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FRI0351

DOES SEX OR BODY MASS INDEX IMPACT RESPONSE TO THERAPY IN PSORIATIC ARTHRITIS?: RESULTS FROM A PHASE 3, DOUBLE-BLIND, RANDOMIZED TRIAL EXAMINING METHOTREXATE AND ETANERCEPT AS MONOTHERAPY OR IN COMBINATION FOR TREATING PSORIATIC ARTHRITIS

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Background: In psoriatic arthritis (PsA), contextual factors such as sex and body mass index (BMI) may affect response to therapy.

Objectives: To examine if sex and BMI influenced 24-week (wk) outcomes in a 48-wk PsA trial of methotrexate (MTX) and etanercept (ETN) as monotherapy (mono) or combined.¹

Methods: MTX- and biologic-naïve adult patients with active PsA were randomized to weekly: MTX 20mg (n=284), ETN 50mg (n=284), or MTX 20mg+ETN 50mg (n=283). Wk-24 outcomes included ACR 20, MDA, VLDA, PASDAS, DAPSA, LDI, SPARCC, BSA, sPGA, and mNAPSI. Descriptive statistics examined outcomes in each treatment arm by sex (male vs female) or BMI ($\leq 30\text{kg/m}^2$ vs $>30\text{kg/m}^2$). Modeling analyses also examined sex or BMI effect on outcomes when comparing MTX mono to the ETN-containing arms (analyses were adjusted for any prior use of a nonbiologic disease-modifying antirheumatic drug; the model for the influence of sex also adjusted for baseline BMI status). Nominal P-values are provided.

Results: Baseline disease activity was slightly higher in women, especially with MTX+ETN. Descriptive statistics showed men and women had similar results at wk 24 in the MTX mono and ETN mono arms; with MTX+ETN, men had better outcomes for ACR20, MDA, VLDA, and PASDAS. In treatment-interaction analyses, men had more favorable responses at wk 24 with MTX+ETN vs MTX mono for PASDAS, MDA, and LDI (Table).

Baseline disease activity was similar in both BMI categories. Descriptive statistics in each treatment arm showed no consistent differences in results at wk 24 between BMI categories. In treatment-interaction analyses, BMI $\leq 30\text{kg/m}^2$ had a more favorable response at wk 24 with MTX+ETN vs MTX mono for sPGA (Table).

Conclusion: Results suggest contextual factors may affect response to therapy in PsA. The treatment-interaction analyses suggest disparate responses to MTX+ETN by sex; BMI only affected skin response.

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FRI0352

PROBABILITY OF ACHIEVING LOW DISEASE ACTIVITY OR REMISSION WITH APREMILAST TREATMENT AMONG DMARD-NAIVE SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS

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Table. Week 24 Treatment-Interaction Outcomes Adjusted by Sex and BMI

	MTX Mono			ETN Mono			MTX+ETN		
Adjusted by Sex ^a	Male	Female	Male vs Female	Male	Female	Male vs Female	Male	Female	Male vs Female
PASDAS ^b (Full Analysis Set)	-1.80 (0.17)	-1.95 (0.15)	0.15 (0.21)	-2.45 (0.15)	-2.59 (0.16)	0.13 (0.20) P=0.96 ^c	-2.87 (0.15)	-2.14 (0.16)	-0.74 (0.20) P=0.002 ^c
MDA ^d (Full Analysis Set)	0.23 (0.04)	0.19 (0.03)	0.04 (0.05)	0.34 (0.04)	0.31 (0.04)	0.03 (0.06) P=0.86 ^c	0.42 (0.04)	0.22 (0.04)	0.21 (0.05) P=0.02 ^c
LDI ^e (LDI Analysis Set)	-186.67 (37.69)	-70.17 (34.51)	-116.51 (46.64)	-120.15 (34.23)	-109.17 (37.07)	-10.98 (46.75) P=0.11 ^c	-85.80 (36.10)	-127.90 (34.82)	42.10 (47.05) P=0.017 ^c
Adjusted by BMI^a	$\leq 30\text{kg/m}^2$	$>30\text{kg/m}^2$	≤ 30 vs $>30\text{kg/m}^2$	$\leq 30\text{kg/m}^2$	$>30\text{kg/m}^2$	≤ 30 vs $>30\text{kg/m}^2$ P=0.75 ^c	$\leq 30\text{kg/m}^2$	$>30\text{kg/m}^2$	≤ 30 vs $>30\text{kg/m}^2$ P=0.05 ^c
sPGA of 0 or 1 ^d (Full Analysis Set of Patients With Baseline BSA $\geq 10\text{m}^2$)	0.49 (0.08)	0.58 (0.07)	-0.10 (0.10)	0.69 (0.07)	0.74 (0.07)	-0.05 (0.08)	0.81 (0.05)	0.64 (0.08)	0.17 (0.09) P=0.05 ^c

