail psoriasis, particularly in the United States.

Objectives: To characterize the disease activity, quality of life, and work productivity of patients with PsA with and without nail psoriasis in the US-based Corrona PsA/SpA Registry.

Methods: This study included all patients in the Corrona PsA/SpA registry enrolled between March 2013 and October 2018 with a diagnosis of PsA who had non-missing data on physician-reported nail psoriasis. Patients were stratified by presence vs absence of nail psoriasis at the time of enrollment, defined as a non-zero response on the nail psoriasis visual analog scale (VAS) of 0-100. Descriptive analyses of patient demographics, disease activity, quality of life, and work productivity were assessed at enrollment and compared between nail psoriasis groups using *t*-tests or Wilcoxon rank-sum tests for continuous variables and χ^2 or Fisher's exact tests for categorical variables.

Results: A total of 2841 patients with PsA met the inclusion criteria, including 1152 patients (40.5%) with nail psoriasis and 1689 patients (59.5%) without nail psoriasis at enrollment. Patients with and without nail psoriasis were similar in terms of demographic and clinical characteristics; however, patients with nail psoriasis were slightly younger (53.1 vs 54.4 years) and more likely to be male (51.9% vs 44.1%) and have a higher history of depression (17.8% vs 13.3%) compared with patients without nail psoriasis (all *P* < 0.05). Patients with nail psoriasis had more severe psoriasis and PsA disease activity, as reflected by statistically significantly higher percentage of affected body surface area (BSA), higher tender and swollen joint counts, decreased likelihood of being in minimal disease activity, worse mean Disease Activity in Psoriatic Arthritis (DAPSA) and Psoriatic Arthritis Disease Activity Score (PASDAS) values, and increased likelihood of having enthesitis and dactylitis at enrollment compared with patients without nail psoriasis (Table 1; all *P* < 0.05). Patients with nail psoriasis had worse self-reported physical function (HAQ-DI), pain, fatigue, EQ-5D scores, and work and activity impairment compared with patients without nail psoriasis (Table 2; all *P* < 0.05).

Conclusion: PsA patients with nail psoriasis at the time of registry enrollment had worse disease activity, quality of life, and work productivity compared with those patients without nail involvement. These findings emphasize the importance of identification and management of nail disease in patients with PsA.

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Table 1. Disease Activity Among Patients With PsA at Enrollment Stratified by Presence of Nail Psoriasis

Characteristic*	With Nail PsO (N = 1152)	Without Nail PsO (N = 1689)	P Value†
Nail PsO (VAS 0–100)	18.9 (22.5) [1152]	0 [1689]	—
Tender joint count (0–68)	6.0 (9.9) [1127]	3.5 (7.1) [1639]	< 0.01
Swollen joint count (0–66)	2.4 (4.4) [1125]	1.7 (3.5) [1639]	< 0.01
MDA, n/m (%)‡	359/1027 (35.0)	716/1503 (47.6)	< 0.01
DAPSA	18.1 (15.7) [643]	13.4 (12.4) [994]	< 0.01
DAPSA group, n (%)	n = 643	n = 994	< 0.01
Remission	90 (14.0)	232 (23.3)	
Low	231 (35.9)	402 (40.4)	
Moderate	195 (30.3)	247 (24.8)	
High	127 (19.8)	113 (11.4)	
PASDAS	3.8 (1.6) [619]	3.3 (1.5) [972]	< 0.01
PASDAS group, n (%)	n = 619	n = 972	< 0.01
Inactive	215 (34.7)	465 (47.8)	
Moderate	132 (21.3)	227 (23.4)	
Active	228 (36.8)	239 (24.6)	
Very active	44 (7.1)	41 (4.2)	
Enthesitis, n/m (%)	319/1152 (27.7)	287/1689 (17.0)	< 0.01
SPARCC Enthesitis Index (1–16)	3.8 (2.9) [319]	3.5 (2.8) [287]	0.14
Dactylitis, n/m (%)	140/1152 (12.2)	125/1689 (7.4)	< 0.01
Dactylitis count (1–20)	2.4 (2.3) [140]	2.2 (1.8) [125]	0.50
BSA, % affected	7.9 (14.8) [1125]	3.5 (7.6) [1636]	< 0.01
BSA (categorical), n (%)	n = 1125	n = 1636	< 0.01
No disease (0%)	201 (17.9)	583 (35.6)	
Mild disease (> 0% to ≤ 3%)	469 (41.7)	680 (41.6)	
Moderate disease (> 3% to ≤ 10%)	258 (22.9)	254 (15.5)	
Severe disease (> 10%)	197 (17.5)	119 (7.3)	

BSA, body surface area; DAPSA, Disease Activity in Psoriatic Arthritis; MDA, minimal disease activity; PASDAS, Psoriatic Arthritis Disease Activity Score; PsO, psoriasis; SPARCC, Spondyloarthritis Research Consortium of Canada; VAS, visual analog scale.

* All values were calculated based on available data and are presented as "mean (SD) [n]" unless otherwise stated.

† t-test or Wilcoxon rank-sum test for continuous variables and χ^2 or Fisher's exact test for categorical variables.

‡ MDA is defined as 'yes' if a patient met at least 5 of the 7 following categories: tender joint count ≤ 1, swollen joint count ≤ 1, body surface area ≤ 3%, patient pain VAS ≤ 15, patient global activity visual analogue scale ≤ 20, health assessment questionnaire ≤ 0.5, and tender entheses points ≤ 1.

