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PATIENT- AND PHYSICIAN-REPORTED OUTCOMES FROM RAJ4: A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE EFFICACY AND SAFETY OF PEFICITINIB (ASP015K) IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA) WHO HAD AN INADEQUATE RESPONSE TO METHOTREXATE (MTX)

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Background: The novel oral Janus kinase inhibitor, peficitinib, demonstrated efficacy and tolerability as once-daily combination therapy with MTX for moderate-to-severe RA in the RAJ4 phase 3 study (NCT02305849).¹ For the first time, we focussed on patient and physician outcome measures in this Japanese study.

Objectives: To assess health-related quality of life (HRQoL) of Japanese patients with RA who had an inadequate response to MTX.

Methods: This multicentre, randomised, double-blind, parallel-group, placebo-controlled, phase 3 study recruited patients in Japan with active RA and inadequate response to MTX.¹ Patients were randomised 1:1:1 to 52-week placebo+MTX (PBO), peficitinib 100 mg QD+MTX (PEFI 100 mg) or peficitinib 150 mg QD+MTX (PEFI 150 mg). The PBO group was switched to PEFI 100 mg or 150 mg at Week 12 (for non-responders) or Week 28 (for remaining patients). Patient- and physician-reported outcome assessments included: Physician's Global Assessment of disease activity (PGA); Subject's Global Assessment of disease activity (SGA); and Subject's Global Assessment of pain (SGAP) by visual analogue scale. Physical function was evaluated using Health Assessment Questionnaire-Disability Index (HAQ-DI). All assessments were conducted at each visit from baseline to the end of study.

Results: 519 patients were treated: PBO (n=170), PEFI 100 mg (n=175) and PEFI 150 mg (n=174). One PEFI 100 mg patient was excluded from the analysis due to protocol deviation. At Weeks 12/early termination (ET) and 28/ET, both PEFI groups were associated with significant improvements in PGA, SGA, SGAP and HAQ-DI (**Table 1**). These outcomes were maintained or improved at end of treatment (EOT; Week 52/ET), when mean change from baseline for PGA, SGA, SGAP and HAQ-DI in the PEFI 100 mg and PEFI 150 mg groups were: -38.41, -43.33; -29.34, -34.05; -28.94, -32.68; and -0.36, -0.51, respectively. Significantly greater proportions of patients achieved functional remission and a minimum clinically important (MCI) reduction in HAQ-DI score (≤ 0.5 and reduction of ≥ 0.22 , respectively) at Weeks 12/ET and 28/ET in both PEFI groups than in the PBO group ($p < 0.001$ vs PBO for both PEFI doses; **Table 1**). In the PEFI 100 mg and PEFI 150 mg groups at EOT, functional remission occurred in 105/172 (61.0%) and 106/171 (62.0%) patients and MCI reduction in HAQ-DI score occurred in 99/172 (57.6%) and 120/171 (70.2%) patients, respectively.

Table 1 Physician- and patient-reported outcome results at Week 12/ET and Week 28/ET

