

References:

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FRI0489 CERTOLIZUMAB PEGOL IS ASSOCIATED WITH LONG-TERM IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES IN PSORIATIC ARTHRITIS: 4-YEAR OUTCOMES FROM THE RAPID-PSA STUDY

D. Gladman¹, R. Fleischmann², K. Harris³, L. Peterson⁴, P.J. Mease⁵.
¹University of Toronto and Krembil Research Institute, Toronto Western Hospital, Toronto, Canada; ²UT Southwestern Medical Center and Dallas Metroplex Clinical Research Center, Dallas, United States; ³UCB Pharma, Brussels, Belgium; ⁴UCB Pharma, Raleigh; ⁵Swedish Medical Center and University of Washington, Seattle, United States

Background: Psoriatic arthritis (PsA) is a heterogeneous inflammatory disease that has a substantial impact on patients' (pts) physical and emotional wellbeing.¹ Certolizumab pegol (CZP) is an Fc-free, PEGylated anti-TNF that has been shown to improve patient-reported outcomes (PROs) in pts with PsA over 96 weeks (wks) of treatment in the RAPID-PsA study (NCT01087788).²

Objectives: To investigate whether initial improvements in PROs observed with CZP treatment were maintained over 4 years in the RAPID-PsA study.

Methods: RAPID-PsA was double-blind and placebo-controlled to Wk24, dose-blind to Wk48, and open-label to Wk216. Pts were aged ≥18 years, with a diagnosis of active PsA, and had failed treatment with ≥1 DMARD. Pts originally randomized to CZP (400mg at Wks0,2,4 [loading dose] followed by either 200mg every 2 wks [Q2W] or 400mg every 4 wks [Q4W]) continued on their assigned dose during the open-label period. PROs assessed included Patient's Global Assessment of Arthritis Pain (PtAAP; visual analog scale), fatigue (numeric rating scale), Health Assessment Questionnaire-Disability Index (HAQ-DI), Short Form-36 Physical and Mental Component Summary (SF-36 PCS/MCS), Psoriatic Arthritis Quality of Life (PsAQoL), and Dermatology Life Quality Index (DLQI; assessed in the subgroup of pts with ≥3% body surface area affected by psoriasis at baseline [BL]). Data are reported as the mean change from BL (CFB) for pts randomized to CZP at Wk0, with last observation carried forward (LOCF) imputation for Wk24, and LOCF imputation and observed case (OC) values for Wk216.

Results: Of 273 pts randomized to CZP at Wk0, 248 (91%) completed Wk24 and 183 (67%) completed Wk216. Improvements observed to Wk24 of treatment were generally maintained over 4 years (to Wk216) in all PROs assessed, regardless of prior anti-TNF exposure (Table). Similar improvements were observed in both CZP dose regimens for all PROs examined, including PtAAP (CFB at Wk216 in the 200mg Q2W group [with LOCF imputation]: -30.5, in the 400mg Q4W group: -33.8); fatigue (-2.3, -2.3); HAQ-DI (-0.50, -0.49); SF-36 PCS (8.73, 8.77); SF-36 MCS (3.91, 3.28); PsAQoL (-4.6, -4.4); and DLQI (-8.4, -6.8).

Conclusions: Early improvements with CZP treatment were maintained over 4 years in all PROs assessed in the RAPID-PsA study. Similar improvements were observed in pts with and without prior anti-TNF exposure, and in both CZP dose regimens.