Table 2. Patient-Reported Outcome Measures Among Patients With PsA at Enrollment Stratified by Presence of Nail Psoriasis

Characteristic*	With Nail PsO (N = 1152)	Without Nail PsO (N = 1689)	P Value†
Patient pain (VAS 0–100)	41.7 (30.1) [1081]	36.1 (29.1) [1603]	< 0.01
Patient-reported fatigue (VAS 0–100)	43.9 (29.4) [1135]	39.0 (29.6) [1661]	< 0.01
Patient global assessment of arthritis (VAS 0–100)	41.8 (29.5) [1132]	38.0 (30.1) [1663]	< 0.01
Patient global assessment of arthritis and psoriasis (VAS 0–100)	41.6 (29.0) [1130]	37.4 (30.0) [1659]	< 0.01
Morning stiffness	n = 1118	n = 1644	< 0.01
< 30 minutes	380 (34.0)	600 (36.5)	
≥ 30 minutes	738 (66.0)	1044 (63.5)	
HAQ (0–3)	0.7 (0.7) [1087]	0.6 (0.6) [1613]	< 0.01
EQ-5D (0–1)	0.7 (0.2) [1080]	0.8 (0.2) [1600]	< 0.01
EQ VAS (0–100)	68.6 (21.4) [1127]	72.1 (21.1) [1663]	< 0.01
WPAI domains			
Current employment, n/m (%)	678/1109 (61.1)	1003/1636 (61.3)	0.93
% Work time missed	5.9 (16.9) [575]	4.6 (14.9) [868]	0.26
% Impairment while working	20.3 (23.8) [605]	18.1 (23.1) [929]	0.02
% Overall work impairment	23.2 (26.1) [540]	20.5 (25.3) [839]	0.02
% Activity impairment	32.5 (30.2) [1026]	26.6 (28.0) [1543]	< 0.01

EQ-5D, EuroQol 5 Dimensions questionnaire; HAQ-DI, Health Assessment Questionnaire Disability Index; MDA, minimal disease activity; PsO, psoriasis; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment questionnaire.

* All values were calculated based on available data and are presented as "mean (SD) [n]" unless otherwise stated.

† t-test or Wilcoxon rank-sum test for continuous variables and χ^2 or Fisher's exact test for categorical variables.

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SAT0389

INHIBITION OF RADIOGRAPHIC PROGRESSION WAS ACHIEVED WITH INTRAVENOUS GOLIMUMAB IN ACTIVE PSA PATIENTS REGARDLESS OF CHANGES IN COMPOSITE INDICES OF DISEASE ACTIVITY IN A PHASE III TRIAL

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Background: GO-VIBRANT is a Phase 3 trial of intravenous (IV) golimumab (GLM), an anti-tumor necrosis factor alpha (TNF α) monoclonal antibody, in adult patients (pts) with active psoriatic arthritis (PsA).

Objectives: To assess if changes in Disease Activity in PsA (DAPSA), PsA Activity Score (PASDAS), Minimal Disease Activity (MDA), Very Low Disease Activity (VLDA), and Clinical Disease Activity Index (CDAI) measures correlate with X-ray progression.

Methods: In this multicenter, randomized, double-blind, placebo (PBO)-controlled trial, 480 bionative PsA pts with active disease (≥ 5 swollen & ≥ 5 tender joints, C-reactive protein ≥ 0.6 mg/dL, active plaque psoriasis or documented history despite treatment w/csDMARDs &/or NSAIDs) received IV GLM 2mg/kg (N=241) at Wks0/4 then q8wks or PBO (N=239) at Wks0/4/12/20 with crossover to GLM at Wk24. In a post-hoc analysis, association of disease activity measures DAPSA, PASDAS, MDA, VLDA, & CDAI with X-ray progression was examined. Total modified van der Heijde-Sharp (vdH-S) score assessed X-ray progression at Wks 0/24/52. Last observation carried forward imputation was used for partially missing data & non-responder imputation for missing data. Nominal p-values are reported without multiplicity adjustment.

Results: Mean changes from baseline in vdH-S scores were lower with GLM than PBO at Wk24 (-0.36 vs 1.95, respectively, p<0.001) and at Wk52 after crossover from PBO to GLM arm (-0.49 vs 0.76). Changes in all disease activity measures appeared to correlate with X-ray progression (Table). GLM-treated pts had less X-ray progression regardless of disease activity measure. GLM treated pts in remission or with low disease activity tended to have less X-ray progression at Wk52 vs pts with moderate or high disease activity (mean change in vdH-S: DAPSA remission or low disease activity -0.88, moderate activity -0.48, high disease activity 0.41). Similar patterns were seen with PASDAS and CDAI (Table). Irrespective of level of disease activity, GLM-treated pts from Wk 0-52 tended to have less X-ray progression vs PBO-treated pts who switched to GLM at Wk24 (mean change in vdH-S 0-52 wk GLM vs PBO→GLM: DAPSA remission or low disease activity -0.88 vs 1.49, moderate activity -0.48 vs 1.38, high disease activity 0.41 vs 1.27).

Interestingly, pts treated with GLM who did not achieve MDA or VLDA by Wk52 also tended to have less X-ray progression vs PBO pts (mean change no MDA GLM 0.03 vs PBO 1.50; p=0.0011 and mean change no VLDA GLM -0.30 vs PBO 1.45; p<0.0001).

Conclusion: In this analysis, all disease activity measures generally correlated with X-ray progression from baseline to Wk24 and to Wk52. Higher disease activity was associated with increased X-ray progression. GLM-treated pts not achieving MDA & VLDA at Wk52 tended to have less X-ray progression vs PBO→GLM pts. GLM's ability to inhibit X-ray progression, despite pts not being in clinical remission or low disease activity, illustrates an example of "disconnect" between clinical outcomes & X-ray progression seen in other studies.

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