Outcome type	Result	Week 12/ET			Week 28/ET		
		PBO (n=168) ¹	PEFI 100 mg QD (n=172) ¹	PEFI 150 mg QD (n=171) ¹	PBO (n=168) ¹	PEFI 100 mg QD (n=172) ¹	PEFI 150 mg QD (n=171) ¹
Physician-reported	Mean (SD) change from baseline in PGA	-11.88 (21.46)	-28.83 (22.21)	-35.96 (25.00)	-12.55 (22.63)	-36.80 (23.57)	-40.61 (22.41)
	LS mean (SE) treatment difference vs PBO ²	-	-17.67 (2.26)***	-24.09 (2.33)***	-	-25.11 (2.36)***	-28.07 (2.24)***
	Mean (SD) change from baseline in SGA	-7.11 (23.05)	-21.09 (23.63)	-26.57 (25.43)	-8.08 (25.99)	-27.70 (26.15)	-32.62 (26.60)
	LS mean (SE) treatment difference vs PBO ²	-	-16.64 (2.26)***	-20.34 (2.40)***	-	-22.81 (2.47)***	-25.55 (2.57)***
Patient-reported	Mean (SD) change from baseline in SGAP	-6.64 (25.22)	-21.09 (27.04)	-26.87 (26.65)	-7.61 (27.81)	-26.33 (28.22)	-32.23 (27.59)
	LS mean (SE) treatment difference vs PBO ²	-	-17.19 (2.44)***	-20.89 (2.50)***	-	-21.73 (2.59)***	-25.35 (2.63)***
	Mean (SD) change from baseline in HAQ-DI	0.01 (0.47)	-0.22 (0.44)	-0.37 (0.48)	0.00 (0.60)	-0.33 (0.51)	-0.47 (0.54)
	LS mean (SE) treatment difference vs PBO ²	-	-0.27 (0.05)***	-0.39 (0.05)***	-	-0.38 (0.06)***	-0.48 (0.06)***
	Patients achieving HAQ-DI ≤ 0.5 , n (%)	48 (28.4)	87 (50.6)***	85 (49.7)***	51 (30.2)	103 (59.9)***	100 (58.5)***
	Patients achieving HAQ-DI ≥ 0.22 reduction, n (%)	53 (31.5)	85 (49.4)***	105 (61.4)***	57 (33.9)	95 (55.2)***	114 (66.7)***

¹Higher VAS score indicates greater disease activity.

²Analysis of covariance models were used. ³Number of patients in PBO group assessed for HAQ-DI ≤ 0.5 reduction from baseline was 168; 290A (100 mm VAS) change + treatment + baseline PGA (100 mm VAS); 350A (100 mm VAS) change + treatment + baseline SGA (100 mm VAS); 450A (100 mm VAS) change + treatment + baseline SGAP (100 mm VAS); 550A (100 mm VAS); 650A (100 mm VAS); 750A (100 mm VAS); 850A (100 mm VAS); 950A (100 mm VAS); 1050A (100 mm VAS); 1150A (100 mm VAS); 1250A (100 mm VAS); 1350A (100 mm VAS); 1450A (100 mm VAS); 1550A (100 mm VAS); 1650A (100 mm VAS); 1750A (100 mm VAS); 1850A (100 mm VAS); 1950A (100 mm VAS); 2050A (100 mm VAS); 2150A (100 mm VAS); 2250A (100 mm VAS); 2350A (100 mm VAS); 2450A (100 mm VAS); 2550A (100 mm VAS); 2650A (100 mm VAS); 2750A (100 mm VAS); 2850A (100 mm VAS); 2950A (100 mm VAS); 3050A (100 mm VAS); 3150A (100 mm VAS); 3250A (100 mm VAS); 3350A (100 mm VAS); 3450A (100 mm VAS); 3550A (100 mm VAS); 3650A (100 mm VAS); 3750A (100 mm VAS); 3850A (100 mm VAS); 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Methods: Adult (≥ 18 yo) patients with symptomatic, refractory inflammatory mono- or oligoarthritis were included for RSO with Yttrium-90 citrate as part of a phase-III, prospective, open-label non-controlled trial. All patients were required to have failed 6-months of medical therapy and 2 intra-articular injections and have minimal evidence of cartilage or bone destruction. Only large and medium-sized joints were included (i.e. knees, ankles, wrists and elbows). The dose of Yttrium was adjusted based on the size of joint. Follow-up evaluations were done at 3, 6 and 12 months after RSO. Safety was assessed by patient and clinician reported adverse events. Clinical response was measured by improvement in joint tenderness, effusion and range of motion.

Results: A total of 74 patients and 83 joints (88% knees) were treated with Yttrium-90 citrate. The underlying diagnosis included 25.7% RA, 34% SpA, 11% JIA, and 30.3% other inflammatory arthritis. Complications included 3 post-RSO flares, 1 septic joint and 2 injection site skin infections. Joint tenderness was reported in 93.8% of joints at baseline, compared to 50.0% at 3mo ($p<0.001$), 55.6% at 6mo ($p<0.001$) and 40.4% at 12mo ($p<0.001$). Joint effusion was present in 95.1% of joints at baseline, 44.3% at 3mo ($p<0.001$), 51.4% at 6mo ($p<0.001$) and 47.4% at 12mo ($p<0.001$). 73.9% of joints had improvement in range of motion at 3mo, 55.9% at 6mo and 60.7% at 12mo.

