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FRI0365

REAL-WORLD EFFECTIVENESS AND SAFETY OF APREMILAST IN A LARGE COHORT OF GERMAN PATIENTS WITH PSORIATIC ARTHRITIS: 1-YEAR ANALYSIS OF AN ONGOING MULTICENTER, PROSPECTIVE, NON-INTERVENTIONAL STUDY

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Background: Apremilast (APR) has been studied extensively in phase III randomized, controlled trials. However, real-world information is limited on the effectiveness and safety of APR in patients with psoriatic arthritis (PsA).

Objectives: To assess the effectiveness and safety of APR in a large cohort of patients with active PsA from routine clinical practice settings in Germany.

Methods: In this multicenter, prospective, non-interventional study, the primary endpoint was the proportion of patients reaching ≥ 1 point ($\geq 20\%$) improvement from baseline (BL) in the Physician's Global Assessment of Disease Activity (PhGA) score. Other endpoints included effects on swollen and tender joint counts (SJC/TJC), psoriasis-involved body surface area (BSA), enthesitis, dactylitis, Patient's Global Assessment of Disease Activity score (PtGA), Psoriatic Arthritis Impact of Disease (PsAID) tool, pain, and pruritus. The current analysis is based on observed data through 1 year of study duration.

Results: A total of 545 German patients were enrolled and followed up to 12 months of APR treatment; 488 patients were included in the safety analysis and 418 in the final analysis set. The mean age was 55 years, mean body mass index was 29.5 kg/m², and 60% were female. The mean duration of psoriasis and PsA was 26 years and 18 years, respectively. At BL, 46.7% of patients had enthesitis based on the Leeds Enthesitis Index (LEI; mean [SD]: 2.9 [1.72]) and 23% had dactylitis (mean [SD]: 2.2±2.03); 74% of patients were biologic-naïve. Effectiveness is shown after ~1 month (Visit 1 [V1]) and ~4 months (Visit 2 [V2]) and for up to 225 patients after 12 months (Visit 5 [V5]) of treatment (Table). Improvements were also seen in PtGA, overall pain, and pruritus. A subanalysis suggests APR was associated with greater benefits in biologic-naïve patients compared with patients who previously received biologic therapy. Observed safety and tolerability through V5 were consistent with the known overall safety profile of APR. Common adverse events in clinical trials were similar, with a lower incidence of diarrhea (11.1%), nausea (7.0%), headache (3.9%), and respiratory tract infection (0.8%).

Conclusion: Data from this large, real-world cohort of patients with PsA show the effectiveness of APR. In patients with up to 12 months of follow-up, APR was associated with rapid and maintained improvements in physician-assessed and patient-reported outcomes. Safety and tolerability were consistent with the known profile of APR.

Table. Effectiveness of APR Treatment

	BL n=418*	V1 n=326*	V2 n=360*	V5 n=214*
≥ 1 -point PhGA improvement, %	NA	56.2	77.2	86.4
PhGA score, mean (95% CI)	2.5 (2.4, 2.5)	1.8 (1.7, 1.9)	1.4 (1.3, 1.5)	1.1 (1.0, 1.2)
PhGA score=0-1, %	NA	34.3	60.8	77.0
SJC mean improvement, % (95% CI)	NA	42.1 (34.7, 49.5)	54.7 (45.4, 64.1)	75.7 (65.5, 86.0)
TJC mean improvement, % (95% CI)	NA	38.3 (27.2, 40.4)	36.0 (23.8, 48.3)	57.1 (41.1, 73.1)
Psoriasis-involved BSA (%), mean (95% CI)	10.0 (8.6, 11.4)	7.7 (6.3, 9.1)	4.7 (3.8, 5.7)	2.4 (1.8, 2.9)
Achievement of LEI=0 [†] , %	NA	38	50	58
Achievement of dactylitis count=0 [†] , %	NA	48	71	88
PsAID score, mean (95% CI)	5.33 (5.12, 5.53)	4.65 (4.41, 4.89)	3.97 (3.73, 4.20)	3.22 (2.94, 3.50)

*Based on the number of patients with data available at the given visit; the n may vary for individual parameters at a given visit. [†]In patients affected at BL. CI=confidence interval; NA=not applicable.

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CARDIOVASCULAR RISK RECLASSIFICATION USING CAROTID ULTRASOUND IN PSORIATIC ARTHRITIS: A CASE-CONTROL STUDY

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Background: Patients with psoriatic arthritis (PsA) have an increased risk of cardiovascular disease (CVD). Risk stratification algorithms for general population, such as cardiovascular risk calculators, have been developed to improve primary prevention and early detection of CVD; however, it underestimates cardiovascular risk in PsA patients¹. Carotid ultrasound, which measures both carotid intima-media thickness (cIMT) and carotid plaque (CP), is useful in the detection of subclinical carotid atherosclerosis improving risk stratification.

Objectives: This study aimed to evaluate the use of carotid ultrasound in the reclassification of cardiovascular risk in PsA patients and compare it with controls.

Methods: This cross-sectional study included 70 PsA patients that fulfilled the CASPAR criteria and 70 controls subjects matched by age and comorbidities. Patients with a history of previous atherosclerotic CVD and pregnancy were excluded. Clinical examination, blood tests and Framingham Risk Score Lipids and BMI based (FRS-Lipids/FRS-BMI) and ACC/AHA 2013 calculators were performed. Carotid B-mode ultrasonography was used for measurements of cIMT and CP presence. *Increased cIMT was defined as ≥ 0.9 mm. CP was defined as a focal narrowing ≥ 0.5 mm of the surrounding lumen or a cIMT ≥ 1.2 mm.* Descriptive analysis was done with measures of central tendency and dispersion and comparisons with Chi-square, Student's t and Mann-Whitney U tests.

Results: A total of 138 subjects were included. Clinical and demographic characteristics are shown in Table 1. Differences were found in the cardiovascular risk classification between the calculators and the carotid ultrasound. However, these were not significant when compared to controls, with the exception of the FRS-Lipids which had a significant difference when recategorized as high risk by the increase in the cIMT ($p = 0.016$). A 70.8% and a 56% of patients with PsA who had CP were not classified as high risk according to FRS-Lipids ($p = 0.010$) and ACC / AHA 2013 ($p < 0.001$) respectively.

Table 1. Clinical and demographic characteristics.

	PsA (n=69)	Controls (n=69)	P
Age, (mean±SD)	53.58±10.946	53.86±7.313	NS
Women, n (%)	38(55.1)	59(85.5)	<0.001
Type 2 Diabetes Mellitus, n (%)	14(20.3)	9(13)	NS
Hypertension, n (%)	27(39.1)	19(27.5)	NS
Dyslipidemia, n (%)	29(42)	24(34.8)	NS
Obese, n (%)	26(37.7)	28(40.6)	NS
Active smoker, n (%)	15(21.7)	12(17.4)	NS
Disease duration, median (q25-q75)	5(2.5-8)	-	-
DAS28-ESR, (mean±SD)	3.74±1.477	-	-
DAPSA, median (q25-q75)	35(27.5-58.5)	-	-

Conclusion: None of the traditional calculators used in the general population correctly estimates cardiovascular risk in patients with PsA. Among the calculators we performed, FRS-Lipids was the worst, underestimating PsA individuals with CP up to 70.8%. Therefore, it is advisable to perform a carotid ultrasound without relying on the results obtained by any of these calculators in order to achieve an adequate classification and accomplish a correct management of the disease.

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