

POS1041

PREVALENCE, INCIDENCE AND ANTIRHEUMATIC DRUG USE IN PSORIATIC ARTHRITIS (PsA) IN NORWAY

A. Kerola^{1,2}, J. Sexton¹, S. Rollefstad¹, G. Wibetoe¹, C. S. Crowson³, E. Haavardsholm¹, T. K. Kvien¹, A. G. Semb¹. ¹Diakonhjemmet Hospital, Division of Rheumatology and Research, Oslo, Norway; ²Päijät-Häme Joint Authority for Health and Wellbeing, Rheumatology, Lahti, Finland; ³Mayo Clinic, Department of Quantitative Health Sciences, Rochester, Minnesota, United States of America

Background: Incidence estimates of PsA in Norway have varied from 6.9/100,000 person-years (pyrs) in Northern Norway to 41.3/100,000 pyrs in Central Norway, and point prevalence estimates have ranged from 1.3 to 6.9 per 1,000 adult inhabitants^{1,2}, while nationwide epidemiologic data on PsA in Norway have been lacking.

Objectives: To estimate prevalence, incidence and use of disease-modifying antirheumatic drugs (DMARDs) among PsA patients in Norway.

Methods: The Norwegian Cardio-Rheuma register includes pseudonymized data from the total Norwegian population ≥18 years of age during 2008-2017, identified from the National Population register. Demographic and socioeconomic data were retrieved from Statistics Norway. Data on public or private somatic specialized care episodes were collected from the Norwegian Patient register (NPR) [ICD-10 codes for diagnoses and medical procedure codes for biologic DMARD infusions]. Information on dispensed DMARD prescriptions was captured from the Norwegian Prescription Database. Based on NPR data, PsA cases were defined as persons fulfilling three criteria: 1) 1st episode with ICD-10 code M07.0-M07.3 or L40.5 as main or contributory diagnosis (index date), 2) 2nd episode with code M07.0-M07.3 or L40.5 within 2-year period following index date, 3) an episode in internal medicine or rheumatology clinic with recorded M07.0-M07.3 or L40.5 within 2 years from index date. Years 2008-2010 served as a look-back period to identify prevalent PsA cases. To estimate pyrs at risk, we calculated number of individuals aged ≥ 18 years living in Norway on the 1st of January of each year 2011-2015 multiplied by one year (prevalent PsA cases excluded). Age- and sex-standardized incidence rates were calculated with 5-year age groups using the Norwegian adult population on January 1st 2015 as the standard.

Results: During the look-back period 2008-2010, 7,697 cases fulfilled the PsA definition. In total, 6,183 incident PsA cases were identified during 2011-2015 (incidence 32/100,000 pyrs, 28 among men and 35 among women). Based on a sensitivity analysis comprising 5,065 PsA cases with no dispensed DMARD prescriptions ≥12 months before index date, incidence was slightly lower (26/100,000 pyrs). Patient characteristics and DMARD use are shown in Table 1. The incidence was highest among those aged 50-59 years in both sexes (Figure 1). PsA incidence was lower among those with higher education level (crude/age- and sex-standardized incidence per 100,000 pyrs for those below upper secondary education 34/38, upper secondary or post-secondary non-tertiary education 36/36, higher education 26/25). Point prevalence of PsA was 3.3/1,000 adult inhabitants on January 1st 2016.

Table 1. Characteristics and treatment penetration of incident PsA patients 2011-2015

	All	Excluding cases with DMARDs >1 yr prior to index date			
N	6183	5065			
Women, n (%)	3442 (55.7)	2783 (54.9)			
Age at index date, median (IQR)	50.5 (40.7 - 59.8)	49.9 (40.2 - 59.3)			
Use of DMARDs after index date, n (%)		12 months	24 months	12 months	24 months
Any conventional DMARD	3706 (59.9)	4048 (65.4)	2894 (57.1)	3184 (62.9)	
Methotrexate	3313 (53.6)	3650 (59.0)	2638 (52.1)	2933 (57.9)	
Sulfasalazine	440 (7.1)	586 (9.5)	330 (6.5)	457 (9.0)	
Any biologic DMARD	842 (13.6)	1197 (19.4)	485 (9.6)	771 (15.2)	
TNF-inhibitors	810 (13.1)	1154 (18.7)	477 (9.4)	758 (15.0)	
Oral glucocorticoids	1773 (28.7)	2240 (36.2)	1449 (28.6)	1807 (35.7)	
Any DMARD or glucocorticoids	4365 (70.6)	4742 (76.7)	3384 (66.8)	3725 (73.5)	

Conclusion: Our estimate of PsA incidence and prevalence are in the mid-range compared to studies from smaller regions in Norway. Methotrexate was initiated for more than half of PsA cases within one year from index date, whereas 19% had used biologic DMARDs within two years.

