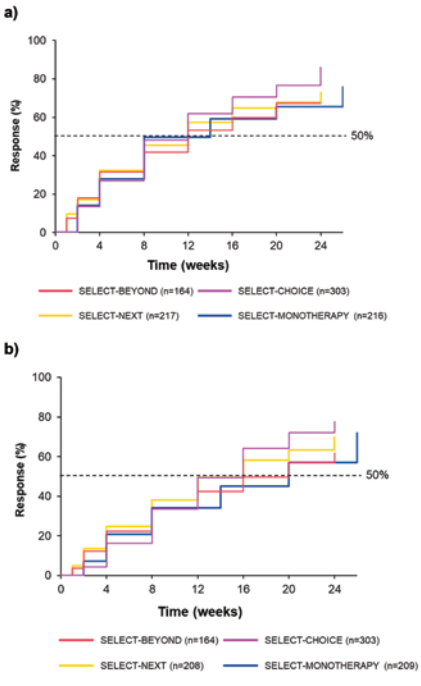
MONOTHERAPY (UPA 15 mg in methotrexate-IR patients). Time to response was estimated using Kaplan–Meier method for clinical outcomes over 24/26 weeks. Clinical outcomes included achievement of 28-joint Disease Activity Score with C-reactive protein (DAS28[CRP]) ≤ 3.2; low disease activity (LDA) defined as Clinical Disease Activity Index (CDAI) ≤ 10 and Simple Disease Activity Index (SDAI) ≤ 11; and 50% improvement in American College of Rheumatology (ACR) core components and morning stiffness (MS) duration/severity. Data presented as observed.

Results: 905 patients were included (SELECT-BEYOND: n = 164; SELECT-CHOICE: n = 303; SELECT-NEXT: n = 221; SELECT-MONOTHERAPY: n = 217). csDMARD-IR patients had mean disease duration of 7.3 (SELECT-NEXT) or 7.5 years (SELECT-MONOTHERAPY); bDMARD-IR patients had mean disease duration of 12.4 years, with a more refractory population (≥ 3 prior bDMARDs) in SELECT-BEYOND (23%) than SELECT-CHOICE (10%). The median time to DAS28(CRP) ≤ 3.2, CDAI LDA, 50% improvement in ACR core components, and 50% improvement in MS duration/severity were consistent across studies. For SELECT-BEYOND, SELECT-CHOICE, SELECT-NEXT, and SELECT-MONOTHERAPY, median (95% CI) time to achieve DAS28(CRP) ≤ 3.2 was 12 (12-16), 12 (8-12), 12 (8-12), and 14 (8-14) weeks(Figure 1a), and median time to achieve CDAI LDA was 20 (12-24), 16 (12-16), 16 (12-16), and 20 (14-20) weeks, respectively (Figure 1b). A longer median (95% CI) time to achieve SDAI LDA was observed with UPA monotherapy (20 [14-20] weeks) versus UPA + csDMARDs (12 [12-16] weeks) in csDMARD-IR patients. Among bDMARD-IR patients, median (95% CI) time to 50% improvement in pain was longer in SELECT-BEYOND versus SELECT-CHOICE (16 [12-20] versus 8 [8-12] weeks).

Conclusion: In diverse patient populations with RA, patients treated with UPA 15 mg, as monotherapy or with csDMARDs, demonstrated consistent time to achieving DAS28(CRP) ≤ 3.2, CDAI LDA, and 50% improvement in clinical outcomes.

Figure 1. Kaplan–Meier plot of a) time to first achievement of DAS28(CRP) ≤3.2 , and b) time to first achievement of CDAI ≤10 (LDA)



DAS28(CRP), 28-joint Disease Activity Score with C-reactive protein
CDAI, Clinical Disease Activity Index; LDA, low disease activity

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Characteristics and Outcomes of Rheumatoid Arthritis Patients Treated With Upadacitinib in Real-world Canadian Clinical Practice

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Objectives: Upadacitinib (UPA) is a selective Janus Kinase 1 receptor inhibitor, approved for the treatment of rheumatoid arthritis (RA) in Canada in January 2020. Our objective was to describe clinical usage and outcomes of Canadian RA patients receiving UPA.