References:

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Table: Mean change from baseline in patient-reported outcomes at Weeks 24 and 216 in patients with or without prior anti-TNF exposure

Outcome	Patients with prior anti-TNF exposure CZP dose combined (n=54)			Patients without prior anti-TNF exposure CZP dose combined (n=219)			Overall CZP dose combined (N=273)		
	Wk24 (LOCF)	Wk216 (LOCF)	Wk216 (OC) (n=34)	Wk24 (LOCF)	Wk216 (LOCF)	Wk216 (OC) (n=161)	Wk24 (LOCF)	Wk216 (LOCF)	Wk216 (OC) (n=185)
Pain (PtAAP) [a]	-33.3	-34.6	-44.2	-27.3	-31.5	-35.9	-28.5	-32.1	-37.4
Fatigue [b]	-2.1	-2.0	-2.5	-2.0	-2.3	-2.8 [n=147]	-2.0	-2.3	-2.7 [n=181]
HAQ-DI [c]	-0.60	-0.59	-0.67	-0.45	-0.47	-0.54	-0.48	-0.50	-0.57
SF-36 PCS [d]	8.37	9.79	11.18 [n=33]	7.92	8.50	9.64 [n=148]	8.01	8.75	9.92 [n=181]
SF-36 MCS [e]	4.57	2.38	5.29 [n=33]	4.49	3.90	5.36 [n=148]	4.50	3.60	5.35 [n=181]
PsAQoL [f]	-4.1	-4.2	-5.1	-3.8	-4.6	-5.1 [n=150]	-3.9	-4.5	-5.1 [n=184]
DLQI [g]	-9.0 [n=36]	-8.1 [n=36]	-10.9 [n=20]	-7.2 [n=130]	-7.5 [n=130]	-7.9 [n=87]	-7.6 [n=166]	-7.6 [n=166]	-6.4 [n=180]

[a] Range: 0–100, where 0=no pain and 100=worst pain (Minimal Clinically Important Difference [MCID]: -10); [b] Range: 0–10, where 0=no fatigue and 10=worst fatigue (MCID: -1); [c] Range: 0–3, where 0=no disability and 3=very severe disability (MCID: -0.3); [d] Range: 1–81, where higher scores indicate better physical status (MCID: +2.5); [e] Range: -9–82, where higher scores indicate better mental status (MCID: +2.5); [f] Range: 0–20, where lower scores indicate better quality of life; [g] Range: 0–30, where lower scores indicate better quality of life (MCID: -5). LOCF: last observation carried forward; OC: observed case.

Sanofi-Aventis, Novartis, AstraZeneca, Janssen, K. Harris Employee of: UCB Pharma, L. Peterson Employee of: UCB Pharma, P. Mease Grant/research support from: (Abbott) AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Janssen, Lilly, Novartis, Pfizer, Sun, UCB Pharma, Consultant for: (Abbott) AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Crescendo, Corrona, Dermira, Janssen, Lilly, Merck, Novartis, Pfizer, Sun, UCB Pharma, Zynerba, Speakers bureau: (Abbott) AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Crescendo, Genentech, Janssen, Novartis, Pfizer, UCB Pharma

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FRI0490 REAL-LIFE EFFECTIVENESS OF TNF INHIBITORS IN PSORIATIC ARTHRITIS: ARE CHANGING NATIONAL POLICIES ON CHOICE OF TNF INHIBITOR REFLECTED IN RESPONSE TO TREATMENT?

E.K. Kristianslund¹, K.M. Fagerli¹, E. Lie¹, A. Wierød², S. Kalstad³, E. Rødevand⁴, F. Krøll⁵, P. Mielnik⁶, T.K. Kvien¹, I.C. Olsen¹. ¹Department of Rheumatology, Diakonhjemmet Hospital, Oslo; ²Department of Rheumatology, Drammen Hospital, Drammen; ³Department of Rheumatology, University Hospital of North Norway, Tromsø; ⁴Department of Rheumatology, St. Olavs Hospital, Trondheim; ⁵Revmatismesykehuset, Lillehammer; ⁶Department of Rheumatology, Førde Central Hospital, Førde, Norway

Background: Tumour necrosis factor inhibitors (TNFi) are essential in the treatment of psoriatic arthritis (PsA). Whether the effectiveness of the five different TNFi differs is not known, as they have not been directly compared. In Norway the national authorities consider the TNFi to be equivalent, and since 2009 the least expensive drug in an annual national tender has been preferred in the publicly funded healthcare system. This has led to substantial year-to-year differences in choice of first TNFi, the system has acted as an unbiased factor distributing patients between different agents across years.