REFERENCES:

- [1] Hoff M, Gulati A, Romundstad P et al. Prevalence and incidence rates of psoriatic arthritis in central Norway: data from the Nord-Trøndelag health study. *Ann Rheum Dis* 2015;74:60-64.
- [2] Nossent J & Gran J. Epidemiological and clinical characteristics of psoriatic arthritis in northern Norway. *Scand J Rheumatol* 2009; 8:251-5.

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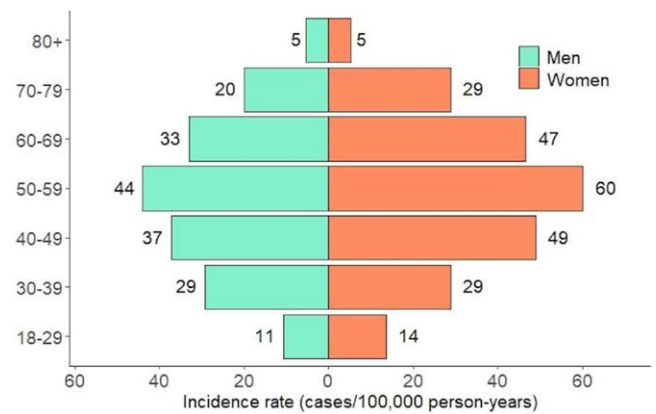


Figure 1.

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POS1042

EFFICACY AND SAFETY OF DEUCRAVACITINIB, AN ORAL, SELECTIVE TYROSINE KINASE 2 (TYK2) INHIBITOR, COMPARED WITH PLACEBO AND APREMILAST IN MODERATE TO SEVERE PLAQUE PSORIASIS: RESULTS FROM THE PHASE 3 POETYK PSO-1 STUDY

A. Armstrong¹, M. Gooderham², R. B. Warren³, K. Papp⁴, B. Strober^{5,6}, D. Thaçi⁷, E. Colston⁸, J. Throup⁹, S. Kundu¹⁰, S. Banerjee¹¹, A. Blauvelt¹². ¹Keck School of Medicine, University of Southern California, Los Angeles, United States of America; ²SKiN Center for Dermatology, Queen's University and Proby Medical Research, Peterborough, Canada; ³Dermatology Center, Salford Royal NHS Foundation Trust Hospital, Manchester NIHR Biomedical Research Center, University of Manchester, Manchester, United Kingdom; ⁴Clinical Research and Proby Medical Research, K. Papp Clinical Research, Waterloo, Canada; ⁵Yale University, Dermatology, New Haven, United States of America; ⁶Central Connecticut Dermatology Research, Co-founder, Cromwell, United States of America; ⁷University of Lübeck, Comprehensive Centre for Inflammation Medicine, Lübeck, Germany; ⁸Bristol Myers Squibb, Dermatology, Princeton, United States of America; ⁹Bristol Myers Squibb, Immunoscience R&D, Princeton, United States of America; ¹⁰Bristol Myers Squibb, Global Biometrics Sciences, Princeton, United States of America; ¹¹Bristol Myers Squibb, Rheumatology and Dermatology, Princeton, United States of America; ¹²Oregon Medical Research Center, Dermatology, Portland, United States of America

Background: Tyrosine kinase 2 (TYK2) is an intracellular kinase that mediates interleukin (IL)-23, IL-12, and interferon (IFN) α/β signaling. Deucravacitinib is a novel, oral, selective inhibitor of TYK2 acting via binding to the TYK2 regulatory domain.¹ Phase 2 results showed deucravacitinib was efficacious and well tolerated versus placebo in patients with moderate to severe plaque psoriasis or active psoriatic arthritis.^{2,3} No herpes zoster infections, opportunistic infections, thromboembolic events, or hematologic or lipid abnormalities characteristic of Janus kinase (JAK) 1-3 inhibitors were reported in the Phase 2 trials.^{2,3}

Objectives: To compare the efficacy and safety of deucravacitinib versus placebo and apremilast in plaque psoriasis.

Methods: This Phase 3, double-blinded, 52-week study (NCT03624127) randomized patients with moderate to severe plaque psoriasis (BSA \geq 10%, PASI \geq 12, sPGA \geq 3) to deucravacitinib 6mg once daily, placebo, or apremilast 30mg twice daily (2:1:1). Patients receiving placebo were switched to deucravacitinib at Week 16; apremilast-treated patients not achieving PASI 50 at Week 24 were switched to deucravacitinib. Coprimary endpoints were PASI 75 and sPGA 0/1 response versus placebo at Week 16. Key secondary endpoints included superiority versus apremilast, assessed via multiple measures.

