therapy with conventional disease-modifying anti-rheumatic drugs (cDMARD). Data comparing cDMARD and TNFi in clinical trial settings are common, but there is limited published real-world evidence on their comparative effectiveness.

Objectives: Compare disease status and outcomes in UK patients with RA receiving cDMARD vs TNFi.

Methods: Data derive from Adelphi's RA Disease Specific Programme 2017, a cross-sectional survey of 49 UK rheumatologists providing information on demographics, disease history, disease status and treatment of patients with RA. All patients (n=640) were included in the RA treatment analysis; patients were included in the comparative analysis if at the time of survey they had been receiving current treatment for at least 3 months, with either cDMARD (and had never received biologic(b)DMARD), or a TNFi (and had never received prior bDMARD). A propensity score based on BMI, duration on current therapy, RA severity and disease duration at initiation of current therapy was used to match treatment groups. Using Abadie-Imbens standard errors, clinical characteristics and measures of disease activity were compared between the matched groups.

Results: Current therapy of 640 patients: 379 (59.2%) bDMARD, of which 253 (66.8%) were receiving TNFi; 212 (33%) cDMARD; 18 (2.8%) had never received any DMARD, 15 (2.3%) had discontinued bDMARD. Mean DAS28 at initiation of therapy was 4.94 in overall cDMARD and 5.77 in TNFi groups. Table 1 shows the comparative analysis of cDMARD vs TNFi matched treatment groups. The cDMARD group had a higher proportion of moderate/severe and active/very active disease at time of survey, a higher proportion of patients in this group had no improvement in disease severity or activity since initiation of current therapy, and they were less likely to have achieved a EULAR response. A higher proportion of cDMARD patients and physicians were not satisfied with their disease control. Mean DAS28 scores at time of survey had declined from time of initiation of therapy to time of survey in matched cDMARD vs TNFi groups, from 5.27 to 3.1 vs 5.77 to 2.7 respectively.

Table 1

	%	%	P=
Physician reported current disease status			
Moderate or severe	43.5	22.4	0.02
'Active' or 'very active' disease	58.8	44.1	0.10
Change in disease status since initiation of current treatment			
'No improvement' in severity	25.3	7.7	0.04
'No improvement' in disease activity ¹	22.0	7.7	0.08
Not achieved EULAR response (based on DAS28) ²	16.0	6.9	0.08
Satisfaction with current disease control			
Physicians 'not satisfied'	39.4	8.2	<0.01
Patients 'not satisfied' ³	31.7	16.7	0.35

Lower sample size due to missing values: ¹ cDMARD 147, TNFi 168; ² cDMARD 75, TNFi 131; ³ cDMARD 54, TNFi 60

Conclusions: UK patients with RA receiving cDMARD have poorer outcomes, in terms of measured disease status and control, than their matched counterparts receiving TNFi. Despite having a higher mean DAS score at initiation, patients in the TNFi group had a lower mean score at time of survey than patients receiving cDMARD. This real-world evidence highlights the continued utility of TNFi as effective treatments for patients with RA. Potential benefit of early TNFi initiation merits further research.

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RESULTS OF THE ALTERRA CLINICAL TRIAL – THE EFFICACY OF THE ALTERNATIVE DOSING REGIMEN FOR RITUXIMAB BIOSIMILAR IN bDMARDS NAIVE PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Rituximab (RTX) is successfully used in patients with active rheumatoid arthritis (RA) who previously received biological disease-modifying

antirheumatic drugs (bDMARDs) at a dose of 1000 mg. Previous preclinical and clinical studies showed that BCD-020 is highly similar to innovator RTX. ALTERRA study demonstrated that first-line use of 600 mg BCD-020 is very effective in bDMARDs naive patients with RA.

Objectives: The goal of ALTERRA study was to evaluate the efficacy and safety of the alternative dosing regimen (600 mg) of BCD-020 in bDMARDs naive patients with RA.

Methods: ALTERRA study was conducted as multicenter randomized double-blind placebo-controlled phase 3 study. After the screening patients were stratified by age, anti-CCP level and DAS28 score, randomized (2:1) into 2 arms and received BCD-020 (in combination with methotrexate (MTX)) in a dose 600 mg IV or placebo (in combination with MTX) on day 1 and day 15, then, if the activity of arthritis persisted after 24 wks of study, a second course was provided. Patients were observed up to 52 wks.

Results: A total of 159 patients were enrolled in ALTERRA study, 107 patients in BCD-020 arm and 52 patients in placebo arm.

Efficacy: ACR20 at wk 24 was reached by 65.69% of patients in BCD-020 arm and 29.41% in placebo arm (p=0.00005, the difference in proportion of registration ACR20 with 95%CI was 29.41 [19.27%; 53.28%], margin 10.5%) in per protocol population, so hypothesis of superiority was confirmed. The performed analysis showed a much more pronounced decrease in the DAS28-4 (ESR) index in BCD-020 arm compared with placebo arm (p=0.0006) at wk 24. A much more significant decrease in change of the HAQ-DI index was also shown in the BCD-020 arm (p=0.008). Analysis of efficacy at wk 52 showed the preservation of the response after 2 courses of therapy with BCD-020, 600 mg (in combination with MTX): ACR20 reached by 84.5%, ACR50 – by 54.6%, ACR70 – by 29.9 % of patients.

Safety: BCD-020 showed a favorable safety profile with no significant difference with placebo use (in combination with MTX). After 24 wks patients of both groups developed high similar level of related adverse events: 16.8% of patients in BCD-020 arm and 11.76% in placebo arm (p=0.555). There were only 3 cases of severe adverse events (2.8%) in BCD-020 arm and 2 cases (3.92%) in placebo group. From wk 24 to wk 52: 13.08% of patients (who received 2 courses of BCD-020) and 19.61% of patients (who received one course of BCD-020 after 24 wk) developed related adverse events.

Figure 1 ACR 20/50/70 in bDMARDs naive patients with RA after 24-wk treatment of BCD-020/placebo (in combination with MTX).

Conclusions: ALTERRA study showed high efficacy and favorable safety profile of RTX biosimilar BCD-020 at a dose of 600 mg in combination with MTX in bDMARDs naive patients with RA.

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