Clinical Response to The First Biologic in Rheumatoid Arthritis Patients with Moderate Disease in a Real World Clinical Cohort

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Objectives: While most randomized trials assess the effectiveness of biologic DMARDs (bDMARDs) in rheumatoid arthritis (RA) patients with high disease activity, in the real world or routine care, patients with moderate disease activity are often treated with bDMARDs as well. This study aims to evaluate the effectiveness of the first biologic with or without conventional synthetic DMARD (csDMARDs) in patients with moderate disease activity.

Methods: Biologic naïve patients enrolled in the Ontario Best Practices Initiative (OBRI), with moderate disease activity score (DAS28: >3.2-5.1), or high disease activity score (DAS28: >5.1) were included. Patients were also required to remain on the biologic for 6 months and to have complete follow up data during this time period. Clinical response to their first biologic was measured by the change in DAS28 and by the proportion of patients who reached low disease activity (LDA) during the first 6 months of treatment. The change in DAS28 was assessed using linear regression modelling, adjusted for potential confounders (age, gender, disease duration, and physician global assessment). Multivariate logistic regression was used to compare the proportion of patients who reached LDA in each group at 6 months, adjusting for the same potential confounders.

Results: The analysis included 443 patients. At initiation of their first biologic, 238 patients had a moderate DAS28 and 205 had a high DAS28. Patient demographics for the two groups are shown in Table 1. At initiation of their first bDMARD, the two groups were similar with respect to age, gender, and disease duration. All of the DAS28 components, as well as the physician global were significantly different between the two groups. A significant change in DAS28 was found in both the moderate disease group [-0.89 (95% CI -1.12, -0.66)] and the high disease group [-1.86 (95% CI -2.10, -1.62)], with greater improvement seen in the high disease activity group. A comparison of the change in DAS28 between the two groups was also significant (0.97±0.16, p<0.0001). After 6 months of biologic treatment, a higher proportion of patients in the moderate DAS28 group reached LDA, when compared to the high DAS28 group (OR: 1.65; 95%CI: 1.03-2.65, p=0.04).

Table 1. Patient Characteristics at initiation of first bDMARD, by DAS28 group

DAS28 group at bDMARDs start	Moderate DAS28 3.2-5.1	High DAS28 >5.1	P - value
N	238	205	
Age, years	55.3 (13.2)	57.1 (12.9)	0.14
Female n(%)	192 (80.7%)	169 (82.4%)	0.63
Disease duration, years	7.4 (8.8)	6.7 (7.6)	0.36
DAS28	4.18 (0.54)	5.98 (0.63)	<0.0001
28 swollen joint count	5.4 (3.7)	9.1 (4.7)	<0.0001
28 tender joint count	4.5 (3.5)	12.4 (5.8)	<0.0001
ESR, mm/h	19.1 (16.5)	34.3 (22.7)	<0.0001
CRP, mg/L	8.7 (15.4)	17.7 (24.6)	<0.0001
Patient global assessment (0-10)	5.0 (2.5)	6.7 (2.2)	<0.0001
Physician global assessment (0-10)	4.6 (2.0)	6.3 (1.8)	<0.0001
Rheumatoid factor positive n (%)	160 (72.7%)	143 (75.7%)	0.50
Previous CsDMARDs use ≥2 n(%)	213 (90%)	182 (89%)	0.81

Receiving oral steroid, n (%)	50 (21.0%)	37 (18.1%)	0.43

Values are given as mean (standard deviation) unless otherwise specified.

Conclusions: Treatment with bDMARDs is effective in patients with moderate disease activity. While patients with high disease activity showed greater improvment after 6 months of biologic treatment, patients with moderate disease activity at initiation of a bDMARD were more likely to reach a LDA state.