^aAdjusted for sex by treatment arm, prior nonbiologic DMARD use, and baseline BMI

^bLeast square estimate (SE) change from baseline at week 24

^cP-value is nominal and for comparison with MTX mono

^dAdjusted risk ratio (SE)

^eAdjusted for BMI by treatment arm and prior nonbiologic DMARD use

BMI, body mass index; BSA, body surface area; DMARD, disease-modifying antirheumatic drug; ETN, etanercept; LDI, Leeds Dactylitis Index; MDA, Minimal Disease Activity; Mono, monotherapy; MTX, methotrexate; PASDAS, Psoriatic Arthritis Disease Activity Score; SE, standard error; sPGA, static Physicians' Global Assessment

Background: Apremilast (APR) is associated with comparable ACR response rates in DMARD-naïve vs DMARD-experienced patients (pts) with psoriatic arthritis (PsA).^{1,2} A question that remains is if DMARD-naïve pts treated with APR have greater chances of achieving treatment targets than DMARD-experienced pts. cDAPSA is a commonly used treatment target.

Objectives: To assess the predictive value of baseline (BL) clinical disease status on achieving long-term cDAPSA treatment targets at Wk 52 among DMARD-naïve subjects in PALACE 4; to compare these findings vs those recently reported from the PALACE 1-3 studies in subjects with prior exposure to DMARDs; and to provide further evidence that at a group level, achievement of cDAPSA disease targets with APR is associated with no or mild articular and extra-articular disease activity by Wk 52.

Methods: This post hoc analysis included subjects assigned to APR 30 mg twice daily at BL who had available cDAPSA data at BL. We calculated the probabilities of shifting across different cDAPSA categories (remission [REM]: ≤4; low disease activity [LDA]: >4 to ≤13; moderate disease activity [Mod]: >13 to ≤27; high disease activity [HDA]: >27) from BL to Wk 52. Mean values of articular and non-articular variables (e.g., PASI, SJC/TJC, MASES, dactylitis) from BL to Wk 52 were assessed by cDAPSA category achieved at Wk 52 to determine the association between achievement of targets and control of articular and non-articular manifestations. Results from the current analyses were compared with the previously reported results from PALACE 1-3.

Results: A total of 175 subjects receiving APR were included; at BL, 66.3% were in HDA, 31.4% in Mod, and 2.3% were in LDA. Overall, subjects who achieved treatment targets (LDA or REM) by Wk 52 had lower levels of disease activity at BL, as shown by a lower number of swollen and tender joints and lower presence of enthesitis and dactylitis. Higher prevalence of psoriasis-involved body surface area ≥3% at BL was observed. Subjects in Mod at BL were estimated to be more than twice as likely to achieve REM or LDA at Wk 52 vs subjects in HDA at BL; for subjects in LDA at BL, the estimated probability of achieving cDAPSA treatment targets was 100% (Figure). PALACE 4 subjects with LDA and Mod at BL exhibited higher estimated probabilities of achieving treatment targets (100.0% and 61.7%, respectively) than those observed in the DMARD-experienced population of PALACE 1-3 (71.1% and 46.9%). Subjects in PALACE 4 who achieved REM or LDA by Wk 52 showed no or mild articular and extra-articular disease activity by Wk 52, similar to what was observed in the PALACE 1-3 population.⁴

Conclusion: DMARD-naïve subjects in PALACE 4 who had LDA or Mod at BL had the highest likelihood of achieving treatment targets (cDAPSA REM or LDA) by Wk 52 with continued APR treatment. Results from the current probability analyses revealed higher probability rates than those observed in the DMARD-experienced PALACE 1-3 population; control of articular and extra-articular manifestations was observed in the DMARD-naïve and DMARD-experienced populations.