Objectives: Comparing response to TNFi during the first year of treatment of PsA over years with highly varying uptake of different TNFi.

Methods: From the NOR-DMARD register we included the 715 biologics-naïve patients with PsA who started their first TNFi from 2009 through 2015. The preferred TNFi in national recommendations were: 2009 adalimumab, 2010 golimumab, 2011 and 2012 etanercept, 2013 golimumab, 2014 certolizumab, 2015 certolizumab/biosimilar infliximab (CT-P13). The estimated Disease Activity Score 28 joints (DAS28) at 3, 6 and 12 months after treatment start was compared between treatment years using a mixed-model, adjusted for baseline disease activity, age, sex and treatment centre.

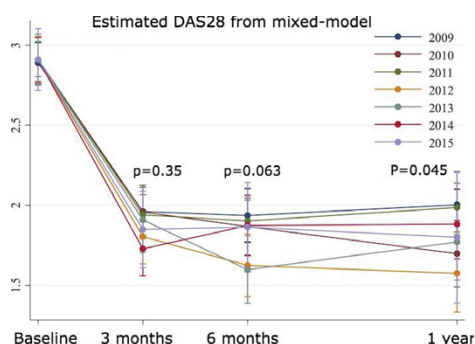
Results: Demographics, choice of TNFi and baseline characteristics are listed for each year 2009–2015 in Table 1. The preferred drug was started in 56–91% of patients. There was a trend towards lower disease activity at baseline over time. There were no significant differences in DAS28 at 3 and 6 months between treatment years, but a difference was found at 1 year (figure).

Conclusions: The results from this innovative analytic approach indicate similar effectiveness of different TNFi in PsA, and consequently supports the practice of selecting agent based on cost and feasibility of use. However, there are potential differences after 1 year. The interpretation of this is challenging, especially as there is a marked difference in outcomes between the years 2011 and 2012, where the distribution of type of TNFi was similar.

Abstract FRI0490 – Table 1

	2009	2010	2011	2012	2013	2014	2015	p-value
N	104	90	162	99	90	108	62	
Age (years), mean (SD)	42.3 (11.2)	40.5 (11.8)	42.5 (12.6)	40.3 (11.1)	42.1 (12.8)	42.9 (11.6)	42.8 (12.4)	0.59
Proportion female	33.0%	36.0%	47.8%	38.4%	40.0%	37.0%	38.7%	0.29
Years since diagnosis, median (IQR)	4.5 (0.8, 14.5)	4.6 (0.7, 15.4)	5.4 (0.7, 16.0)	3.3 (0.6, 13.6)	1.3 (0.4, 8.5)	1.9 (0.2, 7.0)	2.5 (0.2, 10.8)	0.088
Disease Activity Score 28 joints, mean (SD)	3.04 (1.18)	3.09 (1.06)	2.97 (1.04)	2.76 (1.06)	2.78 (0.91)	2.79 (0.94)	2.60 (0.81)	0.051
Clinical Disease Activity Index, mean (SD)	11.02 (5.54)	11.43 (6.92)	10.20 (4.87)	10.08 (4.99)	9.41 (2.83)	10.42 (5.41)	9.08 (4.28)	0.15
Simplified Disease Activity Index, mean (SD)	12.52 (6.11)	12.90 (7.21)	11.34 (5.45)	10.43 (5.27)	10.45 (3.14)	11.41 (5.97)	9.63 (4.49)	0.015
Adalimumab	91.3%	33.3%	22.2%	15.2%	18.9%	13.0%	0.0%	<0.001
Certolizumab	0.0%	2.2%	0.0%	0.0%	11.1%	74.1%	43.5%	
Etanercept	7.7%	7.8%	61.7%	67.7%	5.6%	2.8%	3.2%	
Golimumab	0.0%	55.6%	12.3%	12.1%	63.3%	3.7%	4.8%	
Infliximab	1.0%	1.1%	3.7%	5.1%	1.1%	0.0%	0.0%	
Infliximab biosimilar	0.0%	0.0%	0.0%	0.0%	0.0%	6.5%	48.4%	

p-values for between-year differences.