Methods: The Adelphi RA Disease Specific Programme™ is a point-in-time survey conducted amongst rheumatologists. Physicians completed online record forms for RA patients who had received upadacitinib for at least 6 months. We report here the interim demographic and clinical outcomes data of an ongoing survey.

Results: Current data was provided by 8 rheumatologists for 47 patients (expected total: 20 rheumatologists, 200 patients). The mean age of these patients was 49.6 (SD 11.3), 74% were female and mean RA duration of 4.2 years (SD 3.8, n = 46). Mean Charlson Comorbidity Index was 1.2 (SD 0.7). Patients were receiving upadacitinib for an average of 10.5 months (SD 3.5). UPA was the first advanced therapy in 51% of patients and as a second or later line therapy after a JAKi (28%), a TNFi (21%), and/or other modes of action (9%) in the remaining patients. UPA was initiated predominantly in combination with background csDMARDs (74%) and after ≥ 6 months of UPA use, this combination decreased to 23%. 11% of patients received UPA in combination with a steroid, dropping to 2% after ≥ 6 months of UPA use. Disease activity measures were documented inconsistently. Physician-perceived disease severity improved in 62% of patients with ≥ 6 months of UPA use. At UPA initiation, mean tender joint count was 12.0 (SD 3.0, n = 34), mean swollen joint count was 9.0 (SD 4.0, n = 44) and mean CDAI score was 30.7 (SD 7.4, n = 21). After ≥ 6 months of UPA use, this had reduced to 1.8 (SD 2.1, n = 26), 0.6 (SD 1.1, n = 33) and 3.8 (SD 3.5, n = 18) respectively, with 44% (n = 8) of patients with reported CDAI scores (n = 18) in remission (0.0-2.8) and 44% (n = 8) with low disease activity (2.9-10.0) (Table 1).

Conclusion: Interim analysis of real-world data in Canadian RA patients demonstrates expected rates of improvement in disease activity after ≥ 6 months of treatment with UPA. In addition, ≥ 6 months of treatment with UPA led to a reduction in combination csDMARD and steroid therapy use. Full analysis is planned when data collection is complete. Rheumatologists may need better tools for documenting routine disease activity measures in the real world.

Physician-perceived disease severity change (based on mild/moderate/severe) (n=47)	Improved, n (%)	29 (62%)
	No change, n (%)	18 (38%)
28 Tender joint count	Mean at initiation (SD) (n=34)	12.0 (SD 3.0)
	Mean after ≥6 months of UPA use (SD) (n=26)	1.8 (SD 2.1)
28 Swollen joint count	Mean at initiation (SD) (n=44)	9.0 (SD 4.0)
	Mean after ≥6 months of UPA use (SD) (n=33)	0.6 (SD 1.1)
CDAI score at initiation (n=21)	Mean (SD)	30.7 (SD 7.4)
CDAI score after ≥6 months UPA (n=18)	Mean (SD)	3.8 (SD 3.5)
	Remission (0.0-2.8)/Low Disease Activity (2.9-10.0), n (%)	8 (44%)/ 8 (44%)
	Moderate Disease Activity (10.1-22.0), n (%)	2 (11%)

Table 1. Clinical outcomes of RA patients with ≥ 6 months of UPA use.

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Assessing the Relationship of Patient Global Assessment of Disease Activity and Health Related Quality of Life by SF-36 with Other Patient-Reported Outcomes in Rheumatoid Arthritis: Post Hoc Analyses of Data from Phase 3 Trials of Baricitinib

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Objectives: To examine the relative importance of patient reported outcomes (PROs) on the Patient Global Assessment of Disease Activity (PtGA) and health-related quality of life (HRQoL) and whether these differ in patients with good disease control vs. those not in low disease activity (LDA) or remission in different patient populations in baricitinib (bari) phase 3 studies.