Results: 666 patients were randomized. Demographic and baseline disease characteristics were balanced across groups; mean age was 46.1 years, mean

disease duration was 17.3 years, 18.2% of patients had psoriatic arthritis at baseline, and 38.9% had previously used biologic therapy. Mean BSA involvement at baseline was 26.3%, mean PASI was 21.4, and the percentage with severe sPGA (score=4) at baseline was 21.2%. Significantly greater proportions of patients in the deucravacitinib versus placebo and apremilast arms achieved PASI 75 (58.7% vs 12.7% vs 35.1%, respectively; $P<0.0001$) and sPGA 0/1 (53.6% vs 7.2% vs 32.1%, respectively; $P<0.0001$) response at Week 16 (Figure 1). Deucravacitinib was also superior to apremilast at Week 24, with 69.0% versus 38.1% of patients achieving PASI 75 and 58.4% versus 31.0% achieving sPGA 0/1 ($P<0.0001$ for both). In addition, DLQI 0/1 responses at Week 16 were significantly higher with deucravacitinib versus placebo and apremilast, demonstrating improved quality of life (40.7% vs 10.6% vs 28.6%, respectively; Figure 1). During the 16-week, placebo-controlled period, the most common AEs ($\geq 5\%$ in any arm) were nasopharyngitis, upper respiratory tract infection, headache, diarrhea, and nausea (Table 1). Frequencies of SAEs and treatment discontinuations due to AEs were low (Table 1).

Table 1. Summary of adverse events (AEs) through Week 16

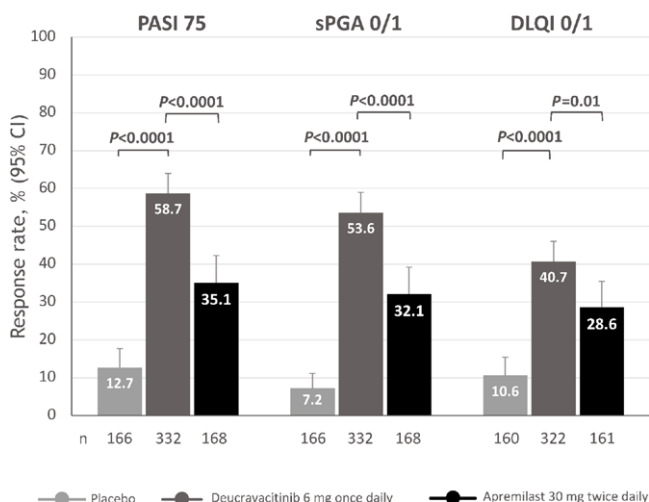
Patients, n (%)	Deucravacitinib	Placebo	Apremilast
	n=332	n=165	n=168
Any AEs	176 (53.0)	70 (42.4)	93 (55.4)
Severe AEs	5 (1.5)	7 (4.2)	5 (3.0)
Serious AEs	7 (2.1)	9 (5.5)	4 (2.4)
AEs leading to treatment discontinuation	6 (1.8)	7 (4.2)	10 (6.0)
Most common AEs ($\geq 5\%$ in any arm)			
Nasopharyngitis	21 (6.3)	7 (4.2)	14 (8.3)
Upper respiratory tract infection	21 (6.3)	6 (3.6)	3 (1.8)
Headache	16 (4.8)	5 (3.0)	17 (10.1)
Diarrhea	13 (3.9)	6 (3.6)	17 (10.1)
Nausea	7 (2.1)	4 (2.4)	19 (11.3)

Conclusion: Deucravacitinib demonstrated superiority versus placebo and apremilast across multiple efficacy endpoints in patients with moderate to severe plaque psoriasis, and was generally well tolerated. Overall, the efficacy and safety profile of deucravacitinib was consistent with that observed in the Phase 2 plaque psoriasis and psoriatic arthritis trials.^{2,3}

REFERENCES:

- Burke JR et al. *Sci Transl Med*. 2019;11:1-16.
- Papp K et al. *N Engl J Med*. 2018;379:1313-21.
- Mease PJ et al. Presented at: Annual Scientific Meeting of the American College of Rheumatology; November 5-9, 2020; Virtual meeting.

Figure. Efficacy responses at Week 16



DLQI=Dermatology Life Quality Index; PASI=Psoriasis Area Severity Index; sPGA=static Physician's Global Assessment.

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POS1043 NETAKIMAB REDUCES PSORIATIC ARTHRITIS ACTIVITY IN PATIENTS WITH OR WITHOUT AXIAL DISEASE: SUBANALYSIS OF THE PATERA STUDY

I. Korotkova¹, I. Gaydukova², V. Mazurov², A. Samtsov³, V. Khayrutdinov³, A. Bakulev⁴, A. Kundzer⁵, N. Soroka⁶, A. Ereemeeva⁷. ¹Nasonova Research Institute of Rheumatology, Laboratory of Spondyloarthritides and Psoriatic Arthritis, Moscow, Russian Federation; ²Mechnikov North-Western State Medical University, Department of Therapy and Rheumatology of Temporary Disability and Medical Care Quality Expertise, St-Petersburg, Russian Federation; ³Kirov Military Medical Academy, Department of Skin and Venereal Diseases, St-Petersburg, Russian Federation; ⁴Razumovsky Saratov State Medical University, Department of Dermatovenereology and Cosmetology, Saratov, Russian Federation; ⁵Belarusian Medical Academy of Postgraduate Education, Department of Cardiology and Rheumatology, Minsk, Belarus; ⁶Belarusian State Medical University, Department of Internal Diseases