improvement in pain scores and other PROs may be seen in patients who do not respond to treatment based on disease activity measures that evaluate inflammation. **Objectives:** To assess changes in pain scores and other PROs in patients with RA who did or did not achieve $\geq 20\%$ improvement in SJC in TCZ clinical trials.

Methods: Data from patients with active RA who received intravenous TCZ 8 mg/kg + MTX or PBO + MTX in 3 Phase III studies (OPTION [NCT00106548], TOWARD [NCT00106574] and LITHE [NCT00109408]) were included. All patients had moderate to severe RA with an inadequate response or intolerance of MTX (OPTION, LITHE) or conventional synthetic disease-modifying antirheumatic drugs (csDMARDs; TOWARD). Changes in pain (visual analog scale [VAS], 0-100 mm), Health Assessment Questionnaire Disability Index (HAQ-DI, 0-3), 36-Item Short Form Survey (SF-36) physical component score (PCS) and mental component score (MCS; 0-50) and Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score (0-52) from baseline to Week 24 were evaluated. Results were compared between patients receiving TCZ + MTX and those receiving PBO + MTX in both patients who achieved $\geq 20\%$ improvement in SJC (responders) and those who did not (nonresponders). The changes from baseline were analyzed using a mixed model with repeated measures, including the following covariates and interactions: treatment, visit, baseline of endpoint, region, baseline DAS28 and interactions of visit with treatment and baseline of endpoint.

Figure:

Figure 1. LSM Change in Pain Score and HAQ-DI From Baseline to Week 24 in Responder and Nonresponder Groups

HAQ-DI, Health Assessment Questionnaire Disability Index; LSM, least squares mean; MTX, methotrexate; PBO, placebo; TCZ, tofacitinib; VAS, visual analog scale.
* $P < 0.0001$ for comparison between TCZ + MTX and PBO + MTX.
†Patients who achieved $\geq 20\%$ improvement in swollen joint counts.
‡Patients who did not achieve $\geq 20\%$ improvement in swollen joint counts; at Week 16, patients were permitted to receive rescue therapy.

Figure 2. LSM Change in SF-36 PCS and MCS From Baseline to Week 24 in Responder and Nonresponder Groups

LSM, least squares mean; MTX, methotrexate; MCS, mental component score; PCS, physical component score; PBO, placebo; SF-36, 36-Item Short Form Survey; TCZ, tofacitinib.
* $P < 0.0001$ for comparison between TCZ + MTX and PBO + MTX.
† $P < 0.005$ for comparison between TCZ + MTX and PBO + MTX.
‡Patients who achieved $\geq 20\%$ improvement in swollen joint counts; at Week 16, patients were permitted to receive rescue therapy.

Results: Data from 1254 responders (TCZ + MTX, $n = 831$; PBO + MTX, $n = 423$) and 620 nonresponders (TCZ + MTX, $n = 225$; PBO + MTX, $n = 395$) were included. Patients receiving TCZ + MTX had significantly greater improvement in pain scores and HAQ-DI compared with PBO + MTX in the responder group (-27.19 vs -16.77 and -0.55 vs -0.34 , respectively; $P < 0.0001$ for both) and non-responder group (-9.59 vs 2.53 and -0.20 vs 0.01 ; $P < 0.0001$ for both) at Week 24

(Figure 1). Similar results were seen at Week 16 in the nonresponder group (-11.06 vs -2.38 and -0.23 vs -0.04 ; $P < 0.0001$ for both) prior to initiation of rescue treatment. At Week 24 in the responder group, patients receiving TCZ + MTX had significantly greater improvements compared with PBO + MTX in SF-36 PCS and MCS (9.16 vs 5.71 and 6.55 vs 3.79 , respectively; $P < 0.0001$ for both) (Figure 2) and FACIT-Fatigue (8.39 vs 5.11 ; $P < 0.0001$). In the nonresponder group, patients receiving TCZ + MTX had significantly greater improvements compared with PBO + MTX in SF-36 PCS at Week 16 (3.81 vs 1.65 ; $P = 0.0006$) and Week 24 (4.42 vs 1.01 ; $P < 0.0001$) (Figure 2) and FACIT-Fatigue at Week 16 (3.82 vs 1.32 ; $P = 0.0039$) and Week 24 (3.90 vs 1.40 ; $P = 0.0111$).