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FRI0491 EFFECT OF THE TIGHT CONTROL TREAT-TO-TARGET STRATEGY ON THE DYNAMICS OF ACTIVE MRI SACROILIITIS IN THE RUSSIAN COHORT OF EARLY PERIPHERAL PSORIATIC ARTHRITIS PATIENTS (PRELIMINARY RESULTS OF AN ONGOING OPEN-LABEL REMARCA STUDY)

E.E. Gubar, E.Y. Loginova, T.V. Korotaeva, D.E. Karateev, V. A. Nasonova
Research Institute of Rheumatology, Moscow, Russian Federation

Background: Axial involvement in early psoriatic arthritis (ePsA) patients (pts) is often poorly diagnosed. Magnetic resonance imaging (MRI) of sacroiliac joints (SIJs) helps to better define spinal involvement and is used as an outcome measure to evaluate treatment of axial disease with TNF blockers. Treat-to-target (T2T) strategy was studied in various manifestations of PsA except axial involvement.

Objectives: to assess the effect of tight control T2T strategy on the 12-months dynamics of active MRI sacroiliitis (MRI-SI) in peripheral ePsA pts.

Methods: 89 treatment-naïve pts (M/F=42 /47) with active peripheral ePsA, according to CASPAR criteria were included; mean age 36.5±10.9 yrs., disease duration 12.1±10.1 mo., disease activity index (DAS) 5.2±2.8, C-RP 16.1 [6.6; 31.0] mg/l, ESR 22.5±19.2 mm/h. At baseline and every 3 mo. of therapy all pts underwent standard clinical examination of PsA activity. All patients were evaluated for the presence of inflammatory back pain (IBP) by ASAS criteria. In pts having IBP, disease activity was also measured by BASDAI. At baseline MRI of SIJs was performed in 79 pts, both with and without IBP, on Signa Ovation 0.35T. Bone marrow edema (BME) on MRI (STIR), considered as active MRI sacroiliitis (MRI-SI), was evaluated by an independent reader. MRI of SIJs was repeated after 12 mo. in 20 pts who had completed a year of therapy having MRI-SI at baseline. Positive dynamics was indicated by the disappearance of BME on MRI (STIR). The main goal of T2T strategy was to reach remission or low/minimal disease activity (LDA/MDA). LDA was considered at DAS<1.6 or DAS28<2.6, remission was considered at DAS<1.6 or DAS28<2.6. At baseline all pts were treated with methotrexate (MTX) subcutaneous (s/c). The dose of MTX was escalated by 5 mg eow from 10 mg/wk to 20–25mg/wk. If the patient

did not achieve LDA/MDA or remission after 3 mo. of MTX mono-therapy (MoT), combination therapy (CoT) with MTX+ adalimumab (ADA) 40 mg (s/c) eow was started. All pts were treated with NSAIDs: nimesulide 100–200mg or etorikoxib 60–90 mg per day.

Results: IBP was found in 58 out of 89 pts (65.1%). Disease activity by BASDAI in pts with IBP was 4.5±1.6. At baseline MRI-SI was observed in 28 out of 79 (35.4%) pts. Among the group of 20 pts who had completed a year of therapy having MRI-SI at baseline, 16 (80%) pts after 12 mo. of therapy demonstrated positive dynamics. Among these 16 pts, 8 (50%) pts underwent MoT and 8 (50%) pts underwent CoT. In the CoT-group pts received ADA for 6–9 mo. After 12 mo. of therapy, BME of SIJs on MRI still remained in 4 out of 20 (20%) pts. Among these 4 pts 2 pts underwent MoT and 2 pts underwent CoT (both pts received ADA for 3 mo., 9 th-12th mo. of therapy).

