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SAT0395

RESPONSIVENESS AND CLINICAL TRIAL DISCRIMINATION OF SWOLLEN AND TENDER JOINT COUNTS FOR THE MEASUREMENT OF MSK DISEASE ACTIVITY IN PSORIATIC ARTHRITIS

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Background: While tender and swollen joint counts (TJC and SJC) are key instruments for the assessment of peripheral arthritis in PsA, little is known about the psychometric properties of TJC and SJC in randomized controlled trials (RCTs) and how these properties differ among patient subgroups. ¹

Objectives: To assess the responsiveness and discrimination of TJC and SJC in PsA using RCT datasets and evaluate subgroups of patients with early vs. established disease and 3 or less vs 4 or more active joints.

Methods: Patient-level data from 8 phase III RCTs and the Tight Control of Psoriatic Arthritis (TICOPA) trial were analyzed². The standardized response mean (SRM, mean difference between baseline and follow up divided by the standard deviation (SD) of the mean difference) and standardized mean differences (SMD, mean difference in the treated group minus the mean difference in the placebo group divided by the pooled SD for the change) were used to address responsiveness and discrimination respectively. TJC28, SJC28, TJC68, and SJC66 were the primary measures of interest but physician and patient global assessments (PhGA and PtGA) and pain were included for comparison. SRMs

Figure 2. Responsiveness by Number of Active Joints

were calculated in subgroups of patients with less than 3 (TJC68/SJC66 ≤ 3) or more than 3 (TJC68/SJC66 > 3) active joints as well as early (< 2 years) and established (≥ 2 years) disease.

Results: In traditional phase III RCTs, TJC and SJC were responsive and had good clinical trial discrimination. SRMs were similar and ranged from -0.8 to -0.4 ('moderate' responsiveness) (Figure 1). SMDs were similar among SJC28 and SJC66 and likewise between TJC28 and TJC68 but mostly within the small effect range (-0.2 to -0.5; not shown). PhGA and PtGA had higher SMDs than the joint counts. SRMs were substantially lower for joint counts (and also PtGA) among the low compared with the higher joint count groups (Figure 2). There were no substantial differences in SRMs between patients with early and established disease.

Conclusion: Joint counts are responsive to change and have reasonable discrimination in RCTs among patients higher disease activity at baseline. However, joint counts may not be ideal outcome measures in oligoarticular disease and have lower responsiveness and discrimination in this subgroup.

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Figure 1. SRM among treated patients by trial

Each bar represents an individual trial. Only active treatment groups are included in this figure. Dashed lines are cut offs for moderate effect and large effect.

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SAT0396

IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF PSORIATIC ARTHRITIS WITH IXEKIZUMAB COMPARED TO PLACEBO IN PATIENT SUBGROUPS DEFINED BY BASELINE DISEASE CHARACTERISTICS

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Background: Ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets interleukin-17A, was superior to placebo (PBO) in two randomized Phase 3 studies in patients (pts) with active psoriatic arthritis (PsA).^{1,2}

Objectives: To assess the consistency of response of IXE across subgroups of pts defined by specific baseline disease characteristics.

Methods: Data were analyzed from an integrated database of 2 randomized, double-blind, Phase 3 studies in pts who were either biologic Disease Modifying Anti-Rheumatic Drug (bDMARD)-naïve (SPIRIT-P1) or who had prior inadequate response or intolerance to TNF inhibitors (SPIRIT-P2). Analyses included pts randomly assigned to the approved dosing regimen of IXE (80 mg IXE every 4 wks [IXE Q4W]) with a starting dose of 160 mg IXE) or to PBO through Wk 24. Efficacy was measured as the percentage of pts achieving $\geq 20\%$, 50%, or 70% improvement from baseline in the American College of Rheumatology criteria (ACR20/50/70) or minimal disease activity (MDA) in subgroups of pts defined by baseline presence of enthesitis, dactylitis, psoriasis body surface area (BSA) involvement ($<3\%$ or $\geq 3\%$), and c-reactive protein (CRP) >6 or ≤ 6 mg/L. Missing data were imputed by nonresponder imputation.

Results: Clinical response rates at Wk 24 in each subgroup are summarized (Table). Significantly ($p < 0.05$) more patients achieved ACR20, ACR50, ACR70, and MDA with IXE compared to placebo across patient subgroups defined by presence of enthesitis, presence of dactylitis, percentage of psoriasis BSA involvement, and by CRP levels at baseline.