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Figure. Probability of Achieving cDAPSA Treatment Targets at Week 52 by Baseline cDAPSA Category

		cDAPSA Categories at Week 52				
		HDA	Mod	LDA	REM	LDA/REM
cDAPSA Categories at Baseline*	LDA	0.0%	0.0%	50.0%	50.0%	100.0%
	Mod	9.1%	29.2%	39.8%	21.9%	61.7%
	HDA	27.1%	44.7%	24.3%	3.9%	28.2%

*Subjects randomized to APR 30 mg twice daily with cDAPSA scores available at baseline (n=175). Percentage represents the proportion of subjects in each cDAPSA category at baseline (from left to right, HDA, Mod, LDA, and REM at Week 52=100%). Multiple imputation. REM, cDAPSA ≤4; LDA, cDAPSA >4 to ≤13; Mod, cDAPSA >13 to ≤27; HDA, cDAPSA >27. Mod=moderate disease activity.

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FRI0353

FACTORS ASSOCIATED WITH DISCORDANCE BETWEEN PATIENT AND RHEUMATOLOGIST ASSESSMENT OF DISEASE ACTIVITY IN PSORIATIC ARTHRITIS CONSIDERED IN REMISSION

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Background: Assessment of disease activity in psoriatic arthritis (PsA) requires evaluation of multiple aspects. Perception of disease activity by patient and physician is frequently discordant.

Objectives: The aim of our study was to evaluate factors associated with persistence of disease activity evaluated by patients yet considered in remission by their rheumatologist.

Methods: We performed a transversal monocentric study. PsA patients were included if they met the CASPAR criteria and if they were considered in remission. Disease activity was evaluated by scores: Disease Activity Score (DAS28-CRP), Simple Disease Activity Index (SDAI), Clinical Disease Activity Index (CDAI), Disease Activity in Psoriatic Arthritis (DAPSA), Minimal Disease Activity (MDA), modified Boolean remission criteria for PsA. We collected multiple Patient's Reported Outcomes (PROs): Psoriatic Arthritis Impact of Disease (PsAID), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Health Assessment Questionnaire (HAQ), Dermatology Life Quality Index (DLQI), Beck Depression Inventory (BDI), Fibromyalgia Rapid Screening Tool (FIRST), Pain Catastrophizing Scale (PCS). Discordance was defined by a difference between patient's and rheumatologist's global assessment ≥30/100 on a Visual Analogue Scale (VAS). Univariate and multivariate analyses were performed to evaluate factors associated with the presence of discordance.

Results: 62 PsA patients were included. 40.3% were women and the mean (SD) age was 55 (14) years. 61% patients were in remission (rheumatologist definition) for more than 12 months and 19% for less than 3 months. 50% met MDA, 63% DAS28-CRP < 2.6, 39% SDAI and CDAI remission, 27% DAPSA remission. 39% had a discordant disease activity assessment from their rheumatologist. In univariate analysis, factors associated with discordance were a history of depression, an associated fibromyalgia, a history of clinical enthesitis and a history of corticosteroid use (Table 1). All disease activity scores and PROs were higher in discordant group and were associated with discordance in univariate analysis. In multivariate analysis, discordance was associated with no previous corticosteroid use (OR 24.5 (95%CI 2.9-203.7), p=0.003), a higher BDI scale (OR 1.4 (95%CI 1.1-1.8) by supplementary point, p=0.017) and a higher DAPSA score (OR 1.5 (95%CI 1.2-2), p<0.001) by supplementary point.

Conclusion: In this PsA cohort, discordance between patient and rheumatologist is very common. Discordance in assessment of disease activity was associated with no previous corticosteroid use, probably reflecting a less severe disease, presence of depressive symptoms and an increase of DAPSA, reflecting a more active disease.

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