Conclusion: These results confirm the clinical efficacy and safety of Yttrium90-citrate RSO for refractory synovitis with a sustained clinical benefit at 12 months. This is the first such study in a Canadian cohort. RSO with Yttrium is a safe alternative to surgical synovectomy in refractory cases.

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in both groups were significantly improved 1 month after treatment. This tendency continued for 3 months after treatment. There were no significant differences in the improvement rate of SJC, TJC, CDAI scores, VAS pain, and PGA between the two groups at each follow-up time point after treatment. VAS pain scores were significantly correlated with SJC and CDAI scores in both groups (B group; $r = 0.651$, $p < 0.01$ and TNFi group; $r = 0.688$, $p < 0.01$). PGA scores were significantly correlated with SJC and CDAI scores in both groups (B group; $r = 0.657$, $p < 0.01$ and TNFi group; $r = 0.613$, $p < 0.01$).

Table 1. Patient's background

	Bari group	TNFi group
Age (year)	60.2 ± 10.4	60.6 ± 10.1
Disease duration (year)	4.0 ± 5.1	4.2 ± 5.1
Male/female	8/16	7/16
MTX dose (mg/week)	7.0 ± 0.8	7.0 ± 0.8
PLA dose (mg/day)	3.0 ± 0.6	3.0 ± 0.6
CRP at baseline (mg/dL)	66.7 ± 7.0	70.4 ± 7.0
ESR at baseline (mm/h)	105.7 ± 7.1	105.7 ± 7.1

Table 2. Changes of clinical assessment

	Baseline	1 month	3 months
SJC	6.67 ± 3.81	3.90 ± 2.02*	3.90 ± 2.02*
TJC	7.93 ± 3.69	2.77 ± 1.40*	2.77 ± 1.40*
CDAI	26.35 ± 8.77	8.00 ± 3.94*	8.00 ± 3.94*
VAS pain (mm)	62.2 ± 18.4	26.7 ± 12.4*	26.7 ± 12.4*
PGA (mm)	62.2 ± 18.4	26.7 ± 12.4*	26.7 ± 12.4*

*p < 0.05 vs baseline

	Baseline	1 month	3 months
SJC	6.13 ± 3.21	2.80 ± 1.30*	2.80 ± 1.30*
TJC	7.27 ± 3.56	2.07 ± 1.00*	2.07 ± 1.00*
CDAI	24.65 ± 9.72	9.00 ± 4.00*	9.00 ± 4.00*
VAS pain (mm)	64.2 ± 18.4	26.7 ± 12.4*	26.7 ± 12.4*
PGA (mm)	64.2 ± 18.4	26.7 ± 12.4*	26.7 ± 12.4*

*p < 0.05 vs baseline

Conclusion: Our results indicate that the effect of bari on pain and PGA is correlated with the improvement rate in disease activity. Bari treatment is not significantly different than TNFi, at least during the short term, in real world clinical data.

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[1] Perricone C, et al. Rheumatology (Oxford) 2012;51:866-73

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FRI0167

DOES BARICITINIB HAVE A SPECIFIC EFFECT PATIENT'S REPORTED OUTCOME? COMPARISON OF EFFECTS ON PAIN AND PATIENT GLOBAL ASSESSMENT WITH TNF INHIBITORS

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Background: Baricitinib (bari) is approved for treating moderate-severe rheumatoid arthritis (RA) in many countries, including Japan. Bari is an oral Janus kinase (JAK1)/JAK2 selective inhibitor and has shown good efficacy in RA and an adequate response to conventional synthetic DMARDs in some clinical trials. Pain and patient global assessment (PGA) are common symptoms for patients with RA. Some trials suggest that bari may have a supplementary benefit on patients' reported outcomes (PRO). Our goal was to determine the impact of each treatment on pain and PGA.