Conclusion: At Wk 24, IXE was superior to placebo for the treatment of PsA signs and symptoms regardless of baseline presence of dactylitis or enthesitis, BSA involvement, or CRP levels.

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SAT0397

DESCRIPTIVE COMPARISONS OF THE IMPACT OF APREMILAST AND METHOTREXATE MONOTHERAPY ON PATIENTS WITH OLIGOARTICULAR PSORIATIC ARTHRITIS IN THE CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS REGISTRY

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Background: Therapeutic effectiveness has rarely been studied in a sub-population of patients with oligoarticular PsA.

Objectives: To examine baseline characteristics and 6-month clinical assessments of PsA patients with oligoarthritis (≤ 4 swollen joints) who initiated apremilast (APR) or methotrexate (MTX) monotherapy in the Corrona PsA/SpA Registry, a prospective, US-based, observational cohort study. Patients initiating bDMARD monotherapy were also examined as a point of reference.

Methods: Patients ≥ 18 years of age with PsA and oligoarthritis in the registry who initiated APR, MTX or a bDMARD (reference group) monotherapy and had a 6-month follow-up visit between June 2014 and March 2018 were included. Descriptive statistics were calculated for patients' clinical characteristics and disease assessments at treatment initiation and at the 6-month follow-up visit.

Results: The analysis included 150 patients initiating therapy (APR: n=34; MTX: n=15; bDMARD: n=101). Among APR and MTX initiators, 79% and 20% received at least 1 prior bDMARD, respectively. APR initiators, compared with MTX initiators, were younger (mean [SD]: 55.7 [12.6] vs. 61.5 [16.6] years), had longer disease duration (mean [SD]: 8.0 [6.7] vs. 5.4 [7.8] years), and had higher levels of disease activity

Clinical responses at Week 24 in subgroups defined by baseline disease characteristics (NRI)

	ACR20		ACR50		ACR70		MDA	
	PBO (N=224)	IXE Q4W (N=229)	PBO (N=224)	IXE Q4W (N=229)	PBO (N=224)	IXE Q4W (N=229)	PBO (N=224)	IXE Q4W (N=229)
Enthesitis Present	29/142 (20)	88/159 (55)†	12/142 (9)	58/159 (37)†	2/142 (1)	31/159 (20)†	6/142 (4)	41/159 (26)†
Enthesitis Absent	26/81 (32)	39/70 (56)‡	10/81 (12)	28/70 (40)†	4/81 (5)	21/70 (30)†	14/81 (17)	25/70 (36)*
Dactylitis Present	12/59 (20)	55/92 (60)†	6/59 (10)	38/92 (41)†	2/59 (3)	24/92 (26)†	5/59 (9)	33/92 (36)†
Dactylitis Absent	43/164 (26)	72/137 (53)†	16/164 (10)	48/137 (35)†	4/164 (2)	28/137 (20)†	15/164 (9)	33/137 (24)†
BSA $<3\%$	20/85 (24)	44/80 (55)†	8/85 (9)	29/80 (36)†	2/85 (2)	17/80 (21)†	6/85 (7)	21/80 (26)‡
BSA $\geq 3\%$	35/134 (26)	77/141 (55)†	14/134 (10)	55/141 (39)†	4/134 (3)	34/141 (24)†	13/134 (10)	42/141 (30)†
CRP ≤ 6 mg/L	29/100 (29)	45/97 (46)*	11/100 (11)	31/97 (32)†	2/100 (2)	16/97 (17)†	11/100 (11)	25/97 (26)‡
CRP >6 mg/L	26/122 (21)	80/129 (62)†	11/122 (9)	54/129 (42)†	4/122 (3)	36/129 (28)†	9/122 (7)	41/129 (32)†

Data are provided as n/Ns (%) where n=number of responders and Ns=number of patients in each subgroup p-values from Fisher's exact test; *= $p < 0.05$, ‡= $p < 0.01$, †= $p < 0.001$

ACR20/50/70 = $\geq 20\%$, 50%, or 70% improvement from baseline in the American College of Rheumatology criteria; BSA = body surface area; CRP = c-reactive protein; IXE Q4W = 80 mg IXE every 4 weeks; MDA = minimal disease activity; PBO = placebo