Table 1. Outcomes at 12 months among patients with RA who initiated the first biologic

	Moderate-RA (n=264)	Severe-RA (n=219)	P-Value
Remission, n (%)	111 (50)	45 (23)	<0.0001
Low disease activity, n (%)	151 (59)	74 (35)	<0.0001
Change in DAS from baseline ≥ 1.2 , n (%)	168 (66)	164 (78)	0.0049
HAQ-DI change >0.22 , n (%)	98 (53)	83 (52)	0.7974
Change in DAS28 from baseline, mean (SD)	-1.4 (1.3)	-2.2 (1.5)	<0.0001
Change in HAQ-DI from baseline, mean (SD)	-0.29 (0.57)	-0.30 (0.66)	<0.0001
Change in fatigue from baseline, mean (SD)	-0.98 (3.2)	-1.11 (3.2)	<0.0001
Change in sleep from baseline, mean (SD)	-0.85 (3.6)	-1.05 (3.9)	0.0004

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POS0450

INCIDENCE RATES OF DIFFICULT-TO-TREAT RHEUMATOID ARTHRITIS IN REAL-WORLD CLINICAL PRACTICE

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Background: A definition of difficult-to-treat rheumatoid arthritis (D2T RA) was recently proposed by the European League Against Rheumatism (EULAR) [1]. However, information on the incidence rates of D2T RA in real-world clinical practice is lacking.

Objectives: The aim of this retrospective cross-sectional study was to evaluate the incidence rates of D2T RA in clinical practice in Japan.

Methods: Data from the Toyohashi RA database (TRAD) was used. The TRAD is a collection of single-center retrospective data. Patients with RA who fulfilled the following three requirements were included in this study: (1) had been treated with >1 biological or targeted synthetic disease-modifying antirheumatic drug (b/tsDMARD); (2) >1 year had passed since b/tsDMARD treatment was initiated; and (3) regularly visited our institute at the time of investigation. The number of targeted patients was 363. The criteria of D2T RA used in this study were modified from the EULAR definition for simplification of the investigation as follows: (a) ≥ 2 b/tsDMARDs with different mechanisms of action had been administered; (b) at least moderate disease activity (DAS28-ESR > 3.2 or clinical disease activity index [CDAI] > 10) at the time of investigation; and (c) 7.5-mg/day of prednisolone (PSL) or more was administered at the time of investigation. In this study, D2T RA was defined as criteria (a) + (b) or (a) + (c) or (a) + (b) + (c). The 363 patients were categorized into four groups as follows: group A, D2T RA; group B, patients with RA who had been treated with ≥ 2 b/tsDMARDs and did not fulfill the D2T RA definition; group C, RA patients who had been treated with one kind of b/tsDMARD with the same mechanism of action (e.g., two kinds of tumor necrosis factor inhibitors) and fulfilled either or both criteria (b) and (c); and group D, patients with RA who had been treated with one kind of b/tsDMARD with the same mechanism of action (e.g., a tumor necrosis factor inhibitors or two interleukin 6 inhibitors) and did not fulfill either or both criteria (b) and (c). The incidence rates of D2T RA were calculated, and the patients' characteristics at the time of initiation of the b/tsDMARD treatment were compared between the groups.

Results: The number of patients in groups A, B, C, and D were 34, 53, 94, and 182, respectively. Of all the patients included in this study, 9.4% were categorized into group A, those with D2T RA, and 39.1% were treated with ≥ 2 b/tsDMARDs and categorized into group A (Fig 1). The patients' characteristics were as follows (group A/B/C/D): mean age (57.1/54.3/61.4/56.2 years), RA duration (10.0/6.7/13.8/8.2 years), %Steinbrocker stage III+IV (%; 84.0/60.0/77.3/54.3), %Steinbrocker class 3+4 (%; 68.0/33.3/43.4/23.0), methotrexate (MTX) concomitant rate (%; 79.4/92.5/74.5/91.8), PSL concomitant rate (%; 91.2/52.8/55.3/43.4), DAS28-ESR score (5.5/5.0/5.5/4.7), and CDAI score (12.3/13.7/22.7/16.9). There were statistically significant differences in RA duration, %stage III+IV, %class 3+4 and PSL concomitant rate between group A and B.

Conclusion: D2T RA occurred in 9.4% of patients treated with b/tsDMARDs. Incidence rate was increased to 39.1% after the treatment with ≥ 2 b/tsDMARDs. The patients with D2T RA tended to be older, have a long RA duration, be treated

without concomitant MTX, be treated with concomitant PSL, and have higher disease activity at the time of starting the b/tsDMARD treatment. The baseline patient characteristics in group C were similar to those in group A. In the future, we suggest that patients with D2T RA be included in group C.

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Figure1. Incidence rate of difficult-to-treat rheumatoid arthritis

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POS0451

SERUM FETUIN-A AND VISFATIN LEVELS IN WOMEN WITH RHEUMATOID ARTHRITIS DEPENDING ON DISEASE ACTIVITY

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Background: In recent years, the systemic effects of a number of cytokines have been actively studied, in particular, fetuin-A is considered a negative protein of the acute phase response, and visfatin, on the contrary, affects the activation of the cytokine cascade and has a pro-inflammatory effect. Taking into account that women suffer from rheumatoid arthritis (RA) more often, we investigated the levels of fetuin-A and visfatin in the blood serum of females in comparison with a group of healthy individuals and depending on the activity of the disease.

Objectives: to study the levels of fetuin-A and visfatin in the blood serum of women suffering from RA, depending on the activity of the disease

Methods: The study included 110 women with RA and 30 apparently healthy individuals. The inclusion criteria were: a diagnosis of RA verified based on the criteria of the American College of Rheumatology/European Anti-Rheumatic League (ACR/EULAR) 2010. The patients' age ranged from 18 to 90 years. The control group included 30 conventionally healthy individuals. Serum fetuin-A and visfatin levels were determined by indirect enzyme-linked immunosorbent assay using commercial kits. RA activity was determined by the DAS28-CRP index. Activity 0-I was in 33 (30%) patients, grade II in 67 (60.9%), grade III in 10 (9.09%) patients.

Results: The normal level of fetuin-A was calculated using the formula $M \pm 2\sigma$ in the group of conventionally healthy individuals and ranged from 653.55 to 972.19 $\mu\text{g/ml}$. In patients with grade 0-I RA activity according to DAS28, the mean serum fetuin-A level was $843.92 \pm 130.73 \mu\text{g/ml}$, in patients with grade II activity - $742.37 \pm 98.85 \mu\text{g/ml}$, with III the degree of activity - $663.9 \pm 123.7 \mu\text{g/ml}$ ($p < 0.001$).

The average level of visfatin in the blood serum in healthy individuals was $2.43 \pm 0.17 \text{ ng/ml}$. The level of normal values of visfatin in healthy individuals, defined as $M \pm 2\sigma$, ranged from 0 to 5.07 ng/ml . The average level of visfatin in patients with RA was $6.27 \pm 0.18 \text{ ng/ml}$, which is significantly higher than in healthy individuals ($p < 0.001$).

In patients with 0-I degree of RA activity according to DAS28, the average level of visfatin in blood serum was $4.94 \pm 0.02 \text{ ng/ml}$, in patients with degree II activity - $5.08 \pm 0.02 \text{ ng/ml}$, with III degree of activity - $6.82 \pm 0.23 \text{ ng/ml}$ ($p < 0.001$).