Methods: We report post-hoc analyses of: RA-BEGIN (conventional synthetic DMARD-naive patients [n = 588]); RA-BEAM (MTX-inadequate response (IR) patients [n = 1307]); and RA-BEACON (biologic DMARD-IR patients (n = 527). PtGA was measured by a visual analog scale (VAS, 0-100 mm) and HRQoL was measured by SF-36 physical component summary (PCS) and mental component summary (MCS) scores. PROs included pain (VAS, 0-100 mm), Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), duration of morning joint stiffness (AMJtS), and Health Assessment Questionnaire-Disability Index (HAQ-DI). Good disease control was defined as either LDA or remission by Clinical Disease Activity Index (CDAI, ≤ 10 and ≤ 2.8, respectively). Within each RCT, treatment-agnostic correlation analyses at all time points from baseline to Week 24 were performed. Multiple regression analyses for the overall population and for patients in LDA, remission or nonresponse were conducted; we present standardized parameter estimates from the regression analyses for each PRO to assess their relative importance on the PtGA, PCS score and MCS score.

Results: Across RCTs, pain strongly correlated with PtGA (r: 0.9); FACIT-F moderately correlated with PtGA, PCS, and MCS scores (r: 0.6 to 0.7; FACIT-F and PtGA are negatively correlated); and HAQ-DI moderately-to-strongly correlated with PtGA and PCS score (r: 0.6 to 0.8; HAQ-DI and PCS are negatively correlated). Duration of AMJtS was weakly correlated with the other PROs (r: -0.2 to -0.3 for PCS and MCS and 0.3 to 0.4 for PtGA). In regression analyses across RCTs at baseline and Week 24 for the overall populations, the most significant factors were pain with PtGA, HAQ-DI with SF-36 PCS score, and FACIT-F with SF-36 MCS score. Similar results were observed in patients in LDA, remission, or nonresponse.

Conclusion: These results confirm prior findings, such as high correlations of pain with PtGA. We, however, observed that the relationships between other PROs with PtGA, PCS, or MCS scores were stable across time points over the first 6 months of treatment in differing patient populations, ranging from early to later disease. PtGA, PCS, and MCS scores were each associated with different PROs, indicating the importance of collecting multiple PROs in RCTs and real-world clinical practice.

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Rapid Clinical Response in Patients with Moderately to Severely Active Rheumatoid Arthritis Treated with Baricitinib

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Objectives: To investigate the speed of response to baricitinib (BARI) across disease measures in patients (pts) with rheumatoid arthritis who had an inadequate response (IR) to conventional synthetic DMARDs (csDMARDs) and biological DMARDs (bDMARD).

Methods: Data were assessed from two phase 3 studies, RA-BUILD (NCT01721057; csDMARD-IR pts) and RA-BEACON (NCT01721044; bDMARD-IR pts). Time to first achievement of each of the following responses over 24 weeks were evaluated: ACR 20% and 50% improvement (ACR20 and ACR50), DAS28-CRP low disease activity (DAS28-CRP LDA) ≤ 3.2, Clinical Disease Activity Index (CDAI) LDA ≤ 10, and 50% reduction in 68 Tender Joint Count (TJC68) or 66 swollen joint count (SJC66). Hazard ratios (HR) between BARI 2-mg and placebo (PBO) and the corresponding p-values were obtained using Cox proportional hazards model adjusted for treatment group and main stratification factors (RA-BUILD: region and baseline joint erosion status; RA-BEACON: region and history of bDMARD use). All analyses were based on observed data without imputation.

Table 1. Summary of hazard ratios and median time to achieve clinical responses from RA-BUILD and RA-BEACON