Objectives: We evaluated and compared the impact of bari and TNF inhibitors (TNFi) on pain and PGA and correlation with PRO and clinical assessments for Japanese RA patients who have an inadequate response to csDMARDs in real world multicenter clinical data.

Methods: We included 60 Japanese RA patients with an inadequate response to csDMARDs. We classified patients into two groups, one treated with bari (B group; 24 females and 8 males) and the other with TNFi (TNFi group; 22 females and 6 males). Patients were scheduled to receive TNFi (GLM 50 mg/month or ETN 50 mg/week) in TNFi group or bari 4 or 2 mg/day in B group as a monotherapy or in combination with csDMARDs. We evaluated swollen joint counts on 28 joints (SJC), tender joint counts on 28 joints (TJC), visual analog scale of pain (VAS pain) (0–100 mm), PGA (0–100 mm), and Clinical Disease Activity Index (CDAI) at baseline, 4 weeks, and 12 weeks. First, we compared the changes in SJC, TJC, CDAI, VAS pain, and PGA at 4 and 12 weeks after treatments between the two groups. Second, we evaluated the correlation between PROs (VAS pain or PGA) and variations in clinical evaluation items (SJC, TJC, and CDAI).

Results: There were no significant differences in background at baseline between the two groups (Table 1). Baseline SJC, TJC, and CDAI scores; VAS pain; and PGA were 6.67 ± 3.81 , 7.93 ± 3.69 , 26.35 ± 8.77 , 61.2 ± 21.8 , and 62.2 ± 18.4 in the bari group, respectively, and 6.13 ± 3.21 , 7.27 ± 3.56 , 24.65 ± 9.72 , 63.9 ± 22.7 , and 64.2 ± 18.4 in the TNFi group, respectively. SJC, TJC, CDAI scores, VAS pain, and PGA

FRI0168

POSITIVE EFFECTS OF AN ANTI-INFLAMMATORY DIET IN RHEUMATOID ARTHRITIS

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Background: Many patients with rheumatoid arthritis (RA) experience symptom relief of certain foods and earlier research has shown positive effects of food and food components on clinical outcomes of RA. Food components may potentiate each other in their effects on RA, but even so, studies combining foods and food components with probable effects on RA are scarce. Furthermore, comorbidities are common in RA and the risk of cardiovascular disease is elevated in this group. Assumed mechanisms include classical risk factors such as systemic inflammation, dyslipidemia as well as an unfavorable body composition.

Objectives: We investigated if a diet combining foods with anti-inflammatory effects, i.e. an anti-inflammatory portfolio diet, could reduce RA disease activity, markers of inflammation, body composition and blood lipid levels compared to a control diet.

Methods: In this controlled cross-over trial, 50 patients with RA were randomized to start with either intervention or control diet for ten weeks followed by a wash-out period of four months. The intervention diet was an anti-inflammatory portfolio diet containing foods rich in omega-3 fatty acids, fibers and probiotics. The control diet was a typical Swedish diet. Food equivalent to 50% of daily energy needs was delivered home weekly. For the remaining intake, participants were instructed to consume similar foods as the study diet regimen. Primary outcome measure was change in DAS28, using ESR. Secondary outcomes included changes in blood lipid levels, ESR and CRP as well as body composition.

Results: No significant difference in DAS28 between the groups was seen using Mixed Models analyze ($p=0.116$). However, DAS28 was significantly lower after the intervention diet compared to after control diet ($p=0.04$) and a significant reduction over time was seen in the intervention group ($p=0.012$) using Wilcoxon signed rank test. HDL-cholesterol was increased and TG were lowered after intervention compared to control, analyzed using Mixed Models ($p=0.046$ and $p=0.006$ respectively). In addition, there was a non-significant trend towards lowered LDL-cholesterol ($p=0.077$). Comparing after intervention to after control, there were non-significant lower weight, BMI and fat mass after the intervention ($p=0.077$, $p=0.075$ and $p=0.058$ respectively). None of the other outcomes changed significantly between groups.