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AB0261

A MULTINATIONAL, PROSPECTIVE, OBSERVATIONAL STUDY IN PATIENTS WITH RHEUMATOID ARTHRITIS RECEIVING BARICITINIB, TARGETED SYNTHETIC OR BIOLOGIC DISEASE-MODIFYING THERAPIES (RA-BE-REAL) – STUDY DESIGN AND BASELINE CHARACTERISTICS

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Background: Baricitinib (BARI) is a JAK1-2 inhibitor approved for the treatment of adults with moderately to severely active rheumatoid arthritis (RA). RA-BE-REAL is a 3-year, prospective, observational study of adult RA patients (pts) evaluating adherence to treatment in clinical practice.

Objectives: To describe pt and disease characteristics of pts enrolling into RA-BE-REAL in 5 European countries.

Methods: The primary endpoint of RA-BE-REAL is time until discontinuation of initial treatment for all causes (excluding sustained clinical response) over a 24-month (M) period. Secondary endpoints include clinical and pt reported outcomes, healthcare resource utilization and treatment patterns over a 36M period. Two pt cohorts are assessed: cohort A, started treatment with BARI (2-mg or 4-mg), and cohort B, any other targeted synthetic (ts)DMARDs or biologic (b)DMARD (Fig. 1). Treatment initiation and changes are at the discretion of the pt and physician. Data is collected at baseline and at routine visits (~3M, 6M, 12M, 18M, 24M and 36M). Summaries are presented with t-test and chi-square test of independence.

Results: Between October 2018 and March 2020, 1074 adult RA pts were enrolled from France, Germany, Italy, Spain, and UK. In cohort A, 88.2% of pts are treated with BARI 4-mg. At time of enrolment pts in cohort A are more likely to commence treatment as a monotherapy as compared to pts in cohort B who are more likely to commence treatment in combination with csDMARDs ($p<0.001$). Cohort A are more likely to be older (59.2 vs 57.0, mean years $p=0.009$) and have higher Health Assessment Questionnaire-Disability Index (HAQ-DI) scores (1.4 vs 1.3, $p=0.03$). A greater percentage of cohort A pts have received prior treatment with either 1 b/tsDMARD (15.3 vs 11.0%), 2 b/tsDMARD (20.2 vs 14.7%) or >2 b/tsDMARD (15.9 vs 12.9%), while cohort B are more likely to be treatment naïve (61.4 vs 48.5%). There are no significant differences in other baseline characteristics shown in Table 1.

Conclusion: There are few but potentially clinically important differences between cohorts. Pts in cohort A are more likely to be older, have a longer disease duration, have received prior b/tsDMARD treatment, and are more likely to receive treatment as a monotherapy as compared to pts in cohort B.

Figure 1. Study Design. Participants entered cohort A or B based on their treatment decision for BARI or another b/tsDMARD, pts in each cohort were with/without concomitant csDMARDs.

Table 1. Patient disposition and baseline characteristics.

	Cohort A Baricitinib (n=509)	Cohort B			Overall (n=1074)
		TNFi (n=338)	non-TNFi (n=161)	tsDMARD (n=66)	
Combination Therapy with any csDMARD	238 (46.8)	231 (40.9)	110 (19.5)	38 (6.7)	617 (57.4)
monotherapy	271 (53.2)	107 (18.9)	51 (9.0)	28 (5.0)	457 (42.6)
Values represent n (%)	Cohort A	Cohort B	p-value		Overall (n=1074)
	(n=509)	(n=565)			
Age in years	59.2 (13.2)	57.0 (13.9)	0.009		58.0 (13.6)
Disease duration in years	10.3 (9.2)	9.1 (9.8)	0.05		9.7 (9.5)
CDAI	24.1 (11.7)	23.9 (12.4)	0.75		24.0 (12.1)
Swollen joint count	5.2 (4.8)	4.7 (4.9)	0.18		4.9 (4.8)
Tender joint count	7.3 (6.1)	7.8 (6.5)	0.19		7.6 (6.3)
PhGA	5.6 (2.0)	5.5 (2.1)	0.39		5.6 (2.0)
PGA	5.9 (2.3)	5.8 (2.4)	0.49		5.9 (2.4)
Pain VAS	59.0 (23.1)	56.4 (24.3)	0.08		57.6 (23.8)
HAQ-DI	1.4 (0.7)	1.3 (0.7)	0.03		1.4 (0.7)
b/tsDMARDs treatment any time before enrolment; n (%)			<0.001*		
Naïve	247 (48.5)	347 (61.4)			594 (55.3)
1 b/tsDMARD	78 (15.3)	62 (11.0)			140 (13.0)
2 b/tsDMARDs	103 (20.2)	83 (14.7)			186 (17.3)
>2 b/tsDMARDs	81 (15.9)	73 (12.9)			154 (14.3)

Values represent mean (SD), unless otherwise stated. b/tsDMARD, biologic/targeted synthetic disease-modifying antirheumatic drug; CDAI, Clinical Disease Activity Index; HAQ-DI, Healthy Assessment Questionnaire-Disability Index; P(h)GA, Patient's (Physician's) global assessment of disease activity; VAS, Visual analogue scale. *chi-square test of independence for comparison of b/tsDMARD treatment received before enrolment.

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AB0262

CLINICAL EFFICACY OF SWITCHING FROM ORAL TO SUBCUTANEOUS METHOTREXATE IN MANAGEMENT OF RHEUMATOID ARTHRITIS: EXPERIENCE FROM OUT-PATIENT SETTING OF A DISTRICT GENERAL HOSPITAL IN UK

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Background: Methotrexate (MTX) is an anchor drug in the treatment of Rheumatoid arthritis. The literature review has shown that subcutaneous (SC) methotrexate has shown better efficacy, less adverse side effects and better compliance in inflammatory arthritis. Our department modified Inflammatory arthritis pathway in 2018 where all patient with moderate or severe disease are switched from oral to SC Methotrexate injection for improved management.

Objectives: The aim of our study is to review whether switching of oral methotrexate (PO MTX) to subcutaneous methotrexate (SC MTX) helps to improve disease activity in patients with rheumatoid arthritis and avoids the need to introduce biologic therapy.

Methods: We conducted a retrospective audit of patients with rheumatoid arthritis seen between January 2018 to January 2020 recording their age, gender, diagnosis, date of MTX switch and disease activity score 6 months after switching to SC MTX. Significance of change was calculated with test of proportion/chi square test.