RA-BUILD (csDMARD-IR pts)	Treatment	Sample Size	Median (wk)	HR (95% CI) vs. Placebo, P-value
ACR20	Placebo	228	8.0	1.53 (1.25, 1.87), <0.001
	Baricitinib 2-mg	229	4.0	
ACR50	Placebo	228	NE	1.84 (1.41, 2.42), <0.001
	Baricitinib 2-mg	229	16.0	
DAS28-CRP LDA	Placebo	228	24.9	1.90 (1.46, 2.48), <0.001
	Baricitinib 2-mg	229	14.0	
CDAI LDA	Placebo	228	NE	1.54 (1.19, 1.99), <0.001
	Baricitinib 2-mg	229	14.9	
SJC66 50% Reduction	Placebo	228	4.0	1.27 (1.05, 1.53), 0.013
	Baricitinib 2-mg	229	2.3	
TJC68 50% Reduction	Placebo	228	8.0	1.29 (1.06, 1.57), 0.011
	Baricitinib 2-mg	229	4.0	
RA-BEACON (bDMARD-IR pts)	**Treatment**	**Sample Size**	**Median (wk)**	**HR (95% CI) vs. Placebo, P-value**
ACR20	Placebo	176	12.0	1.62 (1.25, 2.09), <0.001
	Baricitinib 2-mg	174	4.9	
ACR50	Placebo	176	NE	1.90 (1.33, 2.71), <0.001
	Baricitinib 2-mg	174	NE	
DAS28-CRP LDA	Placebo	176	NE	1.95 (1.35, 2.84), <0.001
	Baricitinib 2-mg	174	24.9	
CDAI LDA	Placebo	176	NE	1.66 (1.14, 2.39), 0.007
	Baricitinib 2-mg	174	NE	
SJC66 50% Reduction	Placebo	176	8.1	1.17 (0.93, 1.49), 0.183
	Baricitinib 2-mg	174	4.1	
TJC68 50% Reduction	Placebo	176	8.4	1.13 (0.89, 1.44), 0.313
	Baricitinib 2-mg	174	8.0	

RA-BUILD (csDMARD-IR pts), RA-BEACON (bDMARD-IR pts); Hazard ratio and p-value from Cox proportional hazards model; NE: not estimable as the response was not reached within 24 weeks. All subjects received csDMARDs as background therapy.

Results: In the csDMARD-IR population, BARI 2-mg treated pts were significantly more likely to achieve ACR20 (HR: 1.53, P < 0.001), ACR50 (HR: 1.84, P < 0.001), DAS28-CRP LDA (HR: 1.90, P < 0.001), CDAI LDA (HR: 1.54, P < 0.001), SJC66 50% reduction (HR: 1.27, P = 0.013) and TJC68 50% reduction (HR: 1.29, P = 0.011) compared with PBO (Table 1). Median time to first achievement of ACR20, DAS28-CRP LDA, SJC66 50% reduction and TJC68 50% reduction with BARI 2-mg was 4 weeks, 10.9 weeks, 1.7 weeks, and 4 weeks faster than PBO, respectively. Median time to first achievement of ACR50 with BARI 2-mg was 16 weeks and 14.9 weeks for CDAI LDA, whereas the median did not occur for PBO during the 24 weeks. In the bDMARD-IR population, BARI 2-mg-treated pts were significantly more likely to achieve ACR20 (HR: 1.62, P < 0.001), ACR50 (HR: 1.90, P < 0.001), DAS28-CRP LDA (HR: 1.95, P < 0.001), and CDAI LDA (HR: 1.66, P = 0.007) and had numerical quicker response in SJC66 50% reduction and TJC68 50% reduction compared with PBO (SJC66: HR: 1.17, P = 0.183; TJC68: HR: 1.13, P = 0.313). As for the median time to achieve clinical response, similar trends were observed between the csDMARD-IR and bDMARD-IR populations.

Conclusion: In csDMARD and bDMARD-IR patient populations, treatment with BARI was more likely to achieve quicker clinical response than PBO. Time to achieve clinically meaningful responses was faster in pts treated with BARI than those who received PBO.

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Rheumatoid Arthritis and Oral Health Associations in the Canadian Longitudinal Study of Aging

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Objectives: Periodontal disease (PD) is a frequent but neglected comorbidity of rheumatoid arthritis (RA) and may contribute to RA development or persistent disease activity. The Canadian Longitudinal Study of Aging (CLSA) collected data from community-residing older individuals including medical history, medication use, function assessments and oral health symptoms and habits. The aim of this study was to evaluate the association between RA and oral health using the CLSA data.

Methods: The CLSA baseline data from 300,097 individuals was analyzed. Individuals who self-reported an RA diagnosis and taking DMARDs were considered to have RA. Individuals who self-reported having at least one