Conclusions: tight control T2T strategy in the Russian cohort of peripheral ePsA pts, demonstrated positive dynamics of active MRI-SI in 80% of pts after 12 months of therapy irrespective of the treatment used. These preliminary results demonstrate that tight control T2T strategy is effective not only in peripheral arthritis but also in axial involvement in ePsA. To confirm its effectiveness the strategy still needs to be verified on larger cohorts of pts.

Disclosure of Interest: None declared

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FRI0492 OBESITY IS HIGHLY OVERREPRESENTED AMONG SWEDISH PATIENTS WITH PSORIATIC ARTHRITIS COMPARED WITH THE GENERAL POPULATION

E. Klingberg¹, A. Bilberg¹, B. Eliasson², I. Larsson³. ¹Department of Rheumatology and Inflammation Research, Sahlgrenska Academy at University of Gothenburg; ²Department of Medicine; ³Department of Gastroenterology and Hepatology, Sahlgrenska University Hospital, Göteborg, Sweden

Background: Patients with psoriatic arthritis (PsA) are at increased risk of developing cardiovascular disease.

Objectives: To determine the prevalence of cardiovascular risk factors among patients with PsA followed at a Swedish Rheumatology Clinic in comparison with the general population (GP).

Methods: A questionnaire including weight, height, smoking habits, hypertension, diabetes and hyperlipidemia was sent to all PsA patients registered at the Rheumatology Clinic at Sahlgrenska University Hospital, Gothenburg (N=982). Obesity was defined as body mass index (BMI) ≥30 kg/m² and overweight as BMI 25–29.9 kg/m². Comparison with the Swedish GP was made using data from the National public health survey, "Health on equal terms", which is sent yearly to 20 000 citizens by the Public Health Agency of Sweden.

Results: 686 (70%) of the PsA patients with mean age 56±11 yrs (mean: SD), 52% women, responded. Higher prevalence of self-reported obesity and several cardiovascular risk factors was found in the PsA patients compared with the GP: Obesity 28.7% [GP 15% (95% C.I. 14.5–15.9%)], current smoking 10.5% [GP 9% (8.2–9.3%)], former smoking 43.4% [GP 23% (22.3–24.0%)], never smoking 48.8% [GP 63% (61.9–63.9%)], treatment of hypertension 32.9% [GP 20% (19.6–21.2%)] and diabetes 8.3% [GP 6% (5.4–6.3%)] Treatment of hyperlipidemia was reported by 15.0% [GP no data] and overweight by 36.2% [GP 36% (34.5–36.5%)]. Data stratified by age and sex is shown in the table. (Numbers are % and 95% C.I.)

Conclusions: Obesity was highly overrepresented among the PsA patients. It is imperative to take action against weight gain in overweight patients and promote weight loss in obese patients with PsA, since obesity may be involved in the pathogenesis of the disease and may fuel disease activity.

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Abstract FRI0492 – Table 1

Sex Age	Obesity		Current smoking		Former smoking		Hypertension		Diabetes	
	PsA	GP	PsA	GP	PsA	GP	PsA	GP	PsA	GP
♀ 30–44 (N=58)	27.6	14 (11.5–15.8)	13.8	8 (6.5–9.8)	34.5	19 (16.1–20.9)	3.4	4 (2.9–5.4)	3.4	2 (1.0–2.6)
♀ 45–64 (N=189)	33.9	18 (16.3–19.9)	14.3	13 (11.3–14.4)	49.2	31 (28.7–32.9)	33.9	20 (18.5–22.2)	5.8	5 (4.0–6.0)
♂ 30–44 (N=55)	25.5	12 (9.8–14.4)	7.3	5 (3.9–7.1)	21.8	14 (11.3–16.1)	9.1	7 (4.9–8.4)	1.8	2 (1.0–2.9)
♂ 45–64 (N=202)	26.7	20 (18.3–22.3)	7.4	9 (7.6–10.5)	34.7	25 (23.3–27.7)	31.2	28 (25.9–30.5)	6.4	7 (6.2–8.8)