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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.

References:

[1] Mease et al. *Arthritis Rheumatol*. 2019;71:1112-24

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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