Conclusion: Patients with RA who received TCZ + MTX had significantly greater improvements in pain score and other PROs than those who received PBO + MTX regardless of whether they achieved $\geq 20\%$ improvement in SJC. Clinical outcome at Week 24 correlated well with PROs, with a relatively larger improvement in pain score and other PROs in the responder group than in the nonresponder group; relative to PBO + MTX, these improvements appear numerically similar in the responder and nonresponder groups with consistently smaller difference between the groups in TCZ-treated arms. The consistent effect of TCZ on PROs in both responder and nonresponder groups warrants further study on the impact of TCZ on sources of pain independent of that caused by joint inflammation.

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SAT0122

HIGHER DOSES OF METHOTREXATE ASSOCIATED WITH DISCONTINUATION OF ORAL GLUCOCORTICOIDS AFTER INITIATION OF BIOLOGICAL DMARDs: A RETROSPECTIVE OBSERVATIONAL STUDY BASED ON DATA FROM A JAPANESE MULTICENTER REGISTRY STUDY

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Background: Glucocorticoids exert anti-inflammatory effects and are important drugs used to treat rheumatoid arthritis(1). We recommend glucocorticoid discontinuation as soon as possible because glucocorticoid caused several side effects, but many patients continue to take oral glucocorticoids long-term in daily clinical practice. The frequency of use of glucocorticoid has gradually declined, and there are several reports on discontinuation of glucocorticoid due to the initiation of biological disease-modifying antirheumatic drugs (bDMARDs)(2). However, there is no report showing the relation between discontinuation of glucocorticoid and MTX dose.

Objectives: The present study aimed to explore factors associated with glucocorticoid discontinuation at 52 weeks after initiating bDMARDs.

Methods: We established the large observational cohort, the Nagoya University orthopedic facility multicenter study (TBCR), and a total of 3119 patients used bDMARD and examined the status of oral glucocorticoid use at 52 weeks after initiating the 1st bDMARD. In predictive analyses, the outcome variable was glucocorticoid discontinuation at 52 weeks after bDMARD initiation. Factors associated with baseline characteristics at bDMARD initiation were assessed with univariate and stepwise forward multivariate logistic regression analyses. This cohort study was not randomized. Propensity score (PS) matching was used to align patient backgrounds to avoid selection bias.

Results: Subjects were 564 patients administered glucocorticoids and methotrexate (MTX) following initiation of the 1st bDMARD (Figure 1). Mean DAS28-CRP at bDMARD initiation was 4.70 ± 1.16 . Percentages of patients with low, moderate, and high disease activity as evaluated by DAS28-CRP at bDMARD initiation were 4.7%, 23.5%, and 71.8%, respectively. By 52 weeks after bDMARD initiation, 164 patients (29.1%) discontinued glucocorticoids. Multivariate analysis identified age (odds ratio (OR), 0.98), MTX dose (OR, 1.11), and glucocorticoid dose (OR, 0.87) as factors independently associated with glucocorticoid discontinuation at the time of bDMARD initiation (Table 1). After adjusting for baseline characteristics using propensity score matching among patient groups administered MTX ≤ 8 mg/week and MTX > 8 mg/week, 105 pairs remained. Among patients administered MTX > 8 mg/week, 41.0% discontinued glucocorticoids. Among those administered MTX ≤ 8 mg/week, 22.9% discontinued glucocorticoids, with a significant difference between the two groups (Figure 2, $P=0.007$).

Table 1. Factors associated with baseline characteristics at bDMARD initiation

	Continuation (n=400)	Discontinuation (n=164)	Univariate Odds ratio (95% CI)	Multivariate Odds ratio (95% CI)
Age, years	58.4 ± 12.9	54.3 ± 14.3	0.98 (0.97-0.99)	0.98 (0.97-0.99)
Disease duration, years	9.4 ± 9.4	7.5 ± 8.5	0.98 (0.95-0.99)	—
Female, %	80.3	81.1	1.06 (0.67-1.68)	—
DAS28-CRP	4.78 ± 1.15	4.50 ± 1.16	0.81 (0.69-0.96)	—
Seropositivity, %	90.0	86.1	0.69 (0.38-1.25)	—
MTX dose, mg/week	7.7 ± 2.5	8.8 ± 3.0	1.16 (1.09-1.24)	1.11 (1.03-1.21)
Glucocorticoid dose, mg/day	4.9 ± 2.1	4.3 ± 2.1	0.86 (0.78-0.95)	0.87 (0.78-0.97)
TNF inhibitor use, %	88.8	85.4	0.74 (0.43-1.26)	—

Data are presented as mean ± standard deviation.

Conclusion: Data from the TBCR revealed that, from a clinical perspective, glucocorticoid use decreased among RA patients treated with bDMARDs. Higher doses of MTX (> 8 mg/week) at the time of bDMARD initiation were found to be associated with glucocorticoid discontinuation in patients treated with bDMARDs. In addition, we found that aggressive use of MTX was sufficient to fulfill the Treat-to-Target approach, demonstrating that glucocorticoid discontinuation is a viable option.

Figure 1: Flowchart depicting the study design.

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Figure 2: Glucocorticoid discontinuation rates in groups administered MTX ≤ 8 mg/week and MTX > 8 mg/week after propensity score matching. * P < 0.05.

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SAT0123

TREATMENT SATISFACTION, EXPECTATIONS, PATIENT PREFERENCES AND CHARACTERISTICS, INCLUDING DIGITAL HEALTH LITERACY (DHL), AND THE IMPACT OF SUBOPTIMAL DISEASE CONTROL IN A LARGE INTERNATIONAL COHORT OF PATIENTS WITH RHEUMATOID ARTHRITIS (RA): THE SENSE STUDY

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Background: Patient characteristics, their treatment preferences and goals are important determinants of treatment success in rheumatoid arthritis (RA).

Objectives: SENSE study aimed at assessing the impact of inadequate response to disease-modifying anti-rheumatic drugs on disease outcomes, and analyze their attitude, their treatment and disease.

Methods: Non-interventional, cross-sectional study conducted in 18 countries in Europe, Asia, and America. Adult RA patients with moderate/high disease activity were eligible. Patient satisfaction was assessed by Treatment Satisfaction Questionnaire for Medication, Version 1.4 (TSQM v1.4). Treatment adherence, patient preferences, and expectations were evaluated by visual analog scale. eHealth Literacy Scale was employed for evaluating DHL. Work Productivity and Activity Impairment Questionnaire-Rheumatoid Arthritis, v2.0 (WPAI-RA) was used to assess workability and patient documentation for healthcare resource utilization (HRU).

Results: 1624 patients were included in this analysis; most were female (84.2%), middle-aged, and had a mean (standard deviation [SD]) disease duration of 10.5 (9.3) years. 11.9% of the patients had retired early and 6.0% were unemployed due to RA. Mean (SD) total WPAI-RA score was 55.1% (26.7). In the previous 3 months, the mean (SD) number of healthcare professional and emergency room visits were 2.2 (2.5) and 1.6 (1.3), respectively. Mean (SD) TSQM v1.4 global satisfaction subscore was 60.9 (20.9), with only 13.5% reporting good treatment satisfaction (TSQM global ≥80). The leading treatment expectations were 'general improvement of arthritis,' 'less joint pain,' and 'lasting relief of RA symptoms,' with mean (SD) scores of 5.7 (1.6-1.7) for each. 60.7% of patients preferred oral administration and 31.3% preferred not to use drug combinations for RA. Preferred time to effect was predominantly 'up to one week' (71.1%). Least frequently side effects rated 'acceptable' were 'increased risk for malignancies' (3.5%) and 'increased risk for cardiovascular diseases' (3.3%). Most patients (67.4%) had poor DHL. Good adherence (in 87.4% of patients) was significantly associated with lower levels of joint pain.

Conclusion: Suboptimal disease control has a significant impact on satisfaction, workability, and HRU. Our results can support shared decision-making when setting RA treatment strategy.

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